iOrthopedics, Inc.

Patent Portfolio Overview

R. Thomas Grotz, M.D., is the surgeon inventor responsible for the patent documents in this portfolio. The content of these inventions intends to outline improvements warranted in treatment pathways for orthopedic patients based on his several decades experience treating 25,000 patients through 100,000 injuries performing 10,000 surgeries, including limb repairs, reconstructions, and total joint replacements of the shoulder, elbow, wrist, thumb, finger, hip, knee, and ankle. Dr. Grotz focused on saving joints rather than ablating and replacing them, developing medical devices and minimally invasive methods of surgery to halt and reverse arthritis in arms and legs. His microsurgical subspecialty generated an attention to detail allowing living bone and muscle transfer and refurbishment. This work has resulted in the RAD (Resilient Arthroplasty Device) patent portfolio wherein polymer custom fitting joint surfaces are used to renew function and alleviate pain of arthritis by padding damaged cartilage, restoring cushioning and by delivering pharmacologics and stems cells, so that patients can “grow new joints’ rather than succumb to morbid archaic prostheses. In the spine, the UEC (Universally Expanding Cage) has captured technologies to maximally adjust the axial skeleton with disc fusions horizontally and deformity corrections longitudinally as of scoliosis and kyphosis — with novel disruptive treatment approaches. These patents are the IP protection sector of plans to Heal Mankind based on experience with prototypes, 510k FDA clearances, and successful human trials.

TABLE OF CONTENTS

Patent Portfolio Overview

RAD - Knee and iKnee

iOI has patents and applications covering the knee arthroplasty implant in the US, China and Europe (Germany, France and Great Brittan)

RAD HIP and Generic

iOI has patents and patent applications in the US and China covering an arthroplasty implant for use in the hip joint as well as patents and patent applications covering arthroplasty implants for generalized use in any joint in the US and Europe

UEC - spine cage

iOI has patents and patent applications in the US, Europe and China covering a universally expanding spine cage

STABILIZER FOR HUMAN JOINTS

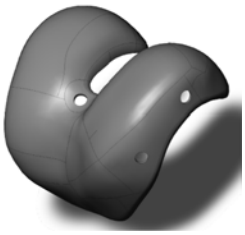
Stabilizers are medical devices for securing bodily tissues to bone and are designed specifically as triangular shaped toothed bone anchors that are forcibly spread into bone.

Issued Patents and Applications Grouped by Technology

RAD Knee	Applications	Patents
	US Application 15/807901 US Application 16/033050 US Application 15/939480 US Application 62/796559	Patent US9,757,241 Patent US8,771,363 Patent US9,662,218 Patent US10,004,605 Patent US10,045,851 Patent USD833613S1 Granted EP Pat 2750629 (Granted in DE, FR, GB) CN Patent ZL201180015087.4
RAD Hip and Generic	Applications	Patents
	US Application 16/132458	Patent US9,808,345 Patent US10,092,405 EP Pat 2344083 B1 (Granted in DE, FR, GB) CN Patent ZL201180015073.2
UEC	Applications	Patents
	US Application 16/122534 US Application 16/251014 EP Application 15858213.0 CN CN2015800725935	Patent US9,622,878 Patent US9,861,494 Patent US9,872,778 Patent US9,999,515 Patent US10,085,846
Stabilizer	To be filed	Patent US5782865 Patent US5968078

Patent Portfolio Details RAD-Knee

RADs are custom fitting robust polymer joint caps intended to resurface and create realignment of the knee joint by padding damaged cartilage, restoring cushioning, and ultimately delivering pharmaceutical agents to halt and reverse arthritis. Their implant design resembles that of the natural joint and will allow for the most natural movement possible.



The RAD patents cover the device itself as well as methods of using the device and methods of treating arthritis in particular.

The most recently allowed application contains claims directed to an implant configured for deployment between a femur and a tibia of a knee joint, an implant configured for deployment between a femur and a patella of a knee joint, and an implant configured for deployment between a tibia and a patella of a knee joint.

Patents

Patent US8,771,363
Patent US9,662,218
Patent US9,757,241
Patent US10,004,605
Patent US10,045,851
Patent USD833613S1
Granted EP Pat 2750629 (Granted in DE, FR, GB)
CN Patent CN102834073

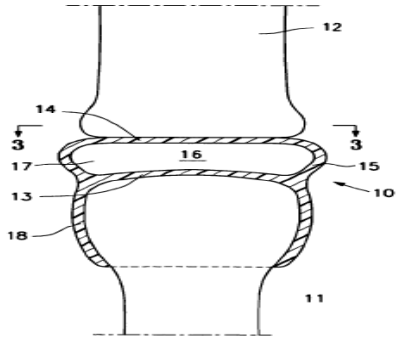
Applications

US Application 15/807901
US Application 16/033050
US Application 15/939480
US Application 62/796559

Patent Portfolio Details

RAD-Hip and Generic

In addition to the issued Chinese patent on the RAD-Hip, iOrthopedics has two pending US Applications covering a contiguous polymeric inflatable implant for deployment between a femur head and an acetabulum of a hip joint, one of which has been indicated as allowable.



The recently granted EP application contains claims directed to arthroplasty implants and procedures for a wide variety of joints such as, for example, hips, knees, shoulders, ankles, elbows, wrists, fingers, toes, temporomandibular joints and the like.

Claims similar to those granted in Europe are expected to be issued in our US Application.

Patents

Patent US9,808,345
Patent US10,092,405

EP Pat 2344083 B1 (Granted in DE, FR, GB)

CN Patent CN102821715

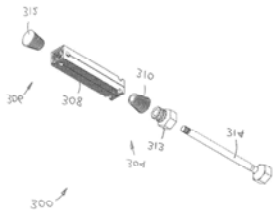
Applications

US Application 16/132458

Patent Portfolio Details

UEC

The UEC or Universally Expanding Cage is a medical device for stabilizing the vertebral motion segment or other bone segments. iOrthopedics patents are directed to the UEC device and method of use for providing controlled spinal correction or other bond segment spacing and/or alignment.



The UEC provides advantages over currently existing technology that include correction of coronal plane deformity; introduction of interbody lordosis and early stabilization of the interbody space with rigidity that is greater than present spacer devices. This early stability may improve post-operative pain, preclude the need for posterior implants including pedicle screws, and improve the rate of successful arthrodesis.

Patents

Patent US9,622,878
Patent US9,861,494
Patent US9,872,778
Patent US9,999,515
Patent US10,085,846

Applications

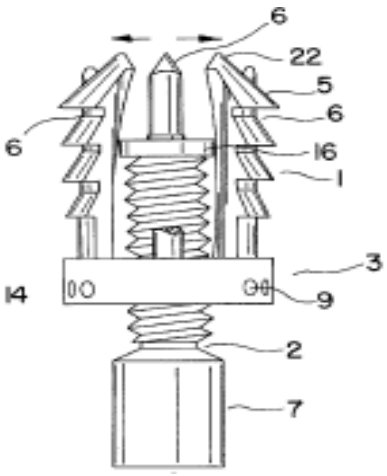
US Application 16/122534
US Application 16/251014
EP Application 15858213.0
CN CN2015800725935

Patent Portfolio Details

Stabilizers

Ongoing development of stabilizers and surgical anchors is expected to result in additional patents. iOI is currently drafting applications directed at new and improved surgical anchoring systems for use in the RAD products as well as in any suitable orthopedic.

Although expired, iOI's initial patents on the stabilizers are directed to a bone anchor design with increased pull-out strength relative to currently available joint stabilizers, and a device which affords the capacity to use multiple sutures for gathering up a maximum amount of soft tissue for rejoining with bone. This technology is currently very applicable in the field of arthroplasty.



Patents

US5782865
US5968078

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US008771363B2

(12) **United States Patent**
Grotz

(10) **Patent No.: US 8,771,363 B2**
(45) **Date of Patent: Jul. 8, 2014**

(54) **RESILIENT KNEE IMPLANT AND METHODS**

(76) Inventor: **R. Thomas Grotz**, Novato, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 69 days.

(21) Appl. No.: **13/574,499**

(22) PCT Filed: **Jan. 19, 2011**

(86) PCT No.: **PCT/US2011/021674**

§ 371 (c)(1),
(2), (4) Date: **Oct. 8, 2012**

(87) PCT Pub. No.: **WO2011/091005**

PCT Pub. Date: **Jul. 28, 2011**

(65) **Prior Publication Data**

US 2013/0030542 A1 Jan. 31, 2013

Related U.S. Application Data

(60) Provisional application No. 61/297,698, filed on Jan. 22, 2010.

(51) **Int. Cl.**
A61F 2/38 (2006.01)

(52) **U.S. Cl.**
USPC **623/20.21**; 623/18.11

(58) **Field of Classification Search**
CPC A61F 2/28; A61F 2/38
USPC 623/11.1, 16.11, 18.11, 20.14–20.21
See application file for complete search history.

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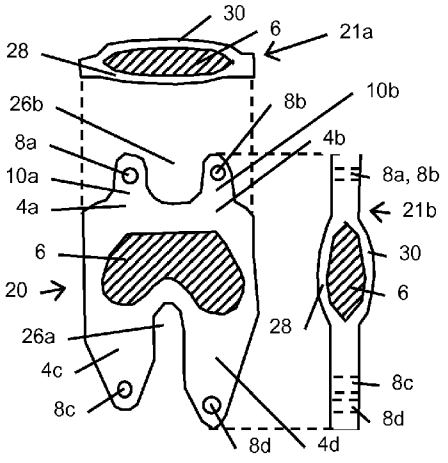
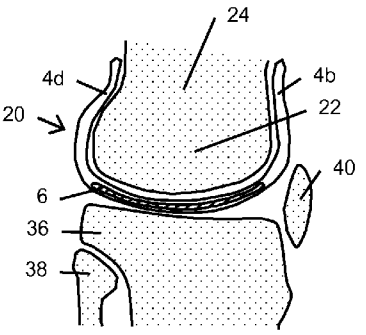
Primary Examiner — Jason-Dennis Stewart
(74) *Attorney, Agent, or Firm* — Wilson, Sonsini, Goodrich & Rosati

(57) **ABSTRACT**

This disclosure is directed to a resilient interpositional arthroplasty implant for application into a knee joint to pad cartilage defects, cushion a joint, and replace or restore the articular surface, which may preserve joint integrity, reduce pain and improve function. The implant may endure variable joint compressive and shear forces and cyclic loads. The implant may repair, reconstruct, and regenerate joint anatomy, and thereby improve upon joint replacement alternatives. Rather than using periosteal harvesting for cell containment in joint resurfacing, the walls of this invention may capture, distribute and hold living cells until aggregation and hyaline cartilage regrowth occurs. The implant may be deployed into debrided joint spaces, molding and conforming to surrounding structures with sufficient stability to avoid extrusion or dislocation. Appendages of the implant may repair or reconstruct tendons or ligaments, and an interior of the implant that is inflatable may accommodate motions which mimic or approximate normal joint motion.

69 Claims, 7 Drawing Sheets





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U.S. Appl. No. 13/514,539 Office action Feb. 7, 2014.
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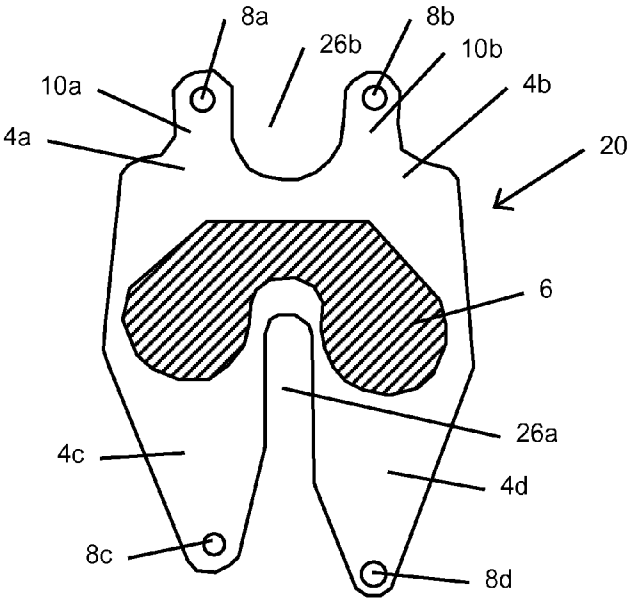


FIG. 1

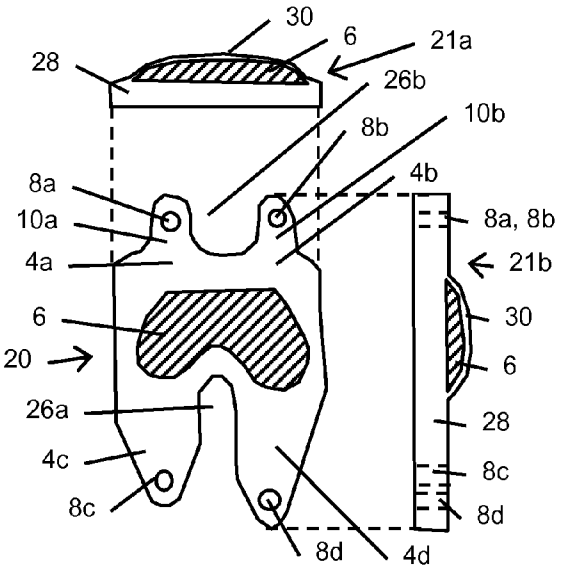


FIG. 2

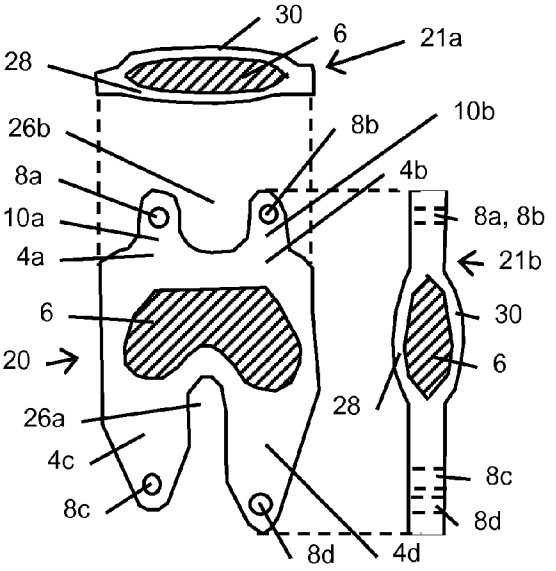


FIG. 3

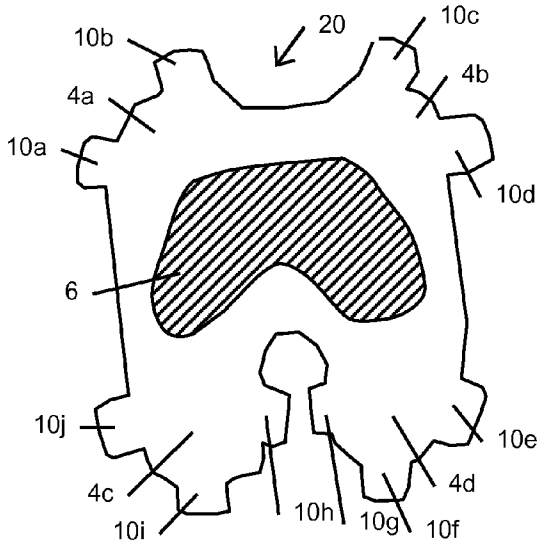


FIG 4A

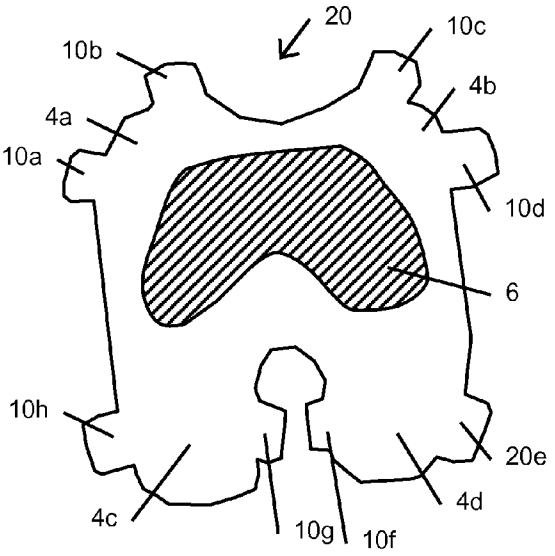
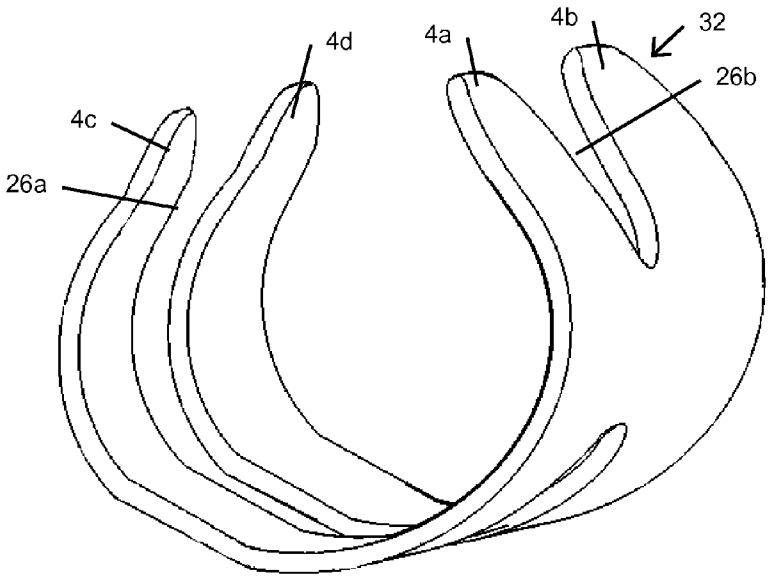


FIG 4B



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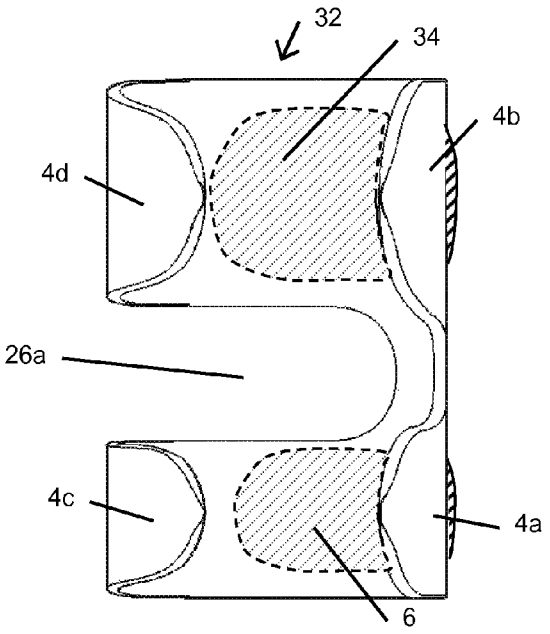

FIG 6A

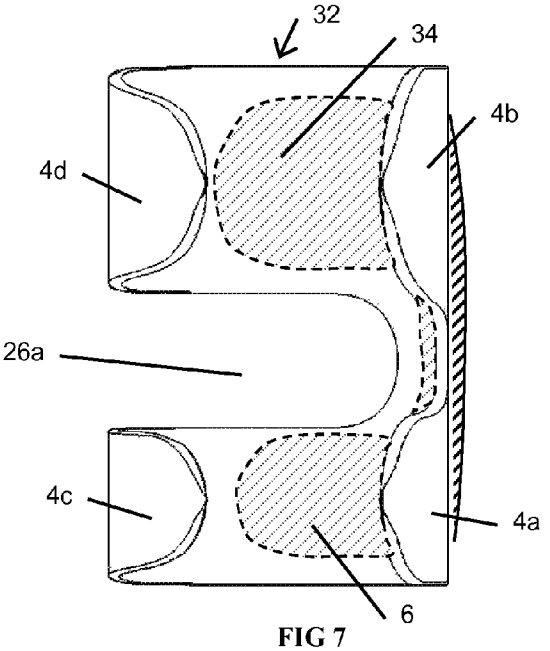

FIG 7

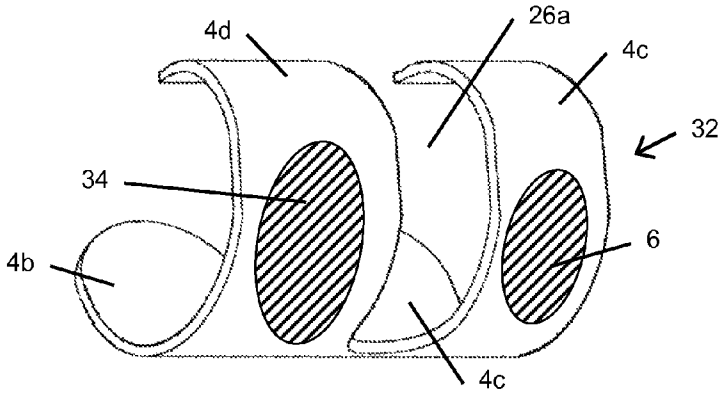

FIG 6B

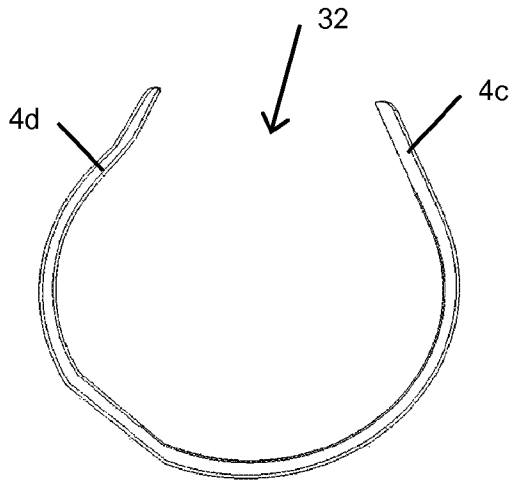

FIG 8

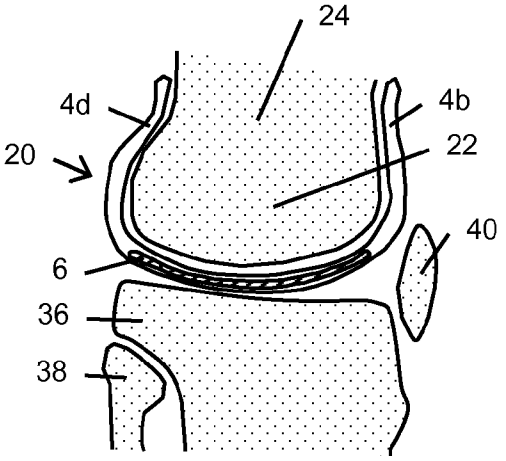

FIG 9A

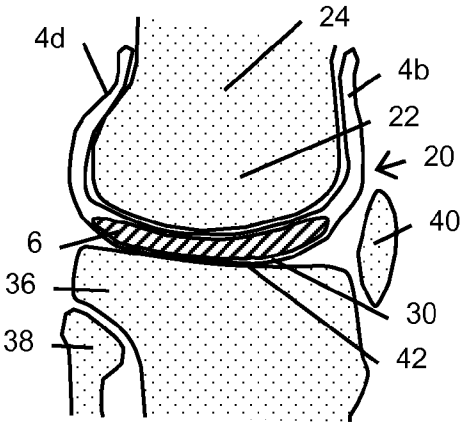

FIG 9B

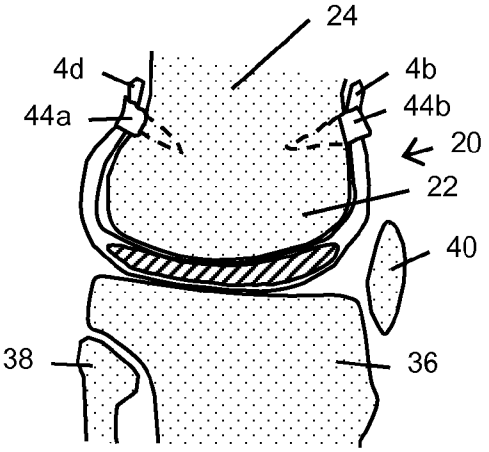

FIG 9C

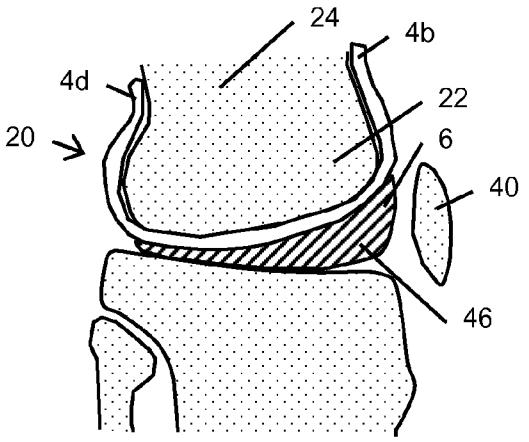

FIG 10A

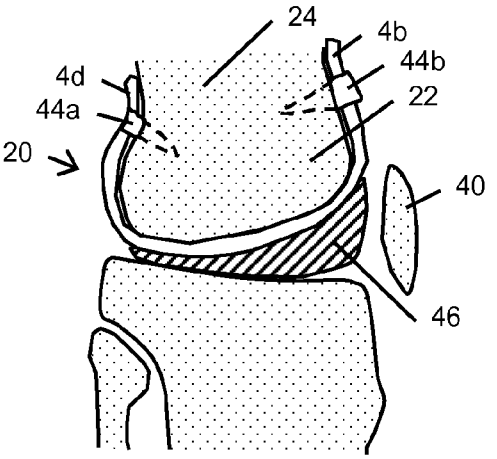

FIG 10B

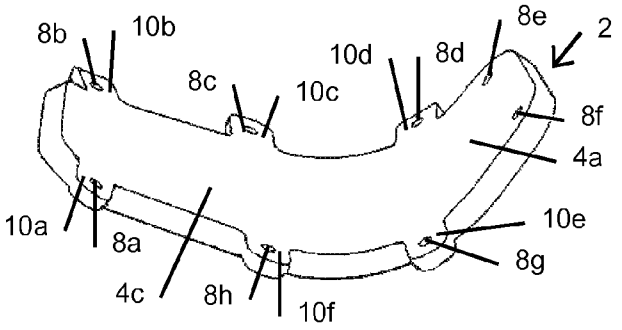

FIG 11A

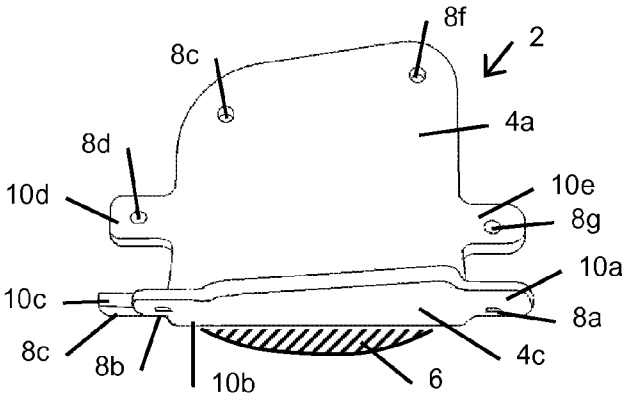

FIG 11B

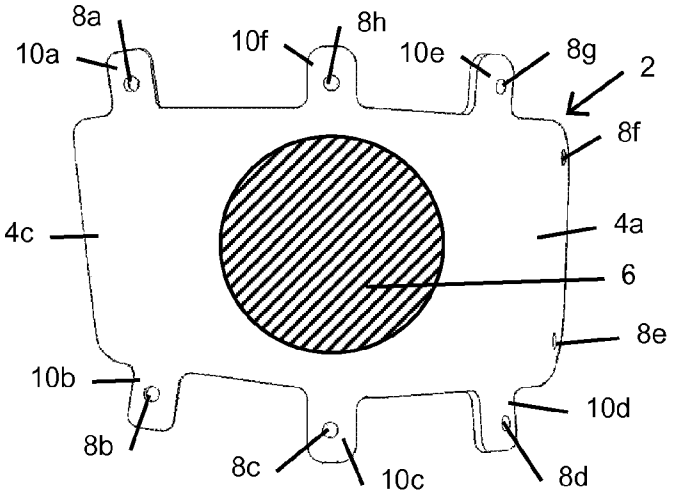

FIG 11C

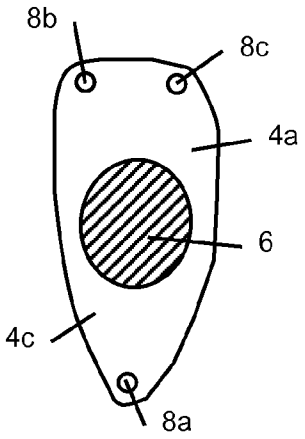

FIG 12A

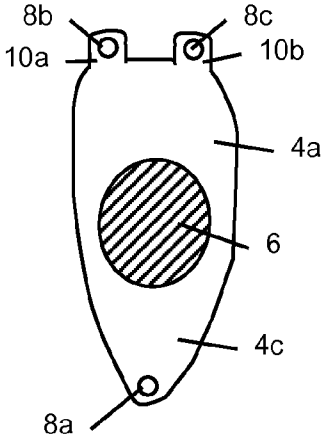

FIG 12B

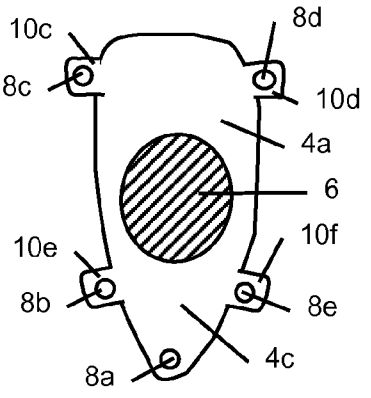

FIG 12C

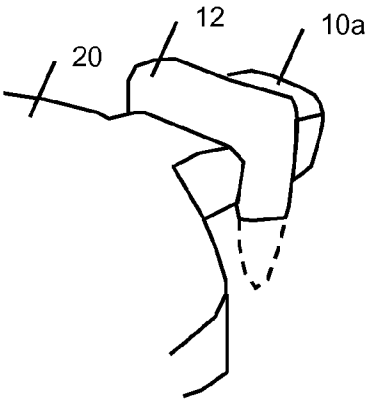

FIG 13A

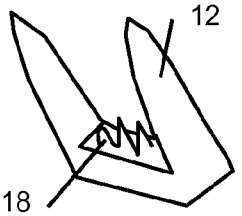

FIG 13B

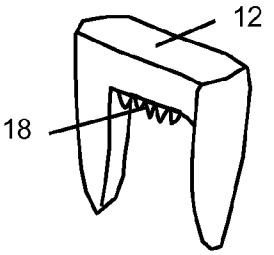

FIG 13C

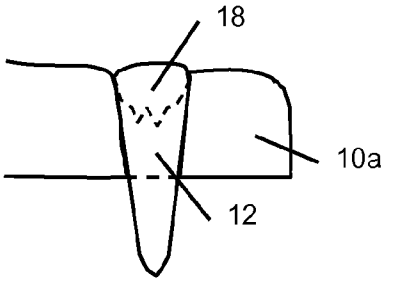

FIG 13D

RESILIENT KNEE IMPLANT AND METHODS

CROSS REFERENCE

This application is filed pursuant to 35 U.S.C. 371 as a United States National Phase Application of International Application No. PCT/US2011/021674, entitled "Resilient Knee Implant and Methods," filed on Jan. 19, 2011, which claims the benefit of U.S. Provisional Application No. 61/297,698, filed Jan. 22, 2010 which is incorporated herein by reference in its entirety.

BACKGROUND OF THE INVENTION

This invention relates to arthroplasty, and more particularly, to an implant for use in arthroplasty when hyaline articular cartilage is damaged, it breaks down and joint space is lost. Inflammatory enzymes such as from the Cox-1, Cox-2 and/or 5-Lox systems, are released and loose bodies form adding to the degradation of joint function. Such joint damage is conventionally treated by physical therapy, analgesics, pain medication and injections. When these treatments fail, the traditionally accepted treatment option is arthroplasty implantation or replacing the joint with an artificial joint construct. Current arthroplasty techniques typically use "plastic and metal" implants that are rigid and which ultimately fail due to loosening or infection. Conventional materials for the artificial joint components include chrome-cobalt-molybdenum alloy (metal) and high molecular weight polyethylene (plastic). Each is often fixed by a cement-like mixture of methyl methacrylate to the ends of the bones that define the joint that is the subject of the arthroplasty, or coated with a surface that enables bone ingrowth. Replacement surgeries are known to fail in a number of years.

Conditions requiring arthroplasty include traumatic arthritis, osteoarthritis, rheumatoid arthritis, osteonecrosis, and failed surgical procedures.

SUMMARY OF THE INVENTION

The present invention is directed to an orthopedic implant configured for deployment between opposing members of a joint structure that addresses many of the shortcomings of prior artificial joints. The arthroplasty implants embodying features of the invention are configured to preserve joint motions while removing the pain and dysfunction following the development of arthritis or joint injury. The arthroplasty implant in accordance with the present invention achieves improved physiologic motion and shock absorption during gait and acts as a resilient spacer between moving bones during limb movement. The combined characteristics of the implant include anatomic design symmetry, balanced rigidity with variable attachment connections to at least one of adjacent normal structures, and durability which addresses and meets the needs for repair or reconstruction thus far missed in the prior art. The implant should be secured to at least one of the bones of the joint structure.

Provided herein is an implant configured for deployment between a femur and a tibia of a knee joint, the implant comprising a balloon comprising a first portion that is configured to engage a medial condyle and a lateral condyle of the femur of the knee joint, a second portion that is configured to engage the tibia of the knee joint, a side portion connecting the first portion and the second portion, in which the side portion facilitates relative motion between the first portion and the second portion, and an interior that is optionally inflatable with a first inflation medium; and a first appendage configured to couple the balloon to the femur of the knee joint.

In some embodiments, the implant comprises at least one attachment element in the intercondylar notch. In some embodiments, the implant comprises at least one attachment element superiorly at the distal end of the femur anteriorly. In some embodiments, the implant comprises at least one posterior reign configured to cinch up the implant from inside a posterior intercondylar notch toward a connection site around the femur. In some embodiments, the implant comprises at least one suture-like lanyard configured to cinch up the implant from inside a posterior intercondylar notch toward a connection site around the femur.

In some embodiments, the first portion comprises a first wall, the second portion comprises a second wall, and the side portion comprises a side wall.

In some embodiments, the implant comprises an inflation port in communication with the interior of the balloon for inflation of the interior of the balloon with the first inflation medium. In some embodiments, the interior comprises a plurality of inflatable chambers. In some embodiments, a first chamber of the plurality of individually inflatable chambers is adapted to be inflated with the first inflation medium, and a second chamber of the plurality of individually inflatable chambers is adapted to be inflated with a second inflation medium. In some embodiments, the first inflation medium imparts at least one of rigidity in the implant and cushion in the implant.

In some embodiments, the implant comprises a second appendage coupling the balloon to at least one of: the femur of the joint and the tibia of the joint.

Provided herein is an implant configured for deployment between a femur and a tibia of a knee joint, the implant comprising a balloon comprising a first portion that is configured to engage at least one condyle of the femur of the knee joint, a second portion that is configured to engage the tibia of the knee joint, a side portion connecting the first portion and the second portion, in which the side portion facilitates relative motion between the first portion and the second portion, and an interior that is optionally inflatable with a first inflation medium; and a first appendage configured to couple the balloon to the femur of the knee joint.

In some embodiments, the at least one condyle is the medial condyle. In some embodiments, the at least one condyle is the lateral condyle.

In some embodiments, the balloon is at least one of: at most about 1.5 cm in diameter, at most about 1.75 cm in diameter, at most about 2 cm in diameter, at most about 2.25 cm in diameter, at most about 2.5 cm in diameter, at most about 2.75 cm in diameter, at most about 3 cm in diameter, at most about 3.25 cm in diameter, at most about 3.5 cm in diameter, at most about 3.75 cm in diameter, at most about 4 cm in diameter, at most about 4.25 cm in diameter, at most about 4.5 cm in diameter, at most about 4.75 cm in diameter, at most about 5 cm in diameter, at most about 5.25 cm in diameter, at most about 5.5 cm in diameter, at most about 5.75 cm in diameter, at most about 6 cm in diameter, at most about 6.25 cm in diameter, at most about 6.5 cm in diameter, at most about 6.75 cm in diameter, at most about 7 cm in diameter, at most about 7.25 cm in diameter, at most about 7.5 cm in diameter, at most about 7.75 cm in diameter, at most about 8 cm in diameter, at most about 3 cm in length along the longest length of the balloon, at most about 3.25 cm in length along the longest length of the balloon, at most about 3.5 cm in length along the longest length of the balloon, at most about 3.75 cm in length along the longest length of the balloon, at most about 4 cm in

length along the longest length of the balloon, at most about 4.25 cm in length along the longest length of the balloon, at most about 4.5 cm in length along the longest length of the balloon, at most about 4.75 cm in length along the longest length of the balloon, at most about 5 cm in length along the longest length of the balloon, at most about 5.25 cm in length along the longest length of the balloon, at most about 5.5 cm in length along the longest length of the balloon, at most about 5.75 cm in length along the longest length of the balloon, at most about 6 cm in length along the longest length of the balloon, 6.25 cm in length along the longest length of the balloon, at most about 6.5 cm in length along the longest length of the balloon, at most about 6.75 cm in length along the longest length of the balloon, at most about 7 cm in length along the longest length of the balloon, at most about 7.25 cm in length along the longest length of the balloon, at most about 7.5 cm in length along the longest length of the balloon, at most about 7.75 cm in length along the longest length of the balloon, and at most about 8 cm in length along the longest length of the balloon.

In some embodiments, the first portion comprises a first wall, the second portion comprises a second wall, and the side portion comprises a side wall.

In some embodiments, the implant comprises an inflation port in communication with the interior of the balloon for inflation of the interior of the balloon with the first inflation medium. In some embodiments, the interior comprises a plurality of inflatable chambers. In some embodiments, a first chamber of the plurality of individually inflatable chambers is adapted to be inflated with the first inflation medium, and a second chamber of the plurality of individually inflatable chambers is adapted to be inflated with a second inflation medium. In some embodiments, the first inflation medium imparts at least one of rigidity in the implant and cushion in the implant.

In some embodiments, the implant comprises a second appendage coupling the balloon to at least one of: the femur of the joint and the tibia of the joint. In some embodiments, the implant comprises at least one attachment element in the intercondylar notch. The In some embodiments, the implant comprises at least one attachment element superiorly at the distal end of the femur anteriorly. In some embodiments, the implant comprises at least one posterior reign configured to cinch up the implant from inside a posterior intercondylar notch toward a connection site around the femur. In some embodiments, the implant comprises at least one suture-like lanyard configured to cinch up the implant from inside a posterior intercondylar notch toward a connection site around the femur.

Provided herein is an implant configured for patch a defect of a bone of a knee joint, the implant comprising a balloon configured to engage the defect of the bone of the knee joint and comprising an interior that is optionally inflatable with a first inflation medium; and a first appendage configured to couple the balloon to the bone of the knee joint.

In some embodiments, at least one of the appendage and the balloon are configured to replace cartilage.

In some embodiments, the balloon is at least one of: at most about 0.5 cm in diameter, at most about 0.75 cm in diameter, at most about 1 cm in diameter, at most about 1.25 cm in diameter, at most about 1.5 cm in diameter, at most about 1.75 cm in diameter, at most about 2 cm in diameter, at most about 2.25 cm in diameter, at most about 2.5 cm in diameter, at most about 2.75 cm in diameter, at most about 3 cm in diameter, at most about 3.25 cm in diameter, at most about 3.5 cm in diameter, at most about 3.75 cm in diameter, at most about 0.5 cm in length along the longest length of the balloon, at most about 0.75 cm in length along the longest length of the balloon, at most about 1 cm in length along the longest length of the balloon, at most about 1.25 cm in length along the longest length of the balloon, at most about 1.5 cm in length along the longest length of the balloon, at most about 1.75 cm in length along the longest length of the balloon, at most about 2 cm in length along the longest length of the balloon, at most about 2.25 cm in length along the longest length of the balloon, at most about 2.5 cm in length along the longest length of the balloon, at most about 2.75 cm in length along the longest length of the balloon, at most about 3 cm in length along the longest length of the balloon, at most about 3.25 cm in length along the longest length of the balloon, at most about 3.5 cm in length along the longest length of the balloon, at most about 3.75 cm in length along the longest length of the balloon, and at most about 4 cm in length along the longest length of the balloon.

In some embodiments, the size of the balloon size is preset. In some embodiments, the balloon comprises multiple chambers which may be selectively inflated. In some embodiments, the balloon comprises multiple chambers which may be selectively deflated. In some embodiments, the balloon comprises multiple chambers which may be selectively inflated in situ to fill the defect. In some embodiments, the balloon comprises multiple chambers which may be selectively inflated just prior to implantation.

In some embodiments, the balloon or a chamber thereof may be secondarily inflated, deflated, or a combination thereof in situ.

In some embodiments, the implant comprises an ingrowth matrix on at least a portion of the implant adjacent the femur. In some embodiments, the ingrowth matrix comprises living chondrocytes. In some embodiments, the implant is configured to release the chondrocytes over time. In some embodiments, the implant comprises a bioabsorbable polymer configured to release the chondrocytes over time. In some embodiments, the implant comprises a polymer configured to release the chondrocytes over time, wherein the polymer is not bioabsorbable. In some embodiments, the ingrowth matrix comprises at least one of: autologous cells, allograph cells, and xenograph cells to restore an articular surface of the femur. In some embodiments, the ingrowth matrix comprises at least one of: autologous cells, allograph cells, and xenograph cells to repair an articular surface of the femur.

In some embodiments, the implant comprises couplers that couple the appendage to the femur. In some embodiments, the coupler is bioabsorbable. In some embodiments, the coupler is at least one of: a screw, a washer, a suture, a suture anchor, a rivot, a staple, a staple having teeth, a stabilizer, a glue, a hook, a wire, a string, a lasso, a lanyard, a spike, and combinations thereof. The implant may also and/or alternatively be attached via bone ingrowth.

In some embodiments, the implant comprises a phamacologic agent. In some embodiments, the pharmacologic agent is on a surface of the implant adjacent the femur. In some embodiments, the pharmacologic agent is released from the implant over time. In some embodiments, the pharmacologic agent is released from within the implant over time. In some embodiments, the pharmacologic agent is released from within the balloon over time.

In some embodiments, the inflation medium is compressible. In some embodiments, the inflation medium comprises a viscolubricant. In some embodiments, the inflation medium comprises an NSAID. In some embodiments, the inflation medium comprises chondrocytes.

In some embodiments, at least a portion of the implant is configured to anneal to a periphery of a cartilage defect.

In some embodiments, the implant comprises vacuoles of pharmacologic substances. In some embodiments, the vacuoles may be on a bone-engaging portion of the implant. In some embodiments, the implant comprises bubbles comprising an active substance such as a pharmacologic substance or other active agent. In some embodiments, the active agent comprises at least one of: stem cells, growth factors, antibiotics, and viscolubricants. In some embodiments, the active agent comprises iatrigenically gene mutated cells.

In some embodiments, the implant comprises enzyme absorptive microscopic sponges that could be sucked out or evacuated at or around the time of implant delivery to the joint.

In some embodiments, the implant comprises spaces filled with an active substance such as a pharmacologic substance or other active substance. In some embodiments, the implant is configured to deliver by dissolution of the implant material In some embodiments, the implant is configured to deliver by release through pores of the implant. In some embodiments, the implant is configured to deliver by fracture of a vacuole by a catalyst such as ultrasound or pressure or other fracturing catalyst.

In some embodiments, the implant is configured to at least one of: pad cartilage, cushion the joint, deliver a pharmacologic substance, remove noxious enzymes, debride upon implantation, debride the joint following implantation, deliver a therapeutic substance, deliver a biologic substance, and deliver living stem cells. In some embodiments, the implant is configured to deliver a chemotherapeutic agent to a bone or other surrounding tissues. In some embodiments, the implant is configured to deliver an anti-infectious medication to a bone or other surrounding tissues. In some embodiments, the implant is configured to deliver at least one of an antibiotic, antifungals, and analgesics agent.

In some embodiments, the implant is configured to be selectively inflated to realign limbs.

Provided herein is a method comprising: implanting a knee implant as described herein into a subject, wherein the implant reverses arthritis in the subject.

Provided herein is a method comprising: implanting a knee implant as described herein into a knee joint of a subject and treating a component of the knee joint of the subject with at least one of an allograph tissue, an autograph tissue, and an xenograph tissue. In some embodiments, the implanting step is at least one of: prior to the treating step, simultaneous with the treating step, and following the treating step.

Provided herein is a method comprising: implanting a knee implant as described herein into a subject, wherein the implant at least one of: restores joint function and controls arthopathies. In some embodiments, the implanting spares existing anatomy.

Provided herein is a method comprising: debriding a femur condyle of a knee joint of a subject, and implanting a knee implant as described herein into the knee joint of the subject, whereby the implant is configured to anneal to the cartilage of the subject. In some embodiments, the debriding is achieved by steam application.

Provided herein is a method comprising implanting a knee implant as described herein into a joint previously treated with a joint replacement. In some embodiments, the method comprises removing the joint replacement prior to implanting the knee implant. In some embodiments, the method comprises clearing infectious matter from the joint and/or surrounding tissues. In some embodiments, the method comprises implanting a second implant of any implant described herein following removing the implant previously implanted in the joint. In some embodiments, the method comprises replacing the joint of the subject following removing the implant previously implanted in the joint. In some embodiments, the method comprises debriding the bone of the joint, and implanting an implant of any implant described herein. In some embodiments, the method comprises repeating the debriding and implanting steps.

These and other advantages of the invention will become more apparent from the following detailed description and the attached exemplary drawings.

INCORPORATION BY REFERENCE

All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

FIG. **1** depicts an embodiment of the knee implant having appendages including holes and tabs extending from a balloon and including slots to accommodate ligaments of the knee joint.

FIG. **2** depicts an embodiment of the knee implant having appendages including holes and tabs extending from a balloon and including slots to accommodate ligaments of the knee joint as well as side views of the same knee implant.

FIG. **3** depicts an embodiment of the knee implant having appendages including holes and tabs extending from a balloon and including slots to accommodate ligaments of the knee joint as well as side views of the same knee implant.

FIG. **4**A depicts an embodiment of the knee implant having appendages including ten tabs extending from a balloon and including a slot to accommodate components of the knee joint.

FIG. **4**B depicts an embodiment of the knee implant having appendages including eight tabs extending from a balloon and including a slot to accommodate components of the knee joint.

FIG. **5** depicts an embodiment of the knee implant curved to simulate curvature about the condyles of a femur, the implant having appendages extending from an uninflated balloon (not shown) and including slots to accommodate ligaments of the knee joint.

FIG. **6**A depicts a top-down view of an embodiment of the knee implant curved to simulate curvature about the condyles of a femur, the implant having appendages extending from two inflated balloons and including slots to accommodate components of the knee joint.

FIG. **6**B depicts a bottom-up view of an embodiment of the knee implant curved to simulate curvature about the condyles of a femur, the implant having appendages extending from two inflated balloons and including slots to accommodate components of the knee joint.

FIG. **7** depicts a top-down view of an embodiment of the knee implant curved to simulate curvature about the condyles of a femur, the implant having appendages extending from an inflated balloon and including slots to accommodate components of the knee joint.

FIG. **8** depicts a side view of an embodiment of the knee implant curved to simulate curvature about at least one condyle of a femur, the implant having appendages extending from an uninflated balloon (not shown).

FIG. **9**A depicts a side view of an embodiment of the knee implant curved about at least one condyle of a femur, the implant having appendages extending from an uninflated or minimally inflated balloon.

FIG. **9**B depicts a side view of an embodiment of the knee implant curved about at least one condyle of a femur, the implant having appendages extending from an inflated balloon.

FIG. **9**C depicts a side view of an embodiment of the knee implant curved about at least one condyle of a femur, the implant having appendages extending from an inflated balloon and having staples or screws coupling the appendages to the femur.

FIG. **10**A depicts a side view of an embodiment of the knee implant curved about at least one condyle of a femur, the implant having appendages extending from an inflated balloon and showing the inflation medium moved anteriorly toward the patella when the knee joint is flexed.

FIG. **10**B depicts a side view of an embodiment of the knee implant curved about at least one condyle of a femur, the implant having appendages extending from an inflated balloon and having staples or screws coupling the appendages to the femur and showing the inflation medium moved anteriorly toward the patella when the knee joint is flexed.

FIG. **11**A depicts an embodiment of the unicompartment knee implant curved to simulate curvature about one condyle of a femur, the implant having appendages extending from an uninflated balloon (not shown) and including tabs and holes which may be used with couplers to couple the implant to the femur of the knee joint.

FIG. **11**B depicts an embodiment of the unicompartment knee implant curved to simulate curvature about one condyle of a femur, the implant having appendages extending from an inflated balloon and including tabs and holes which may be used with couplers to couple the implant to the femur of the knee joint.

FIG. **11**C depicts a bottom-up view of an embodiment of the unicompartment knee implant curved to simulate curvature about one condyle of a femur, the implant having appendages extending from an inflated balloon and including tabs and holes which may be used with couplers to couple the implant to the femur of the knee joint.

FIG. **12**A depicts a bottom-up view of an embodiment of the unicompartment knee implant or patch implant, the implant having appendages, extending from a balloon and including holes, which may be used with couplers (not shown) to couple the implant to the femur of the knee joint.

FIG. **12**B depicts a bottom-up view of an embodiment of the unicompartment knee implant or patch implant, the implant having appendages, extending from a balloon and including tabs and a hole which may be used with couplers (not shown) to couple the implant to the femur of the knee joint.

FIG. **12**C depicts a bottom-up view of an embodiment of the unicompartment knee implant or patch implant, the implant having appendages, extending from a balloon and including tabs and a hole which may be used with couplers (not shown) to couple the implant to the femur of the knee joint.

FIGS. **13**A-**13**D depict multiple views of a staple adapted to couple an implant to a bone of the joint.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is directed to arthroplasty implants and procedures for a knee.

Knee interpositional arthroplasty can replace existing total joint metal/plastic technology. It intends to fill the gap (literally in some embodiments of the implant) in cases where arthroscopic debridement fails to provide cure, since we can only 'polish arthritis' and 'clean up the joints' to date. The polymer medically inflatable implants may physiologically restore joint function. Padding is provided where cartilage is damaged, cushioning to both the femoral tibial and patella femoral joints when narrowed or pathologic. The implant in some embodiments is adapted to deliver cells, autologous (from the patient), allograph (from another member of the same species) or xenograph (from another species,) that restore articular surfaces. Since cartilage is an immunologically privileged tissue, the antigens are buried in the cartilage matrix and antibodies do not reject the refurbished surface coating.

The gap (or gaps) filled by the balloon or balloons of the implant will provide compliance between opposing joint surfaces (the femoral condyle or condyles and tibial plateau). The femur may have some portion (of not all) of the retropatellar rounded facet "V" shape of hyaline, normally about 5 mm thick, or it may not have such hyaline when the implant is inserted. The tibial plateau may have some portion of meniscal fibrocartilages, including all of said fibrocartilages, none of said fibrocartilages, or some portion thereof. When the knee is extended (straight) the implant buffers the femorotibial joint. When the knee is flexed, the implant balloon apposition is more between the trochlear groove portion of the anterior distal femur (groove between the condyles on the 'front of the knee') and the patella.

The knee anatomy is unique to other joint anatomies and thus has a unique set of challenges that are addressed by the implant embodiments described herein. For example, the knee is not a ball and socket joint like a hip; it is a combination of two joints—the femoral-tibial joint and the patellar-femoral joint. The bones of the knee have facets and irregularities that must be accommodated by a conformable implant directed to the particular shapes of the bones without impeding the joints' functions and movements, and/or which minimizes impedence to such function and movement. Not only do the joints of the knee work together to allow extension and flexion of the knee, but the knee is also designed to allow rotational movement in a screw-like manner. That is, as the tibia is twisted relative to the femur, the joints are uniquely designed to allow this twist, but to limit the twist as well. Furthermore, the knee joints are able to withstand forces that vary depending on the particular movement of the individual, not only in force strength, but in direction as well. Thus, the implants as described herein are uniquely designed to account for these factors and result in a knee having preserved natural tissues as well as preserved function and movement as compared to typical arthroplasty procedures (such as partial or full knee replacements).

As described herein, embodiments of the implant conform to the patient's own joint features not only in that it can be pre-molded and/or adapted to couple to the contours of the patient's bone (condyle, etc), but in that it has a balloon having an inflation medium that is conformable to the joint anatomy and allow freedom of joint movement much like natural joint while preserving the joint and bone natural tissues as much as possible. With the ability to fill various chambers of the balloon with varying materials, and to add rigid and/or semi-rigid pieces to the implant, the implant can additionally have leveling capabilities and alignment capabilities.

Diagnoses:

Patients may complain of pain and knee joint dysfunction signaled by locking, clicking, or giving way. Knees may be swollen, malaligned or show crepitus (palpable crunching on movement.) Instability of ligaments whether anterior/posterior cruciates, or medial/lateral conlaterals, are treated by techniques separate for those entities via allowance for healing (as for collaterals) or via cruciate repair or reconstruction.

Indications for use of implants provided herein may be those patients recognizing greater than or equal to 2 Sq cm of 3-4+/4 traumatic arthritis (ala Carticel). In such cases, the cartilage defect is often precisely locally symptomatic, with point tenderness, clicking if a loose cartilage flap exists, and may be visible on MRI and/or arthroscopic inspection and/or through palpation. The implants used herein may additionally and/or alternatively be appropriate when existed techniques such as 'picking', K wire drills, and/or allograph implants fail.

Patients with knee problems typically complain of pain and dysfunction. Pathognomonic symptoms for meniscal tearing include locking, clicking, giving way from wear or twisting the knee. Aching diffusely may arise from arthritis or synovitis; anterior knee pain is generally patella-femoral, increased with stair use due to magnified body weight forces. Diagnosis should be accurate as distinguished from pain through the knee actually arising in the back caused by L4 nerve root irritation. Physical Exam findings of pathologic knees include observed swelling, redness, or deformity. Palpation often aids focus on which compartments are involved. The patella inhibition test position connotes retropatellar pathology, and often tracking problems that warrant soft tissue or boney correct. Improved limb alignment will increase benefits, and can in part accrue from selective inflation of embodiments of the implants provided herein. X-rays of the knee are best evaluated in weight bearing views, and should be coupled with other data including MRI or CT. Relative compartment narrowing suggests cartilage degradation. Once an embodiment of an implant described herein has been successfully implanted and the knee adequately rehabilitated, the appearance of a knee with such implant should resemble a normal joint X-ray. Knee distension is from saline and/or air insufflation. Knee implant patients will benefit from tailored rehab programs, cautious weight bearing, early motion, and potential the use of constant passive motion machine regimens.

General Features

Implant Aspects

Provided herein is a resilient implant for implantation into knee joints to act as a cushion allowing for renewed joint motion. The implant may endure variable knee joint forces and cyclic loads while reducing pain and improving function after injury or disease to repair, reconstruct, and regenerate joint integrity. The implant may be deployed in a prepared debrided knee joint space, secured to at least one of the knee joint bones and expanded in the space, molding to surrounding structures with sufficient stability to avoid extrusion or dislocation. The implant may have has opposing walls that move in varied directions, and an inner space filled with suitable filler to accommodate motions which mimic or approximate normal knee joint motion. The implant may pad the damaged joint surfaces, restores cushioning immediately and may be employed to restore cartilage to normal by delivering regenerative cells.

Provided herein is a resilient interpositional arthroplasty implant for application into knee joints to pad cartilage defects, cushion joints, and replace or restore the articular surface, preserving joint integrity, reducing pain and improving function. The implant may endure variable knee joint compressive and shear forces, and millions of cyclic loads, after injury or disease requires intervention. The implant may repair, reconstruct, and regenerate knee joint anatomy in a minimally morbid fashion, with physiologic solutions that improve upon the rigid existing joint replacement alternatives of plastic and metal. In cases where cells have been used for joint resurfacing requiring massive periosteal harvesting for containment, the polymer walls of some embodiments of the implant can capture, distribute and hold living cells until aggregation and hyaline cartilage regrowth occurs. The implant may be deployed into a prepared debrided knee joint space, molding and conforming to surrounding structures with sufficient stability to avoid extrusion or dislocation. Appendages (or tabs) of the implant may serve to repair or reconstruct tendons or ligaments. The implant may have opposing walls that move in varied directions, and an inner space, singular or divided, filled with suitable gas, liquid, and/or complex polymer layers as force-absorbing mobile constituents, such than robust valid and reliable joint motion is enabled.

Provided herein is a resilient orthopedic implant configured for deployment between a femur and at least one second bone of a joint. The second bone may be a tibia. The second bone may be a patella. The implant further comprises a balloon comprising a first portion that is configured to engage the femur, a second portion that is configured to engage the second bone of the joint, a side portion connecting the first portion and the second portion, in which the side portion facilitates relative motion between the first portion and the second portion, and an interior that is optionally inflatable with a first inflation medium; and a first appendage configured to couple the balloon to the femur. The terms "balloon" and "bladder" may be used interchangeably throughout this disclosure to describe an implant having the features described herein.

In some embodiments, at least two of the first portion, the second portion, and the side portion are contiguous. In some embodiments, the first portion comprises a first wall, the second portion comprises a second wall, and the side portion comprises a side wall. As used herein, each of the terms the "first portion", the "second portion", and the "side portion" is used to describe a part of the balloon, and may not be separate parts in some embodiments. Rather, in some embodiments, each is named in order to indicate the general geometry and location of each portion relative to the other of the portions and/or relative to bones and/or ligaments and/or tendons of the joint. Likewise, as used herein, each of the terms the "first wall", the "second wall", and the "side wall" is used to describe a part of the balloon, and may not be separate parts of the balloon in some embodiments. Rather, in some embodiments, each of the walls is named in order to indicate the general geometry and location of each portion relative to the other of the portions and/or relative to bones and/or ligaments and/or tendons of the joint. In some embodiments, at least two of first wall, the second wall, and the side wall are contiguous. Nevertheless, each of the walls may, in some embodiments, be separate parts of the implant that are joined to form the implant. Likewise, each of the portions may, indeed, in some embodiments, be separate parts of the implant that are joined to form the implant.

In some embodiments, the first portion is a term used interchangeably with the first wall. In some embodiments, the second portion is a term used interchangeably with the second wall. In some embodiments, the side portion is a term used interchangeably with the side wall. In some embodiments, a wall (whether a first wall, a second wall, and/or a side wall) of

the implant may comprise a plurality of layers. The wall may comprise multiple materials to impart physical and/or therapeutic characteristics to the wall.

In some embodiments, the implant comprises a second appendage coupling the balloon to the first bone of the joint. In some embodiments, the implant comprises a second appendage coupling the balloon to at least one second bone of the joint. In some embodiments, the implant comprises a second appendage configured to couple at least one of the first portion, the second portion, and the side portion to at least one of the first bone and at least one second bone of the joint. In some embodiments, the first appendage and the second appendage are configured to provide ligamentary-like support to the first bone and the at least one second bone of the joint. In some embodiments, the first appendage and the second appendage are configured to provide ligamentary-like support to the joint. In some embodiments, the first appendage and the second appendage are configured to provide tendon-like support to the first bone and the at least one second bone of the joint. In some embodiments, the first appendage and the second appendage are configured to provide tendon-like support to the joint.

In some embodiments, the implant comprises an inflation port in communication with the interior of the balloon for inflation of the interior of the balloon with the first inflation medium. In some embodiments, the balloon is punctured to inflate the interior of the balloon with the first inflation medium. In some embodiments, the balloon is self-sealing. In some embodiments, the balloon is self-sealing upon inflation of the interior of the balloon with the first inflation medium. In some embodiments, the implant comprises a seal capable of closing the interior of the balloon.

In some embodiments, the interior comprises a plurality of inflatable chambers. In some embodiments, the interior comprises a plurality of individually inflatable chambers. In some embodiments, a first chamber of the plurality of individually inflatable chambers is adapted to be inflated with the first inflation medium, and a second chamber of the plurality of individually inflatable chambers is adapted to be inflated with a second inflation medium.

In some embodiments, the interior comprises a honeycomb structure. In some embodiments, the interior comprises a mesh structure. In some embodiments, the interior comprises a sponge structure.

In many embodiments the implant (or a portion thereof, such as the balloon or balloons) is a weight bearing spacer that will allow joint motions to approach normal, whether filling the space left by an entirely collapsed joint bone or the space of ablated cartilage proximate surfaces diffusely as in osteoarthritis or succinctly as in osteonecrotic defects or localized trauma. The walls of the implant may be used as a membrane for holding living cells in proximity of the osteochondral defect long enough for the cells to attach (e.g. 24 hours) or to deeply adhere (up to 28 days) or return to normal (up to one year). Weight bearing will be expected to increase as distal lower extremity joints are treated.

Movement (whether linear or curvilinear) between the first and second walls of the implant (i.e. of the balloon) as a result of movement of the femur and the tibia is illustrated in the comparison between FIGS. **9**B and **10**A, or in the comparison between FIGS. **9**C and **10**B. In some embodiments, the implant may comprise a balloon that is configured to allow a wall of the implant rolling upon another wall (or the same wall) of the implant (e.g. the side wall rolling upon the first wall, the first wall rolling upon the second wall, the second wall rolling upon the first wall, the first wall rolling upon the side wall, the second wall rolling upon the side wall, the side wall rolling upon the second wall, the first wall rolling upon the first wall, the second wall rolling upon the second wall, and/or the side wall rolling upon the side wall). In some embodiments, the implant may comprise a balloon that is configured to allow a portion of the implant rolling upon another portion (or the same portion) of the implant (for non-limiting example, the side wall rolling upon an appendage, the first wall rolling upon an appendage, and/or the second wall rolling upon an appendage). In some embodiments, the implant may comprise a balloon that is configured to allow movement of a portion of the implant rolling upon cartilage. While not shown in the drawings, there may be slippage between the a portion of the implant (whether an appendage, a wall, or some other portion of the implant) and a joint component (whether a bone, ligament, tendon or other tissue). This slippage may be in addition to wall movements within the implant per se to provide desired joint movements. While not shown in the drawings, there may be slippage between the second bone (for example, the tibia) and the second wall in addition to wall movements within the implant per se to provide desired joint movements. The appendage (or appendages) is (are) designed to secure the implant to the knee joint structure so as to avoid dislocation of the implant. Movement of the joint with the implant in place will be a shared function of both the moving opposing walls of the implant but also a function of the movement of the wall which may be less attached to the joint members. There may be slight movement between the appendage, first wall and the femur. The walls of the balloon may compress and/or stretch to accommodate bone interface movement. Material choices, material dimensions, and implant dimensions, placement and/or coupling may be chosen to allow for the desired amount of compression, stretching relative movement of various joint and/or implant components. For non-limiting example, the walls of the implant may be thicker is some areas to accommodate particular loads and the side wall may be thinner and more elastic to accommodate rolling and stretching thereof.

Motion is believed to be primarily between the spaced walls (or portions) of the implant peripherally secured to joint structures, although some motion may occur between the implant and the joint surfaces. As shown multiple Figures (including, FIGS. **1**-**7**), the implant may be provided with a slot extending from the periphery of the implant toward the balloon of the implant to accommodate at least one ligament of the joint. Knee implants may have two slots leading to separate passages for receiving the anterior and posterior cruciate ligaments. Implant walls should have sufficient inherent flexibility to mold to the existing deformities imposed by either natural ligament, bone, tendon and remaining cartilage deformities of the internal joint space filled as a cushion. The wall exteriors may be flat or formed with random or specific patterns for purposes of glide or trends for traction against adjacent surfaces, or as sulci or venues for cell delivery materials.

The exterior of the implant may have a mesh material with a plurality of chords (or appendages) for securing the implant to adjacent bones or to remnant ligaments which are attached to adjacent bones.

The dimensions of the various implant walls will vary depending upon the material properties thereof as well as the needs for a particular joint. Additionally, the first and second walls may require a thickness different from the side wall. Generally, the implant may have a wall thicknesses of about 0.125 mm to about 3 mm, preferably about 0.5 mm to about 1.5 mm. The spacing between the first and second wall within the interior can vary from about 0.5 mm to about 5 mm.

In some embodiments, the implant has a first wall, a second wall, and a side wall which define the implant interior (or interior) which contains filling material. In some embodiments, the filling material is an inflation medium. The first wall is secured to the end of the femur by at least one appendage that extends from the first wall and the second wall engages the end surface of the second bone (which in the case of a femoral-tibial joint implant, would be the tibia) and may also be secured thereto. The side wall extending between the first and second walls defines at least in part the implant interior which is filled with filling material (or an inflation medium). The inner surfaces of wall and appendage may conform to the particular surface femur, for example by being wider in particular locations and/or longer in particular areas. For example a dual compartment implant (described herein) may have a wider section to cover the medial condyle than the lateral condyle (as shown in FIGS. **1**, **2**, **3**, **6**A, **6**B, and **7**). In another example, the length of the implant the along the external edge may be longer than the length of the implant along the trochlear groove edge (as shown in FIGS. **11**A, **11**B and **11**C). In yet another example, the width may vary along a single condyle, such as is shown in FIGS. **12**A-**12**C, wherein the wider edge of the implant is adapted to fit over at least a portion of the anterior condyle, and the narrower portion is adapted to fit over at least a portion of the posterior condyle. In some embodiments, the inner surfaces of the first wall and appendages preferably conform to the particular surface of the patient's femur, and do so by not only dimensions of the implant (lengths, widths, balloon location and shape), but also and/or alternatively due to appendage and/or tab and/or hole and/or coupler location and/or surface contours of the first wall. The outer surface of the second wall may be configured to conform to the end surface of the second bone (which may be a tibia or a patella, for example). In some embodiments, the outer surface of the second wall is configured to conform to a surface of the second bone (which may be a tibia or a patella, for example). The figures provided herein are highly schematic and do not depict details of the joint surface features, since human pathology and variation reflects both the patient's immediate and evolving pathophysiology. Neither do the figures depict other joint features such as cartilage, tendons, ligaments and other soft tissues and fluids of the joint for ease of viewing that which is depicted.

In some embodiments, the implant is configured to resemble the shape of the natural hyaline of a normal knee. For example, the normal hyaline is typically "H" shaped, thus certain embodiments of the implant are generally "H" shaped.

Implant Materials and Material Features

In some embodiments, the implant comprises polymer. Polymers may comprise at least one of: a polyurethane (such as, for example, ChronoFlex AR), a polycarbonate urethane, a thermoplastic polycarbonate urethane (such as Bionate 55), ethylene-vinyl acetate copolymer, multiblock copolymers of poly(ethylene oxide) (PEO) and poly(butylene terephthalate) (PBT), PEG, PEO, and a polyetheylene. In some embodiments the implant comprises a 125 micron thickness thermoplastic polycarbonate urethane.

The implant may comprise to a plurality of layers of polymer (such as ChronoFlex AR) in a solvent and evaporating the solvent after applying each layer. In some embodiments, the implant comprises a polyurethane that is sprayed and dried (wherein the spraying and drying is repeated at least once) to a desired thickness.

In some embodiments, the implant is created by dip molding a mandrel having a shape of a bone of the knee joint (the medial condyle, the lateral condyle, the tibia, for non-limiting example) into a polymer solution (for non-limiting example, a urethane polymer such as Chronoflex). Following each dip, the implant is dried for a specified time, which may be, for example, about 3 seconds, about 4 seconds, about 5 seconds, about 6 seconds, about 7 seconds, about 8 seconds, about 9 seconds, about 10 seconds, about 15 seconds, about 20 seconds, about 25 seconds, about 30 seconds, about 45 seconds, about 1 minute, about 2 minutes, about 5 minutes, about 10 minutes, about 15 minutes, and over about 15 minutes. The term "about" used herein in reference to drying time of the implant can mean variations of at least one of 5%, 10%, 25%, and 50%, In some embodiments, no drying step is used. The dipping may be repeated multiple times. In some embodiments a single dip is sufficient. In some embodiments, the dipping is repeated 2 times. In some embodiments, the dipping is repeated 3 times. In some embodiments, the dipping is repeated 4 times. In some embodiments, the dipping is repeated 5 times. In some embodiments, the dipping is repeated 6 times. In some embodiments, the dipping is repeated 7 times. In some embodiments, the dipping is repeated 8 times. In some embodiments, the dipping is repeated 9 times. In some embodiments, the dipping is repeated 10 times. In some embodiments, the dipping is repeated 11 times. In some embodiments, the dipping is repeated 12 times. In some embodiments, the dipping is repeated 13 times. In some embodiments, the dipping is repeated 14 times. In some embodiments, the dipping is repeated 15 times. In some embodiments, the dipping is repeated 16 times. In some embodiments, the dipping is repeated 17 times. In some embodiments, the dipping is repeated 18 times. In some embodiments, the dipping is repeated 19 times. In some embodiments, the dipping is repeated 20 times. In some embodiments, the dipping is repeated 21 times. In some embodiments, the dipping is repeated 22 times. In some embodiments, the dipping is repeated 23 times. In some embodiments, the dipping is repeated 24 times. In some embodiments, the dipping is repeated 25 times. In some embodiments, the dipping is repeated over 25 times. In some embodiments, the dipping is repeated a sufficient number of times to create an implant that is a prescribed thickness. The thickness may vary depending on the polymer and depending on the embodiment of the implant. The thickness may be at least one of: about 25 microns thick, about 50 microns thick, about 100 microns thick, about 125 microns thick, about 150 microns thick, about 200 microns thick, about 250 microns thick, about 300 microns thick, about 350 microns thick, about 400 microns thick, about 25-50 microns thick, about 50-100 microns thick, about 50-200 microns thick, about 100-150 microns thick, about 150-300 microns thick, about 100-300 microns thick, about 100-500 microns thick, about 200-500 microns thick, and about 200-1000 microns thick. The term "about" used herein in reference to thickness of the implant can mean variations of at least one of 5%, 10%, 25%, and 50%, The thickness may vary at different locations of the implant. In some embodiments, the implant is fabricated in two pieces, one or more of which is molded to form an interior when the two pieces are put together. In some embodiments, the implant is filled by puncturing the implant wall and sealing the puncture hole with a plug, patch or other sealant. The plug, patch, or other sealant may comprise Chronoflex material, for non-limiting example. The plug, patch, or other sealant may comprise the same material from which the implant is constructed, for non-limiting example.

The walls of the implant embodying features of the invention may be composite structures. For example, the innermost layer may be impervious to preclude escape of inflation or

other filling media, a central layer may be porous or otherwise contain treatment or cell regeneration agents, and the outer layer may be a thin, but strong layer of a thermoplastic, such as a thermoplastic polyurethane for non-limiting example, which has microporosity sufficient to allow passage or egress of treatment or cell regeneration agents from the central layer (or second layer). The degree of microporosity to enable egress of treatment or cell regeneration agents from the central layer is found in polymer layers such as Chronoflex or Bionate 55.

The external wall (and/or the bone engaging surface) of the implant may be coated and/or impregnated with a latticework of polymer that is surface sprayed or layered on the outside (or bone engaging surface) of the implant to promote cartilage tissue regeneration. This most external surface coating may contain living chondrocytes (for example, as is provided in the Carticel procedure by the Genzyme company), and/or may contain stem cells with directed gene mutations to enhance adherence of the coating to the implant. The bone engaging surface may comprise peaks and troughs. The living cells may be imposed in between (and/or provided in the) troughs of the implant surface while the surface areas of prominence (the peaks of the surface) may be used for at least one of: space validation, traction, and cell protection.

The implant may be formed of suitable bioabsorbable materials so that the implant may be absorbed within a particular predetermined time frame. Suitable bioabsorbable materials include polylactic acid, polyglycolic acid, polycaprolactone, copolymers, blends and variants thereof. Suitable bioabsorbable materials may also/alternatively include poly (hydroxyalkanoate)s of the PHB-PHV class, additional poly (ester)s, and natural polymers, particularly, modified poly (saccharide)s, e.g., starch, cellulose, and chitosan. The walls of the implant may be (in whole and/or in part) bioabsorbable. The balloon may be (in whole and/or in part) bioabsorbable. As used herein the terms bioabsorbable, bioerodable, and/or bioabsorbable may be used interchangeably. The walls of the implant may release a pharmaceutical agent or an biological agent (such as stem cells, living chondrocytes, gene therapies, and the like). The release of such agents (whether biological or pharmaceutical, or a combination thereof) may occur over time, as the wall of the implant (or as the balloon) bioabsorbs in some embodiments, or as the joint is used (i.e. through pressure, for non-limiting example). In some embodiments, at least one of the implant walls is permeable to a pharmaceutical agent and/or a biological agent, such as in an embodiment wherein the inflation medium comprises the pharmaceutical agent and/or biological agent. In some embodiments, at least one of the implant walls has pores through which the pharmaceutical agent and/or the biological agent may fit, such as in an embodiment wherein the inflation medium comprises the pharmaceutical agent and/or biological agent.

The implant may be provided with latticework or other reinforcing strands, preferably on the exterior or within the wall thereof to control the maximum expansion of the implant when deployed at the orthopedic site.

In some embodiments, the implant comprises amniotic membrane (and/or a component thereof). In some embodiments, the implant comprises amniotic sac (and/or a component thereof). In some embodiments, the implant comprises amniotic tissue (and/or a component thereof). Amniotic membrane (and/or sac and/or tissue) is unique in that its mechanical properties include that it slippery on one side (lubricious, low modulus of elasticity) and sticky (adherent) on the other. In some embodiments, at least one of the first wall, the second wall and the side wall comprise amniotic membrane or a component thereof. In some embodiments, at least one of the first wall, the second wall and the side wall comprise amniotic sac or a component thereof. In some embodiments, at least one of the first wall, the second wall and the side wall comprise amniotic tissue or a component thereof. The amniotic membrane and/or amniotic sac and/or amniotic tissue may be used in conjunction with other biologic agents, pharmaceutical agents, and/or therapeutic agents. Amniotic tissue is used extensively in pleuripotential cells. It qualifies as HTBP (Human Tissue Based Product) because of the short term time span on the product and origin.

In some embodiments, the balloon is a composite structure. In some embodiments, the balloon comprises layers of porous and/or non-porous materials, or otherwise contain treatment or cell regeneration agents. In some embodiments, a first layer of the balloon is a thin, but strong layer of a thermoplastic, such as a thermoplastic polyurethane, for non-limiting example, which has microporosity sufficient to allow passage or egress of treatment or cell regeneration agents from a second layer. The second layer may be a central layer (which lies between the first layer and a third layer or a fourth layer or more layers). The first layer may comprise a bone engaging surface in some embodiments. The degree of microporosity to enable egress of treatment or cell regeneration agents from the second layer is found in polymer layers such as Chronoflex or Bionate 55. The bone engaging surface of the implant may be coated and/or impregnated with a latticework of polymer that is surface sprayed or layered on the bone engaging surface of the implant to promote cartilage tissue regeneration. This bone engaging surface coating may contain living chondrocytes (for example, as is provided in the Carticel procedure by the Genzyme company), and/or may contain stem cells with directed gene mutations to enhance adherence of the coating to the implant. The bone engaging surface may comprise peaks and troughs. The living cells may be provided in troughs while the surface peaks may be used for at least one of: space validation, traction, and cell protection.

In some embodiments, the implant is pre-molded to fit about at least one condyle of the femur. In some embodiments, the implant comprises a memory plastic. In some embodiments, the implant comprises a wire frame. In some embodiments, the wire of the wire frame comprises a memory metal. In some embodiments, the memory metal comprises nitinol. In some embodiments, the wire frame is disposed in the periphery of the implant or a portion thereof. In some embodiments, the wire frame is configured to aid in placement against the posterior of the condyle.

In some embodiments, at least a portion of the implant comprises a slippery surface. In some embodiments the slippery surface is configured to allow for relative movement between the implant (or a portion thereof) that is coupled to the femur and the tibia. In some embodiments the slippery surface is configured to allow for relative movement between the implant (or a portion thereof) that is coupled to the femur and the patella.

Inflation Medium and Inflation or Filling of the Implant Interior

In some embodiments, the implant comprises an inflation medium that is compressible. In some embodiments, the implant comprises an inflation medium that comprises a viscolubricant. In some embodiments, the implant comprises an inflation medium that comprises a pharmacologic substance. In some embodiments, the implant comprises an inflation medium that comprises an NSAID. In some embodiments, the implant comprises an inflation medium that comprises chondrocytes. In some embodiments the implant is configured to anneal the outer most layer of the implant (or a portion thereof) to the peripheral of succinct cartilage defects so as to

cover them, allowing for healing. In some embodiments the implant is configured to anneal the outer most layer of the implant (or a portion thereof) to the peripheral of succinct cartilage defects so as to cover them, allowing for healing once new chondrocytes have been installed.

The implant interior (balloon interior) may be inflated with gas. The implant interior (balloon interior) may be inflated with liquid. The implant interior (balloon interior) may be inflated with saline. The implant interior (balloon interior) may be inflated with suspended stem cells. The implant interior (balloon interior) may be inflated with gel. The implant interior (balloon interior) may be inflated with a viscolubricant. The inflation medium in some embodiments stays within the balloon, or a portion thereof (as where there are multiple chambers to the balloon). In some embodiments, balloon contents disburse through microporosities and/or dissolving membranes into the joint. In some embodiments, balloon contents disburse by expulsive or evacuation precipitated through an implant wall after pressure from limb use. In some embodiments, balloon contents disburse by expulsive or evacuation precipitated through an implant wall from planned osmosis. In some embodiments, balloon contents disburse by expulsive or evacuation precipitated through an implant wall from vacuole rupture (whether mechanical rupture, ultrasound, or chemical rupture, for non-limiting example). In some embodiments, balloon contents disburse by expulsive or evacuation precipitated through an implant wall thereby distributing contents of the implant interior to joints as lubricious, analgesic, anti-inflammatory and/or otherwise healing substances. In some embodiments, the implant may comprise solid beads or beads containing gel or liquid for sequential disbursement by compressive force through rupture with varied bead wall thicknesses, or the beads may be time-released (opened) chemically, pharmacologically, or by an outside ultrasound or magnetic force external knee application at appropriate clinical intervals. In some embodiments, the implant may comprise vacuoles containing gel or liquid for sequential disbursement by compressive force through rupture with varied vacuole wall thicknesses, or the vacuoles may be time-released (opened) chemically, pharmacologically, or by an outside ultrasound or magnetic force external knee application at appropriate clinical intervals.

The implant interior (or balloon interior) between the first wall and the second wall is filled with filler material (or an inflation medium) which aids in maintaining the desired implant dynamics within the joint structure. The nature of the filler material such as a fluid and the characteristics of the walls may be selected to maintain a desired spacing between the walls in order to accommodate the pressure applied by the bones of the joint structure to the implant and to allow suitable motion between the first and second walls of the implant which facilitate bone motion which mimics or approximates normal movement for the joint members involved.

Alternatively (and/or additionally), the inner chamber (interior or a portion thereof) may be filled with resilient material to provide the desired spacing, pressure accommodation, while allowing desired physiologic motion between implant layers. The implant may be configured to be shaped like the joint space and bone surfaces being replaced or to fill the void produced by injury or disease so that the natural joint spacing and cushioning of the joint interface is restored toward normal physiologic appearance and function. Fluids such as saline, mineral oil and the like may be employed to inflate the implant.

The interior of implant is adjustably filled by the physician from an appropriate source thereof after the implant is deployed to ensure that the pathologic joint space becomes a resilient cushion again which aids restoration of worn or damaged cartilage interfaces in the joint by covering cartilage defects with the implant material, cushioning the joint and defects therein and delivering cell regeneration agents. In one embodiment, the implant comprises a bio-compatible inflatable member (balloon) that is filled with a biocompatible fill material (inflation medium) such as a gas, liquid, gel or slurry, or fluid that becomes a resilient solid to provide relative movement between the first and second walls. The filling or inflation media may be inserted through an injection valve site leading to the cannula which delivers the material into the interior of the implant. In an alternative embodiment, the implant may be filled with or have an interior formed of biologically compatible resilient material, e.g. a closed cell sponge filled with suitable fluid that is inserted into the interior of the implant prior to the implant's deployment or injected into the interior after the implant is deployed at the joint site. The interior of the implant may be provided with lubricious material to facilitate movement between the inner wall surfaces and to minimize contact wear therebetween. The polymeric walls of the implant may be impregnated with or otherwise carry tissue regeneration agents such as stem cells, living chondrocytes, and/or genes to repair joint surfaces.

In some embodiments, the first inflation medium imparts rigidity in the implant. In some embodiments, the first inflation medium imparts cushion in the implant. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium aligns the joint. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium aligns the bones of the joint. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium changes the bone alignment. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium improves joint alignment. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium restores, at least in part, joint alignment. In some embodiments, individual chambers of the interior may be selectively inflated with a first inflation medium and/or a second inflation medium. In some embodiments, individual chambers of the interior are selectively inflated with a first inflation medium and/or a second inflation medium in order to reconstruct the joint and/or bones of the joint.

In some embodiments the inflation medium comprises living chondrocytes.

The implant interior (balloon interior) may be inflated with methymethacrylate as a liquid that becomes a solid or semi-solid (rigid or semi-rigid). In some embodiments, the inflation medium is a methyl methacrylate or other biocompatible hardening substance which can flow when initially put into the chamber, and hardens to become a rigid piece or semi-rigid piece or solid piece. The methyl methacrylate or other biocompatible hardening substance may conform to the shape of the chamber, or may conform to the shape of a space between bones and/or other joint structures. The methyl methacrylate or other biocompatible hardening substance may conform to a form chosen by the surgeon using tools

and/or pressure to influence the final shape of the rigid piece formed by the methyl methacrylate or other biocompatible hardening substance upon hardening.

The side wall extends between the first and second walls to form an interior which receives filling material through tube (also called a conduit herein, or may be called an inflation port). In some embodiments, the inflation port is not a tube, but is a valve which may or may not extend from a wall of the implant. The valve may be part of a wall of the implant, or part of the balloon or a portion thereof. The implant would also be appropriate for one condyle of the knee, but other shapes may be desired for other joint configurations whether relatively flat or more inflated toward a ballooning construct. In some embodiments, the inner diameter of the inflation port (or tube) is 5 millimeters maximum. In some embodiments, the inner diameter of the inflation port is about 1 millimeter. In some embodiments, the inner diameter of the inflation port is about 2 millimeters. In some embodiments, a needle (of typical needle sizes) may be used to inflate the implant.

A separate portal or tube (not shown) or the existing conduit (tube or valve), may be used to extract noxious inflammatory enzymes that can be aspirated at appropriate clinical intervals. Inflammatory enzymes in the COX1, COX2 and or 5LOX pathways can be extracted. Viscolubricants can be injected into the interior of the resilient arthroplasty implant through existing conduit or through a long needle to aide in distension, expansion, lubrication (with predetermined microporosity).

In some embodiments, an inflation medium that generates heat (by means of a catalyst reaction or other means) may be used to delver heat to a joint structure. The heat may aide hyaline cartilage annealing. Thermal effects of the implant materials are calculated accordingly to benefit and protect the joint surface analogous to a dry suit or wet suit for a scuba diver exposed to temperature extremes. Embodiments of the implant generally seek to avoid head from friction via lubricious coatings whether allograph as amniotic membrane or polymer, for non-limiting example.

The implant in some embodiments is inserted arthroscopically through a cannula about 10 mm in diameter with the implant in the deflated construct, and once inside the prepared joint space and secured therein by the appendages or tabs, the implant will be distended or inflated with gas, gel, fluid or fluid that becomes a resilient solid to fill the original natural space of a bone of the joint (whether the tibia, femur or patella). Tensioning will be by the surgeon's sense of proper pressure application aided by a gauged syringe for insertion of viscolubricants such as Synvisc, Hyalgan, Supartz and/or analgesics such as lidocaine gel. The insertion of liquids to the joint per se may be directly, through a cannula to the joint space previously in place for debridement, and or via a cannula or tube that is not part of the original implant assembly. Once the joint is cleaned, the implant is inserted and appropriately fixed to avoid extrusion or dislocation thereof. This may be via attachment of the implant tabs and/or by a combination of tab use plus intended friction created by implant surface coverings (analogous to Velcro) or a draw string at the smaller base of the implant.

Attachment Elements and Couplers

In some embodiments the attachment elements of the implant comprises holes through which screws or other couplers may be placed to attach the implant to an attachment site (or connection site) in the bone of the knee. In some embodiments, the holes are created arthroscopically. In some embodiments the holes are pre-fabricated in the implant. In some embodiments, the holes may be made prior to implantation based on the patient's particular anatomy. In some embodiments, the holes are reinforced by a reinforcing material of the implant. The reinforcing material may be a polymer of sufficient durometer and/or tear resistance to reinforce the screw hole. The reinforcing material may be comprise metal. In some embodiments, there is no pre-formed hole, but rather screws (or another coupler) secure the attachment tabs (which may be a non-balloon portion of the implant) to the joint component (bone, etc) by creating their own hole when implanted. In some embodiments, the implant may comprise tabs that are adapted to receive staples or other couplers described elsewhere herein.

The implants described herein may comprise attachment elements (or tabs) which may then by attached or coupled to tissue of a component of the joint (whether to a bone or a ligament or a tendon or other joint component) by a coupling device. Coupling devices (or couplers) may comprise at least one of screws, washers, sutures, suture anchors (metal and/or biodegradable), rivots, staples (with and/or without teeth), stabilizers, glues, hooks of cylindrical wire or flattened sheet metal into bone holes or slots respectively. The coupling devices may be resorbable or not. Also, the coupling devices may comprise at least one of strings (i.e. drawstrings), reigns, lassos, sutures, and lanyards. The strings, reigns. lassos, sutures, and/or lanyards may join with themselves and/or other coupling devices. The strings, reigns. lassos, sutures and/or lanyards may be directed not only into bone with or without anchors, but also through ligaments, tendons or loose segments of cartilage that the surgeon intends to preserve.

The posterior of the knee can be difficult to access without disturbing joint components (or in order to minimize such disturbance) such as tendons, ligaments, etc. Thus, in some embodiments, the implant comprises strings, reigns. lassos, and/or lanyards that may pass from the posterior of the implant via the intercondylar notch anteriorly to join with themselves and/or other coupling devices. These couplers may be pre-coupled to the implant, and the implant and its couplers may be configured to be pulled (or cinched) from the anterior of the implant once the implant is in its general location relative to the condyle in order to finally position the implant about the condyle—in particular in order to cinch the implant about the posterior of the condyle. Likewise, in some embodiments where the implant is pre-molded, the coupler as described are adapted to move the implant to its final position with conformity to the condyle's posterior with minimal disturbance to the joint structures at the joint's posterior (minimal cutting, minimal moving, and or minimal detachment, for non-limiting example).

In some embodiments, the implant comprises a skirt (or sleeve) that conforms to the contours of the bone (whether a condyle of the femur, a patella, or a tibia) as a coupler.

In some embodiments, a screw through tab having reinforced center holes may be part of the implant. For example, the implant may comprise polymer covered metal washer holes. The screw may go through the holes. Another embodiment may comprise a staple having spikes as shown in FIGS. **13**A-**13**D. FIGS. **13**A-**13**D depict multiple views of a staple adapted to couple an implant to a bone of the joint. FIG. **13**A depicts an embodiment of an implant **20** having a tab **10***a* that is coupled to bone using a staple **12**. FIGS. **13**B & **13**C depict a staple **12** as described herein having teeth **18**. FIG. **13**C depicts an embodiment of a tab **10***a* that is coupled to bone using a staple **12** having teeth **18**. Combinations of spikes and screws may be used in some embodiments, or combinations of other couplers. The implant may be configured to allow a surgeon the option of several types and sizes of couplers, as each patient differs with regard to size and depth of lesion, bone stock, regrowth capability, and compliance with advised

recovery, and each surgeon has his own strengths and comforts when working with such implants.

The edge of the implant may have a depending skirt to secure or anchor the implant to the end of bone (femur), but may have one or more depending tabs (or appendages) that may be employed for similar functions as will be discussed in other embodiments. The skirt (and/or tabs, and/or appendages) may tightly fit about the end of the femur, or the skirt can be secured by adhesive (e.g. methyl methacrylate, bone ingrowth) to the supporting bone structure or be mechanically connected by staples, screws and the like. Moreover, the lower portion of the skirt may be secured by a purse string suture or a suitable strand (elastic or tied) that is tightly bound about the outside of the skirt.

FIGS. **12**A, **12**B, and/or **12**C alternatively may be used to describe a patch implant or a unicompartment knee implant described herein, having appendages **4***a*, **4***c*, extending from a balloon **6** and including holes **8***a*, **8***b*, **8***c*, and/or tabs **10***a*, **10***b*. **10***c*, **10***d*, **10***e*, **10***f*, which may be used with couplers (not shown) to couple the implant to a bone of the knee joint (which may be the femur, the tibia, or the patella). Features shown in FIGS. **12**A, **12**B, and or **12**C are common to both the unicompartment knee implant (also discussed elsewhere herein) and the patch implant (also discussed elsewhere herein), although dimensions may differ as described elsewhere herein.

FIGS. **13**A-**13**D depict multiple views of a staple **12** adapted to couple implant **14** (such as those described herein) to a bone **16** of the joint. FIG. **13**A depicts a staple **12** coupling a tab **10***a* of an appendage **4***a* to the bone **16** of the joint (wherein the portion of the staple **12** embedded in the bone **16** is shown as a dashed line). FIG. **13**B depicts a view of a staple **12** having teeth **18** to grasp the tab **10***a* of the implant **14**. Similarly, FIG. **13**C depicts a view of a staple **12** having teeth **18** to grasp the tab **10***a* of the implant **14**. FIG. **13**D depicts a staple **12** attaching the tab **10***a* of an implant to a bone **16**, the dotted lines show the portion of the tab **10***a* that is compressed by the staple **12** and teeth **18** thereof.

In some embodiments, the implant is configured such that the tabs and/or couplers of the implant couple to the bone where there is no natural cartilage. In some embodiments, the implant may be adapted by the surgeon at the time of surgery such that the tabs are positioned where there is no natural cartilage.

In some embodiments, the implant comprises a tab and a hook that couples to the tab by wrapping around a component of the knee and securing the tab to the hook. In some embodiments, the implant comprises a tab and a hook that couples to the tab by wrapping around a condyle of the knee and securing the tab to the hook. In some embodiments, the implant is configured to wrap around a condyle of the knee and to secure a first appendage to a second appendage of the implant. In some embodiments the appendages are secured by couplers described herein. In some embodiments, the implant is preformed to fit to the condyle in such a wrapping manner.

In some embodiments, the implant comprises a methymethacrylate what is placed into a balloon chamber that fits into a bone hole. Such an embodiment would generally fix the implant to the bone once the methymethacrylate cures to a solid.

In some embodiments, the implant can be anchored with generic available sutures and suture anchors fixing and positioning material to bone with proper tensioning.

Ingrowth Features

In addition to the general ingrowth that may occur based on the implant features described herein, the implant undersurface (adjacent the femur) may comprise an ingrowth matrix. In some embodiments, at least a portion of the implant adjacent to the femur comprises bone ingrowth materials. Such an implant can be attached by a series of tabs with or without holes, using screws, rivots, stabilizers, staples, tacks, or Sutures and suture anchors, for non-limiting example. The polymer of the implant substitutes for periosteum when the implant comprises living chondrocytes (e.g. Carticel) as the ingrowth matrix on a surface of the implant. The polymer of the implant substitutes for periosteum when the implant comprises living chondrocytes (e.g. Carticel) as the ingrowth matrix within an implant embodiment configured to reveal and/or release said chondrocytes over time and/or upon implantation.

The bone ingrowth undersurface may be used for long term fixation of the tabs or rim. That is, whereas it is important for the surgery to secure the implant to the joint surface in the most desirable corrective location, it is also important in some embodiments to prepare the anatomic undersurface of bone by abraiding it, removing about 0.5 mm of cortical bone so as to expose the underlying oxygen, blood, and nutrients of the patient to the undersurface of the implant that can gradually become incorporated into the limb bone. As this healing occurs over the course of weeks and months to one year post operation, the localized tacking sites may become less relevant and potentially inert. Thus, in some embodiments, the implant may comprise a biodegradable (bioresorbable) polymer or other material. The couplers may additionally and/or alternatively be biodegradable. Once the implant is in place, it will serve to at least one of: pad defects, cushion the joint, and restore the original damage to the joint components. The end goal is to apply minimally morbid treatment that will refurbish arthritic limb regions, leaving only the small skin scar and remote memory of the healed physical mishap.

Undersurface implant materials may involve used of the art and science from Artelon or Gore-Tex research, as each has advantages and limitations. Several implant options per joint damage area may be available to enjoy the primary surgeons manipulation to fit the clinically recovery requirements best.

In some embodiments the implant comprises an ingrowth patch on at least one of the first portion configured to engage the femur, the second portion configured to engage the second bone (whether the tibia or the patella), the side portion, and the appendage. The ingrowth patch may be configured to encourage and/or promote tissue ingrowth, such as bone ingrowth, for non-limiting example. The patch may be as large as the portion itself (whether the first portion the second portion, the side portion, or the appendage) or may be smaller than the portion (such as in the shape of a strip or other shaped patch). The ingrowth patch may comprise a surface irregularity or roughness. The ingrowth patch may be Velcro-like. In some embodiments the implant comprises an ingrowth patch on the first portion and/or the second portion, from (and in some embodiments including) a first appendage to a second appendage. In some embodiments, wherein the appendages loosen from attachment from the bone (by design and/or from wear and/or over time), the ingrowth patch aids in securing the implant to the bone. In some embodiments, the ingrowth patch comprises beads and/or bead-like elements attached to the implant. Such an ingrowth patch may be configured to simulate trabecular bone space of a normally cancellous latticework. In some embodiments, the beads are sintered beads of various sizes. In some embodiments, the beads are sintered beads about 400 microns in size. With respect to bead size, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%. In some embodiments, the first bone and/or the second bone

is roughened to acquire a bleeding bone to facilitate ingrowth. In some embodiments, tissue is removed to facilitate ingrowth.

The walls of the implant embodying features of the invention may be composite structures. For example, the innermost layer may be impervious to preclude escape of inflation or other filling media, a central layer may be porous or otherwise contain treatment or cell regeneration agents, and the outer layer may be a thin, but strong layer of a thermoplastic, such as a thermoplastic polyurethane for non-limiting example, which has microporosity sufficient to allow passage or egress of treatment or cell regeneration agents from the central layer (or second layer). The degree of microporosity to enable egress of treatment or cell regeneration agents from the central layer is found in polymer layers such as Chronoflex or Bionate 55. The external wall (and/or the bone engaging surface) of the implant may be coated and/or impregnated with a latticework of polymer that is surface sprayed or layered on the outside (or bone engaging surface) of the implant to promote cartilage tissue regeneration. This most external surface coating may contain living chondrocytes (for example, as is provided in the Carticel procedure by the Genzyme company), and/or may contain stem cells with or without directed gene mutations to enhance adherence of the coating to the implant. The bone engaging surface may comprise peaks and troughs. The living cells may be imposed in between (and/or provided in the) troughs of the implant surface while the surface areas of prominence (the peaks of the surface) may be used for at least one of: space validation, traction, and cell protection.

The implant embodying features of the invention may be used in a series of treatments wherein the first treatment involves use of autologous or minimally manipulated allograph interpositional tissues or xenograph, the second treatment involves the use of the same type of tissue added to stem cells or chondrocytes and the third treatment involving deployment of the implant if the first two fail or are ineffective.

Pharmacologics and Therapeutic Agents

In some embodiments the implant may comprise vacuoles of pharmacologic substances. The vacuoles may be on a bone-engaging portion of the implant. In some embodiments, the implant comprises bubbles comprising an active substance such as a pharmacologic substance or other active substance. In some embodiments, the implant comprises spaces filled with an active substance such as a pharmacologic substance (pharmacologic agent) or other active substance (active agent). The implant may deliver by dissolution of the implant material (i.e. a biodegradable polymer which releases the active substance), and/or by release through pores of the implant (wherein the polymer is permeable to the active substance), and/or by fracture of the vacuole (or bubble, or space) by a catalyst such as ultrasound or pressure or other fracturing catalyst. The implant may deliver the active substance at a time after the actual implanting of the implant into the joint, for example an hour later, less than a day later, a day later, less than a week later, a week later, less than a month later, and/or a month later. In some embodiments, stem cells that are percolating in the bubble (or vacuole, or space) may be delivered to the joint space (or a constituent of the joint) after the implant is inserted into the joint. Active agents may, for non-limiting example, include stem cells, growth factors, antibiotics, and/or viscolubricants. In some embodiments, the implant may comprise enzyme absorptive 'microscopic sponges' that could be sucked out or evacuated at or around the time of implant delivery to the joint. In some embodiments, the active substance comprises iatrigenically gene mutated cells.

Patient Symptoms

Symptoms for the patient requiring an implant described herein may include, for non-limiting example, osteoarthritis or rheumatoid or gouty arthritis.

Total Knee Arthroplasty (Dual Compartment):

Provided herein is an implant for placement on both condyles (medial and lateral) of the distal femur. In some embodiments, this is called a dual compartment implant since it covers both condyles of the femur. Such an implant comprises at least one interior (or inflatable chamber), and in some embodiments comprises a plurality of inflatable chambers (or interiors).

In some embodiments, the implant will cover the "H" distal femoral cartilage segment (made up of both femoral condyles and the trochlear groove in between). The implant may absorb diffuse force, endure the millions of annual cyclic loads of both knee joints (including the patella-femur joint and the femur-tibia joints), along with rotational and shear forces up to six times body weight, at least.

In some embodiments, the implant comprises attachment tabs or attachment elements over the sides of both condyles medially and laterally. In some embodiments, the implant comprises attachment tabs or attachment elements in the intercondylar notch (or slot). In some embodiments, the implant comprises attachment tabs or attachment elements superiorly at the distal end of the femur anteriorly. In some embodiments, posterior reigns or suture-like lanyards cinch up the implant from inside the posterior intercondylar notch toward another connection site around the femur.

The posterior of the knee can be difficult to access without disturbing joint components (or in order to minimize such disturbance) such as tendons, ligaments, etc. Thus, in some embodiments, the implant comprises strings, reigns, lassos, and/or lanyards that may pass from the posterior of the implant via the intercondylar notch anteriorly to join with themselves and/or other coupling devices. These couplers may be pre-coupled to the implant, and the implant and its couplers may be configured to be pulled (or cinched) from the anterior of the implant once the implant is in its general location relative to the condyle in order to finally position the implant about the condyle—in particular in order to cinch the implant about the posterior of the condyle. Likewise, in some embodiments where the implant is pre-molded, the coupler as described are adapted to move the implant to its final position with conformity to the condyle's posterior with minimal disturbance to the joint structures at the joint's posterior (minimal cutting, minimal moving, and or minimal detachment, for non-limiting example). In some embodiments at least a portion of the ligamentary structure of the knee is spared.

Although this application focuses on the distal femur as it articulates with the retropatellar and proximal tibial cartilages implants as described generally herein may be also and/or alteratively be used in conjunction with the tibia and/or the patella. Furthermore, separate and/or connected implant components may be inserted to restore natural function to the knee.

Coupling devices to be used as part of the dual compartment implant may include any of those mentioned or described herein, for example. Such coupling devices may comprise at least one of strings (i.e. drawstrings), reigns, lassos, sutures, and lanyards. The strings, reigns. lassos, sutures, and/or lanyards may join with themselves and/or other coupling devices. The strings, reigns. lassos, sutures and/or lanyards may be directed not only into bone with or

without anchors, but also through ligaments, tendons or loose segments of cartilage that the surgeon intends to preserve.

FIG. **1** depicts an embodiment of the implant **20** in a 2D view configured for dual condyle (distal femur) coverage. FIG. **1** depicts an embodiment of the knee implant **20** having appendages **4***a*, **4***b*, **4***c*, **4***d*, including holes **8***a*, **8***b*, **8***c*, **8***d* and tabs **10***a*, **10***b* extending from a balloon **6** and including slots **26***a*, **26***b* to accommodate ligaments (not shown) of the knee joint. Couplers as described elsewhere herein may be used to couple the implant **20** to the distal femur. In some embodiments, there may only tabs, only holes, or only appendages, or combinations thereof. In some embodiments, there may be other ways to couple the implant to the distal femur, as described elsewhere herein (sutures, drawstrings, skirts, glue, etc). In some embodiments, the couplers create the holes **8***a*, **8***b*, **8***c*, **8***d*, or other holes (not shown) when the implant is placed against the distal femur **24**. In some embodiments, the holes are pre-formed in the appendage prior to implantation. In some embodiments, the holes are reinforced as described elsewhere herein. As shown here, the appendages in some embodiments be different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage **4***d* that is intended to wrap over the medial condyle may be longer and/or wider than the appendage **4***c* intended to wrap over the lateral condyle. Likewise, the slots may be different in shape and/or size and/or position to accommodate the ligaments and/or tendons of the joint or other structures and functions of the joints of the knee, and to allow for placement of the implant with minimal disturbance (cutting, manipulation, for example) of the joint components such as tendons, ligaments, and other soft or hard tissues. For example, slot **26***a* is shaped and positioned to accommodate the cruciate ligaments of the knee, at least.

FIG. **2** depicts an embodiment of the knee implant **20** having appendages **4***a*, **4***b*, **4***c*, **4***d*, including holes **8***a*, **8***b*, **8***c*, **8***d* and tabs **10***a*, **10***b* extending from a balloon **6** and including slots **26***a*, **26***b* to accommodate ligaments of the knee joint as well as side views of the same knee implant. Couplers as described elsewhere herein may be used to couple the implant **20** to the distal femur. In some embodiments, there may only tabs, only holes, or only appendages, or combinations thereof. In some embodiments, there may be other ways to couple the implant to the distal femur, as described elsewhere herein (sutures, drawstrings, skirts, glue, etc). In some embodiments, the couplers create the holes **8***a*, **8***b*, **8***c*, **8***d*, or other holes (not shown) when the implant is placed against the distal femur. In some embodiments, the holes are pre-formed in the appendage prior to implantation. In some embodiments, the holes are reinforced as described elsewhere herein. As shown here, the appendages in some embodiments are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage **4***d* that is intended to wrap over the medial condyle may be longer and/or wider than the appendage **4***c* intended to wrap over the lateral condyle. Shown in the embodiment depicted in FIG. **2** are the different hole placements from the side view, showing the differences in positioning of the holes to accommodate the differences in anatomic structure and size of the condyles. Likewise, the slots may be different in shape and/or size and/or position to accommodate the ligaments and/or tendons of the joint or other structures and functions of the joints of the knee, and to allow for placement of the implant with minimal disturbance (cutting, manipulation, for example) of the joint components such as tendons, ligaments, and other soft or hard tissues. For example, slot **26***a* is shaped and positioned to accommodate the cruciate ligaments of the knee, at least. Additionally, as shown in the side views of the embodiment shown in FIG. **2**, the balloon has a first wall **28** adapted to be adjacent the femur that is of a greater thickness than the second wall **30**. In some embodiments, the first wall **28** is configured to have therapeutic benefits (pharmacologic, healing, and/or ingrowth properties) as described elsewhere herein. The second wall **30** may additionally and/or alternatively be configured to have a therapeutic effect (pharmacologic, healing, and/or ingrowth properties).

Nevertheless, differing thicknesses of the first wall **28** and the second wall **30** are not necessarily required in order to impart the therapeutic benefits (pharmacologic, healing, and/or ingrowth) described elsewhere herein. For example, FIG. **3** depicts an embodiment of the knee implant **20** having appendages **4***a*, **4***b*, **4***c*, **4***d*, including holes **8***a*, **8***b*, **8***c*, **8***d* and tabs **10***a*, **10***b* extending from a balloon **6** and including slots **26***a*, **26***b* to accommodate ligaments of the knee joint as well as side views of the same knee implant. Couplers as described elsewhere herein may be used to couple the implant **20** to the distal femur. In some embodiments, there may only tabs, only holes, or only appendages, or combinations thereof. In some embodiments, there may be other ways to couple the implant to the distal femur, as described elsewhere herein (sutures, drawstrings, skirts, glue, etc). In some embodiments, the couplers create the holes **8***a*, **8***b*, **8***c*, **8***d*, or other holes (not shown) when the implant is placed against the distal femur. In some embodiments, the holes are pre-formed in the appendage prior to implantation. In some embodiments, the holes are reinforced as described elsewhere herein. As shown here, the appendages in some embodiments are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage **4***d* that is intended to wrap over the medial condyle may be longer and/or wider than the appendage **4***c* intended to wrap over the lateral condyle. Shown in the embodiment depicted in FIG. **3** are the different hole placements from the side view, showing the differences in positioning of the holes to accommodate the differences in anatomic structure and size of the condyles. Likewise, the slots may be different in shape and/or size and/or position to accommodate the ligaments and/or tendons of the joint or other structures and functions of the joints of the knee, and to allow for placement of the implant with minimal disturbance (cutting, manipulation, for example) of the joint components such as tendons, ligaments, and other soft or hard tissues. For example, slot **26***a* is shaped and positioned to accommodate the cruciate ligaments of the knee, at least. Additionally, as shown in the side views of the embodiment shown in FIG. **3**, the balloon has a first wall **28** adapted to be adjacent the femur that is of approximately the same thickness than the second wall **30**. In some embodiments, the first wall **28** is configured to have therapeutic benefits (pharmacologic, healing, and/or ingrowth properties) as described elsewhere herein. The second wall **30** may additionally and/or alternatively be configured to have a therapeutic effect (pharmacologic, healing, and/or ingrowth properties).

FIG. **4**A depicts an embodiment of the knee implant **20** having appendages **4***a*-**4***d* including ten tabs **10***a*-**10***j* extending from a balloon **6** and including a slot **26***a* to accommodate components (such as ligaments or other tissues whether soft tissues, hard tissues, tendons, and/or others) of the knee joint (not shown). The tabs **10***a*-**10***j* are not shown with holes in this embodiment, however if screws are used as couplers, such holes may be pre-drilled or formed in situ by the screws. Additionally and/or alternatively, staples or sutures may be used (as described elsewhere herein) in order to couple the

implant to the bone (femur, for example). Other couplers as described elsewhere herein may also and/or alternatively be used in this coupling process. Furthermore, the number of tabs may be fewer or greater than the ten depicted in order to achieve optimal placement and coupling to the bone. For example, FIG. **4**B depicts an embodiment of the knee implant **20** having appendages **4***a*-**4***d* including eight tabs **10***a*-**10***h* extending from a balloon **6** and including a slot **26***a* to accommodate components (such as ligaments or other tissues whether soft tissues, hard tissues, tendons, and/or others) of the knee joint (not shown).

FIG. **5** depicts an embodiment of the knee implant **32** curved to simulate curvature about the condyles of a femur, the implant having appendages **4***a*-**4***d* extending from an uninflated balloon (not shown) and including slots **26***a*, **26***b* to accommodate components (such as ligaments or other tissues whether soft tissues, hard tissues, tendons, and/or others) of the knee joint (not shown). The implant may comprise additional curvatures and/or slots to accommodate other ligaments and/or tissues. In some embodiments, the implant is configured to conform about various hard and/or soft tissues of the joint, such as bone, ligaments, tendons, etc. In some embodiments, the balloon is inflated once the implant is positioned within the joint. In other embodiments, the balloon is partially inflated prior to being positioned within the joint. In other embodiments, the balloon is at least partially inflated prior to being positioned within the joint. In some embodiments, the balloon is fully inflated prior to being positioned within the joint. In some embodiments, the implant is configured to allow an operator to adjust the amount of balloon inflation in situ (whether by adding inflation medium or removing inflation medium, or both, or neither). Couplers as described elsewhere herein may be used to couple the implant **32** to the distal femur.

FIG. **6**A depicts a top-down view of an embodiment of the knee implant **32** curved to simulate curvature about the condyles of a femur, the implant having appendages **4***a*-**4***d* extending from two inflated balloons **6**, **34** and including a slot **26***a* to accommodate components of the knee joint. FIG. **6**B depicts a bottom-up or anterior oblique view of the same embodiment of the knee implant **32** curved to simulate curvature about the condyles of a femur, the implant having appendages **4***a*-**4***d* extending from two inflated balloons **6**, **32** and including a slot **26***a* to accommodate components of the knee joint. Couplers as described elsewhere herein may be used to couple the implant **32** to the distal femur. As shown in FIGS. **6**A and **6**B, the appendages **4***a*-**4***d* in some embodiments are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage **4***d* that is intended to wrap over the medial condyle may be longer and/or wider than the appendage **4***c* intended to wrap over the lateral condyle. Likewise, the dimensions of the balloon **34** that is adapted for placement over the medial condyle may be a different shape and/or size than the balloon **6** over the lateral condyle (the medial condyle being larger, thus the balloon **34** may be larger for that location) Alternatively and/or additionally, as described elsewhere herein, for various reasons such as injury, realignment needs, injury, etc, there may be a need for more reconstruction of one condyle than needed for the other, thus the inflation medium might be different in one balloon (or a portion thereof) than in the other balloon (or another chamber within the same balloon), or there may be need for a different shaped balloon in one location than in another location. Embodiments provided herein can accommodate these requirements based on materials of fillers, appendages, balloons, walls, and dimensions and chamber options of the implant and its components.

FIG. **7** depicts a top-down view of an embodiment of the knee implant **32** curved to simulate curvature about the condyles of a femur, the implant having appendages **4***a*-**4***d* extending from an inflated balloon **6** and including slots to accommodate components of the knee joint. Couplers as described elsewhere herein may be used to couple the implant **32** to the distal femur. As shown here, the appendages **4***a*-**4***d* in some embodiments are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage **4***d* that is intended to wrap over the medial condyle may be longer and/or wider than the appendage **4***c* intended to wrap over the lateral condyle. Likewise, the dimensions of the portion of the balloon that is adapted for placement over the medial condyle may be a different shape and/or size than the portion of the balloon over the lateral condyle (the medial condyle being larger, thus the balloon may be larger for that location) Alternatively and/or additionally, as described elsewhere herein, for various reasons such as injury, realignment needs, injury, etc, there may be a need for more reconstruction of one condyle than needed for the other, thus the inflation medium might be different in a portion or chamber of an implant embodiment having a plurality of inflation chambers in a single balloon, or there may be need for a non-symmetric balloon. Embodiments provided herein can accommodate these requirements based on materials of fillers, appendages, balloons, walls, and dimensions and chamber options of the implant and its components.

FIG. **8** depicts a side view of an embodiment of the knee implant **32** curved to simulate curvature about at least one condyle of a femur, the implant having appendages **4***b*, **4***d* extending from an uninflated balloon (not shown). This depiction covers the maximum anticipated distal femoral contour; other iterations may be smaller, or shorter covering limited areas of the circumference of the femoral curvatures.

FIG. **9**A depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4***b*, **4***d* extending from an uninflated or minimally inflated balloon **6**. In this view, the knee is positioned essentially in extension (straight), showing the tibia **36**, fibula **38**, and patella **40** of the knee. Note that although there would be other joint structures and knee structures in a true depiction of an implant positioned in the knee, this view of the implant and bones is greatly simplified for ease of understanding of the implant and the joint relative (and approximate) positions and placement. Couplers as described elsewhere herein may be used to couple the implant **20** to the distal femur **24** and/or the condyle **22** thereof (in this image the medial condyle, at least since it is primarily a one-side view of the joint and implant). For the sake of simplicity FIG. **9**A and the implant embodiment depicted show of the femur with opposition to the other surfaces of both knee joints (between femur and tibia, and femur and patella), the areas of contact varying according to activity, forces, and range of motion. Other implant iterations may apply to opposing surfaces.

FIG. **9**B depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4***b*, **4***d* extending from an inflated balloon **6**. In this view, the knee is positioned essentially in extension (straight), showing the tibia **36**, fibula **38**, and patella **40** of the knee. Note that although there would be other joint structures and knee structures in a true depiction of

an implant positioned in the knee, this view of the implant and bones is greatly simplified for ease of understanding of the implant and the joint relative (and approximate) positions and placement. Couplers as described elsewhere herein may be used to couple the implant **20** to the distal femur **24** and/or the condyle **22** thereof (in this image the medial condyle, at least since it is primarily a one-side view of the joint and implant). In FIG. **9**B wherein the balloon is inflated, as compared to FIG. **9**A wherein the balloon is not inflated or is minimally inflated, the balloon second wall **30** is closer to and/or contacting the tibial plateau **42** (articular surface) when the balloon **6** is inflated. Likewise, FIG. **9**C depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4***b*, **4***d* extending from an inflated balloon **6** and having couplers **44***a*, **44***b* (which may be, for non-limiting example, staples or screws) coupling the appendages **4***b*, **4***d* to the femur. In this view, the knee is positioned essentially in extension (straight), showing the tibia **36**, fibula **38**, and patella **40** of the knee. Where the inflated balloon as seen in FIG. **9**B may fill in existing pathologic defects of the joint surface, the medium of inflated and specific balloon location and durometry with the material of the implant may also be constructed so as to force the bones opposed, e.g. the femur and tibia, into a more natural limb alignment such as six (6) degrees valgus. However, if the patient being treated has variations from normal in the affected knee as illustrated by examining and measuring the opposite normal side, then the implant inflation and pressures or balloon location may be adjusted from the population norms thus customizing this implant to the clinical case under consideration. Fixation devices may be appropriately applied at various knee range of motion intervals from full extension (zero degrees) to full flexion (usually 135 degrees) as the knee is adjusted and the implant secured under anesthesia.

FIG. **10**A depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4***b*, **4***d* extending from an inflated balloon **6** and showing the inflation medium **46** moved anteriorly toward the patella **40** when the knee joint is slightly flexed. Likewise, FIG. **10**B depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4***b*, **4***d* extending from an inflated balloon **6** and having couplers **44***a*, **44***b* (which may be, for non-limiting example, staples or screws) coupling the appendages **4***b*, **4***d* to the femur **24** and showing the inflation medium **46** moved anteriorly toward the patella **40** when the knee joint is slightly flexed.

In all descriptions provided herein of the dual compartment implant, the implant may instead be configured to couple to or emerge from the tibia and/or patella. In all descriptions provided herein of the dual compartment implant, the implant may instead be configured to couple to the tibia. It is the intention and understanding that the implant is suited for this purpose in certain embodiments with adjustments to account for dimensional differences of the tibia. Most descriptions provided herein are directed to embodiments coupling the implant to the femur, however, this is primarily for ease of description and continuity, and does not preclude embodiments wherein the implant is coupled to the tibia. Likewise, as noted elsewhere herein, there are embodiments where the implant may be coupled to two bones (at least), for example to both a tibia and a femur.

Patch

Some embodiments of the implant are configured to repair isolated lesions wherein osteochondral defects as in osteonecrosis create craters in the cartilage that need 'filling in' with a patch. Various size lesions of cartilage defects can be accommodated by the implants provided herein which may have balloons of at least one of: at most about 0.5 cm in diameter, at most about 0.75 cm in diameter, at most about 1 cm in diameter, at most about 1.25 cm in diameter, at most about 1.5 cm in diameter, at most about 1.75 cm in diameter, at most about 2 cm in diameter, at most about 2.25 cm in diameter, at most about 2.5 cm in diameter, at most about 2.75 cm in diameter, at most about 3 cm in diameter, at most about 3.25 cm in diameter, at most about 3.5 cm in diameter, at most about 3.75 cm in diameter, at most about 0.5 cm in length along the longest length of the balloon, at most about 0.75 cm in length along the longest length of the balloon, at most about 1 cm in length along the longest length of the balloon, at most about 1.25 cm in length along the longest length of the balloon, at most about 1.5 cm in length along the longest length of the balloon, at most about 1.75 cm in length along the longest length of the balloon, at most about 2 cm in length along the longest length of the balloon, at most about 2.25 cm in length along the longest length of the balloon, at most about 2.5 cm in length along the longest length of the balloon, at most about 2.75 cm in length along the longest length of the balloon, at most about 3 cm in length along the longest length of the balloon, at most about 3.25 cm in length along the longest length of the balloon, at most about 3.5 cm in length along the longest length of the balloon, at most about 3.75 cm in length along the longest length of the balloon, at most about 4 cm in length along the longest length of the balloon, at most about 4.25 cm in diameter, at most about 4.5 cm in diameter, at most about 4.75 cm in diameter, at most about 5 cm in diameter, at most about 5.25 cm in diameter, at most about 5.5 cm in diameter, at most about 5.75 cm in diameter, at most about 6 cm in diameter, at most about 6.25 cm in diameter, at most about 6.5 cm in diameter, at most about 6.75 cm in diameter, at most about 7 cm in diameter, at most about 7.25 cm in diameter, at most about 7.5 cm in diameter, at most about 7.75 cm in diameter, at most about 8 cm in diameter, at most about 3 cm in length along the longest length of the balloon, at most about 3.25 cm in length along the longest length of the balloon, at most about 3.5 cm in length along the longest length of the balloon, at most about 3.75 cm in length along the longest length of the balloon, at most about 4 cm in length along the longest length of the balloon, at most about 4.25 cm in length along the longest length of the balloon, at most about 4.5 cm in length along the longest length of the balloon, at most about 4.75 cm in length along the longest length of the balloon, at most about 5 cm in length along the longest length of the balloon, at most about 5.25 cm in length along the longest length of the balloon, at most about 5.5 cm in length along the longest length of the balloon, at most about 5.75 cm in length along the longest length of the balloon, at most about 6 cm in length along the longest length of the balloon, 6.25 cm in length along the longest length of the balloon, at most about 6.5 cm in length along the longest length of the balloon, at most about 6.75 cm in length along the longest length of the balloon, at most about 7 cm in length along the longest length of the balloon, at most about 7.25 cm in length along the longest length of the balloon, at most about 7.5 cm in length along the longest length of the balloon, at most about 7.75 cm in length along the longest length of the balloon, and at most about 8 cm in length along the longest length of the balloon. As used herein with respect to balloon dimensions whether length or diameter, the term "about" means variations of at least one of 0.1 cm, 0.2 cm, 0.25 cm, 0.5 cm, and 1 cm.

Thus, provided herein is an implant configured to patch osteochondral defects. The defects may occur due to injury, stress, naturally occurring, and/or may created or enhanced by a medical professional during a medical procedure. In some embodiments, the implant may be called a patch having the balloon and an attachment element (or elements—which may be called appendages) described herein and may be sized to fit within a defect in a manhole-cover type manner. In some embodiments, the implant may comprise balloon and attachment elements described elsewhere herein and may be configured to lay over a defect (full defect or partial defect). In some embodiments the implant as described herein as used to patch or repair osteochondral defects may be called a patch or a patch implant.

In some embodiments, the size of the balloon dimensions are prechosen based on the individual patient need, and the balloon size (dimensions, geometry, length, depth, for non-limiting examples) is pre-set. In some embodiments, the balloon comprises multiple chambers which may be inflated (or deflated) selectively to fill the defect in situ or just prior to implantation in order to adjust the implant's balloon size (dimensions, length, width, depth, geometry, for non-limiting example) as needed at the time of implantation. The balloon (or any chamber thereof) of some embodiments can be secondarily inflated or deflated (or both) in situ.

FIGS. **11**A, **11**B, and/or **11**C may be used to describe a patch implant described herein, having appendages **4***a*, **4***c*, extending from a balloon **6** (not shown in FIG. **11**A) and including holes **8***a*-**8***h*, and/or tabs **10***a*-**10***f* which may be used with couplers (not shown) to couple the implant to a bone of the knee joint (which may be the femur, the tibia, or the patella). Features shown in FIGS. **11**A, **11**B, and/or **11**C are common to both the unicompartment knee implant (discussed elsewhere herein) and the patch implant, although dimensions may differ as described herein. Thus, FIGS. **11**A, **11**B, and/or **11**C may be used to describe the unicompartment knee implant and/or the patch implant. FIG. **11**A depicts an embodiment of the patch implant **2** curved to simulate curvature about one condyle of a femur, the implant **2** having appendages **4***a*, **4***c*, extending from an uninflated balloon (not shown) and including tabs **10***a*-**10***f* and/or holes **8***a*-**8***h*, which may be used with couplers (not shown, described elsewhere herein) to couple the implant **2** to the femur of the knee joint. FIG. **11**B depicts an embodiment of the patch implant **2** curved to simulate curvature about one condyle of a femur, the implant **2** having appendages **4***a*, **4***c*, extending from an inflated balloon **6** and including tabs **10***a*-**10***f* and/or holes **8***a*-**8***h*, which may be used with couplers (not shown, described elsewhere herein) to couple the implant **2** to the femur of the knee joint. FIG. **11**C depicts a bottom-up of gliding surface view of an embodiment of the patch implant **2** curved to simulate curvature about one condyle of a femur, the implant **2** having appendages **4***a*, **4***c*, extending from an inflated balloon **6** and including tabs **10***a*-**10***f* and/or holes **8***a*-**8***h*, which may be used with couplers (not shown, described elsewhere herein) to couple the implant **2** to the femur of the knee joint. In some embodiments, the implant is configured to couple to a tibia. In some embodiments, the implant is configured to couple to a trochlear groove of a femur. In some embodiments, the implant is configured to couple to only a portion of a condyle of a femur.

FIGS. **12**A, **12**B, and/or **12**C may be used to describe a patch implant described herein, having appendages **4***a*, **4***c*, extending from a balloon **6** and including holes **8***a*, **8***b*, **8***c*, and/or tabs **10***a*, **10***b*. **10***c*, **10***d*, **10***e*, **10***f* which may be used with couplers (not shown) to couple the implant to a bone of the knee joint (which may be the femur, the tibia, or the patella). Features shown in FIGS. **12**A, **12**B, and/or **12**C are common to both the unicompartment knee implant (discussed elsewhere herein) and the patch implant, although dimensions may differ as described herein. Thus, FIGS. **12**A, **12**B, and/or **12**C may be used to describe the unicompartment knee implant and/or the patch implant. FIG. **12**A depicts a bottom-up view of an embodiment of the implant **2** (unicompartment or patch), the implant having appendages **4***a*, **4***c*, extending from a balloon **6** and including holes **8***a*, **8***b*, **8***c*, which may be used with couplers (not shown) to couple the implant **2** to the femur of the knee joint. FIG. **12**B depicts a bottom-up view of an embodiment of the implant **2** (unicompartment or patch), the implant having appendages **4***a*, **4***c*, extending from a balloon **6** and including tabs **10***a*, **10***b* and hole **8***a* which may be used with couplers (not shown) to couple the implant to the femur of the knee joint. FIG. **12**C depicts a bottom-up view of an embodiment of the implant **2** (unicompartment or patch), the implant having appendages **4***a*, **4***c*, extending from a balloon **6** and including tabs **10***c*, **10***d*, **10***e*, and **10***f* and hole **8***a* which may be used with couplers (not shown) to couple the implant to the femur of the knee joint. In some embodiments, the implant is configured to couple to a tibia. In some embodiments, the implant is configured to couple to a trochlear groove of a femur. In some embodiments, the implant is configured to couple to only a portion of a condyle of a femur. In some embodiments the implant is coupled to the patella. In any embodiment the balloon **6** may extend from one surface of the implant as a focal protuberance to fill a defect, space, or to aide in alignment correct, or the balloon may be full thickness as differences in FIGS. **2** and **3** show respectively. In any embodiment there may be a singular or multiple major balloons, if off a primary surface resembling bubble wrap, and there may be microscopic balloons or vacuoles containing gas, gel, or solid in the material matrix.

In all descriptions provided herein of the patch implant, the implant may instead be configured to couple to the tibia or to the fibula or the patella. It is the intention and understanding that the implant is suited for this purpose in certain embodiments with adjustments to account for dimensional differences of these bones. Most descriptions provided herein are directed to embodiments coupling the implant to the femur, however, this is primarily for ease of description and continuity, and does not preclude embodiments wherein the implant is coupled to the tibia (or other bones). Likewise, as noted elsewhere herein, there are embodiments where the implant may be coupled to two bones (at least), for example to both a tibia and a femur.

Partial Knee Arthroplasty (Unicompartment)

In addition to the total knee-type (dual condyle) and patch implants are implants that serve to cover and adjust alignment for either the medial or lateral condyle of the femur with varus or valgus knees requiring added cushioning to recreate the natural six degrees of knee valgus.

Thus, provided herein is an implant for placement on at least one condyle of the distal femur (a unicompartment implant—named so due to their coverage of a single condyle of the femur). The implant may be configured to be placed over the lateral condyle. The implant may be configured to be placed over the medial condyle. The implant may be configured to be placed over either the medial condyle or the lateral condyle. Two unicompartment implants may be placed in the same knee, one over the medial condyle, one over the lateral condyle.

FIGS. **11**A-**12**C depict example embodiments of unicompartment implants. In some embodiments, the unicompartment implant comprises a balloon that is at least one of: at most about 1.5 cm in diameter, at most about 1.75 cm in

diameter, at most about 2 cm in diameter, at most about 2.25 cm in diameter, at most about 2.5 cm in diameter, at most about 2.75 cm in diameter, at most about 3 cm in diameter, at most about 3.25 cm in diameter, at most about 3.5 cm in diameter, at most about 3.75 cm in diameter, at most about 4 cm in diameter, at most about 4.25 cm in diameter, at most about 4.5 cm in diameter, at most about 4.75 cm in diameter, at most about 5 cm in diameter, at most about 5.25 cm in diameter, at most about 5.5 cm in diameter, at most about 5.75 cm in diameter, at most about 6 cm in diameter, at most about 6.25 cm in diameter, at most about 6.5 cm in diameter, at most about 6.75 cm in diameter, at most about 7 cm in diameter, at most about 7.25 cm in diameter, at most about 7.5 cm in diameter, at most about 7.75 cm in diameter, at most about 8 cm in diameter, at most about 3 cm in length along the longest length of the balloon, at most about 3.25 cm in length along the longest length of the balloon, at most about 3.5 cm in length along the longest length of the balloon, at most about 3.75 cm in length along the longest length of the balloon, at most about 4 cm in length along the longest length of the balloon, at most about 4.25 cm in length along the longest length of the balloon, at most about 4.5 cm in length along the longest length of the balloon, at most about 4.75 cm in length along the longest length of the balloon, at most about 5 cm in length along the longest length of the balloon, at most about 5.25 cm in length along the longest length of the balloon, at most about 5.5 cm in length along the longest length of the balloon, at most about 5.75 cm in length along the longest length of the balloon, at most about 6 cm in length along the longest length of the balloon, 6.25 cm in length along the longest length of the balloon, at most about 6.5 cm in length along the longest length of the balloon, at most about 6.75 cm in length along the longest length of the balloon, at most about 7 cm in length along the longest length of the balloon, at most about 7.25 cm in length along the longest length of the balloon, at most about 7.5 cm in length along the longest length of the balloon, at most about 7.75 cm in length along the longest length of the balloon, and at most about 8 cm in length along the longest length of the balloon. As used herein with respect to balloon dimensions whether length or diameter, the term "about" means variations of at least one of 0.1 cm, 0.2 cm, 0.25 cm, 0.5 cm, and 1 cm.

In some embodiments, the implant comprises attachment tabs or attachment elements over the anterior and/or posterior and/or medial side, and/or lateral side (and/or some combination thereof) of a condyle. In some embodiments, the implant comprises attachment tabs or attachment elements in the intercondylar notch. In some embodiments, the implant comprises attachment tabs or attachment elements superiorly at the distal end of the femur anteriorly.

The posterior of the knee can be difficult to access without disturbing joint components (or in order to minimize such disturbance) such as tendons, ligaments, etc. Thus, in some embodiments, the implant comprises strings, reigns, lassos, and/or lanyards that may pass from the posterior of the implant via the intercondylar notch anteriorly to join with themselves and/or other coupling devices. In some embodiments, posterior reigns or suture-like lanyards cinch up the implant from inside the posterior intercondylar notch toward another connection site around the femur. These couplers may be pre-coupled to the implant, and the implant and its couplers may be configured to be pulled (or cinched) from the anterior of the implant once the implant is in its general location relative to the condyle in order to finally position the implant about the condyle—in particular in order to cinch the implant about the posterior of the condyle. Likewise, in some embodiments where the implant is pre-molded, the coupler as described are adapted to move the implant to its final position with conformity to the condyle's posterior with minimal disturbance to the joint structures at the joint's posterior (minimal cutting, minimal moving, and or minimal detachment, for non-limiting example). In some embodiments at least a portion of the ligamentary structure of the knee is spared.

FIG. **10**A depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4***b*, **4***d* extending from an inflated balloon **6** and showing the inflation medium **46** moved anteriorly toward the patella **40** when the knee joint is slightly flexed. Likewise, FIG. **10**B depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4***b*, **4***d* extending from an inflated balloon **6** and having couplers **44***a*, **44***b* (which may be, for non-limiting example, staples or screws) coupling the appendages **4***b*, **4***d* to the femur **24** and showing the inflation medium **46** moved anteriorly toward the patella **40** when the knee joint is slightly flexed.

FIGS. **11**A, **11**B, and/or **11**C may be used to describe a unicompartment implant **2** (or unicompartment knee implant, terms which may be used interchangeably) described herein, having appendages **4***a*, **4***c*, extending from a balloon **6** (not shown in FIG. **11**A) and including holes **8***a*-**8***h*, and/or tabs **10***a*-**10***f* which may be used with couplers (not shown) to couple the implant to a bone of the knee joint (which may be the femur, the tibia, or the patella). Features shown in FIGS. **11**A, **11**B, and/or **11**C are common to both the unicompartment knee implant and the patch implant (discussed elsewhere herein), although dimensions may differ as described herein. Thus, FIGS. **11**A, **11**B, and/or **11**C may be used to describe the unicompartment knee implant and/or the patch implant. FIG. **11**A depicts an embodiment of the unicompartment knee implant **2** curved to simulate curvature about one condyle of a femur, the implant **2** having appendages **4***a*, **4***c*, extending from an uninflated balloon (not shown) and including tabs **10***a*-**10***f* and/or holes **8***a*-**8***h*, which may be used with couplers (not shown, described elsewhere herein) to couple the implant **2** to the femur of the knee joint. FIG. **11**B depicts an embodiment of the unicompartment knee implant **2** curved to simulate curvature about one condyle of a femur, the implant having appendages **4***a*, **4***c*, extending from an inflated balloon **6** and including tabs **10***a*-**10***f* and/or holes **8***a*-**8***h*, which may be used with couplers (not shown, described elsewhere herein) to couple the implant **2** to the femur of the knee joint. FIG. **11**C depicts a bottom-up view of an embodiment of the unicompartment knee implant **2** curved to simulate curvature about one condyle of a femur, the implant **2** having appendages **4***a*, **4***c*, extending from an inflated balloon **6** and including tabs **10***a*-**10***f* and/or holes **8***a*-**8***h*, which may be used with couplers (not shown, described elsewhere herein) to couple the implant **2** to the femur of the knee joint.

In some embodiments, the unicompartment implant including attachment tabs is at least one of: at most about 15 cm in length along the longest length of the implant, at most about 15.25 cm in length along the longest length of the implant, at most about 15.5 cm in length along the longest length of the implant, at most about 15.75 cm in length along the longest length of the implant, at most about 16 cm in length along the longest length of the implant, at most about 16.25 cm in length along the longest length of the implant, at most about 16.5 cm in length along the longest length of the implant, at most about 16.75 cm in length along the longest length of the implant, at most about 17 cm in length along the longest length of the implant, at most about 17.25 cm in length along the longest length of the implant, at most about

17.5 cm in length along the longest length of the implant, at most about 17.75 cm in length along the longest length of the implant, at most about 18 cm in length along the longest length of the implant, 18.25 cm in length along the longest length of the implant, at most about 18.5 cm in length along the longest length of the implant, at most about 18.75 cm in length along the longest length of the implant, at most about 19 cm in length along the longest length of the implant, at most about 19.25 cm in length along the longest length of the implant, at most about 19.5 cm in length along the longest length of the implant, at most about 19.75 cm in length along the longest length of the implant, at most about 20 cm in length along the longest length of the implant, at most about 20.25 cm in length along the longest length of the implant, at most about 20.5 cm in length along the longest length of the implant, at most about 20.75 cm in length along the longest length of the implant, at most about 21 cm in length along the longest length of the implant, at most about 21.25 cm in length along the longest length of the implant, at most about 21.5 cm in length along the longest length of the implant, at most about 21.75 cm in length along the longest length of the implant, at most about 22 cm in length along the longest length of the implant, at most about 22.25 cm in length along the longest length of the implant, at most about 22.5 cm in length along the longest length of the implant, at most about 22.75 cm in length along the longest length of the implant, at most about 23 cm in length along the longest length of the implant, 23.25 cm in length along the longest length of the implant, at most about 23.5 cm in length along the longest length of the implant, at most about 23.75 cm in length along the longest length of the implant, at most about 24 cm in length along the longest length of the implant, at most about 24.25 cm in length along the longest length of the implant, at most about 24.5 cm in length along the longest length of the implant, at most about 24.75 cm in length along the longest length of the implant, at most about 25 cm in length along the longest length of the implant, at most about 25.25 cm in length along the longest length of the implant, at most about 25.5 cm in length along the longest length of the implant, at most about 25.75 cm in length along the longest length of the implant, and at most about 26 cm in length along the longest length of the implant. As used herein with respect to implant length dimensions, the term "about" means variations of at least one of 0.1 cm, 0.2 cm, 0.25 cm, 0.5 cm, and 1 cm.

In some embodiments, the unicompartment implant is longer than it is wide, and the longer portion of the implant wraps from the anterior of the condyle to the posterior of the condyle. In some embodiments, the length of the implant is longer on the outer edge of the implant than on the inner edge nearest the trochlear groove (whether used on the lateral or medial condyle).

FIGS. **12**A, **12**B, and/or **12**C may be used to describe a unicompartment knee implant (unicompartment implant) described herein, having appendages **4***a*, **4***c*, extending from a balloon **6** and including holes **8***a*, **8***b*, **8***c*, and/or tabs **10***a*, **10***b*. **10***c*, **10***d*, **10***e*, **10***f* which may be used with couplers (not shown) to couple the implant to a bone of the knee joint (which may be the femur, the tibia, or the patella). Features shown in FIGS. **12**A, **12**B, and/or **12**C are common to both the unicompartment knee implant and the patch implant (discussed elsewhere herein), although dimensions may differ as described herein. Thus, FIGS. **12**A, **12**B, and/or **12**C may be used to describe the unicompartment knee implant and/or the patch implant. FIG. **12**A depicts a bottom-up view of an embodiment of the implant **2** (unicompartment or patch), the implant having appendages **4***a*, **4***c*, extending from a balloon **6** and including holes **8***a*, **8***b*, **8***c*, which may be used with couplers (not shown) to couple the implant **2** to the femur of the knee joint. FIG. **12**B depicts a bottom-up view of an embodiment of the implant **2** (unicompartment or patch), the implant having appendages **4***a*, **4***c*, extending from a balloon **6** and including tabs **10***a*, **10***b* and hole **8***a* which may be used with couplers (not shown) to couple the implant to the femur of the knee joint. FIG. **12**C depicts a bottom-up view of an embodiment of the implant **2** (unicompartment or patch), the implant having appendages **4***a*, **4***c*, extending from a balloon **6** and including tabs **10***c*, **10***d*, **10***e*, and **10***f* and hole **8***a* which may be used with couplers (not shown) to couple the implant to the femur of the knee joint.

In all descriptions provided herein of the unicompartment implant, the implant may instead be configured to couple to the tibia or to the fibula or the patella. It is the intention and understanding that the implant is suited for this purpose in certain embodiments with adjustments to account for dimensional differences of the particular bones. Most descriptions provided herein are directed to embodiments coupling the implant to the femur, however, this is primarily for ease of description and continuity, and does not preclude embodiments wherein the implant is coupled to the tibia (or other bones). Likewise, as noted elsewhere herein, there are embodiments where the implant may be coupled to two bones (at least), for example to both a tibia and a femur.

Meniscal Replacement or Repair, and Solid, Rigid, or Semi-Rigid Components:

Provided herein is an implant having a balloon having a first and second chamber. The implant may be any of the Dual Compartment, Unicompartment, and Patch implants described herein. The second chamber may be configured to replace and/or partially replace fibrocartilage meniscal loss. The implant may have two lobes of chambers which may be alternatively described as two superimposed balloon radii in apposition to each other. The implant may be configured to provide stability between the femur and tibia by providing a meniscus wedge. In some embodiments the implant comprises a portion configured to replace and/or partially replace fibrocartilage meniscal loss. Such an embodiment may not require a second chamber.

In some embodiments a chamber of the implant is configured to receive a solid piece configured to restore joint and/or bone alignment. In some embodiments, the chamber is configured to receive a plurality of solid pieces, each of which can be used to increase the space between a first bone and a second bone in order to restore and/or improve joint and/or bone alignment. The solid pieces may be wedge-shaped, or be provided in various sizes and/or shapes. The solid pieces may individually or together be used in a chamber or multiple chambers of the implant. The solid piece (or pieces) may be used to ratchet adjacent bones to a desired distraction and/or alignment to restore and/or improve joint and/or bone alignment. The solid piece may be put in a chamber of the implant, which may enclose or partially enclose the piece to hold the piece in place. In some embodiments, a block of biocompatible material (such as PMMA or another bone-like substitute) may be provided and may be formed (by carving or other forming method) by the surgeon to a desired shape. The formed piece may then be put in a chamber of the implant, which may enclose or partially enclose the piece to hold the piece in place.

In some embodiments, the inflation medium is a methyl methacrylate or other biocompatible hardening substance which can flow when initially put into the chamber, and hardens to become a rigid piece (or solid piece). The methyl methacrylate or other biocompatible hardening substance may conform to the shape of the chamber, or may conform to

the shape of a space between bones and/or other joint structures. The methyl methacrylate or other biocompatible hardening substance may conform to a form chosen by the surgeon using tools and/or pressure to influence the final shape of the rigid piece formed by the methyl methacrylate or other biocompatible hardening substance upon hardening.

The solid piece (whether formed in situ or by a surgeon or pre-formed) may be cushioned by the implant. The implant may comprise an inflatable chamber between the solid piece and the femur. The implant may comprise an inflatable chamber between the solid piece and the tibia. The implant may comprise an inflatable chamber between the solid piece and the patella. The implant may comprise an inflatable chamber between the solid piece and the second bone. The implant may comprise a pad between the solid piece and the femur as a cushion. The implant may comprise a pad between the solid piece and the tibia as a cushion. The implant may comprise a pad between the solid piece and the patella as a cushion.

The solid piece may provide at least one of about 1 degree of joint correction, about 2 degrees of joint correction, about 3 degrees of joint correction, about 4 degrees of joint correction, about 5 degrees of joint correction, about 6 degrees of joint correction, about 7 degrees of joint correction, about 8 degrees of joint correction, about 9 degrees of joint correction, and about 10 degrees of joint correction. With respect to degrees of joint correction, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%.

The implant can be used in a variety of joints where the implant replaces a bone on bone surface and cushions the interaction between the articular ends of any two bones, such as at the femoral tibial and patella femoral knee interfaces. Where the implant is substituting or enhancing articular cartilage, the rigidity can be reduced or enhanced to maximize conformation changes that arise during motion as enabled by the two opposing walls and intended inner space, coupled with considerations in any joint surgical reconstruction with accommodation to or amplification of the existing joint ligaments, tendons or dearth thereof. The implant **10** may be deflated and removed by minimally invasive surgery, for example, after the implant has served its purpose of regenerating tissue or if another clinical condition warrants its removal. However, it may not be clinically necessary to remove the implant even if inflation is lost, since the two remaining functions of patching the injured cartilage, and delivering restorative cells may justify implant retention.

In many embodiments the implant (or a portion thereof, such as the balloon or balloon) is a weight bearing spacer that will allow joint motions to approach normal, whether filling the space left by an entirely collapsed peripheral joint bone or the space of ablated cartilage proximate surfaces diffusely as in osteoarthritis or succinctly as in osteonecrotic defects or localized trauma. The walls may be used as a membrane for holding living cells in proximity of the osteochondral defect long enough for the cells to attach (e.g. 24 hours) or to deeply adhere (up to 28 days) or return to normal (up to one year). Weight bearing will be expected to increase as distal lower extremity joints are treated.

Kits

Provided herein are kits comprising multiple implants described herein. A kit may comprise multiple sizes of a single type of implant. A kit may comprise various implant types, such as the patch, the unicompartment, and/or the dual compartment types of implants described herein. A kit may comprise various couplers, which may be selected by the surgeon depending on his comfort and expertise, and/or based on the particular patient anatomy and/or needs. The kit may further comprise any insertion tools and/or surgery tools that may uniquely assist in implanting the implant in the patient.

Implantation Methods

Implantation of implants provided herein will depend on the size of joint surface intended for reconstruction by use of the implant. In some embodiments, an arthroscope can be inserted in one side of the knee joint through a 0.5 cm wound, while the implant is inserted into the opposite joint line wound from 1-10 cm in size. The joint may be first inspected and debrided, performing an arthroscopic synovectomy, chondroplasty, and meniscectomy as needed. Additional distraction under general anesthesia with the knee at variable degrees of flex may allow for implant introduction, systematic peripheral attachment, balancing, and inflation.

In some embodiments, the implant may be selectively inflatable depending on the particular needs of the patient. In some embodiments, the filler of the interior of the implant may be rigid, semi-rigid, fluid, air, or combinations thereof, as described herein. In some embodiments, the implant may be used in conjunction with fibrocartilage repair or replacement. In some embodiments, the implant may be used without fibrocartilage repair or replacement. In some embodiments, the implant may be used in conjunction with boney osteotomy. In some embodiments, the implant may be used without boney osteotomy.

The posterior of the knee can be difficult to access without disturbing joint components (or in order to minimize such disturbance) such as tendons, ligaments, etc. Thus, in some embodiments, the method comprises providing an implant comprising strings, reigns, lassos, and/or lanyards that may pass from the posterior of the implant via the intercondylar notch anteriorly to join with themselves and/or other coupling devices. In some embodiments, posterior reigns or suture-like lanyards cinch up the implant from inside the posterior intercondylar notch toward another connection site around the femur. In some embodiments, the methods comprise conforming the implant posterior to the condyle by pulling the strings (or reigns, or lassos, or lanyards or the like) of the implant. Such couplers (strings, reigns, lassos, lanyards, etc) may comprise suture materials and/or wire materials.

These couplers (i.e. strings, reigns, lassos, lanyards, etc) may be pre-coupled to the implant, and the implant and its couplers may be configured to be pulled (or cinched) from the anterior of the implant once the implant is in its general location relative to the condyle in order to finally position the implant about the condyle—in particular in order to cinch the implant about the posterior of the condyle. Likewise, in some embodiments where the implant is pre-molded, the coupler as described are adapted to move the implant to its final position with conformity to the condyle's posterior with minimal disturbance to the joint structures at the joint's posterior (minimal cutting, minimal moving, and or minimal detachment, for non-limiting example). In some embodiments at least a portion of the ligamentary structure of the knee is spared.

The implant is inserted arthroscopically through a cannula about 10 mm in diameter with the implant in the deflated construct, and once inside the prepared joint space and secured therein by the skirt or tabs, the implant will be distended or inflated with gas, gel, fluid or fluid that becomes a resilient solid to fill the original natural space of about 0.5 cm between the bones of the joint (between at least two bones of the joint). If the implant is not inserted through a cannula, it may be inserted through an open incision from one to forty centimeters in length at the surgeons discretion. Tensioning will be by the surgeon's sense of proper pressure application aided by a gauged syringe for insertion of viscolubricants such as Synvisc, Hyalgan, Supartz and/or analgesics such as

lidocaine gel. The insertion of liquids to the joint per se may be directly, through a cannula to the joint space previously in place for debridement, and or via a cannula or tube that is not part of the original implant assembly. Once the joint is cleaned, the implant is inserted and appropriately fixed to avoid extrusion or dislocation thereof. This may be via attachment of the implant tabs and/or by a combination of tab use plus intended friction created by implant surface coverings (analogous to Velcro) or a draw string at the smaller base of the implant.

In some embodiments the attachment tabs are positioned on the implant to both secure the implant to the joint components, and to enable a physician to ensure the implant has a minimum amount of slack that could create wrinkles or loose areas to avoid unnecessary friction and/or wear of the implant of the patient's anatomy. Figures depicted herein show examples of properly situated attachment tabs configured for these dual purposes. In some embodiments, fewer tabs are needed to achieve these goals.

In some embodiments, where slack or voids exist, the balloon under compression may fill such areas. The implant in some embodiments is configured to allow hyaline and/or cartilage cells to fill any irregularities or craters in the joint components and grow to refurbish natural joint contour. When the implant implantation is combined with, for example, movement of the treated joint in a constant passive motion machine for 12 hrs a day for 6 weeks after surgery implanting the implant, cell growth will create renewed hyaline cartilage, and/or blood/fibrin and scar to create fibrocartilage filler material.

Each attachment tab insert site may be clinically determined centripitally around the implant during surgery, driving slots or holes sequentially with an osteotome or drill immediately followed by insertion of the triangled tab extension into the bone slots or screw respectively. For example, if the implant were viewed like a clockface the first tab could be tacked/tapped in a 2 o'clock, then 7, 10, 4 11, 5, 12, 6 (wherein #2, 7, 10, 4 are over the bilateral femurs superior/inferior to collateral ligaments, 11, 12 are superior at the distal anterior femur beneath the upper patella, and 5, 6 are inside the intercondylar notch anterior to cruciates.) This can be like putting a saddle on a horse, going around the knee end with a grasper, to tug the polymer toward fit, tapping a slot over the side of the femur with a thin one-half inch osteotome, angling cuts distally, one by one, as if to pull the implant (or saddle) into its angle of repose, seating ideally over the condyles and ridings nicely in the trochlear groove.

In some embodiments, the metal clips could be set angled at about 120 degrees, as greater than 90 will favorably distract/hold the implant to tighter fit analogous to a mylar compliant balloon or stretch sock fitting over a protuberance as opposed to a piece of (non-compliant) paper that results is wrinkles and areas of incongruence between the implant and bone end. Reducing dislodgement tendency and snugging the polymer once stretched to best fit may avoid the failure history as illustrated in the Danish Polymer hip cap solid crescent shaped hip resurfacing implants which lacked inflation, surface stability, accommodation, and fixation.

Inflation may also be specified by clinical need, and modifications in the implant multi-cell (multi-compartment) construction allows for selective inflation with substances ranging from gas to solid, including gels or semi-solids that can as part of material layered integrity either provide calculated hardness (durometer) to overcome and resist limb adjacent bone mal-alignment, and/or to deliver new regenerative tissues for restoration of natural anatomy of time. That is, certain sections of the implant may be electively inflated of left without expansion, to adjust to fit as matching a normal or uninjured contralateral limb for the involved patient.

Indeed, patient interaction and feedback may be sought so as to bring to orthopedic conceived art and science the individual's own needs and concerns. It is said that for patients who have anterior cruciate injuries, one third require reconstruction for knee joint stabilizer, one third do not—living with a reduced activity level, and one third deliberate extensively until a choice between the two continuum options is made.

A goal of embodiments of implants described herein is to maintain remnant living tissue by using minimally invasive technologies, smaller incisions when they serve the patient equally to larger, sacrificing the least normal tissue as possible. Implants described herein assist and improve on current treatment options available by avoiding as much as possible the ablative bone and cartilage resecting, ligament removing total knee arthroplasty and instead to restore the padding lost in injury or disease or surgery.

Examples from within the techniques include electing to repair rather than reconstruct anterior cruciate ligaments in certain situations, proved warranted and effective at a $p<0.3$ statistical level. Whereas Carticel chondrocyte implantation is useful to enable articular surface regrowth with hyaline, rather than scar/fibrocartilage from picking/drilling, the massive morbidity from periosteal harvesting is unnecessary. This is because it takes only 24 hours for the cartilage cloned chondrocytes to attach to the prepared joint surface, and the polymer membrane (patch implant described herein, for example, or use of chondrocytes on surfaces of the dual compartment implant or the unicompartment implant) over the prepared defect (like a manhole cover) will adeptly substitute for periosteum.

With these concepts in mind in is the overall intent to do what is necessary to restore function and nothing more in order to spare the patient removal of injured tissues that may recover or regrow, by implementing a common sense approach to limb repair and reconstruction with the implant and methods of use thereof. In animals as horses and dogs, where recovery instructions are even less likely to be followed than with humans, implanting secure restorative implants for joint surface refurbishment may offer renewed function and save lives that would have otherwise been sacrificed.

Rehabilitation of knee implant treated patients will engage prudent early motion. The amount of weight bearing allowed with be analogous to the procedures written by this primary surgery for Carticel implanted cases, following the principles that excessive amounts and repetitions of stress upon reconstructed areas should be avoided for 6-12 weeks after surgery. However, the knee implant surgeries per se are expected to take less than one hour, involve less than 1 cc blood loss, require wounds less than or equal to 10 cm overall (depending on the embodiment of the implant), and the end result intends to permit early full weight bearing. Zealous sports activities may be restricted until the bone ingrowth and cartilage renewal is reasonably expected, between 2 and 12 months after surgery depending upon the amount of joint tissue replaced.

In some situations, the removal of the implant may be needed, and embodiments of the implants described herein are configured for removal arthroscopically, and with the allowance to perform all regular older routine accepted techniques ranging from joint debridement to drilling, partial or total replacement. In some embodiments the implant is configured for removal and replacement with a replacement implant—either immediately (within a week), or after a

period of longer time (for example, after about 6 weeks to 1 year in the case of infection once all foreign bodies are removed and depending upon the surgeon's and/or infectious disease consultant's opinion

Specific surgical decisions related to size matching, fixation and or concomitant osteotomy warranted reconstruction are left to the primary surgeon and patient in each case.

The implant is inserted by minimally invasive surgery, in some embodiments, however, in other embodiments, the implant may not be inserted by minimally invasive surgery. In some embodiments, the implant is delivered through an incision that is about 0.5 inches long. In some embodiments, the implant is delivered through an incision that is about 1 centimeter long. In some embodiments, the implant is delivered through an incision that is at most about 1 inch long. In some embodiments, the implant is delivered non-arthroscopically through an incision that is at least 1 centimeter long. In some embodiments, the implant is delivered through an incision that is at most about 0.75 inches long. In some embodiments, the implant is delivered through an incision that is at most about 0.5 inches long. In some embodiments, the implant is delivered through an incision that is about 8 centimeters long. In some embodiments, the implant is delivered through an incision that is about 9 centimeters long. In some embodiments, the implant is delivered through an incision that is about 10 centimeters long. In some embodiments, the implant is delivered through an incision that is about 11 centimeters long. In some embodiments, the implant is delivered through an incision that is about 12 centimeters long. In some embodiments, the implant is delivered through an incision that is over about 10 centimeters long. In some embodiments, the implant is delivered through an incision that is at up to about 40 centimeters long. In some embodiments, the implant is delivered through multiple incisions. With respect to incision length, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%.

In some embodiments the implant is configured to be delivered to the joint arthroscopically. In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most 10 millimeters. In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most 9 millimeters. In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most 5 millimeters.

In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most 10 millimeters. In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most 9 millimeters. In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most 5 millimeters.

In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most 10 millimeters. In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most 9 millimeters. In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most 5 millimeters.

In some embodiments the implant is configured to be delivered to the joint arthroscopically. In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most about 10 millimeters. In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most about 9 millimeters. In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most about 5 millimeters. With respect to cannula distal end inner diameter, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%.

In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most about 10 millimeters. In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most about 9 millimeters. In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most about 5 millimeters. With respect to cannula distal end inner diameter, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%.

In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most about 10 millimeters. In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most about 9 millimeters. In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most about 5 millimeters. With respect to cannula distal end inner diameter, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%.

In some embodiments the implant may be provided as a deflated balloon for insertion into the joint space. In some embodiments the implant may be provided as folded balloon that may be collapsed like an umbrella for insertion into the joint space. In some embodiments the implant may be provided as collapsed balloon that is of an irregular folded pattern to minimize its folded (or collapsed) size for insertion into the joint space. In some embodiments, the implant is configured to blow up (or expand) to take the form of the expanded, distracted, debrided joint.

In some embodiments, the implant replaces periosteum.

In some embodiments, the implant is implanted to preserve bone as compared to a typical arthroplasty procedure of the joint. In some embodiments, the implant is implanted to preserve cartilage as compared to a typical arthroplasty procedure of the joint. In some embodiments, the implant is implanted with minimal soft tissue dissection as compared to a typical arthroplasty procedure of the joint. In some embodiments, the implant is implanted without joint dislocation. In some embodiments, once implanted, the joint is adaptable to revision surgery. In some embodiments once implanted, the joint retains at least one of: about 90% of normal joint function, about 95% of normal joint function, about 85% of normal joint function, about 80% of normal joint function, about 75% of normal joint function, about 70% of normal joint function, about 65% of normal joint function, about 60% of normal joint function, about 55% of normal joint function, about 50% of normal joint function, at least 95% of normal joint function, at least 90% of normal joint function, at least 85% of normal joint function, at least 80% of normal joint function, at least 75% of normal joint function, at least 70% of normal joint function, at least 65% of normal joint function, at least 60% of normal joint function, at least 55% of normal joint functions at least 50% of normal joint function, about 50%-about 75% of normal joint function, about 50%-about 70% of normal joint function, about 60-about 70% of normal joint function, about 70%-about 80% of normal joint function, about 70%-about 90% of normal joint function, about 80%-about 95% of normal joint function, about 80%-about 90% of normal joint function, and about 90%-about 95% of normal joint function. As used herein with respect to percentage of normal joint function, the term "about" can be ranges

of 1%, 5%, 10%, or 25%. For example, a range of 1% with respect to about 90% of normal joint function covers 89% to 90% of normal joint function.

In some embodiments, prior to deploying the implant embodying features of the invention, the cartilage lining the joint is prepared by removing hyaline or fibro cartilage flaps or tears, and areas of chondral advanced fissuring are excised or debrided to create precisely defined defects surrounded by stable normal remnant hyaline cartilage with vertical edges in relation to the damaged surface. It is these defects of the cartilage previously normal surface into which new living cells may be injected or otherwise inserted, and allowed to aggregate by the implant interpositional arthroplasty proximate expanded compressive external wall material. Synovitis invading the joint periphery may be vaporized and extracted conventionally or by the use of steam. Areas of greater cartilage damage are removed for subsequent regeneration and the less afflicted areas having stable cracks are treated to seal or weld the cracks. Areas where the tugor or consistency or minimally damaged cartilage can be preserved are intentionally saved rather than destroyed so as to support the normal spacing and gliding opportunity of the more normal joint interface. Thus, normal cartilage is left behind and abnormal cartilage is removed with the implant making up for the deficiencies. With the present invention, it is preferred in some embodiments to avoid joint dislocation so as to preserve natural innervations and vascularity and thus preserving the blood supply.

Joint preparation is usually performed under a brief general anesthetic of outpatient surgery. Increasing the joint space may be necessary and allows the surgeon to wash out noxious enzymes, to remove invasive synovitis, to remove loose bodies, to prepare osteochondral defects ideally and otherwise prepare the joint for the implant. Partial or complete inflation of the implant may precede release of traction in some embodiments. In some embodiments, regeneration agents or cells are inserted with the implant or as a fluid or 3-D template prior to release of traction and wound closure. It is preferred, in some embodiments, to perform joint debridement, implant deployment and application of cell regeneration agent, e.g. stem cell application, under the same anesthetic. As described by several companies in the Stem Cell Summit held in New York, N.Y. on Feb. 17, 2009, it is desirable to obtain an aspiration of the patient's bone marrow from the iliac crest after anesthesial sterilely at the beginning of the operation. The intraoperative technologist will "dial in the cells" to regenerate areas of maximum pathophysiology while the surgeon debrides or otherwise prepares the joint and inserts the implant, placing the cells at the best time. Cell implantation may also occur as a secondary or tertiary reconstructive treatment adjunct.

Provided herein is a method for restoring a joint comprising: providing an implant configured for deployment between a femur and at least one second bone of a joint, the implant comprising a balloon comprising a first portion that is configured to engage the femur of the joint, a second portion that is configured to engage at least one second bone of the joint, a side portion connecting the first portion and the second portion, in which the side portion facilitates relative motion between the first portion and the second portion, and an interior that is optionally inflatable with a first inflation medium; and coupling a first appendage of the balloon to the femur of the joint. Provided herein is a method for restoring a joint comprising: providing an implant configured for deployment between a tibia and at least one second bone of a joint, the implant comprising a balloon comprising a first portion that is configured to engage the tibia of the joint, a second portion that is configured to engage at least one second bone of the joint, a side portion connecting the first portion and the second portion, in which the side portion facilitates relative motion between the first portion and the second portion, and an interior that is optionally inflatable with a first inflation medium; and coupling a first appendage of the balloon to the tibia of the joint.

In some embodiments, at least two of first portion, the second portion, and the side portion are contiguous. In some embodiments, the first portion comprises a first wall, the second portion comprises a second wall, and the side portion comprises a side wall.

In some embodiments the method comprises providing an ingrowth patch on at least one of the first portion configured to engage the femur, the second portion configured to engage the second bone, the side portion, and the appendage. In some embodiments the method comprises providing an ingrowth patch on at least one of the first portion configured to engage the tibia, the second portion configured to engage the second bone, the side portion, and the appendage. The ingrowth patch may be configured to encourage and/or promote tissue ingrowth, such as bone ingrowth, for non-limiting example. The patch may be as large as the portion itself (whether the first portion the second portion, the side portion, or the appendage) or may be smaller than the portion (such as in the shape of a strip or other shaped patch). The ingrowth patch may comprise a surface irregularity or roughness. The ingrowth patch may be Velcro-like. In some embodiments the implant comprises an ingrowth patch on the first portion and/or the second portion, from (and in some embodiments including) a first appendage to a second appendage. In some embodiments, wherein the appendages loosen from attachment from the bone (by design and/or from wear and/or over time), the ingrowth patch aids in securing the implant to the bone. In some embodiments, the ingrowth patch comprises beads and/or bead-like elements attached to the implant. Such an ingrowth patch may be configured to simulate trabecular bone space of a normally cancellous latticework. In some embodiments, the beads are sintered beads of various sizes. In some embodiments, the beads are sintered beads about 400 microns in size. With respect to bead size, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%. In some embodiments, the first bone and/or the second bone is roughened to acquire a bleeding bone to facilitate ingrowth. In some embodiments, about 0.5 mm of cortical tissue is removed to facilitate ingrowth.

In some embodiments, the method comprises coupling a second appendage of the balloon to the femur of the joint. In some embodiments, the method comprises coupling a second appendage of the balloon to the tibia of the joint. In some embodiments, the method comprises coupling a second appendage of the balloon to at least one second bone of the joint. In some embodiments, the method comprises coupling a second appendage of at least one of the first portion, the second portion, and the side portion to at least one of the femur and at least one second bone of the joint. In some embodiments, the method comprises coupling a second appendage of at least one of the first portion, the second portion, and the side portion to at least one of the tibia and at least one second bone of the joint. In some embodiments, coupling at least one of the first appendage and the second appendage provides ligamentary-like support to the femur and the at least one second bone of the joint. In some embodiments, coupling at least one of the first appendage and the second appendage provides ligamentary-like support to the tibia and the at least one second bone of the joint. In some embodiments, coupling at least one of the first appendage and

the second appendage provides ligamentary-like support to the joint. In some embodiments, the first appendage and the second appendage are configured to provide tendon-like support to the femur and the at least one second bone of the joint. In some embodiments, the first appendage and the second appendage are configured to provide tendon-like support to the tibia and the at least one second bone of the joint. In some embodiments, the first appendage and the second appendage are configured to provide tendon-like support to the joint.

In some embodiments, the method comprises providing an inflation port in communication with the interior of the balloon for inflation of the interior of the balloon with the first inflation medium. In some embodiments, the method comprises using an inflation port of the implant that is in communication with the interior of the balloon to inflate the interior of the balloon with the first inflation medium. In some embodiments, the method comprises puncturing the balloon to inflate the interior of the balloon with the first inflation medium. In some embodiments, the method comprises providing a balloon having self-sealing capability. In some embodiments, the method comprises providing a balloon having self-sealing capability upon inflation of the interior of the balloon with the first inflation medium. In some embodiments, the method comprises providing a balloon comprising a seal capable of closing the interior of the balloon.

In some embodiments, the method comprises providing a balloon having an interior comprising a plurality of inflatable chambers. In some embodiments, the interior comprises a plurality of individually inflatable chambers. In some embodiments, the method comprises inflating a first chamber of the plurality of inflatable chambers with a first inflation medium. In some embodiments, the first chamber and the inflation medium is selected based on the particular needs of the patient. For non-limiting example, if the patient has bone loss due to an injury, the chamber may be selected at the location of the missing bone, and may be filled with a rigid inflation medium (or one that becomes rigid once in the chamber) in order to replace the missing and/or damaged bone. Alternatively, or in addition, a chamber may be chosen to restore alignment of the joint, and inflated with an appropriate inflation medium to impart both alignment and cushion to the joint. In some embodiments, the method comprises inflating a second chamber of the plurality of individually inflatable chambers with a second inflation medium.

In some embodiments, the balloon is a composite structure. In some embodiments, the balloon comprises layers of porous and/or non-porous materials, or otherwise contain treatment or cell regeneration agents. In some embodiments, a first layer of the balloon is a thin, but strong layer of a thermoplastic, such as a thermoplastic polyurethane, for non-limiting example, which has microporosity sufficient to allow passage or egress of treatment or cell regeneration agents from a second layer. The second layer may be a central layer (which lies between the first layer and a third layer or a fourth layer or more layers). The first layer may comprise a bone engaging surface in some embodiments. The degree of microporosity to enable egress of treatment or cell regeneration agents from the second layer is found in polymer layers such as Chronoflex or Bionate 55. The bone engaging surface of the implant may be coated and/or impregnated with a latticework of polymer that is surface sprayed or layered on the bone engaging surface of the implant to promote cartilage tissue regeneration. This bone engaging surface coating may contain living chondrocytes (for example, as is provided in the Carticel procedure by the Genzyme company), and/or may contain stem cells with directed gene mutations to enhance adherence of the coating to the implant. The bone engaging surface may comprise peaks and troughs. The living cells may be provided in troughs while the surface peaks may be used for at least one of: space validation, traction, and cell protection.

In some embodiments, the first inflation medium imparts rigidity in the implant. In some embodiments, the first inflation medium imparts cushion in the implant. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium aligns the joint. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium aligns the bones of the joint. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium changes the bone alignment. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium improves joint alignment. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium restores, at least in part, joint alignment. In some embodiments, individual chambers of the interior are selectively inflated with a first inflation medium and/or a second inflation medium. In some embodiments, individual chambers of the interior are selectively inflated with a first inflation medium and/or a second inflation medium in order to reconstruct the joint and/or in order to reconstruct bones of the joint.

Over time, ingrowth of repair tissue aids in fixation and stability externally to the implant, while the soft cushioning implant interior will absorb forces across the joint surfaces and permit proper motion. The turgor or wall tension of the implant as well as the inside distension of the implant per se can be adjusted by adding or removing the inflation substance to the implant's interior space.

Accordingly, the present invention provides a new approach to arthroplasty that involves a resilient implant deployed between bones of the knee joint. Whereas a joint is comprised of the interface between bone cartilage space cartilage bone, in certain joint spaces such as the knee, the invention cushion may expand to fit the spaces between both "knee joints"—the femoral tibial involved on standing or walking on a level plane, and the patella femoral bones of the knee more involved on stair ascent and decent. For example, pressures behind the knee cap or patella when lying are zero, when standing are 0.7 times body weight, and when going up and down the patella femoral pressures are 3-4 times body weight. Thus, the implants will need to accommodate all the normal body functional pressures and complex space movements. The implant embodying features of the present invention provides more physiologic motion and shock absorption within the joint and has combined characteristics of anatomic design symmetry, balanced rigidity with sufficient attachment connections to adjacent normal structures, and durability that meet the needs of joint reconstruction.

The opposing internal surfaces of the first and second walls of the invention may either move together in synchrony or in opposite directions from one another (e.g. the superior wall moving medially in the hip and the inferior wall moving laterally). Optionally, the implant may be fixed to a concave surface of the joint or to a convex surface of the joint, to both, or to neither (e.g., having an interference fit within the joint with an expanding balloon or cushion that fills the existing

space). The implant may be inserted arthroscopically like a deflated balloon and then inflated through a cannula into the joint structure) to act as a cushion or renewed interface for painless and stable limb motion. When feasible joint capsular and adjacent ligament tissue as well as bone will be left in place to preserve the natural body, unless interfering with reconstructed limb function.

The application of steam in addition to removing damaged debris, can smooth out and reform the joint surface. The high temperature of the steam tends to weld cracks or fissures which can be present in the cartilage surface of a damaged joint. Smoothing of joint surface cartilage with steam welds or seals existing cracks or flaps in the cartilage, especially superficially as the lamina splendors, which melt together to provide a white shiny gliding joint surface. In cases where bone is exposed, the steam can be used to stabilize the periphery of the defect in the joint surface via capsulorrhaphy or joint tightening. Open mechanical and chemical debridement may also be employed to prepare the surfaces for the implant.

Once the implant is secured to the femur by means of the skirt or tabs or using other couplers, an impregnated transfer medium or cell template may be used, as described by Histogenics and Tygenix chondrocytes delivery systems wherein the position of concentrated cells is mechanically placed about the implant at areas of greatest cartilage damage to promote regrowth, or as in Carticel wherein watery cells are implanted beneath a periosteal membrane (a wall of the implant serving as the membrane), prior to completion of the inflation or expansion of the implant. At syringe or gauged device with measured screw-home pressure is used to inflate the implant.

Once the joint is ready to receive the implant, the deflated implant is advanced through the diaphragm of a delivery cannula (such as the Acufex from Smith & Nephew) or through the open incision site into the joint. It can be inflated by the attached cannula using a common syringe, inserting several cc's of filler material. Inserted contents and locations of cell placements depend on areas of need and joint size. In some embodiments of the methods several cc's of filler material and a viscolubricant in the interior of the implant will allow distension, cushioning, and gliding movements. Cell regeneration agents are placed in the areas of greatest need.

Methods of living stem cell or chondrocyte placement depend on the lesions and specific implant construct. Direct infusion into the joint with completion of implant inflation will press the cells into the hyaline surface, whereupon they attach within the first 24 hours. As a result, the patient may be forced to remain sedentary and the joint where the implant is deployed, non-weight bearing for the first day after surgery. Deeper osteochondral defects can be treated by 'hyper-perfusion of cells' via either 3-D cell transfer templates, or microneedle injection as used in treatment of diabetic patients for blood sugar testing and insulin/transdermal drug delivery. In cases of osteochondritis dissecans or localized both cartilage and bone lose, bone graft may be packed into the base of the defect followed by addition cell/tissue application. The cannula attached to the implant may be sealed and detached, or left in place for periodic aspiration of noxious enzymes as for the Cox-1, Cox-2, and 5-Lox systems, followed by reinsertion of activated substances including viscolubricants, or even more cells.

Implants embodying features of the invention may be designed for permanent or temporary deployment within a joint structure. Moreover, the implant may be formed of suitable bioabsorbable materials so that the implant may be absorbed within a particular predetermined time frame. Suitable bioabsorbable materials include polylactic acid, polyglycolic acid, polycaprolactone, copolymers, blends and variants thereof. One present method of forming the implant is to apply numerous layers of polymer such as ChronoFlex AR in a solvent and evaporating the solvent after applying each layer.

The coupling aspects (couplers) including but not limited to skirting or fixation tabs of the present implant prevent joint migration during use.

In some embodiments, the implant is adapted to restore natural joint function. In some embodiments, the implant is adapted to preserve viable joint tissue. In some embodiments, the implant is adapted to be placed with minimal surgery as compared to joint replacement therapy currently marketed. In some embodiments, the implant is adapted to permit weight bearing post surgery within at least one of: about 1 week, within about 1 day, within about 2 days, within about 3 days, within about 4 days, within about 5 days, within about 6 days, within about 10 days, within about 2 weeks, within about 3 weeks, within about 4 weeks, within about 5 weeks, within about 6 weeks. In some embodiments, the implant is adapted to permit weight bearing post surgery after about 1 day wherein full weight bearing is allowed in about 6 weeks. As used herein with respect to weight bearing timing, the term "about" can be a range of 1 day, 2 days, or 3 days, in some embodiments. In some embodiments, the implant is adapted to be allow for faster recovery and resumption of normal activities as compared to joint replacement therapy currently marketed.

In some embodiments, the balloon (or a portion thereof) is adapted to conform to the patient's anatomy. In some embodiments, the implant (or a portion thereof) is adapted to conform to the patient's anatomy. In some embodiments, the inflation medium is adapted to absorb a force (or forces) exerted on the joint. In some embodiments, the inflation medium is adapted to absorb a force (or forces) exerted on the bones of the joint. In some embodiments, the inflation medium is adapted to absorb a force (or forces) exerted on at least one bone of the joint. In some embodiments, the balloon is adapted to absorb shocks exerted on at least one of a bone, multiple bones, a ligament of the joint, ligaments of the joint, a tendon of the joint, tendons of the joint, and the joint in general. In some embodiments, the implant is adapted to restore natural cartilage cushion with stem cells.

In some embodiments, the balloon (or a portion thereof) is adapted to renew joint space. In some embodiments, the balloon (or a portion thereof) is adapted to reducing pain as compared to the pain felt prior to the implantation of the implant. In some embodiments, the balloon (or a portion thereof) is adapted to restore joint function. In some embodiments, the implant (or a portion thereof) is adapted to renew joint space. In some embodiments, the implant (or a portion thereof) is adapted to reducing pain as compared to the pain felt prior to the implantation of the implant. In some embodiments, the implant (or a portion thereof) is adapted to restore joint function.

In some embodiments, the implant is adapted to reverse arthritis in the joint.

In some embodiments, the balloon (or a portion thereof) is adapted to be placed into a debrided limb joint arthroscopically. In some embodiments, the balloon is adapted to pad cartilage defects. In some embodiments, the balloon is inflated to cushion the joint. In some embodiments the implant is adapted to deliver stem cells to at least one of the joint and a bone of the joint. In some embodiments the implant is adapted to deliver living chondrocytes to at least one of the joint and a bone of the joint. In some embodiments, the implant is adapted to provide a new articular surface for

the joint. In some embodiments, the implant is adapted to act as a spacer in the joint. In some embodiments, the implant is adapted to space the bones of the joint apart for proper joint articulation. In some embodiments, the implant is adapted to space the bones of the joint apart for reduced bone-on-bone rubbing.

In some embodiments, the implant is configured to at least one of: pad cartilage, cushion the joint, deliver a pharmacologic substance, remove noxious enzymes, debride upon implantation, debride the joint following implantation, deliver a therapeutic substance, deliver a biologic substance, and deliver living stem cells. In some embodiments, the implant is configured to deliver a chemotherapeutic agent to a bone or other surrounding tissues. In some embodiments, the implant is configured to deliver an anti-infectious medication to a bone or other surrounding tissues. In some embodiments, the implant is configured to deliver at least one of an antibiotic, antifungals, and analgesics agent.

In some embodiments, the implant is configured to be selectively inflated to realign limbs.

Provided herein is a method comprising: implanting a knee implant as described herein into a subject, wherein the implant reverses arthritis in the subject.

Provided herein is a method comprising: implanting a knee implant as described herein into a knee joint of a subject and treating a component of the knee joint of the subject with at least one of an allograph tissue, an autograph tissue, and an xenograph tissue. In some embodiments, the implanting step is at least one of: prior to the treating step, simultaneous with the treating step, and following the treating step.

Provided herein is a method comprising: implanting a knee implant as described herein into a subject, wherein the implant at least one of: restores joint function and controls arthopathies. In some embodiments, the implanting spares existing anatomy.

Provided herein is a method comprising: debriding a femur condyle of a knee joint of a subject, and implanting a knee implant as described herein into the knee joint of the subject, whereby the implant is configured to anneal to the cartilage of the subject. In some embodiments, the debriding is achieved by steam application.

Provided herein is a method comprising implanting a knee implant as described herein into a joint previously treated with a joint replacement. In some embodiments, the method comprises removing the joint replacement prior to implanting the knee implant. In some embodiments, the method comprises clearing infectious matter from the joint and/or surrounding tissues. In some embodiments, the method comprises implanting a second implant of any implant described herein following removing the implant previously implanted in the joint. In some embodiments, the method comprises replacing the joint of the subject following removing the implant previously implanted in the joint. In some embodiments, the method comprises debriding the bone of the joint, and implanting an implant of any implant described herein. In some embodiments, the method comprises repeating the debriding and implanting steps.

While particular forms of the invention have been illustrated and described herein, it will be apparent that various modifications and improvements can be made to the invention. One alternative implant construction involves the use of an upper portion of the implant having a net-like construction and filled with balls or ball bearing like elements that are larger than the openings in the netting. The balls or ball bearing like elements provide motion to the implant. The netting and ball bearing like elements may include regeneration agents as previously discussed, and the bearing construction may be directed toward favorable implant movement balanced with content disbursement.

The invention is intended primarily for human use but may be extended to mammalian use. To the extent not otherwise disclosed herein, materials and structure may be of conventional design.

Moreover, individual features of embodiments of the invention may be shown in some drawings and not in others, but those skilled in the art will recognize that individual features of one embodiment of the invention can be utilized in another embodiment. Moreover, individual features of one embodiment may be combined with any or all the features of another embodiment. Accordingly, it is not intended that the invention be limited to the specific embodiments illustrated. It is therefore intended that this invention be defined by the scope of the appended claims as broadly as the prior art will permit.

Terms such as "element", "member", "component", "device", "means", "portion", "section", "steps" and words of similar import when used herein shall not be construed as invoking the provisions of 35 U.S.C §112(6) unless the following claims expressly use the terms "means for" or "step for" followed by a particular function without reference to a specific structure or a specific action. All patents and all patent applications referred to above are hereby incorporated by reference in their entirety.

While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

What is claimed is:

1. An implant configured for deployment between a femur and a tibia of a knee joint, the implant comprising:

a balloon comprising:

a first portion that is configured to engage a medial condyle and a lateral condyle of the femur of the knee joint,

a second portion that is configured to engage the tibia of the knee joint,

a side portion connecting the first portion and the second portion, in which the side portion facilitates relative motion between the first portion and the second portion, and

an interior comprising of a plurality of inflatable non-communicating chambers configured to be selectively inflated and selectively deflated; and

a first appendage configured to couple the balloon to the femur of the knee joint.

2. The implant of claim **1**, comprising at least one attachment element in configured to couple with the intercondylar notch.

3. The implant of claim **1**, comprising at least one attachment element superiorly configured to couple with the distal end of the femur anteriorly.

4. The implant of claim **1**, comprising at least one posterior reign configured to cinch up the implant from inside a posterior intercondylar notch toward a connection site around the femur.

5. The implant of claim 1, comprising at least one suture-like lanyard configured to cinch up the implant from inside a posterior intercondylar notch toward a connection site around the femur.

6. The implant of claim 1, in which the first portion comprises a first wall, the second portion comprises a second wall, and the side portion comprises a side wall.

7. The implant of claim 1 further comprising an inflation port in communication with the interior of the balloon for inflation of the interior of the balloon with the first inflation medium.

8. The implant of claim 1, in which a first chamber of the plurality of individually inflatable chambers is adapted to be inflated with the first inflation medium, and a second chamber of the plurality of individually inflatable chambers is adapted to be inflated with a second inflation medium.

9. The implant of claim 8, in which the first inflation medium imparts at least one of rigidity in the implant and cushion in the implant.

10. The implant of claim 1, comprising a second appendage coupling the balloon to at least one of: the femur of the joint and the tibia of the joint.

11. An implant configured for deployment between a femur and a tibia of a knee joint, the implant comprising:

a balloon comprising:

a first portion that is configured to engage at least one condyle of the femur of the knee joint,

a second portion that is configured to engage the tibia of the knee joint,

a side portion connecting the first portion and the second portion, in which the side portion facilitates relative motion between the first portion and the second portion, and

an interior comprising of a plurality of non-communicating chambers configured to be selectively inflated and selectively deflated; and

a first appendage configured to couple the balloon to the femur of the knee joint.

12. The implant of claim 11, in which the at least one condyle is the medial condyle.

13. The implant of claim 11, in which the at least one condyle is the lateral condyle.

14. The implant of claim 11, wherein the balloon is at least one of: at most about 1.5 cm in diameter, at most about 1.75 cm in diameter, at most about 2 cm in diameter, at most about 2.25 cm in diameter, at most about 2.5 cm in diameter, at most about 2.75 cm in diameter, at most about 3 cm in diameter, at most about 3.25 cm in diameter, at most about 3.5 cm in diameter, at most about 3.75 cm in diameter, at most about 4 cm in diameter, at most about 4.25 cm in diameter, at most about 4.5 cm in diameter, at most about 4.75 cm in diameter, at most about 5 cm in diameter, at most about 5.25 cm in diameter, at most about 5.5 cm in diameter, at most about 5.75 cm in diameter, at most about 6 cm in diameter, at most about 6.25 cm in diameter, at most about 6.5 cm in diameter, at most about 6.75 cm in diameter, at most about 7 cm in diameter, at most about 7.25 cm in diameter, at most about 7.5 cm in diameter, at most about 7.75 cm in diameter, at most about 8 cm in diameter, at most about 3 cm in length along the longest length of the balloon, at most about 3.25 cm in length along the longest length of the balloon, at most about 3.5 cm in length along the longest length of the balloon, at most about 3.75 cm in length along the longest length of the balloon, at most about 4 cm in length along the longest length of the balloon, at most about 4.25 cm in length along the longest length of the balloon, at most about 4.5 cm in length along the longest length of the balloon, at most about 4.75 cm in length along the longest length of the balloon, at most about 5 cm in length along the longest length of the balloon, at most about 5.25 cm in length along the longest length of the balloon, at most about 5.5 cm in length along the longest length of the balloon, at most about 5.75 cm in length along the longest length of the balloon, at most about 6 cm in length along the longest length of the balloon, 6.25 cm in length along the longest length of the balloon, at most about 6.5 cm in length along the longest length of the balloon, at most about 6.75 cm in length along the longest length of the balloon, at most about 7 cm in length along the longest length of the balloon, at most about 7.25 cm in length along the longest length of the balloon, at most about 7.5 cm in length along the longest length of the balloon, at most about 7.75 cm in length along the longest length of the balloon, and at most about 8 cm in length along the longest length of the balloon.

15. The implant of claim 11, in which the first portion comprises a first wall, the second portion comprises a second wall, and the side portion comprises a side wall.

16. The implant of claim 11 further comprising an inflation port in communication with the interior of the balloon for inflation of the interior of the balloon with the first inflation medium.

17. The implant of claim 11, in which a first chamber of the plurality of individually inflatable chambers is adapted to be inflated with the first inflation medium, and a second chamber of the plurality of individually inflatable chambers is adapted to be inflated with a second inflation medium.

18. The implant of claim 17, in which the first inflation medium imparts at least one of rigidity in the implant and cushion in the implant.

19. The implant of claim 11, comprising a second appendage coupling the balloon to at least one of: the femur of the joint and the tibia of the joint.

20. The implant of claim 11, comprising at least one attachment element in configured to couple with the intercondylar notch.

21. The implant of claim 11, comprising at least one attachment element superiorly at the distal end of the femur anteriorly.

22. The implant of claim 11, comprising at least one posterior reign configured to cinch up the implant from inside a posterior intercondylar notch toward a connection site around the femur.

23. The implant of claim 11, comprising at least one suture-like lanyard configured to cinch up the implant from inside a posterior intercondylar notch toward a connection site around the femur.

24. An implant configured for deployment between a femur and a patella of a knee joint, the implant comprising:

a balloon comprising:

a first portion that is configured to engage at a trochlear groove of the femur of the knee joint,

a second portion that is configured to engage the patella of the knee joint,

a side portion connecting the first portion and the second portion, in which the side portion facilitates relative motion between the first portion and the second portion, and

an interior comprising of a plurality of non-communicating chambers configured to be selectively inflated and selectively deflated; and

a first appendage configured to couple the balloon to the femur of the knee joint.

25. The implant of any of claims 1, 11, and 24 comprising couplers that couple the appendage to the femur.

26. The implant claim 25, wherein the coupler is bioabsorbable.

27. The implant claim 25, wherein the coupler is at least one of: a screw, a washer, a suture, a suture anchor, a rivot, a staple, a staple having teeth, a stabilizer, a glue, a hook, a wire, a string, a lasso, a lanyard, a spike, and combinations thereof.

28. An implant configured for deployment between a tibia and a patella of a knee joint, the implant comprising:

a balloon comprising:

a first portion that is configured to engage at a tibia of the knee joint,

a second portion that is configured to engage the patella of the knee joint,

a side portion connecting the first portion and the second portion, in which the side portion facilitates relative motion between the first portion and the second portion, and

an interior comprising of a plurality of non-communicating chambers configured to be selectively inflated and selectively deflated; and

a first appendage configured to couple the balloon to a femur of the knee joint.

29. The implant of any of claims 1, 11, 24, and 28, comprising an ingrowth matrix on at least a portion of the implant adjacent the femur.

30. The implant of claim 29, wherein the ingrowth matrix comprises at least one of: autologous cells, allograph cells, and xenograph cells to restore an articular surface of the femur.

31. The implant of claim 29, wherein the ingrowth matrix comprises at least one of: autologous cells, allograph cells, and xenograph cells to repair an articular surface of the femur.

32. The implant of claim 29, wherein the ingrowth matrix comprises living chondrocytes.

33. The implant of claim 32, wherein the implant is configured to release the chondrocytes over time.

34. The implant of claim 32, wherein the implant comprises a bioabsorbable polymer configured to release the chondrocytes over time.

35. The implant of claim 32, wherein the implant comprises a polymer configured to release the chondrocytes over time, wherein the polymer is not bioabsorbable.

36. The implant of claim 28, comprising couplers that couple the appendage to the tibia.

37. The implant claim 36, wherein the coupler is bioabsorbable.

38. The implant claim 36, wherein the coupler is at least one of: a screw, a washer, a suture, a suture anchor, a rivot, a staple, a staple having teeth, a stabilizer, a glue, a hook, a wire, a string, a lasso, a lanyard, a spike, and combinations thereof.

39. The implant of any of claims 1, 11, 24, and 28, comprising a phamacologic agent.

40. The implant of claim 39, wherein the pharmacologic agent is on a surface of the implant adjacent the femur.

41. The implant of claim 39, wherein the pharmacologic agent is released from the implant over time.

42. The implant of claim 39, wherein the pharmacologic agent is released from within the implant over time.

43. The implant of claim 39, wherein the pharmacologic agent is released from within the balloon over time.

44. The implant of any of claims 1, 11, 24, and 28, wherein the inflation medium is compressible.

45. The implant of any of claims 1, 11, 24, and 28, wherein the inflation medium comprises a viscolubricant.

46. The implant of any of claims 1, 11, 24, and 28, wherein the inflation medium comprises an NSAID.

47. The implant of any of claims 1, 11, 24, and 28, wherein the inflation medium comprises chondrocytes.

48. The implant of any of claims 1, 11, 24, and 28, wherein at least a portion of the implant is configured to anneal to a periphery of a cartilage defect.

49. The implant of any of claims 1, 11, 24, and 28, wherein at least one of the first portion, the second portion, and the side portion of the implant comprises of vacuoles that contain at least one of a pharmacologic substance and an active agent.

50. The implant of claim 49, wherein the vacuoles may be on a bone-engaging portion of the implant.

51. The implant of claim 49, wherein the active agent comprises at least one of: stem cells, growth factors, antibiotics, and viscolubricants.

52. The implant of claim 49, wherein the active agent comprises iatrigenically gene mutated cells.

53. The implant of any of claims 1, 11, 24, and 28, wherein the implant comprises bubbles comprising an active substance such as a pharmacologic substance or other active agent.

54. The implant of any of claims 1, 11, 24, and 28, wherein the implant comprises enzyme absorptive sponges that could be sucked out or evacuated at or around the time of implant delivery to the joint.

55. The implant of any of claims 1, 11, 24, and 28, wherein the implant comprises spaces filled with an active substance such as a pharmacologic substance or other active substance.

56. The implant of any of claims 1, 11, 24, and 28, wherein the implant is configured to deliver by dissolution of the implant material.

57. The implant of any of claims 1, 11, 24, and 28, wherein the implant is configured to deliver by release through pores of the implant.

58. The implant of any of claims 1, 11, 24, and 28, wherein the implant is configured to deliver by fracture of a vacuole by a catalyst such as ultrasound or pressure or other fracturing catalyst.

59. The implant of any of claims 1, 11, 24, and 28, wherein the implant is configured to at least one of: pad cartilage, cushion the joint, deliver a pharmacologic substance, remove noxious enzymes, debride upon implantation, debride the joint following implantation, deliver a therapeutic substance, deliver a biologic substance, and deliver living stem cells.

60. The implant of any of claims 1, 11, 24, and 28, wherein the implant is configured to deliver a chemotherapeutic agent to a bone or other surrounding tissues.

61. The implant of any of claims 1, 11, 24, and 28, wherein the implant is configured to deliver an anti-infectious medication to a bone or other surrounding tissues.

62. The implant of any of claims 1, 11, 24, and 28, wherein the implant is configured to deliver at least one of an antibiotic, antifungals, and analgesics agent.

63. The implant of any of claims 1, 11, 24, and 28, wherein the implant is configured to be selectively inflated to realign limbs.

64. An implant configured for deployment between a femur and a tibia of a knee joint, the implant comprising:

a balloon comprising:

a first portion that is configured to engage at least one condyle of the femur of the knee joint,

a second portion that is configured to engage the tibia of the knee joint,

a side portion connecting the first portion and the second portion, in which the side portion facilitates relative motion between the first portion and the second portion, and

an interior comprising of a plurality of non-communicating chambers configured to be selectively inflated and selectively deflated; and

a first appendage configured to couple the balloon to the femur of the knee joint;

wherein the first portion, the second portion, and the side portion each have an interior surface, and wherein at least one interior surface comprises of a honeycomb structure.

65. The implant of claim **64**, wherein at least one of the first portion, the second portion, and the side portion of the implant comprises of vacuoles that contain at least one of a pharmacologic substance and an active agent.

66. The implant of claim **65**, wherein the vacuoles may be on a bone-engaging portion of the implant.

67. The implant of claim **65**, wherein the active agent comprises at least one of: stem cells, growth factors, antibiotics, and viscolubricants.

68. An implant configured for deployment between a femur and a tibia of a knee joint, the implant comprising:

a balloon comprising:

a first portion that is configured to engage at least one condyle of the femur of the knee joint,

a second portion that is configured to engage the tibia of the knee joint,

a side portion connecting the first portion and the second portion, in which the side portion facilitates relative motion between the first portion and the second portion, and

an interior comprising of a plurality of non-communicating chambers configured to be selectively inflated and selectively deflated; and

a first appendage configured to couple the balloon to the femur of the knee joint;

wherein the balloon comprises of a polymer.

69. The implant of claim **68**, wherein the polymer is polycarbonate urethane.

* * * * *

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(12) **United States Patent**
Grotz

(10) **Patent No.: US 9,622,878 B2**
(45) **Date of Patent: Apr. 18, 2017**

(54) **UNIVERSALLY EXPANDING CAGE**

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A61F 2/30	(2006.01)

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(58) **Field of Classification Search**

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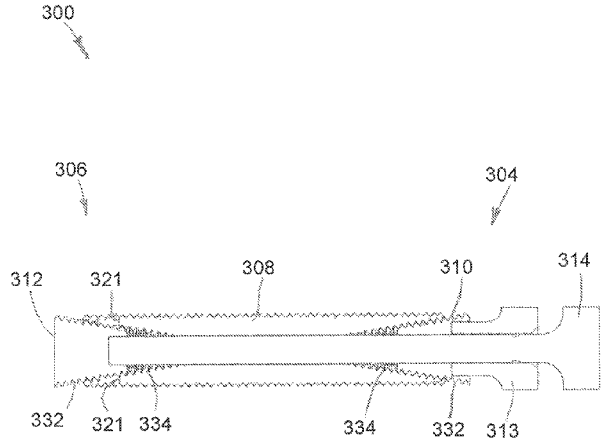
(57) **ABSTRACT**

An expandable medical implant is provided with an implantable cage body. The proximal and distal ends of the cage body may each be provided with a tapered or cam portion. The implant may further include a proximal flexure, a distal flexure, a proximal plug member having a tapered portion configured to mate with the tapered portion of the proximal end of the cage body, and a distal plug member having a tapered portion configured to mate with the tapered portion of the distal end of the cage body. The proximal plug member may be configured to move longitudinally such that the distal flexure moves and the circumference of the proximal end of the cage body resiliently expands. The distal plug member may be configured to move longitudinally such that the proximal flexure moves and the circumference of the distal end of the cage body resiliently expands. Methods are also disclosed.

14 Claims, 28 Drawing Sheets



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See application file for complete search history.

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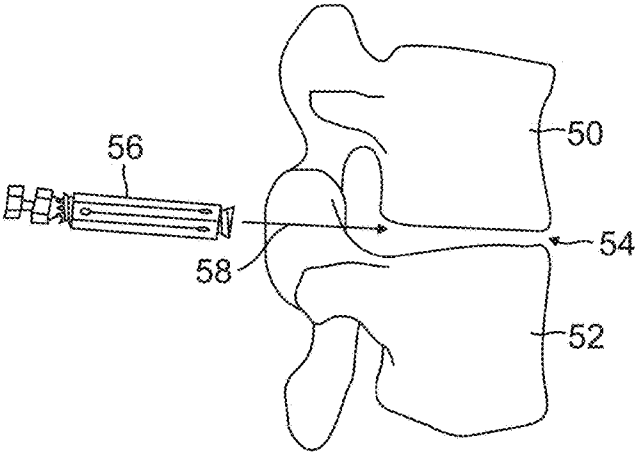

FIG. 1

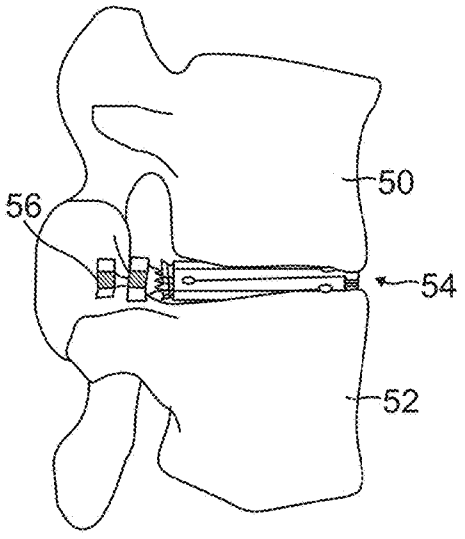

FIG. 2

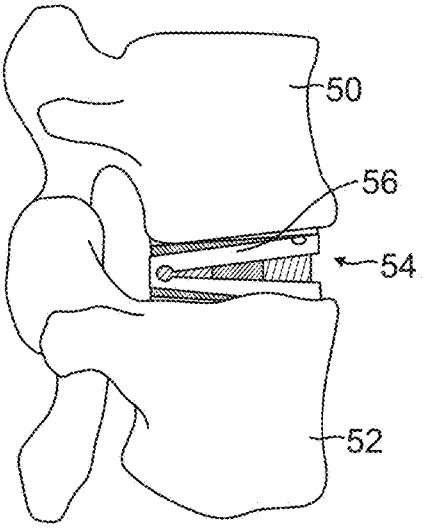

FIG. 3

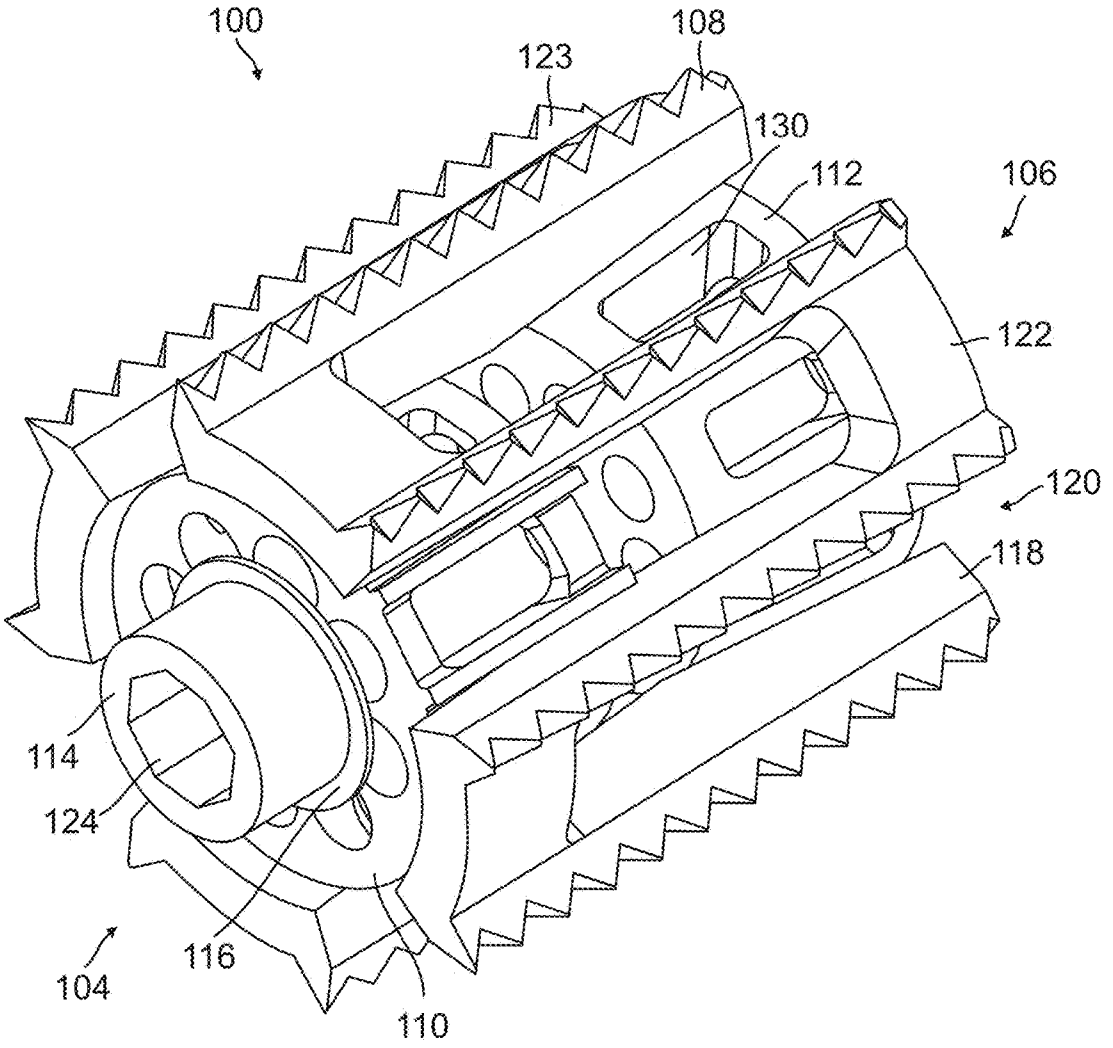

FIG. 4

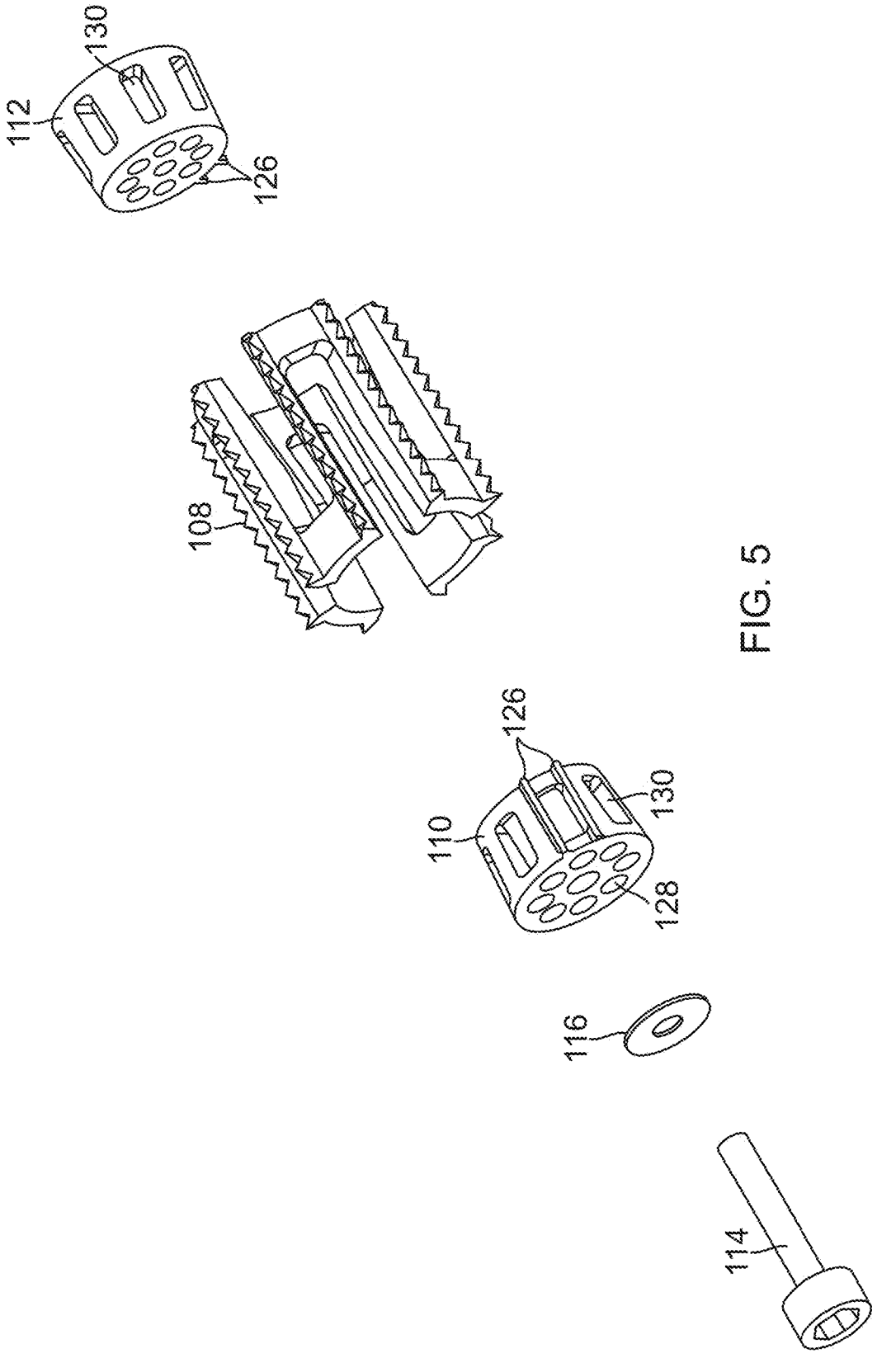

FIG. 5

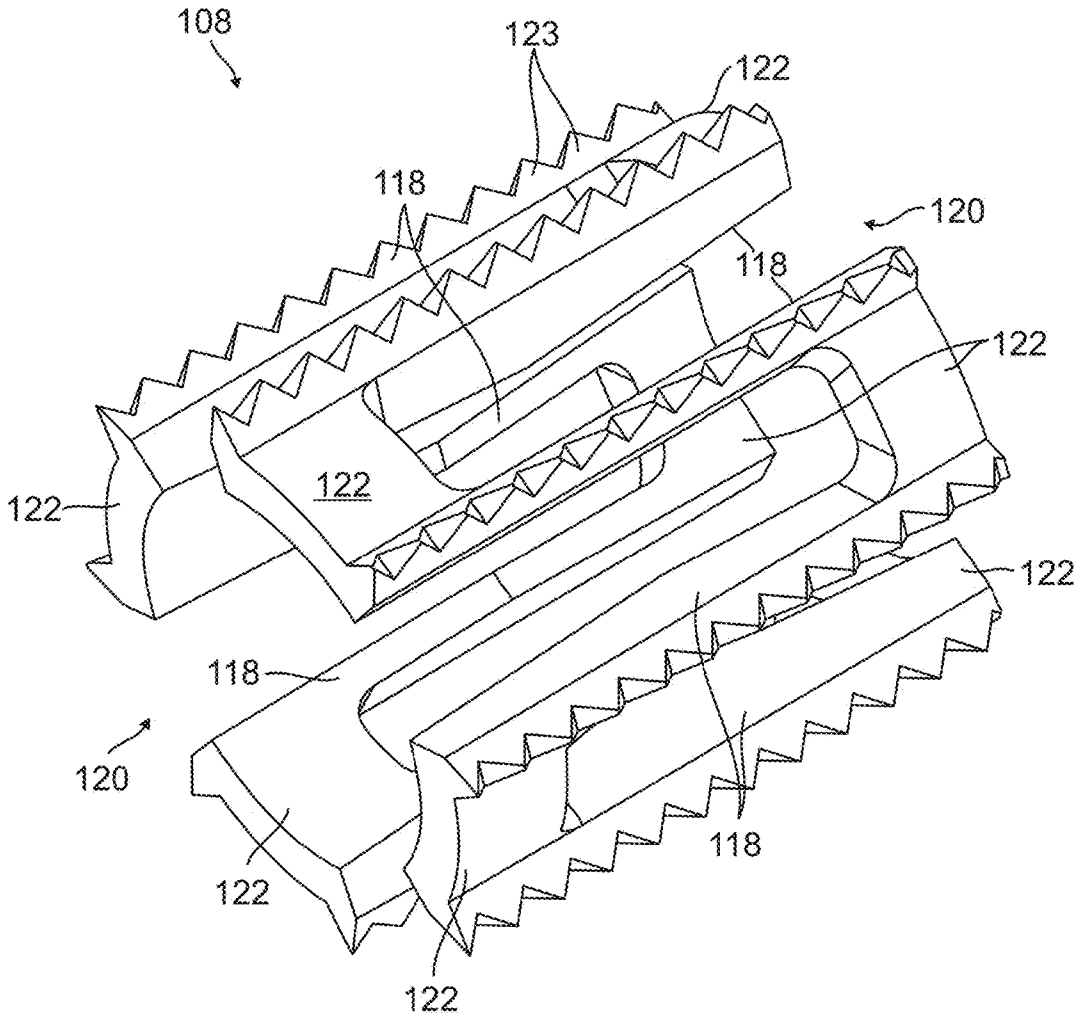

FIG. 6

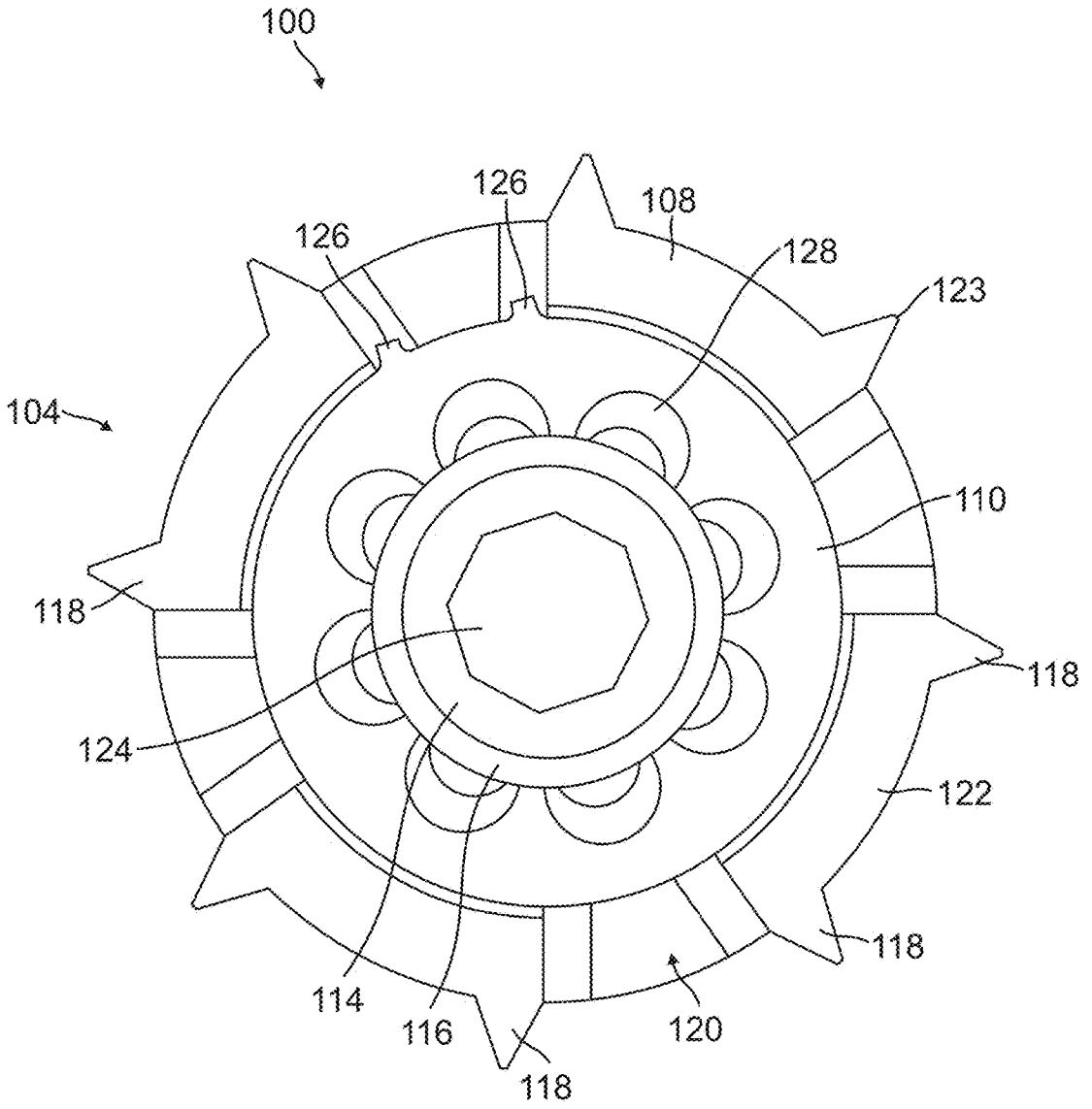
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FIG. 7

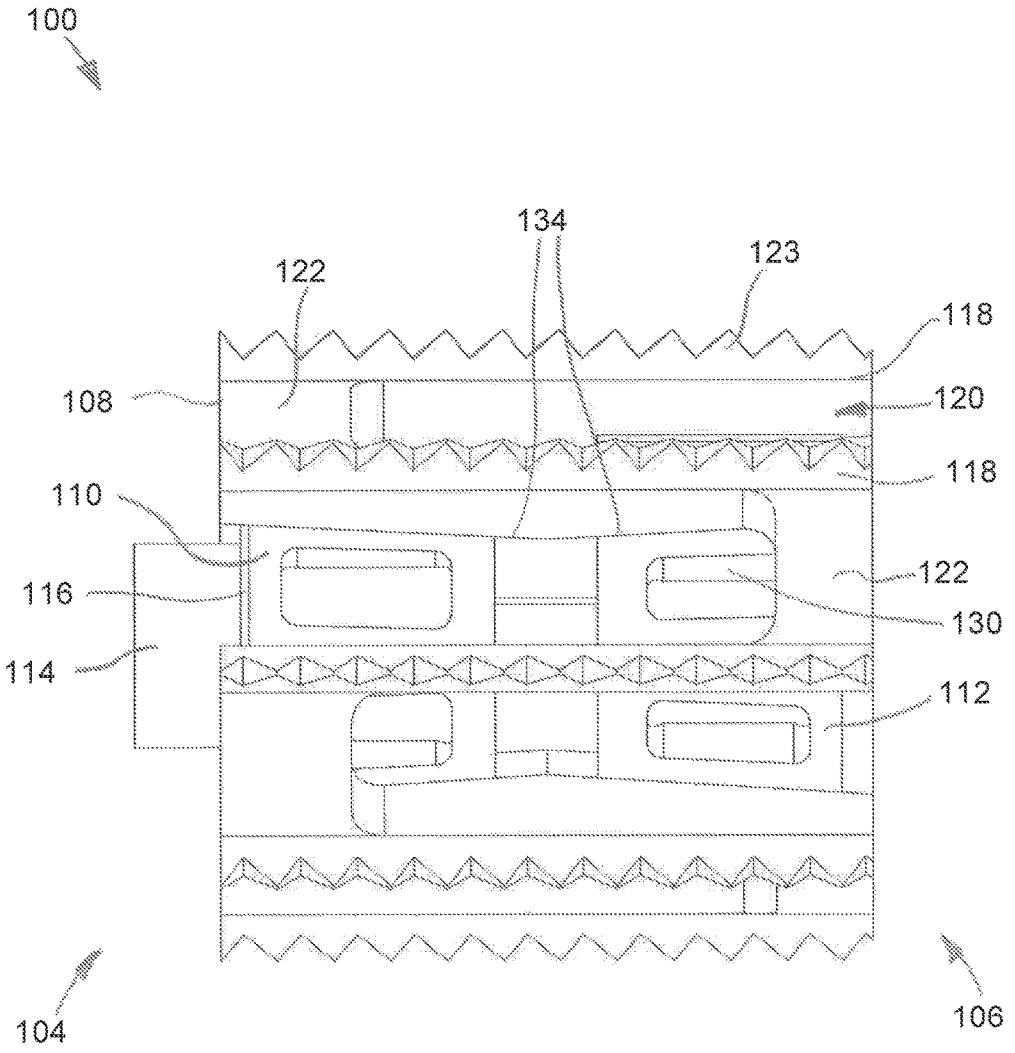

FIG. 8

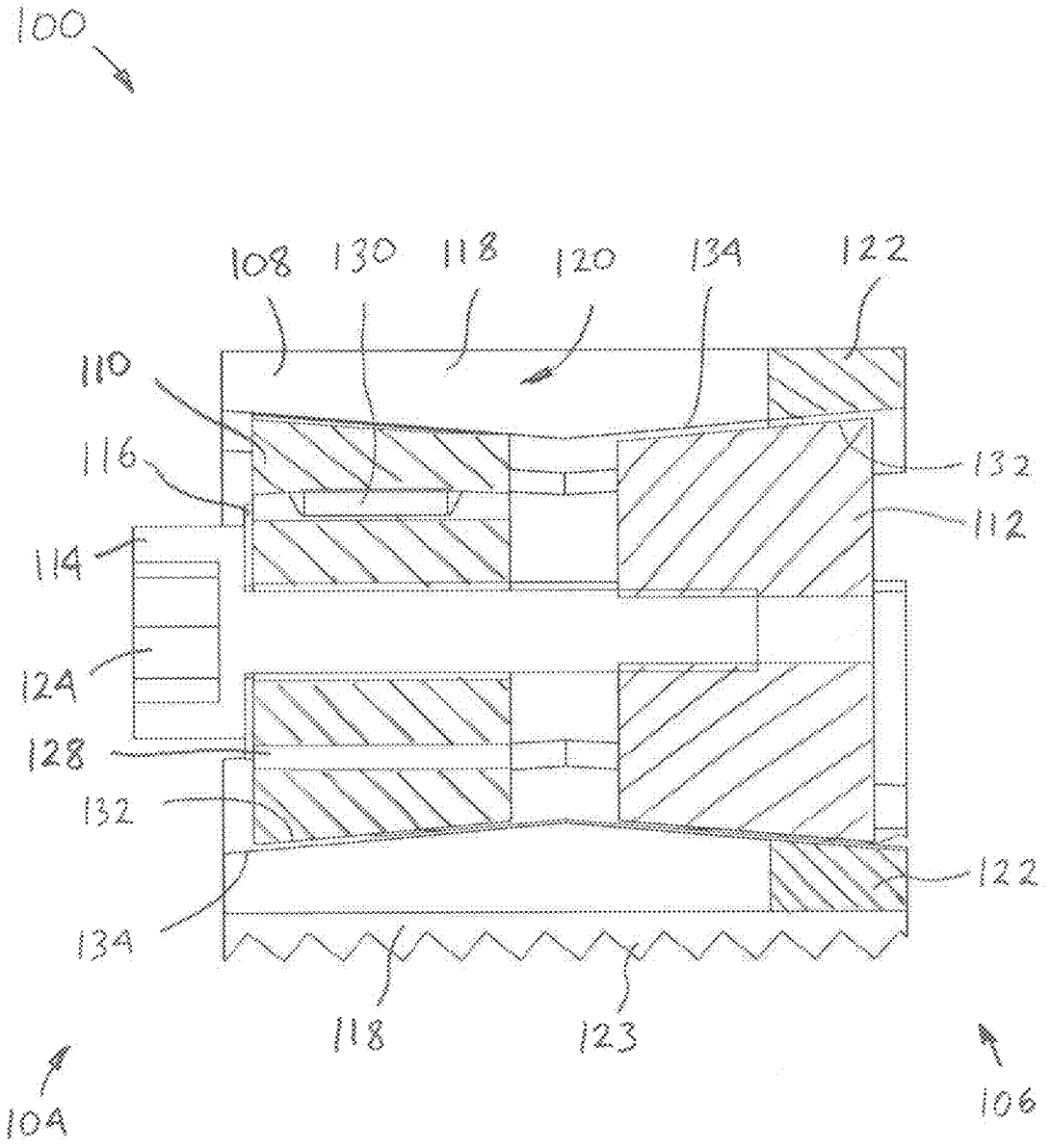
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FIG. 9

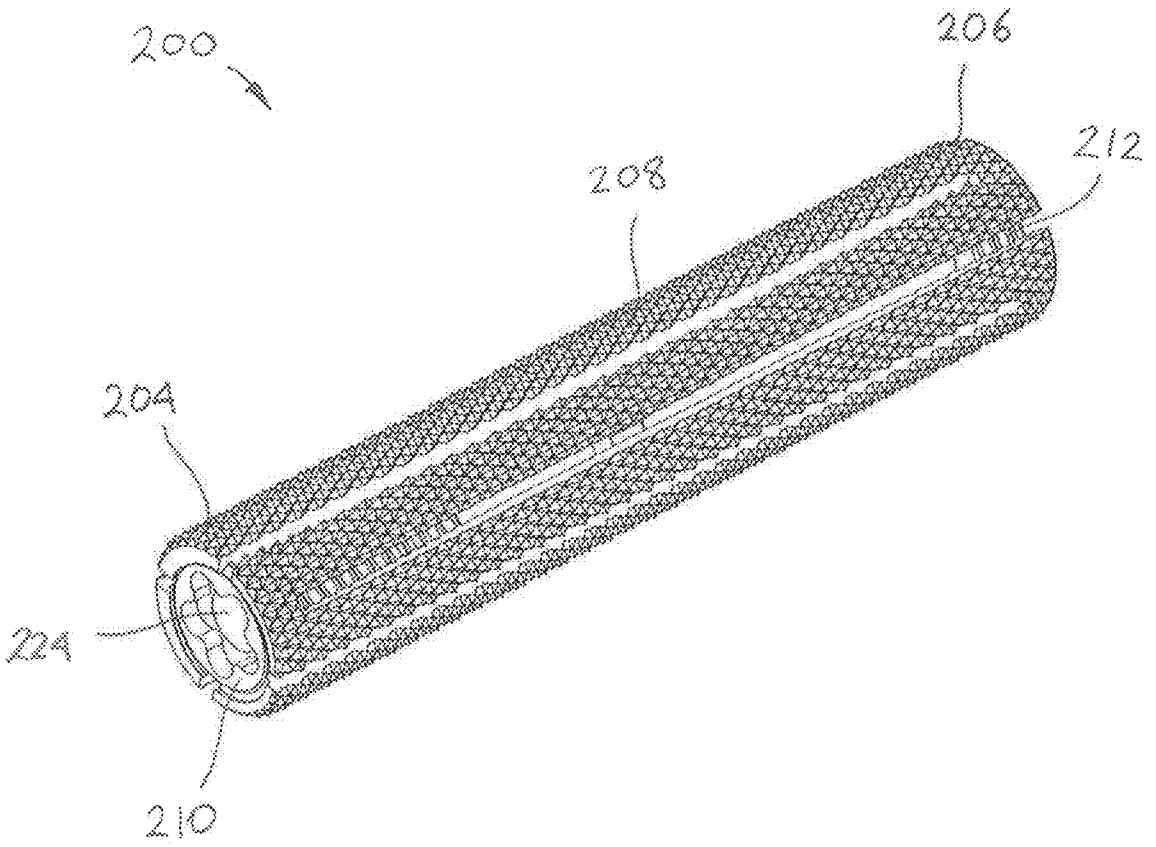

FIG. 10

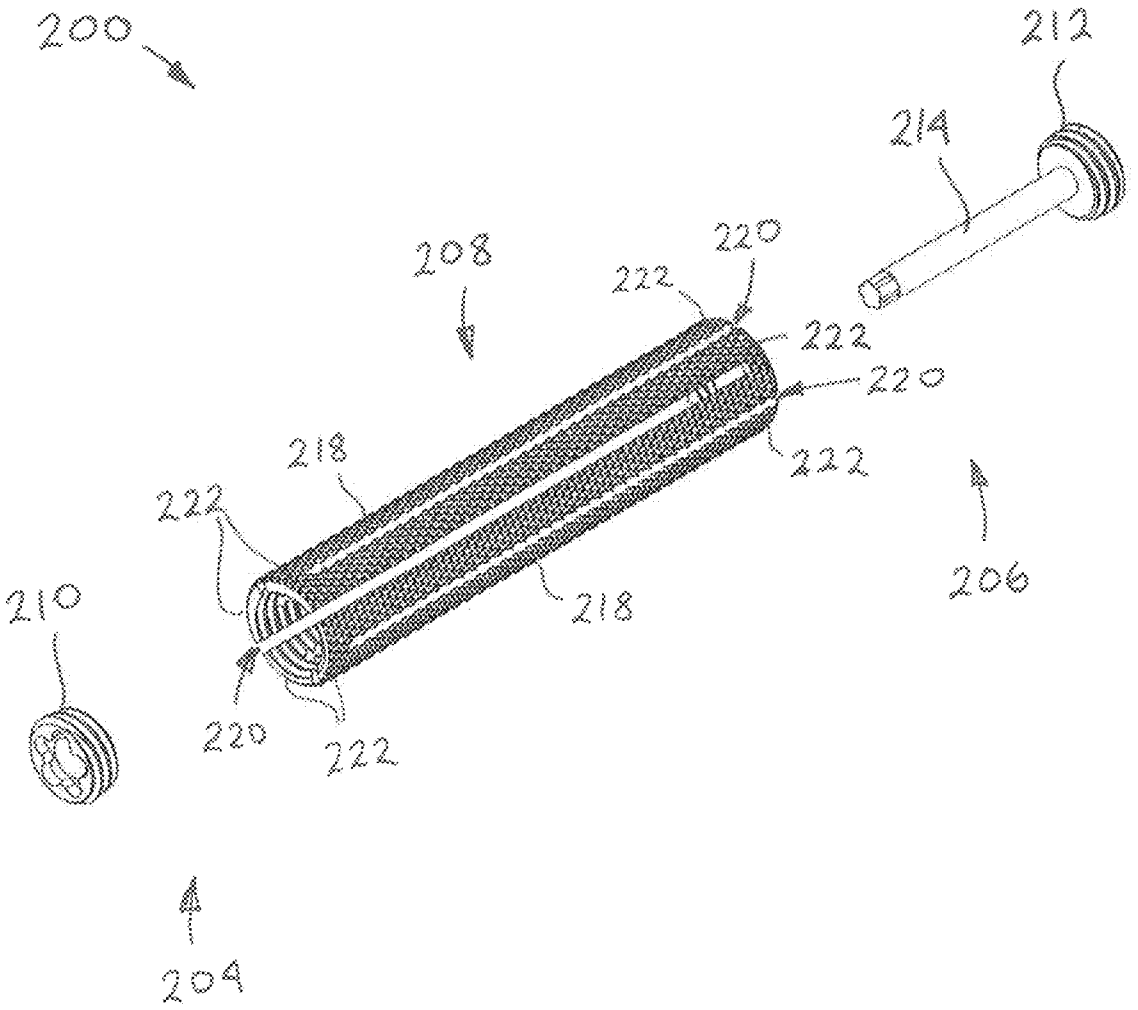
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FIG. 11

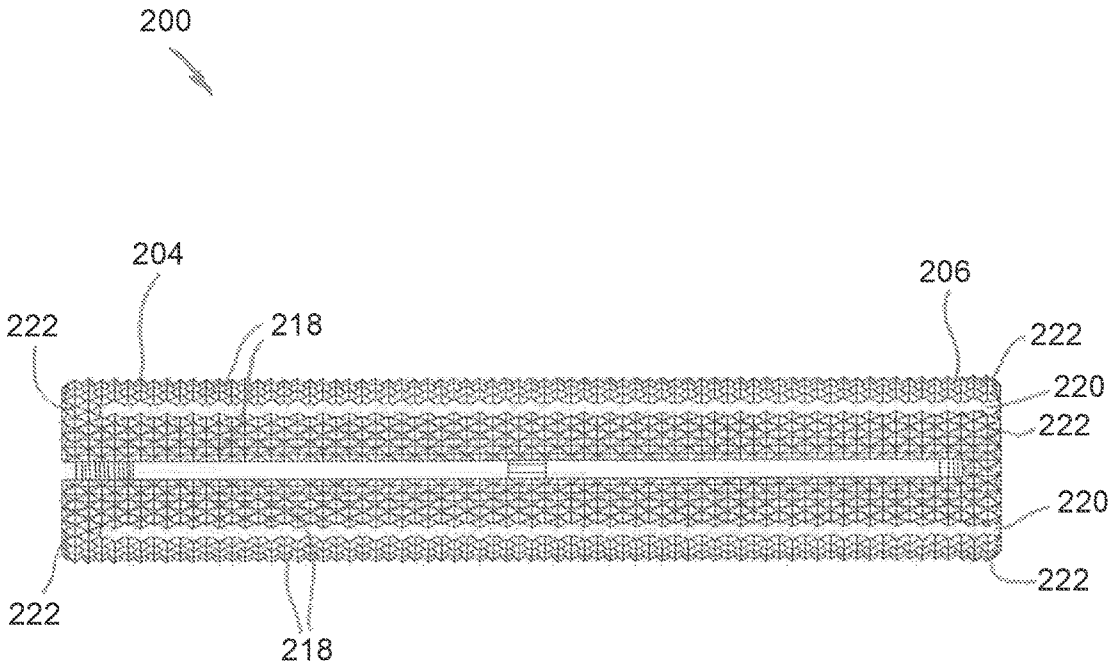

FIG. 12

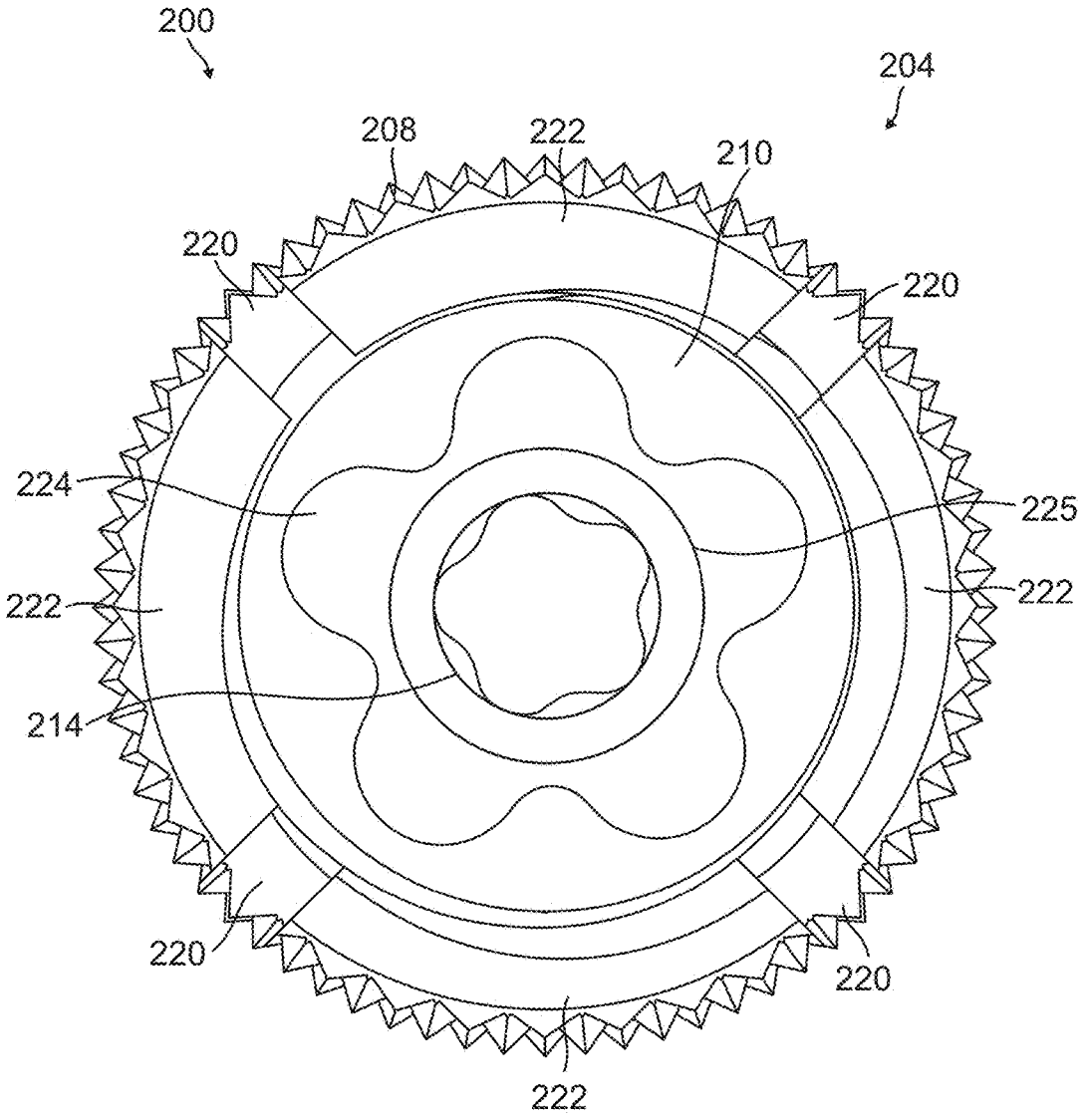

FIG. 13

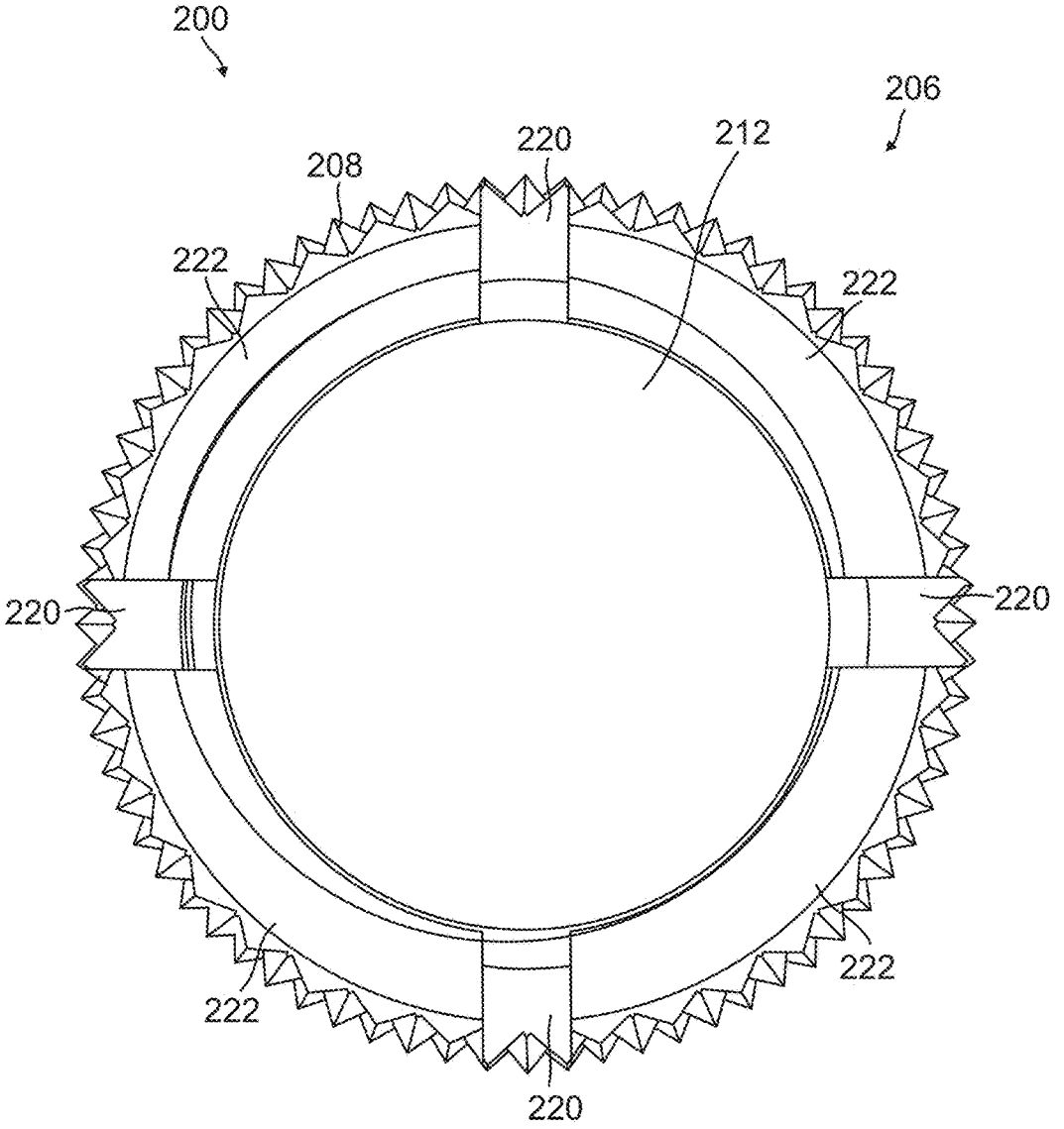

FIG. 14

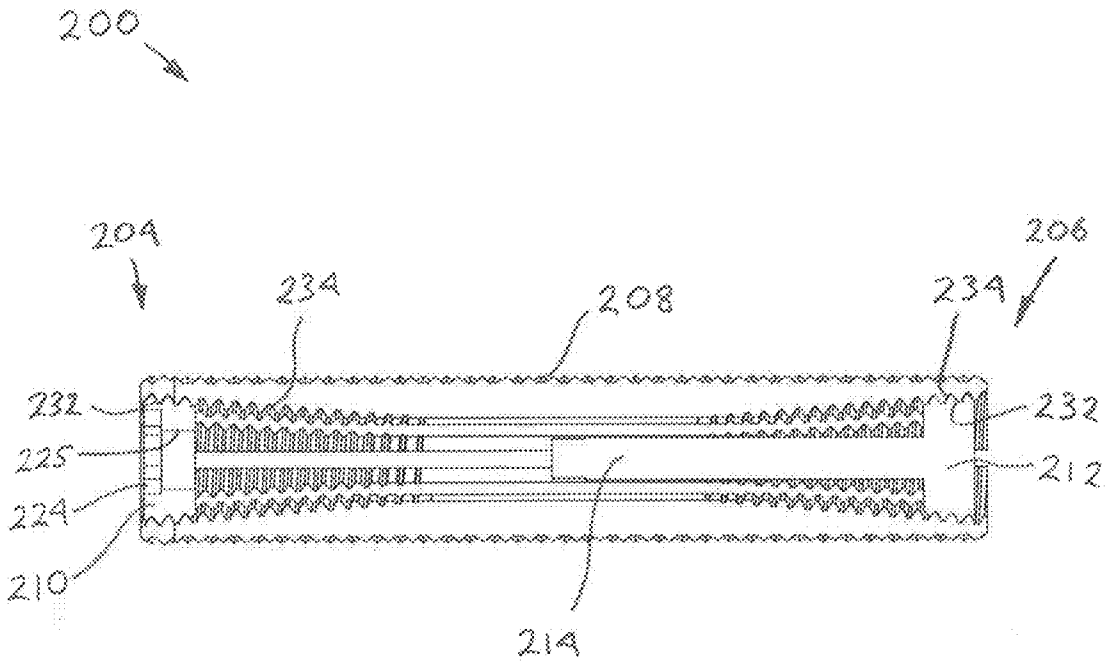

FIG. 15

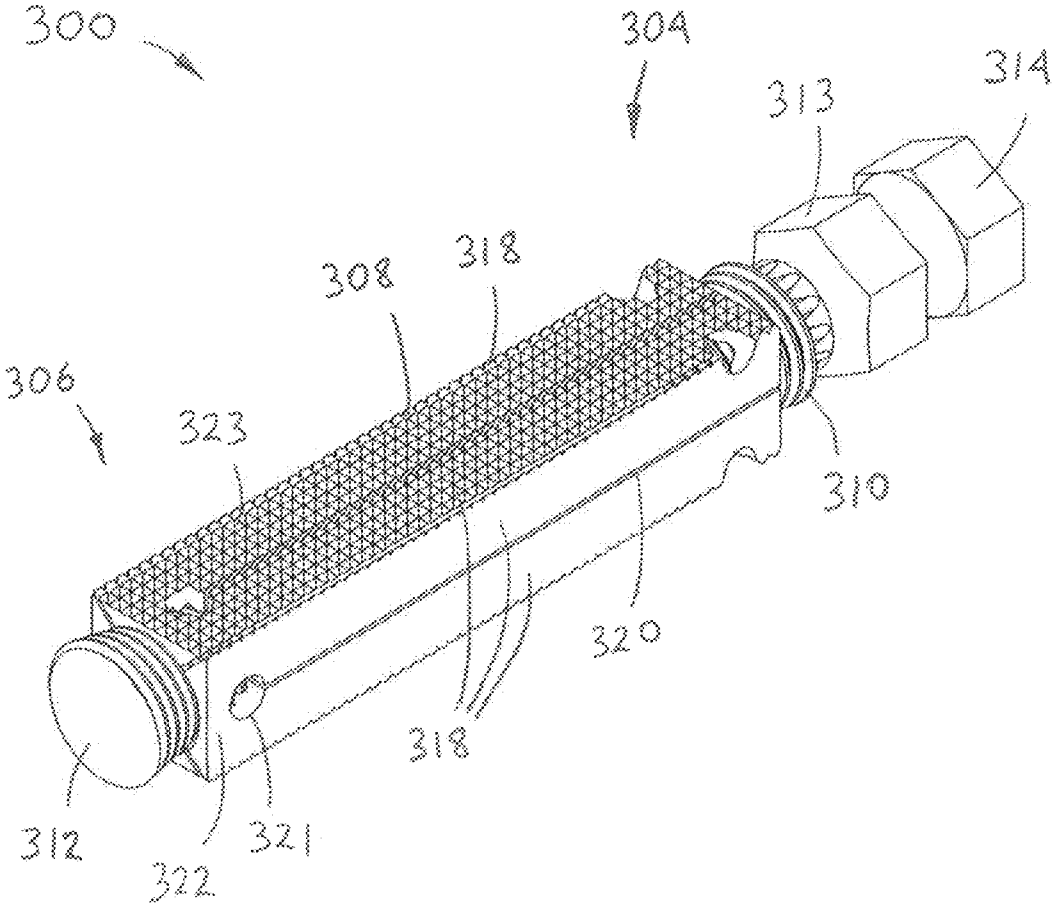

FIG. 16

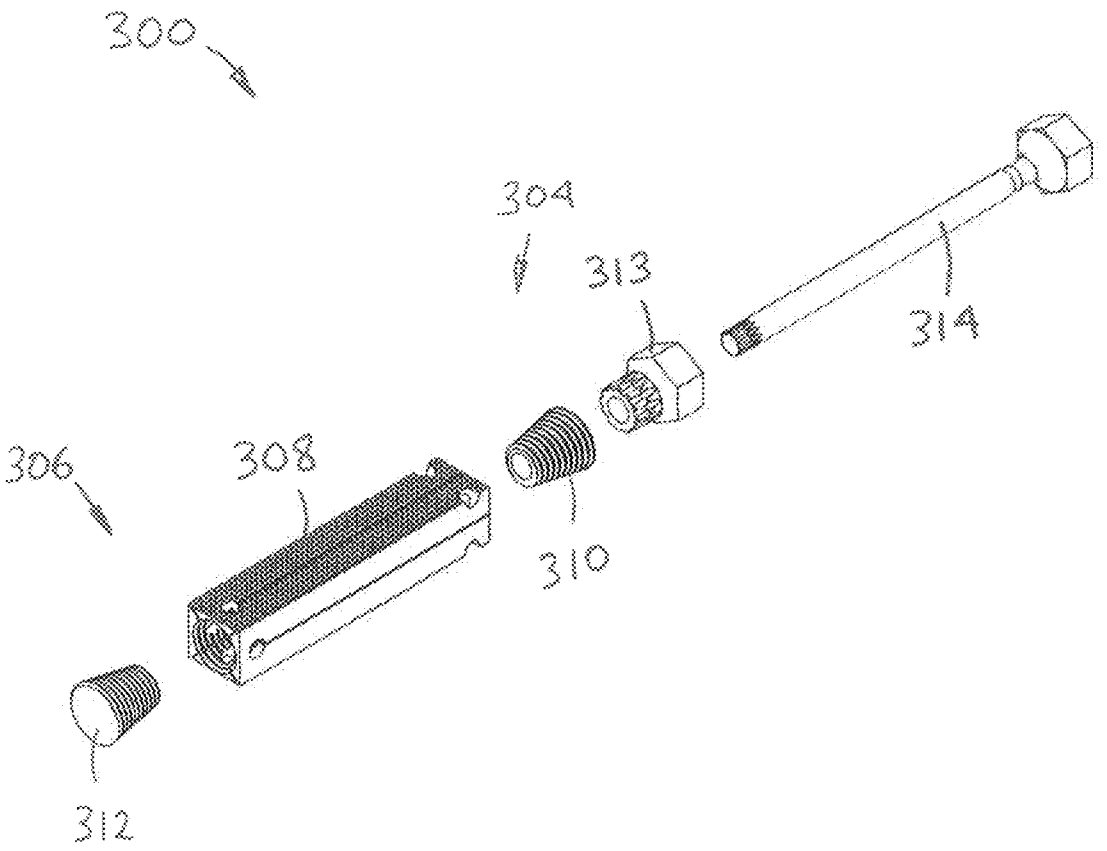

FIG. 17

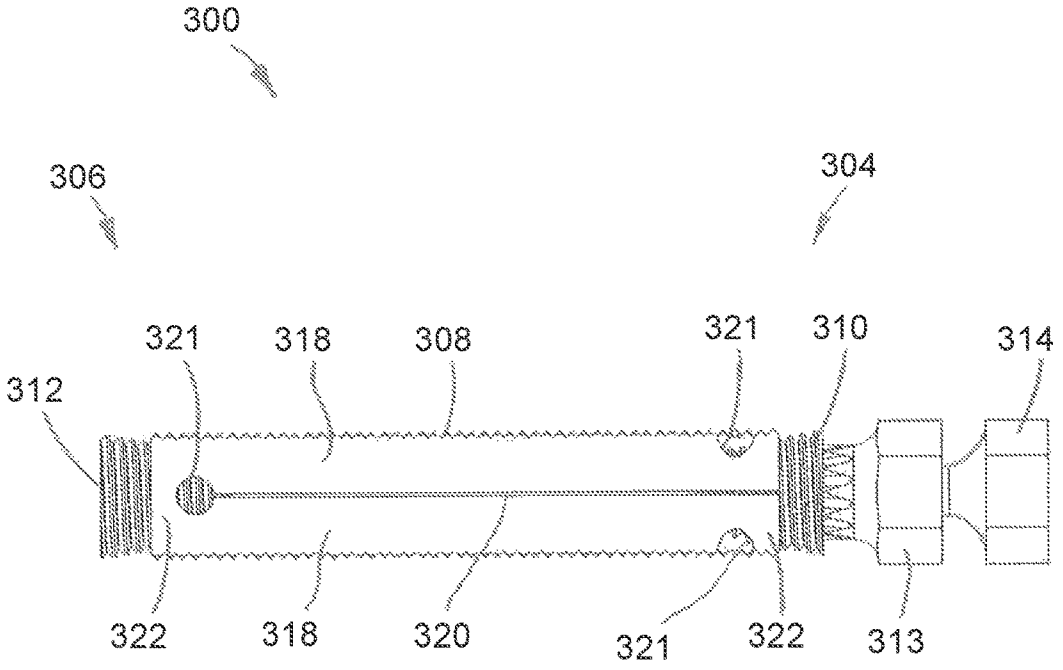

FIG. 18

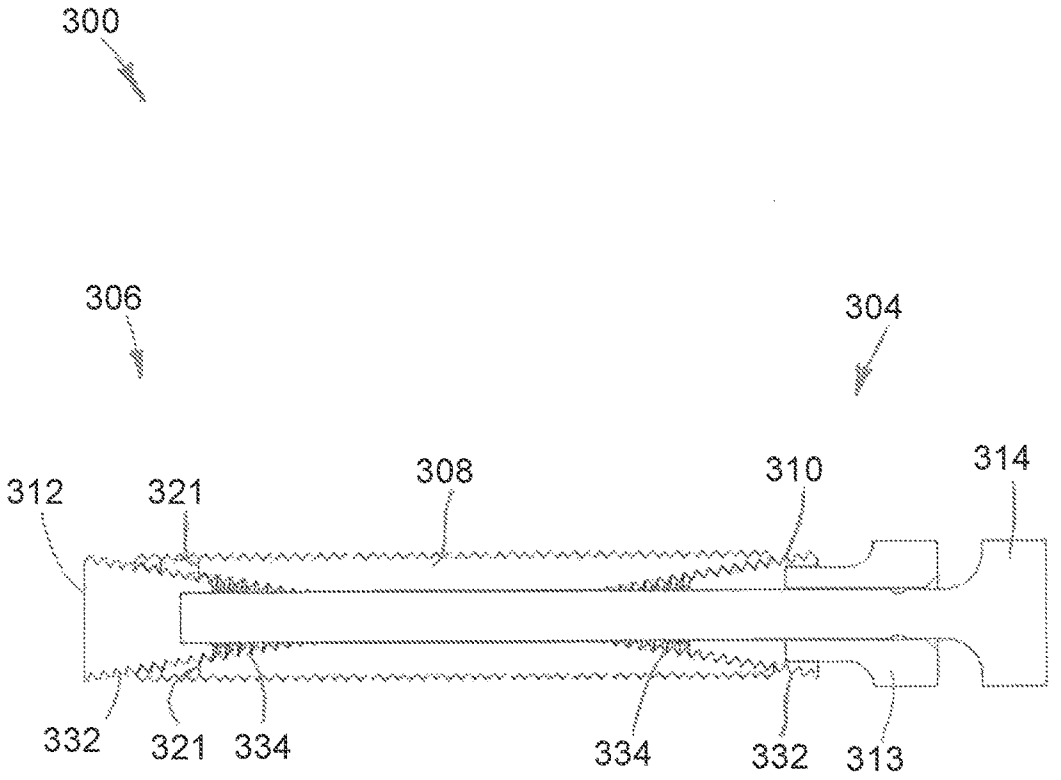

FIG. 19A

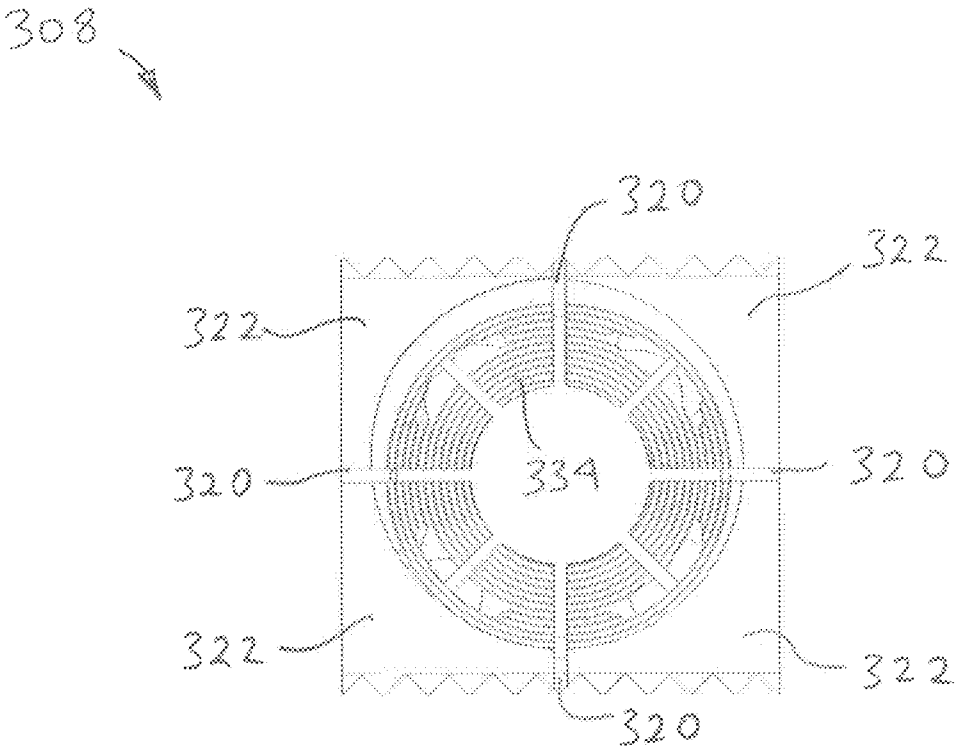

FIG 19B

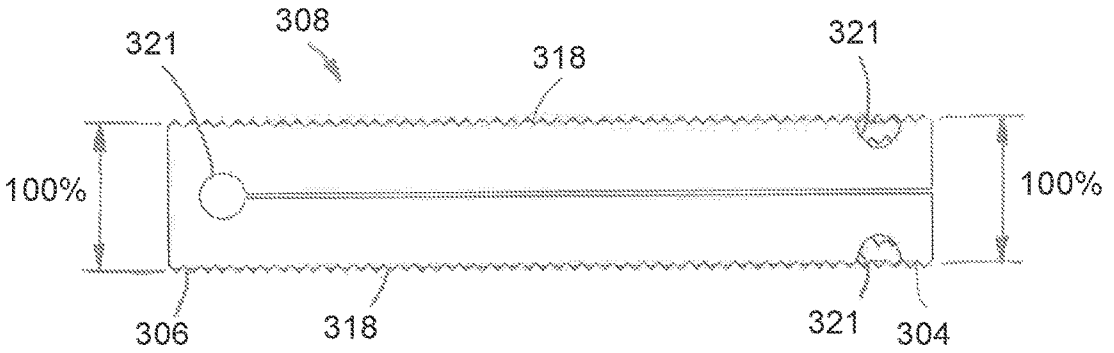

FIG. 20A

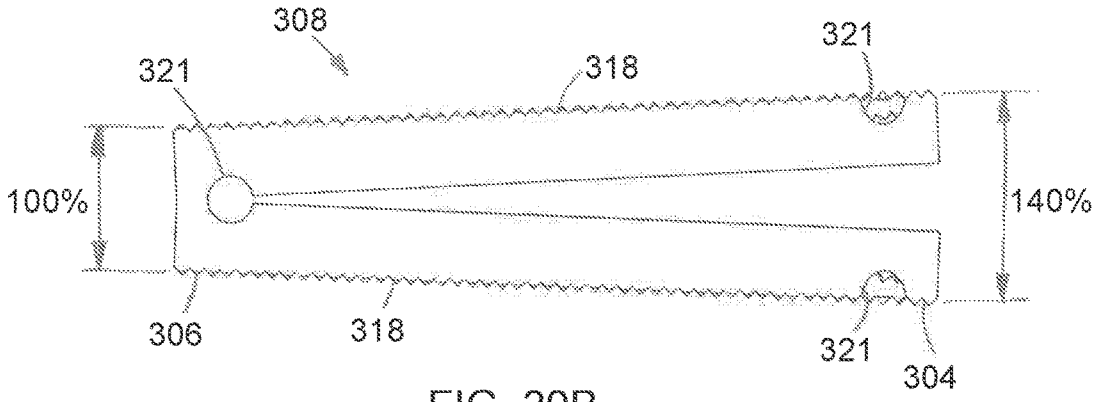

FIG. 20B

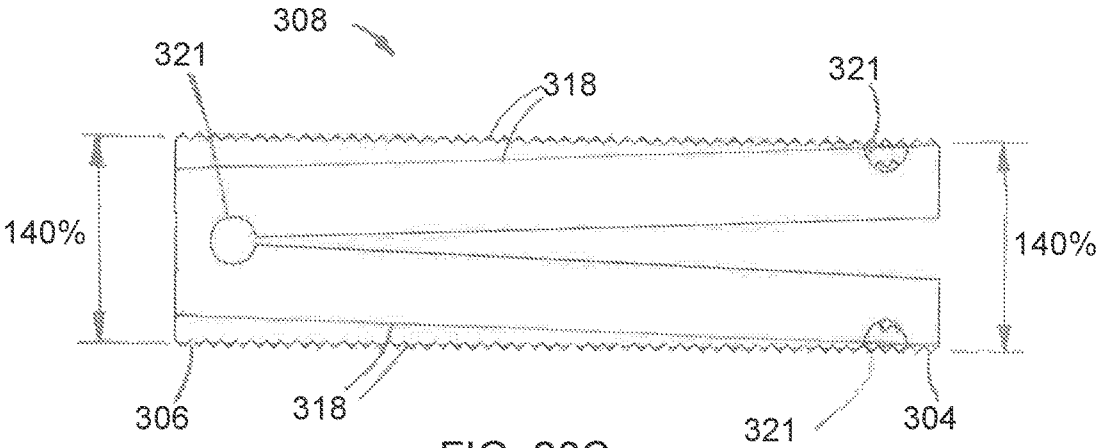

FIG. 20C

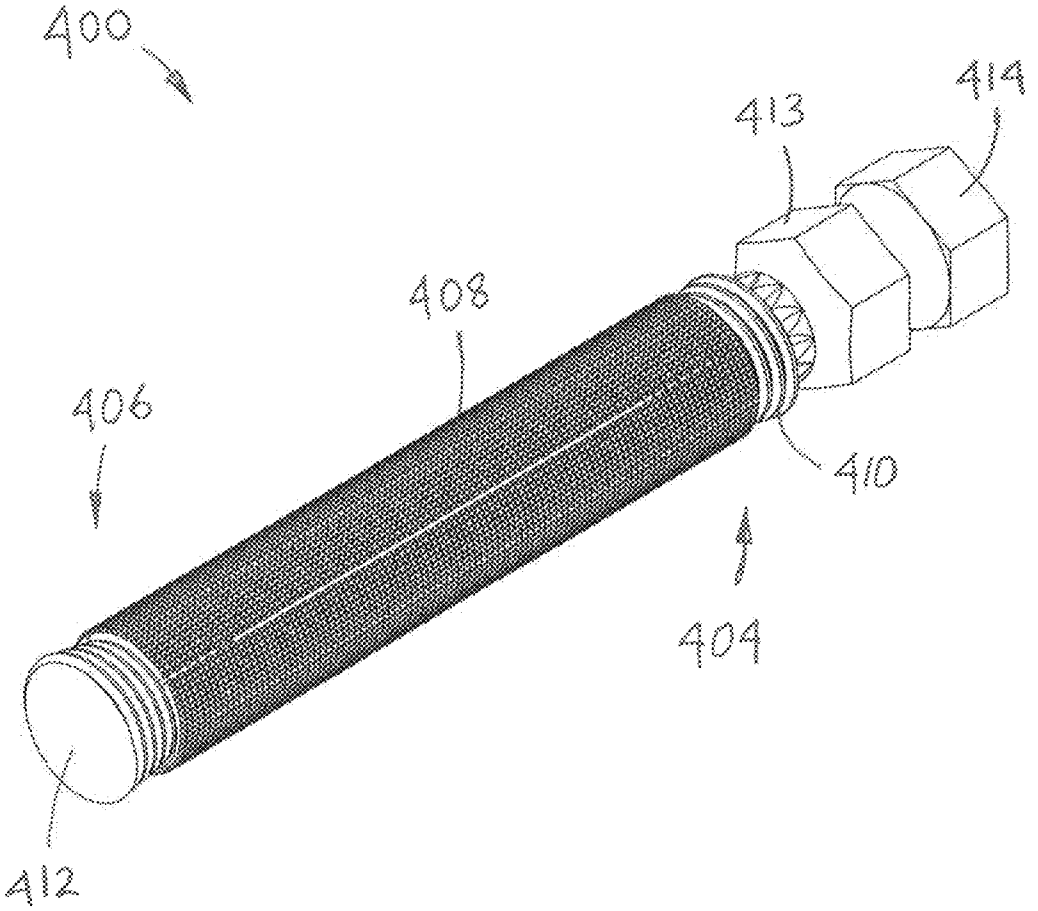

FIG 21

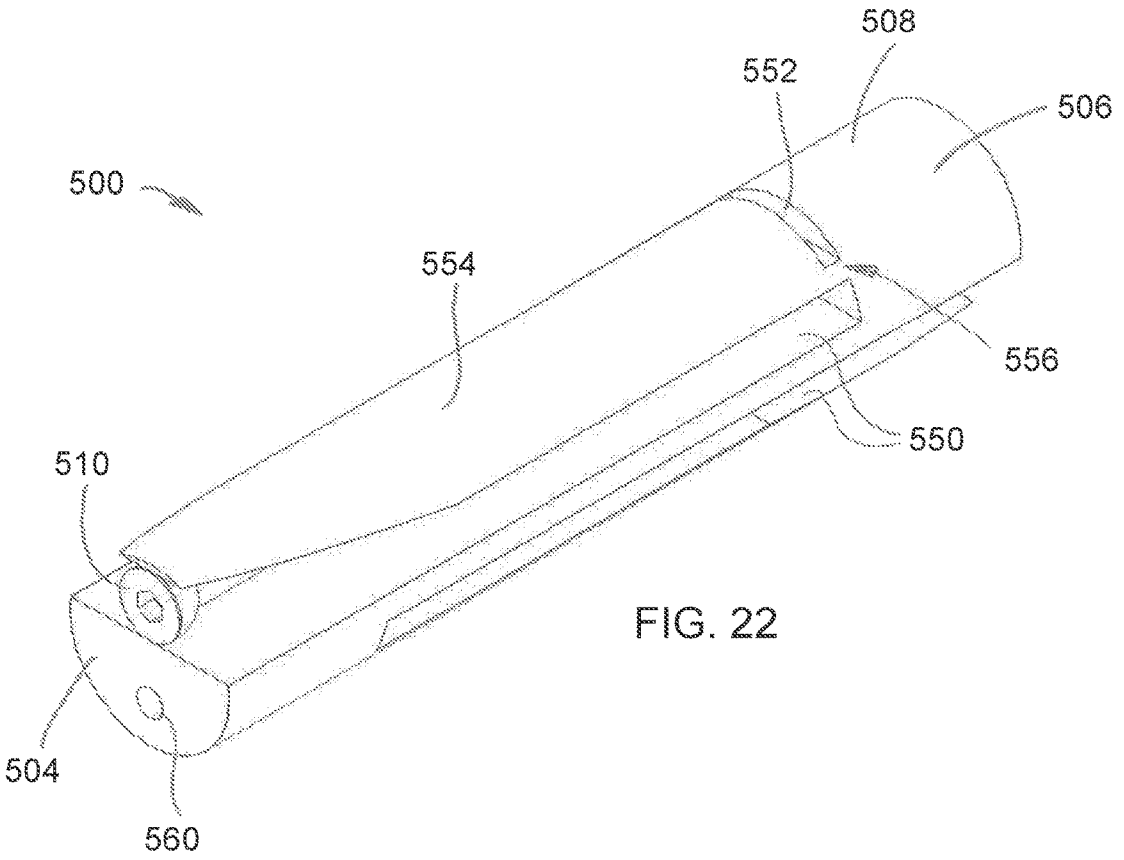
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FIG. 22

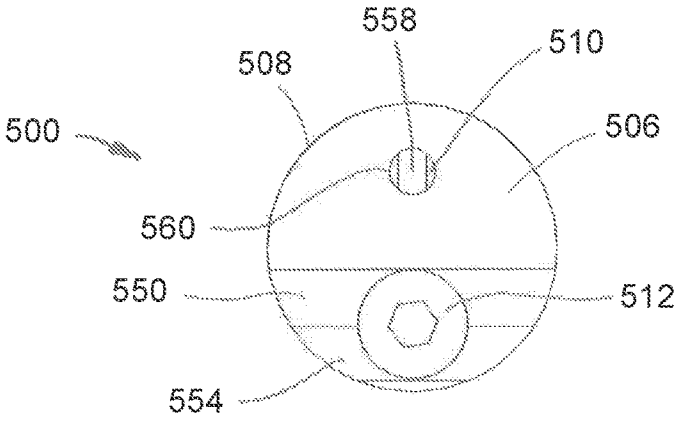
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FIG. 23

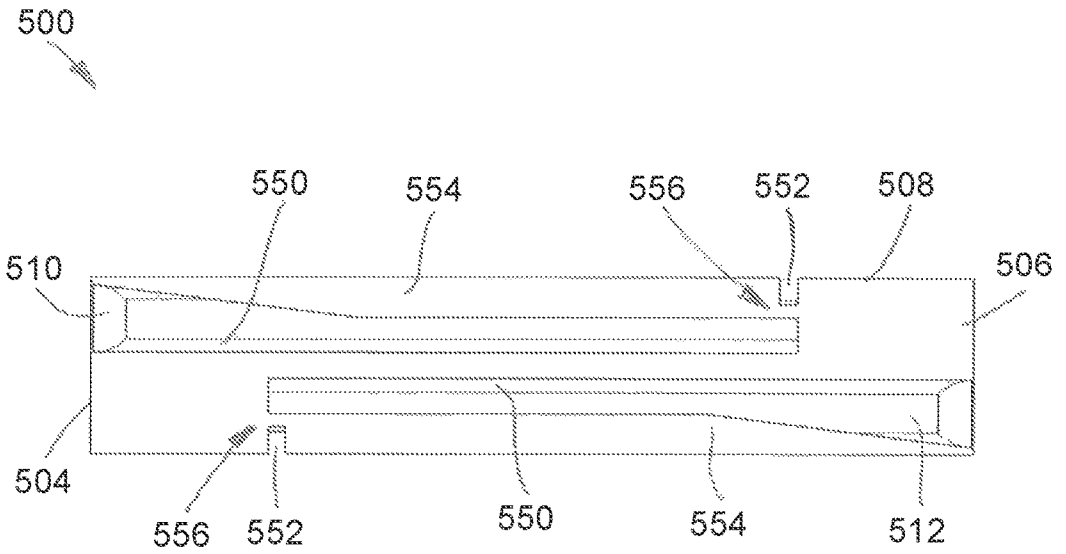
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FIG. 24

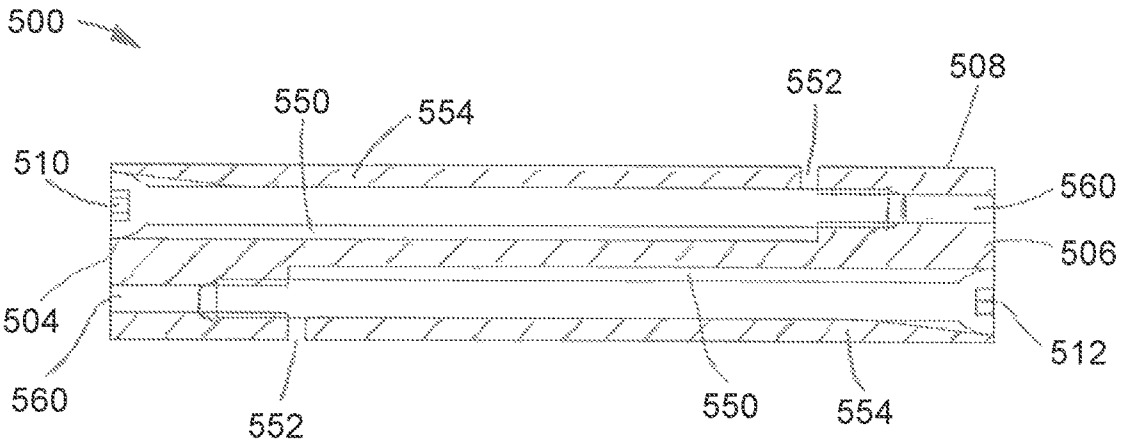
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FIG. 25

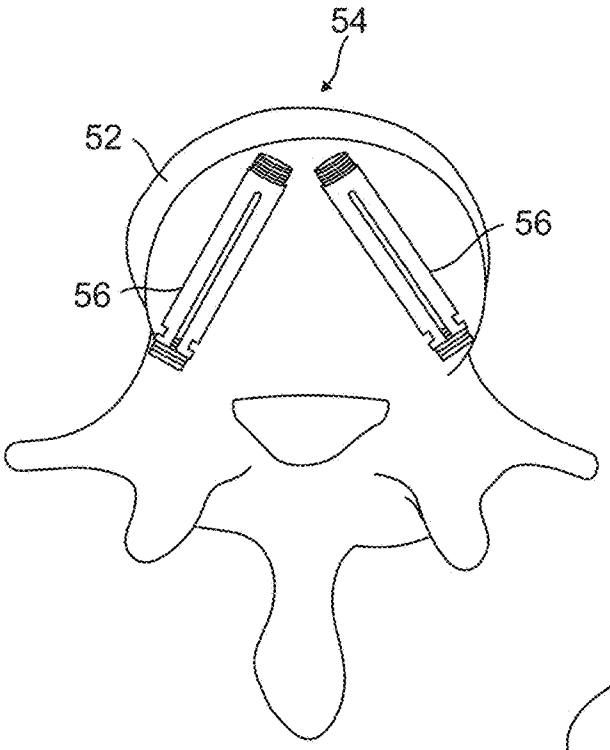

FIG. 26

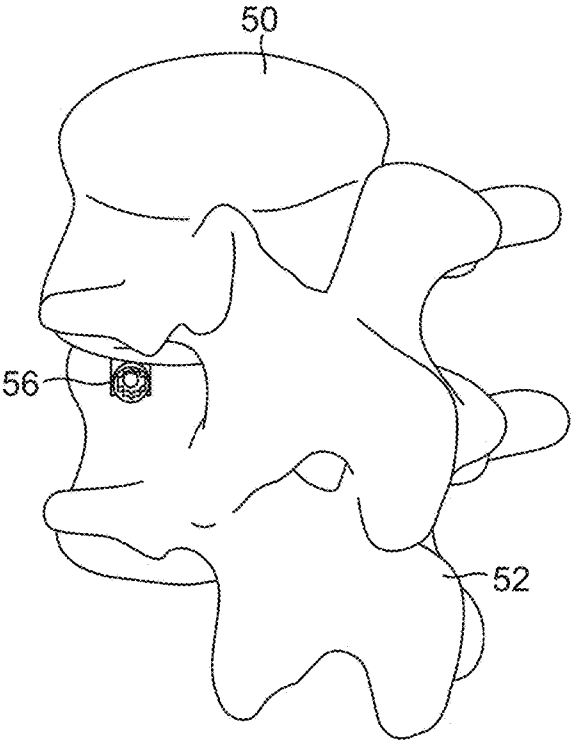

FIG. 27

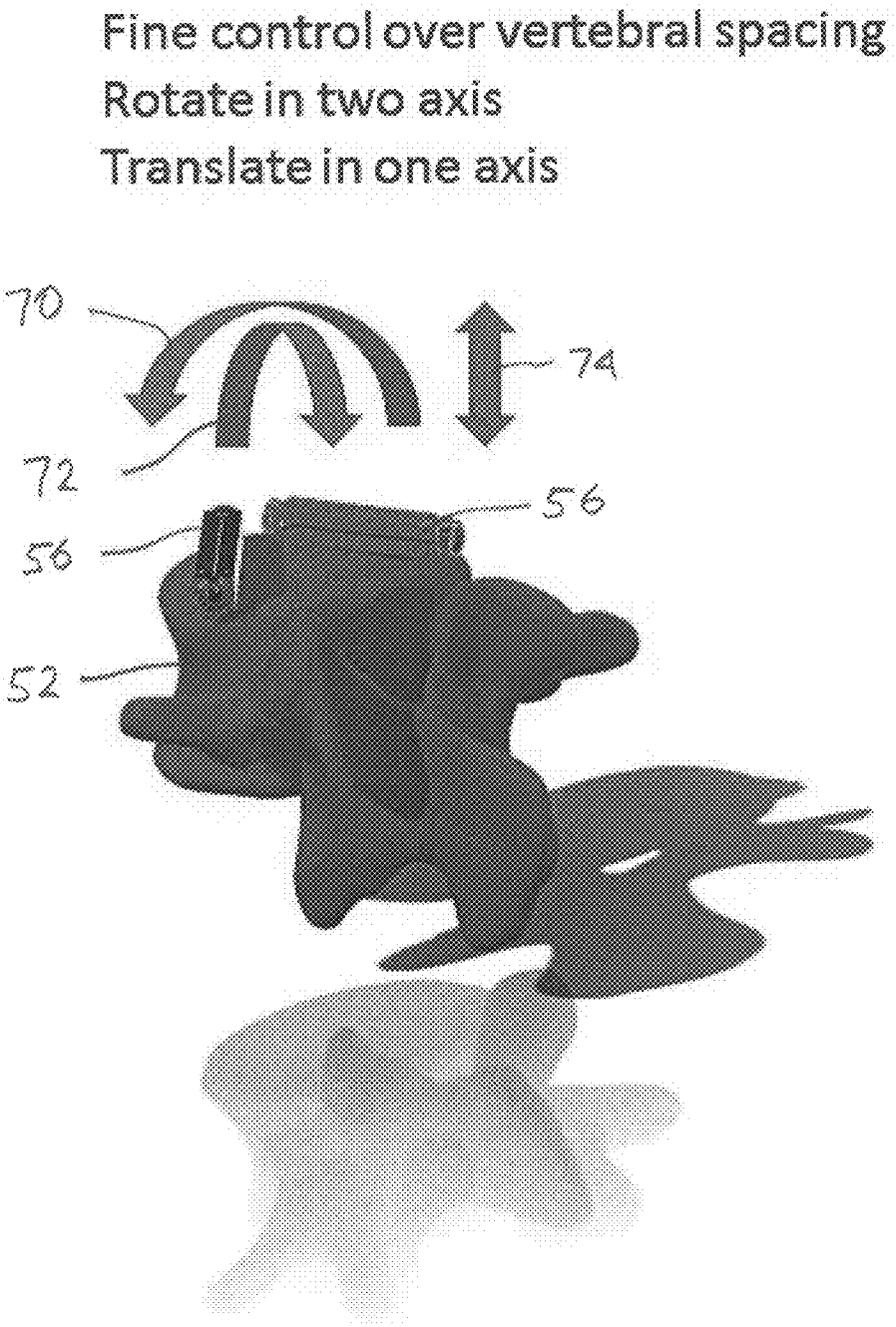
Fine control over vertebral spacing
Rotate in two axis
Translate in one axis
70
74
72
56
56
52

FIG. 28

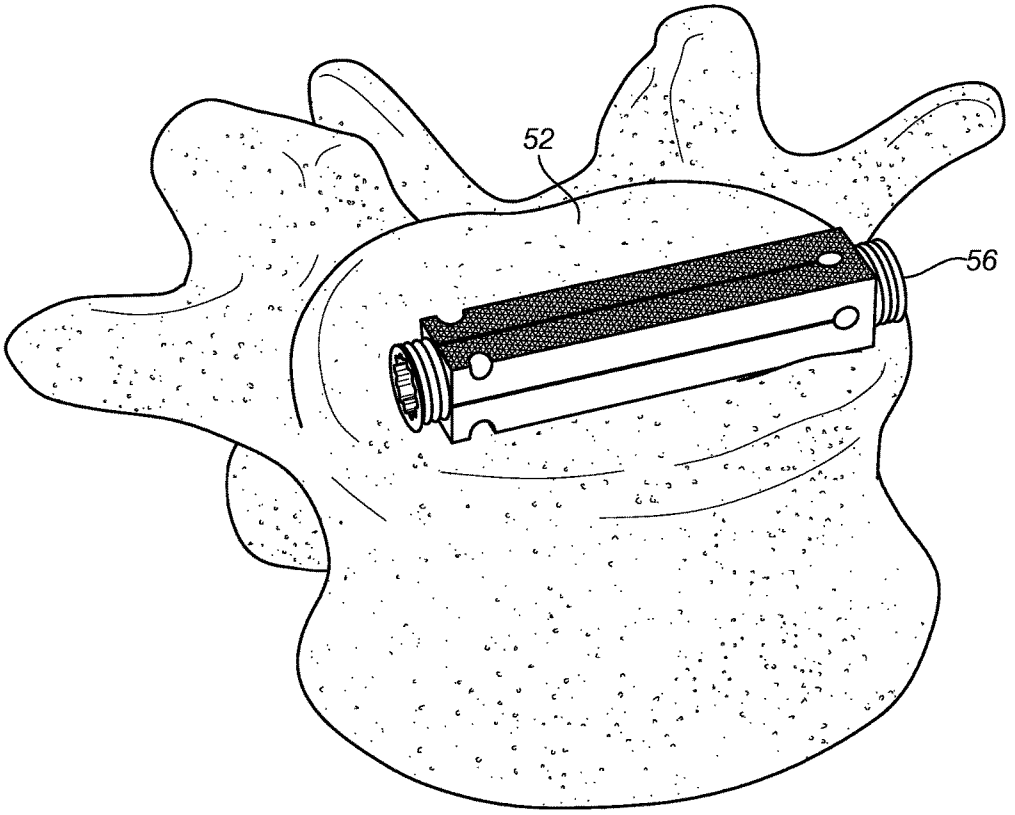

FIG. 29

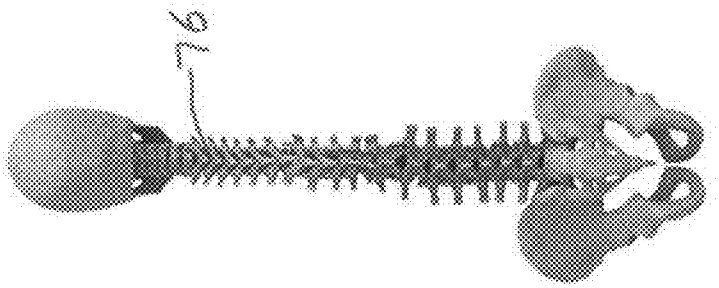

FIG. 31

Scoliosis Correction

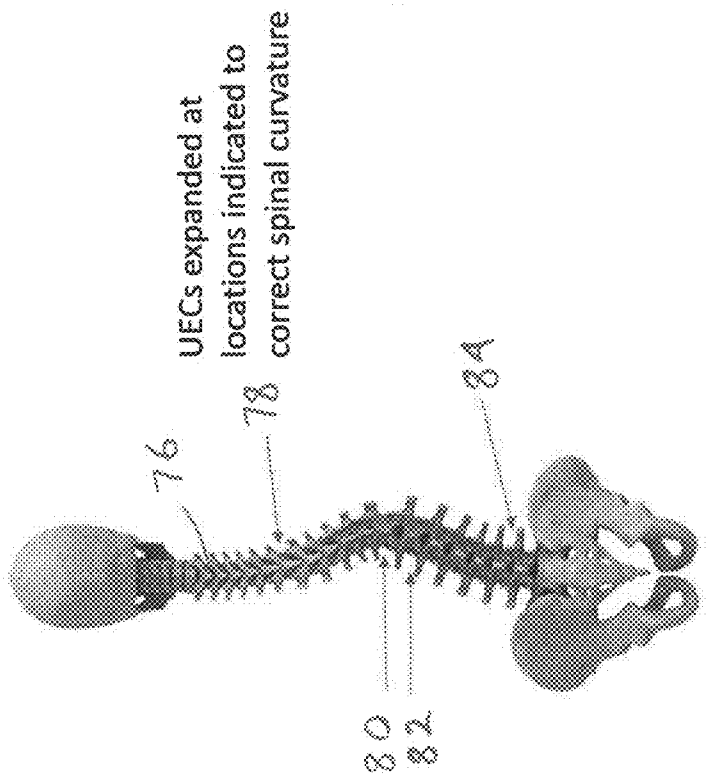

FIG. 30

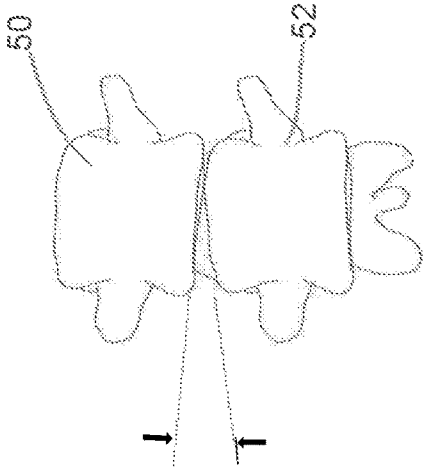

FIG. 32A

Misalignments

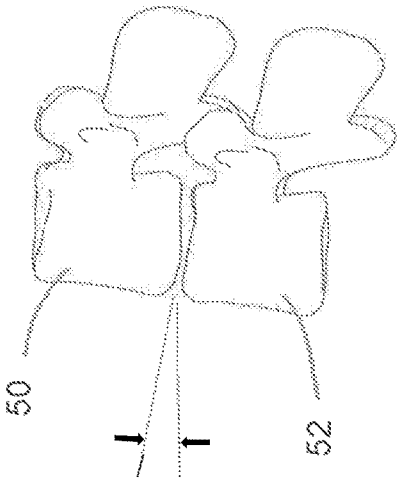

FIG. 32B

Uneven Spacing

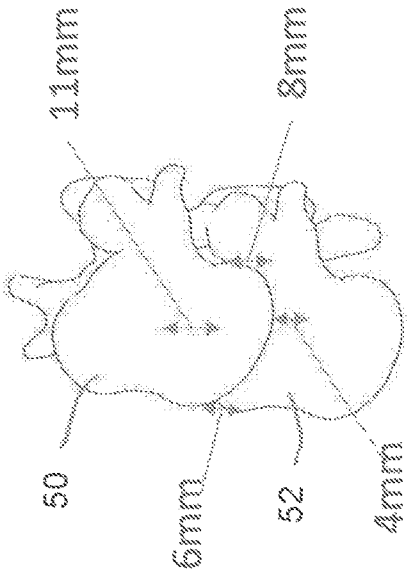

FIG. 32C

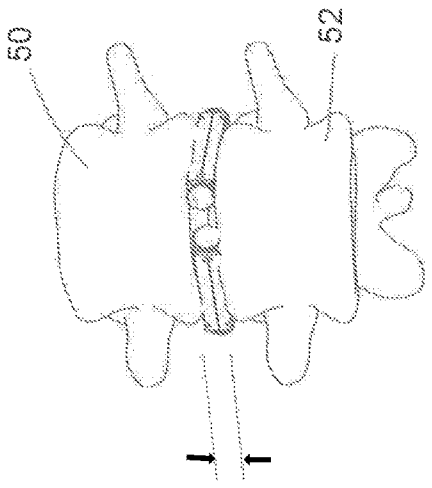

FIG. 33A

Alignment Restored

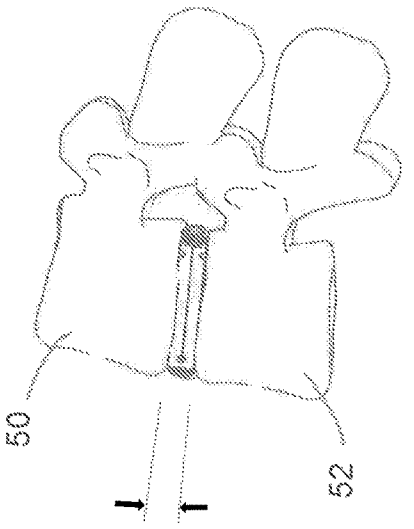

FIG. 33B

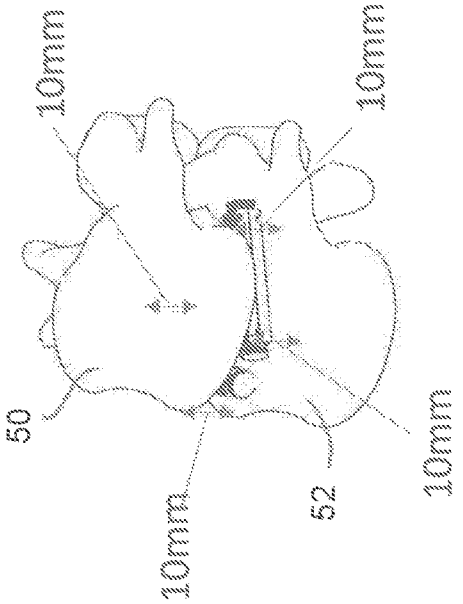

FIG. 33C

UNIVERSALLY EXPANDING CAGE

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims benefit of U.S. Provisional Application No. 62/078,850 filed Nov. 12, 2014.

INCORPORATION BY REFERENCE

All publications and patent applications mentioned in this specification are herein incorporated by reference in their entirety to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

FIELD

The present disclosure generally relates to medical devices for stabilizing the vertebral motion segment or other bone segments. More particularly, the field of the disclosure relates to a universally expanding cage (UEC) and method of use for providing controlled spinal correction or other bond segment spacing and/or alignment.

BACKGROUND

Conventional spine cages or implants are typically characterized by a kidney bean-shaped body comprising a hydroxyapatite-coated surface provided on the exterior surface for contact with adjacent vertebral segments or endplates which are shown in FIG. **1**. A conventional spine cage with flat endplates is typically inserted posterolaterally proximate to the neuroforamen of the distracted spine after a trial implant creates a pathway. Optionally two parallel externally threaded conduits are inserted anteriorly to achieve lumbar arthrodesis. The implants are often of constant diameter whereas the L5-S1 disc space is trapezoidal, thus a 'flat back' syndrome may be iatrogenically created. Generally spine intradiscal implants are for lumbar fusion or cervical motion preservation, while a separate system of rods and screws corrects alignment.

With the novel UECs disclosed herein, additional options include fusion throughout the spinal column, and deformity angular correction.

Existing devices for interbody stabilization have important and significant limitations. Among the limitations are an inability to expand and distract the endplates. Consequently, if a cage that is "to small" is inserted it can 'rattle around and never heal'. If the static cage is too big, it can injure adjacent nerves or destabilize the spine via end plate resection or subsidence.

Current devices for interbody stabilization include static spacers composed of titanium, PEEK, and high performance thermoplastic polymer produced by VICTREX, (Victrex USA Inc, 3A Caledon Court, Greenville, S.C. 29615), carbon fiber, or resorbable polymers. Current interbody spacers may not maintain interbody lordosis and can contribute to the formation of a straight or even kyphotic segments and the clinical problem of "flatback syndrome." Separation of the endplates increases space available for the neural elements, specifically the neural foramen. Existing static cages do not reliably improve space for the neural elements. Therefore, what is needed is an expanding cage that will increase space for the neural elements posteriorly between the vertebral bodies, or at least maintain the natural bone contours to avoid neuropraxia (nerve stretch) or encroachment.

U.S. Pat. No. 7,985,256, filed Sep. 26, 2006 and titled "Selectively Expanding Spine Cage, Hydraulically Controllable in Three Dimensions for Enhanced Spinal Fusion", and U.S. Pat. No. 7,819,921, filed Oct. 31, 2007 and titled "Linearly expanding spine cage for enhanced spinal fusion", both provide detailed background on expanding spine cages.

The cages disclosed in U.S. Pat. No. 7,985,256 above are restricted to use with hydraulics, and lumbar fusion. The cage disclosed in U.S. Pat. No. 7,819,921 allows for trapezoidal linear expanding, not uniform expansion, thus a trapezoidal L5 cage as disclosed therein will preserve natural lumbar lordosis. The disclosed cage was never developed. It is intended for use as two (2) parallel linearly expanding split conduits inserted anteriorly for lumbar fusion.

In contrast, the UEC cages disclosed herein expands either uniformly, or at either end proximally or distally. Given the adjustment option the surgeon can correct angulation deformity with the novel UEC.

Another problem with conventional devices of interbody stabilization includes poor interface between bone and biomaterial. Conventional static interbody spacers form a weak interface between bone and biomaterial. Although the surface of such implants is typically provided with a series of ridges or coated with hydroxyapetite, the ridges may be in parallel with applied horizontal vectors or side-to-side motion. That is, the ridges or coatings offer little resistance to movement applied to either side of the endplates. Thus, nonunion is common in allograft, titanium and polymer spacers, due to motion between the implant and host bone. Conventional devices typically do not expand between adjacent vertebrae. Since the UEC expands under surgeon control, the visible, palpable 'goodness of fit' setting can ideal lock opposing vertebral endplates at the time of surgery. As healing accrues, the implants become inert. Since no motion equates with no pain, clinical results are improved with UECs.

Therefore, what is needed is a way to expand an implant to develop immediate fixation forces that can exceed the ultimate strength at healing, with improved abilities to enable disc space fixation solidarity while correcting spine angular deformity. Such an expandable implant ideally will maximize stability of the interface and enhance stable fixation. The immediate fixation of such an expandable interbody implant advantageously will provide stability that is similar to that achieved at the time of healing. Such an implant will have valuable implications enhancing early post-operative rehabilitation for the patient.

Another problem of conventional interbody spacers is their large diameter requiring wide exposure. Existing devices used for interbody spacers include structural allograft, threaded cages, cylindrical cages, and boomerang-shaped cages. Conventional devices have significant limitation with regard to safety and efficacy. Regarding safety of the interbody spacers, injury to neural and aortic elements may occur with placement from an anterior or posterior approach. A conventional spine cage lacks the ability to expand, diminishing its fixation capabilities. Prior attempts to preserve lumbar motion have failed by extrusion of the implant after implantation. The risks to neural elements are primarily due to the disparity between the large size of the cage required to adequately support the interbody space, and the small space available for insertion of the device, especially when placed from a posterior or transforaminal

approach. Existing boomerang cages are shaped like a partially flattened kidney bean. Their implantation requires a wide exposure and potential compromise of vascular and neural structures, both because of their inability to enter small and become larger, and due to the fact that their insertion requires mechanical manipulation during insertion and expanding of the implant. Once current boomerang implants are prepared for insertion via a trial spacer to make a pathway toward the anterior spinal column, the existing static cage is shoved toward the end point with the hope that it will reach a desired anatomic destination. Given the proximity of nerve roots and vascular structures to the insertion site, and the solid, relatively large size of conventional devices, such constraints predispose a patient to foraminal (nerve passage site) encroachment, and possible neural and vascular injury.

Therefore, what is needed is a minimally invasive expanding spine cage that is capable of insertion with minimal invasion into a smaller aperture. Such a minimally invasive spine cage advantageously could be expanded with completely positional control or adjustment in three dimensions. What is also needed is a smaller expanding spine cage that is easier to operatively insert into a patient with minimal surgical trauma in contrast to conventional, relatively large devices that create the needless trauma to nerve roots in the confined space of the vertebral region. Existing interbody implants have limited space available for bone graft. Adequate bone graft or bone graft substitute is critical for a solid interbody arthrodesis. It would be desirable to provide an expandable interbody cage that will permit a large volume of bone graft material to be placed within the cage and around it, to fill the intervertebral space. Additionally, conventional interbody implants lack the ability to stabilize endplates completely and prevent them from moving. Therefore, what is also needed is an expanding spine cage wherein the vertebral end plates are subject to forces that both distract them apart, and hold them from moving. Such an interbody cage would be capable of stabilization of the motion segment, thereby reducing micromotion, and discouraging pseudoarthrosis (incomplete fusion) and pain.

Ideally, what is needed is a spine cage or implant that is capable of increasing its expansion in height and angle, spreading to a calculated degree. Furthermore, what is needed is a spine cage that can adjust the amount of not only overall anterior posterior expansion, but also medial and lateral variable expansion so that both the normal lordotic curve is maintained, and adjustments can be made for scoliosis or bone defects. Such a spine cage or implant would permit restoration of normal spinal alignment after surgery and hold the spine segments together rigidly, mechanically, until healing occurs.

What is also needed is an expanding cage or implant that is capable of holding the vertebral or joint sections with increased pullout strength to minimize the chance of implant fixation loss during the period when the implant is becoming incorporated into the arthrodesis bone block.

SUMMARY OF THE DISCLOSURE

According to some aspects of the disclosure, an expandable medical implant is provided with an implantable cage body having a proximal end and a distal end. In some embodiments, the proximal and distal ends of the cage body are each provided with a tapered or cam portion. The cage body further has a longitudinal axis extending between the proximal end and the distal end of the cage body. The implant may further comprise at least one proximal flexure at least partially located adjacent to the proximal end of the cage body and configured to allow a circumference of the distal end of the cage body to resiliently expand. The implant may further comprise at least one distal flexure at least partially located adjacent to the distal end of the cage body and configured to allow a circumference of the proximal end of the cage body to resiliently expand. The implant may further comprise a proximal plug member having a tapered portion configured to mate with the tapered portion of the proximal end of the cage body. The proximal plug member may be configured to move longitudinally relative to the cage body from a first position to a second position such that the at least one distal flexure moves and the circumference of the proximal end of the cage body resiliently expands. The proximal plug member may also be configured to move from the second position to the first position such that the circumference of the proximal end resiliently contracts. The implant may further comprise a distal plug member having a tapered portion configured to mate with the tapered portion of the distal end of the cage body. The distal plug member may be configured to move longitudinally relative to the cage body from a third position to a fourth position such that the at least one proximal flexure moves and the circumference of the distal end of the cage body resiliently expands. The distal plug member may also be configured to move from the fourth position to the third position such that the circumference of the distal end resiliently contracts.

In some embodiments, the cage body further comprises a first tapered bore at the proximal end configured to slidably receive the proximal plug member, and a second tapered bore at the distal end configured to slidably receive the distal plug member. The first tapered bore may threadably engage the proximal plug member such that when the proximal plug member is rotated relative to the cage body, the proximal plug member advances in a longitudinal direction relative to the cage body. The second tapered bore may threadably engage the distal plug member such that when the distal plug member is rotated relative to the cage body, the distal plug member advances in a longitudinal direction relative to the cage body.

In some embodiments, the at least one proximal flexure comprises a generally circular and open ended aperture and a pair of generally flexible beam portions extending longitudinally from the aperture. The at least one proximal flexure may include a pair of longitudinally extending beam portions separated by a longitudinally extending gap, wherein the at least one proximal flexure further comprises a connector portion interconnecting proximal ends of the beam portions. The at least one proximal flexure may include a plurality of circumferentially spaced proximal flexures, and the at least one distal flexure may include a plurality of circumferentially spaced distal flexures. The plurality of proximal flexures may be rotationally staggered from the plurality of distal flexures.

In some embodiments, each of the proximal flexures includes a pair of longitudinally extending beam portions separated by a longitudinally extending gap and bridged together by a connector portion interconnecting only proximal ends of the beam portions. Each of the distal flexures may include a pair of longitudinally extending beam portions separated by a longitudinally extending gap and bridged together by a connector portion interconnecting only distal ends of the beam portions. Each of the proximal flexures can share a beam portion with two of the distal flexures that are adjacent to each proximal flexure, thereby forming a continuous serpentine pattern along the cage body.

In some embodiments, the implant includes a first adjustment member coupled to at least the proximal plug member such that when the first adjustment member is rotated, the proximal plug member is caused to move longitudinally. The implant may further include a second adjustment member coupled to the distal plug member such that when the second adjustment member is rotated, the distal plug member is caused to move longitudinally, thereby allowing the proximal and the distal ends of the cage body to be expanded and contracted independent from one another. The first and the second adjustment members may be coaxially nested one within the other and independently rotatable. In some embodiments, the first and the second adjustment members each have knobs axially spaced but adjacent to one another such that the knobs may alternately be rotated in unison or individually. At least one of the first and the second adjustment members may have a keyed end configured to slidably mate and rotationally couple with its associated plug member such that the at least one adjustment member can be removed from the expandable medical implant.

In some embodiments, the cage body has a square or circular cross-section transverse to the longitudinal axis.

In some embodiments, an expandable medical implant includes an implantable cage, a plurality of proximal flexures, a plurality of distal flexures, a proximal plug member, a distal plug member, and first and second adjustment members. In these embodiments, the implantable cage body has a proximal end and a distal end each provided with a threaded and tapered bore. The cage body has a longitudinal axis extending between the proximal end and the distal end of the cage body. The plurality of proximal flexures are circumferentially spaced and each is at least partially located adjacent to the proximal end of the cage body and configured to allow a circumference of the distal end of the cage body to resiliently expand. Each of the proximal flexures comprises a pair of longitudinally extending beam portions separated by a longitudinally extending gap and bridged together by a connector portion interconnecting only proximal ends of the beam portions. The plurality of distal flexures are circumferentially spaced and each is at least partially located adjacent to the distal end of the cage body and configured to allow a circumference of the proximal end of the cage body to resiliently expand. Each of the distal flexures comprises a pair of longitudinally extending beam portions separated by a longitudinally extending gap and bridged together by a connector portion interconnecting only distal ends of the beam portions. Each of the proximal flexures shares a beam portion with two of the distal flexures that are adjacent to each proximal flexure, thereby forming a continuous serpentine pattern along the cage body. The proximal plug member has a threaded and tapered circumference configured to mate with the threaded and tapered bore of the proximal end of the cage body. The proximal plug member is configured to move along the longitudinal axis relative to the cage body from a first position to a second position such that the plurality of distal flexures move and the circumference of the proximal end of the cage body resiliently expands. The proximal plug member is also configured to move from the second position to the first position such that the circumference of the proximal end resiliently contracts. The distal plug member has a threaded and tapered circumference configured to mate with the threaded and tapered bore of the distal end of the cage body. The distal plug member is configured to move along the longitudinal axis relative to the cage body from a third position to a fourth position such that the plurality of proximal flexures move and the circumference of the distal end of the cage body resiliently expands. The distal plug member is also configured to move from the fourth position to the third position such that the circumference of the distal end resiliently contracts. The first adjustment member is rotationally coupled to the proximal plug member such that when the first adjustment member is rotated, the proximal plug member is caused to move along the longitudinal axis. The second adjustment member rotationally coupled to the distal plug member such that when the second adjustment member is rotated, the distal plug member is caused to move longitudinally, thereby allowing the proximal and the distal ends of the cage body to be expanded and contracted independent from one another. The first and the second adjustment members are coaxially nested one within the other and independently rotatable. The first and the second adjustment members each have knobs axially spaced but adjacent to one another such that the knobs may alternately be rotated in unison or individually. At least one of the first and the second adjustment members may have a keyed end configured to slidably mate and rotationally couple with its associated plug member such that the at least one adjustment member can be removed from the expandable medical implant.

According to some aspects of the disclosure, a method of distracting adjacent bone segments having opposing surfaces is provided. The method comprises the steps of inserting an expandable medical implant as described above between the opposing surfaces of the bone segments, and moving the proximal and the distal plug members longitudinally and independently from one another such that the proximal and the distal ends of the cage body expand independently to alter the distance and the angle between the opposing surfaces of the bone segments. In some embodiments, the method further includes the step of removing at least one adjustment member from the medical implant after the adjustment member has been used to move at least one of the proximal and distal plug members. In some embodiments, the bone segments are adjacent vertebrae, and the opposing surfaces are end plates of the adjacent vertebrae.

BRIEF DESCRIPTION OF THE DRAWINGS

For the purpose of illustrating concepts of the disclosure, the drawings show aspects of one or more embodiments. However, it should be understood that the present disclosure is not limited to the precise arrangements and instrumentalities shown in the drawings, wherein:

FIGS. **1-3** are a series of lateral representations of two vertebral bodies, wherein FIG. **1** depicts the insertion of an exemplary Universally Expanding Cage (UEC) in its unexpanded state, FIG. **2** depicts the UEC in place between the vertebral bodies and still in its unexpanded state, and FIG. **3** depicts the inserted UEC in its expanded state.

FIG. **4** is a perspective view of a first embodiment of a UEC in an unexpanded state according to aspects of the disclosure.

FIG. **5** is an exploded perspective view showing the UEC of FIG. **4**.

FIG. **6** is a perspective view showing the cage body of the UEC of FIG. **4**.

FIG. **7** is a proximal end view of the UEC of FIG. **4**.

FIG. **8** is a side view of the UEC of FIG. **4**.

FIG. **9** is a side cross-sectional view of the UEC of FIG. **4**.

FIG. **10** is a perspective view of a second embodiment of a UEC in an unexpanded state according to aspects of the disclosure.

FIG. **11** is an exploded perspective view showing the UEC of FIG. **10**.

FIG. **12** is a side view showing the UEC of FIG. **10**.

FIG. **13** is a proximal end view showing the UEC of FIG. **10**.

FIG. **14** is a distal end view showing the UEC of FIG. **10**.

FIG. **15** is a side cross-sectional view showing the UEC of FIG. **10**.

FIG. **16** is a perspective view of a third embodiment of a UEC in an unexpanded state according to aspects of the disclosure.

FIG. **17** is an exploded perspective view showing the UEC of FIG. **16**.

FIG. **18** is a side view showing the UEC of FIG. **16**.

FIG. **19**A is a side cross-sectional view showing the UEC of FIG. **16**.

FIG. **19**B is an end cross-sectional view showing the UEC of FIG. **16**.

FIGS. **20**A-**20**C are a series of side views showing the progressive expansion of the UEC of FIG. **16**, wherein FIG. **20**A shows both ends of the UEC in the unexpanded state, FIG. **20**B shows only one end expanded, and FIG. **20**C shows both ends expanded.

FIG. **21** is a perspective view of a fourth embodiment of a UEC in an unexpanded state according to aspects of the disclosure.

FIG. **22** is a perspective view of a fifth embodiment of a UEC in an unexpanded state according to aspects of the disclosure.

FIG. **23** is a distal end view showing the UEC of FIG. **22**.

FIG. **24** is a side view showing the UEC of FIG. **22**.

FIG. **25** is a side cross-sectional view showing the UEC of FIG. **22**.

FIG. **26** is a cranial to caudal view showing the insertion sites of dual UECs on a vertebral body in one example implementation.

FIG. **27** is an oblique posterolateral view showing one of the insertion sites of the implementation of FIG. **26**.

FIG. **28** is an oblique posterolateral view showing the axes of adjustment provided by the implementation of FIG. **26**.

FIG. **29** is an oblique anterior view showing an anterior column implant.

FIG. **30** is a posterior view showing a human spine exhibiting scoliosis.

FIG. **31** is a posterior view showing the spine of FIG. **29** after being corrected according to aspects of the disclosure.

FIGS. **32**A-**32**C are anterior, lateral and oblique views, respectively, showing adjacent vertebral bodies having misalignments/uneven spacing.

FIGS. **33**A-**33**C are anterior, lateral and oblique views, respectively, showing the vertebral bodies of FIGS. **32**A-**32**C with the misalignments/uneven spacing corrected according to aspects of the disclosure.

DETAILED DESCRIPTION

Referring to FIG. **1-3**, a series of lateral views of vertebral segments **50** and **52** are shown, depicting the insertion and expansion of one embodiment of UEC (Universally Expanding Cage). The depicted vertebral bodies **50** and **52** have an average 8 mm gap between vertebral end plates, representing an average intervertebral space **54**. In a typical implementation, a complete discectomy is performed prior to the insertion of the UEC **56**. The intervertebral disc occupying space **54** is removed using standard techniques including rongeur, curettage, and endplate preparation to bleeding subcondral bone. The posterior longitudinal ligament is divided to permit expansion of the intervertebral space.

The intervertebral space **54** may be distracted to about 10 mm using a rotating spatula (not shown). This is a well-known device that looks like a wide screw driver that can be placed into the disc space horizontally and turned 90 degrees to separate the endplates. A novel feature of the UEC is that after intervertebral disc space expansion and preparation (by curetting or ideally arthroscopically facilitated disc material removal), the UEC implant per se can be inserted through any orifice or angle that does not cause injury to nerves or other structures, positioned at the immediate implant location and consequent expansion platform to yield both the best fusion and angular correction results.

In the example implementation depicted in FIGS. **1-3**, UEC **56** is inserted posteriorly (in the direction of arrow **58**) between vertebral bodies **50** and **52**, as shown in FIG. **1**. The vertebral space **54** depicted is meant to represent any vertebral space in which it is desired to insert the UEC (sacral, lumbar, thoracic and/or cervical), and from any direction permitted by the surrounding anatomy. In accordance with an aspect of the disclosure, the UEC is reduced to a small size in its unexpanded state to enable it to be inserted through into the intervertebral space **54** as shown in FIG. **1**. FIG. **2** shows UEC **56** inserted between vertebral bodies **50** and **52**, with UEC **56** still in its unexpanded state. In one exemplary embodiment, dimensions of an unexpanded UEC are: 10-12 mm wide, 10 mm high and 28 mm long to facilitate insertion and thereby minimize trauma to the patient and risk of injury to nerve roots. These dimensions may accommodate the flat external surfaces. Once in place, the exemplary UEC **56** may be expanded to 140 percent of its unexpanded size (as shown in FIG. **3**), enabling 20 degrees or more of spinal correction depending on the 3D clinical pre-operation anatomic analysis.

It should be noted that while the exemplary UEC **56** depicted in FIGS. **1-3** is an implant intended to ideally fill the warranted space, other shapes of implants such as those shown in later figures and/or described herein may be used. In various embodiments, the implants may have a transverse cross-section that is circular, oval, elliptical, square, rectangular, trapezoidal, or other shape suited to fill the implant site and transmit the required loads. The implants may straight, curved, bean-shaped, and/or include other shapes and aspect ratios. Additionally, the external surfaces may be smooth, spiked, threaded, coated and/or further adapted as subsequently described in more detail. The UEC can be used at any spinal level the surgeon deems in need of fusion, and may be placed at any position and angle relative to the vertebral endplates as may be needed. One, two, or more UECs may be placed at any particular level to achieve the desired height and angles between vertebral bodies. As will be later described, multiple UECs may be used to adjust the overall cranio-caudal height, the anterior-posterior angle, and the medio-lateral angle between adjacent vertebral bodies. UECs may be implanted at multiple levels to obtain or restore the desired three dimensional curvature and positioning of the spine.

Referring to FIGS. **4-9**, a first embodiment of an exemplary UEC **100** according to aspects of the disclosure is shown. FIG. **4** is an enlarged perspective view which shows details of UEC **100**. For ease of understanding, a proximal end **104** and a distal end **106** of UEC **100** can be defined as shown in FIG. **4**. It should be noted that while the distal end **106** of UEC **100** is typically inserted first into a patient and proximal end **104** is typically closest to the surgeon, other orientations of this exemplary device and other devices

described herein may be adopted in certain procedures despite the distal and proximal nomenclature being used.

Referring to FIG. **5**, an exploded perspective view shows the individual components of UEC **100**. In this first embodiment, UEC **100** includes a cylindrically-shaped cage body **108**, a proximal plug **110**, a distal plug **112**, a threaded actuator **114**, and a washer **116**. The terms "plug" and "plug member" are used interchangeably herein. Actuator **114** has a shank sized to slidably pass through a central bore within proximal plug **110** when UEC **100** is assembled. Actuator **114** also has threads on its distal end for engaging with a threaded central bore within distal plug **112**. Proximal plug **110** and distal plug **112** each have outer surfaces that are inwardly tapered to match inwardly tapered surfaces within cage body **108** (as best seen in FIG. **9**) With this arrangement, actuator **114** may be rotated in a first direction to draw distal plug **112** toward proximal plug **110** to outwardly expand cage body **108**, as will be subsequently described in more detail.

Referring to FIG. **6**, this perspective view shows details of cage body **108** of the first exemplary embodiment of UEC **100**. In this embodiment, cage body **108** includes eight longitudinally extending beam portions **118**, each separated from an adjacent beam portion **118** by a longitudinally extending gap **120**. In other embodiments (not shown), the cage body may include fewer or more than eight beam portions, and/or beam portions having a different or varying cross-section or shape. Cage body **108** of the current embodiment also includes eight circumferentially extending connector portions **122**. The connector portions **122** interconnect the ends of the beam portions **118**. Four of the connector portions **122** are located at the proximal end **104** of cage body **108**, and the other four connector portions **122** are located at the distal end **106**. The connector portions **122** located at the proximal end **104** are staggered in relation to the connector portions **122** located at the distal end **106** such that each pair of adjacent beam portions **118** are connected at only one end by a connector portion **122**. With this arrangement the beam portions **118** and connector portions **122** form a continuous serpentine or repeating S-shaped pattern. The beam portions **118** and or the connector portions **122** are configured to resiliently flex to allow the cage body **108** to increase in diameter when urged radially outward by plugs **110** and **112** (shown in FIG. **4**). When plugs **110** and **112** are not urging cage body **108** radially outward, the resiliency of beam portions **118** and or connector portions **122** allows cage body **108** to return to its original reduced diameter. It can be appreciated that as beam portions **118** and or connector portions **122** flex outwardly, gaps **120** become wider at their open ends opposite connector portions **122**. The outwardly facing surfaces of beam portions **118** may each be provided with one or more points or spikes **123** as shown, to permit cage body **108** to grip the end plates of the vertebral bodies.

Referring to FIG. **7**, an end view of the proximal end **104** of UEC **100** is shown. The enlarged head at the proximal end of actuator **114** may be provided with a recessed socket **124** as shown for removably receiving a tool for turning actuator **114**. Proximal plug **110** (and distal plug **112**, not shown) may be provided with radially outwardly extending protuberances **126** that reside in one or more gaps **120** and abut against the side of beam portions **118**. This arrangement prevents plugs **110** and **112** from rotating when actuator **114** is turned, thereby constraining plugs **110** and **112** to only move axially toward or away from each other. Proximal plug **110** (and distal plug **112**) may be provided with through holes and or recesses **128** to allow for bony ingrowth from the vertebral bodies for more solidly healing/fusing UEC **100** in place. Longitudinally extending slots **130** (shown in FIG. **4**) may also be provided for this purpose, and or for packing plugs **110** and **112** with autograft, allograft, and/or other materials for promoting healing/fusion.

Referring to FIGS. **8** and **9**, a side view and side cross-sectional view, respectively, are shown. In operation, UEC **100** is expanded by inserting a tool such as a hex key wrench or driver (not shown) into the recessed socket **124** at the proximal end of actuator **114** and turning it clockwise. As best seen in FIG. **9**, the distal end of actuator **114** is threaded into the central bore of distal plug **112**. Turning actuator **114** clockwise causes the distal end of actuator **114** to pull distal plug **112** towards the center of cage body **108** while the enlarged head at the proximal and of actuator **114** pushes proximal plug **110** towards the center. This movement in turn causes the ramped surfaces **132** of plugs **110** and **112** to slide inwardly along the ramped surfaces **134** located along the inside of beam portions **118** and connector portions **122** to cause these elements to flex and expand radially outward as previously described. This process may be reversed by turning actuator **114** counterclockwise. The resilient inward forces from the beam portions **118** and or connector portions **122** (and or the compressive forces from adjacent vertebral bodies) against plugs **110** and **112** causes the two plugs to separate axially, thereby allowing UEC **100** to return to its non-expanded state.

Referring to FIGS. **10-15**, a second embodiment of an exemplary UEC **200** according to aspects of the disclosure is shown. FIG. **10** is a perspective view which shows details of UEC **200**. UEC **200** includes a proximal end **204** and a distal end **206**, and shares many of the same features of previously described UEC **100**, which are identified with similar reference numerals.

Referring to FIG. **11**, an exploded perspective view shows the individual components of UEC **200**. In this second embodiment, UEC **200** includes an elongated cylindrical cage body **208**, a proximal plug **210**, and a distal plug **212**. Distal plug **212** includes an integrally formed actuator rod **214** that extends along the internal central axis of cage body **208** towards proximal plug **210** when UEC **200** is assembled. Proximal plug **210** and distal plug **212** each have outer surfaces that are threaded and inwardly tapered to match threaded and inwardly tapered surfaces within cage body **208** (as best seen in FIG. **15**). With this arrangement, each plug **210** and **212** may be independently rotated to move the particular plug axially toward the middle of cage body **208** to outwardly expand that particular end **204** or **206** of cage body **208**, as will be subsequently described in more detail.

As shown in FIGS. **11** and **12**, cage body **208** includes eight longitudinally extending beam portions **218**, each separated from an adjacent beam portion **218** by a longitudinally extending gap **220**. In other embodiments (not shown), the cage body may include fewer or more than eight beam portions, and/or beam portions having a different or varying cross-section or shape. Cage body **208** of the current embodiment also includes eight circumferentially extending connector portions **222**. The connector portions **222** interconnect the ends of the beam portions **218**. Four of the connector portions **222** are located at the proximal end **204** of cage body **208**, and the other four connector portions **222** are located at the distal end **206**. The connector portions **222** located at the proximal end **204** are staggered in relation to the connector portions **222** located at the distal end **206** such that each pair of adjacent beam portions **218** are connected at only one end by a connector portion **222**. With this

arrangement the beam portions **218** and connector portions **222** form a continuous serpentine or repeating S-shaped pattern. The beam portions **218** and or the connector portions **222** are configured to resiliently flex to allow the cage body **208** to increase in diameter when urged radially outward by plugs **210** and **212**. When plugs **210** and **212** are not urging cage body **208** radially outward, the resiliency of beam portions **218** and or connector portions **222** allows cage body **208** to return to its original reduced diameter. It can be appreciated that as beam portions **218** and or connector portions **222** flex outwardly, gaps **220** become wider at their open ends opposite connector portions **222**. The outwardly facing surfaces of beam portions **218** may each be provided with one or more points or spikes **223** as shown, to permit cage body **208** to grip the end plates of the vertebral bodies.

Referring to FIG. **13**, an end view of the proximal end **204** of UEC **200** is shown. The proximal plug **210** may be provided with a recessed socket **224** as shown for removably receiving a tool for turning proximal plug **210** in either direction, such as a five-lobed driver (not shown). Alternatively, other suitable types of recessed sockets, slots, protruding and/or keyed features may be utilized with a mating driver. The proximal end of actuator shaft **214** (which extends proximally from distal plug **212** inside cage body **208**) may be accessed through a central bore **225** in proximal plug **210**. The proximal end of actuator shaft **214** may be shaped as shown to be received within a mating driver socket (such as a five-lobed socket, not shown), which can be removably extended into the center of cage body **208** through central bore **225**. With this arrangement, both the proximal plug **210** and the distal plug **212** can be independently accessed and rotated from the proximal end of UEC **200** so that the proximal end **204** and the distal end **206** of UEC **200** can be expanded or contracted independently.

Referring to FIG. **14**, an end view of the distal end **206** of UEC **200** is shown. By comparing FIGS. **13** and **14**, it can be appreciated that connector portions **222** at the proximal end **204** of UEC **200** are staggered (i.e. rotated 45°) in relation to the connector portions **222** at the distal end **206** of UEC **200**.

Referring to FIG. **15**, a side cross-sectional view of UEC **200** is shown. In operation, the proximal end **204** of UEC **200** may be independently expanded by inserting a tool such as a five-lobed driver (not shown) into the recessed socket **224** of proximal plug **210** and turning it clockwise. Turning proximal plug **210** clockwise causes the threaded ramped surfaces **232** of plug **210** to translate inwardly (to the right in FIG. **15**) along the threaded ramped surfaces **234** located along the inside of beam portions **218** and connector portions **222** to cause these elements to flex and expand radially outward as previously described. This process may be reversed by turning proximal plug **210** counterclockwise, thereby allowing the proximal end **204** of UEC **200** to return to its non-expanded state. Similarly, the distal end **206** of UEC **200** may be independently expanded by inserting a tool such as a five-lobed socket (not shown) through the central bore **225** in proximal plug **210** until it engages with the proximal end of actuator **214**, which is attached to distal plug **212**. Turning distal plug **212** counterclockwise (from the perspective of the proximal end) causes the threaded ramped surfaces **232** of plug **212** to translate inwardly (to the left in FIG. **15**) along the threaded ramped surfaces **234** located along the inside of beam portions **218** and connector portions **222** to cause these elements to flex and expand radially outward as previously described. This process may be reversed by turning distal plug **212** clockwise, thereby allowing the distal end **206** of UEC **200** to return to its non-expanded state.

The adjustment tools described above (not shown) for turning proximal plug **210** and distal plug **212** may be inserted one at a time into UEC **200**. Alternatively, the two tools may be nested together, with the tool for turning the distal plug **212** passing through a central bore in the tool for turning the proximal plug, as will be subsequently shown and described in relation to other embodiments. With this arrangement, both tools may be turned simultaneously or individually. In some embodiments, both proximal plug **210** and distal plug **212** are provided with right-handed threads, so that when both tools are simultaneously turned in the same direction, one end of UEC **200** expands while the other end contracts, thereby changing the outer surface angle of UEC **200** without substantially changing its overall diameter (i.e. without substantially changing the diameter or height of the midpoint of UEC **200**.) For example, by turning the two tools in the same direction, the lordotic angle between two vertebral bodies can be changed by UEC **200** without substantially changing the height between the two vertebral bodies.

In other embodiments, one of the plugs **210** or **212** may be provides with a right-handed thread and the other plug provided with a left-handed thread. In these embodiments, when both adjustment tools are simultaneously turned in the same direction, both ends **204** and **206** of UEC **200** expand or contact together without substantially changing the outer surface angle of UEC **200**. For example, by turning the two tools in the same direction, the height between the two vertebral bodies can be changed by UEC **200** without substantially changing the lordotic angle between two vertebral bodies.

In some embodiments, plugs **210** and **212** may each be provided with threads having a different pitch from the other. Such an arrangement allows both the height and the angle between adjacent vertebral bodies to be adjusted simultaneously in a predetermined relationship when both adjustment tools are turned together in unison. For example, proximal plug **210** may be provided with right-handed threads of a particular pitch while distal plug **212** may be provided with finer, left-handed threads having half the pitch of the proximal plug threads. In this embodiment, when both adjustment tools are turned together in a clockwise direction, both ends of UEC **200** expand at the same time but the proximal end **204** expands at twice the rate of the distal end **206**. This allows the surgeon to increase the height between adjacent vertebral bodies and at the same time angle the bodies away from him or her. One or both of the tools may then be turned individually to more finely adjust the height and angle between the vertebral bodies.

In some embodiments the above-described adjustment tools may be removed from UEC **200** before the surgical procedure is completed. In some embodiments the above adjustment tools may remain in place after the procedure is completed.

In some embodiments, UEC **200** is 50 mm long, has an unexpanded diameter of 10 mm, and an expanded diameter of 14 mm. In other embodiments, the UEC may be configured to expand to about 11, 12, or 13 mm, or more than 14 mm. In still other embodiments, the UEC may be configured with dimensions larger or smaller than these to conform to a particular anatomy or procedure.

Referring to FIGS. **16-20**, a third embodiment of an exemplary UEC **300** according to aspects of the disclosure is shown. FIG. **16** is a perspective view which shows details

of UEC **300**. UEC **300** includes a proximal end **304** and a distal end **306**, and shares many of the same features of previously described UECs **100** and **200**, which are identified with similar reference numerals.

Referring to FIG. **17**, an exploded perspective view shows the individual components of UEC **300**. In this third embodiment, UEC **300** includes a rectangular cage body **308**, a proximal plug **310**, a distal plug **312**, a proximal plug adjustment tool **313**, and a distal plug adjustment tool **314**. As in the previously described UEC **200**, both plugs **310** and **312** are threaded and tapered, and each end of cage body **308** is provided with an inwardly tapered and threaded bore configured to receive one of the plugs **310** or **312**. Adjustment tools **313** and **314** are similar in construction and operation to the adjustment tools previously described (but not shown) in reference to UEC **200**. Proximal plug **310** includes a mating recess on its proximal end (not shown) configured to removably receive the splined distal end of proximal plug adjustment tool **313** for rotating proximal plug **310**. Distal plug **312** includes a smaller mating recess on its proximal end (not shown) configured to removably receive the smaller splined distal end of distal plug adjustment tool **314** for rotating distal plug **312**. Both proximal plug adjustment tool **313** and proximal plug **312** are provided with central bores that permit the distal end of distal plug adjustment tool **314** to pass therethrough, through the center of cage body **308**, and partially into distal plug **312**. In this exemplary embodiment, the proximal ends of adjustment tools **313** and **314** each have a hexagonally-shaped head that permits them to be turned together in unison or individually (as previously described in relation to UEC **200**), using wrench(es), socket(s) (not shown) and/or by hand.

As shown in FIGS. **16** and **17**, cage body **308** includes eight longitudinally extending beam portions **318**, each separated from an adjacent beam portion **318** by a longitudinally extending gap **320**. In other embodiments (not shown), the cage body may include fewer or more than eight beam portions, and/or beam portions having a different or varying cross-section or shape. It can be seen that in this embodiment, four of the gaps **320** are formed through the middle of the four faces of cage body **308**, and the other four gaps **320** are formed along the corner edges of cage body **308**. Cage body **308** also includes eight circumferentially extending connector portions **322**. The connector portions **322** interconnect the ends of the beam portions **318**. Circular apertures **321** may be provided as shown between the ends of gaps **320** and the connector portions **322** to relieve stress concentrations at those locations as connector portions **322** flex. Four of the connector portions/flexures **322** are located at the proximal end **304** of cage body **308** (across the corner edges of cage body **308**), and the other four connector portions/flexures **322** are located at the distal end **306** (across the distal end of the faces of cage body **308**.) The connector portions **322** located at the proximal end **304** are staggered in relation to the connector portions **322** located at the distal end **306** such that each pair of adjacent beam portions **318** are connected at only one end by a connector portion **322**. As with previously described embodiments, the beam portions **318** and connector portions **322** form a continuous serpentine or repeating S-shaped pattern. The beam portions **318** and or the connector portions **322** are configured to resiliently flex to allow the cage body **308** to increase in circumference when urged radially outward by plugs **310** and **312**. When plugs **310** and **312** are not urging cage body **308** radially outward, the resiliency of beam portions **318** and or connector portions **322** allows cage body **308** to return to its original reduced circumference. It can be appreciated that as beam portions **318** and or connector portions **322** flex outwardly, gaps **320** become wider at their open ends opposite connector portions **322**. The outwardly facing surfaces of beam portions **318** may each be provided with one or more points or spikes **323** as shown, to permit cage body **308** to grip the end plates of the vertebral bodies. In this exemplary embodiment, spiked or knurled surfaces are provided along the top and bottom of UEC **300** while the side surfaces are left smooth.

Referring to FIGS. **18** and **19**, a side view and a side cross-sectional view, respectively, of UEC **300** are shown. In operation, the proximal end **304** of UEC **300** may be independently expanded by inserting proximal plug adjustment tool **313** into the mating recessed socket of proximal plug **310** (as shown in FIG. **19**) and turning it clockwise. Turning proximal plug **310** clockwise causes the threaded ramped surfaces **332** of plug **310** to translate inwardly (to the left in FIGS. **18** and **19**) along the threaded ramped surfaces **334** located along the inside of beam portions **318** and connector portions **322** to cause these elements to flex and expand radially outward as previously described. This process may be reversed by turning proximal plug **310** counterclockwise, thereby allowing the proximal end **304** of UEC **300** to return to its non-expanded state. Similarly, the distal end **306** of UEC **300** may be independently expanded by inserting a tool such as a five-lobed socket (not shown) through the central bore **325** in proximal plug **310** until it engages with the proximal end of actuator **314**, which is attached to distal plug **312**. Turning distal plug **312** counterclockwise (from the perspective of the proximal end) causes the threaded ramped surfaces **332** of plug **312** to translate inwardly (to the right in FIGS. **18** and **19**) along the threaded ramped surfaces **334** located along the inside of beam portions **318** and connector portions **322** to cause these elements to flex and expand radially outward as previously described. This process may be reversed by turning distal plug **312** clockwise, thereby allowing the distal end **306** of UEC **300** to return to its non-expanded state.

Referring to FIGS. **20**A-**20**C, a series of sides views depicts the progression from a fully retracted and a fully expanded UEC **300**. In FIG. **20**A, cage body **308** is shown in a fully retracted position. In this figure, the height of each end of cage body **308** is labeled as 100% of retracted cage height. In FIG. **20**B, the proximal end **304** of cage body **308** has been fully expanded while the distal end **306** remains fully retracted. In this exemplary embodiment, each end is capable of being expanded to a height (and therefore also a width) that is 140% of the fully retracted height, as shown. In FIG. **20**C, the distal end **306** has also been expanded by 40%.

In some embodiments, UEC **300** has a cage length of 50 mm, an unexpanded cage height of 10 mm, and an expanded cage height of 14 mm. The overall length of UEC **300** with adjustment tools **313** and **314** in place and in the unexpanded state may be 75 mm. In other embodiments, the UEC may be configured to expand to about 11, 12, or 13 mm, or more than 14 mm. In still other embodiments, the UEC may be configured with dimensions larger or smaller than these to conform to a particular anatomy or procedure. In some embodiments, the UEC can form an included angle between its top and bottom surfaces of at least 20 degrees.

Referring to FIG. **21**, a fourth embodiment of an exemplary UEC **400** according to aspects of the disclosure is shown. FIG. **21** is a perspective view which shows details of UEC **400**. UEC **400** includes a proximal end **404**, a distal end **406**, cage body **408**, proximal plug **410**, distal plug **412**,

proximal plug adjusting tool **413**, and distal plug adjusting tool **414**. Other than cage body **408** having a circular cross-section rather than a square cross-section, UEC **400** is essentially identical in construction and operation to previously described UEC **300**. In other embodiments (not shown), the UEC may have a cross-section transverse to the central longitudinal axis that is rectangular, trapezoidal, oval, elliptical or other shape.

Referring to FIGS. **22-25**, a fifth embodiment of an exemplary UEC **500** according to aspects of the disclosure is shown. FIG. **16** is a perspective view which shows details of UEC **500**. UEC **500** includes a proximal end **504** and a distal end **506**, and shares many of the same features of previously described UECs **100-400**, which are identified with similar reference numerals.

UEC **500** includes three components: a generally cylindrical, unitary cage body **508**; a proximal actuator screw **510**; and a distal actuator screw **512**. The heads of actuator screws **510** and **512** may be referred to as plug members. Cage body **508** includes two longitudinal, off-center slots **550** which each extend about three-quarters of the length of cage body **508**, and emanate from opposite ends and opposite sides of cage body **508**. Cage body **508** is also provided with two transverse slots **552**, each located adjacent to the closed end of one of the longitudinal slots **550**. Each transverse slot **552** extends from the outer circumference of cage body **508** and approaches the base of a longitudinal slot **550**. Each of the two pairings of a longitudinal slot **550** with a transverse slot **552** defines a cantilevered arm **554** that is connected with the remainder of the cage body **508** by a living hinge **556** near the closed ends of the two slots **550** and **552**. Each living hinge **556** allows its associated arm **554** to flex outwardly against a vertebral body.

The open ends of longitudinal slots **550** are outwardly tapered to receive the enlarged, tapered heads of an actuator screw **510** or **512**, as best seen in FIG. **24**. The opposite ends of actuator screws **510** and **512** extend through longitudinal slots **550** and thread into the opposite ends of cage body **508**. With this arrangement, each actuator screw **510** and **512** may be turned independently of the other, causing the screw to move axially relative to bone cage **508**. This axial movement causes the head of the screw to urge the tapered tip of the associated arm **554** outward, or allowing it to flex back inward when the screw is turned in the opposite direction. If both actuator screws **510** and **512** are turned in the same direction the same amount, UEC **500** expands uniformly and increases the height between adjacent vertebral bodies. If one of the two actuator screws **510** or **512** is turned more than the other, the surgeon is able to change the angle between the vertebral bodies.

As best seen in FIG. **23**, a slot **558** or other suitable feature may be provided in the end of each actuator screw **510** and **512** at the opposite end from the screw head. A hole **560** may also be provided through each end of cage body **508** to allow access to each of the two slots **558**. This arrangement allows both of the actuator screws **510** and **512** to be turned from either end **504** and/or **506** of cage body **508**.

Referring to FIGS. **26-28**, an example implementation utilizing two UECs **56** in tandem is shown. Each UEC **56** may be inserted as previously described in relation to FIGS. **1-3**. In this implementation, UECs **56** are placed non-parallel to one another. As best seen in FIG. **28**, this arrangement allows the surgeon to adjust the angle between the vertebrae about two different axes, and also translate the vertebrae with respect to one another about another axis.

FIG. **29** is an oblique anterior view showing placement of an anterior column implant **56** on a vertebral body **52**. In this implementation, implant **56** is placed laterally across the vertebral body **52**, forward of the lateral midline. After adjustment of implant **56**, its plugs are flush with or recessed within the outer perimeter of the endplate of vertebral body **52** so as not to impinge upon adjacent tissue.

Referring to FIG. **30**, a human spine **76** is shown that exhibits scoliosis. According to aspects of the disclosure, dual UECs may be placed at various levels of the spine to treat the condition. For example, a single UEC or pairs of UECs may be implanted at the levels depicted by reference numerals **78**, **80**, **82** and **84** shown in FIG. **30**. By using the adjustments described above relative to FIG. **28**, the curvature of the spine may be adjusted in three dimensions at these four levels to a correct alignment, as shown in FIG. **31**.

FIGS. **32A-32C** are anterior, lateral and oblique views, respectively, showing adjacent vertebral bodies **50** and **52** having misalignments/uneven spacing.

FIGS. **33A-33C** are anterior, lateral and oblique views, respectively, showing the vertebral bodies **50** and **52** of FIGS. **32A-32C** with the misalignments/uneven spacing corrected according to aspects of the disclosure.

The implants can be made of, for example, such materials as titanium, 64 titanium, or an alloy thereof, 316 or 321 stainless steel, biodegradeable and biologically active materials, e.g. stem cells, and polymers, such as semi-crystalline, high purity polymers comprised of repeating monomers of two ether groups and a ketone group, e.g. polyaryetheretherketone (PEEK)™, or Teflon™.

To prevent movement of proximal and distal plugs or actuators after implantation, in some implementations a biocompatible adhesive or thread locking compound may be applied to one or more of the moving parts. In some embodiments (not shown) a pin may be inserted radially or axially between the plug/actuator and the cage body to lock the parts in place post operatively. In some embodiments, a ratchet, spring loaded detent, or other locking mechanism may be provided for this purpose.

In general, as disclosed in the above embodiments, the cage body is cut with openings at every other end of each slot, like a sine wave, allowing expansion when the center of the cage becomes occupied with a cone or mandrill shaped unit. The cage body's series of alternating slots allows the expansion to take place while keeping the outside of the UEC one single piece. The slots plus the teeth on the surface allow for a solid grip on the bone surfaces and plenty of opportunities for good bone ingrowth. Also, by allowing the surgeon to make one end of the UEC thicker than the other, the effects of the cone (mandrill) introduction vary from uniform to selective conduit expansion. The UEC expansion mechanism is adaptable to both fixed fusion and mobile 'motion preservation' implants, with exteriors of the expanding implant per surgeon's choice (round, flat, custom, etc.) As such, in some implementations, relative motion may be preserved between the vertebral bodies adjacent the implanted UEC(s). In other implementations, it may be desirable to fuse the adjacent vertebral bodies around the implanted UEC(s).

To provide motion preservation between adjacent vertebrae, robust compressible materials may be used between the UEC and one or both of the vertebral endplates, and/or one or more components of the UEC may comprise such materials. These materials may replicate the load distributing and shock absorbing functions of the annulus and nucleus of a natural disk. For example, in some embodiments the UEC may be provided with tapered plugs made of a resilient polymer to allow the UEC to compress and expand to accommodate relative motion of the adjacent

vertebrae. Examples of biocompatible materials suitable for some UEC embodiments include Bionate®, a thermoplastic polycarbonate-urethane (PCU) provided by DSM Biomedical in Exton, Pa., and ChronoFlex®, a PCU provided by AdvanSource Biomaterials in Wilmington, Mass.

The UEC provides advantages over currently existing technology that include correction of coronal plane deformity; introduction of interbody lordosis and early stabilization of the interbody space with rigidity that is greater than present spacer devices. This early stability may improve post-operative pain, preclude the need for posterior implants including pedicle screws, and improve the rate of successful arthrodesis. Importantly, the UEC provides improvement of space available for the neural elements while improving lordosis. Traditional implants are limited to spacer effects, as passive fillers of the intervertebral disc locations awaiting eventual fusion if and when bone graft in and around the implant fuses. By expanding and morphing into the calculated shape which physiologically corrects spine angulation, the UEC immediately fixes the spine in its proper, painless, functional position. As infused osteoinductive/osteoconductive bone graft materials heal, the patient becomes well and the implant becomes inert and quiescent, embedded in bone, and no longer needed.

In some embodiments, the external surface of the UEC may be 3D printed to not only fit into the intervertebral space per se, but to match the surface topography at each insertion location. In other words, a 3D printed endplate may be utilized, computer calculated to fit and expand the disc space of the individual patient, resulting in both best 'goodness of fit' for fusion, and improved axial skeletal alignment.

By creating to 'maps' that fit e.g. as a precisely congruent superior and inferior surface to fit into a particular patients disc space, and placing these UEC end plates on either side the novel UEC expansion mechanism, a patient's disc space AND overall spine alignment will be ideally treated toward best fusion (or motion preservation) and alignment.

"Method of Surgery" instructions may recommend the surgeon and/or robotic unit deploy expansion as programmed to insert the UEC into a particular disc level of pathology, to achieve best results. For example, preoperative patient scans/films can predict ideal UEC surgeon use, such as "turn Knob A a certain number of rotations clockwise," to maximize visible, palpable, and roentgenographic 'Goodness of Fit'. With this approach, post activation, the UEC implant fits the location, entering at the predetermined best angle (in 3 axes) using the proprietary Method of Surgery and UEC insertion tools provided.

In some embodiments, the UEC may be coated with hydroxyapatite. In some embodiments, toothed or 400 μm beaded surfaces may be utilized to promote bony ingrowth. Inflatable chambers may be provided within the endplate that can expand after being implanted. This approach addresses the 3-D congruence to proximate disc pathology. It can also allow for intervertebral arthrodesis or arthroplasty treatment and overall improved spinal alignment, integrating the internal proprietary expansion with the variable external endplate shapes and their contents. UEC inflatable endplates of polymer may be employed, such as tiny vacuoles, "bubblewrap", and multiple or singular bladder constructs. If a portion of the disk space were collapsed, that region could be aptly elevated or expanded by the UEC endplate variation in material and/or inflation. The inflatable chambers may contain compressible gas (such as air), granules as pharmacologics, and/or stem cells that are delivered via liquids. In cases where the UEC is compressible or force absorbing, the material and/or chamber could be used as a cushion or to 'selectively direct and protect chondrocytes' toward improvement of existing pathophysiology via best drug use or regeneration.

The 'preparation' of the UEC insertion site will vary per surgeon. In some implementations, an arthroscopic burr may be advisable for removing 0.5 mm of cortical bone along with all aberrant disc contents under digital arthroscopic camera control. In other implementations, the surgeon may just carefully curette the intervertebral space to 'clean it out' in preparation for the UEC implant insertion.

The UEC may be inserted directly into the insertion site, or may be inserted through proprietary or commercially available insertion tube. The insertion tube typically will have a blunt distal tip so that it can be inserted through an incision without causing tissue damage. The tube can be used with or without additional tissue retractors. The UEC may be preloaded into the insertion tube, or placed into the tube after the tube has been introduced into the insertion site. A pusher rod or other device may be utilized to deploy the UEC from the insertion tube into the insertion site. In some procedures, the placement of the UEC may be arthroscopically assisted.

Note that regardless of the endplate preparation, in the deformed, aging, pathologic spine there will be pathology to correct. According to various aspects of the present disclosure, the UECs provided herein may accomplish this in several ways as pertains to the external implant composition. For example, the UEC can expand as an externally threaded conduit, either uniformly end to end resulting in same diameters at each end post-operatively (such as 40% overall expansion), or precisely at either end, thus creating an overall conical albeit expanded UEC. Also, the UEC can be flat superiorly and inferiorly as shown in the above drawings, thus more likely matching the rather flat vertebral body end plates. However, according to further aspects of the present disclosure, special care should be taken to consider both the peripheral end plate boney rim as thicker more prominent cortical bone at the vertebral end plates with a sunken or concave thinner interior (thus subject to potential subsidence). The UEC MOS (Method of Surgery) contemplated herein considers the preoperative findings (e.g. MRI, 3D CT scan, X-rays) to integrate information on bone density, specific disc space and longitudinal spine anatomy, topography and alignment.

The various expanding cages disclosed herein and variations thereof are not limited to use in the spinal column but may be used between other bone segments throughout the human or animal body. For example, a UEC can be used during arthrodesis of a metatarsal joint. The UEC can aid in setting the orientation of the toe to a desired angle before fusion of the apposing bone segments occurs. Similarly, a UEC may be utilized in the knee, elbow or other body joints, or between two or more bone segments that have been fractured by trauma.

According to various aspects of the disclosure:

1) the UEC corrects spine surgical pathology both locally via horizontal (disc) and longitudinal vertical axial (scoliotic/kyphotic) spine deformity improvements.

2) the UEC is applicable cervical through lumbar for

A) arthrodesis (fusion) or

B) arthroplasty (motion preservation)

C) drug/cell therapy delivery

3) the UEC can expand uniformly throughout implant length, and/or expand only proximally (toward the surgical incision) or distally, thus enabling clinical adjustments favorable to spine diseased or injured patients for local and overall spondylopathies.

4) the UEC can be surgically inserted via outpatient MIS (Minimally Invasive—outpatient Surgery) as safe, efficacious implants "doing no harm" applying advantages from

A) materials thicknesses for height differentials or

B) expansion adjustments surgically controlled (before/during or after implantation) or via prefabricated portals or injections—programing implant 'mapped' corrections using

C) polymers durometrically calculated with variable compressions, permanent or biodegradable activations at will.

D) inflation of the implant as via UEC surface chambers or bladder(s).

E) adding endplate biologics, foam, or other adaptables for best results.

F) UEC expansion can adapt to expand variable external surface parameters including flat, round, or customized external maximally congruent surfaces to interface as with proximate endplates.

5) Delivery either via UEC materials per se (eluding substances—cells or pharmacologics) or through extrusion from a UEC container or delivery vesicle/depot/chamber/portal will enable not only immediate surgically correction but long term enhanced bone in growth and local/general therapeutic and/or regenerative clinical benefits.

While the disclosure has been described in connection with example embodiments, it is to be understood that the disclosure is not limited to the disclosed embodiments and alternatives as set forth above, but on the contrary is intended to cover various modifications and equivalent arrangements included within the claim scope.

What is claimed as the invention is:

1. An expandable medical implant comprising:

an implantable cage body having a proximal end and a distal end each provided with a tapered portion, the cage body further having a longitudinal axis extending between the proximal end and the distal end of the cage body;

at least one proximal flexure at least partially located adjacent to the proximal end of the cage body and configured to allow a circumference of the distal end of the cage body to resiliently expand;

at least one distal flexure at least partially located adjacent to the distal end of the cage body and configured to allow a circumference of the proximal end of the cage body to resiliently expand;

a proximal plug member having a tapered portion configured to mate with the tapered portion of the proximal end of the cage body, the proximal plug member being configured to move longitudinally relative to the cage body from a first position to a second position such that the at least one distal flexure moves and the circumference of the proximal end of the cage body resiliently expands, and from the second position to the first position such that the circumference of the proximal end resiliently contracts;

a distal plug member having a tapered portion configured to mate with the tapered portion of the distal end of the cage body, the distal plug member being configured to move longitudinally relative to the cage body from a third position to a fourth position such that the at least one proximal flexure moves and the circumference of the distal end of the cage body resiliently expands, and from the fourth position to the third position such that the circumference of the distal end resiliently contracts;

a first adjustment member coupled to at least the proximal plug member such that when the first adjustment member is rotated, the proximal plug member is caused to move longitudinally; and

a second adjustment member coupled to the distal plug member such that when the second adjustment member is rotated, the distal plug member is caused to move longitudinally, thereby allowing the proximal and the distal ends of the cage body to be expanded and contracted independent from one another,

wherein the first and the second adjustment members are coaxially nested one within the other and independently rotatable.

2. The expandable medical implant of claim **1**, wherein the cage body further comprises a first tapered bore at the proximal end configured to slidably receive the proximal plug member, and a second tapered bore at the distal end configured to slidably receive the distal plug member.

3. The expandable medical implant of claim **2**, wherein the first tapered bore threadably engages the proximal plug member such that when the proximal plug member is rotated relative to the cage body, the proximal plug member advances in a longitudinal direction relative to the cage body, and wherein the second tapered bore threadably engages the distal plug member such that when the distal plug member is rotated relative to the cage body, the distal plug member advances in a longitudinal direction relative to the cage body.

4. The expandable medical implant of claim **1**, wherein the at least one proximal flexure comprises a generally circular and open ended aperture and a pair of generally flexible beam portions extending longitudinally from the aperture.

5. The expandable medical implant of claim **1**, wherein the at least one proximal flexure comprises a pair of longitudinally extending beam portions separated by a longitudinally extending gap, wherein the at least one proximal flexure further comprises a connector portion interconnecting proximal ends of the beam portions.

6. The expandable medical implant of claim **1**, wherein the at least one proximal flexure comprises a plurality of circumferentially spaced proximal flexures, and wherein the at least one distal flexure comprises a plurality of circumferentially spaced distal flexures.

7. The expandable medical implant of claim **6**, wherein the plurality of proximal flexures are rotationally staggered from the plurality of distal flexures.

8. The expandable medical implant of claim **7**, wherein each of the proximal flexures comprises a pair of longitudinally extending beam portions separated by a longitudinally extending gap and bridged together by a connector portion interconnecting only proximal ends of the beam portions, wherein each of the distal flexures comprises a pair of longitudinally extending beam portions separated by a longitudinally extending gap and bridged together by a connector portion interconnecting only distal ends of the beam portions, and wherein each of the proximal flexures shares a beam portion with two of the distal flexures that are adjacent to each proximal flexure, thereby forming a continuous serpentine pattern along the cage body.

9. The expandable medical implant of claim **1**, wherein the first and the second adjustment members each have knobs axially spaced but adjacent to one another such that the knobs may alternately be rotated in unison or individually.

10. The expandable medical implant of claim **1**, wherein at least one of the first and the second adjustment members

has a keyed end configured to slidably mate and rotationally couple with its associated plug member such that the at least one adjustment member can be removed from the expandable medical implant.

11. The expandable medical implant of claim **1**, wherein the cage body has a square cross-section transverse to the longitudinal axis.

12. The expandable medical implant of claim **1**, wherein the cage body has a circular cross-section transverse to the longitudinal axis.

13. An expandable medical implant comprising:

an implantable cage body having a proximal end and a distal end each provided with a threaded and tapered bore, the cage body further having a longitudinal axis extending between the proximal end and the distal end of the cage body;

a plurality of circumferentially spaced proximal flexures each at least partially located adjacent to the proximal end of the cage body and configured to allow a circumference of the distal end of the cage body to resiliently expand, wherein each of the proximal flexures comprises a pair of longitudinally extending beam portions separated by a longitudinally extending gap and bridged together by a connector portion interconnecting only proximal ends of the beam portions;

a plurality of circumferentially spaced distal flexures each at least partially located adjacent to the distal end of the cage body and configured to allow a circumference of the proximal end of the cage body to resiliently expand, wherein each of the distal flexures comprises a pair of longitudinally extending beam portions separated by a longitudinally extending gap and bridged together by a connector portion interconnecting only distal ends of the beam portions, and wherein each of the proximal flexures shares a beam portion with two of the distal flexures that are adjacent to each proximal flexure, thereby forming a continuous serpentine pattern along the cage body;

a proximal plug member having a threaded and tapered circumference configured to mate with the threaded and tapered bore of the proximal end of the cage body, the proximal plug member being configured to move along the longitudinal axis relative to the cage body from a first position to a second position such that the plurality of distal flexures move and the circumference of the proximal end of the cage body resiliently expands, and from the second position to the first position such that the circumference of the proximal end resiliently contracts;

a distal plug member having a threaded and tapered circumference configured to mate with the threaded and tapered bore of the distal end of the cage body, the distal plug member being configured to move along the longitudinal axis relative to the cage body from a third position to a fourth position such that the plurality of proximal flexures move and the circumference of the distal end of the cage body resiliently expands, and from the fourth position to the third position such that the circumference of the distal end resiliently contracts;

a first adjustment member rotationally coupled to the proximal plug member such that when the first adjustment member is rotated, the proximal plug member is caused to move along the longitudinal axis; and

a second adjustment member rotationally coupled to the distal plug member such that when the second adjustment member is rotated, the distal plug member is caused to move longitudinally, thereby allowing the proximal and the distal ends of the cage body to be expanded and contracted independent from one another,

wherein the first and the second adjustment members are coaxially nested one within the other and independently rotatable, and

wherein the first and the second adjustment members each have knobs axially spaced but adjacent to one another such that the knobs may alternately be rotated in unison or individually.

14. The expandable medical implant of claim **13**, wherein at least one of the first and the second adjustment members has a keyed end configured to slidably mate and rotationally couple with its associated plug member such that the at least one adjustment member can be removed from the expandable medical implant.

* * * * *

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(12) **United States Patent**
Grotz

(10) **Patent No.: US 9,662,218 B2**
(45) **Date of Patent: May 30, 2017**

(54) **RESILIENT KNEE IMPLANT AND METHODS**

(71) Applicant: **R. Thomas Grotz**, Las Vegas, NV (US)

(72) Inventor: **R. Thomas Grotz**, Las Vegas, NV (US)

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(21) Appl. No.: **14/289,431**

(22) Filed: **May 28, 2014**

(65) **Prior Publication Data**

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Related U.S. Application Data

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(Continued)

(51) **Int. Cl.**
A61F 2/38 (2006.01)
A61B 17/064 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61F 2/3859*** (2013.01); ***A61B 17/0642*** (2013.01); ***A61B 17/562*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC . A61B 17/155; A61B 17/0642; A61B 17/562; A61F 2/38; A61F 2/28; A61F 2/3859
See application file for complete search history.

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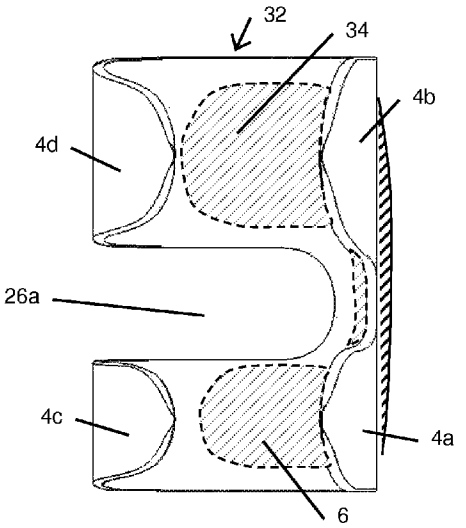
Primary Examiner — Jason-Dennis Stewart
(74) *Attorney, Agent, or Firm* — Shay Glenn LLP

(57) **ABSTRACT**

This disclosure is directed to a resilient interpositional arthroplasty implant for application into a knee joint to pad cartilage defects, cushion a joint, and replace or restore the articular surface, which may preserve joint integrity, reduce pain and improve function. The implant may endure variable joint compressive and shear forces and cyclic loads. The implant may repair, reconstruct, and regenerate joint anatomy, and thereby improve upon joint replacement alternatives. Rather than using periosteal harvesting for cell containment in joint resurfacing, the walls of this invention may capture, distribute and hold living cells until aggregation and hyaline cartilage regrowth occurs. The implant may be deployed into debrided joint spaces, molding and conforming to surrounding structures with sufficient stability to avoid extrusion or dislocation. Appendages of the implant may repair or reconstruct tendons or ligaments, and an interior of the implant that is inflatable may accommodate motions which mimic or approximate normal joint motion.

8 Claims, 7 Drawing Sheets



Related U.S. Application Data

(60) Provisional application No. 61/297,698, filed on Jan. 22, 2010.

(51) **Int. Cl.**

A61B 17/56	(2006.01)
A61L 27/18	(2006.01)
A61L 27/38	(2006.01)
A61L 27/54	(2006.01)
A61F 2/30	(2006.01)

(52) **U.S. Cl.**

CPC ***A61L 27/18*** (2013.01); ***A61L 27/3817*** (2013.01); ***A61L 27/54*** (2013.01); *A61B 2017/561* (2013.01); *A61F 2/38* (2013.01); *A61F 2/3872* (2013.01); *A61F 2002/30563* (2013.01); *A61F 2002/30583* (2013.01); *A61F 2002/30586* (2013.01); *A61F 2002/30677* (2013.01); *A61F 2002/30754* (2013.01); *A61F 2002/3863* (2013.01); *A61L 2300/402* (2013.01); *A61L 2300/404* (2013.01); *A61L 2300/406* (2013.01); *A61L 2300/414* (2013.01); *A61L 2300/416* (2013.01); *A61L 2300/452* (2013.01); *A61L 2300/64* (2013.01)

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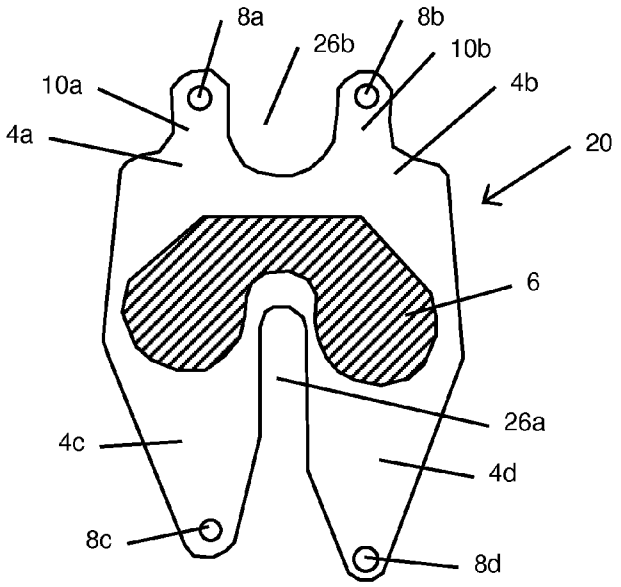


FIG. 1

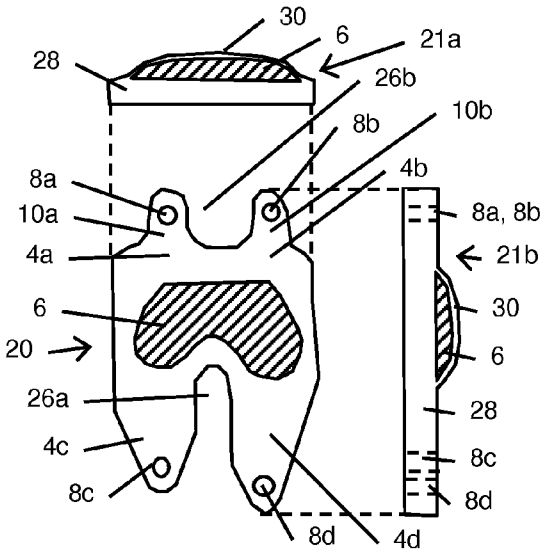


FIG. 2

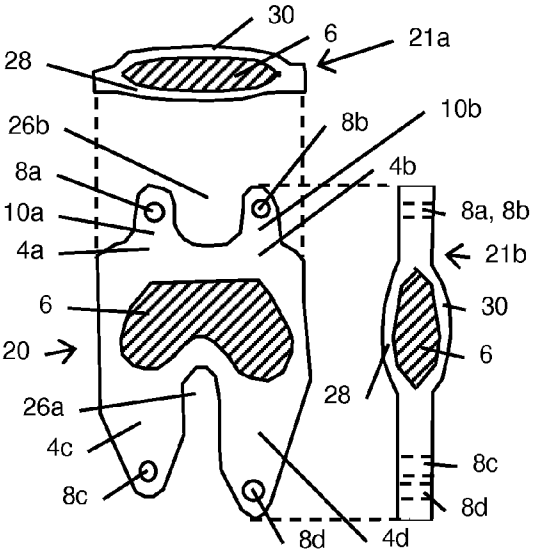


FIG. 3

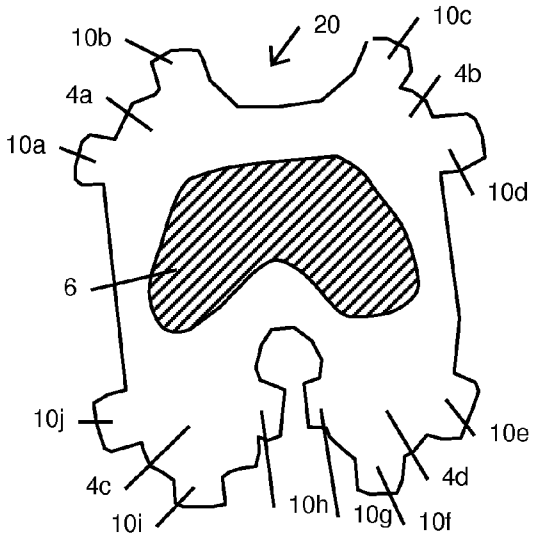


FIG 4A

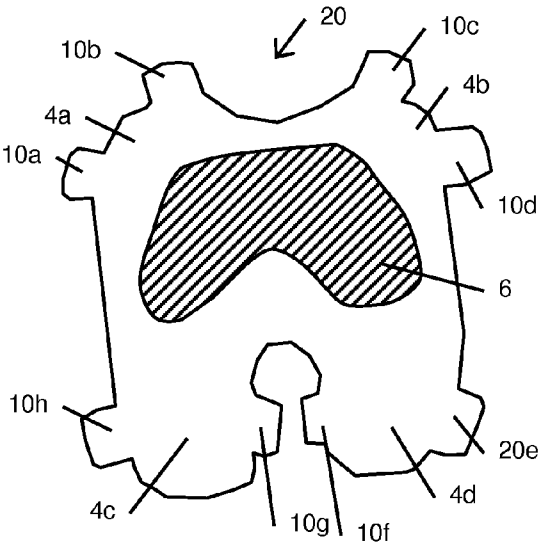


FIG 4B

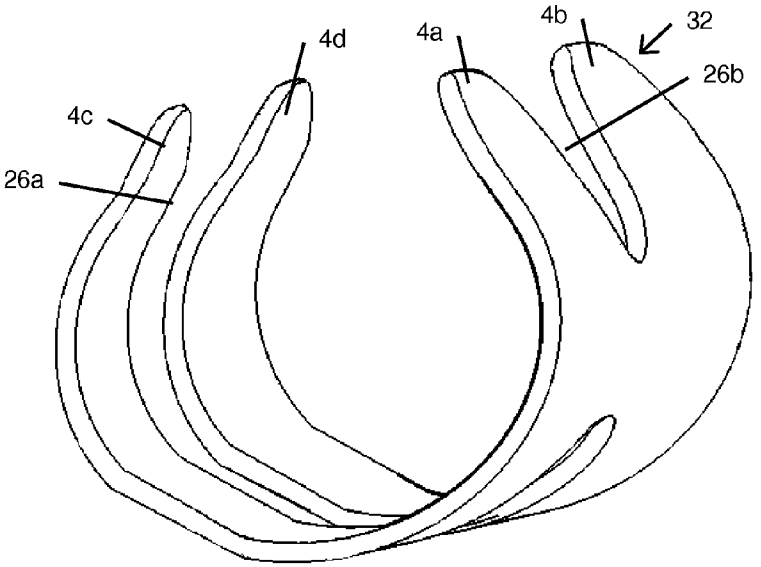


FIG 5

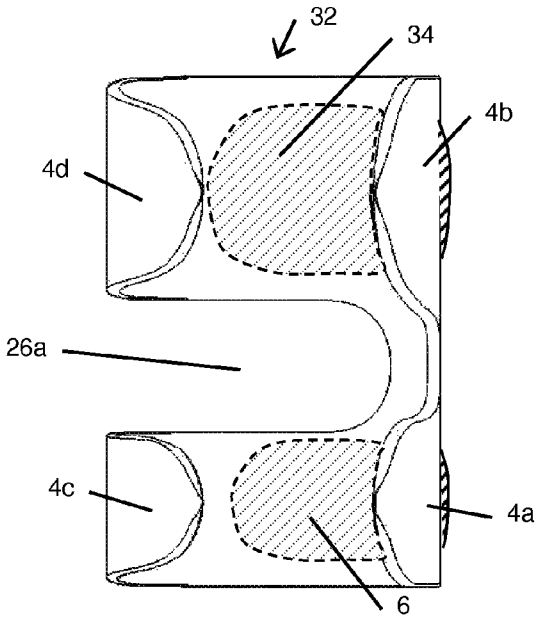


FIG 6A

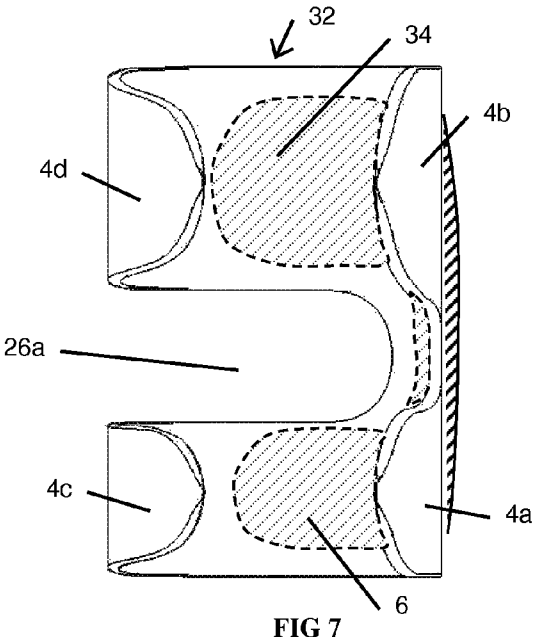


FIG 7

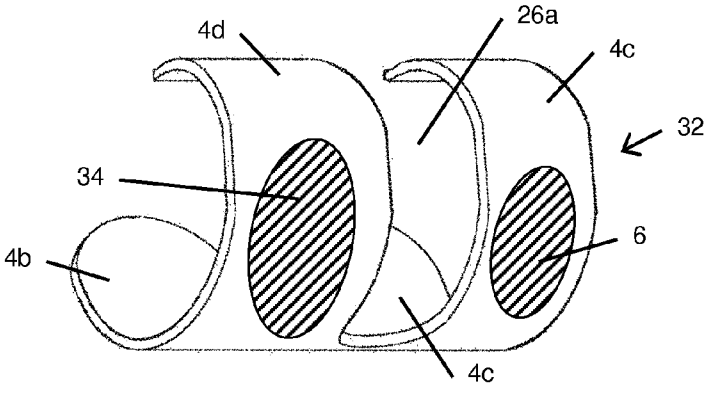


FIG 6B

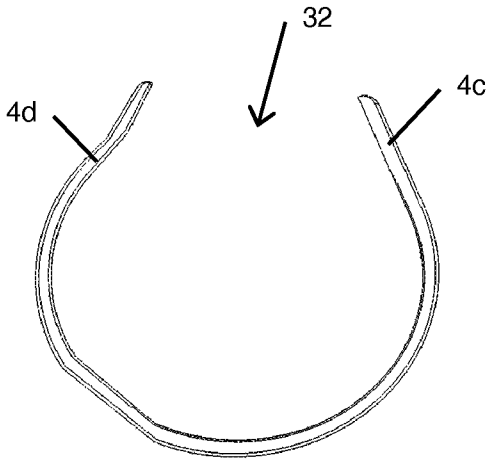


FIG 8

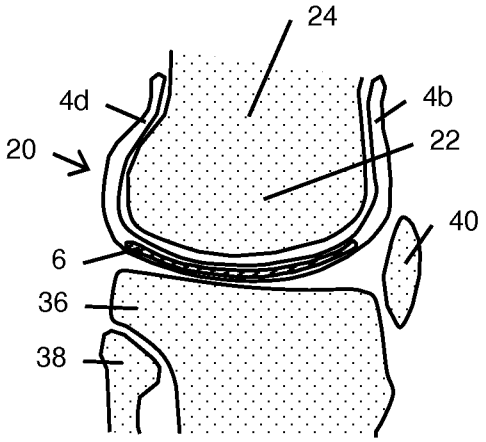


FIG 9A

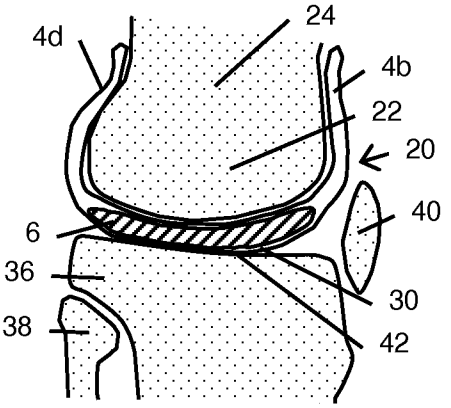


FIG 9B

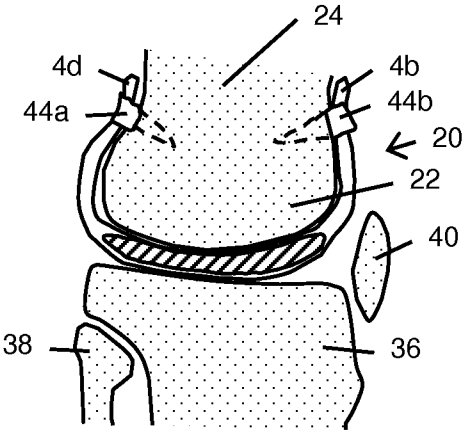


FIG 9C

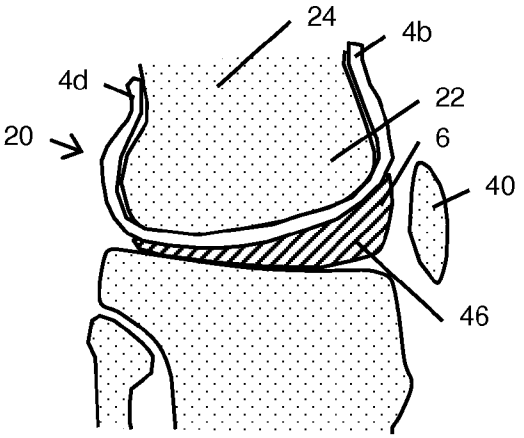


FIG 10A

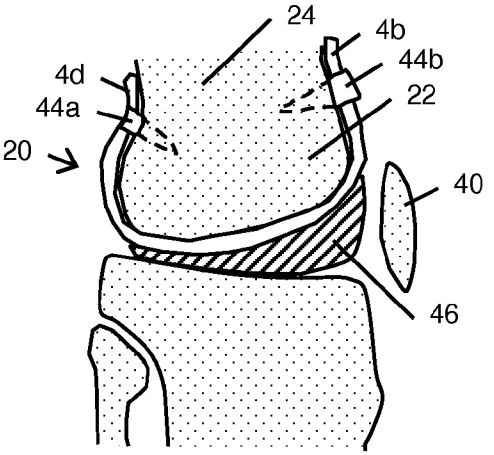


FIG 10B

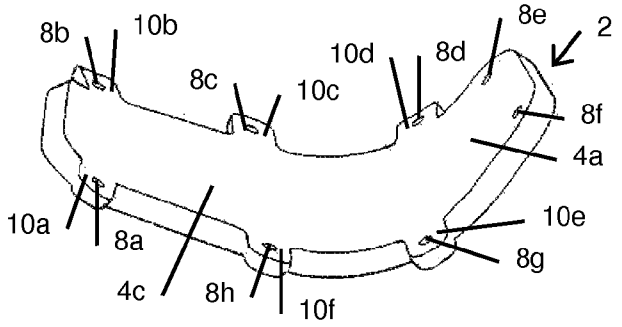


FIG 11A

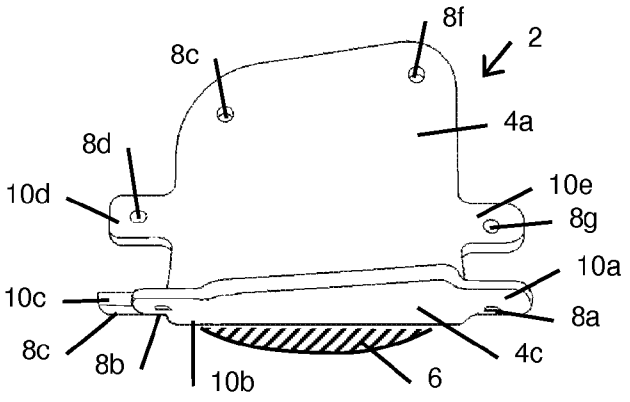


FIG 11B

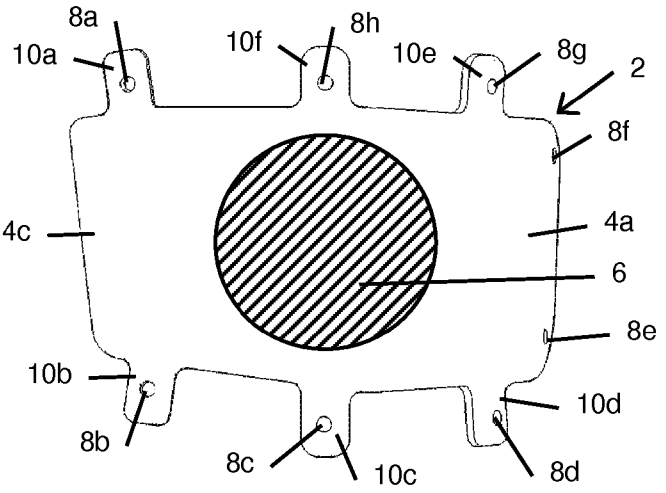


FIG 11C

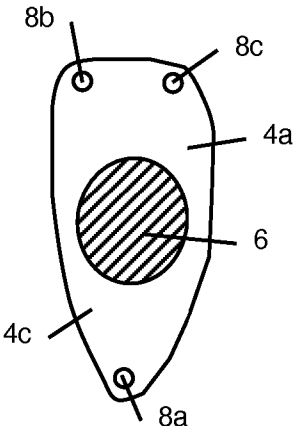
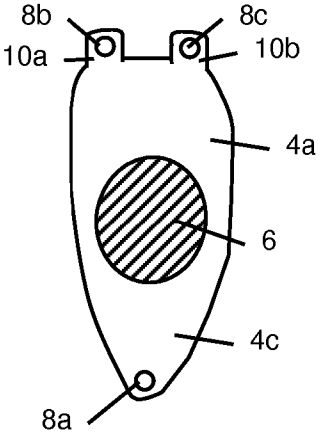


FIG 12A



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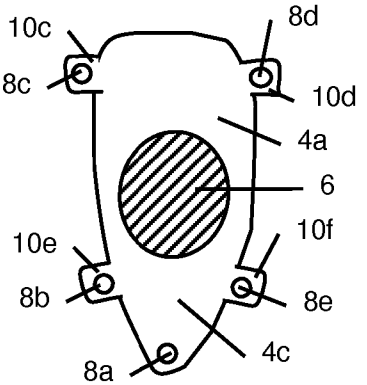

FIG 12C

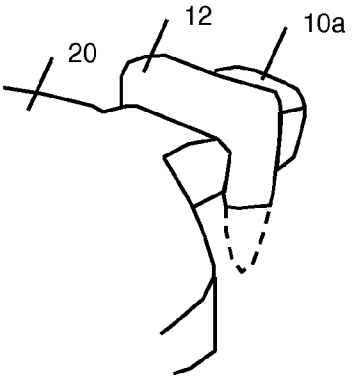

FIG 13A

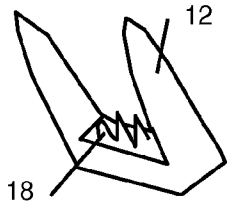

FIG 13B

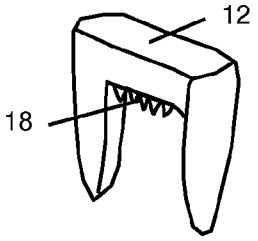

FIG 13C

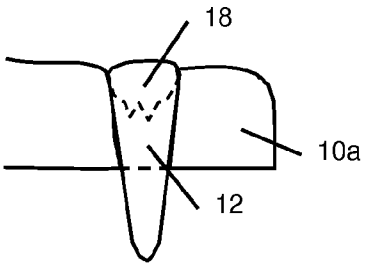

FIG 13D

RESILIENT KNEE IMPLANT AND METHODS

CROSS REFERENCE

This application is a continuation of U.S. patent application Ser. No. 13/574,499, filed on Oct. 8, 2012, now U.S. Pat. No. 8,771,363, which is a U.S. National Phase Entry of PCT Application No. PCT/US2011/021674, filed on Jan. 19, 2011, which claims the benefit of U.S. Provisional Application No. 61/297,698, filed on Jan. 22, 2010; the entire contents of each of the above listed patents and applications are incorporated herein by reference.

BACKGROUND OF THE INVENTION

This invention relates to arthroplasty, and more particularly, to an implant for use in arthroplasty when hyaline articular cartilage is damaged, it breaks down and joint space is lost. Inflammatory enzymes such as from the Cox-1, Cox-2 and/or 5-Lox systems, are released and loose bodies form adding to the degradation of joint function. Such joint damage is conventionally treated by physical therapy, analgesics, pain medication and injections. When these treatments fail, the traditionally accepted treatment option is arthroplasty implantation or replacing the joint with an artificial joint construct. Current arthroplasty techniques typically use "plastic and metal" implants that are rigid and which ultimately fail due to loosening or infection. Conventional materials for the artificial joint components include chrome-cobalt-molybdenum alloy (metal) and high molecular weight polyethylene (plastic). Each is often fixed by a cement-like mixture of methyl methacrylate to the ends of the bones that define the joint that is the subject of the arthroplasty, or coated with a surface that enables bone ingrowth. Replacement surgeries are known to fail in a number of years.

Conditions requiring arthroplasty include traumatic arthritis, osteoarthritis, rheumatoid arthritis, osteonecrosis, and failed surgical procedures.

SUMMARY OF THE INVENTION

The present invention is directed to an orthopedic implant configured for deployment between opposing members of a joint structure that addresses many of the shortcomings of prior artificial joints. The arthroplasty implants embodying features of the invention are configured to preserve joint motions while removing the pain and dysfunction following the development of arthritis or joint injury. The arthroplasty implant in accordance with the present invention achieves improved physiologic motion and shock absorption during gait and acts as a resilient spacer between moving bones during limb movement. The combined characteristics of the implant include anatomic design symmetry, balanced rigidity with variable attachment connections to at least one of adjacent normal structures, and durability which addresses and meets the needs for repair or reconstruction thus far missed in the prior art. The implant should be secured to at least one of the bones of the joint structure.

Provided herein is an implant configured for deployment between a femur and a tibia of a knee joint, the implant comprising a balloon comprising a first portion that is configured to engage a medial condyle and a lateral condyle of the femur of the knee joint, a second portion that is configured to engage the tibia of the knee joint, a side portion connecting the first portion and the second portion, in which the side portion facilitates relative motion between the first portion and the second portion, and an interior that is optionally inflatable with a first inflation medium; and a first appendage configured to couple the balloon to the femur of the knee joint.

In some embodiments, the implant comprises at least one attachment element in the intercondylar notch. In some embodiments, the implant comprises at least one attachment element superiorly at the distal end of the femur anteriorly. In some embodiments, the implant comprises at least one posterior reign configured to cinch up the implant from inside a posterior intercondylar notch toward a connection site around the femur. In some embodiments, the implant comprises at least one suture-like lanyard configured to cinch up the implant from inside a posterior intercondylar notch toward a connection site around the femur.

In some embodiments, the first portion comprises a first wall, the second portion comprises a second wall, and the side portion comprises a side wall.

In some embodiments, the implant comprises an inflation port in communication with the interior of the balloon for inflation of the interior of the balloon with the first inflation medium. In some embodiments, the interior comprises a plurality of inflatable chambers. In some embodiments, a first chamber of the plurality of individually inflatable chambers is adapted to be inflated with the first inflation medium, and a second chamber of the plurality of individually inflatable chambers is adapted to be inflated with a second inflation medium. In some embodiments, the first inflation medium imparts at least one of rigidity in the implant and cushion in the implant.

In some embodiments, the implant comprises a second appendage coupling the balloon to at least one of: the femur of the joint and the tibia of the joint.

Provided herein is an implant configured for deployment between a femur and a tibia of a knee joint, the implant comprising a balloon comprising a first portion that is configured to engage at least one condyle of the femur of the knee joint, a second portion that is configured to engage the tibia of the knee joint, a side portion connecting the first portion and the second portion, in which the side portion facilitates relative motion between the first portion and the second portion, and an interior that is optionally inflatable with a first inflation medium; and a first appendage configured to couple the balloon to the femur of the knee joint.

In some embodiments, the at least one condyle is the medial condyle. In some embodiments, the at least one condyle is the lateral condyle.

In some embodiments, the balloon is at least one of: at most about 1.5 cm in diameter, at most about 1.75 cm in diameter, at most about 2 cm in diameter, at most about 2.25 cm in diameter, at most about 2.5 cm in diameter, at most about 2.75 cm in diameter, at most about 3 cm in diameter, at most about 3.25 cm in diameter, at most about 3.5 cm in diameter, at most about 3.75 cm in diameter, at most about 4 cm in diameter, at most about 4.25 cm in diameter, at most about 4.5 cm in diameter, at most about 4.75 cm in diameter, at most about 5 cm in diameter, at most about 5.25 cm in diameter, at most about 5.5 cm in diameter, at most about 5.75 cm in diameter, at most about 6 cm in diameter, at most about 6.25 cm in diameter, at most about 6.5 cm in diameter, at most about 6.75 cm in diameter, at most about 7 cm in diameter, at most about 7.25 cm in diameter, at most about 7.5 cm in diameter, at most about 7.75 cm in diameter, at most about 8 cm in diameter, at most about 3 cm in length along the longest length of the balloon, at most about 3.25 cm in length along the longest length of the balloon, at most

about 3.5 cm in length along the longest length of the balloon, at most about 3.75 cm in length along the longest length of the balloon, at most about 4 cm in length along the longest length of the balloon, at most about 4.25 cm in length along the longest length of the balloon, at most about 4.5 cm in length along the longest length of the balloon, at most about 4.75 cm in length along the longest length of the balloon, at most about 5 cm in length along the longest length of the balloon, at most about 5.25 cm in length along the longest length of the balloon, at most about 5.5 cm in length along the longest length of the balloon, at most about 5.75 cm in length along the longest length of the balloon, at most about 6 cm in length along the longest length of the balloon, 6.25 cm in length along the longest length of the balloon, at most about 6.5 cm in length along the longest length of the balloon, at most about 6.75 cm in length along the longest length of the balloon, at most about 7 cm in length along the longest length of the balloon, at most about 7.25 cm in length along the longest length of the balloon, at most about 7.5 cm in length along the longest length of the balloon, at most about 7.75 cm in length along the longest length of the balloon, and at most about 8 cm in length along the longest length of the balloon.

In some embodiments, the first portion comprises a first wall, the second portion comprises a second wall, and the side portion comprises a side wall.

In some embodiments, the implant comprises an inflation port in communication with the interior of the balloon for inflation of the interior of the balloon with the first inflation medium. In some embodiments, the interior comprises a plurality of inflatable chambers. In some embodiments, a first chamber of the plurality of individually inflatable chambers is adapted to be inflated with the first inflation medium, and a second chamber of the plurality of individually inflatable chambers is adapted to be inflated with a second inflation medium. In some embodiments, the first inflation medium imparts at least one of rigidity in the implant and cushion in the implant.

In some embodiments, the implant comprises a second appendage coupling the balloon to at least one of: the femur of the joint and the tibia of the joint. In some embodiments, the implant comprises at least one attachment element in the intercondylar notch. The In some embodiments, the implant comprises at least one attachment element superiorly at the distal end of the femur anteriorly. In some embodiments, the implant comprises at least one posterior reign configured to cinch up the implant from inside a posterior intercondylar notch toward a connection site around the femur. In some embodiments, the implant comprises at least one suture-like lanyard configured to cinch up the implant from inside a posterior intercondylar notch toward a connection site around the femur.

Provided herein is an implant configured for patch a defect of a bone of a knee joint, the implant comprising a balloon configured to engage the defect of the bone of the knee joint and comprising an interior that is optionally inflatable with a first inflation medium; and a first appendage configured to couple the balloon to the bone of the knee joint.

In some embodiments, at least one of the appendage and the balloon are configured to replace cartilage.

In some embodiments, the balloon is at least one of: at most about 0.5 cm in diameter, at most about 0.75 cm in diameter, at most about 1 cm in diameter, at most about 1.25 cm in diameter, at most about 1.5 cm in diameter, at most about 1.75 cm in diameter, at most about 2 cm in diameter, at most about 2.25 cm in diameter, at most about 2.5 cm in diameter, at most about 2.75 cm in diameter, at most about 3 cm in diameter, at most about 3.25 cm in diameter, at most about 3.5 cm in diameter, at most about 3.75 cm in diameter, at most about 0.5 cm in length along the longest length of the balloon, at most about 0.75 cm in length along the longest length of the balloon, at most about 1 cm in length along the longest length of the balloon, at most about 1.25 cm in length along the longest length of the balloon, at most about 1.5 cm in length along the longest length of the balloon, at most about 1.75 cm in length along the longest length of the balloon, at most about 2 cm in length along the longest length of the balloon, at most about 2.25 cm in length along the longest length of the balloon, at most about 2.5 cm in length along the longest length of the balloon, at most about 2.75 cm in length along the longest length of the balloon, at most about 3 cm in length along the longest length of the balloon, at most about 3.25 cm in length along the longest length of the balloon, at most about 3.5 cm in length along the longest length of the balloon, at most about 3.75 cm in length along the longest length of the balloon, and at most about 4 cm in length along the longest length of the balloon.

In some embodiments, the size of the balloon size is pre-set. In some embodiments, the balloon comprises multiple chambers which may be selectively inflated. In some embodiments, the balloon comprises multiple chambers which may be selectively deflated. In some embodiments, the balloon comprises multiple chambers which may be selectively inflated in situ to fill the defect. In some embodiments, the balloon comprises multiple chambers which may be selectively inflated just prior to implantation.

In some embodiments, the balloon or a chamber thereof may be secondarily inflated, deflated, or a combination thereof in situ.

In some embodiments, the implant comprises an ingrowth matrix on at least a portion of the implant adjacent the femur. In some embodiments, the ingrowth matrix comprises living chondrocytes. In some embodiments, the implant is configured to release the chondrocytes over time. In some embodiments, the implant comprises a bioabsorbable polymer configured to release the chondrocytes over time. In some embodiments, the implant comprises a polymer configured to release the chondrocytes over time, wherein the polymer is not bioabsorbable. In some embodiments, the ingrowth matrix comprises at least one of: autologous cells, allograph cells, and xenograph cells to restore an articular surface of the femur. In some embodiments, the ingrowth matrix comprises at least one of: autologous cells, allograph cells, and xenograph cells to repair an articular surface of the femur.

In some embodiments, the implant comprises couplers that couple the appendage to the femur. In some embodiments, the coupler is bioabsorbable. In some embodiments, the coupler is at least one of: a screw, a washer, a suture, a suture anchor, a rivot, a staple, a staple having teeth, a stabilizer, a glue, a hook, a wire, a string, a lasso, a lanyard, a spike, and combinations thereof. The implant may also and/or alternatively be attached via bone ingrowth.

In some embodiments, the implant comprises a phamacologic agent. In some embodiments, the pharmacologic agent is on a surface of the implant adjacent the femur. In some embodiments, the pharmacologic agent is released from the implant over time. In some embodiments, the pharmacologic agent is released from within the implant over time. In some embodiments, the pharmacologic agent is released from within the balloon over time.

In some embodiments, the inflation medium is compressible. In some embodiments, the inflation medium comprises

a viscolubricant. In some embodiments, the inflation medium comprises an NSAID. In some embodiments, the inflation medium comprises chondrocytes.

In some embodiments, at least a portion of the implant is configured to anneal to a periphery of a cartilage defect.

In some embodiments, the implant comprises vacuoles of pharmacologic substances. In some embodiments, the vacuoles may be on a bone-engaging portion of the implant. In some embodiments, the implant comprises bubbles comprising an active substance such as a pharmacologic substance or other active agent. In some embodiments, the active agent comprises at least one of: stem cells, growth factors, antibiotics, and viscolubricants. In some embodiments, the active agent comprises iatrigenically gene mutated cells.

In some embodiments, the implant comprises enzyme absorptive microscopic sponges that could be sucked out or evacuated at or around the time of implant delivery to the joint.

In some embodiments, the implant comprises spaces filled with an active substance such as a pharmacologic substance or other active substance. In some embodiments, the implant is configured to deliver by dissolution of the implant material In some embodiments, the implant is configured to deliver by release through pores of the implant. In some embodiments, the implant is configured to deliver by fracture of a vacuole by a catalyst such as ultrasound or pressure or other fracturing catalyst.

In some embodiments, the implant is configured to at least one of: pad cartilage, cushion the joint, deliver a pharmacologic substance, remove noxious enzymes, debride upon implantation, debride the joint following implantation, deliver a therapeutic substance, deliver a biologic substance, and deliver living stem cells. In some embodiments, the implant is configured to deliver a chemotherapeutic agent to a bone or other surrounding tissues. In some embodiments, the implant is configured to deliver an anti-infectious medication to a bone or other surrounding tissues. In some embodiments, the implant is configured to deliver at least one of an antibiotic, antifungals, and analgesics agent.

In some embodiments, the implant is configured to be selectively inflated to realign limbs.

Provided herein is a method comprising: implanting a knee implant as described herein into a subject, wherein the implant reverses arthritis in the subject.

Provided herein is a method comprising: implanting a knee implant as described herein into a knee joint of a subject and treating a component of the knee joint of the subject with at least one of an allograph tissue, an autograph tissue, and an xenograph tissue. In some embodiments, the implanting step is at least one of: prior to the treating step, simultaneous with the treating step, and following the treating step.

Provided herein is a method comprising: implanting a knee implant as described herein into a subject, wherein the implant at least one of: restores joint function and controls arthopathies. In some embodiments, the implanting spares existing anatomy.

Provided herein is a method comprising: debriding a femur condyle of a knee joint of a subject, and implanting a knee implant as described herein into the knee joint of the subject, whereby the implant is configured to anneal to the cartilage of the subject. In some embodiments, the debriding is achieved by steam application.

Provided herein is a method comprising implanting a knee implant as described herein into a joint previously treated with a joint replacement. In some embodiments, the method comprises removing the joint replacement prior to implanting the knee implant. In some embodiments, the method comprises clearing infectious matter from the joint and/or surrounding tissues. In some embodiments, the method comprises implanting a second implant of any implant described herein following removing the implant previously implanted in the joint. In some embodiments, the method comprises replacing the joint of the subject following removing the implant previously implanted in the joint. In some embodiments, the method comprises debriding the bone of the joint, and implanting an implant of any implant described herein. In some embodiments, the method comprises repeating the debriding and implanting steps.

These and other advantages of the invention will become more apparent from the following detailed description and the attached exemplary drawings.

INCORPORATION BY REFERENCE

All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

FIG. **1** depicts an embodiment of the knee implant having appendages including holes and tabs extending from a balloon and including slots to accommodate ligaments of the knee joint.

FIG. **2** depicts an embodiment of the knee implant having appendages including holes and tabs extending from a balloon and including slots to accommodate ligaments of the knee joint as well as side views of the same knee implant.

FIG. **3** depicts an embodiment of the knee implant having appendages including holes and tabs extending from a balloon and including slots to accommodate ligaments of the knee joint as well as side views of the same knee implant.

FIG. **4**A depicts an embodiment of the knee implant having appendages including ten tabs extending from a balloon and including a slot to accommodate components of the knee joint.

FIG. **4**B depicts an embodiment of the knee implant having appendages including eight tabs extending from a balloon and including a slot to accommodate components of the knee joint.

FIG. **5** depicts an embodiment of the knee implant curved to simulate curvature about the condyles of a femur, the implant having appendages extending from an uninflated balloon (not shown) and including slots to accommodate ligaments of the knee joint.

FIG. **6**A depicts a top-down view of an embodiment of the knee implant curved to simulate curvature about the condyles of a femur, the implant having appendages extending from two inflated balloons and including slots to accommodate components of the knee joint.

FIG. **6**B depicts a bottom-up view of an embodiment of the knee implant curved to simulate curvature about the condyles of a femur, the implant having appendages extend-

ing from two inflated balloons and including slots to accommodate components of the knee joint.

FIG. **7** depicts a top-down view of an embodiment of the knee implant curved to simulate curvature about the condyles of a femur, the implant having appendages extending from an inflated balloon and including slots to accommodate components of the knee joint.

FIG. **8** depicts a side view of an embodiment of the knee implant curved to simulate curvature about at least one condyle of a femur, the implant having appendages extending from an uninflated balloon (not shown).

FIG. **9**A depicts a side view of an embodiment of the knee implant curved about at least one condyle of a femur, the implant having appendages extending from an uninflated or minimally inflated balloon.

FIG. **9**B depicts a side view of an embodiment of the knee implant curved about at least one condyle of a femur, the implant having appendages extending from an inflated balloon.

FIG. **9**C depicts a side view of an embodiment of the knee implant curved about at least one condyle of a femur, the implant having appendages extending from an inflated balloon and having staples or screws coupling the appendages to the femur.

FIG. **10**A depicts a side view of an embodiment of the knee implant curved about at least one condyle of a femur, the implant having appendages extending from an inflated balloon and showing the inflation medium moved anteriorly toward the patella when the knee joint is flexed. FIG. **10**B depicts a side view of an embodiment of the knee implant curved about at least one condyle of a femur, the implant having appendages extending from an inflated balloon and having staples or screws coupling the appendages to the femur and showing the inflation medium moved anteriorly toward the patella when the knee joint is flexed.

FIG. **11**A depicts an embodiment of the unicompartment knee implant curved to simulate curvature about one condyle of a femur, the implant having appendages extending from an uninflated balloon (not shown) and including tabs and holes which may be used with couplers to couple the implant to the femur of the knee joint.

FIG. **11**B depicts an embodiment of the unicompartment knee implant curved to simulate curvature about one condyle of a femur, the implant having appendages extending from an inflated balloon and including tabs and holes which may be used with couplers to couple the implant to the femur of the knee joint.

FIG. **11**C depicts a bottom-up view of an embodiment of the unicompartment knee implant curved to simulate curvature about one condyle of a femur, the implant having appendages extending from an inflated balloon and including tabs and holes which may be used with couplers to couple the implant to the femur of the knee joint.

FIG. **12**A depicts a bottom-up view of an embodiment of the unicompartment knee implant or patch implant, the implant having appendages, extending from a balloon and including holes, which may be used with couplers (not shown) to couple the implant to the femur of the knee joint.

FIG. **12**B depicts a bottom-up view of an embodiment of the unicompartment knee implant or patch implant, the implant having appendages, extending from a balloon and including tabs and a hole which may be used with couplers (not shown) to couple the implant to the femur of the knee joint.

FIG. **12**C depicts a bottom-up view of an embodiment of the unicompartment knee implant or patch implant, the implant having appendages, extending from a balloon and including tabs and a hole which may be used with couplers (not shown) to couple the implant to the femur of the knee joint.

FIGS. **13**A-**13**D depict multiple views of a staple adapted to couple an implant to a bone of the joint.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is directed to arthroplasty implants and procedures for a knee. Knee interpositional arthroplasty can replace existing total joint metal/plastic technology. It intends to fill the gap (literally in some embodiments of the implant) in cases where arthroscopic debridement fails to provide cure, since we can only 'polish arthritis' and 'clean up the joints' to date. The polymer medically inflatable implants may physiologically restore joint function. Padding is provided where cartilage is damaged, cushioning to both the femoral tibial and patella femoral joints when narrowed or pathologic. The implant in some embodiments is adapted to deliver cells, autologous (from the patient), allograph (from another member of the same species) or xenograph (from another species,) that restore articular surfaces. Since cartilage is an immunologically privileged tissue, the antigens are buried in the cartilage matrix and antibodies do not reject the refurbished surface coating.

The gap (or gaps) filled by the balloon or balloons of the implant will provide compliance between opposing joint surfaces (the femoral condyle or condyles and tibial plateau). The femur may have some portion (of not all) of the retropatellar rounded facet "V" shape of hyaline, normally about 5 mm thick, or it may not have such hyaline when the implant is inserted. The tibial plateau may have some portion of meniscal fibrocartilages, including all of said fibrocartilages, none of said fibrocartilages, or some portion thereof. When the knee is extended (straight) the implant buffers the femoro-tibial joint. When the knee is flexed, the implant balloon apposition is more between the trochlear groove portion of the anterior distal femur (groove between the condyles on the 'front of the knee') and the patella.

The knee anatomy is unique to other joint anatomies and thus has a unique set of challenges that are addressed by the implant embodiments described herein. For example, the knee is not a ball and socket joint like a hip; it is a combination of two joints—the femoral-tibial joint and the patellar-femoral joint. The bones of the knee have facets and irregularities that must be accommodated by a conformable implant directed to the particular shapes of the bones without impeding the joints' functions and movements, and/or which minimizes impedence to such function and movement. Not only do the joints of the knee work together to allow extension and flexion of the knee, but the knee is also designed to allow rotational movement in a screw-like manner. That is, as the tibia is twisted relative to the femur, the joints are uniquely designed to allow this twist, but to limit the twist as well. Furthermore, the knee joints are able to withstand forces that vary depending on the particular movement of the individual, not only in force strength, but in direction as well. Thus, the implants as described herein are uniquely designed to account for these factors and result in a knee having preserved natural tissues as well as preserved function and movement as compared to typical arthroplasty procedures (such as partial or full knee replacements).

As described herein, embodiments of the implant conform to the patient's own joint features not only in that it can be pre-molded and/or adapted to couple to the contours of the

patient's bone (condyle, etc), but in that it has a balloon having an inflation medium that is conformable to the joint anatomy and allow freedom of joint movement much like natural joint while preserving the joint and bone natural tissues as much as possible. With the ability to fill various chambers of the balloon with varying materials, and to add rigid and/or semi-rigid pieces to the implant, the implant can additionally have leveling capabilities and alignment capabilities.

Diagnoses:

Patients may complain of pain and knee joint dysfunction signaled by locking, clicking, or giving way. Knees may be swollen, malaligned or show crepitus (palpable crunching on movement.) Instability of ligaments whether anterior/posterior cruciates, or medial/lateral conlaterals, are treated by techniques separate for those entities via allowance for healing (as for collaterals) or via cruciate repair or reconstruction.

Indications for use of implants provided herein may be those patients recognizing greater than or equal to 2 Sq cm of 3-4+/4 traumatic arthritis (ala Carticel). In such cases, the cartilage defect is often precisely locally symptomatic, with point tenderness, clicking if a loose cartilage flap exists, and may be visible on MRI and/or arthroscopic inspection and/or through palpation. The implants used herein may additionally and/or alternatively be appropriate when existed techniques such as 'picking', K wire drills, and/or allograph implants fail.

Patients with knee problems typically complain of pain and dysfunction. Pathognomonic symptoms for meniscal tearing include locking, clicking, giving way from wear or twisting the knee. Aching diffusely may arise from arthritis or synovitis; anterior knee pain is generally patella-femoral, increased with stair use due to magnified body weight forces. Diagnosis should be accurate as distinguished from pain through the knee actually arising in the back caused by L4 nerve root irritation. Physical Exam findings of pathologic knees include observed swelling, redness, or deformity. Palpation often aids focus on which compartments are involved. The patella inhibition test position connotes retropatellar pathology, and often tracking problems that warrant soft tissue or bony correct. Improved limb alignment will increase benefits, and can in part accrue from selective inflation of embodiments of the implants provided herein. X-rays of the knee are best evaluated in weight bearing views, and should be coupled with other data including MRI or CT. Relative compartment narrowing suggests cartilage degradation. Once an embodiment of an implant described herein has been successfully implanted and the knee adequately rehabilitated, the appearance of a knee with such implant should resemble a normal joint X-ray. Knee distension is from saline and/or air insufflation. Knee implant patients will benefit from tailored rehab programs, cautious weight bearing, early motion, and potential the use of constant passive motion machine regimens.

General Features

Implant Aspects

Provided herein is a resilient implant for implantation into knee joints to act as a cushion allowing for renewed joint motion. The implant may endure variable knee joint forces and cyclic loads while reducing pain and improving function after injury or disease to repair, reconstruct, and regenerate joint integrity. The implant may be deployed in a prepared debrided knee joint space, secured to at least one of the knee joint bones and expanded in the space, molding to surrounding structures with sufficient stability to avoid extrusion or dislocation. The implant may have has opposing walls that move in varied directions, and an inner space filled with suitable filler to accommodate motions which mimic or approximate normal knee joint motion. The implant may pad the damaged joint surfaces, restores cushioning immediately and may be employed to restore cartilage to normal by delivering regenerative cells.

Provided herein is a resilient interpositional arthroplasty implant for application into knee joints to pad cartilage defects, cushion joints, and replace or restore the articular surface, preserving joint integrity, reducing pain and improving function. The implant may endure variable knee joint compressive and shear forces, and millions of cyclic loads, after injury or disease requires intervention. The implant may repair, reconstruct, and regenerate knee joint anatomy in a minimally morbid fashion, with physiologic solutions that improve upon the rigid existing joint replacement alternatives of plastic and metal. In cases where cells have been used for joint resurfacing requiring massive periosteal harvesting for containment, the polymer walls of some embodiments of the implant can capture, distribute and hold living cells until aggregation and hyaline cartilage regrowth occurs. The implant may be deployed into a prepared debrided knee joint space, molding and conforming to surrounding structures with sufficient stability to avoid extrusion or dislocation. Appendages (or tabs) of the implant may serve to repair or reconstruct tendons or ligaments. The implant may have opposing walls that move in varied directions, and an inner space, singular or divided, filled with suitable gas, liquid, and/or complex polymer layers as force-absorbing mobile constituents, such than robust valid and reliable joint motion is enabled.

Provided herein is a resilient orthopedic implant configured for deployment between a femur and at least one second bone of a joint. The second bone may be a tibia. The second bone may be a patella. The implant further comprises a balloon comprising a first portion that is configured to engage the femur, a second portion that is configured to engage the second bone of the joint, a side portion connecting the first portion and the second portion, in which the side portion facilitates relative motion between the first portion and the second portion, and an interior that is optionally inflatable with a first inflation medium; and a first appendage configured to couple the balloon to the femur. The terms "balloon" and "bladder" may be used interchangeably throughout this disclosure to describe an implant having the features described herein.

In some embodiments, at least two of the first portion, the second portion, and the side portion are contiguous. In some embodiments, the first portion comprises a first wall, the second portion comprises a second wall, and the side portion comprises a side wall. As used herein, each of the terms the "first portion", the "second portion", and the "side portion" is used to describe a part of the balloon, and may not be separate parts in some embodiments. Rather, in some embodiments, each is named in order to indicate the general geometry and location of each portion relative to the other of the portions and/or relative to bones and/or ligaments and/or tendons of the joint. Likewise, as used herein, each of the terms the "first wall", the "second wall", and the "side wall" is used to describe a part of the balloon, and may not be separate parts of the balloon in some embodiments. Rather, in some embodiments, each of the walls is named in order to indicate the general geometry and location of each portion relative to the other of the portions and/or relative to bones and/or ligaments and/or tendons of the joint. In some embodiments, at least two of first wall, the second wall, and the side wall are contiguous. Nevertheless, each of the walls

may, in some embodiments, be separate parts of the implant that are joined to form the implant. Likewise, each of the portions may, indeed, in some embodiments, be separate parts of the implant that are joined to form the implant.

In some embodiments, the first portion is a term used interchangeably with the first wall. In some embodiments, the second portion is a term used interchangeably with the second wall. In some embodiments, the side portion is a term used interchangeably with the side wall. In some embodiments, a wall (whether a first wall, a second wall, and/or a side wall) of the implant may comprise a plurality of layers. The wall may comprise multiple materials to impart physical and/or therapeutic characteristics to the wall.

In some embodiments, the implant comprises a second appendage coupling the balloon to the first bone of the joint. In some embodiments, the implant comprises a second appendage coupling the balloon to at least one second bone of the joint. In some embodiments, the implant comprises a second appendage configured to couple at least one of the first portion, the second portion, and the side portion to at least one of the first bone and at least one second bone of the joint. In some embodiments, the first appendage and the second appendage are configured to provide ligamentary-like support to the first bone and the at least one second bone of the joint. In some embodiments, the first appendage and the second appendage are configured to provide ligamentary-like support to the joint. In some embodiments, the first appendage and the second appendage are configured to provide tendon-like support to the first bone and the at least one second bone of the joint. In some embodiments, the first appendage and the second appendage are configured to provide tendon-like support to the joint.

In some embodiments, the implant comprises an inflation port in communication with the interior of the balloon for inflation of the interior of the balloon with the first inflation medium. In some embodiments, the balloon is punctured to inflate the interior of the balloon with the first inflation medium. In some embodiments, the balloon is self-sealing. In some embodiments, the balloon is self-sealing upon inflation of the interior of the balloon with the first inflation medium. In some embodiments, the implant comprises a seal capable of closing the interior of the balloon.

In some embodiments, the interior comprises a plurality of inflatable chambers. In some embodiments, the interior comprises a plurality of individually inflatable chambers. In some embodiments, a first chamber of the plurality of individually inflatable chambers is adapted to be inflated with the first inflation medium, and a second chamber of the plurality of individually inflatable chambers is adapted to be inflated with a second inflation medium.

In some embodiments, the interior comprises a honeycomb structure. In some embodiments, the interior comprises a mesh structure. In some embodiments, the interior comprises a sponge structure.

In many embodiments the implant (or a portion thereof, such as the balloon or balloons) is a weight bearing spacer that will allow joint motions to approach normal, whether filling the space left by an entirely collapsed joint bone or the space of ablated cartilage proximate surfaces diffusely as in osteoarthritis or succinctly as in osteonecrotic defects or localized trauma. The walls of the implant may be used as a membrane for holding living cells in proximity of the osteochondral defect long enough for the cells to attach (e.g. 24 hours) or to deeply adhere (up to 28 days) or return to normal (up to one year). Weight bearing will be expected to increase as distal lower extremity joints are treated.

Movement (whether linear or curvilinear) between the first and second walls of the implant (i.e. of the balloon) as a result of movement of the femur and the tibia is illustrated in the comparison between FIGS. **9**B and **10**A, or in the comparison between FIGS. **9**C and **10**B. In some embodiments, the implant may comprise a balloon that is configured to allow a wall of the implant rolling upon another wall (or the same wall) of the implant (e.g. the side wall rolling upon the first wall, the first wall rolling upon the second wall, the second wall rolling upon the first wall, the first wall rolling upon the side wall, the second wall rolling upon the side wall, the side wall rolling upon the second wall, the first wall rolling upon the first wall, the second wall rolling upon the second wall, and/or the side wall rolling upon the side wall). In some embodiments, the implant may comprise a balloon that is configured to allow a portion of the implant rolling upon another portion (or the same portion) of the implant (for non-limiting example, the side wall rolling upon an appendage, the first wall rolling upon an appendage, and/or the second wall rolling upon an appendage). In some embodiments, the implant may comprise a balloon that is configured to allow movement of a portion of the implant rolling upon cartilage. While not shown in the drawings, there may be slippage between the a portion of the implant (whether an appendage, a wall, or some other portion of the implant) and a joint component (whether a bone, ligament, tendon or other tissue). This slippage may be in addition to wall movements within the implant per se to provide desired joint movements. While not shown in the drawings, there may be slippage between the second bone (for example, the tibia) and the second wall in addition to wall movements within the implant per se to provide desired joint movements. The appendage (or appendages) is (are) designed to secure the implant to the knee joint structure so as to avoid dislocation of the implant. Movement of the joint with the implant in place will be a shared function of both the moving opposing walls of the implant but also a function of the movement of the wall which may be less attached to the joint members. There may be slight movement between the appendage, first wall and the femur. The walls of the balloon may compress and/or stretch to accommodate bone interface movement. Material choices, material dimensions, and implant dimensions, placement and/or coupling may be chosen to allow for the desired amount of compression, stretching relative movement of various joint and/or implant components. For non-limiting example, the walls of the implant may be thicker is some areas to accommodate particular loads and the side wall may be thinner and more elastic to accommodate rolling and stretching thereof.

Motion is believed to be primarily between the spaced walls (or portions) of the implant peripherally secured to joint structures, although some motion may occur between the implant and the joint surfaces. As shown multiple Figures (including, FIGS. **1**-**7**), the implant may be provided with a slot extending from the periphery of the implant toward the balloon of the implant to accommodate at least one ligament of the joint. Knee implants may have two slots leading to separate passages for receiving the anterior and posterior cruciate ligaments. Implant walls should have sufficient inherent flexibility to mold to the existing deformities imposed by either natural ligament, bone, tendon and remaining cartilage deformities of the internal joint space filled as a cushion. The wall exteriors may be flat or formed with random or specific patterns for purposes of glide or trends for traction against adjacent surfaces, or as sulci or venues for cell delivery materials.

The exterior of the implant may have a mesh material with a plurality of chords (or appendages) for securing the implant to adjacent bones or to remnant ligaments which are attached to adjacent bones.

The dimensions of the various implant walls will vary depending upon the material properties thereof as well as the needs for a particular joint. Additionally, the first and second walls may require a thickness different from the side wall. Generally, the implant may have a wall thicknesses of about 0.125 mm to about 3 mm, preferably about 0.5 mm to about 1.5 mm. The spacing between the first and second wall within the interior can vary from about 0.5 mm to about 5 mm.

In some embodiments, the implant has a first wall, a second wall, and a side wall which define the implant interior (or interior) which contains filling material. In some embodiments, the filling material is an inflation medium. The first wall is secured to the end of the femur by at least one appendage that extends from the first wall and the second wall engages the end surface of the second bone (which in the case of a femoral-tibial joint implant, would be the tibia) and may also be secured thereto. The side wall extending between the first and second walls defines at least in part the implant interior which is filled with filling material (or an inflation medium). The inner surfaces of wall and appendage may conform to the particular surface femur, for example by being wider in particular locations and/or longer in particular areas. For example a dual compartment implant (described herein) may have a wider section to cover the medial condyle than the lateral condyle (as shown in FIGS. **1**, **2**, **3**, **6**A, **6**B, and **7**). In another example, the length of the implant the along the external edge may be longer than the length of the implant along the trochlear groove edge (as shown in FIGS. **11**A, **11**B and **11**C). In yet another example, the width may vary along a single condyle, such as is shown in FIGS. **12**A-**12**C, wherein the wider edge of the implant is adapted to fit over at least a portion of the anterior condyle, and the narrower portion is adapted to fit over at least a portion of the posterior condyle. In some embodiments, the inner surfaces of the first wall and appendages preferably conform to the particular surface of the patient's femur, and do so by not only dimensions of the implant (lengths, widths, balloon location and shape), but also and/or alternatively due to appendage and/or tab and/or hole and/or coupler location and/or surface contours of the first wall. The outer surface of the second wall may be configured to conform to the end surface of the second bone (which may be a tibia or a patella, for example). In some embodiments, the outer surface of the second wall is configured to conform to a surface of the second bone (which may be a tibia or a patella, for example). The figures provided herein are highly schematic and do not depict details of the joint surface features, since human pathology and variation reflects both the patient's immediate and evolving pathophysiology. Neither do the figures depict other joint features such as cartilage, tendons, ligaments and other soft tissues and fluids of the joint for ease of viewing that which is depicted.

In some embodiments, the implant is configured to resemble the shape of the natural hyaline of a normal knee. For example, the normal hyaline is typically "H" shaped, thus certain embodiments of the implant are generally "H" shaped.

Implant Materials and Material Features

In some embodiments, the implant comprises polymer. Polymers may comprise at least one of: a polyurethane (such as, for example, ChronoFlex AR), a polycarbonate urethane, a thermoplastic polycarbonate urethane (such as Bionate 55), ethylene-vinyl acetate copolymer, multiblock copolymers of poly(ethylene oxide) (PEO) and poly(butylene terephthalate) (PBT), PEG, PEO, and a polyetheylene. In some embodiments the implant comprises a 125 micron thickness thermoplastic polycarbonate urethane.

The implant may comprise to a plurality of layers of polymer (such as ChronoFlex AR) in a solvent and evaporating the solvent after applying each layer. In some embodiments, the implant comprises a polyurethane that is sprayed and dried (wherein the spraying and drying is repeated at least once) to a desired thickness.

In some embodiments, the implant is created by dip molding a mandrel having a shape of a bone of the knee joint (the medial condyle, the lateral condyle, the tibia, for non-limiting example) into a polymer solution (for non-limiting example, a urethane polymer such as Chronoflex). Following each dip, the implant is dried for a specified time, which may be, for example, about 3 seconds, about 4 seconds, about 5 seconds, about 6 seconds, about 7 seconds, about 8 seconds, about 9 seconds, about 10 seconds, about 15 seconds, about 20 seconds, about 25 seconds, about 30 seconds, about 45 seconds, about 1 minute, about 2 minutes, about 5 minutes, about 10 minutes, about 15 minutes, and over about 15 minutes. The term "about" used herein in reference to drying time of the implant can mean variations of at least one of 5%, 10%, 25%, and 50%, In some embodiments, no drying step is used. The dipping may be repeated multiple times. In some embodiments a single dip is sufficient. In some embodiments, the dipping is repeated 2 times. In some embodiments, the dipping is repeated 3 times. In some embodiments, the dipping is repeated 4 times. In some embodiments, the dipping is repeated 5 times. In some embodiments, the dipping is repeated 6 times. In some embodiments, the dipping is repeated 7 times. In some embodiments, the dipping is repeated 8 times. In some embodiments, the dipping is repeated 9 times. In some embodiments, the dipping is repeated 10 times. In some embodiments, the dipping is repeated 11 times. In some embodiments, the dipping is repeated 12 times. In some embodiments, the dipping is repeated 13 times. In some embodiments, the dipping is repeated 14 times. In some embodiments, the dipping is repeated 15 times. In some embodiments, the dipping is repeated 16 times. In some embodiments, the dipping is repeated 17 times. In some embodiments, the dipping is repeated 18 times. In some embodiments, the dipping is repeated 19 times. In some embodiments, the dipping is repeated 20 times. In some embodiments, the dipping is repeated 21 times. In some embodiments, the dipping is repeated 22 times. In some embodiments, the dipping is repeated 23 times. In some embodiments, the dipping is repeated 24 times. In some embodiments, the dipping is repeated 25 times. In some embodiments, the dipping is repeated over 25 times. In some embodiments, the dipping is repeated a sufficient number of times to create an implant that is a prescribed thickness. The thickness may vary depending on the polymer and depending on the embodiment of the implant. The thickness may be at least one of: about 25 microns thick, about 50 microns thick, about 100 microns thick, about 125 microns thick, about 150 microns thick, about 200 microns thick, about 250 microns thick, about 300 microns thick, about 350 microns thick, about 400 microns thick, about 25-50 microns thick, about 50-100 microns thick, about 50-200 microns thick, about 100-150 microns thick, about 150-300 microns thick, about 100-300 microns thick, about 100-500 microns thick, about 200-500 microns

thick, and about 200-1000 microns thick. The term "about" used herein in reference to thickness of the implant can mean variations of at least one of 5%, 10%, 25%, and 50%, The thickness may vary at different locations of the implant. In some embodiments, the implant is fabricated in two pieces, one or more of which is molded to form an interior when the two pieces are put together. In some embodiments, the implant is filled by puncturing the implant wall and sealing the puncture hole with a plug, patch or other sealant. The plug, patch, or other sealant may comprise Chronoflex material, for non-limiting example. The plug, patch, or other sealant may comprise the same material from which the implant is constructed, for non-limiting example.

The walls of the implant embodying features of the invention may be composite structures. For example, the innermost layer may be impervious to preclude escape of inflation or other filling media, a central layer may be porous or otherwise contain treatment or cell regeneration agents, and the outer layer may be a thin, but strong layer of a thermoplastic, such as a thermoplastic polyurethane for non-limiting example, which has microporosity sufficient to allow passage or egress of treatment or cell regeneration agents from the central layer (or second layer). The degree of microporosity to enable egress of treatment or cell regeneration agents from the central layer is found in polymer layers such as Chronoflex or Bionate 55.

The external wall (and/or the bone engaging surface) of the implant may be coated and/or impregnated with a latticework of polymer that is surface sprayed or layered on the outside (or bone engaging surface) of the implant to promote cartilage tissue regeneration. This most external surface coating may contain living chondrocytes (for example, as is provided in the Carticel procedure by the Genzyme company), and/or may contain stem cells with directed gene mutations to enhance adherence of the coating to the implant. The bone engaging surface may comprise peaks and troughs. The living cells may be imposed in between (and/or provided in the) troughs of the implant surface while the surface areas of prominence (the peaks of the surface) may be used for at least one of: space validation, traction, and cell protection.

The implant may be formed of suitable bioabsorbable materials so that the implant may be absorbed within a particular predetermined time frame. Suitable bioabsorbable materials include polylactic acid, polyglycolic acid, polycaprolactone, copolymers, blends and variants thereof. Suitable bioabsorbable materials may also/alternatively include poly(hydroxyalkanoate)s of the PHB-PHV class, additional poly(ester)s, and natural polymers, particularly, modified poly(saccharide)s, e.g., starch, cellulose, and chitosan. The walls of the implant may be (in whole and/or in part) bioabsorbable. The balloon may be (in whole and/or in part) bioabsorbable. As used herein the terms bioabsorbable, bioerodable, and/or bioabsorbable may be used interchangeably. The walls of the implant may release a pharmaceutical agent or an biological agent (such as stem cells, living chondrocytes, gene therapies, and the like). The release of such agents (whether biological or pharmaceutical, or a combination thereof) may occur over time, as the wall of the implant (or as the balloon) bioabsorbs in some embodiments, or as the joint is used (i.e. through pressure, for non-limiting example). In some embodiments, at least one of the implant walls is permeable to a pharmaceutical agent and/or a biological agent, such as in an embodiment wherein the inflation medium comprises the pharmaceutical agent and/or biological agent. In some embodiments, at least one of the implant walls has pores through which the pharmaceutical agent and/or the biological agent may fit, such as in an embodiment wherein the inflation medium comprises the pharmaceutical agent and/or biological agent.

The implant may be provided with latticework or other reinforcing strands, preferably on the exterior or within the wall thereof to control the maximum expansion of the implant when deployed at the orthopedic site.

In some embodiments, the implant comprises amniotic membrane (and/or a component thereof). In some embodiments, the implant comprises amniotic sac (and/or a component thereof). In some embodiments, the implant comprises amniotic tissue (and/or a component thereof). Amniotic membrane (and/or sac and/or tissue) is unique in that its mechanical properties include that it slippery on one side (lubricious, low modulus of elasticity) and sticky (adherent) on the other. In some embodiments, at least one of the first wall, the second wall and the side wall comprise amniotic membrane or a component thereof. In some embodiments, at least one of the first wall, the second wall and the side wall comprise amniotic sac or a component thereof. In some embodiments, at least one of the first wall, the second wall and the side wall comprise amniotic tissue or a component thereof. The amniotic membrane and/or amniotic sac and/or amniotic tissue may be used in conjunction with other biologic agents, pharmaceutical agents, and/or therapeutic agents. Amniotic tissue is used extensively in pleuripotential cells. It qualifies as HTBP (Human Tissue Based Product) because of the short term time span on the product and origin.

In some embodiments, the balloon is a composite structure. In some embodiments, the balloon comprises layers of porous and/or non-porous materials, or otherwise contain treatment or cell regeneration agents. In some embodiments, a first layer of the balloon is a thin, but strong layer of a thermoplastic, such as a thermoplastic polyurethane, for non-limiting example, which has microporosity sufficient to allow passage or egress of treatment or cell regeneration agents from a second layer. The second layer may be a central layer (which lies between the first layer and a third layer or a fourth layer or more layers). The first layer may comprise a bone engaging surface in some embodiments. The degree of microporosity to enable egress of treatment or cell regeneration agents from the second layer is found in polymer layers such as Chronoflex or Bionate 55. The bone engaging surface of the implant may be coated and/or impregnated with a latticework of polymer that is surface sprayed or layered on the bone engaging surface of the implant to promote cartilage tissue regeneration. This bone engaging surface coating may contain living chondrocytes (for example, as is provided in the Carticel procedure by the Genzyme company), and/or may contain stem cells with directed gene mutations to enhance adherence of the coating to the implant. The bone engaging surface may comprise peaks and troughs. The living cells may be provided in troughs while the surface peaks may be used for at least one of: space validation, traction, and cell protection.

In some embodiments, the implant is pre-molded to fit about at least one condyle of the femur. In some embodiments, the implant comprises a memory plastic. In some embodiments, the implant comprises a wire frame. In some embodiments, the wire of the wire frame comprises a memory metal. In some embodiments, the memory metal comprises nitinol. In some embodiments, the wire frame is disposed in the periphery of the implant or a portion thereof. In some embodiments, the wire frame is configured to aid in placement against the posterior of the condyle.

In some embodiments, at least a portion of the implant comprises a slippery surface. In some embodiments the slippery surface is configured to allow for relative movement between the implant (or a portion thereof) that is coupled to the femur and the tibia. In some embodiments the slippery surface is configured to allow for relative movement between the implant (or a portion thereof) that is coupled to the femur and the patella.

Inflation Medium and Inflation or Filling of the Implant Interior

In some embodiments, the implant comprises an inflation medium that is compressible. In some embodiments, the implant comprises an inflation medium that comprises a viscolubricant. In some embodiments, the implant comprises an inflation medium that comprises a parmacologic substance. In some embodiments, the implant comprises an inflation medium that comprises an NSAID. In some embodiments, the implant comprises an inflation medium that comprises chondrocytes. In some embodiments the implant is configured to anneal the outer most layer of the implant (or a portion thereof) to the peripheral of succinct cartilage defects so as to cover them, allowing for healing. In some embodiments the implant is configured to anneal the outer most layer of the implant (or a portion thereof) to the peripheral of succinct cartilage defects so as to cover them, allowing for healing once new chondrocytes have been installed.

The implant interior (balloon interior) may be inflated with gas. The implant interior (balloon interior) may be inflated with liquid. The implant interior (balloon interior) may be inflated with saline. The implant interior (balloon interior) may be inflated with suspended stem cells. The implant interior (balloon interior) may be inflated with gel. The implant interior (balloon interior) may be inflated with a viscolubricant. The inflation medium in some embodiments stays within the balloon, or a portion thereof (as where there are multiple chambers to the balloon). In some embodiments, balloon contents disburse through microporosities and/or dissolving membranes into the joint. In some embodiments, balloon contents disburse by expulsive or evacuation precipitated through an implant wall after pressure from limb use. In some embodiments, balloon contents disburse by expulsive or evacuation precipitated through an implant wall from planned osmosis. In some embodiments, balloon contents disburse by expulsive or evacuation precipitated through an implant wall from vacuole rupture (whether mechanical rupture, ultrasound, or chemical rupture, for non-limiting example). In some embodiments, balloon contents disburse by expulsive or evacuation precipitated through an implant wall thereby distributing contents of the implant interior to joints as lubricious, analgesic, anti-inflammatory and/or otherwise healing substances. In some embodiments, the implant may comprise solid beads or beads containing gel or liquid for sequential disbursement by compressive force through rupture with varied bead wall thicknesses, or the beads may be time-released (opened) chemically, pharmacologically, or by an outside ultrasound or magnetic force external knee application at appropriate clinical intervals. In some embodiments, the implant may comprise vacuoles containing gel or liquid for sequential disbursement by compressive force through rupture with varied vacuole wall thicknesses, or the vacuoles may be time-released (opened) chemically, pharmacologically, or by an outside ultrasound or magnetic force external knee application at appropriate clinical intervals.

The implant interior (or balloon interior) between the first wall and the second wall is filled with filler material (or an inflation medium) which aids in maintaining the desired implant dynamics within the joint structure. The nature of the filler material such as a fluid and the characteristics of the walls may be selected to maintain a desired spacing between the walls in order to accommodate the pressure applied by the bones of the joint structure to the implant and to allow suitable motion between the first and second walls of the implant which facilitate bone motion which mimics or approximates normal movement for the joint members involved.

Alternatively (and/or additionally), the inner chamber (interior or a portion thereof) may be filled with resilient material to provide the desired spacing, pressure accommodation, while allowing desired physiologic motion between implant layers. The implant may be configured to be shaped like the joint space and bone surfaces being replaced or to fill the void produced by injury or disease so that the natural joint spacing and cushioning of the joint interface is restored toward normal physiologic appearance and function. Fluids such as saline, mineral oil and the like may be employed to inflate the implant.

The interior of implant is adjustably filled by the physician from an appropriate source thereof after the implant is deployed to ensure that the pathologic joint space becomes a resilient cushion again which aids restoration of worn or damaged cartilage interfaces in the joint by covering cartilage defects with the implant material, cushioning the joint and defects therein and delivering cell regeneration agents. In one embodiment, the implant comprises a bio-compatible inflatable member (balloon) that is filled with a biocompatible fill material (inflation medium) such as a gas, liquid, gel or slurry, or fluid that becomes a resilient solid to provide relative movement between the first and second walls. The filling or inflation media may be inserted through an injection valve site leading to the cannula which delivers the material into the interior of the implant. In an alternative embodiment, the implant may be filled with or have an interior formed of biologically compatible resilient material, e.g. a closed cell sponge filled with suitable fluid that is inserted into the interior of the implant prior to the implant's deployment or injected into the interior after the implant is deployed at the joint site. The interior of the implant may be provided with lubricious material to facilitate movement between the inner wall surfaces and to minimize contact wear therebetween. The polymeric walls of the implant may be impregnated with or otherwise carry tissue regeneration agents such as stem cells, living chondrocytes, and/or genes to repair joint surfaces.

In some embodiments, the first inflation medium imparts rigidity in the implant. In some embodiments, the first inflation medium imparts cushion in the implant. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium aligns the joint. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium aligns the bones of the joint. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium changes the bone alignment. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium improves joint alignment. In some

embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium restores, at least in part, joint alignment. In some embodiments, individual chambers of the interior may be selectively inflated with a first inflation medium and/or a second inflation medium. In some embodiments, individual chambers of the interior are selectively inflated with a first inflation medium and/or a second inflation medium in order to reconstruct the joint and/or bones of the joint.

In some embodiments the inflation medium comprises living chondrocytes.

The implant interior (balloon interior) may be inflated with methymethacrylate as a liquid that becomes a solid or semi-solid (rigid or semi-rigid). In some embodiments, the inflation medium is a methyl methacrylate or other biocompatible hardening substance which can flow when initially put into the chamber, and hardens to become a rigid piece or semi-rigid piece or solid piece. The methyl methacrylate or other biocompatible hardening substance may conform to the shape of the chamber, or may conform to the shape of a space between bones and/or other joint structures. The methyl methacrylate or other biocompatible hardening substance may conform to a form chosen by the surgeon using tools and/or pressure to influence the final shape of the rigid piece formed by the methyl methacrylate or other biocompatible hardening substance upon hardening.

The side wall extends between the first and second walls to form an interior which receives filling material through tube (also called a conduit herein, or may be called an inflation port). In some embodiments, the inflation port is not a tube, but is a valve which may or may not extend from a wall of the implant. The valve may be part of a wall of the implant, or part of the balloon or a portion thereof. The implant would also be appropriate for one condyle of the knee, but other shapes may be desired for other joint configurations whether relatively flat or more inflated toward a ballooning construct. In some embodiments, the inner diameter of the inflation port (or tube) is 5 millimeters maximum. In some embodiments, the inner diameter of the inflation port is about 1 millimeter. In some embodiments, the inner diameter of the inflation port is about 2 millimeters. In some embodiments, a needle (of typical needle sizes) may be used to inflate the implant.

A separate portal or tube (not shown) or the existing conduit (tube or valve), may be used to extract noxious inflammatory enzymes that can be aspirated at appropriate clinical intervals. Inflammatory enzymes in the COX1, COX2 and or 5LOX pathways can be extracted. Viscolubricants can be injected into the interior of the resilient arthroplasty implant through existing conduit or through a long needle to aide in distension, expansion, lubrication (with predetermined microporosity).

In some embodiments, an inflation medium that generates heat (by means of a catalyst reaction or other means) may be used to deliver heat to a joint structure. The heat may aide hyaline cartilage annealing. Thermal effects of the implant materials are calculated accordingly to benefit and protect the joint surface analogous to a dry suit or wet suit for a scuba diver exposed to temperature extremes. Embodiments of the implant generally seek to avoid head from friction via lubricious coatings whether allograph as amniotic membrane or polymer, for non-limiting example.

The implant in some embodiments is inserted arthroscopically through a cannula about 10 mm in diameter with the implant in the deflated construct, and once inside the prepared joint space and secured therein by the appendages or tabs, the implant will be distended or inflated with gas, gel, fluid or fluid that becomes a resilient solid to fill the original natural space of a bone of the joint (whether the tibia, femur or patella). Tensioning will be by the surgeon's sense of proper pressure application aided by a gauged syringe for insertion of viscolubricants such as Synvisc, Hyalgan, Supartz and/or analgesics such as lidocaine gel. The insertion of liquids to the joint per se may be directly, through a cannula to the joint space previously in place for debridement, and or via a cannula or tube that is not part of the original implant assembly. Once the joint is cleaned, the implant is inserted and appropriately fixed to avoid extrusion or dislocation thereof. This may be via attachment of the implant tabs and/or by a combination of tab use plus intended friction created by implant surface coverings (analogous to Velcro) or a draw string at the smaller base of the implant.

Attachment Elements and Couplers

In some embodiments the attachment elements of the implant comprises holes through which screws or other couplers may be placed to attach the implant to an attachment site (or connection site) in the bone of the knee. In some embodiments, the holes are created arthroscopically. In some embodiments the holes are pre-fabricated in the implant. In some embodiments, the holes may be made prior to implantation based on the patient's particular anatomy. In some embodiments, the holes are reinforced by a reinforcing material of the implant. The reinforcing material may be a polymer of sufficient durometer and/or tear resistance to reinforce the screw hole. The reinforcing material may be comprise metal. In some embodiments, there is no preformed hole, but rather screws (or another coupler) secure the attachment tabs (which may be a non-balloon portion of the implant) to the joint component (bone, etc) by creating their own hole when implanted. In some embodiments, the implant may comprise tabs that are adapted to receive staples or other couplers described elsewhere herein.

The implants described herein may comprise attachment elements (or tabs) which may then by attached or coupled to tissue of a component of the joint (whether to a bone or a ligament or a tendon or other joint component) by a coupling device. Coupling devices (or couplers) may comprise at least one of screws, washers, sutures, suture anchors (metal and/or biodegradable), rivots, staples (with and/or without teeth), stabilizers, glues, hooks of cylindrical wire or flattened sheet metal into bone holes or slots respectively. The coupling devices may be resorbable or not. Also, the coupling devices may comprise at least one of strings (i.e. drawstrings), reigns, lassos, sutures, and lanyards. The strings, reigns. lassos, sutures, and/or lanyards may join with themselves and/or other coupling devices. The strings, reigns. lassos, sutures and/or lanyards may be directed not only into bone with or without anchors, but also through ligaments, tendons or loose segments of cartilage that the surgeon intends to preserve.

The posterior of the knee can be difficult to access without disturbing joint components (or in order to minimize such disturbance) such as tendons, ligaments, etc. Thus, in some embodiments, the implant comprises strings, reigns. lassos, and/or lanyards that may pass from the posterior of the implant via the intercondylar notch anteriorly to join with themselves and/or other coupling devices. These couplers may be pre-coupled to the implant, and the implant and its couplers may be configured to be pulled (or cinched) from the anterior of the implant once the implant is in its general location relative to the condyle in order to finally position

the implant about the condyle—in particular in order to cinch the implant about the posterior of the condyle. Likewise, in some embodiments where the implant is pre-molded, the coupler as described are adapted to move the implant to its final position with conformity to the condyle's posterior with minimal disturbance to the joint structures at the joint's posterior (minimal cutting, minimal moving, and or minimal detachment, for non-limiting example).

In some embodiments, the implant comprises a skirt (or sleeve) that conforms to the contours of the bone (whether a condyle of the femur, a patella, or a tibia) as a coupler.

In some embodiments, a screw through tab having reinforced center holes may be part of the implant. For example, the implant may comprise polymer covered metal washer holes. The screw may go through the holes. Another embodiment may comprise a staple having spikes as shown in FIGS. **13**A-**13**D. FIGS. **13**A-**13**D depict multiple views of a staple adapted to couple an implant to a bone of the joint. FIG. **13**A depicts an embodiment of an implant **20** having a tab **10***a* that is coupled to bone using a staple **12**. FIGS. **13**B & **13**C depict a staple **12** as described herein having teeth **18**. FIG. **13**C depicts an embodiment of a tab **10***a* that is coupled to bone using a staple **12** having teeth **18**. Combinations of spikes and screws may be used in some embodiments, or combinations of other couplers. The implant may be configured to allow a surgeon the option of several types and sizes of couplers, as each patient differs with regard to size and depth of lesion, bone stock, regrowth capability, and compliance with advised recovery, and each surgeon has his own strengths and comforts when working with such implants.

The edge of the implant may have a depending skirt to secure or anchor the implant to the end of bone (femur), but may have one or more depending tabs (or appendages) that may be employed for similar functions as will be discussed in other embodiments. The skirt (and/or tabs, and/or appendages) may tightly fit about the end of the femur, or the skirt can be secured by adhesive (e.g. methyl methacrylate, bone ingrowth) to the supporting bone structure or be mechanically connected by staples, screws and the like. Moreover, the lower portion of the skirt may be secured by a purse string suture or a suitable strand (elastic or tied) that is tightly bound about the outside of the skirt.

FIGS. **12**A, **12**B, and/or **12**C alternatively may be used to describe a patch implant or a unicompartment knee implant described herein, having appendages **4***a*, **4***c*, extending from a balloon **6** and including holes **8***a*, **8***b*, **8***c*, and/or tabs **10***a*, **10***b*. **10***c*, **10***d*, **10***e*, **10***f*, which may be used with couplers (not shown) to couple the implant to a bone of the knee joint (which may be the femur, the tibia, or the patella). Features shown in FIG. **12**A, **12**B, and or **12**C are common to both the unicompartment knee implant (also discussed elsewhere herein) and the patch implant (also discussed elsewhere herein), although dimensions may differ as described elsewhere herein.

FIGS. **13**A-**13**D depict multiple views of a staple **12** adapted to couple implant **14** (such as those described herein) to a bone **16** of the joint. FIG. **13**A depicts a staple **12** coupling a tab **10***a* of an appendage **4***a* to the bone **16** of the joint (wherein the portion of the staple **12** embedded in the bone **16** is shown as a dashed line). FIG. **13**B depicts a view of a staple **12** having teeth **18** to grasp the tab **10***a* of the implant **14**. Similarly, FIG. **13**C depicts a view of a staple **12** having teeth **18** to grasp the tab **10***a* of the implant **14**. FIG. **13**D depicts a staple **12** attaching the tab **10***a* of an implant to a bone **16**, the dotted lines show the portion of the tab **10***a* that is compressed by the staple **12** and teeth **18** thereof.

In some embodiments, the implant is configured such that the tabs and/or couplers of the implant couple to the bone where there is no natural cartilage. In some embodiments, the implant may be adapted by the surgeon at the time of surgery such that the tabs are positioned where there is no natural cartilage.

In some embodiments, the implant comprises a tab and a hook that couples to the tab by wrapping around a component of the knee and securing the tab to the hook. In some embodiments, the implant comprises a tab and a hook that couples to the tab by wrapping around a condyle of the knee and securing the tab to the hook. In some embodiments, the implant is configured to wrap around a condyle of the knee and to secure a first appendage to a second appendage of the implant. In some embodiments the appendages are secured by couplers described herein. In some embodiments, the implant is pre-formed to fit to the condyle in such a wrapping manner.

In some embodiments, the implant comprises a methymethacrylate what is placed into a balloon chamber that fits into a bone hole. Such an embodiment would generally fix the implant to the bone once the methymethcrylate cures to a solid.

In some embodiments, the implant can be anchored with generic available sutures and suture anchors fixing and positioning material to bone with proper tensioning.

Ingrowth Features

In addition to the general ingrowth that may occur based on the implant features described herein, the implant undersurface (adjacent the femur) may comprise an ingrowth matrix. In some embodiments, at least a portion of the implant adjacent to the femur comprises bone ingrowth materials. Such an implant can be attached by a series of tabs with or without holes, using screws, rivots, stabilizers, staples, tacks, or Sutures and suture anchors, for non-limiting example. The polymer of the implant substitutes for periosteum when the implant comprises living chondrocytes (e.g. Carticel) as the ingrowth matrix on a surface of the implant. The polymer of the implant substitutes for periosteum when the implant comprises living chondrocytes (e.g. Carticel) as the ingrowth matrix within an implant embodiment configured to reveal and/or release said chondrocytes over time and/or upon implantation.

The bone ingrowth undersurface may be used for long term fixation of the tabs or rim. That is, whereas it is important for the surgery to secure the implant to the joint surface in the most desirable corrective location, it is also important in some embodiments to prepare the anatomic undersurface of bone by abraiding it, removing about 0.5 mm of cortical bone so as to expose the underlying oxygen, blood, and nutrients of the patient to the undersurface of the implant that can gradually become incorporated into the limb bone. As this healing occurs over the course of weeks and months to one year post operation, the localized tacking sites may become less relevant and potentially inert. Thus, in some embodiments, the implant may comprise a biodegradable (bioresorbable) polymer or other material. The couplers may additionally and/or alternatively be biodegradable. Once the implant is in place, it will serve to at least one of: pad defects, cushion the joint, and restore the original damage to the joint components. The end goal is to apply minimally morbid treatment that will refurbish arthritic limb regions, leaving only the small skin scar and remote memory of the healed physical mishap.

Undersurface implant materials may involve used of the art and science from Artelon or Gore-Tex research, as each has advantages and limitations. Several implant options per joint damage area may be available to enjoy the primary surgeons manipulation to fit the clinically recovery requirements best.

In some embodiments the implant comprises an ingrowth patch on at least one of the first portion configured to engage the femur, the second portion configured to engage the second bone (whether the tibia or the patella), the side portion, and the appendage. The ingrowth patch may be configured to encourage and/or promote tissue ingrowth, such as bone ingrowth, for non-limiting example. The patch may be as large as the portion itself (whether the first portion the second portion, the side portion, or the appendage) or may be smaller than the portion (such as in the shape of a strip or other shaped patch). The ingrowth patch may comprise a surface irregularity or roughness. The ingrowth patch may be Velcro-like. In some embodiments the implant comprises an ingrowth patch on the first portion and/or the second portion, from (and in some embodiments including) a first appendage to a second appendage. In some embodiments, wherein the appendages loosen from attachment from the bone (by design and/or from wear and/or over time), the ingrowth patch aids in securing the implant to the bone. In some embodiments, the ingrowth patch comprises beads and/or bead-like elements attached to the implant. Such an ingrowth patch may be configured to simulate trabecular bone space of a normally cancellous latticework. In some embodiments, the beads are sintered beads of various sizes. In some embodiments, the beads are sintered beads about 400 microns in size. With respect to bead size, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%. In some embodiments, the first bone and/or the second bone is roughened to acquire a bleeding bone to facilitate ingrowth. In some embodiments, tissue is removed to facilitate ingrowth.

The walls of the implant embodying features of the invention may be composite structures. For example, the innermost layer may be impervious to preclude escape of inflation or other filling media, a central layer may be porous or otherwise contain treatment or cell regeneration agents, and the outer layer may be a thin, but strong layer of a thermoplastic, such as a thermoplastic polyurethane for non-limiting example, which has microporosity sufficient to allow passage or egress of treatment or cell regeneration agents from the central layer (or second layer). The degree of microporosity to enable egress of treatment or cell regeneration agents from the central layer is found in polymer layers such as Chronoflex or Bionate 55. The external wall (and/or the bone engaging surface) of the implant may be coated and/or impregnated with a latticework of polymer that is surface sprayed or layered on the outside (or bone engaging surface) of the implant to promote cartilage tissue regeneration. This most external surface coating may contain living chondrocytes (for example, as is provided in the Carticel procedure by the Genzyme company), and/or may contain stem cells with or without directed gene mutations to enhance adherence of the coating to the implant. The bone engaging surface may comprise peaks and troughs. The living cells may be imposed in between (and/or provided in the) troughs of the implant surface while the surface areas of prominence (the peaks of the surface) may be used for at least one of: space validation, traction, and cell protection.

The implant embodying features of the invention may be used in a series of treatments wherein the first treatment involves use of autologous or minimally manipulated allograph interpositional tissues or xenograph, the second treatment involves the use of the same type of tissue added to stem cells or chondrocytes and the third treatment involving deployment of the implant if the first two fail or are ineffective.

Pharmacologics and Therapeutic Agents

In some embodiments the implant may comprise vacuoles of pharmacologic substances. The vacuoles may be on a bone-engaging portion of the implant. In some embodiments, the implant comprises bubbles comprising an active substance such as a pharmacologic substance or other active substance. In some embodiments, the implant comprises spaces filled with an active substance such as a pharmacologic substance (pharmacologic agent) or other active substance (active agent). The implant may deliver by dissolution of the implant material (i.e. a biodegradable polymer which releases the active substance), and/or by release through pores of the implant (wherein the polymer is permeable to the active substance), and/or by fracture of the vacuole (or bubble, or space) by a catalyst such as ultrasound or pressure or other fracturing catalyst. The implant may deliver the active substance at a time after the actual implanting of the implant into the joint, for example an hour later, less than a day later, a day later, less than a week later, a week later, less than a month later, and/or a month later. In some embodiments, stem cells that are percolating in the bubble (or vacuole, or space) may be delivered to the joint space (or a constituent of the joint) after the implant is inserted into the joint. Active agents may, for non-limiting example, include stem cells, growth factors, antibiotics, and/or viscolubricants. In some embodiments, the implant may comprise enzyme absorptive 'microscopic sponges' that could be sucked out or evacuated at or around the time of implant delivery to the joint. In some embodiments, the active substance comprises iatrigenically gene mutated cells.

Patient Symptoms

Symptoms for the patient requiring an implant described herein may include, for non-limiting example, osteoarthritis or rheumatoid or gouty arthritis.

Total Knee Arthroplasty (Dual Compartment):

Provided herein is an implant for placement on both condyles (medial and lateral) of the distal femur. In some embodiments, this is called a dual compartment implant since it covers both condyles of the femur. Such an implant comprises at least one interior (or inflatable chamber), and in some embodiments comprises a plurality of inflatable chambers (or interiors).

In some embodiments, the implant will cover the "H" distal femoral cartilage segment (made up of both femoral condyles and the trochlear groove in between). The implant may absorb diffuse force, endure the millions of annual cyclic loads of both knee joints (including the patella-femur joint and the femur-tibia joints), along with rotational and shear forces up to six times body weight, at least.

In some embodiments, the implant comprises attachment tabs or attachment elements over the sides of both condyles medially and laterally. In some embodiments, the implant comprises attachment tabs or attachment elements in the intercondylar notch (or slot). In some embodiments, the implant comprises attachment tabs or attachment elements superiorly at the distal end of the femur anteriorly. In some embodiments, posterior reigns or suture-like lanyards cinch up the implant from inside the posterior intercondylar notch toward another connection site around the femur.

The posterior of the knee can be difficult to access without disturbing joint components (or in order to minimize such

disturbance) such as tendons, ligaments, etc. Thus, in some embodiments, the implant comprises strings, reigns, lassos, and/or lanyards that may pass from the posterior of the implant via the intercondylar notch anteriorly to join with themselves and/or other coupling devices. These couplers may be pre-coupled to the implant, and the implant and its couplers may be configured to be pulled (or cinched) from the anterior of the implant once the implant is in its general location relative to the condyle in order to finally position the implant about the condyle—in particular in order to cinch the implant about the posterior of the condyle. Likewise, in some embodiments where the implant is pre-molded, the coupler as described are adapted to move the implant to its final position with conformity to the condyle's posterior with minimal disturbance to the joint structures at the joint's posterior (minimal cutting, minimal moving, and or minimal detachment, for non-limiting example). In some embodiments at least a portion of the ligamentary structure of the knee is spared.

Although this application focuses on the distal femur as it articulates with the retropatellar and proximal tibial cartilages implants as described generally herein may be also and/or alternatively be used in conjunction with the tibia and/or the patella. Furthermore, separate and/or connected implant components may be inserted to restore natural function to the knee.

Coupling devices to be used as part of the dual compartment implant may include any of those mentioned or described herein, for example. Such coupling devices may comprise at least one of strings (i.e. drawstrings), reigns, lassos, sutures, and lanyards. The strings, reigns. lassos, sutures, and/or lanyards may join with themselves and/or other coupling devices. The strings, reigns. lassos, sutures and/or lanyards may be directed not only into bone with or without anchors, but also through ligaments, tendons or loose segments of cartilage that the surgeon intends to preserve.

FIG. **1** depicts an embodiment of the implant **20** in a 2D view configured for dual condyle (distal femur) coverage. FIG. **1** depicts an embodiment of the knee implant **20** having appendages **4***a*, **4***b*, **4***c*, **4***d*, including holes **8***a*, **8***b*, **8***c*, **8***d* and tabs **10***a*, **10***b* extending from a balloon **6** and including slots **26***a*, **26***b* to accommodate ligaments (not shown) of the knee joint. Couplers as described elsewhere herein may be used to couple the implant **20** to the distal femur. In some embodiments, there may only tabs, only holes, or only appendages, or combinations thereof. In some embodiments, there may be other ways to couple the implant to the distal femur, as described elsewhere herein (sutures, drawstrings, skirts, glue, etc). In some embodiments, the couplers create the holes **8***a*, **8***b*, **8***c*, **8***d*, or other holes (not shown) when the implant is placed against the distal femur **24**. In some embodiments, the holes are pre-formed in the appendage prior to implantation. In some embodiments, the holes are reinforced as described elsewhere herein. As shown here, the appendages in some embodiments be different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage **4***d* that is intended to wrap over the medial condyle may be longer and/or wider than the appendage **4***c* intended to wrap over the lateral condyle. Likewise, the slots may be different in shape and/or size and/or position to accommodate the ligaments and/or tendons of the joint or other structures and functions of the joints of the knee, and to allow for placement of the implant with minimal disturbance (cutting, manipulation, for example) of the joint components such as tendons, ligaments, and other soft or hard tissues. For example, slot **26***a* is shaped and positioned to accommodate the cruciate ligaments of the knee, at least.

FIG. **2** depicts an embodiment of the knee implant **20** having appendages **4***a*, **4***b*, **4***c*, **4***d*, including holes **8***a*, **8***b*, **8***c*, **8***d* and tabs **10***a*, **10***b* extending from a balloon **6** and including slots **26***a*, **26***b* to accommodate ligaments of the knee joint as well as side views of the same knee implant. Couplers as described elsewhere herein may be used to couple the implant **20** to the distal femur. In some embodiments, there may only tabs, only holes, or only appendages, or combinations thereof. In some embodiments, there may be other ways to couple the implant to the distal femur, as described elsewhere herein (sutures, drawstrings, skirts, glue, etc). In some embodiments, the couplers create the holes **8***a*, **8***b*, **8***c*, **8***d*, or other holes (not shown) when the implant is placed against the distal femur. In some embodiments, the holes are pre-formed in the appendage prior to implantation. In some embodiments, the holes are reinforced as described elsewhere herein. As shown here, the appendages in some embodiments are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage **4***d* that is intended to wrap over the medial condyle may be longer and/or wider than the appendage **4***c* intended to wrap over the lateral condyle. Shown in the embodiment depicted in FIG. **2** are the different hole placements from the side view, showing the differences in positioning of the holes to accommodate the differences in anatomic structure and size of the condyles. Likewise, the slots may be different in shape and/or size and/or position to accommodate the ligaments and/or tendons of the joint or other structures and functions of the joints of the knee, and to allow for placement of the implant with minimal disturbance (cutting, manipulation, for example) of the joint components such as tendons, ligaments, and other soft or hard tissues. For example, slot **26***a* is shaped and positioned to accommodate the cruciate ligaments of the knee, at least. Additionally, as shown in the side views of the embodiment shown in FIG. **2**, the balloon has a first wall **28** adapted to be adjacent the femur that is of a greater thickness than the second wall **30**. In some embodiments, the first wall **28** is configured to have therapeutic benefits (pharmacologic, healing, and/or ingrowth properties) as described elsewhere herein. The second wall **30** may additionally and/or alternatively be configured to have a therapeutic effect (pharmacologic, healing, and/or ingrowth properties).

Nevertheless, differing thicknesses of the first wall **28** and the second wall **30** are not necessarily required in order to impart the therapeutic benefits (pharmacologic, healing, and/or ingrowth) described elsewhere herein. For example, FIG. **3** depicts an embodiment of the knee implant **20** having appendages **4***a*, **4***b*, **4***c*, **4***d*, including holes **8***a*, **8***b*, **8***c*, **8***d* and tabs **10***a*, **10***b* extending from a balloon **6** and including slots **26***a*, **26***b* to accommodate ligaments of the knee joint as well as side views of the same knee implant. Couplers as described elsewhere herein may be used to couple the implant **20** to the distal femur. In some embodiments, there may only tabs, only holes, or only appendages, or combinations thereof. In some embodiments, there may be other ways to couple the implant to the distal femur, as described elsewhere herein (sutures, drawstrings, skirts, glue, etc). In some embodiments, the couplers create the holes **8***a*, **8***b*, **8***c*, **8***d*, or other holes (not shown) when the implant is placed against the distal femur. In some embodiments, the holes are pre-formed in the appendage prior to implantation. In some

embodiments, the holes are reinforced as described elsewhere herein. As shown here, the appendages in some embodiments are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage **4***d* that is intended to wrap over the medial condyle may be longer and/or wider than the appendage **4***c* intended to wrap over the lateral condyle. Shown in the embodiment depicted in FIG. **3** are the different hole placements from the side view, showing the differences in positioning of the holes to accommodate the differences in anatomic structure and size of the condyles. Likewise, the slots may be different in shape and/or size and/or position to accommodate the ligaments and/or tendons of the joint or other structures and functions of the joints of the knee, and to allow for placement of the implant with minimal disturbance (cutting, manipulation, for example) of the joint components such as tendons, ligaments, and other soft or hard tissues. For example, slot **26***a* is shaped and positioned to accommodate the cruciate ligaments of the knee, at least. Additionally, as shown in the side views of the embodiment shown in FIG. **3**, the balloon has a first wall **28** adapted to be adjacent the femur that is of approximately the same thickness than the second wall **30**. In some embodiments, the first wall **28** is configured to have therapeutic benefits (pharmacologic, healing, and/or ingrowth properties) as described elsewhere herein. The second wall **30** may additionally and/or alternatively be configured to have a therapeutic effect (pharmacologic, healing, and/or ingrowth properties).

FIG. **4**A depicts an embodiment of the knee implant **20** having appendages **4***a*-**4***d* including ten tabs **10***a*-**10***j* extending from a balloon **6** and including a slot **26***a* to accommodate components (such as ligaments or other tissues whether soft tissues, hard tissues, tendons, and/or others) of the knee joint (not shown). The tabs **10***a*-**10***j* are not shown with holes in this embodiment, however if screws are used as couplers, such holes may be pre-drilled or formed in situ by the screws. Additionally and/or alternatively, staples or sutures may be used (as described elsewhere herein) in order to couple the implant to the bone (femur, for example). Other couplers as described elsewhere herein may also and/or alternatively be used in this coupling process. Furthermore, the number of tabs may be fewer or greater than the ten depicted in order to achieve optimal placement and coupling to the bone. For example, FIG. **4**B depicts an embodiment of the knee implant **20** having appendages **4***a*-**4***d* including eight tabs **10***a*-**10***h* extending from a balloon **6** and including a slot **26***a* to accommodate components (such as ligaments or other tissues whether soft tissues, hard tissues, tendons, and/or others) of the knee joint (not shown).

FIG. **5** depicts an embodiment of the knee implant **32** curved to simulate curvature about the condyles of a femur, the implant having appendages **4***a*-**4***d* extending from an uninflated balloon (not shown) and including slots **26***a*, **26***b* to accommodate components (such as ligaments or other tissues whether soft tissues, hard tissues, tendons, and/or others) of the knee joint (not shown). The implant may comprise additional curvatures and/or slots to accommodate other ligaments and/or tissues. In some embodiments, the implant is configured to conform about various hard and/or soft tissues of the joint, such as bone, ligaments, tendons, etc. In some embodiments, the balloon is inflated once the implant is positioned within the joint. In other embodiments, the balloon is partially inflated prior to being positioned within the joint. In other embodiments, the balloon is at least partially inflated prior to being positioned within the joint. In some embodiments, the balloon is fully inflated prior to being positioned within the joint. In some embodiments, the implant is configured to allow an operator to adjust the amount of balloon inflation in situ (whether by adding inflation medium or removing inflation medium, or both, or neither). Couplers as described elsewhere herein may be used to couple the implant **32** to the distal femur.

FIG. **6**A depicts a top-down view of an embodiment of the knee implant **32** curved to simulate curvature about the condyles of a femur, the implant having appendages **4***a*-**4***d* extending from two inflated balloons **6**, **34** and including a slot **26***a* to accommodate components of the knee joint. FIG. **6**B depicts a bottom-up or anterior oblique view of the same embodiment of the knee implant **32** curved to simulate curvature about the condyles of a femur, the implant having appendages **4***a*-**4***d* extending from two inflated balloons **6**, **32** and including a slot **26***a* to accommodate components of the knee joint. Couplers as described elsewhere herein may be used to couple the implant **32** to the distal femur. As shown in FIGS. **6**A and **6**B, the appendages **4***a*-**4***d* in some embodiments are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage **4***d* that is intended to wrap over the medial condyle may be longer and/or wider than the appendage **4***c* intended to wrap over the lateral condyle. Likewise, the dimensions of the balloon **34** that is adapted for placement over the medial condyle may be a different shape and/or size than the balloon **6** over the lateral condyle (the medial condyle being larger, thus the balloon **34** may be larger for that location) Alternatively and/or additionally, as described elsewhere herein, for various reasons such as injury, realignment needs, injury, etc, there may be a need for more reconstruction of one condyle than needed for the other, thus the inflation medium might be different in one balloon (or a portion thereof) than in the other balloon (or another chamber within the same balloon), or there may be need for a different shaped balloon in one location than in another location. Embodiments provided herein can accommodate these requirements based on materials of fillers, appendages, balloons, walls, and dimensions and chamber options of the implant and its components.

FIG. **7** depicts a top-down view of an embodiment of the knee implant **32** curved to simulate curvature about the condyles of a femur, the implant having appendages **4***a*-**4***d* extending from an inflated balloon **6** and including slots to accommodate components of the knee joint. Couplers as described elsewhere herein may be used to couple the implant **32** to the distal femur. As shown here, the appendages **4***a*-**4***d* in some embodiments are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage **4***d* that is intended to wrap over the medial condyle may be longer and/or wider than the appendage **4***c* intended to wrap over the lateral condyle. Likewise, the dimensions of the portion of the balloon that is adapted for placement over the medial condyle may be a different shape and/or size than the portion of the balloon over the lateral condyle (the medial condyle being larger, thus the balloon may be larger for that location) Alternatively and/or additionally, as described elsewhere herein, for various reasons such as injury, realignment needs, injury, etc, there may be a need for more reconstruction of one condyle than needed for the other, thus the inflation medium might be different in a portion or chamber of an implant embodiment having a plurality of inflation chambers in a single balloon, or there may be need for a non-

symmetric balloon. Embodiments provided herein can accommodate these requirements based on materials of fillers, appendages, balloons, walls, and dimensions and chamber options of the implant and its components.

FIG. **8** depicts a side view of an embodiment of the knee implant **32** curved to simulate curvature about at least one condyle of a femur, the implant having appendages **4***b*, **4***d* extending from an uninflated balloon (not shown). This depiction covers the maximum anticipated distal femoral contour; other iterations may be smaller, or shorter covering limited areas of the circumference of the femoral curvatures.

FIG. **9**A depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4***b*, **4***d* extending from an uninflated or minimally inflated balloon **6**. In this view, the knee is positioned essentially in extension (straight), showing the tibia **36**, fibula **38**, and patella **40** of the knee. Note that although there would be other joint structures and knee structures in a true depiction of an implant positioned in the knee, this view of the implant and bones is greatly simplified for ease of understanding of the implant and the joint relative (and approximate) positions and placement. Couplers as described elsewhere herein may be used to couple the implant **20** to the distal femur **24** and/or the condyle **22** thereof (in this image the medial condyle, at least since it is primarily a one-side view of the joint and implant). For the sake of simplicity FIG. **9**A and the implant embodiment depicted show of the femur with opposition to the other surfaces of both knee joints (between femur and tibia, and femur and patella), the areas of contact varying according to activity, forces, and range of motion. Other implant iterations may apply to opposing surfaces.

FIG. **9**B depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4***b*, **4***d* extending from an inflated balloon **6**. In this view, the knee is positioned essentially in extension (straight), showing the tibia **36**, fibula **38**, and patella **40** of the knee. Note that although there would be other joint structures and knee structures in a true depiction of an implant positioned in the knee, this view of the implant and bones is greatly simplified for ease of understanding of the implant and the joint relative (and approximate) positions and placement. Couplers as described elsewhere herein may be used to couple the implant **20** to the distal femur **24** and/or the condyle **22** thereof (in this image the medial condyle, at least since it is primarily a one-side view of the joint and implant). In FIG. **9**B wherein the balloon is inflated, as compared to FIG. **9**A wherein the balloon is not inflated or is minimally inflated, the balloon second wall **30** is closer to and/or contacting the tibial plateau **42** (articular surface) when the balloon **6** is inflated. Likewise, FIG. **9**C depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4***b*, **4***d* extending from an inflated balloon **6** and having couplers **44***a*, **44***b* (which may be, for non-limiting example, staples or screws) coupling the appendages **4***b*, **4***d* to the femur. In this view, the knee is positioned essentially in extension (straight), showing the tibia **36**, fibula **38**, and patella **40** of the knee. Where the inflated balloon as seen in FIG. **9**B may fill in existing pathologic defects of the joint surface, the medium of inflated and specific balloon location and durometry with the material of the implant may also be constructed so as to force the bones opposed, e.g. the femur and tibia, into a more natural limb alignment such as six (6) degrees valgus. However, if the patient being treated has variations from normal in the affected knee as illustrated by examining and measuring the opposite normal side, then the implant inflation and pressures or balloon location may be adjusted from the population norms thus customizing this implant to the clinical case under consideration. Fixation devices may be appropriately applied at various knee range of motion intervals from full extension (zero degrees) to full flexion (usually 135 degrees) as the knee is adjusted and the implant secured under anesthesia.

FIG. **10**A depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4***b*, **4***d* extending from an inflated balloon **6** and showing the inflation medium **46** moved anteriorly toward the patella **40** when the knee joint is slightly flexed. Likewise, FIG. **10**B depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4***b*, **4***d* extending from an inflated balloon **6** and having couplers **44***a*, **44***b* (which may be, for non-limiting example, staples or screws) coupling the appendages **4***b*, **4***d* to the femur **24** and showing the inflation medium **46** moved anteriorly toward the patella **40** when the knee joint is slightly flexed.

In all descriptions provided herein of the dual compartment implant, the implant may instead be configured to couple to or emerge from the tibia and/or patella. In all descriptions provided herein of the dual compartment implant, the implant may instead be configured to couple to the tibia. It is the intention and understanding that the implant is suited for this purpose in certain embodiments with adjustments to account for dimensional differences of the tibia. Most descriptions provided herein are directed to embodiments coupling the implant to the femur, however, this is primarily for ease of description and continuity, and does not preclude embodiments wherein the implant is coupled to the tibia. Likewise, as noted elsewhere herein, there are embodiments where the implant may be coupled to two bones (at least), for example to both a tibia and a femur.

Patch

Some embodiments of the implant are configured to repair isolated lesions wherein osteochondral defects as in osteonecrosis create craters in the cartilage that need 'filling in' with a patch. Various size lesions of cartilage defects can be accommodated by the implants provided herein which may have balloons of at least one of: at most about 0.5 cm in diameter, at most about 0.75 cm in diameter, at most about 1 cm in diameter, at most about 1.25 cm in diameter, at most about 1.5 cm in diameter, at most about 1.75 cm in diameter, at most about 2 cm in diameter, at most about 2.25 cm in diameter, at most about 2.5 cm in diameter, at most about 2.75 cm in diameter, at most about 3 cm in diameter, at most about 3.25 cm in diameter, at most about 3.5 cm in diameter, at most about 3.75 cm in diameter, at most about 0.5 cm in length along the longest length of the balloon, at most about 0.75 cm in length along the longest length of the balloon, at most about 1 cm in length along the longest length of the balloon, at most about 1.25 cm in length along the longest length of the balloon, at most about 1.5 cm in length along the longest length of the balloon, at most about 1.75 cm in length along the longest length of the balloon, at most about 2 cm in length along the longest length of the balloon, at most about 2.25 cm in length along the longest length of the balloon, at most about 2.5 cm in length along the longest length of the balloon, at most about 2.75 cm in length along the longest length of the balloon, at most about 3 cm in length along the longest length of the balloon, at most about 3.25 cm in length along the longest length of the balloon, at most about 3.5 cm in length along the longest length of the

balloon, at most about 3.75 cm in length along the longest length of the balloon, at most about 4 cm in length along the longest length of the balloon, at most about 4.25 cm in diameter, at most about 4.5 cm in diameter, at most about 4.75 cm in diameter, at most about 5 cm in diameter, at most about 5.25 cm in diameter, at most about 5.5 cm in diameter, at most about 5.75 cm in diameter, at most about 6 cm in diameter, at most about 6.25 cm in diameter, at most about 6.5 cm in diameter, at most about 6.75 cm in diameter, at most about 7 cm in diameter, at most about 7.25 cm in diameter, at most about 7.5 cm in diameter, at most about 7.75 cm in diameter, at most about 8 cm in diameter, at most about 3 cm in length along the longest length of the balloon, at most about 3.25 cm in length along the longest length of the balloon, at most about 3.5 cm in length along the longest length of the balloon, at most about 3.75 cm in length along the longest length of the balloon, at most about 4 cm in length along the longest length of the balloon, at most about 4.25 cm in length along the longest length of the balloon, at most about 4.5 cm in length along the longest length of the balloon, at most about 4.75 cm in length along the longest length of the balloon, at most about 5 cm in length along the longest length of the balloon, at most about 5.25 cm in length along the longest length of the balloon, at most about 5.5 cm in length along the longest length of the balloon, at most about 5.75 cm in length along the longest length of the balloon, at most about 6 cm in length along the longest length of the balloon, 6.25 cm in length along the longest length of the balloon, at most about 6.5 cm in length along the longest length of the balloon, at most about 6.75 cm in length along the longest length of the balloon, at most about 7 cm in length along the longest length of the balloon, at most about 7.25 cm in length along the longest length of the balloon, at most about 7.5 cm in length along the longest length of the balloon, at most about 7.75 cm in length along the longest length of the balloon, and at most about 8 cm in length along the longest length of the balloon. As used herein with respect to balloon dimensions whether length or diameter, the term "about" means variations of at least one of 0.1 cm, 0.2 cm, 0.25 cm, 0.5 cm, and 1 cm.

Thus, provided herein is an implant configured to patch osteochondral defects. The defects may occur due to injury, stress, naturally occurring, and/or may created or enhanced by a medical professional during a medical procedure. In some embodiments, the implant may be called a patch having the balloon and an attachment element (or elements—which may be called appendages) described herein and may be sized to fit within a defect in a manhole-cover type manner. In some embodiments, the implant may comprise balloon and attachment elements described elsewhere herein and may be configured to lay over a defect (full defect or partial defect). In some embodiments the implant as described herein as used to patch or repair osteochondral defects may be called a patch or a patch implant.

In some embodiments, the size of the balloon dimensions are prechosen based on the individual patient need, and the balloon size (dimensions, geometry, length, depth, for non-limiting examples) is pre-set. In some embodiments, the balloon comprises multiple chambers which may be inflated (or deflated) selectively to fill the defect in situ or just prior to implantation in order to adjust the implant's balloon size (dimensions, length, width, depth, geometry, for non-limiting example) as needed at the time of implantation. The balloon (or any chamber thereof) of some embodiments can be secondarily inflated or deflated (or both) in situ.

FIGS. **11**A, **11**B, and/or **11**C may be used to describe a patch implant described herein, having appendages **4***a*, **4***c*, extending from a balloon **6** (not shown in FIG. **11**A) and including holes **8***a*-**8***h*, and/or tabs **10***a*-**10***f* which may be used with couplers (not shown) to couple the implant to a bone of the knee joint (which may be the femur, the tibia, or the patella). Features shown in FIG. **11**A, **11**B, and/or **11**C are common to both the unicompartment knee implant (discussed elsewhere herein) and the patch implant, although dimensions may differ as described herein. Thus, FIGS. **11**A, **11**B, and/or **11**C may be used to describe the unicompartment knee implant and/or the patch implant. FIG. **11**A depicts an embodiment of the patch implant **2** curved to simulate curvature about one condyle of a femur, the implant **2** having appendages **4***a*, **4***c*, extending from an uninflated balloon (not shown) and including tabs **10***a*-**10***f* and/or holes **8***a*-**8***h*, which may be used with couplers (not shown, described elsewhere herein) to couple the implant **2** to the femur of the knee joint. FIG. **11**B depicts an embodiment of the patch implant **2** curved to simulate curvature about one condyle of a femur, the implant **2** having appendages **4***a*, **4***c*, extending from an inflated balloon **6** and including tabs **10***a*-**10***f* and/or holes **8***a*-**8***h*, which may be used with couplers (not shown, described elsewhere herein) to couple the implant **2** to the femur of the knee joint. FIG. **11**C depicts a bottom-up of gliding surface view of an embodiment of the patch implant **2** curved to simulate curvature about one condyle of a femur, the implant **2** having appendages **4***a*, **4***c*, extending from an inflated balloon **6** and including tabs **10***a*-**10***f* and/or holes **8***a*-**8***h*, which may be used with couplers (not shown, described elsewhere herein) to couple the implant **2** to the femur of the knee joint. In some embodiments, the implant is configured to couple to a tibia. In some embodiments, the implant is configured to couple to a trochlear groove of a femur. In some embodiments, the implant is configured to couple to only a portion of a condyle of a femur.

FIGS. **12**A, **12**B, and/or **12**C may be used to describe a patch implant described herein, having appendages **4***a*, **4***c*, extending from a balloon **6** and including holes **8***a*, **8***b*, **8***c*, and/or tabs **10***a*, **10***b*. **10***c*, **10***d*, **10***e*, **10***f* which may be used with couplers (not shown) to couple the implant to a bone of the knee joint (which may be the femur, the tibia, or the patella). Features shown in FIG. **12**A, **12**B, and/or **12**C are common to both the unicompartment knee implant (discussed elsewhere herein) and the patch implant, although dimensions may differ as described herein. Thus, FIGS. **12**A, **12**B, and/or **12**C may be used to describe the unicompartment knee implant and/or the patch implant. FIG. **12**A depicts a bottom-up view of an embodiment of the implant **2** (unicompartment or patch), the implant having appendages **4***a*, **4***c*, extending from a balloon **6** and including holes **8***a*, **8***b*, **8***c*, which may be used with couplers (not shown) to couple the implant **2** to the femur of the knee joint. FIG. **12**B depicts a bottom-up view of an embodiment of the implant **2** (unicompartment or patch), the implant having appendages **4***a*, **4***c*, extending from a balloon **6** and including tabs **10***a*, **10***b* and hole **8***a* which may be used with couplers (not shown) to couple the implant to the femur of the knee joint. FIG. **12**C depicts a bottom-up view of an embodiment of the implant **2** (unicompartment or patch), the implant having appendages **4***a*, **4***c*, extending from a balloon **6** and including tabs **10***c*, **10***d*, **10***e*, and **10***f* and hole **8***a* which may be used with couplers (not shown) to couple the implant to the femur of the knee joint. In some embodiments, the implant is configured to couple to a tibia. In some embodiments, the implant is configured to couple to a trochlear groove of a femur. In some embodiments, the implant is configured to couple to only a portion of a condyle of a femur. In some

embodiments the implant is coupled to the patella. In any embodiment the balloon **6** may extend from one surface of the implant as a focal protuberance to fill a defect, space, or to aide in alignment correct, or the balloon may be full thickness as differences in FIGS. **2** and **3** show respectively. In any embodiment there may be a singular or multiple major balloons, if off a primary surface resembling bubble wrap, and there may be microscopic balloons or vacuoles containing gas, gel, or solid in the material matrix.

In all descriptions provided herein of the patch implant, the implant may instead be configured to couple to the tibia or to the fibula or the patella. It is the intention and understanding that the implant is suited for this purpose in certain embodiments with adjustments to account for dimensional differences of these bones. Most descriptions provided herein are directed to embodiments coupling the implant to the femur, however, this is primarily for ease of description and continuity, and does not preclude embodiments wherein the implant is coupled to the tibia (or other bones). Likewise, as noted elsewhere herein, there are embodiments where the implant may be coupled to two bones (at least), for example to both a tibia and a femur.

Partial Knee Arthroplasty (Unicompartment)

In addition to the total knee-type (dual condyle) and patch implants are implants that serve to cover and adjust alignment for either the medial or lateral condyle of the femur with varus or valgus knees requiring added cushioning to recreate the natural six degrees of knee valgus. Thus, provided herein is an implant for placement on at least one condyle of the distal femur (a unicompartment implant—named so due to their coverage of a single condyle of the femur). The implant may be configured to be placed over the lateral condyle. The implant may be configured to be placed over the medial condyle. The implant may be configured to be placed over either the medial condyle or the lateral condyle. Two unicompartment implants may be placed in the same knee, one over the medial condyle, one over the lateral condyle.

FIGS. **11**A-**12** C depict example embodiments of unicompartment implants. In some embodiments, the unicompartment implant comprises a balloon that is at least one of: at most about 1.5 cm in diameter, at most about 1.75 cm in diameter, at most about 2 cm in diameter, at most about 2.25 cm in diameter, at most about 2.5 cm in diameter, at most about 2.75 cm in diameter, at most about 3 cm in diameter, at most about 3.25 cm in diameter, at most about 3.5 cm in diameter, at most about 3.75 cm in diameter, at most about 4 cm in diameter, at most about 4.25 cm in diameter, at most about 4.5 cm in diameter, at most about 4.75 cm in diameter, at most about 5 cm in diameter, at most about 5.25 cm in diameter, at most about 5.5 cm in diameter, at most about 5.75 cm in diameter, at most about 6 cm in diameter, at most about 6.25 cm in diameter, at most about 6.5 cm in diameter, at most about 6.75 cm in diameter, at most about 7 cm in diameter, at most about 7.25 cm in diameter, at most about 7.5 cm in diameter, at most about 7.75 cm in diameter, at most about 8 cm in diameter, at most about 3 cm in length along the longest length of the balloon, at most about 3.25 cm in length along the longest length of the balloon, at most about 3.5 cm in length along the longest length of the balloon, at most about 3.75 cm in length along the longest length of the balloon, at most about 4 cm in length along the longest length of the balloon, at most about 4.25 cm in length along the longest length of the balloon, at most about 4.5 cm in length along the longest length of the balloon, at most about 4.75 cm in length along the longest length of the balloon, at most about 5 cm in length along the longest length of the balloon, at most about 5.25 cm in length along the longest length of the balloon, at most about 5.5 cm in length along the longest length of the balloon, at most about 5.75 cm in length along the longest length of the balloon, at most about 6 cm in length along the longest length of the balloon, 6.25 cm in length along the longest length of the balloon, at most about 6.5 cm in length along the longest length of the balloon, at most about 6.75 cm in length along the longest length of the balloon, at most about 7 cm in length along the longest length of the balloon, at most about 7.25 cm in length along the longest length of the balloon, at most about 7.5 cm in length along the longest length of the balloon, at most about 7.75 cm in length along the longest length of the balloon, and at most about 8 cm in length along the longest length of the balloon. As used herein with respect to balloon dimensions whether length or diameter, the term "about" means variations of at least one of 0.1 cm, 0.2 cm, 0.25 cm, 0.5 cm, and 1 cm.

In some embodiments, the implant comprises attachment tabs or attachment elements over the anterior and/or posterior and/or medial side, and/or lateral side (and/or some combination thereof) of a condyle. In some embodiments, the implant comprises attachment tabs or attachment elements in the intercondylar notch. In some embodiments, the implant comprises attachment tabs or attachment elements superiorly at the distal end of the femur anteriorly.

The posterior of the knee can be difficult to access without disturbing joint components (or in order to minimize such disturbance) such as tendons, ligaments, etc. Thus, in some embodiments, the implant comprises strings, reigns, lassos, and/or lanyards that may pass from the posterior of the implant via the intercondylar notch anteriorly to join with themselves and/or other coupling devices. In some embodiments, posterior reigns or suture-like lanyards cinch up the implant from inside the posterior intercondylar notch toward another connection site around the femur. These couplers may be pre-coupled to the implant, and the implant and its couplers may be configured to be pulled (or cinched) from the anterior of the implant once the implant is in its general location relative to the condyle in order to finally position the implant about the condyle—in particular in order to cinch the implant about the posterior of the condyle. Likewise, in some embodiments where the implant is pre-molded, the coupler as described are adapted to move the implant to its final position with conformity to the condyle's posterior with minimal disturbance to the joint structures at the joint's posterior (minimal cutting, minimal moving, and or minimal detachment, for non-limiting example). In some embodiments at least a portion of the ligamentary structure of the knee is spared.

FIG. **10**A depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4***b*, **4***d* extending from an inflated balloon **6** and showing the inflation medium **46** moved anteriorly toward the patella **40** when the knee joint is slightly flexed. Likewise, FIG. **10**B depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4***b*, **4***d* extending from an inflated balloon **6** and having couplers **44***a*, **44***b* (which may be, for non-limiting example, staples or screws) coupling the appendages **4***b*, **4***d* to the femur **24** and showing the inflation medium **46** moved anteriorly toward the patella **40** when the knee joint is slightly flexed.

FIGS. **11**A, **11**B, and/or **11**C may be used to describe a unicompartment implant **2** (or unicompartment knee implant, terms which may be used interchangeably)

described herein, having appendages **4***a*, **4***c*, extending from a balloon **6** (not shown in FIG. **11**A) and including holes **8***a*-**8***h*, and/or tabs **10***a*-**10***f* which may be used with couplers (not shown) to couple the implant to a bone of the knee joint (which may be the femur, the tibia, or the patella). Features shown in FIG. **11**A, **11**B, and/or **11**C are common to both the unicompartment knee implant and the patch implant (discussed elsewhere herein), although dimensions may differ as described herein. Thus, FIGS. **11**A, **11**B, and/or **11**C may be used to describe the unicompartment knee implant and/or the patch implant. FIG. **11**A depicts an embodiment of the unicompartment knee implant **2** curved to simulate curvature about one condyle of a femur, the implant **2** having appendages **4***a*, **4***c*, extending from an uninflated balloon (not shown) and including tabs **10***a*-**10***f* and/or holes **8***a*-**8***h*, which may be used with couplers (not shown, described elsewhere herein) to couple the implant **2** to the femur of the knee joint. FIG. **11**B depicts an embodiment of the unicompartment knee implant **2** curved to simulate curvature about one condyle of a femur, the implant having appendages **4***a*, **4***c*, extending from an inflated balloon **6** and including tabs **10***a*-**10***f* and/or holes **8***a*-**8***h*, which may be used with couplers (not shown, described elsewhere herein) to couple the implant **2** to the femur of the knee joint. FIG. **11**C depicts a bottom-up view of an embodiment of the unicompartment knee implant **2** curved to simulate curvature about one condyle of a femur, the implant **2** having appendages **4***a*, **4***c*, extending from an inflated balloon **6** and including tabs **10***a*-**10***f* and/or holes **8***a*-**8***h*, which may be used with couplers (not shown, described elsewhere herein) to couple the implant **2** to the femur of the knee joint.

In some embodiments, the unicompartment implant including attachment tabs is at least one of: at most about 15 cm in length along the longest length of the implant, at most about 15.25 cm in length along the longest length of the implant, at most about 15.5 cm in length along the longest length of the implant, at most about 15.75 cm in length along the longest length of the implant, at most about 16 cm in length along the longest length of the implant, at most about 16.25 cm in length along the longest length of the implant, at most about 16.5 cm in length along the longest length of the implant, at most about 16.75 cm in length along the longest length of the implant, at most about 17 cm in length along the longest length of the implant, at most about 17.25 cm in length along the longest length of the implant, at most about 17.5 cm in length along the longest length of the implant, at most about 17.75 cm in length along the longest length of the implant, at most about 18 cm in length along the longest length of the implant, 18.25 cm in length along the longest length of the implant, at most about 18.5 cm in length along the longest length of the implant, at most about 18.75 cm in length along the longest length of the implant, at most about 19 cm in length along the longest length of the implant, at most about 19.25 cm in length along the longest length of the implant, at most about 19.5 cm in length along the longest length of the implant, at most about 19.75 cm in length along the longest length of the implant, at most about 20 cm in length along the longest length of the implant, at most about 20.25 cm in length along the longest length of the implant, at most about 20.5 cm in length along the longest length of the implant, at most about 20.75 cm in length along the longest length of the implant, at most about 21 cm in length along the longest length of the implant, at most about 21.25 cm in length along the longest length of the implant, at most about 21.5 cm in length along the longest length of the implant, at most about 21.75 cm in length along the longest length of the implant, at most about 22 cm in length along the longest length of the implant, at most about 22.25 cm in length along the longest length of the implant, at most about 22.5 cm in length along the longest length of the implant, at most about 22.75 cm in length along the longest length of the implant, at most about 23 cm in length along the longest length of the implant, 23.25 cm in length along the longest length of the implant, at most about 23.5 cm in length along the longest length of the implant, at most about 23.75 cm in length along the longest length of the implant, at most about 24 cm in length along the longest length of the implant, at most about 24.25 cm in length along the longest length of the implant, at most about 24.5 cm in length along the longest length of the implant, at most about 24.75 cm in length along the longest length of the implant, at most about 25 cm in length along the longest length of the implant, at most about 25.25 cm in length along the longest length of the implant, at most about 25.5 cm in length along the longest length of the implant, at most about 25.75 cm in length along the longest length of the implant, and at most about 26 cm in length along the longest length of the implant. As used herein with respect to implant length dimensions, the term "about" means variations of at least one of 0.1 cm, 0.2 cm, 0.25 cm, 0.5 cm, and 1 cm.

In some embodiments, the unicompartment implant is longer than it is wide, and the longer portion of the implant wraps from the anterior of the condyle to the posterior of the condyle. In some embodiments, the length of the implant is longer on the outer edge of the implant than on the inner edge nearest the trochlear groove (whether used on the lateral or medial condyle).

FIGS. **12**A, **12**B, and/or **12**C may be used to describe a unicompartment knee implant (unicompartment implant) described herein, having appendages **4***a*, **4***c*, extending from a balloon **6** and including holes **8***a*, **8***b*, **8***c*, and/or tabs **10***a*, **10***b*. **10***c*, **10***d*, **10***e*, **10***f* which may be used with couplers (not shown) to couple the implant to a bone of the knee joint (which may be the femur, the tibia, or the patella). Features shown in FIG. **12**A, **12**B, and/or **12**C are common to both the unicompartment knee implant and the patch implant (discussed elsewhere herein), although dimensions may differ as described herein. Thus, FIGS. **12**A, **12**B, and/or **12**C may be used to describe the unicompartment knee implant and/or the patch implant. FIG. **12**A depicts a bottom-up view of an embodiment of the implant **2** (unicompartment or patch), the implant having appendages **4***a*, **4***c*, extending from a balloon **6** and including holes **8***a*, **8***b*, **8***c*, which may be used with couplers (not shown) to couple the implant **2** to the femur of the knee joint. FIG. **12**B depicts a bottom-up view of an embodiment of the implant **2** (unicompartment or patch), the implant having appendages **4***a*, **4***c*, extending from a balloon **6** and including tabs **10***a*, **10***b* and hole **8***a* which may be used with couplers (not shown) to couple the implant to the femur of the knee joint. FIG. **12**C depicts a bottom-up view of an embodiment of the implant **2** (unicompartment or patch), the implant having appendages **4***a*, **4***c*, extending from a balloon **6** and including tabs **10***c*, **10***d*, **10***e*, and **10***f* and hole **8***a* which may be used with couplers (not shown) to couple the implant to the femur of the knee joint.

In all descriptions provided herein of the unicompartment implant, the implant may instead be configured to couple to the tibia or to the fibula or the patella. It is the intention and understanding that the implant is suited for this purpose in certain embodiments with adjustments to account for dimensional differences of the particular bones. Most descriptions provided herein are directed to embodiments coupling the implant to the femur, however, this is primarily for ease of

description and continuity, and does not preclude embodiments wherein the implant is coupled to the tibia (or other bones). Likewise, as noted elsewhere herein, there are embodiments where the implant may be coupled to two bones (at least), for example to both a tibia and a femur.

Meniscal Replacement or Repair, and Solid, Rigid, or Semi-Rigid Components:

Provided herein is an implant having a balloon having a first and second chamber. The implant may be any of the Dual Compartment, Unicompartment, and Patch implants described herein. The second chamber may be configured to replace and/or partially replace fibrocartilage meniscal loss. The implant may have two lobes of chambers which may be alternatively described as two superimposed balloon radii in apposition to each other. The implant may be configured to provide stability between the femur and tibia by providing a meniscus wedge. In some embodiments the implant comprises a portion configured to replace and/or partially replace fibrocartilage meniscal loss. Such an embodiment may not require a second chamber.

In some embodiments a chamber of the implant is configured to receive a solid piece configured to restore joint and/or bone alignment. In some embodiments, the chamber is configured to receive a plurality of solid pieces, each of which can be used to increase the space between a first bone and a second bone in order to restore and/or improve joint and/or bone alignment. The solid pieces may be wedge-shaped, or be provided in various sizes and/or shapes. The solid pieces may individually or together be used in a chamber or multiple chambers of the implant. The solid piece (or pieces) may be used to ratchet adjacent bones to a desired distraction and/or alignment to restore and/or improve joint and/or bone alignment. The solid piece may be put in a chamber of the implant, which may enclose or partially enclose the piece to hold the piece in place. In some embodiments, a block of biocompatible material (such as PMMA or another bone-like substitute) may be provided and may be formed (by carving or other forming method) by the surgeon to a desired shape. The formed piece may then be put in a chamber of the implant, which may enclose or partially enclose the piece to hold the piece in place.

In some embodiments, the inflation medium is a methyl methacrylate or other biocompatible hardening substance which can flow when initially put into the chamber, and hardens to become a rigid piece (or solid piece). The methyl methacrylate or other biocompatible hardening substance may conform to the shape of the chamber, or may conform to the shape of a space between bones and/or other joint structures. The methyl methacrylate or other biocompatible hardening substance may conform to a form chosen by the surgeon using tools and/or pressure to influence the final shape of the rigid piece formed by the methyl methacrylate or other biocompatible hardening substance upon hardening.

The solid piece (whether formed in situ or by a surgeon or pre-formed) may be cushioned by the implant. The implant may comprise an inflatable chamber between the solid piece and the femur. The implant may comprise an inflatable chamber between the solid piece and the tibia. The implant may comprise an inflatable chamber between the solid piece and the patella. The implant may comprise an inflatable chamber between the solid piece and the second bone. The implant may comprise a pad between the solid piece and the femur as a cushion. The implant may comprise a pad between the solid piece and the tibia as a cushion. The implant may comprise a pad between the solid piece and the patella as a cushion.

The solid piece may provide at least one of about 1 degree of joint correction, about 2 degrees of joint correction, about 3 degrees of joint correction, about 4 degrees of joint correction, about 5 degrees of joint correction, about 6 degrees of joint correction, about 7 degrees of joint correction, about 8 degrees of joint correction, about 9 degrees of joint correction, and about 10 degrees of joint correction. With respect to degrees of joint correction, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%.

The implant can be used in a variety of joints where the implant replaces a bone on bone surface and cushions the interaction between the articular ends of any two bones, such as at the femoral tibial and patella femoral knee interfaces. Where the implant is substituting or enhancing articular cartilage, the rigidity can be reduced or enhanced to maximize conformation changes that arise during motion as enabled by the two opposing walls and intended inner space, coupled with considerations in any joint surgical reconstruction with accommodation to or amplification of the existing joint ligaments, tendons or dearth thereof. The implant **10** may be deflated and removed by minimally invasive surgery, for example, after the implant has served its purpose of regenerating tissue or if another clinical condition warrants its removal. However, it may not be clinically necessary to remove the implant even if inflation is lost, since the two remaining functions of patching the injured cartilage, and delivering restorative cells may justify implant retention.

In many embodiments the implant (or a portion thereof, such as the balloon or balloon) is a weight bearing spacer that will allow joint motions to approach normal, whether filling the space left by an entirely collapsed peripheral joint bone or the space of ablated cartilage proximate surfaces diffusely as in osteoarthritis or succinctly as in osteonecrotic defects or localized trauma. The walls may be used as a membrane for holding living cells in proximity of the osteochondral defect long enough for the cells to attach (e.g. 24 hours) or to deeply adhere (up to 28 days) or return to normal (up to one year). Weight bearing will be expected to increase as distal lower extremity joints are treated.

Kits

Provided herein are kits comprising multiple implants described herein. A kit may comprise multiple sizes of a single type of implant. A kit may comprise various implant types, such as the patch, the unicompartment, and/or the dual compartment types of implants described herein. A kit may comprise various couplers, which may be selected by the surgeon depending on his comfort and expertise, and/or based on the particular patient anatomy and/or needs. The kit may further comprise any insertion tools and/or surgery tools that may uniquely assist in implanting the implant in the patient.

Implantation Methods

Implantation of implants provided herein will depend on the size of joint surface intended for reconstruction by use of the implant. In some embodiments, an arthroscope can be inserted in one side of the knee joint through a 0.5 cm wound, while the implant is inserted into the opposite joint line wound from 1-10 cm in size. The joint may be first inspected and debrided, performing an arthroscopic synovectomy, chondroplasty, and meniscectomy as needed. Additional distraction under general anesthesia with the knee at variable degrees of flex may allow for implant introduction, systematic peripheral attachment, balancing, and inflation.

In some embodiments, the implant may be selectively inflatable depending on the particular needs of the patient. In some embodiments, the filler of the interior of the implant

may be rigid, semi-rigid, fluid, air, or combinations thereof, as described herein. In some embodiments, the implant may be used in conjunction with fibrocartilage repair or replacement. In some embodiments, the implant may be used without fibrocartilage repair or replacement. In some embodiments, the implant may be used in conjunction with boney osteotomy. In some embodiments, the implant may be used without boney osteotomy.

The posterior of the knee can be difficult to access without disturbing joint components (or in order to minimize such disturbance) such as tendons, ligaments, etc. Thus, in some embodiments, the method comprises providing an implant comprising strings, reigns, lassos, and/or lanyards that may pass from the posterior of the implant via the intercondylar notch anteriorly to join with themselves and/or other coupling devices. In some embodiments, posterior reigns or suture-like lanyards cinch up the implant from inside the posterior intercondylar notch toward another connection site around the femur. In some embodiments, the methods comprise conforming the implant posterior to the condyle by pulling the strings (or reigns, or lassos, or lanyards or the like) of the implant. Such couplers (strings, reigns, lassos, lanyards, etc) may comprise suture materials and/or wire materials.

These couplers (i.e. strings, reigns, lassos, lanyards, etc) may be pre-coupled to the implant, and the implant and its couplers may be configured to be pulled (or cinched) from the anterior of the implant once the implant is in its general location relative to the condyle in order to finally position the implant about the condyle—in particular in order to cinch the implant about the posterior of the condyle. Likewise, in some embodiments where the implant is pre-molded, the coupler as described are adapted to move the implant to its final position with conformity to the condyle's posterior with minimal disturbance to the joint structures at the joint's posterior (minimal cutting, minimal moving, and or minimal detachment, for non-limiting example). In some embodiments at least a portion of the ligamentary structure of the knee is spared.

The implant is inserted arthroscopically through a cannula about 10 mm in diameter with the implant in the deflated construct, and once inside the prepared joint space and secured therein by the skirt or tabs, the implant will be distended or inflated with gas, gel, fluid or fluid that becomes a resilient solid to fill the original natural space of about 0.5 cm between the bones of the joint (between at least two bones of the joint). If the implant is not inserted through a cannula, it may be inserted through an open incision from one to forty centimeters in length at the surgeons discretion. Tensioning will be by the surgeon's sense of proper pressure application aided by a gauged syringe for insertion of viscolubricants such as Synvisc, Hyalgan, Supartz and/or analgesics such as lidocaine gel. The insertion of liquids to the joint per se may be directly, through a cannula to the joint space previously in place for debridement, and or via a cannula or tube that is not part of the original implant assembly. Once the joint is cleaned, the implant is inserted and appropriately fixed to avoid extrusion or dislocation thereof. This may be via attachment of the implant tabs and/or by a combination of tab use plus intended friction created by implant surface coverings (analogous to Velcro) or a draw string at the smaller base of the implant.

In some embodiments the attachment tabs are positioned on the implant to both secure the implant to the joint components, and to enable a physician to ensure the implant has a minimum amount of slack that could create wrinkles or loose areas to avoid unnecessary friction and/or wear of the implant of the patient's anatomy. Figures depicted herein show examples of properly situated attachment tabs configured for these dual purposes. In some embodiments, fewer tabs are needed to achieve these goals.

In some embodiments, where slack or voids exist, the balloon under compression may fill such areas. The implant in some embodiments is configured to allow hyaline and/or cartilage cells to fill any irregularities or craters in the joint components and grow to refurbish natural joint contour. When the implant implantation is combined with, for example, movement of the treated joint in a constant passive motion machine for 12 hrs a day for 6 weeks after surgery implanting the implant, cell growth will create renewed hyaline cartilage, and/or blood/fibrin and scar to create fibrocaritlage filler material.

Each attachment tab insert site may be clinically determined centripitally around the implant during surgery, driving slots or holes sequentially with an osteotome or drill immediately followed by insertion of the triangled tab extension into the bone slots or screw respectively. For example, if the implant were viewed like a clockface the first tab could be tacked/tapped in a 2 o'clock, then 7, 10, 4 11,5, 12, 6 (wherein #2, 7, 10, 4 are over the bilateral femurs superior/inferior to collateral ligaments, 11,12 are superior at the distal anterior femur beneath the upper patella, and 5,6 are inside the intercondylar notch anterior to cruciates.) This can be like putting a saddle on a horse, going around the knee end with a grasper, to tug the polymer toward fit, tapping a slot over the side of the femur with a thin one-half inch osteotome, angling cuts distally, one by one, as if to pull the implant (or saddle) into its angle of repose, seating ideally over the condyles and ridings nicely in the trochlear groove.

In some embodiments, the metal clips could be set angled at about 120 degrees, as greater than 90 will favorably distract/hold the implant to tighter fit analogous to a mylar compliant balloon or stretch sock fitting over a protuberance as opposed to a piece of (non-compliant) paper that results is wrinkles and areas of incongruence between the implant and bone end. Reducing dislodgement tendency and snugging the polymer once stretched to best fit may avoid the failure history as illustrated in the Danish Polymer hip cap solid crescent shaped hip resurfacing implants which lacked inflation, surface stability, accommodation, and fixation.

Inflation may also be specified by clinical need, and modifications in the implant multi-cell (multi-compartment) construction allows for selective inflation with substances ranging from gas to solid, including gels or semi-solids that can as part of material layered integrity either provide calculated hardness (durometer) to overcome and resist limb adjacent bone mal-alignment, and/or to deliver new regenerative tissues for restoration of natural anatomy of time. That is, certain sections of the implant may be electively inflated of left without expansion, to adjust to fit as matching a normal or uninjured contralateral limb for the involved patient.

Indeed, patient interaction and feedback may be sought so as to bring to orthopedic conceived art and science the individual's own needs and concerns. It is said that for patients who have anterior cruciate injuries, one third require reconstruction for knee joint stabilizer, one third do not—living with a reduced activity level, and one third deliberate extensively until a choice between the two continuum options is made.

A goal of embodiments of implants described herein is to maintain remnant living tissue by using minimally invasive technologies, smaller incisions when they serve the patient

equally to larger, sacrificing the least normal tissue as possible. Implants described herein assist and improve on current treatment options available by avoiding as much as possible the ablative bone and cartilage resecting, ligament removing total knee artrhoplasty and instead to restore the padding lost in injury or disease or surgery.

Examples from within the techniques include electing to repair rather than reconstruct anterior cruciate ligaments in certain situations, proved warranted and effective at a $p<0.3$ statistical level. Whereas Carticel chondrocyte implantation is useful to enable articular surface regrowth with hyaline, rather than scar/fibrocartilage from picking/drilling, the massive morbidity from periosteal harvesting is unnecessary. This is because it takes only 24 hours for the cartilage cloned chondrocytes to attach to the prepared joint surface, and the polymer membrane (patch implant described herein, for example, or use of chondrocytes on surfaces of the dual compartment implant or the unicompartment implant) over the prepared defect (like a manhole cover) will adeptly substitute for periosteum.

With these concepts in mind in is the overall intent to do what is necessary to restore function and nothing more in order to spare the patient removal of injured tissues that may recover or regrow, by implementing a common sense approach to limb repair and reconstruction with the implant and methods of use thereof. In animals as horses and dogs, where recovery instructions are even less likely to be followed than with humans, implanting secure restorative implants for joint surface refurbishment may offer renewed function and save lives that would have otherwise been sacrificed.

Rehabilitation of knee implant treated patients will engage prudent early motion. The amount of weight bearing allowed with be analogous to the procedures written by this primary surgery for Carticel implanted cases, following the principles that excessive amounts and repetitions of stress upon reconstructed areas should be avoided for 6-12 weeks after surgery. However, the knee implant surgeries per se are expected to take less than one hour, involve less than 1 cc blood loss, require wounds less than or equal to 10 cm overall (depending on the embodiment of the implant), and the end result intends to permit early full weight bearing. Zealous sports activities may be restricted until the bone ingrowth and cartilage renewal is reasonably expected, between 2 and 12 months after surgery depending upon the amount of joint tissue replaced.

In some situations, the removal of the implant may be needed, and embodiments of the implants described herein are configured for removal artrhoscopically, and with the allowance to perform all regular older routine accepted techniques ranging from joint debridement to drilling, partial or total replacement. In some embodiments the implant is configured for removal and replacement with a replacement implant—either immediately (within a week), or after a period of longer time (for example, after about 6 weeks to 1 year in the case of infection once all foreign bodies are removed and depending upon the surgeon's and/or infectious disease consultant's opinion

Specific surgical decisions related to size matching, fixation and or concomitant osteotomy warranted reconstruction are left to the primary surgeon and patient in each case.

The implant is inserted by minimally invasive surgery, in some embodiments, however, in other embodiments, the implant may not be inserted by minimally invasive surgery. In some embodiments, the implant is delivered through an incision that is about 0.5 inches long. In some embodiments, the implant is delivered through an incision that is about 1 centimeter long. In some embodiments, the implant is delivered through an incision that is at most about 1 inch long. In some embodiments, the implant is delivered non-arthroscopically through an incision that is at least 1 centimeter long. In some embodiments, the implant is delivered through an incision that is at most about 0.75 inches long. In some embodiments, the implant is delivered through an incision that is at most about 0.5 inches long. In some embodiments, the implant is delivered through an incision that is about 8 centimeters long. In some embodiments, the implant is delivered through an incision that is about 9 centimeters long. In some embodiments, the implant is delivered through an incision that is about 10 centimeters long. In some embodiments, the implant is delivered through an incision that is about 11 centimeters long. In some embodiments, the implant is delivered through an incision that is about 12 centimeters long. In some embodiments, the implant is delivered through an incision that is over about 10 centimeters long. In some embodiments, the implant is delivered through an incision that is at up to about 40 centimeters long. In some embodiments, the implant is delivered through multiple incisions. With respect to incision length, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%.

In some embodiments the implant is configured to be delivered to the joint arthroscopically. In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most 10 millimeters. In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most 9 millimeters. In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most 5 millimeters.

In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most 10 millimeters. In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most 9 millimeters. In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most 5 millimeters.

In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most 10 millimeters. In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most 9 millimeters. In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most 5 millimeters.

In some embodiments the implant is configured to be delivered to the joint arthroscopically. In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most about 10 millimeters. In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most about 9 millimeters. In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most about 5 millimeters. With respect to cannula distal end inner diameter, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%.

In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most about 10 millimeters. In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most about 9 millimeters. In some embodiments, the implant is config-

ured to fold in order to fit within a cannula having a distal end inner diameter of at most about 5 millimeters. With respect to cannula distal end inner diameter, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%.

In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most about 10 millimeters. In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most about 9 millimeters. In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most about 5 millimeters. With respect to cannula distal end inner diameter, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%.

In some embodiments the implant may be provided as a deflated balloon for insertion into the joint space. In some embodiments the implant may be provided as folded balloon that may be collapsed like an umbrella for insertion into the joint space. In some embodiments the implant may be provided as collapsed balloon that is of an irregular folded pattern to minimize its folded (or collapsed) size for insertion into the joint space. In some embodiments, the implant is configured to blow up (or expand) to take the form of the expanded, distracted, debrided joint.

In some embodiments, the implant replaces periosteum.

In some embodiments, the implant is implanted to preserve bone as compared to a typical arthroplasty procedure of the joint. In some embodiments, the implant is implanted to preserve cartilage as compared to a typical arthroplasty procedure of the joint. In some embodiments, the implant is implanted with minimal soft tissue dissection as compared to a typical arthroplasty procedure of the joint. In some embodiments, the implant is implanted without joint dislocation. In some embodiments, once implanted, the joint is adaptable to revision surgery. In some embodiments once implanted, the joint retains at least one of: about 90% of normal joint function, about 95% of normal joint function, about 85% of normal joint function, about 80% of normal joint function, about 75% of normal joint function, about 70% of normal joint function, about 65% of normal joint function, about 60% of normal joint function, about 55% of normal joint function, about 50% of normal joint function, at least 95% of normal joint function, at least 90% of normal joint function, at least 85% of normal joint function, at least 80% of normal joint function, at least 75% of normal joint function, at least 70% of normal joint function, at least 65% of normal joint function, at least 60% of normal joint function, at least 55% of normal joint function, at least 50% of normal joint function, about 50%-about 75% of normal joint function, about 50%-about 70% of normal joint function, about 60-about 70% of normal joint function, about 70%-about 80% of normal joint function, about 70%-about 90% of normal joint function, about 80%-about 95% of normal joint function, about 80%-about 90% of normal joint function, and about 90%-about 95% of normal joint function. As used herein with respect to percentage of normal joint function, the term "about" can be ranges of 1%, 5%, 10%, or 25%. For example, a range of 1% with respect to about 90% of normal joint function covers 89% to 90% of normal joint function.

In some embodiments, prior to deploying the implant embodying features of the invention, the cartilage lining the joint is prepared by removing hyaline or fibro cartilage flaps or tears, and areas of chondral advanced fissuring are excised or debrided to create precisely defined defects surrounded by stable normal remnant hyaline cartilage with vertical edges in relation to the damaged surface. It is these defects of the cartilage previously normal surface into which new living cells may be injected or otherwise inserted, and allowed to aggregate by the implant interpositional arthroplasty proximate expanded compressive external wall material. Synovitis invading the joint periphery may be vaporized and extracted conventionally or by the use of steam. Areas of greater cartilage damage are removed for subsequent regeneration and the less afflicted areas having stable cracks are treated to seal or weld the cracks. Areas where the tugor or consistency or minimally damaged cartilage can be preserved are intentionally saved rather than destroyed so as to support the normal spacing and gliding opportunity of the more normal joint interface. Thus, normal cartilage is left behind and abnormal cartilage is removed with the implant making up for the deficiencies. With the present invention, it is preferred in some embodiments to avoid joint dislocation so as to preserve natural innervations and vascularity and thus preserving the blood supply.

Joint preparation is usually performed under a brief general anesthetic of outpatient surgery. Increasing the joint space may be necessary and allows the surgeon to wash out noxious enzymes, to remove invasive synovitis, to remove loose bodies, to prepare osteochondral defects ideally and otherwise prepare the joint for the implant. Partial or complete inflation of the implant may precede release of traction in some embodiments. In some embodiments, regeneration agents or cells are inserted with the implant or as a fluid or 3-D template prior to release of traction and wound closure. It is preferred, in some embodiments, to perform joint debridement, implant deployment and application of cell regeneration agent, e.g. stem cell application, under the same anesthetic. As described by several companies in the Stem Cell Summit held in New York, N.Y. on Feb. 17, 2009, it is desirable to obtain an aspiration of the patient's bone marrow from the iliac crest after anesthesial sterilely at the beginning of the operation. The intraoperative technologist will "dial in the cells" to regenerate areas of maximum pathophysiology while the surgeon debrides or otherwise prepares the joint and inserts the implant, placing the cells at the best time. Cell implantation may also occur as a secondary or tertiary reconstructive treatment adjunct.

Provided herein is a method for restoring a joint comprising: providing an implant configured for deployment between a femur and at least one second bone of a joint, the implant comprising a balloon comprising a first portion that is configured to engage the femur of the joint, a second portion that is configured to engage at least one second bone of the joint, a side portion connecting the first portion and the second portion, in which the side portion facilitates relative motion between the first portion and the second portion, and an interior that is optionally inflatable with a first inflation medium; and coupling a first appendage of the balloon to the femur of the joint. Provided herein is a method for restoring a joint comprising: providing an implant configured for deployment between a tibia and at least one second bone of a joint, the implant comprising a balloon comprising a first portion that is configured to engage the tibia of the joint, a second portion that is configured to engage at least one second bone of the joint, a side portion connecting the first portion and the second portion, in which the side portion facilitates relative motion between the first portion and the second portion, and an interior that is optionally inflatable with a first inflation medium; and coupling a first appendage of the balloon to the tibia of the joint.

In some embodiments, at least two of first portion, the second portion, and the side portion are contiguous. In some

embodiments, the first portion comprises a first wall, the second portion comprises a second wall, and the side portion comprises a side wall.

In some embodiments the method comprises providing an ingrowth patch on at least one of the first portion configured to engage the femur, the second portion configured to engage the second bone, the side portion, and the appendage. In some embodiments the method comprises providing an ingrowth patch on at least one of the first portion configured to engage the tibia, the second portion configured to engage the second bone, the side portion, and the appendage. The ingrowth patch may be configured to encourage and/or promote tissue ingrowth, such as bone ingrowth, for non-limiting example. The patch may be as large as the portion itself (whether the first portion the second portion, the side portion, or the appendage) or may be smaller than the portion (such as in the shape of a strip or other shaped patch). The ingrowth patch may comprise a surface irregularity or roughness. The ingrowth patch may be Velcro-like. In some embodiments the implant comprises an ingrowth patch on the first portion and/or the second portion, from (and in some embodiments including) a first appendage to a second appendage. In some embodiments, wherein the appendages loosen from attachment from the bone (by design and/or from wear and/or over time), the ingrowth patch aids in securing the implant to the bone. In some embodiments, the ingrowth patch comprises beads and/or bead-like elements attached to the implant. Such an ingrowth patch may be configured to simulate trabecular bone space of a normally cancellous latticework. In some embodiments, the beads are sintered beads of various sizes. In some embodiments, the beads are sintered beads about 400 microns in size. With respect to bead size, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%. In some embodiments, the first bone and/or the second bone is roughened to acquire a bleeding bone to facilitate ingrowth. In some embodiments, about 0.5 mm of cortical tissue is removed to facilitate ingrowth.

In some embodiments, the method comprises coupling a second appendage of the balloon to the femur of the joint. In some embodiments, the method comprises coupling a second appendage of the balloon to the tibia of the joint. In some embodiments, the method comprises coupling a second appendage of the balloon to at least one second bone of the joint. In some embodiments, the method comprises coupling a second appendage of at least one of the first portion, the second portion, and the side portion to at least one of the femur and at least one second bone of the joint. In some embodiments, the method comprises coupling a second appendage of at least one of the first portion, the second portion, and the side portion to at least one of the tibia and at least one second bone of the joint. In some embodiments, coupling at least one of the first appendage and the second appendage provides ligamentary-like support to the femur and the at least one second bone of the joint. In some embodiments, coupling at least one of the first appendage and the second appendage provides ligamentary-like support to the tibia and the at least one second bone of the joint. In some embodiments, coupling at least one of the first appendage and the second appendage provides ligamentary-like support to the joint. In some embodiments, the first appendage and the second appendage are configured to provide tendon-like support to the femur and the at least one second bone of the joint. n some embodiments, the first appendage and the second appendage are configured to provide tendon-like support to the tibia and the at least one second bone of the joint. In some embodiments, the first appendage and the second appendage are configured to provide tendon-like support to the joint.

In some embodiments, the method comprises providing an inflation port in communication with the interior of the balloon for inflation of the interior of the balloon with the first inflation medium. In some embodiments, the method comprises using an inflation port of the implant that is in communication with the interior of the balloon to inflate the interior of the balloon with the first inflation medium. In some embodiments, the method comprises puncturing the balloon to inflate the interior of the balloon with the first inflation medium. In some embodiments, the method comprises providing a balloon having self-sealing capability. In some embodiments, the method comprises providing a balloon having self-sealing capability upon inflation of the interior of the balloon with the first inflation medium. In some embodiments, the method comprises providing a balloon comprising a seal capable of closing the interior of the balloon.

In some embodiments, the method comprises providing a balloon having an interior comprising a plurality of inflatable chambers. In some embodiments, the interior comprises a plurality of individually inflatable chambers. In some embodiments, the method comprises inflating a first chamber of the plurality of inflatable chambers with a first inflation medium. In some embodiments, the first chamber and the inflation medium is selected based on the particular needs of the patient. For non-limiting example, if the patient has bone loss due to an injury, the chamber may be selected at the location of the missing bone, and may be filled with a rigid inflation medium (or one that becomes rigid once in the chamber) in order to replace the missing and/or damaged bone. Alternatively, or in addition, a chamber may be chosen to restore alignment of the joint, and inflated with an appropriate inflation medium to impart both alignment and cushion to the joint. In some embodiments, the method comprises inflating a second chamber of the plurality of individually inflatable chambers with a second inflation medium.

In some embodiments, the balloon is a composite structure. In some embodiments, the balloon comprises layers of porous and/or non-porous materials, or otherwise contain treatment or cell regeneration agents. In some embodiments, a first layer of the balloon is a thin, but strong layer of a thermoplastic, such as a thermoplastic polyurethane, for non-limiting example, which has microporosity sufficient to allow passage or egress of treatment or cell regeneration agents from a second layer. The second layer may be a central layer (which lies between the first layer and a third layer or a fourth layer or more layers). The first layer may comprise a bone engaging surface in some embodiments. The degree of microporosity to enable egress of treatment or cell regeneration agents from the second layer is found in polymer layers such as Chronoflex or Bionate 55. The bone engaging surface of the implant may be coated and/or impregnated with a latticework of polymer that is surface sprayed or layered on the bone engaging surface of the implant to promote cartilage tissue regeneration. This bone engaging surface coating may contain living chondrocytes (for example, as is provided in the Carticel procedure by the Genzyme company), and/or may contain stem cells with directed gene mutations to enhance adherence of the coating to the implant. The bone engaging surface may comprise peaks and troughs. The living cells may be provided in troughs while the surface peaks may be used for at least one of: space validation, traction, and cell protection.

In some embodiments, the first inflation medium imparts rigidity in the implant. In some embodiments, the first inflation medium imparts cushion in the implant. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium aligns the joint. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium aligns the bones of the joint. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium changes the bone alignment. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium improves joint alignment. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium restores, at least in part, joint alignment. In some embodiments, individual chambers of the interior are selectively inflated with a first inflation medium and/or a second inflation medium. In some embodiments, individual chambers of the interior are selectively inflated with a first inflation medium and/or a second inflation medium in order to reconstruct the joint and/or in order to reconstruct bones of the joint.

Over time, ingrowth of repair tissue aids in fixation and stability externally to the implant, while the soft cushioning implant interior will absorb forces across the joint surfaces and permit proper motion. The turgor or wall tension of the implant as well as the inside distension of the implant per se can be adjusted by adding or removing the inflation substance to the implant's interior space.

Accordingly, the present invention provides a new approach to arthroplasty that involves a resilient implant deployed between bones of the knee joint. Whereas a joint is comprised of the interface between bone cartilage space cartilage bone, in certain joint spaces such as the knee, the invention cushion may expand to fit the spaces between both "knee joints"—the femoral tibial involved on standing or walking on a level plane, and the patella femoral bones of the knee more involved on stair ascent and decent. For example, pressures behind the knee cap or patella when lying are zero, when standing are 0.7 times body weight, and when going up and down the patella femoral pressures are 3-4 times body weight. Thus, the implants will need to accommodate all the normal body functional pressures and complex space movements. The implant embodying features of the present invention provides more physiologic motion and shock absorption within the joint and has combined characteristics of anatomic design symmetry, balanced rigidity with sufficient attachment connections to adjacent normal structures, and durability that meet the needs of joint reconstruction.

The opposing internal surfaces of the first and second walls of the invention may either move together in synchrony or in opposite directions from one another (e.g. the superior wall moving medially in the hip and the inferior wall moving laterally). Optionally, the implant may be fixed to a concave surface of the joint or to a convex surface of the joint, to both, or to neither (e.g., having an interference fit within the joint with an expanding balloon or cushion that fills the existing space). The implant may be inserted arthroscopically like a deflated balloon and then inflated through a cannula into the joint structure) to act as a cushion or renewed interface for painless and stable limb motion. When feasible joint capsular and adjacent ligament tissue as well as bone will be left in place to preserve the natural body, unless interfering with reconstructed limb function.

The application of steam in addition to removing damaged debris, can smooth out and reform the joint surface. The high temperature of the steam tends to weld cracks or fissures which can be present in the cartilage surface of a damaged joint. Smoothing of joint surface cartilage with steam welds or seals existing cracks or flaps in the cartilage, especially superficially as the lamina splendors, which melt together to provide a white shiny gliding joint surface. In cases where bone is exposed, the steam can be used to stabilize the periphery of the defect in the joint surface via capsulorrhaphy or joint tightening. Open mechanical and chemical debridement may also be employed to prepare the surfaces for the implant.

Once the implant is secured to the femur by means of the skirt or tabs or using other couplers, an impregnated transfer medium or cell template may be used, as described by Histogenics and Tygenix chondrocytes delivery systems wherein the position of concentrated cells is mechanically placed about the implant at areas of greatest cartilage damage to promote regrowth, or as in Carticel wherein watery cells are implanted beneath a periosteal membrane (a wall of the implant serving as the membrane), prior to completion of the inflation or expansion of the implant. At syringe or gauged device with measured screw-home pressure is used to inflate the implant.

Once the joint is ready to receive the implant, the deflated implant is advanced through the diaphragm of a delivery cannula (such as the Acufex from Smith & Nephew) or through the open incision site into the joint. It can be inflated by the attached cannula using a common syringe, inserting several cc's of filler material. Inserted contents and locations of cell placements depend on areas of need and joint size. In some embodiments of the methods several cc's of filler material and a viscolubricant in the interior of the implant will allow distension, cushioning, and gliding movements. Cell regeneration agents are placed in the areas of greatest need.

Methods of living stem cell or chondrocyte placement depend on the lesions and specific implant construct. Direct infusion into the joint with completion of implant inflation will press the cells into the hyaline surface, whereupon they attach within the first 24 hours. As a result, the patient may be forced to remain sedentary and the joint where the implant is deployed, non-weight bearing for the first day after surgery. Deeper osteochondral defects can be treated by 'hyper-perfusion of cells' via either 3-D cell transfer templates, or microneedle injection as used in treatment of diabetic patients for blood sugar testing and insulin/transdermal drug delivery. In cases of osteochondritis dissecans or localized both cartilage and bone lose, bone graft may be packed into the base of the defect followed by addition cell/tissue application. The cannula attached to the implant may be sealed and detached, or left in place for periodic aspiration of noxious enzymes as for the Cox-1, Cox-2, and 5-Lox systems, followed by reinsertion of activated substances including viscolubricants, or even more cells.

Implants embodying features of the invention may be designed for permanent or temporary deployment within a joint structure. Moreover, the implant may be formed of suitable bioabsorbable materials so that the implant may be absorbed within a particular predetermined time frame.

Suitable bioabsorbable materials include polylactic acid, polyglycolic acid, polycaprolactone, copolymers, blends and variants thereof. One present method of forming the implant is to apply numerous layers of polymer such as ChronoFlex AR in a solvent and evaporating the solvent after applying each layer.

The coupling aspects (couplers) including but not limited to skirting or fixation tabs of the present implant prevent joint migration during use.

In some embodiments, the implant is adapted to restore natural joint function. In some embodiments, the implant is adapted to preserve viable joint tissue. In some embodiments, the implant is adapted to be placed with minimal surgery as compared to joint replacement therapy currently marketed. In some embodiments, the implant is adapted to permit weight bearing post surgery within at least one of: about 1 week, within about 1 day, within about 2 days, within about 3 days, within about 4 days, within about 5 days, within about 6 days, within about 10 days, within about 2 weeks, within about 3 weeks, within about 4 weeks, within about 5 weeks, within about 6 weeks. In some embodiments, the implant is adapted to permit weight bearing post surgery after about 1 day wherein full weight bearing is allowed in about 6 weeks. As used herein with respect to weight bearing timing, the term "about" can be a range of 1 day, 2 days, or 3 days, in some embodiments. In some embodiments, the implant is adapted to be allow for faster recovery and resumption of normal activities as compared to joint replacement therapy currently marketed.

In some embodiments, the balloon (or a portion thereof) is adapted to conform to the patient's anatomy. In some embodiments, the implant (or a portion thereof) is adapted to conform to the patient's anatomy. In some embodiments, the inflation medium is adapted to absorb a force (or forces) exerted on the joint. In some embodiments, the inflation medium is adapted to absorb a force (or forces) exerted on the bones of the joint. In some embodiments, the inflation medium is adapted to absorb a force (or forces) exerted on at least one bone of the joint. In some embodiments, the balloon is adapted to absorb shocks exerted on at least one of a bone, multiple bones, a ligament of the joint, ligaments of the joint, a tendon of the joint, tendons of the joint, and the joint in general. In some embodiments, the implant is adapted to restore natural cartilage cushion with stem cells.

In some embodiments, the balloon (or a portion thereof) is adapted to renew joint space. In some embodiments, the balloon (or a portion thereof) is adapted to reducing pain as compared to the pain felt prior to the implantation of the implant. In some embodiments, the balloon (or a portion thereof) is adapted to restore joint function. In some embodiments, the implant (or a portion thereof) is adapted to renew joint space. In some embodiments, the implant (or a portion thereof) is adapted to reducing pain as compared to the pain felt prior to the implantation of the implant. In some embodiments, the implant (or a portion thereof) is adapted to restore joint function.

In some embodiments, the implant is adapted to reverse arthritis in the joint.

In some embodiments, the balloon (or a portion thereof) is adapted to be placed into a debrided limb joint arthroscopically. In some embodiments, the balloon is adapted to pad cartilage defects. In some embodiments, the balloon is inflated to cushion the joint. In some embodiments the implant is adapted to deliver stem cells to at least one of the joint and a bone of the joint. In some embodiments the implant is adapted to deliver living chondrocytes to at least one of the joint and a bone of the joint. In some embodiments, the implant is adapted to provide a new articular surface for the joint. In some embodiments, the implant is adapted to act as a spacer in the joint. In some embodiments, the implant is adapted to space the bones of the joint apart for proper joint articulation. In some embodiments, the implant is adapted to space the bones of the joint apart for reduced bone-on-bone rubbing.

In some embodiments, the implant is configured to at least one of: pad cartilage, cushion the joint, deliver a pharmacologic substance, remove noxious enzymes, debride upon implantation, debride the joint following implantation, deliver a therapeutic substance, deliver a biologic substance, and deliver living stem cells. In some embodiments, the implant is configured to deliver a chemotherapeutic agent to a bone or other surrounding tissues. In some embodiments, the implant is configured to deliver an anti-infectious medication to a bone or other surrounding tissues. In some embodiments, the implant is configured to deliver at least one of an antibiotic, antifungals, and analgesics agent.

In some embodiments, the implant is configured to be selectively inflated to realign limbs.

Provided herein is a method comprising: implanting a knee implant as described herein into a subject, wherein the implant reverses arthritis in the subject.

Provided herein is a method comprising: implanting a knee implant as described herein into a knee joint of a subject and treating a component of the knee joint of the subject with at least one of an allograph tissue, an autograph tissue, and an xenograph tissue. In some embodiments, the implanting step is at least one of: prior to the treating step, simultaneous with the treating step, and following the treating step.

Provided herein is a method comprising: implanting a knee implant as described herein into a subject, wherein the implant at least one of: restores joint function and controls arthopathies. In some embodiments, the implanting spares existing anatomy.

Provided herein is a method comprising: debriding a femur condyle of a knee joint of a subject, and implanting a knee implant as described herein into the knee joint of the subject, whereby the implant is configured to anneal to the cartilage of the subject. In some embodiments, the debriding is achieved by steam application.

Provided herein is a method comprising implanting a knee implant as described herein into a joint previously treated with a joint replacement. In some embodiments, the method comprises removing the joint replacement prior to implanting the knee implant. In some embodiments, the method comprises clearing infectious matter from the joint and/or surrounding tissues. In some embodiments, the method comprises implanting a second implant of any implant described herein following removing the implant previously implanted in the joint. In some embodiments, the method comprises replacing the joint of the subject following removing the implant previously implanted in the joint. In some embodiments, the method comprises debriding the bone of the joint, and implanting an implant of any implant described herein. In some embodiments, the method comprises repeating the debriding and implanting steps.

While particular forms of the invention have been illustrated and described herein, it will be apparent that various modifications and improvements can be made to the invention. One alternative implant construction involves the use of an upper portion of the implant having a net-like construction and filled with balls or ball bearing like elements that are larger than the openings in the netting. The balls or ball bearing like elements provide motion to the implant.

The netting and ball bearing like elements may include regeneration agents as previously discussed, and the bearing construction may be directed toward favorable implant movement balanced with content disbursement.

The invention is intended primarily for human use but may be extended to mammalian use. To the extent not otherwise disclosed herein, materials and structure may be of conventional design.

Moreover, individual features of embodiments of the invention may be shown in some drawings and not in others, but those skilled in the art will recognize that individual features of one embodiment of the invention can be utilized in another embodiment. Moreover, individual features of one embodiment may be combined with any or all the features of another embodiment. Accordingly, it is not intended that the invention be limited to the specific embodiments illustrated. It is therefore intended that this invention be defined by the scope of the appended claims as broadly as the prior art will permit.

Terms such as "element", "member", "component", "device", "means", "portion", "section", "steps" and words of similar import when used herein shall not be construed as invoking the provisions of 35 U.S.C §112(6) unless the following claims expressly use the terms "means for" or "step for" followed by a particular function without reference to a specific structure or a specific action. All patents and all patent applications referred to above are hereby incorporated by reference in their entirety.

While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

What is claimed is:

1. A method for treating an arthritic knee joint comprising:

inserting an inflatable implant into a knee joint through a cannula;

securing the implant to an articulating end of a femur of the knee joint;

selectively inflating one or more of a plurality of chambers of a balloon of the implant to adjust a size and shape of balloon such that the balloon partially or completely fills a defect in the articulating end of the femur of the knee joint to provide cushioning for the knee joint and restore joint alignment.

2. The method of claim **1**, wherein a distal end of the cannula is about 11 millimeters in diameter.

3. The method of claim **1**, wherein inflating one or more of a plurality of chambers of the balloon comprises filling the one or more chambers with an inflation medium that hardens.

4. The method of claim **1**, further comprising debriding the surface of the articulating end of the femur of the knee joint.

5. The method of claim **1**, wherein the existing anatomy of the knee joint is spared.

6. The method of claim **1**, wherein securing the implant to the articulating end of the femur in the knee joint comprises attaching a plurality of tabs of the implant to the articulating end of the femur.

7. The method of claim **1**, further comprising folding the inflatable implant such that it is sized to fit into the cannula before inserting the implant into the knee joint through the cannula and allowing the folded implant to unfold after inserting the implant into the knee joint through the cannula.

8. The method of claim **1**, wherein selectively inflating one or more of a plurality of chambers comprises inflating a first chamber of the plurality of chambers with a first inflation medium and a second chamber of the plurality of chambers with a second inflation medium that is different from the first inflation medium.

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(12) **United States Patent**
Grotz

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(54) **RESILIENT INTERPOSITIONAL ARTHROPLASTY DEVICE**

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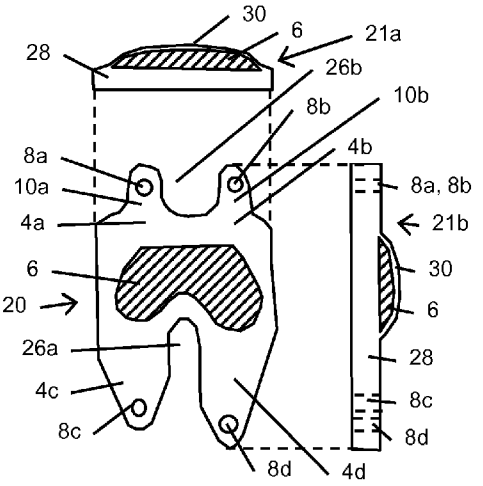
(57) **ABSTRACT**

This disclosure is directed to a resilient interpositional arthroplasty implant for application into a joint to pad cartilage defects, cushion, and replace or restore the articular surface, which may preserve joint integrity, reduce pain and improve function. The implant may endure variable joint compressive and shear forces and cyclic loads. The implant may repair, reconstruct, and regenerate joint anatomy, and thereby improve upon joint replacement alternatives. The walls of this invention may capture, distribute and hold living cells until aggregation and hyaline cartilage regrowth occurs. The implant may be deployed into debrided joint spaces, molding and conforming to surrounding structures with sufficient stability so as to enable immediate limb use after outpatient surgery. Appendages of the implant may repair or reconstruct tendons or ligaments, and menisci by interpositional inflatable or compliant polymer arthroplasties that promote anatomic joint motion.

27 Claims, 14 Drawing Sheets



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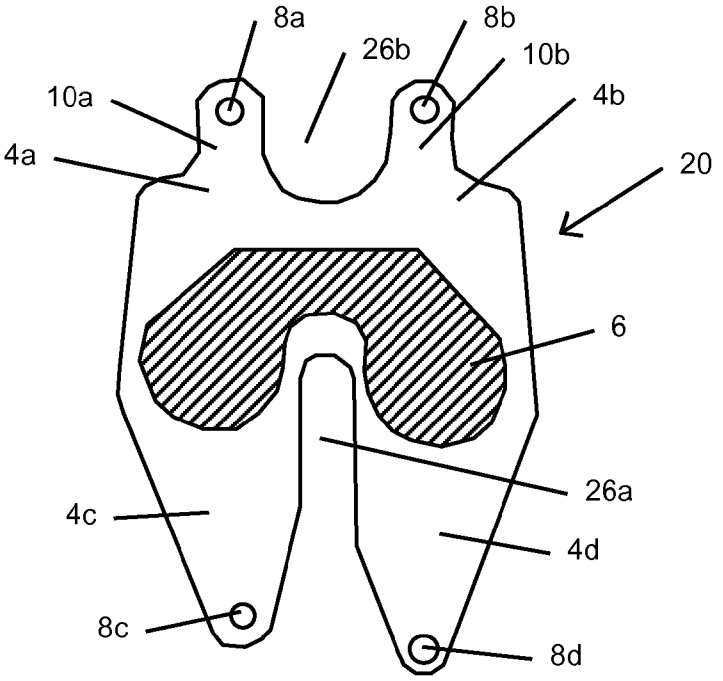
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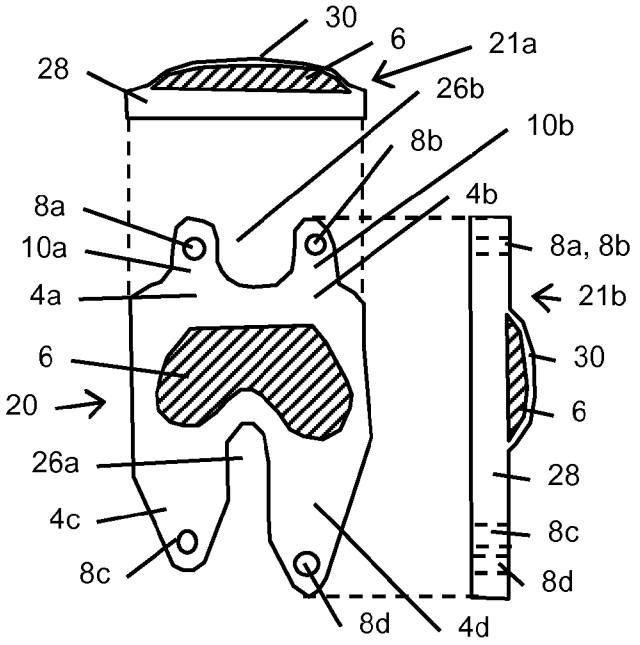
8c
8d

FIG. 1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8a, 8b
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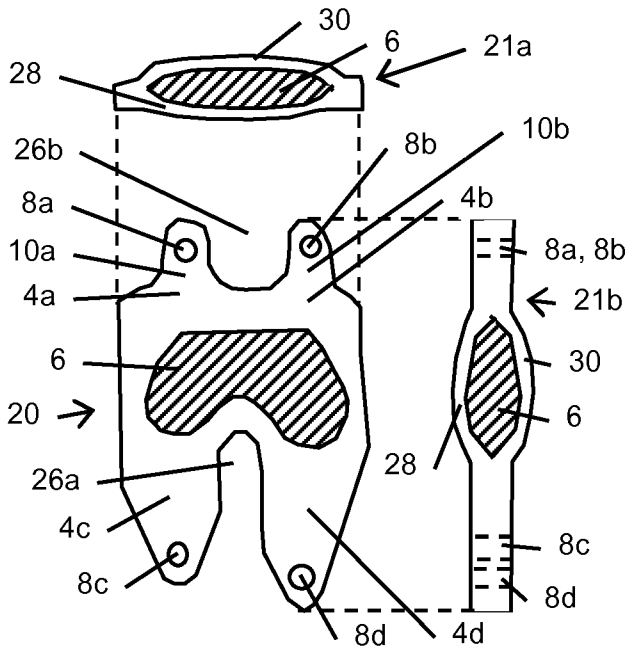
26a
28
4c
8c
8c
8d
8d
4d

FIG. 2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10a
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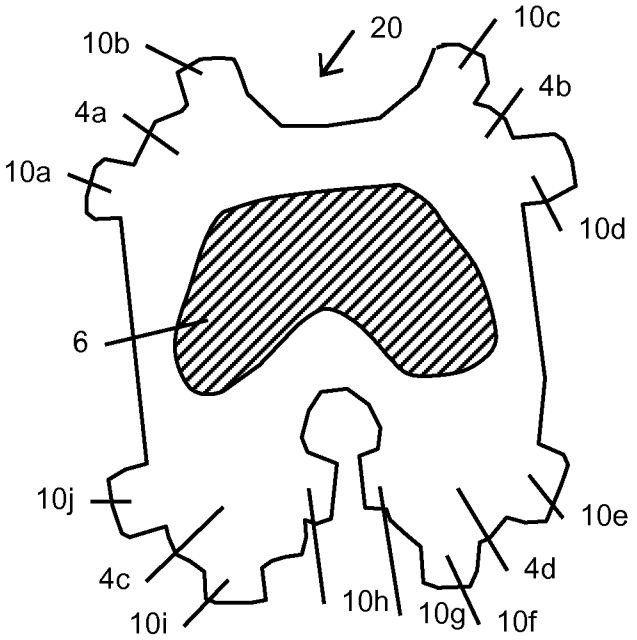
4c
8c
8c
8d
8d
4d

FIG. 3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10c
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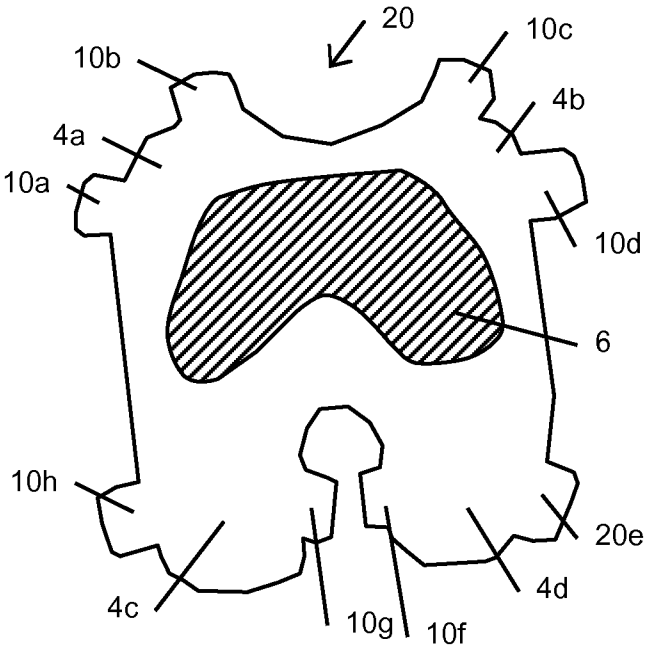
10f
10i

FIG 4A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10f

FIG 4B

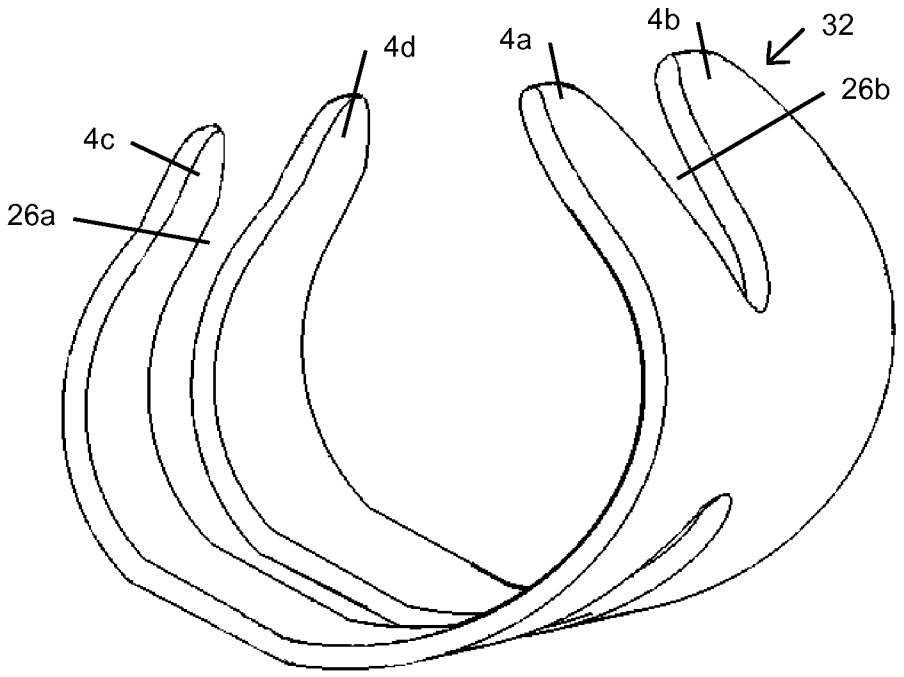

4d
4a
4b
32
26b
4c
26a

FIG 5

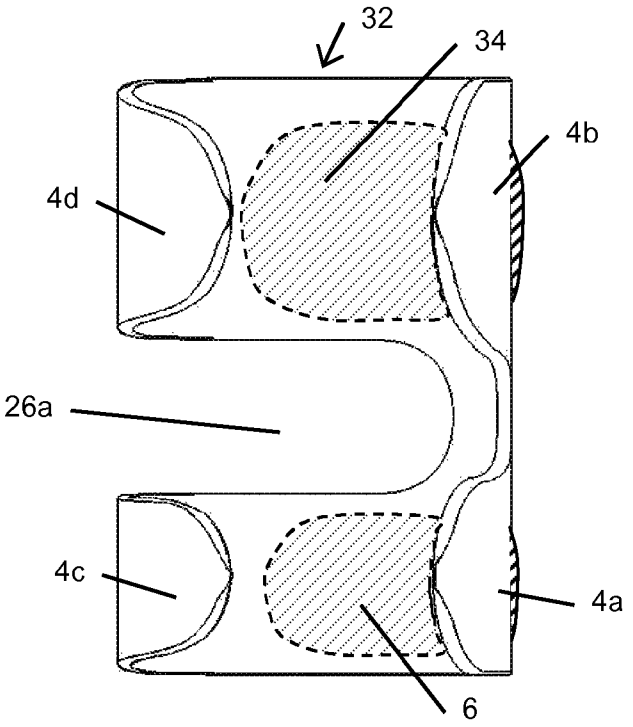


FIG. 6A

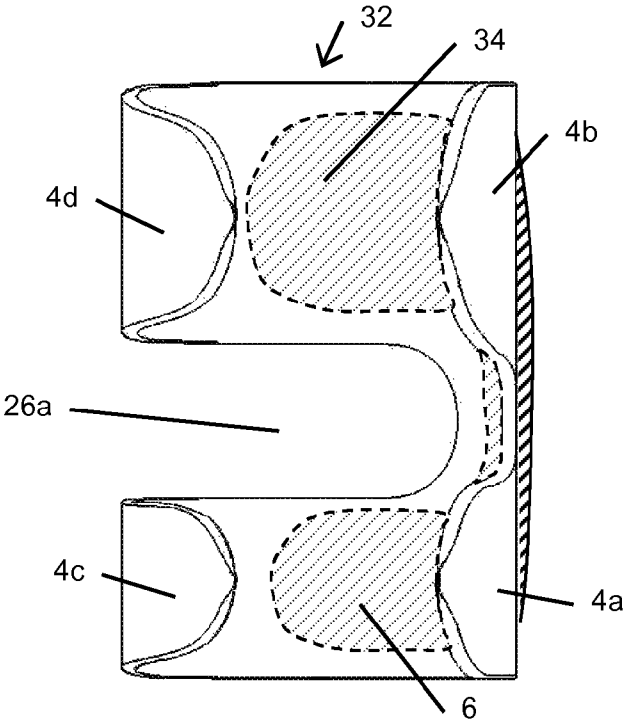


FIG. 7

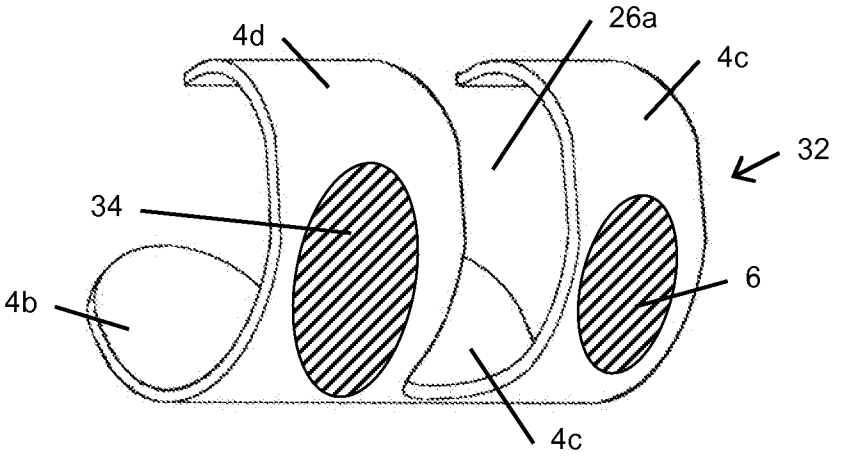


FIG 6B

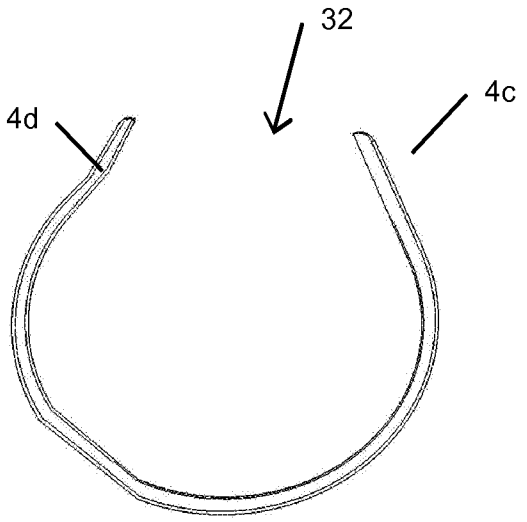


FIG 8

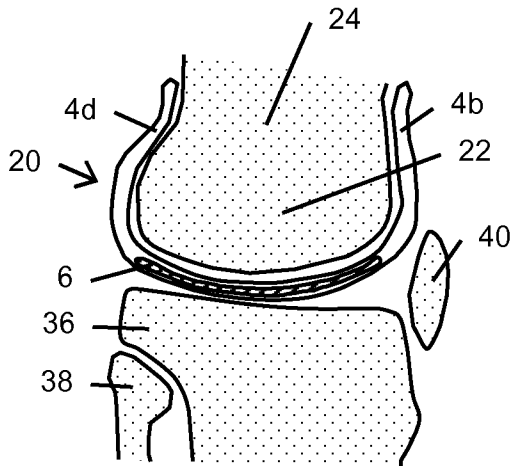


FIG 9A

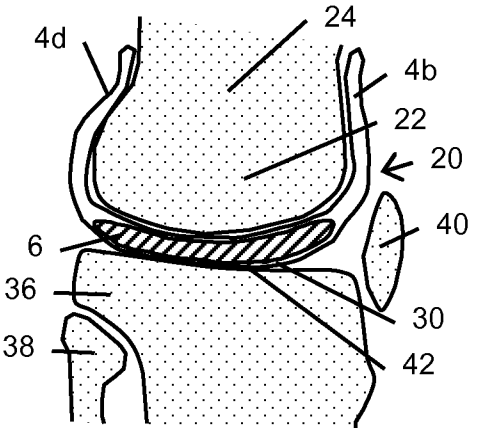


FIG 9B

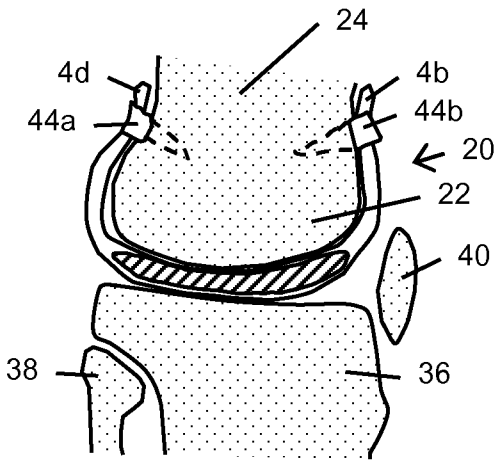


FIG 9C

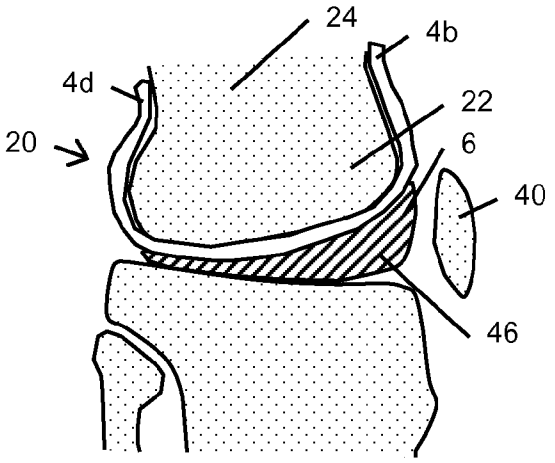


FIG 10A

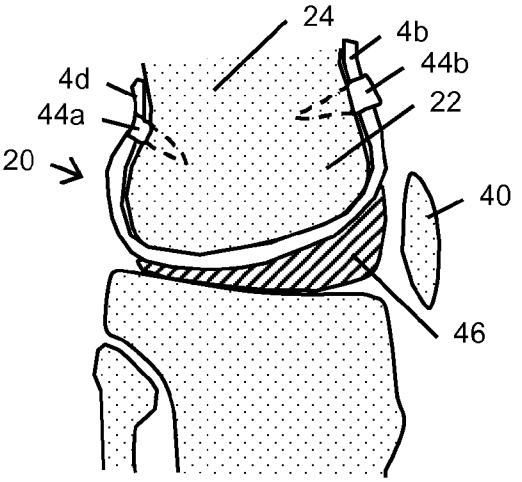


FIG 10B

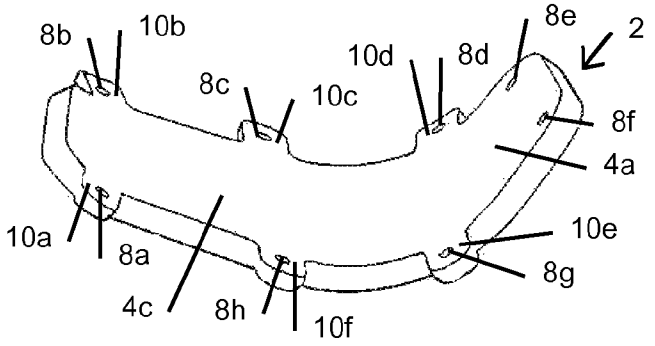


FIG 11A

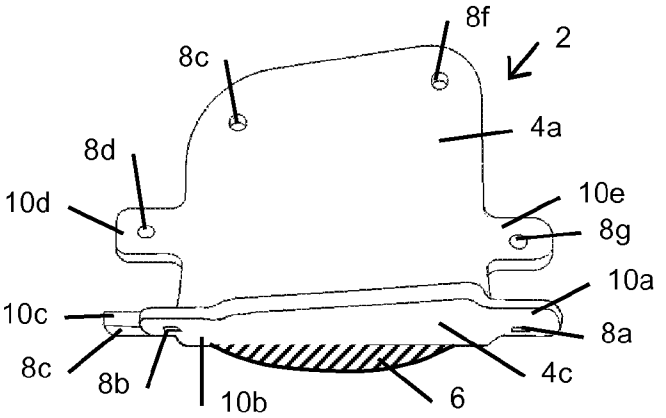


FIG 11B

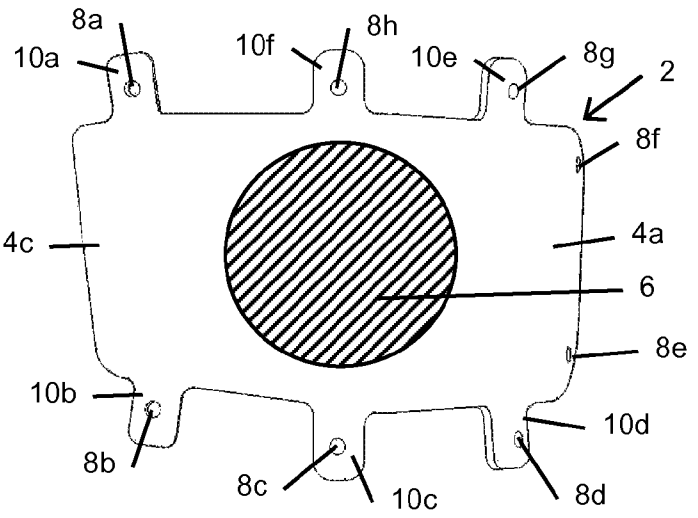


FIG 11C

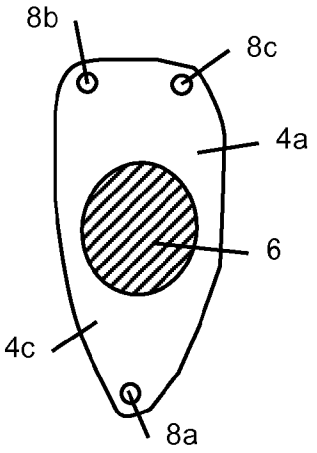


FIG 12A

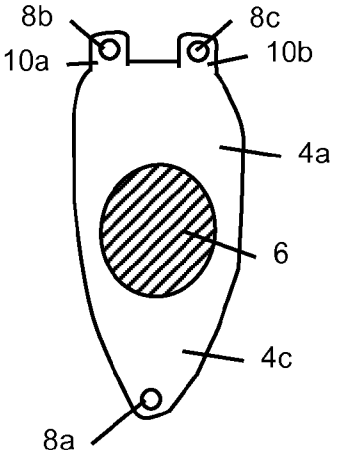


FIG 12B

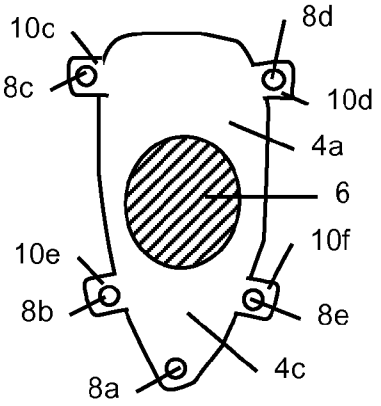


FIG 12C

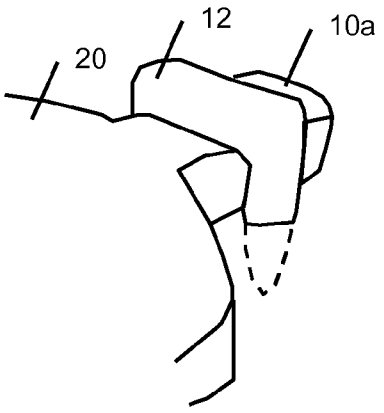


FIG 13A

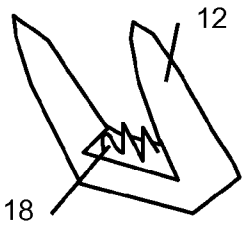


FIG 13B

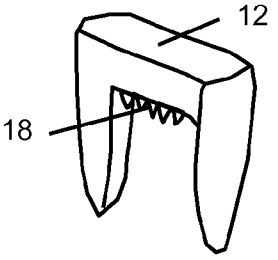


FIG 13C

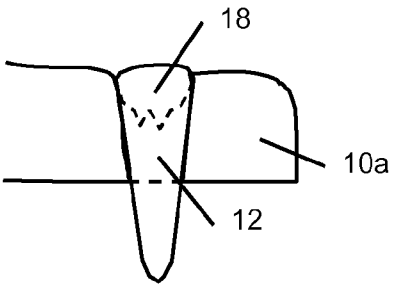


FIG 13D

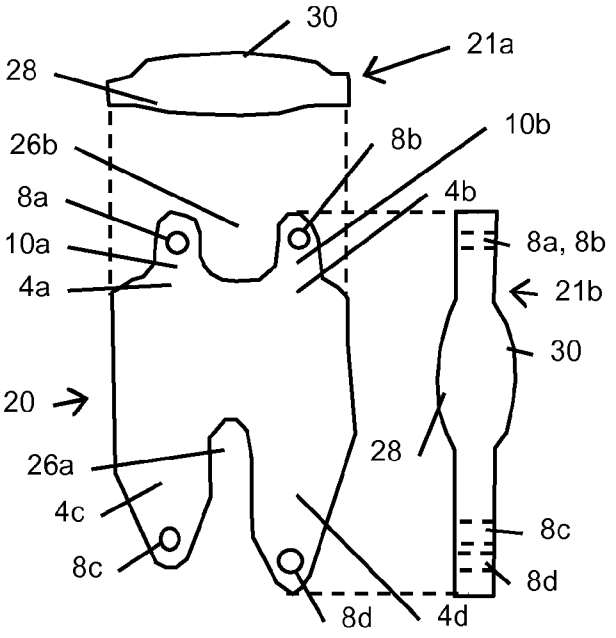


FIG 14

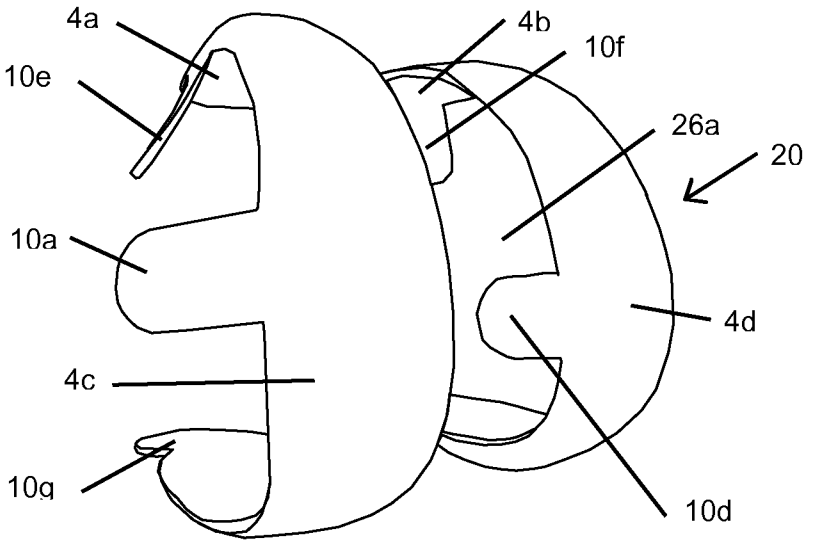


FIG 15A

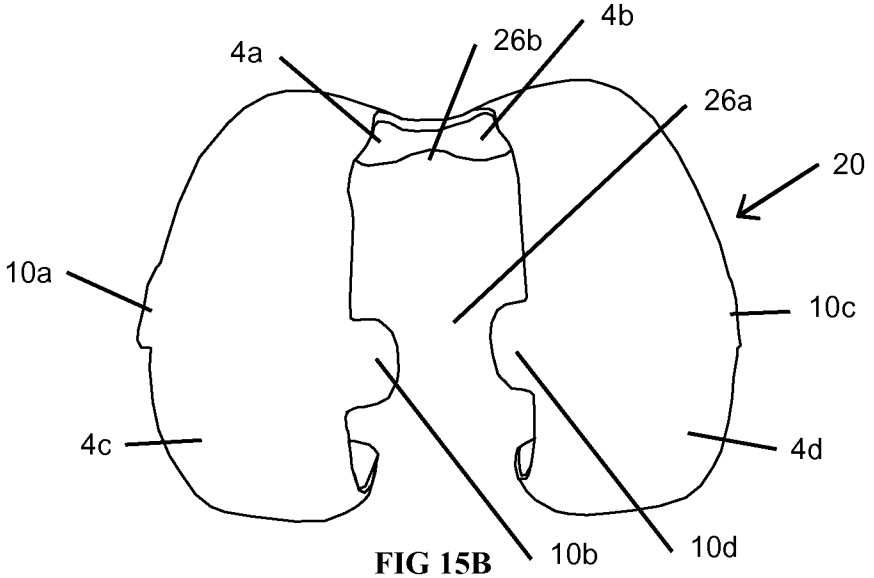


FIG 15B

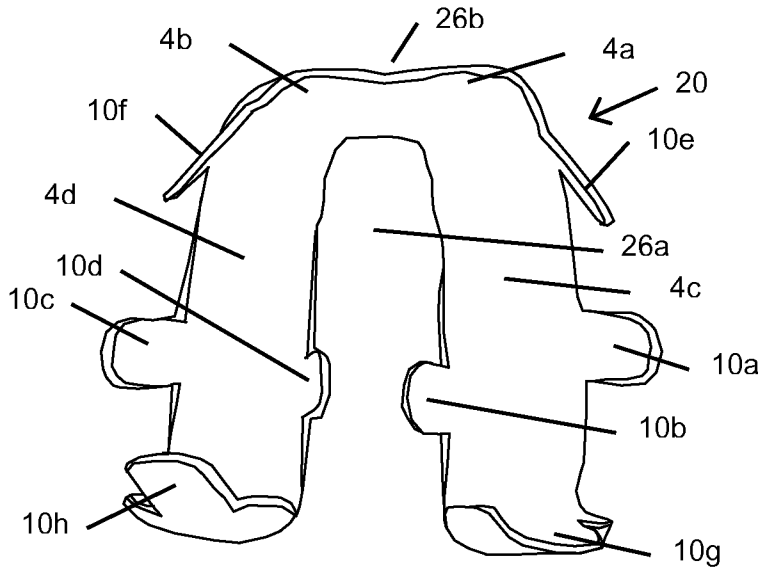


FIG 15C

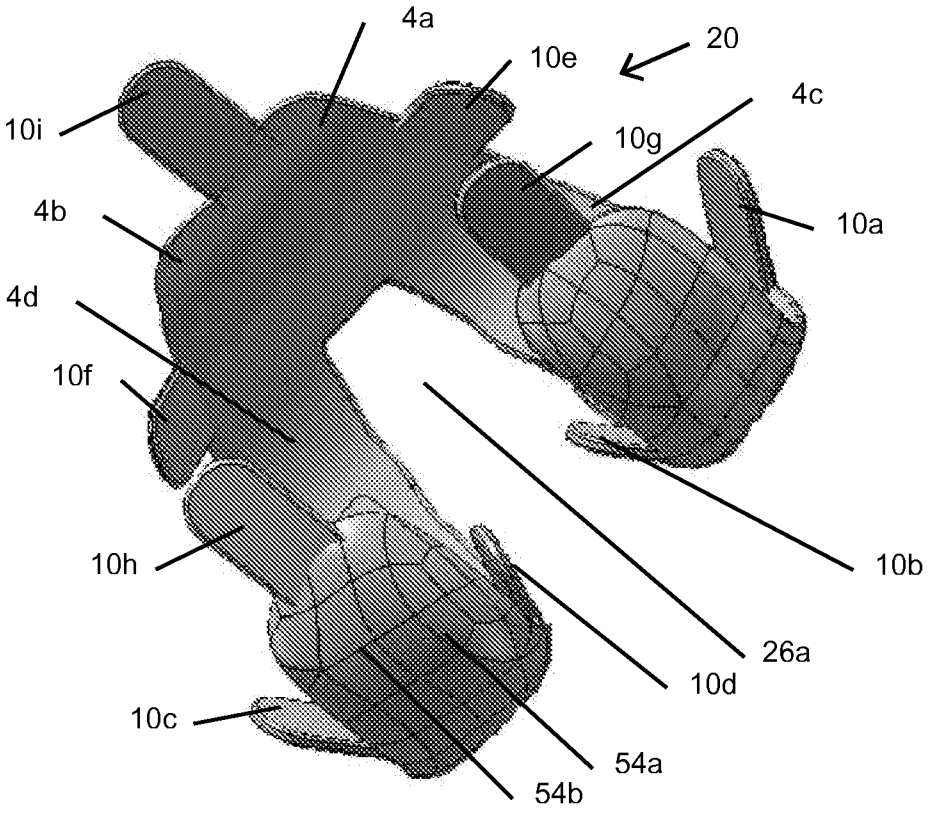
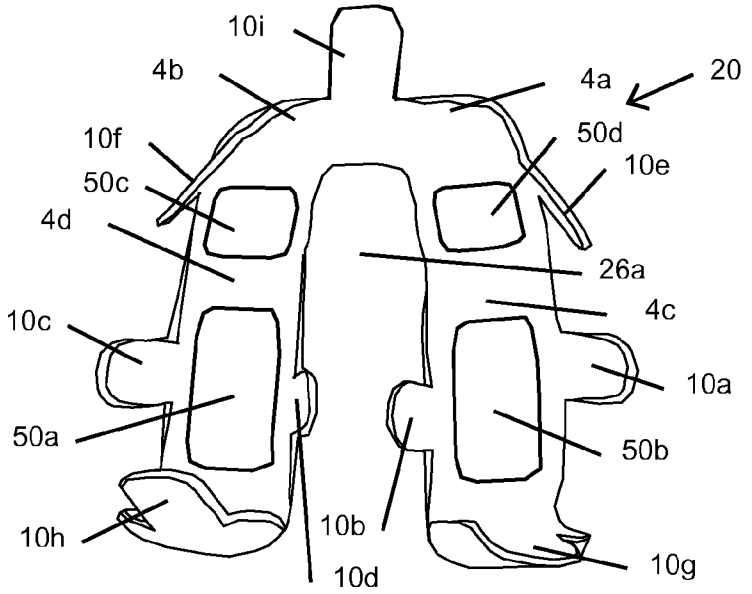


FIG. 16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10b
10d
10g

FIG 17

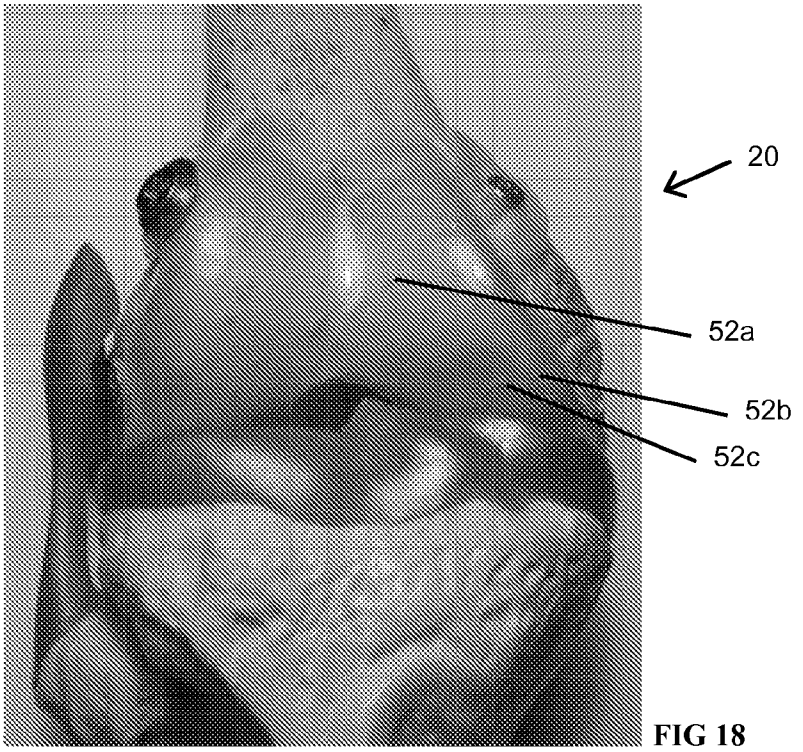
20
52a
52b
52c

FIG 18

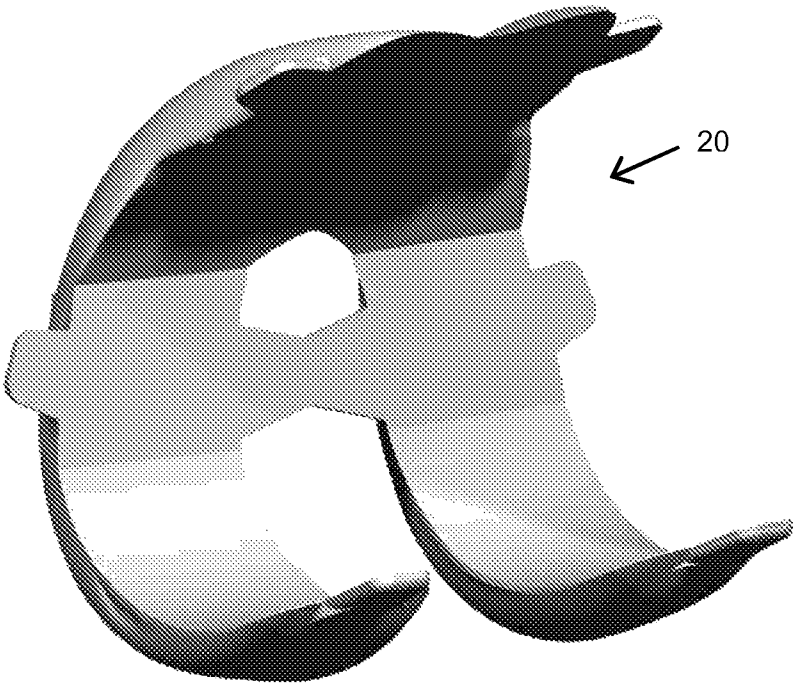

FIG 19

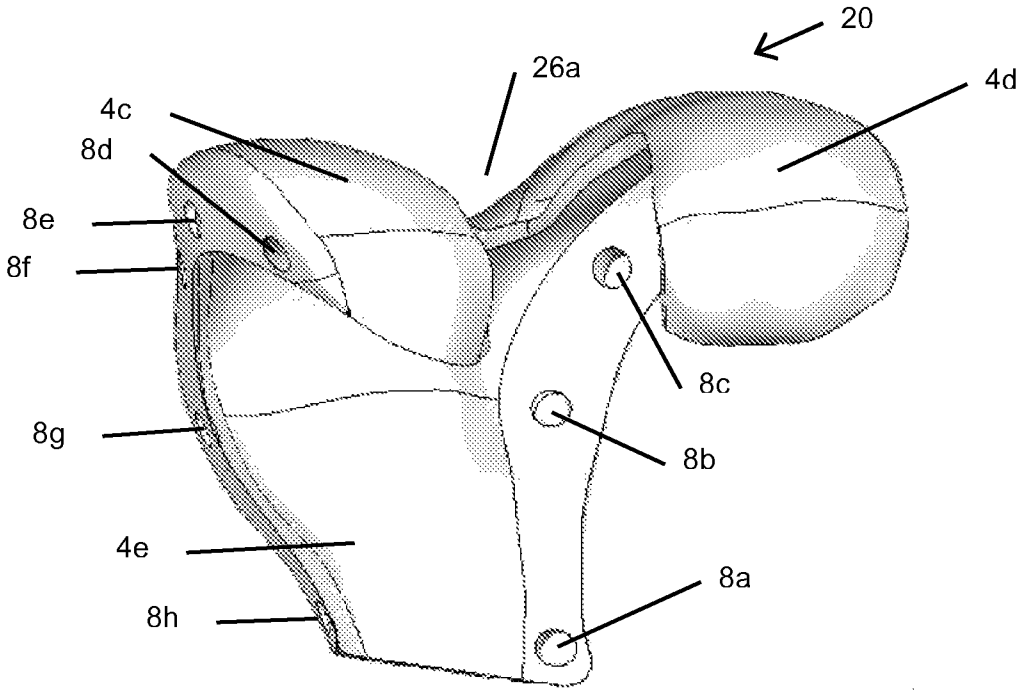

FIG 20A

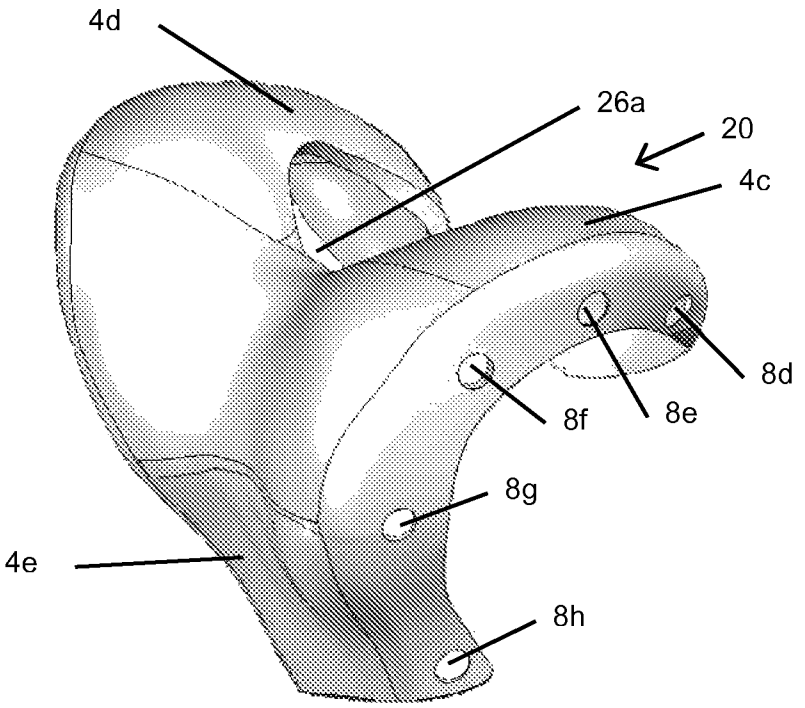

FIG 20B

RESILIENT INTERPOSITIONAL ARTHROPLASTY DEVICE

This application is the National Phase Entry of International Patent Application No. PCT/US2012/053207, filed Aug. 30, 2012, which claims the benefit of U.S. Provisional Application No. 61/530,324 filed on Sep. 1, 2011, and relates to U.S. patent application Ser. No. 12/460,703, filed Jul. 23, 2009; and International Patent Application No. PCT/US2010/058977, filed Dec. 3, 2010, which claims the benefit of U.S. Provisional Application No. 61/267,750, filed Dec. 8, 2009, and U.S. patent application Ser. No. 12/460,730, filed Jul. 23, 2009; and International Application No. PCT/US2011/021674, filed Jan. 19, 2011, which claims the benefit of U.S. Provisional Application No. 61/297,698, filed Jan. 22, 2010; and International Patent Application No. PCT/US2011/021673, filed Jan. 19, 2011, which claims the benefit of U.S. Provisional Application No. 61/297,697, filed Jan. 22, 2010, all of which are incorporated herein by reference in their entireties.

BACKGROUND OF THE INVENTION

This invention relates to arthroplasty, and more particularly, to an implant for use in arthroplasty when hyaline articular cartilage is damaged, it breaks down and joint space is lost. Inflammatory enzymes such as from the Cox-1, Cox-2 and/or 5-Lox systems are released and loose bodies form adding to the degradation of joint function. Such joint damage is conventionally treated by physical therapy, analgesics, pain medication and injections. When these treatments fail, the traditionally accepted treatment option is arthroplasty implantation or replacing the joint with an artificial joint construct. Current arthroplasty techniques typically use "plastic and metal" implants that are rigid and which ultimately fail due to loosening or infection or debris from wear. Conventional materials for the artificial joint components include chrome-cobalt-molybdenum alloy (metal) and high molecular weight polyethylene (plastic). Each is often fixed by a cement-like mixture of methyl methacrylate to the ends of the bones that define the joint that is the subject of the arthroplasty, or coated with a surface that enables bone in-growth. Current hip joint replacements typically last about 10-15 years and knee replacements typically last about 5-10 years. Ankle joint replacements, on the other hand, are not very successful, and often fail in the first several years after surgery.

Conditions requiring arthroplasty include traumatic arthritis, osteoarthritis, rheumatoid arthritis, osteonecrosis, and failed surgical procedures.

SUMMARY OF THE INVENTION

The present invention is directed to an orthopedic implant configured for deployment between opposing members of a joint structure that addresses many of the shortcomings of prior artificial joints. The arthroplasty implants embodying features of the invention are configured to preserve joint motions while removing the pain and dysfunction following the development of arthritis or joint injury. The arthroplasty implant in accordance with the present invention achieves improved physiologic motion and shock absorption during gait and acts as a resilient spacer between moving bones during limb movement. The combined characteristics of the implant include anatomic design symmetry, balanced rigidity with variable attachment connections to at least one of adjacent normal structures, and durability which addresses

and meets the needs for repair or reconstruction thus far missed in the prior art. The implant should be secured to at least one of the bones of the joint structure.

Provided herein is a resilient implant for implantation into human or animal joints to act as a cushion allowing for renewed joint motion. The implant may endure variable joint forces and cyclic loads while reducing pain and improving function after injury or disease to repair, reconstruct, and regenerate joint integrity. The implant may be deployed in a prepared debrided joint space, secured to at least one of the joint bones and expanded in the space, molding to surrounding structures with sufficient stability to avoid extrusion or dislocation. The implant may have opposing walls that move in varied directions, and an inner space filled with suitable filler to accommodate motions which mimic or approximate normal joint motion. The implant may pad the damaged joint surfaces, may restore cushioning immediately and may be employed to restore cartilage to normal by delivering regenerative cells.

Provided herein is a resilient interpositional arthroplasty implant for application into human or animal joints to pad cartilage defects, cushion joints, and replace or restore the articular surface, preserving joint integrity, reducing pain and improving function. The implant may endure variable joint compressive and shear forces, and millions of cyclic loads, after injury or disease requires intervention. The implant may repair, reconstruct, and regenerate joint anatomy in a minimally morbid fashion, with physiologic solutions that improve upon the rigid existing joint replacement alternatives of plastic and metal. In cases where cells have been used for joint resurfacing requiring massive periosteal harvesting for containment, the polymer walls of some embodiments of the implant can capture, distribute and hold living cells until aggregation and hyaline cartilage regrowth occurs. The implant may be deployed into a prepared debrided joint space, molding and conforming to surrounding structures with sufficient stability to avoid extrusion or dislocation. Appendages of the implant may serve to repair or reconstruct tendons or ligaments. Appendages of the implant may serve to repair or reconstruct fibrocartilage as in menisci, or the labrum tissues of hips or shoulders. The implant may have opposing walls that move in varied directions, and an inner space, singular or divided, filled with suitable gas, liquid, and/or complex polymer layers as force-absorbing mobile constituents, such than robust valid and reliable joint motion is enabled.

Provided herein is a resilient orthopedic implant configured for deployment between a first bone and at least one second bone of a joint, the implant comprising a balloon comprising a first portion that is configured to engage the first bone of the joint, a second portion that is configured to engage at least one second bone of the joint, a side portion connecting the first portion and the second portion, in which the side portion facilitates relative motion between the first portion and the second portion, and an interior that is optionally inflatable with a first inflation medium; and a first appendage configured to couple the balloon to the first bone of the joint. As used herein a balloon may also and/or alternatively be called a balloon. In the embodiments wherein the balloon is not inflated, the uninflated balloon may accommodate movement between portions of the balloon wall or a first wall of the balloon and a second wall of the balloon. Alternatively or additionally, the uninflated balloon may provide the opportunity for later inflation following implantation. In some embodiments, the materials of the implant allow for internal expansion. In other embodiments, material layers may be fixed in apposition so as to

encourage strength and anti-creep, as with a mesh. In certain embodiments, the fixed layer itself has pockets containing gas or gel (e.g. viscolubricants) or liquid or a pharmacologic. In other embodiments, the implant walls are contiguous having no discernable pockets, vacuoles or chambers.

Provided herein is a resilient orthopedic implant configured for deployment between a femur and a tibia of a knee joint, the implant comprising a balloon comprising a first portion that is configured to engage a medial condyle and a lateral condyle of the femur of the knee joint, a second portion that is configured to engage the tibia of the knee joint, a side portion connecting the first portion and the second portion, in which the side portion facilitates relative motion between the first portion and the second portion, and an interior that is optionally inflatable with a first inflation medium; and a first appendage configured to couple the balloon to the femur of the knee joint.

In some embodiments, the implant comprises at least one attachment element in the intercondylar notch. In some embodiments, the implant comprises at least one attachment element in the medial region of the intercondylar notch. In some embodiments, the implant comprises at least one attachment element in the lateral region of the intercondylar notch. In some embodiments, the implant comprises at least one attachment element superiorly at the distal end of the femur anteriorly. In some embodiments, the implant comprises at least one posterior reign configured to cinch up the implant from inside a posterior intercondylar notch toward a connection site around the femur. In some embodiments, the implant comprises at least one suture-like lanyard configured to cinch up the implant from inside a posterior intercondylar notch toward a connection site around the femur.

In some embodiments, at least two of first portion, the second portion, and the side portion are contiguous. In some embodiments, the first portion comprises a first wall, the second portion comprises a second wall, and the side portion comprises a side wall.

In some embodiments, the implant comprises an inflation port in communication with the interior of the balloon for inflation of the interior of the balloon with the first inflation medium. In some embodiments, the interior comprises a plurality of inflatable chambers. In some embodiments, a first chamber of the plurality of individually inflatable chambers is adapted to be inflated with the first inflation medium, and a second chamber of the plurality of individually inflatable chambers is adapted to be inflated with a second inflation medium. In some embodiments, the first inflation medium imparts at least one of rigidity in the implant and cushion in the implant. In some embodiments, there is no inflatable chamber and the cushioning is a result of compliant materials of the walls themselves

In some embodiments, the implant comprises a second appendage coupling the balloon to at least one of: the femur of the joint and the tibia of the joint.

Provided herein is an implant configured for deployment between a femur and a tibia of a knee joint, the implant comprising a balloon comprising a first portion that is configured to engage at least one condyle of the femur of the knee joint, a second portion that is configured to engage the tibia of the knee joint, a side portion connecting the first portion and the second portion, in which the side portion facilitates relative motion between the first portion and the second portion, and an interior that is optionally inflatable with a first inflation medium; and a first appendage configured to couple the balloon to the femur of the knee joint.

In some embodiments, the at least one condyle is the medial condyle. In some embodiments, the at least one condyle is the lateral condyle. In some embodiments, the retropatellar surface could be the anatomic region padded. In some embodiments, the tibia-medial or lateral or both is capped. In certain knee implant embodiments, the implant articulates against cartilage of the first bone, second bone, and/or the third bone

In some embodiments, the balloon is at least one of: at most about 1.5 cm in diameter, at most about 1.75 cm in diameter, at most about 2 cm in diameter, at most about 2.25 cm in diameter, at most about 2.5 cm in diameter, at most about 2.75 cm in diameter, at most about 3 cm in diameter, at most about 3.25 cm in diameter, at most about 3.5 cm in diameter, at most about 3.75 cm in diameter, at most about 4 cm in diameter, at most about 4.25 cm in diameter, at most about 4.5 cm in diameter, at most about 4.75 cm in diameter, at most about 5 cm in diameter, at most about 5.25 cm in diameter, at most about 5.5 cm in diameter, at most about 5.75 cm in diameter, at most about 6 cm in diameter, at most about 6.25 cm in diameter, at most about 6.5 cm in diameter, at most about 6.75 cm in diameter, at most about 7 cm in diameter, at most about 7.25 cm in diameter, at most about 7.5 cm in diameter, at most about 7.75 cm in diameter, at most about 8 cm in diameter, at most about 3 cm in length along the longest length of the balloon, at most about 3.25 cm in length along the longest length of the balloon, at most about 3.5 cm in length along the longest length of the balloon, at most about 3.75 cm in length along the longest length of the balloon, at most about 4 cm in length along the longest length of the balloon, at most about 4.25 cm in length along the longest length of the balloon, at most about 4.5 cm in length along the longest length of the balloon, at most about 4.75 cm in length along the longest length of the balloon, at most about 5 cm in length along the longest length of the balloon, at most about 5.25 cm in length along the longest length of the balloon, at most about 5.5 cm in length along the longest length of the balloon, at most about 5.75 cm in length along the longest length of the balloon, at most about 6 cm in length along the longest length of the balloon, 6.25 cm in length along the longest length of the balloon, at most about 6.5 cm in length along the longest length of the balloon, at most about 6.75 cm in length along the longest length of the balloon, at most about 7 cm in length along the longest length of the balloon, at most about 7.25 cm in length along the longest length of the balloon, at most about 7.5 cm in length along the longest length of the balloon, at most about 7.75 cm in length along the longest length of the balloon, and at most about 8 cm in length along the longest length of the balloon.

In some embodiments, the first portion comprises a first wall, the second portion comprises a second wall, and the side portion comprises a side wall.

In some embodiments, the implant comprises an inflation port in communication with the interior of the balloon for inflation of the interior of the balloon with the first inflation medium. In some embodiments, the balloon is punctured to inflate the interior of the balloon with the first inflation medium. In some embodiments, the balloon is self-sealing. In some embodiments, the balloon is self-sealing upon inflation of the interior of the balloon with the first inflation medium. In some embodiments, the implant comprises a seal capable of closing the interior of the balloon. In some embodiments, there is no balloon and inflation into a wall of the implant expands the implant with a compressible material. In some embodiments, inflation is achieved via a needle or cannula that delivers the inflation medium such as lubri-

cating materials or medications or a combination thereof, or other inflation mediums. In some embodiments, despite addition of an inflation medium, there is no ballooning effect or change in thickness in the device, as the inflation medium itself fills empty spaces in the wall (or walls) into which it is delivered.

In some embodiments, the implant comprises an inflation port in communication with the interior of the balloon for inflation of the interior of the balloon with the first inflation medium. In some embodiments, the interior comprises a plurality of inflatable chambers. In some embodiments, a first chamber of the plurality of individually inflatable chambers is adapted to be inflated with the first inflation medium, and a second chamber of the plurality of individually inflatable chambers is adapted to be inflated with a second inflation medium. In some embodiments, the first inflation medium imparts at least one of rigidity in the implant and cushion in the implant. In some embodiments the chambers are constructed as part of a trabecular polymer framework or honeycomb or foam or alveolar network. The chambers may be adapted to increase the surface area of available polymer for disbursement or absorption.

In some embodiments, the implant comprises a second appendage coupling the balloon to at least one of: the femur of the joint and the tibia of the joint. In some embodiments, the implant comprises at least one attachment element in the intercondylar notch. In some embodiments, the implant comprises at least one attachment element in the medial region of the intercondylar notch. In some embodiments, the implant comprises at least one attachment element in the lateral region of the intercondylar notch. In some embodiments, the implant comprises at least one attachment element superiorly at the distal end of the femur anteriorly. In some embodiments, the implant comprises at least one posterior reign configured to cinch up the implant from inside a posterior intercondylar notch toward a connection site around the femur. In some embodiments, the implant comprises at least one suture-like lanyard configured to cinch up the implant from inside a posterior intercondylar notch toward a connection site around the femur.

In some embodiments, the implant is fabricated to resemble a certain anatomic region over which the implant is stretched or pulled into place. The implant then may settle into its angle of repose via inherent elasticity. In some embodiments the ambient environment of the joint via exposure to serum or temperature or acidity has a specified effect on the implant materials such as increasing the implant malleability that affects implant performance.

Provided herein is an implant configured to patch a defect of a bone of a knee joint, the implant comprising a balloon configured to engage the defect of the bone of the knee joint and comprising an interior that is optionally inflatable with a first inflation medium; and a first appendage configured to couple the balloon to the bone of the knee joint.

In some embodiments, at least one of the appendage and the balloon are configured to replace cartilage.

In some embodiments, the balloon is at least one of: at most about 0.5 cm in diameter, at most about 0.75 cm in diameter, at most about 1 cm in diameter, at most about 1.25 cm in diameter, at most about 1.5 cm in diameter, at most about 1.75 cm in diameter, at most about 2 cm in diameter, at most about 2.25 cm in diameter, at most about 2.5 cm in diameter, at most about 2.75 cm in diameter, at most about 3 cm in diameter, at most about 3.25 cm in diameter, at most about 3.5 cm in diameter, at most about 3.75 cm in diameter, at most about 0.5 cm in length along the longest length of the balloon, at most about 0.75 cm in length along the longest length of the balloon, at most about 1 cm in length along the longest length of the balloon, at most about 1.25 cm in length along the longest length of the balloon, at most about 1.5 cm in length along the longest length of the balloon, at most about 1.75 cm in length along the longest length of the balloon, at most about 2 cm in length along the longest length of the balloon, at most about 2.25 cm in length along the longest length of the balloon, at most about 2.5 cm in length along the longest length of the balloon, at most about 2.75 cm in length along the longest length of the balloon, at most about 3 cm in length along the longest length of the balloon, at most about 3.25 cm in length along the longest length of the balloon, at most about 3.5 cm in length along the longest length of the balloon, at most about 3.75 cm in length along the longest length of the balloon, and at most about 4 cm in length along the longest length of the balloon.

In some embodiments, the interior comprises a plurality of inflatable chambers. In some embodiments, the interior comprises a plurality of individually inflatable chambers. In some embodiments, a first chamber of the plurality of individually inflatable chambers is adapted to be inflated with the first inflation medium, and a second chamber of the plurality of individually inflatable chambers is adapted to be inflated with a second inflation medium.

In some embodiments, the balloon or a chamber thereof may be secondarily inflated, deflated, or a combination thereof in situ.

In some embodiments, the implant comprises an in-growth matrix on at least a portion of the implant adjacent the femur. In some embodiments, the in-growth matrix comprises living chondrocytes. In some embodiments, the implant is configured to release the chondrocytes over time. In some embodiments, the implant comprises a bioabsorbable polymer configured to release the chondrocytes over time. In some embodiments, the implant comprises a polymer configured to release the chondrocytes over time, wherein the polymer is not bioabsorbable. In some embodiments, the in-growth matrix comprises cells. In some embodiments, the in-growth matrix comprises at least one of: stem cells, differentiated cells, pluripotent cells, post-mitotic cells. In some embodiments, the cells restore an articular surface of the femur. In other embodiments, the cells repair an articular surface of the femur. In some embodiments, the implant comprises a bioabsorbable polymer configured to release the cells over time. In some embodiments, the implant comprises a polymer configured to release the cells over time, wherein the polymer is not bioabsorbable. In some embodiments, the in-growth matrix comprises at least one of: autologous cells, allograph cells, and xenograph cells to restore an articular surface of the femur. In some embodiments, the in-growth matrix comprises at least one of: autologous cells, allograph cells, and xenograph cells to repair an articular surface of the femur. In some embodiments, the in-growth matrix comprises a pharmacologic substance. In some embodiments, the patch implant comprises a matrix that is coated with a hydrophilic or a hydrophobic polymer. In some embodiments the patch is vessicular with or without matrices in the wall components. In certain embodiments, the patch is a solid compliant material. In some embodiments, the walls or material construct is responsive or performs in a dynamic fashion to exogenous joint forces. For non-limiting example, in bone under normal physiologic stress of bearing weight, calcification yields sufficient bone density so as to deter fracture. However, in circumstances wherein prolonged dearth of weight bearing stress is produced by immobilization the bone becomes osteoporotic and pathologic. The implant

herein may have smart features to adjust to stimulate healing and tissue regeneration. In some embodiments such materials can be composed of macromolecules or dendritic connections that regulate permeability and transfer of adjacent media.

In some embodiments, the implant comprises couplers that couple the appendage to the femur. In some embodiments, the coupler is bioabsorbable. In some embodiments, the coupler is at least one of: a screw, a snap, a washer, a suture, a suture anchor, a rivet, a staple, a staple having teeth, a magnet, an electromagnet, a microminiature transmitter that regulates implant fixation or performance responsive to patient need as perceived by the patient or a care giver, a stabilizer, a glue, a hook, a wire, a string, a lasso, a lanyard, a spike, and combinations thereof. The implant may also and/or alternatively be attached via bone in-growth. In some embodiments, the implant is attached via bone in-growth as described in Vasanji A, In vivo bone growth assessment in preclinical studies and clinical trials, Bonezone, 2012, p. 12-17, herein incorporated by reference in its entirety.

In some embodiments, the implant comprises a pharmacologic agent. In some embodiments, the pharmacologic agent is on a surface of the implant adjacent the femur. In some embodiments, the pharmacologic agent is released from the implant over time. In some embodiments, the pharmacologic agent is released from within the implant over time. In some embodiments, the pharmacologic agent is released from within the balloon over time. In some embodiments, the agent is released as a combination of vessicular and matrix origins using internal or external stimuli from normal or exogenous sources.

In some embodiments, the first inflation medium imparts rigidity in the implant. In some embodiments the implant comprises a bone cement. In some embodiments, the implant comprises methyl methacrylate. In some embodiments, the first inflation medium imparts cushion in the implant.

In some embodiments, the inflation medium is compressible. In some embodiments, the inflation medium comprises a viscolubricant. In some embodiments, the inflation medium comprises a pharmacologic substance. In some embodiments, the inflation medium comprises an NSAID. In some embodiments, the inflation medium comprises chondrocytes. In some embodiments, the inflation medium comprises cells.

In some embodiments, at least a portion of the implant is configured to anneal to a periphery of a cartilage defect.

In some embodiments, the implant comprises vacuoles of pharmacologic substances. In some embodiments, the vacuoles may be on a bone-engaging portion of the implant. In some embodiments, the implant comprises bubbles comprising an active substance such as a pharmacologic substance or other active agent. In some embodiments, the active agent comprises at least one of: stem cells, growth factors, antibiotics, antifungals, antituberculous, antitumor, antigout agents and viscolubricants. In some embodiments, the active agent comprises iatrigenically gene mutated cells.

In some embodiments, the implant comprises enzyme absorptive microscopic sponges that could be sucked out or evacuated at or around the time of implant delivery to the joint.

In some embodiments, the interior comprises a honeycomb structure. In some embodiments, the interior comprises a mesh structure. In some embodiments, the interior comprises a sponge structure. In some embodiments the implant comprises a sponge structure. In some embodiments the implant comprises a compliant membrane.

In some embodiments, the implant comprises spaces filled with an active substance such as a pharmacologic substance or other active substance. In some embodiments, the implant comprises spaces for deliverables (e.g., biologics, antibodies, cells, pharmacologic substances, biomolecules, molecules, compounds). In some embodiments, the implant comprises spaces for compressibles (e.g., gas, air). In some embodiments, the spaces comprise nanovesicles. In some embodiments, the nanovasicles comprise deliverables (e.g., biologics, antibodies, cells, pharmacologic substances, biomolecules, molecules, compounds). In some embodiments, the nanovesicles comprise compressibles (e.g., gas, air).

In some embodiments, the implant comprises a second appendage coupling the balloon to the first bone of the joint. In some embodiments, the implant comprises a second appendage coupling the balloon to at least one second bone of the joint. In some embodiments, the implant comprises a second appendage configured to couple at least one of the first portion, the second portion, and the side portion to at least one of the first bone and at least one second bone of the joint. In some embodiments, the first appendage and the second appendage are configured to provide ligamentary-like support to the first bone and the at least one second bone of the joint. In some embodiments, the first appendage and the second appendage are configured to provide ligamentary-like support to the joint. In some embodiments, the first appendage and the second appendage are configured to provide tendon-like support to the first bone and the at least one second bone of the joint. In some embodiments, the first appendage and the second appendage are configured to provide tendon-like support to the joint.

In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most 10 millimeters. In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most 9 millimeters. In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most 5 millimeters. In some embodiments, the implant may be configured to be introduced surgically arthroscopically as with the cannula 10 mm in diameter or may be introduced through minimal invasive surgery via a large conduit and plunger requiring a small arthrotomy several centimeters in diameter. In some embodiments routine open surgical insertion with a larger wound may be necessary depending on clinical condition, complexity and surgeon choice.

In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most 10 millimeters. In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most 9 millimeters. In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most 5 millimeters.

In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most 10 millimeters. In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most 9 millimeters. In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most 5 millimeters.

In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most 10 millimeters. In some embodiments, the implant is configured to fold in order to fit within a

cannula having a distal end inner diameter of at most 9 millimeters. In some embodiments, the implant is configured to deliver by dissolution of the implant material. In some embodiments, the implant is configured to deliver by release through pores of the implant. In some embodiments, the implant is configured to deliver by release through spaces of the implant. In some embodiments, the implant is configured to deliver by release through nanovesicles of the implant. In some embodiments, the implant is configured to deliver by fracture of a vacuole by a catalyst such as ultrasound or pressure or other fracturing catalyst. In some embodiments the release of contents may be over time as a function of normal cumulative limb use forces.

In some embodiments, the implant is configured to at least one of: pad cartilage, cushion the joint, deliver a pharmacologic substance, remove noxious enzymes, debride upon implantation, debride the joint following implantation, deliver a therapeutic substance, deliver a biologic substance, and deliver living stem cells. In some embodiments, the implant is configured to deliver a cell or tissue to a bone or surrounding tissue. In some embodiments, the cell is at least one of: stem cell, differentiated cell, pluripotent cell, and post-mitotic cell. In some embodiments, the implant is configured to deliver a chemotherapeutic agent to a bone or other surrounding tissues. In some embodiments, the implant is configured to deliver an anti-infectious medication to a bone or other surrounding tissues. In some embodiments, the implant is configured to deliver at least one of an antibiotic, antifungals, and analgesics agent. In some embodiments, the implant is configured to deliver an antibody. In some embodiments the implant is configured as a targeting structure for treatment of proximate pathophysiology. In some embodiments, the implant comprises a transmitter or a sensor that can emit or receive actionable instruction. In some embodiments, the implant comprises a sensor, for non-limiting example: a gauge, camera, fiberoptic, or other meter, to provide information of clinical relevance as it relates to proximate tissue. In some embodiments, the information received from the implant is transferred to the patient to enhance wound healing or other desired effects.

In some embodiments, the implant is configured to be selectively inflated to realign limbs.

Provided herein is a method comprising: implanting a knee implant as described herein into a subject, wherein the implant reverses arthritis in the subject.

Provided herein is a method comprising: implanting a knee implant as described herein into a knee joint of a subject and treating a component of the knee joint of the subject with at least one of an allograph tissue, an autograph tissue, and an xenograph tissue. In some embodiments, the implanting step is at least one of: prior to the treating step, simultaneous with the treating step, and following the treating step.

Provided herein is a method comprising: implanting a knee implant as described herein into a subject, wherein the implant at least one of: restores joint function and controls arthopathies. In some embodiments, the implanting spares existing anatomy.

Provided herein is a method comprising: debriding a femur condyle of a knee joint of a subject, and implanting a knee implant as described herein into the knee joint of the subject, whereby the implant is configured to anneal to the cartilage of the subject. In some embodiments, the debriding is achieved by steam application.

Provided herein is a method comprising implanting a knee implant as described herein into a joint previously treated with a joint replacement. In some embodiments, the method comprises removing the joint replacement prior to implanting the knee implant. In some embodiments, the method comprises clearing infectious matter from the joint and/or surrounding tissues. In some embodiments, the method comprises implanting a second implant of any implant described herein following removing the implant previously implanted in the joint. In some embodiments, the method comprises replacing the joint of the subject following removing the implant previously implanted in the joint. In some embodiments, the method comprises debriding the bone of the joint, and implanting an implant of any implant described herein. In some embodiments, the method comprises repeating the debriding and implanting steps.

In some embodiments, the implant is delivered non-arthroscopically through an incision that is at least 1 centimeter long. In some embodiments, the implant is delivered through an incision that is over about 10 centimeters long. In some embodiments, the implant is delivered through an incision that is at up to about 40 centimeters long.

In some embodiments, the implant replaces periosteum.

In some embodiments, the resilient implant embodying features of the invention has a first wall configured to be secured to a first bone of the joint structure by one or more appendages such as a skirt or one or more tabs and a second wall configured to engage a second and usually opposing bone of the joint structure. A side wall extends between the first and second walls of the implant and together with the first and second walls preferably defines at least in part an inner chamber or space between the first and second walls. The implant is configured to provide linear or curvilinear and/or rotational motion between the first and second bones which mimics or approximates the natural motion between these bones. The inner chamber or space is configured to maintain a filler material therein such as an inflation fluid or a resilient material and preferably to maintain spacing and provide support between the interior of the first and second walls to avoid significant contact therebetween. The walls of the implant are preferably sealed about the periphery thereof to maintain the interior chamber in a sealed condition to avoid loss of inflation fluid or filling media. The side wall or walls may be formed from the edges or periphery of the first and second walls. The properties of the implant walls and the interior are controlled to provide the particular resiliency desired for the joint in which the implant is to be placed as well as any desired motion between the first and second walls. A conduit may extend from a source of inflation fluid or other filling medium to the interior of the implant to facilitate expansion of the implant after deployment within the joint. The inflation fluid may be a gas, a liquid, a gel, a slurry, or a fluid that becomes a suitable resilient solid such as a curable polymer. Selection of the inflation or interior filling medium may depend upon the nature of the joint structure in which the implant is to be deployed, its anatomy, pathophysiology, and the properties of the implant material.

There may be several alternative embodiments depending upon the site in which the implant is to be deployed. For example, the polymer forming the side wall may be semi-compliant or elastic and the inflation fluid may be incompressible (e.g., a liquid). Alternatively, the polymer forming the side wall may be non-compliant (non-elastic) and the inflation fluid or filling medium may be compressible, e.g., a gas or a resilient polymeric foam or sponge-like solid that may have a closed cell structure. The first and second walls of the implant need not have the same properties as the side wall. For example, parts of the implant such as the side wall portion may be compliant and the first and second wall

portions in contact with the bone or other joint structure may be non-compliant. Additionally, the various walls or portions thereof may also be reinforced with non-compliant or semi-compliant polymer strands, beads or gel coating such as biologic or polymer latticework. The thicknesses of the first, second and side walls may be varied to accommodate for the needs of the joint structure from the standpoint of strength, elasticity and wear resistance. Moreover, the walls of the implant may be provided with joint tissue regeneration agents that rebuild the joint structure in which the implant is deployed. The regeneration agent may be incorporated into the wall of the implant prior to delivery or placed between the surface of the implant and the joint structure which it contacts after delivery. All or part of the walls of the implant may also be made of a biodegradable polymer, by minimally manipulated autograph, allograph or xenograph tissues, or a combination thereof. The method of surgery may incorporate a progressive application of the implant embodiments depending upon clinical needs. The walls of the implant may serve one or more functions, including but not limited to filling space, attachment, strengthening, and any physiological function.

The implant is preferably formed of suitable biocompatible polymeric materials, such as Chronoflex (e.g., ChronoFlexAR®, ChronoFlex AL®, ChronoFlec C®), which is a family of thermoplastic polyurethanes based on a polycarbonate structure (Al, the aliphatic version, Ar, the aromatic version and C, the casting version) available from AdvanSource Biomaterials, Corp. Other polymers include BIONATE 80, 80A, 90A, 75D, 65D, 55D, 55 or 56, BIONATE I, or BIONATE II, which are also thermoplastic polyurethane polycarbonate copolymers, available from PTG Medical LLC., an affiliate of the Polymer Technology Group located in Berkeley, Calif. Other commercially available polymers include PurSil® (e.g., PurSil® 10, 20, 35, 40 80A, AL-10 75A) which is a thermoplastic silicone polyether urethane, CarboSil® (e.g., CarboSil® 10 90A, 20 55D, 20 80A, 20 90A, 40 90A, 5) which is a thermoplastic silicone polycarbonate urethane, Elasthane™ (e.g., Elasthane™ 55D, 75D, 80A) which is an aromatic biomedical polymer and Biospan which is a segmented polyurethane. These polymers are available as tubing, molded or dipped components, solution, pellets, as a casting and as a cast film for the side and first and second walls. The implant may be formed by casting, blow molding or by joining sheets of polymeric material by adhesives, laser welding and the like. Other methods of forming the implant may also be suitable. Example methods include melting beads and compression molding. The walls may also be provided with reinforcing strands which are located on the surface of the walls or incorporated within the walls. The implant material should be biocompatible, non-toxic, and non-carcinogenic and should be resistant to particulation.

The present invention provides an improved joint implant which is designed to endure variable joint forces and cyclic loads enabling reduced pain and improved function. Depending upon the particular joint involved there may be linear or curvilinear motion between the first and second walls, rotational motion between the first and second walls or both linear and curvilinear motion and rotation motion between the first and second walls. Preferably, a space is maintained between the inner surfaces of the first and second walls to avoid erosion and wear there between. The walls may be opposite sides of the same solid.

The resilient arthroplasty implant embodying features of the invention is preferably deployed as a minimally invasive procedure to deliver the implant into a prepared space in a preselected joint structure, where upon it is inflated to create a cushion, to cover damaged or arthritic cartilage and to be employed to deliver stem cells or living chondrocytes or other tissue regeneration agents. The goal of such deployment is to reduce pain and improve function, to reverse arthritis, to fill in osteochondral defects succinctly, thereby avoiding living with both dysfunctional and ablative metal/plastic prostheses or the pathophysiologic state necessitating the procedure. The operative plan is simple, systematic, and productive of new joint space with regrowth potential involving joint debridement by routine arthroscopic coblation, electronic chondroplasty methods or steam application, followed by implantation of the implant. The implant provides three things, namely a covering or patch for the damaged or worn joint surface, an inflated cushion to pad gait via inflation or compliant polymer as in normal walking in the lower extremity, and delivery of regenerative cells on the cartilage remnant surface. The stem cells may be injected as the implant is being expanded and/or directed into the adjacent hyaline cartilage via an implant coating or perfused cell template. Viscolubricants such as Synvisc or Hyalgan, analgesics such as Lidoderm, anti-inflammatory and/or antibiotic coatings as well as those stimulating cell growth may accompany the composite external implant. The implant is left in place as long as feasible, at least until regenerative cells can attach to the adjacent natural joint surface (usually in about 24 hours), or until wound healing (which may take up to 28 days or more depending on the joint structure). Preferably, the implant is designed stay within the joint structure for years, providing inert padding, cushioning and a new cell source. The implant may be used in weight bearing and non-weight bearing interfaces. Animal, such as in horses and dogs, can benefit from usage of the implant following hip and knee injuries. The implant is intended primarily for mammalian use. In humans, the implant may be used in any upper or lower extremity joint and temperomandibular joint.

These and other advantages of the invention will become more apparent from the following detailed description and the attached exemplary drawings.

INCORPORATION BY REFERENCE

All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

FIG. **1** depicts an embodiment of the knee implant having appendages including holes and tabs extending from a balloon and including slots to accommodate ligaments of the knee joint.

FIG. **2** depicts an embodiment of the knee implant having appendages including holes and tabs extending from a balloon and including slots to accommodate ligaments of the knee joint as well as side views of the same knee implant.

FIG. **3** depicts an embodiment of the knee implant having appendages including holes and tabs extending from a balloon and including slots to accommodate ligaments of the knee joint as well as side views of the same knee implant.

FIG. **4**A depicts an embodiment of the knee implant having appendages including ten tabs extending from a balloon and including a slot to accommodate components of the knee joint.

FIG. **4**B depicts an embodiment of the knee implant having appendages including eight tabs extending from a balloon and including a slot to accommodate components of the knee joint.

FIG. **5** depicts an embodiment of the knee implant curved to simulate curvature about the condyles of a femur, the implant having appendages extending from an uninflated balloon (not shown) and including slots to accommodate ligaments of the knee joint.

FIG. **6**A depicts a top-down view of an embodiment of the knee implant curved to simulate curvature about the condyles of a femur, the implant having appendages extending from two inflated balloons and including slots to accommodate components of the knee joint.

FIG. **6**B depicts a bottom-up view of an embodiment of the knee implant curved to simulate curvature about the condyles of a femur, the implant having appendages extending from two inflated balloons and including slots to accommodate components of the knee joint.

FIG. **7** depicts a top-down view of an embodiment of the knee implant curved to simulate curvature about the condyles of a femur, the implant having appendages extending from an inflated balloon and including slots to accommodate components of the knee joint.

FIG. **8** depicts a side view of an embodiment of the knee implant curved to simulate curvature about at least one condyle of a femur, the implant having appendages extending from an uninflated balloon (not shown).

FIG. **9**A depicts a side view of an embodiment of the knee implant curved about at least one condyle of a femur, the implant having appendages extending from an uninflated or minimally inflated balloon.

FIG. **9**B depicts a side view of an embodiment of the knee implant curved about at least one condyle of a femur, the implant having appendages extending from an inflated balloon.

FIG. **9**C depicts a side view of an embodiment of the knee implant curved about at least one condyle of a femur, the implant having appendages extending from an inflated balloon and having staples or screws coupling the appendages to the femur.

FIG. **10**A depicts a side view of an embodiment of the knee implant curved about at least one condyle of a femur, the implant having appendages extending from an inflated balloon and showing the inflation medium moved anteriorly toward the patella when the knee joint is flexed. FIG. **10**B depicts a side view of an embodiment of the knee implant curved about at least one condyle of a femur, the implant having appendages extending from an inflated balloon and having staples or screws or snaps or pins coupling the appendages to the femur and showing the inflation medium moved anteriorly toward the patella when the knee joint is flexed.

FIG. **11**A depicts an embodiment of the unicompartment knee implant curved to simulate curvature about one condyle of a femur, the implant having appendages extending from an uninflated balloon (not shown) and including tabs and holes which may be used with couplers to couple the implant to the femur of the knee joint.

FIG. **11**B depicts an embodiment of the unicompartment knee implant curved to simulate curvature about one condyle of a femur, the implant having appendages extending from an inflated balloon and including tabs and holes which may be used with couplers to couple the implant to the femur of the knee joint.

FIG. **11**C depicts a bottom-up view of an embodiment of the unicompartment knee implant curved to simulate curvature about one condyle of a femur, the implant having appendages extending from an inflated balloon and including tabs and holes which may be used with couplers to couple the implant to the femur of the knee joint.

FIG. **12**A depicts a bottom-up view of an embodiment of the unicompartment knee implant or patch implant, the implant having appendages, extending from a balloon and including holes, which may be used with couplers (not shown) to couple the implant to the femur of the knee joint.

FIG. **12**B depicts a bottom-up view of an embodiment of the unicompartment knee implant or patch implant, the implant having appendages, extending from a balloon and including tabs and a hole which may be used with couplers (not shown) to couple the implant to the femur of the knee joint.

FIG. **12**C depicts a bottom-up view of an embodiment of the unicompartment knee implant or patch implant, the implant having appendages, extending from a balloon and including tabs and a hole which may be used with couplers (not shown) to couple the implant to the femur of the knee joint.

FIGS. **13**A-**13**D depict multiple views of a staple adapted to couple an implant to a bone of the joint.

FIG. **14** depicts an embodiment of the knee implant having appendages including holes and tabs and including slots to accommodate ligaments of the knee joint as well as side views of the same knee implant.

FIGS. **15**A, **15**B, and **15**C show several views of an embodiment of an implant which has no definable chamber, rather the material of the implant itself provides the cushion to the bones of the joint (at least).

FIG. **16** depicts a knee implant embodiment that is generally H or V-shaped, having a slot **26***b* that is significantly smaller than other embodiments, and in this embodiment is effectively replaced with a tab **10***i* at the same location (e.g. **10***i*).

FIG. **17** depicts a knee implant embodiment similar to FIG. **16** which shows a posterior view including the location (s) **50***a*-**50***d* where a fill material such as cement may be placed.

FIG. **18** is an anterior-posterior view of an embodiment of the implant **20** attached to a knee model.

FIG. **19** depicts an implant **20** which is more squarely cut for interface with a femur, for example, which has been cut square such as is done in certain total knee arthroplasty procedures.

FIGS. **20**A and **20**B depict a knee implant embodiment that is generally V-shaped or Y-shaped, and in this embodiment the notch **26***b* of other embodiments, or the tab **10***i* of other embodiments is effectively replaced with an appendage **4***e* at the same location.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is directed to arthroplasty implants and procedures for a wide variety of joints such as, for example, hips, knees, shoulders, ankles, elbows, wrists, fingers, toes, temporomandibular joints and the like, but for

clarity, as well as brevity, the discussion herein will focus on an implant for a knee joint or hip joint and an implant for replacing the talus bone of a patient's ankle.

Knee interpositional arthroplasty can replace existing total joint metal/plastic technology. It intends to fill the gap (literally in some embodiments of the implant) in cases where arthroscopic debridement fails to provide cure, since we can only 'polish arthritis' and 'clean up the joints' to date. The polymer medically inflatable implants may physiologically restore joint function. Padding is provided where cartilage is damaged, cushioning to both the femoral tibial and patella femoral joints when narrowed or pathologic. The implant in some embodiments is adapted to deliver cells, autologous (from the patient), allograph (from another member of the same species) or xenograph (from another species,) that restore articular surfaces. Since cartilage is an immunologically privileged tissue, the antigens are buried in the cartilage matrix and antibodies do not reject the refurbished surface coating.

The gap (or gaps) filled by the balloon or balloons of the implant may provide compliance between opposing joint surfaces (the femoral condyle or condyles and tibial plateau). The femur may have some portion (of not all) of the retropatellar rounded facet "V" shape of hyaline, normally about 5 mm thick, or it may not have such hyaline when the implant is inserted. The tibial plateau may have some portion of meniscal fibrocartilages, including all of said fibrocartilages, none of said fibrocartilages, or some portion thereof. When the knee is extended (straight) the implant buffers the femoro-tibial joint. When the knee is flexed, the implant balloon apposition is more between the trochlear groove portion of the anterior distal femur (groove between the condyles on the 'front of the knee') and the patella.

The knee anatomy is unique to other joint anatomies and thus has a unique set of challenges that are addressed by the implant embodiments described herein. For example, the knee is not a ball and socket joint like a hip; it is a combination of two joints—the femoral-tibial joint and the patellar-femoral joint. The bones of the knee have facets and irregularities that must be accommodated by a conformable implant directed to the particular shapes of the bones without impeding the joints' functions and movements, and/or which minimizes impedance to such function and movement. Not only do the joints of the knee work together to allow extension and flexion of the knee, but the joints of the knee are also designed to allow rotational movement in a screw-like manner. That is, as the tibia is twisted relative to the femur, the joints are uniquely designed to allow this twist, but to limit the twist as well. Furthermore, the knee joints are able to withstand forces that vary depending on the particular movement of the individual, not only in force strength, but in direction as well. Thus, the implants as described herein are uniquely designed to account for these factors and result in a knee having preserved natural tissues as well as preserved function and movement as compared to typical arthroplasty procedures (such as partial or full knee replacements).

As described herein, embodiments of the implant conform to the patient's own joint features not only in that it can be pre-molded and/or adapted to couple to the contours of the patient's bone (condyle, etc), but in that it has a balloon having an inflation medium that is conformable to the joint anatomy and allow freedom of joint movement much like natural joint while preserving the joint and bone natural tissues as much as possible. With the ability to fill various chambers of the balloon with varying materials, and to add rigid and/or semi-rigid pieces to the implant, the implant can additionally have leveling capabilities and alignment capabilities.

Diagnoses:

Patients may complain of pain and knee joint dysfunction signaled by locking, clicking, or giving way. Knees may be swollen, malaligned or show crepitus (palpable crunching on movement.) Instability of ligaments whether anterior/posterior cruciates, or medial/lateral condyles, are treated by techniques separate for those entities via allowance for healing (as for collaterals) or via cruciate repair or reconstruction.

Indications for use of implants provided herein may be those patients recognizing greater than or equal to 2 Sq cm of 3-4+/4 traumatic arthritis (ala Carticel). In such cases, the cartilage defect is often precisely locally symptomatic, with point tenderness, clicking if a loose cartilage flap exists, and may be visible on MRI and/or arthroscopic inspection and/or through palpation. The implants used herein may additionally and/or alternatively be appropriate when existing techniques such as 'picking', K wire drills, and/or allograph implants fail.

Patients with knee problems typically complain of pain and dysfunction. Pathognomonic symptoms for meniscal tearing include locking, clicking, giving way from wear or twisting the knee. Aching diffusely may arise from arthritis or synovitis; anterior knee pain is generally patella-femoral, increased with stair use due to magnified body weight forces. Diagnosis should be accurate as distinguished from pain through the knee actually arising in the back caused by L4 nerve root irritation. Physical Exam findings of pathologic knees include observed swelling, redness, or deformity. Palpation often aids focus on which compartments are involved. The patella inhibition test position connotes retropatellar pathology, and often tracking problems that warrant soft tissue or boney correct. Improved limb alignment may increase benefits, and can in part accrue from selective inflation of embodiments of the implants provided herein. X-rays of the knee are best evaluated in weight bearing views, and should be coupled with other data including MRI or CT. Relative compartment narrowing suggests cartilage degradation. Once an embodiment of an implant described herein has been successfully implanted and the knee adequately rehabilitated, the appearance of a knee with such implant should resemble a normal joint X-ray. Knee distension is from saline and/or air insufflation. Knee implant patients will benefit from tailored rehab programs, cautious weight bearing, early motion, and potential the use of constant passive motion machine regimens.

General Features

Implant Aspects

Provided herein is a resilient implant for implantation into human or animal joints to act as a cushion allowing for renewed joint motion. The implant may endure variable joint forces and cyclic loads while reducing pain and improving function after injury or disease to repair, reconstruct, and regenerate joint integrity. The implant may be deployed in a prepared debrided joint space, secured to at least one of the joint bones and expanded in the space, molding to surrounding structures with sufficient stability to avoid extrusion or dislocation. The implant may have has opposing walls that move in varied directions, and an inner space filled with suitable filler to accommodate motions which mimic or approximate normal joint motion. The implant may pad the damaged joint surfaces, restores cushioning immediately and may be employed to restore cartilage to normal by delivering regenerative cells.

The implant may be have no inflation chamber (inner space). The implant may comprise a chamber which is not inflated once implanted. The implant may have varying thicknesses at different locations. The implant may have different features at different locations. Inflation may involve singular balloons for cushioning or realignment, multiple separate or connected vesicles, or small vacuoles that contain gas, fluid, gel, fluid that becomes solid, or combinations thereof. Inflation may be invoked on either both surfaces of the implant or any surface of the implant inside or between variable walls (which can be considered layers in certain embodiments). Cushioning while intending to address deficiencies in cartilage may accrue from inflation or the use of compliant materials without inflation (and without a balloon per se for that matter) or both.

Provided herein is a resilient interpositional arthroplasty implant for application into knee joints to pad cartilage defects, cushion joints, and replace or restore the articular surface, preserving joint integrity, reducing pain and improving function. The implant may endure variable knee joint compressive and shear forces, and millions of cyclic loads, after injury or disease requires intervention. The implant may repair, reconstruct, and regenerate knee joint anatomy in a minimally morbid fashion, with physiologic solutions that improve upon the rigid existing joint replacement alternatives of plastic and metal. In cases where cells have been used for joint resurfacing requiring massive periosteal harvesting for containment, the polymer walls of some embodiments of the implant can capture, distribute and hold living cells until aggregation and hyaline cartilage regrowth occurs. The implant may be deployed into a prepared debrided knee joint space, molding and conforming to surrounding structures with sufficient stability to avoid extrusion or dislocation. Appendages (or tabs) of the implant may serve to repair or reconstruct tendons or ligaments. The implant may have opposing walls that move in varied directions, and an inner space, singular or divided, filled with suitable gas, liquid, and/or complex polymer layers as force-absorbing mobile constituents, such than robust valid and reliable joint motion is enabled. There may be no defined inner chamber, however at a particular location in the device the implant may have different features to aid in cushion, therapeutic effect, wear resistance, defect correction, or the like.

Provided herein is a resilient orthopedic implant configured for deployment between a first bone and at least one second bone of a joint. In the case of a knee joint, the first bone may be a femur, a tibia, or a patella. In the case of a knee joint, the second bone may be a tibia, a patella or a femur. The implant may further comprise a balloon comprising a first portion that is configured to engage the first bone of the joint, a second portion that is configured to engage the second bone of the joint, a side portion connecting the first portion and the second portion, in which the side portion facilitates relative motion between the first portion and the second portion, and an interior that is optionally inflatable with a first inflation medium; and a first appendage configured to couple the balloon to the first bone of the joint. The terms "balloon" and "bladder" may be used interchangeably throughout this disclosure to describe an implant having the features described herein.

In some embodiments, at least two of the first portion, the second portion, and the side portion are contiguous. In some embodiments, the first portion comprises a first wall, the second portion comprises a second wall, and the side portion comprises a side wall. As used herein, each of the terms the "first portion", the "second portion", and the "side portion" is used to describe a part of the balloon, and may not be separate parts in some embodiments. In embodiments wherein no inflation is used, a first portion may be one side and the second portion another side of the same implant. In some embodiments, each portion or wall is named in order to indicate the general geometry and location of each portion relative to the other of the portions and/or relative to bones and/or ligaments and/or tendons of the joint. Likewise, as used herein, each of the terms the "first wall", the "second wall", and the "side wall" is used to describe a part of the balloon or cushioning implant, and may not be separate parts of the balloon in some embodiments. Rather, in some embodiments, each of the walls is named in order to indicate the general geometry and location of each portion relative to the other of the portions and/or relative to bones and/or ligaments and/or tendons of the joint. In some embodiments, at least two of first wall, the second wall, and the side wall are contiguous. Nevertheless, each of the walls may, in some embodiments, be separate parts of the implant that are joined to form the implant. Likewise, each of the portions may, indeed, in some embodiments, be separate parts of the implant that are joined to form the implant. In some embodiments, one wall may become the second wall with body movement changing the anatomy of the implant as it related to joint motion.

In some embodiments, the first portion is a term used interchangeably with the first wall. In some embodiments, the second portion is a term used interchangeably with the second wall. In some embodiments, the side portion is a term used interchangeably with the side wall. In some embodiments, a wall (whether a first wall, a second wall, and/or a side wall) of the implant may comprise a plurality of layers. The wall may comprise multiple materials to impart physical and/or therapeutic characteristics to the wall. In some embodiments, a side wall may become a first or second wall as the implant changes shape through the application of joint forces.

The distinction between the first wall and the second wall may merely be noted to show relative location, and may be a contiguous wall that has a first side (wall) and a second side (wall) where the first side is adapted to contact the first bone, and the second side is adapted to contact the second bone. The walls may be touching or be made of the same materials, or they may be made of different materials, or they may have additional materials therebetween, such as microstructures, vacuoles, therapeutic agents, padding materials, gels, liquids, solid materials, rigid or semi-rigid materials, meshes, foams, honeycombed materials, capsules, urethanes, human tissues or media, soft tissues, or the like, as described herein. Either of the walls themselves may be made of any of these materials and/or have any of these features. For example, a single sheet of BIONATE (e.g., BIONATE I, BIONATE II, BIONATE 55D, BIONATE 65D, BIONATE 75D, BIONATE 80, BIONATE 80A, BIONATE 90A) may be deemed to have a first wall that contacts the first bone, and second wall that contacts the second bone. In another example, a single sheet of Chronoflex (e.g., ChronoFlexAR®, ChronoFlex AL®, ChronoFlec C®) may be deemed to have a first wall that contacts the first bone, and second wall that contacts the second bone. Nevertheless, the single sheet may be contiguous, having no particular separation between the walls that may be deemed a chamber or balloon. Again, each of the first wall and the second wall may be, in certain embodiments, so designated only to depict relative location—i.e. in relation to the bone each wall is adapted to contact. The first wall may be so designated in order to indicate an intent that the first wall is in a

position to contact the first bone, whereas the second wall may be so designated in order to indicate an intent that the second wall is in a position to contact the second bone, but the first wall and the second wall may be part of a contiguous implant, without any chamber or balloon therebetween.

The implant walls (first wall and/or second wall, and/or side wall may comprise a compliant material, and there may not be a separation between any of the walls of the implant which could be deemed a chamber. The material of the wall itself may be compliant such that the material itself accommodates cartilage irregularity and improved alignment of the joint bodies (ligaments, bones, tissue, etc.).

In some embodiments, the implant comprises a sheet. The sheet may be solid (e.g. comprising polyurethane or another biocompatible material), complex (e.g. comprising Dyneema mesh), or with at least one chamber of any size from a micrometer, to larger chambers as depicted and described elsewhere herein. The implant may comprise Dyneema mesh. The implant may comprise Dyneema fiber. In some instances, the implant comprises Dyneema Purity®. The implant may comprise a fiber. The implant may comprise a polyethylene fiber. The implant may comprise a mesh. The mesh may be a random structure or a repeating structure (such as a honeycomb). The mesh may comprise a polymer structure of interwoven or randomly interlinked fibers or a combination thereof. The mesh may comprise a metal structure of interwoven or randomly interlinked metal fibers or a combination thereof. The mesh may comprise a memory metal (e.g. Nitinol or another memory metal). The mesh may comprise a memory polymer. The mesh may aid in fixing the implant in place. The mesh may be adapted to add cushion to the bones of joint. The mesh may be adapted to add durability to implant upon cyclic loading. The mesh may be adapted to add padding to the bones of joint. The mesh may be filled in its interstices with a softer (in durometer) polymer or other material (softer than the material of the mesh itself). The mesh may be filled in its interstices with a softer (in durometer) polymer or other material (softer than the material of the mesh itself). The interstices of the mesh may comprise a pharmacologic or therapeutic agent (or both) as noted herein. The mesh may be filled with a harder material, or a material that becomes harder, such as methyl methacrylate. The mesh may comprise a biodegradable material. In some instances, the mesh does not comprise a biodegradable material. The mesh may comprise a steel wool. Alternatively, the mesh comprises DNA strands. In some embodiments, the mesh comprises intertwined DNA strands. In some embodiments, the mesh is configured to wrap a joint end.

In some embodiments there is no chamber in the implant. In such an embodiment, the implant may have a single composition throughout the implant, and shaped as noted herein with attachment features as noted herein. In such embodiments, distinction between the first wall and the second wall may be noted to indicate relative location, and may be a contiguous wall that has a first side (wall) and a second side (wall) where the first side is adapted to contact the first bone, and the second side is adapted to contact the second bone. In other embodiments of the implant, the implant comprises no chamber, however it comprises various regions which have different features than other regions—such as comprising a mesh between the first wall and the second wall (as noted above), a cushion between the first wall and the second wall, and/or comprising any aspects of the fill materials noted in the inflation mediums noted elsewhere herein, but not necessarily provided in a chamber which is filled following implantation or at the time of implantation. Rather, these aspects may be built into the implant during implant manufacture, by layering or other manufacturing processes, and not necessarily by filling a chamber. In some embodiments, there are multiple regions having different characteristics—cushioning, some therapeutic agent delivery, defect correction, padding, for non-limiting example, or some combination thereof. In some embodiments, the implant achieves these aspects by varying thickness of one of the walls at a particular region of the implant, for non-limiting example, at load-bearing locations. In some embodiments, the implant is inflatable having large chamber (in the 1-100 cm range), or small chamber (in the 1 micrometer to 1 cm range). In some embodiments, the implant may comprise such a chamber (or chambers) but not involve any inflation. In some embodiments, the implant may not have any inflatable chamber (or chambers) whatsoever. The range of inflation can be consistent with a continuum whereas implant spacing or vacuous interspace can vary at a molecular level as allowing for macromolecular sizes or macrodendritic molecules. The molecules covering the exposed or integral implant makeup may be constructed with coatings or without, that may be suspended in gas, liquid, gel, or solids with vacuoles, bubbles, balloons or bladders of a size producing a foam or trabecular framework or honeycomb that has 'inflation' not visually obvious. When encapsulating the cushioning gas or fluid in small containers, the cushioning effect may become more effective, and for a given amount of cushioning the intercell pressure can be reduced. The implant may comprise a foam between the first wall and the second wall. The implant may comprise a microvoid (i.e. a void in the implant material that is in the 1 micrometer to 1 mm size range). The implant may comprise first wall or second wall that may be prefabricated containing compressible material into which substances may be introduced via needle injection or cannula. The compressible material may be a gas or a foam mixed with a liquid. The implant may comprise first wall or second wall that may be prefabricated containing displaceable material into which substances may be introduced via needle injection or cannula. The displaceable material may be a gas or liquid.

In some embodiments, the implant comprises a selectively inflatable chamber that may pad a uniquely damaged and/or collapsed joint region, thus restoring both protective cushioning and adjacent limb alignment as that otherwise accomplished (for example via proximal tibial or distal femoral osteotomy in the case of a knee implant). A chamber or redundant membrane may, depending on the embodiment, not be inflated at all. In other embodiments, the chamber or redundant membrane may be maximally inflated so as to appear as a diffuse balloon appendage fastened to the otherwise capped and adherent polymer solid joint end wrapping. The singular macroscopic cells or inflated polymer segment make take on any shape conforming to the recipient site defect and/or the inflation depo may have a prefabricated shape planned to accommodate a certain amount of infusion whether as an extension into the knee joint as a flattened bladder mimically meniscal fibrocartilage or topping off a femoral head analogous to the external radius of a bipolar hip hemiarthroplasty. In either or any case the natural polymer pliability and ability to elastically deform may match the normal joint motions physiologically.

The implant may comprise materials without obvious or definable inflation of any sort, producing a cushioning effect usually over one primary joint surface but potentially over multiple, providing a useful cushioning via polymers of variable albeit solid material nature and reasoned compli-

ance. In certain embodiments, the implant material per se and/or inflational enlargement immediately or gradually comes to conform to, accommodate, adjust and fill the indentations or defects on the side of implant in apposition to the defect. A semi-fluid tendency of certain embodiments permits both immediate post insertional and delayed joint surface alignment adjustments that may be increased by injection or cannular infusion, or deceased by aspiration or valvular evacuation.

In some embodiments, the filling material is an inflation medium. The first wall is secured to the end of the first bone by a skirt that extends from the first wall and the second wall engages the end surface of the second bone and may also be secured thereto. In some embodiments, the skirt **18** is called an appendage. The side wall extending between the first and second walls and defines at least in part the implant interior which is filled with filling material (or an inflation medium). The inner surfaces of wall and skirt preferably conform to the particular surface of the head of the patient's first bone. In some embodiments, the inner surfaces of wall and skirt preferably conform to the particular surface of the patient's first bone. The outer surface of the second wall is preferably configured to conform to the end surface of the second bone. In some embodiments, the outer surface of the second wall is preferably configured to conform to a surface of the second bone.

The edge of the implant may have a depending skirt to secure or anchor the implant to the end of bone, but may have one or more depending tabs (or appendages) that may be employed for similar functions as will be discussed in other embodiments. The skirt (and/or tabs, and/or appendages) may tightly fit about the end of the first bone as shown, or the skirt can be secured by adhesive (e.g. methyl methacrylate, bone in-growth) to the supporting bone structure or be mechanically connected by staples, screws and the like. Moreover, the lower portion of the skirt may be secured by a purse string suture or a suitable strand (elastic or tied) that is tightly bound about the outside of the skirt.

In some embodiments the implant comprises an in-growth patch on at least one of the first portion configured to engage the first bone, the second portion configured to engage the second bone, the side portion, and the appendage. The in-growth patch may be configured to encourage and/or promote tissue in-growth, such as bone in-growth, for non-limiting example. The patch may be as large as the portion itself (whether the first portion the second portion, the side portion, or the appendage) or may be smaller than the portion (such as in the shape of a strip or other shaped patch). The in-growth patch may comprise a surface irregularity or roughness. The in-growth patch may be Velcro-like. In some embodiments the implant comprises an in-growth patch on the first portion and/or the second portion, from (and in some embodiments including) a first appendage to a second appendage. In some embodiments, wherein the appendages loosen from attachment from the bone (by design and/or from wear and/or over time), the in-growth patch aids in securing the implant to the bone. In some embodiments, the in-growth patch comprises beads and/or bead-like elements attached to the implant. Such an in-growth patch may be configured to simulate trabecular bone space of a normally cancellous latticework. In some embodiments, the beads are sintered beads of various sizes. In some embodiments, the beads are sintered beads about 400 microns in size. With respect to bead size, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%. In some embodiments, the first bone and/or the second bone is roughened to acquire a bleeding bone to facilitate in-growth. In some embodiments, about 0.5 mm of cortical tissue is removed to facilitate in-growth.

In some embodiments, the appendage of the implant comprises a hook. In some embodiments the hook is angled. The hook may comprise a piece of metal sandwiched between two polymer pieces. The hook may comprise a piece of metal encased in polymer. In some embodiments, the hook may comprise a piece of metal and a portion of the metal piece may be encased in polymer. In some embodiments, the hook may comprise a piece of metal and a portion of the metal piece may be sandwiched between two polymer pieces. The metal of the hook may reinforce the appendage tabs for securing the implant to the bone of the joint. In some embodiments, the metal of the hook is formed of a 1 centimeter by 1 centimeter metal piece. The metal of the hook, or a portion thereof, may protrude from the appendage. The metal may be bent toward the bone to which it is configured to attach. The metal may be bent at about a 270 degree angle (as compared to the non-bent portion of the metal, or as compared to the rest of the appendage, for non-limiting example). The term about when referring to angle of bend of the metal of the hook can mean variations of 1%, 5%, 10%, 20%, and/or 25%, or variations of 1 degree, 5 degrees, 10 degrees, 15 degrees, 20 degrees, 25 degrees, 30 degrees, 40 degrees, 45 degrees, and/or up to 90 degrees. In some embodiments, the bone may be prepared to receive the hook, such as by a hole or slot into which the hook (or a portion thereof) is placed. In some embodiments, the bone is not prepared in advance to receive the hook, and the hook may self-seat into the bone by pressure applied to the hook into the bone. In some embodiments, the implant may comprise multiple appendages, and a plurality of the appendages has hooks. In some embodiment the implant may be screwed on or snapped on or secured with a combination of elements, such as stabilizers and sutures.

In some embodiments, the implant comprises a second appendage coupling the balloon to the first bone of the joint. In some embodiments, the implant comprises a second appendage coupling the balloon to at least one second bone of the joint. In some embodiments, the implant comprises a second appendage configured to couple at least one of the first portion, the second portion, and the side portion to at least one of the first bone and at least one second bone of the joint. In some embodiments, the first appendage and the second appendage are configured to provide ligamentary-like support to the first bone and the at least one second bone of the joint. In some embodiments, the first appendage and the second appendage are configured to provide ligamentary-like support to the joint. In some embodiments, the first appendage and the second appendage are configured to provide tendon-like support to the first bone and the at least one second bone of the joint. In some embodiments, the first appendage and the second appendage are configured to provide tendon-like support to the joint.

In some embodiments, the implant comprises an inflation port in communication with the interior of the balloon for inflation of the interior of the balloon with the first inflation medium. In some embodiments, the balloon is punctured to inflate the interior of the balloon with the first inflation medium. In some embodiments, the balloon is self-sealing. In some embodiments, the balloon is self-sealing upon inflation of the interior of the balloon with the first inflation medium. In some embodiments, the implant comprises a seal capable of closing the interior of the balloon. In some embodiments, a series or collection of balloons as bubble-wrap are adjacent to each other or in a series such that they share or distribute forces across joints or with weight

bearing. In some embodiments the contents from one balloon may transfer to another balloon or the size of one balloon may change in relation to adjacent balloons as with shoes that contain air soled subject to roving forces.

The implant interior, if existing depending on the embodiment, between the walls and the wall may be filled with filler material (or an inflation medium) which aids in maintaining the desired implant dynamics within the joint structure. The nature of the filler material such as a fluid and the characteristics of the walls may be selected to maintain a desired spacing between the walls in order to accommodate the pressure applied by the bones of the joint structure to the implant and to allow suitable motion between the first and second walls of the implant which facilitate bone motion which mimics or approximates normal movement for the joint members involved. Alternatively, as mentioned above, the inner chamber may be filled with resilient material to provide the desired spacing, pressure accommodation, while allowing desired physiologic motion between implant layers. The implant is preferably configured to be shaped like the joint space and bone surfaces being replaced or to fill the void produced by injury or disease so that the natural joint spacing and cushioning of the joint interface is restored toward normal physiologic appearance and function. Fluids such as saline, mineral oil and the like may be employed to inflate the implant. In some embodiments, the inflated space can be maintained in the expanded position not by the contents (e.g. gas) but rather by the trabecular framework that props the walls apart, like cancellous bone fills the space between cortices with microscopic cavities that can be filled with various mediums. Such spaces may change with pathology such as bone with osteoporosis or lungs with emphysema. Therapeutic or physiologic filler that may be introduced into the implant, and transferred into the body through varied mechanisms, many of which are described elsewhere herein or would be known to one of skill in the art.

In some embodiments the implant may comprise vacuoles of pharmacologic substances. The vacuoles may be on a bone-engaging portion of the implant. In some embodiments, the implant comprises bubbles comprising an active substance such as a pharmacologic substance or other active substance. The implant may deliver by dissolution of the implant material (i.e. a biodegradable polymer which releases the active substance), and/or by release through pores of the implant (wherein the polymer is permeable to the active substance), and/or by fracture of the vacuole (or bubble, or space) by a catalyst such as ultrasound or pressure or other fracturing catalyst. The implant may deliver the active substance at a time after the actual implanting of the implant into the joint, for example an hour later, less than a day later, a day later, less than a week later, a week later, less than a month later, and/or a month later. In some embodiments, stem cells that are percolating in the bubble (or vacuole, or space) may be delivered to the joint space (or a constituent of the joint) after the implant is inserted into the joint. Active agents may, for non-limiting example, include cells (e.g., stem cells, differentiated cells, pluripotent cells, post-mitotic cells), growth factors, antibodies, biomolecules, biologics, chemical compounds, antibiotics, and/or viscolubricants. In some embodiments, the implant may comprise enzyme absorptive 'microscopic sponges' that could be sucked out or evacuated at or around the time of implant delivery to the joint.

In certain embodiments the implant (or a portion thereof, such as the balloon or balloons) is a weight bearing spacer that allows joint motions to approach normal, whether filling the space left by an entirely collapsed joint bone or the space of ablated cartilage proximate surfaces diffusely as in osteoarthritis or succinctly as in osteonecrotic defects or localized trauma. The walls of the implant may be used as a membrane for holding living cells in proximity of the osteochondral defect long enough for the cells to attach (e.g. 24 hours) or to deeply adhere (up to 28 days) or return to normal (up to one year). Weight bearing may be expected to increase as distal lower extremity joints are treated.

Movement (whether linear or curvilinear) between the first and second walls of the implant (i.e. of the balloon) as a result of movement of the femur and the tibia is illustrated in the comparison between FIGS. **9**B and **10**A, or in the comparison between FIGS. **9**C and **10**B. In some embodiments, the implant may comprise a balloon that is configured to allow a wall of the implant rolling upon another wall (or the same wall) of the implant (e.g. the side wall rolling upon the first wall, the first wall rolling upon the second wall, the second wall rolling upon the first wall, the first wall rolling upon the side wall, the second wall rolling upon the side wall, the side wall rolling upon the second wall, the first wall rolling upon the first wall, the second wall rolling upon the second wall, and/or the side wall rolling upon the side wall). In some embodiments, the implant may comprise a balloon that is configured to allow a portion of the implant rolling upon another portion (or the same portion) of the implant (for non-limiting example, the side wall rolling upon an appendage, the first wall rolling upon an appendage, and/or the second wall rolling upon an appendage). In some embodiments, the implant may comprise a balloon that is configured to allow movement of a portion of the implant rolling upon cartilage. While not shown in the drawings, there may be slippage between a portion of the implant (whether an appendage, a wall, or some other portion of the implant) and a joint component (whether a bone, ligament, tendon or other tissue). This slippage may be in addition to wall movements within the implant per se to provide desired joint movements. While not shown in the drawings, there may be slippage between the second bone (for example, the tibia) and the second wall in addition to wall movements within the implant per se to provide desired joint movements. The appendage (or appendages) is (are) designed to secure the implant to the joint structure so as to avoid dislocation of the implant. Movement of the joint with the implant in place may be a shared function of both the moving opposing walls of the implant but also a function of the movement of the wall which may be less attached to the joint members. There may be slight movement between the appendage, first wall and the first bone. The walls of the balloon may compress and/or stretch to accommodate bone interface movement. Material choices, material dimensions, and implant dimensions, placement and/or coupling may be chosen to allow for the desired amount of compression, stretching relative movement of various joint and/or implant components. For non-limiting example, the walls of the implant may be thicker is some areas to accommodate particular loads and the side wall may be thinner and more elastic to accommodate rolling and stretching thereof.

The interior of implant may be adjustably filled by the physician from an appropriate source thereof after the implant is deployed to ensure that the pathologic joint space becomes a resilient cushion again which aids restoration of worn or damaged cartilage interfaces in the joint by covering cartilage defects with the implant material, cushioning the joint and defects therein and delivering cell regeneration agents. In one embodiment, the arthroplasty implant comprises a bio-compatible inflatable member that is filled with a biocompatible fill material such as a gas, liquid, gel or

slurry, or fluid that becomes a resilient solid to provide relative movement between the first and second walls. The filling or inflation media may be inserted through an injection valve site leading to the cannula which delivers the material into the interior of the implant. In an alternative embodiment, the implant may be filled with or have an interior formed of biologically compatible resilient material, e.g. a closed cell sponge filled with suitable fluid that is inserted into the interior of the implant prior to the implant's deployment or injected into the interior after the implant is deployed at the joint site. The interior of the implant may be provided with lubricious material to facilitate movement between the inner wall surfaces and to minimize contact wear therebetween. The polymeric walls of the implant may be impregnated with or otherwise carry tissue regeneration agents such as stem cells, living chondrocytes, and/or genes to repair joint surfaces.

Motion is believed to be primarily between the spaced walls (or portions) of the implant peripherally secured to joint structures, although some motion may occur between the implant and the joint surfaces. As shown in multiple Figures (including, FIGS. **1**-**7**), the implant may be provided with a slot extending from the periphery of the implant toward the balloon of the implant to accommodate at least one ligament of the joint. Knee implants may have two slots leading to separate passages for receiving the anterior and posterior cruciate ligaments. Implant walls should have sufficient inherent flexibility to mold to the existing deformities imposed by either natural ligament, bone, tendon or remaining cartilage deformities of the internal joint space, and thus filled as a cushion. The wall exteriors may be flat or formed with random or specific patterns for purposes of glide or trends for traction against adjacent surfaces, or as sulci or venues for cell delivery materials.

The exterior of the implant may have a mesh material with a plurality of chords (or appendages) for securing the implant to adjacent bones or to remnant ligaments which are attached to adjacent bones. The exterior of the implant may comprise Dyneema mesh. The exterior of the implant may comprise Dyneema fiber. In some instances, the exterior of the implant comprises Dyneema Purity®. The exterior of the implant may comprise a fiber. The exterior of the implant may comprise a polyethylene fiber.

The dimensions of the various implant walls may vary depending upon the material properties thereof as well as the needs for a particular joint. Additionally, the first and second walls may require a thickness different from the side wall. Generally, the implant may have a wall thicknesses of about 0.125 mm to about 3 mm, preferably about 0.5 mm to about 1.5 mm. The spacing between the first and second wall within the interior can vary from about 0.5 mm to about 5 mm. Thicknesses of the fixation tabs may be at least one of: about 1 mm, about 2 mm, about 3 mm, about 4 mm, about 5 mm, about 6 mm, about 7 mm, about 1 mm to about 6 mm, about 2 mm to about 4 mm, 1 mm to 6 mm, and 2 mm to 4 mm, for non-limiting example. The implant may comprise a reinforcing rim or a reinforced tab, which includes a change in tab material to make it stronger, or include a metal rim to reinforce the attachment location. The reinforcement element may be embedded in the tab or in a wall at the periphery of the implant (for example in instances where the coupler is not located at a tab per se).

In some embodiments, the implant has a first wall, a second wall, and a side wall which define the implant interior (or exterior) which contains filling material. In some embodiments, the filling material is an inflation medium. The first wall is secured to the end of the femur by at least one appendage that extends from the first wall and the second wall engages the end surface of the second bone (which in the case of a femoral-tibial joint implant, would be the tibia) and may also be secured thereto. The side wall extending between the first and second walls defines at least in part the implant interior which is filled with filling material (or an inflation medium). The inner surfaces of wall and appendage may conform to the particular surface femur, for example by being wider in particular locations and/or longer in particular areas. For example a dual compartment implant (described herein) may have a wider section to cover the medial condyle than the lateral condyle (as shown in FIGS. **1**, **2**, **3**, **6**A, **6**B, and **7**). In another example, the length of the implant the along the external edge may be longer than the length of the implant along the trochlear groove edge (as shown in FIGS. **11**A, **11**B and **11**C). In yet another example, the width may vary along a single condyle, such as is shown in FIGS. **12**A-**12**C, wherein the wider edge of the implant is adapted to fit over at least a portion of the anterior condyle, and the narrower portion is adapted to fit over at least a portion of the posterior condyle. In some embodiments, the inner surfaces of the first wall and appendages preferably conform to the particular surface of the patient's femur, and do so by not only dimensions of the implant (lengths, widths, balloon location and shape), but also and/or alternatively due to appendage and/or tab and/or hole and/or coupler location and/or surface contours of the first wall. The outer surface of the second wall may be configured to conform to the end surface of the second bone (which may be a tibia or a patella, for example). In some embodiments, the outer surface of the second wall is configured to conform to a surface of the second bone (which may be a tibia or a patella, for example). The figures provided herein are highly schematic and do not depict details of the joint surface features, since human pathology and variation reflects both the patient's immediate and evolving pathophysiology. Neither do the figures depict other joint features such as cartilage, tendons, ligaments and other soft tissues and fluids of the joint for ease of viewing that which is depicted.

In some embodiments, the implant is configured to resemble the shape of the natural hyaline of a normal knee. For example, the normal hyaline is typically "H" shaped, thus certain embodiments of the implant are generally "H" shaped. The H may be an exaggerated H form, and the notches of the H may be extended on one side, while nearly nonexistent on the other side, such as is shown in certain figures, such the "H" may look more like a "U" or "V" or contain a tab in the notch. For each joint the cartilage surface shapes, implant design, and method of surgery can vary by adapting to normal anatomy in a particular patient, to expected weight bearing, and use intent.

Implant Materials and Material Features

In some embodiments, the implant comprises polymer. Polymers may comprise at least one of: a polyurethane (such as, for example, ChronoFlex AR, ChronoFlex AL®, ChronoFlec C®), a polycarbonate urethane, a thermoplastic polycarbonate urethane (such as BIONATE, e.g., BIONATE I, BIONATE II, BIONATE 55D, BIONATE 65D, BIONATE 75D, BIONATE 80A, BIONATE 90A, BIONATE 55 or BIONATE 80), ethylene-vinyl acetate copolymer, multiblock copolymers of poly(ethylene oxide) (PEO) and poly (butylene terephthalate) (PBT), PEG, PEO, and a polyetheylene. In some embodiments the implant comprises a 125 micron thickness thermoplastic polycarbonate urethane. In some embodiments, the thermoplastic polycarbonate urethane has a low coefficient of friction. In other embodiments,

the thickness of walls intends to mimic natural hyaline cartilage a the involved body location and may be one of: about 0.5 mm, about 1 mm, about 2 mm, about 2.5 mm, about 3 mm, about 3.5 mm, about 4 mm, 0.5 mm, 1 mm, 2 mm, 2.5 mm, 3 mm, 3.5 mm, 4 mm, 1 mm-6 mm, 1 mm-4 mm, and 1 mm-3 mm.

The implant may comprise to a plurality of layers of polymer (such as ChronoFlex AR, ChronoFlexAR®, ChronoFlex AL®), ChronoFlec C®) in a solvent and evaporating the solvent after applying each layer. In some embodiments, the implant comprises a polyurethane that is sprayed and dried (wherein the spraying and drying is repeated at least once) to a desired thickness.

In some embodiments, the implant is created by dip molding a mandrel having a shape of a bone of the knee joint (the medial condyle, the lateral condyle, the tibia, for non-limiting example) into a polymer solution (for non-limiting example, a urethane polymer such as Chronoflex (e.g., ChronoFlexAR®, ChronoFlex AL®), ChronoFlec C®)). Following each dip, the implant is dried for a specified time, which may be, for example, about 3 seconds, about 4 seconds, about 5 seconds, about 6 seconds, about 7 seconds, about 8 seconds, about 9 seconds, about 10 seconds, about 15 seconds, about 20 seconds, about 25 seconds, about 30 seconds, about 45 seconds, about 1 minute, about 2 minutes, about 5 minutes, about 10 minutes, about 15 minutes, and over about 15 minutes. The term "about" used herein in reference to drying time of the implant can mean variations of at least one of 5%, 10%, 25%, and 50%, In some embodiments, no drying step is used. The dipping may be repeated multiple times. In some embodiments a single dip is sufficient. In some embodiments, the dipping is repeated 2 times. In some embodiments, the dipping is repeated 3 times. In some embodiments, the dipping is repeated 4 times. In some embodiments, the dipping is repeated 5 times. In some embodiments, the dipping is repeated 6 times. In some embodiments, the dipping is repeated 7 times. In some embodiments, the dipping is repeated 8 times. In some embodiments, the dipping is repeated 9 times. In some embodiments, the dipping is repeated 10 times. In some embodiments, the dipping is repeated 11 times. In some embodiments, the dipping is repeated 12 times. In some embodiments, the dipping is repeated 13 times. In some embodiments, the dipping is repeated 14 times. In some embodiments, the dipping is repeated 15 times. In some embodiments, the dipping is repeated 16 times. In some embodiments, the dipping is repeated 17 times. In some embodiments, the dipping is repeated 18 times. In some embodiments, the dipping is repeated 19 times. In some embodiments, the dipping is repeated 20 times. In some embodiments, the dipping is repeated 21 times. In some embodiments, the dipping is repeated 22 times. In some embodiments, the dipping is repeated 23 times. In some embodiments, the dipping is repeated 24 times. In some embodiments, the dipping is repeated 25 times. In some embodiments, the dipping is repeated over 25 times. In some embodiments, the dipping is repeated a sufficient number of times to create an implant that is a prescribed thickness. The thickness may vary depending on the polymer and depending on the embodiment of the implant. The thickness may be at least one of: about 25 microns thick, about 50 microns thick, about 100 microns thick, about 125 microns thick, about 150 microns thick, about 200 microns thick, about 250 microns thick, about 300 microns thick, about 350 microns thick, about 400 microns thick, about 25-50 microns thick, about 50-100 microns thick, about 50-200 microns thick, about 100-150 microns thick, about 150-300 microns thick, about 100-300 microns thick, about 100-500 microns thick, about 200-500 microns thick, and about 200-1000 microns thick. The term "about" used herein in reference to thickness of the implant can mean variations of at least one of 5%, 10%, 25%, and 50%, The thickness may vary at different locations of the implant. In some embodiments, the implant is fabricated in two pieces, one or more of which is molded to form an interior when the two pieces are put together. In some embodiments, the implant is filled by puncturing the implant wall and sealing the puncture hole with a plug, patch or other sealant. The plug, patch, or other sealant may comprise Chronoflex material (e.g., ChronoFlexAR®, ChronoFlex AL®, ChronoFlec C®), for non-limiting example. The plug, patch, or other sealant may comprise the same material from which the implant is constructed, for non-limiting example. In some embodiments, the implant thickness may be many millimeters, for example, where larger defects or malignments are being corrected.

The walls of the implant embodying features of the invention may be composite structures. For example, the innermost layer may be impervious to preclude escape of inflation or other filling media, a central layer may be porous or otherwise contain treatment or cell regeneration agents, and the outer layer may be a thin, but strong layer of a thermoplastic, such as a thermoplastic polyurethane for non-limiting example, which has microporosity sufficient to allow passage or egress of treatment or cell regeneration agents from the central layer (or second layer). The degree of microporosity to enable egress of treatment or cell regeneration agents from the central layer is found in polymer layers such as Chronoflex (e.g., ChronoFlexAR®, ChronoFlex AL®, ChronoFlec C®) or BIONATE (e.g., BIONATE I, BIONATE II, BIONATE 55D, BIONATE 65D, BIONATE 75D, BIONATE 80A, BIONATE 90A, BIONATE 55 or BIONATE 80).

The external wall (and/or the bone engaging surface) of the implant may be coated and/or impregnated with a latticework of polymer that is surface sprayed or layered on the outside (or bone engaging surface) of the implant to promote cartilage tissue regeneration. This most external surface coating may contain living chondrocytes (for example, as is provided in the Carticel procedure by the Genzyme company), and/or may contain stem cells with directed gene mutations to enhance adherence of the coating to the implant. Chondrocytes from companies such as Tygenix or Histogenics may be used for greater aggregation potential. The bone engaging surface may comprise peaks and troughs. The living cells may be imposed in between (and/or provided in the) troughs of the implant surface while the surface areas of prominence (the peaks of the surface) may be used for at least one of: space validation, traction, and cell protection.

The implant may be formed of suitable bioabsorbable materials so that the implant may be absorbed within a particular predetermined time frame. Suitable bioabsorbable materials include polylactic acid, polyglycolic acid, polycaprolactone, copolymers, blends and variants thereof. Suitable bioabsorbable materials may also/alternatively include poly(hydroxyalkanoate)s of the PHB-PHV class, additional poly(ester)s, and natural polymers, particularly, modified poly(saccharide)s, e.g., starch, cellulose, and chitosan. The walls of the implant may be (in whole and/or in part) bioabsorbable. The balloon may be (in whole and/or in part) bioabsorbable. As used herein the terms bioabsorbable, bioerodable, and/or bioabsorbable may be used interchangeably. The walls of the implant may release a pharmaceutical

agent or an biological agent (such as stem cells, differentiated cells, pluripotent cells, post-mitotic cells, living chondrocytes, gene therapies, and the like). The release of such agents (whether biological or pharmaceutical, or a combination thereof) may occur over time, as the wall of the implant (or as the balloon) bioabsorbs in some embodiments, or as the joint is used (i.e. through pressure, for non-limiting example). In some embodiments, at least one of the implant walls is permeable to a pharmaceutical agent and/or a biological agent, such as in an embodiment wherein the inflation medium comprises the pharmaceutical agent and/or biological agent. In some embodiments, at least one of the implant walls has pores through which the pharmaceutical agent and/or the biological agent may fit, such as in an embodiment wherein the inflation medium comprises the pharmaceutical agent and/or biological agent. In some embodiments the contents may contain targeting drugs such as gleevac that turn off tumor molecules as those in GIST. Cell-specific drugs targeting tumors by design may require nano-sized micelles with hydrophilic shells to protect core agents. In some embodiment hydrogels are used and tailored to swell thus releasing trapped molecules or cells through weblike surfaces, controlled by internal or external triggers such as ph, magnetic fields, or temperature. Dendritic macromolecules may be used in implants to deliver agents en masse deploying a controllable size and structure. In some embodiments, individual agent molecules or hubs may be incorporated via covalent bonds.

In some embodiments, the interior comprises a plurality of inflatable chambers. In some embodiments, the interior comprises a plurality of individually inflatable chambers. In some embodiments, a first chamber of the plurality of individually inflatable chambers is adapted to be inflated with the first inflation medium, and a second chamber of the plurality of individually inflatable chambers is adapted to be inflated with a second inflation medium. The implant may be provided with latticework or other reinforcing strands, preferably on the exterior or within the wall thereof to control the maximum expansion of the implant when deployed at the orthopedic site.

In some embodiments, the implant comprises amniotic membrane (and/or a component thereof). In some embodiments, the implant comprises amniotic sac (and/or a component thereof). In some embodiments, the implant comprises amniotic tissue (and/or a component thereof). Amniotic membrane (and/or sac and/or tissue) is unique in that its mechanical properties include that it slippery on one side (lubricious, low modulus of elasticity) and sticky (adherent) on the other. In some embodiments, at least one of the first wall, the second wall and the side wall comprise amniotic membrane or a component thereof. In some embodiments, at least one of the first wall, the second wall and the side wall comprise amniotic sac or a component thereof. In some embodiments, at least one of the first wall, the second wall and the side wall comprise amniotic tissue or a component thereof. The amniotic membrane and/or amniotic sac and/or amniotic tissue may be used in conjunction with other biologic agents, pharmaceutical agents, and/or therapeutic agents. Amniotic tissue is used extensively in pleuripotential cells. It qualifies as HTBP (Human Tissue Based Product) because of the short term time span on the product and origin.

In some embodiments, the balloon is a composite structure. In some embodiments, the balloon comprises layers of porous and/or non-porous materials, or otherwise contain treatment or cell regeneration agents. In some embodiments, a first layer of the balloon is a thin, but strong layer of a thermoplastic, such as a thermoplastic polyurethane, for non-limiting example, which has microporosity sufficient to allow passage or egress of treatment or cell regeneration agents from a second layer. The second layer may be a central layer (which lies between the first layer and a third layer or a fourth layer or more layers). The first layer may comprise a bone engaging surface in some embodiments. The degree of microporosity to enable egress of treatment or cell regeneration agents from the second layer is found in polymer layers such as Chronoflex (e.g., ChronoFlexAR®, ChronoFlex AL®, ChronoFlec C®) or BIONATE (e.g., BIONATE I, BIONATE II, BIONATE 55D, BIONATE 65D, BIONATE 75D, BIONATE 80A, BIONATE 90A, BIONATE 55 or BIONATE 80). The bone engaging surface of the implant may be coated and/or impregnated with a latticework of polymer that is surface sprayed or layered on the bone engaging surface of the implant to promote cartilage tissue regeneration. This bone engaging surface coating may contain living chondrocytes (for example, as is provided in the Carticel procedure by the Genzyme company), and/or may contain stem cells with directed gene mutations to enhance adherence of the coating to the implant. The bone engaging surface may comprise peaks and troughs. The living cells may be provided in troughs while the surface peaks may be used for at least one of: space validation, traction, and cell protection.

In some embodiments, the implant is pre-molded to fit about at least one condyle of the femur. In some embodiments, the implant comprises a memory plastic. In some embodiments, the implant comprises a wire frame. In some embodiments, the wire of the wire frame comprises a memory metal. In some embodiments, the memory metal comprises nitinol. In some embodiments, the wire frame is disposed in the periphery of the implant or a portion thereof. In some embodiments, the wire frame is configured to aid in placement against the posterior of the condyle.

In some embodiments, at least a portion of the implant comprises a slippery surface. In some embodiments the slippery surface is configured to allow for relative movement between the implant (or a portion thereof) that is coupled to the femur and the tibia. In some embodiments the slippery surface is configured to allow for relative movement between the implant (or a portion thereof) that is coupled to the femur and the patella.

In some embodiments, the implant comprises a sheet. The sheet may be solid (e.g. comprising polyurethane or another biocompatible material), complex (e.g. comprising Dyneema mesh), or with at least one chamber of any size from a micrometer, to larger chambers as depicted and described elsewhere herein. The implant may comprise Dyneema mesh. The implant may comprise Dyneema fiber. In some instances, the implant comprises Dyneema Purity®. The implant may comprise a fiber. The implant may comprise a polyethylene fiber. The implant may comprise a mesh. The mesh may be a random structure or a repeating structure (such as a honeycomb). The mesh may comprise a polymer structure of interwoven or randomly interlinked fibers or a combination thereof. The mesh may comprise a metal structure of interwoven or randomly interlinked metal fibers or a combination thereof. The mesh may comprise a memory metal (e.g. Nitinol or another memory metal). The mesh may comprise a memory polymer. The mesh may aid in fixing the implant in place. The mesh may be adapted to add cushion to the bones of joint. The mesh may be adapted to add durability to implant upon cyclic loading. The mesh may be adapted to add padding to the bones of joint. The mesh may be filled in its interstices with a softer (in

durometer) polymer or other material (softer than the material of the mesh itself). The mesh may be filled in its interstices with a softer (in durometer) polymer or other material (softer than the material of the mesh itself). The interstices of the mesh may comprise a pharmacologic or therapeutic agent (or both) as noted herein.

To be clear, in some embodiments, there is no chamber in the implant. In such an embodiment, the implant may have a single composition throughout the implant, and shaped as noted herein with attachment features as noted herein. In other embodiments of the implant, the implant comprises no chamber, however it comprises various regions which have different features than other regions—such as comprising a mesh between the first wall and the second wall (as noted above), a cushion between the first wall and the second wall, and/or comprising any aspects of the fill materials noted in the inflation mediums noted elsewhere herein, but not necessarily provided in a chamber which is filled following implantation or at the time of implantation. Rather, these aspects may be built into the implant during implant manufacture, by layering or other manufacturing processes, and not necessarily by filling a chamber. In some embodiments, there are multiple regions having different characteristics—cushioning, some therapeutic agent delivery, defect correction, padding, for non-limiting example, or some combination thereof. In some embodiments, the implant achieves these aspects by varying thickness of one of the walls at a particular region of the implant, for non-limiting example, at load-bearing locations.

Inflation Medium and Inflation or Filling of the Implant Interior

In some embodiments, the implant comprises an inflation medium that is compressible. In some embodiments, the implant comprises an inflation medium that comprises a viscolubricant. In some embodiments, the implant comprises an inflation medium that comprises a pharmacologic substance. In some embodiments, the implant comprises an inflation medium that comprises an NSAID. In some embodiments, the implant comprises an inflation medium that comprises chondrocytes. In some embodiments, the implant comprises an inflation medium that comprises cells (e.g., stem cells, differentiated cells, pluripotent cells, post-mitotic cells). In some embodiments the implant is configured to anneal the outer most layer of the implant (or a portion thereof) to the peripheral of succinct cartilage defects so as to cover them, allowing for healing. In some embodiments the implant is configured to anneal the outer most layer of the implant (or a portion thereof) to the peripheral of succinct cartilage defects so as to cover them, allowing for healing once new chondrocytes have been installed.

The implant interior (balloon interior) may be inflated with gas. The implant interior (balloon interior) may be inflated with liquid. The implant interior (balloon interior) may be inflated with saline. The implant interior (balloon interior) may be inflated with suspended stem cells. The implant interior (balloon interior) may be inflated with gel. The implant interior (balloon interior) may be inflated with a viscolubricant. The inflation medium in some embodiments stays within the balloon, or a portion thereof (as where there are multiple chambers to the balloon). In some embodiments, balloon contents disburse through microporosities and/or dissolving membranes into the joint. In some embodiments, balloon contents disburse by expulsive or evacuation precipitated through an implant wall after pressure from limb use. In some embodiments, balloon contents disburse by expulsive or evacuation precipitated through an implant wall from planned osmosis. In some embodiments, balloon contents disburse by expulsive or evacuation precipitated through an implant wall from vacuole rupture (whether mechanical rupture, ultrasound, or chemical rupture, for non-limiting example). In some embodiments, balloon contents disburse by expulsive or evacuation precipitated through an implant wall thereby distributing contents of the implant interior to joints as lubricious, analgesic, anti-inflammatory and/or otherwise healing substances. In some embodiments, the implant may comprise solid beads or beads containing gel or liquid for sequential disbursement by compressive force through rupture with varied bead wall thicknesses, or the beads may be time-released (opened) chemically, pharmacologically, or by an outside ultrasound or magnetic force external knee application at appropriate clinical intervals. In some embodiments, the implant may comprise vacuoles containing gel or liquid for sequential disbursement by compressive force through rupture with varied vacuole wall thicknesses, or the vacuoles may be time-released (opened) chemically, pharmacologically, or by an outside ultrasound or magnetic force external knee application at appropriate clinical intervals. The implant material may be foam or complaint material (such as a compliant polymer).

The implant interior (or balloon interior) between the first wall and the second wall is filled with filler material (or an inflation medium) which aids in maintaining the desired implant dynamics within the joint structure. The nature of the filler material such as a fluid and the characteristics of the walls may be selected to maintain a desired spacing between the walls in order to accommodate the pressure applied by the bones of the joint structure to the implant and to allow suitable motion between the first and second walls of the implant which facilitate bone motion which mimics or approximates normal movement for the joint members involved.

Alternatively (and/or additionally), the inner chamber (interior or a portion thereof) may be filled with resilient material to provide the desired spacing, pressure accommodation, while allowing desired physiologic motion between implant layers. The implant may be configured to be shaped like the joint space and bone surfaces being replaced or to fill the void produced by injury or disease so that the natural joint spacing and cushioning of the joint interface is restored toward normal physiologic appearance and function. The interior of implant is adjustably filled by the physician from an appropriate source thereof after the implant is deployed to ensure that the pathologic joint space becomes a resilient cushion again which aids restoration of worn or damaged cartilage interfaces in the joint by covering cartilage defects with the implant material, cushioning the joint and defects therein and delivering cell regeneration agents. In one embodiment, the implant comprises a bio-compatible inflatable member (balloon) that is filled with a biocompatible fill material (inflation medium) such as a gas, liquid, gel or slurry, or fluid that becomes a resilient solid to provide relative movement between the first and second walls.

In some embodiments, the features of the implant change over time. For example, prior to, at, or during implantation, the implant may comprise a powder methyl methacrylate and a liquid that becomes a slurry upon insertion or soon thereafter, and that once implanted hardens (or cures) within the implant. The methyl methacrylate (e.g. as a powder) and a catalyst liquid together become solid and are an example of a cement (or bone cement), however other cements or other materials which cure over time or with heat or with loading or by other methods (chemical or physical) are

contemplated as alternatives. In certain embodiments, at least one of the powder methyl methacrylate and the liquid is part of the implant at the time of implantation. In certain embodiments, at least one of the powder methyl methacrylate and the liquid is injected into or loaded into the implant at the time of implantation or soon thereafter. In certain embodiments, both the powder methyl methacrylate and the liquid are injected into or loaded into the implant at the time of implantation or soon thereafter. In certain embodiments, at least one of the powder methyl methacrylate and the liquid is a fill material. In certain embodiments, the implant does not have a chamber prior to injection of (or loading of) a fill material between the first wall and the second wall. The injection (or loading) of a fill material between the first wall and the second wall creates a chamber. In certain embodiments, the implant comprises interstices which are occupied by the fill material. In some embodiments, the methyl methacrylate powder and liquid catalyst are already inside the implant but only mix after intentional deployment in external or internal manners.

In some embodiments, the first inflation medium imparts rigidity in the implant. In some embodiments, the first inflation medium imparts cushion in the implant. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium aligns the joint. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium aligns the bones of the joint. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium changes the bone alignment. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium improves joint alignment. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium restores, at least in part, joint alignment. In some embodiments, individual chambers of the interior may be selectively inflated with a first inflation medium and/or a second inflation medium. In some embodiments, individual chambers of the interior are selectively inflated with a first inflation medium and/or a second inflation medium in order to reconstruct the joint and/or bones of the joint.

In some embodiments the inflation medium comprises living chondrocytes.

The implant interior (balloon interior) may be inflated with methyl methacrylate as a liquid that becomes a solid or semi-solid (rigid or semi-rigid). In some embodiments, the inflation medium is a methyl methacrylate or other biocompatible hardening substance which can flow when initially put into the chamber, and hardens to become a rigid piece or semi-rigid piece or solid piece. The methyl methacrylate or other biocompatible hardening substance may conform to the shape of the chamber, or may conform to the shape of a space between bones and/or other joint structures. The methyl methacrylate or other biocompatible hardening substance may conform to a form chosen by the surgeon using tools and/or pressure to influence the final shape of the rigid piece formed by the methyl methacrylate or other biocompatible hardening substance upon hardening.

The side wall extends between the first and second walls to form an interior which receives filling material through tube (also called a conduit herein, or may be called an inflation port). In some embodiments, the inflation port is not a tube, but is a valve which may or may not extend from a wall of the implant. The valve may be part of a wall of the implant, or part of the balloon or a portion thereof. The implant would also be appropriate for one condyle of the knee, but other shapes may be desired for other joint configurations whether relatively flat or more inflated toward a ballooning construct. In some embodiments, the inner diameter of the inflation port (or tube) is 5 millimeters maximum. In some embodiments, the inner diameter of the inflation port is about 1 millimeter. In some embodiments, the inner diameter of the inflation port is about 2 millimeters. In some embodiments, a needle (of typical needle sizes) may be used to inflate the implant.

A separate portal or tube (not shown) or the existing conduit (tube or valve), may be used to extract noxious inflammatory enzymes that can be aspirated at appropriate clinical intervals. Inflammatory enzymes in the COX1, COX2 and or 5LOX pathways can be extracted. Viscolubricants can be injected into the interior of the resilient arthroplasty implant through existing conduit or through a long needle to aide in distension, expansion, lubrication (with predetermined microporosity).

In some embodiments, an inflation medium that generates heat (by means of a catalyst reaction or other means) may be used to deliver heat to a joint structure. The heat may aide hyaline cartilage annealing. Thermal effects of the implant materials are calculated accordingly to benefit and protect the joint surface analogous to a dry suit or wet suit for a scuba diver exposed to temperature extremes. Embodiments of the implant generally seek to avoid head from friction via lubricious coatings whether allograph as amniotic membrane or polymer, for non-limiting example.

The implant in some embodiments is inserted arthroscopically through a cannula about 10 mm in diameter with the implant in the deflated construct, and once inside the prepared joint space and secured therein by the appendages or tabs, the implant may be distended or inflated with gas, gel, fluid or fluid that becomes a resilient solid to fill the original natural space of a bone of the joint (whether the tibia, femur or patella). Tensioning may be by the surgeon's sense of proper pressure application aided by a gauged syringe for insertion of viscolubricants such as Synvisc, Hyalgan, Supartz and/or analgesics such as lidocaine gel. The insertion of liquids to the joint per se may be directly, through a cannula to the joint space previously in place for debridement, and or via a cannula or tube that is not part of the original implant assembly. Once the joint is cleaned, the implant is inserted and appropriately fixed to avoid extrusion or dislocation thereof. This may be via attachment of the implant tabs and/or by a combination of tab use plus intended friction created by implant surface coverings (analogous to Velcro) or a draw string at the smaller base of the implant.

In some embodiments, the implant comprises a coil (spring). The coil, or multiple coils, may be secured inside the implant. In some embodiments, the materials of the implant secure the coil or coils within the implant. In some embodiments, the implant coil is positioned perpendicular to the primary flat first wall and/or second wall of the implant. In some embodiments, the coil is positioned parallel to the primary load in the joint. In some embodiments, multiple coils are provided in the implant. In some embodiments, each coil is positioned parallel a direction of load during

joint use. In some embodiments, the coil is adapted in material and strength to fix the implant at a desired joint space when not under load by the bones of the joint. In some embodiments, the coil is adapted in material and strength to provide cushion between the unloaded and a loaded state, and/or to provide a minimum joint spacing, for example when the coil is fully compressed. In some embodiments, the coil has an ability to be extended past its unloaded length (i.e. stretched), but to provide resistance to this extension. The resistance from extension provided by the coil may cooperate with the resistance from extension provided by ligaments of the joint and/or by the attachments of the implant to the first bone and/or the second bone. In the case of a medial compartment arthrosis where the normal 6 degrees valgus degrades to a 'bow legged' varus deformity, the implant may pad the damaged cartilage and cushion the joint,—even inflating selectively as described herein. In one embodiment, a combination of metal and polymer could stack shorter to longer parallel (Nitinol, other metal, or polymer) coils to fit the shape of a normal meniscus so that the longer coils are at the wide peripheral portion of the meniscus (joint edge) providing stability of the joint not available following varus deformity or meniscectomy. Another embodiment implant comprises coils between the inner and outer layers of the hip redundant or primary membranes.

Responsive Implants & Shifting Chambers

In some embodiments, the inflation, compliance, and or materials integrity with mesh, coils, or other fill materials fit the patients limb use needs not only structurally and anatomically at the time of surgical placement, but during normal activities of daily living. The implant may be compressed in certain locations during normal loading cycles, and compressed in other locations also during the same cycle. The implant may be responsive to this and shift the contents of a bladder or chambers (whether small or large). An example of this is shown in FIGS. **10**A and **10**B, where in the normal gait of a person the femur loads against the implant at the back of the joint (back of the knee), and pushes the contents of the chamber (s), toward the patella. It can be seen from this that if the angle of the femur to the tibia and load associated therewith were to shift to about 180 degrees, the contents of the chamber(s) could likewise shift to cushion the joint as the use of the joint required. That is, as the weight and axial load of walking moves the body central forces toward the 'step off' moment of that gait cycle, the chamber has also shifted, enduring oscillating balloon (macro) or vacuolar (micro) space size changes to accommodate and buffer the actions incumbent in natural limb use. As such, in some embodiments, the implant not only restores appendicular limb anatomy of the bone alignments and joint spaces, it also can compress with normal use forces and spring back to aid the best use of lever arms and joint interstacies as bones and joints relate to each other in activities of daily living. This type of implant may be used in multiple joint spaces throughout the body. To the degree the implant obtains and restores the joint spaces and are fixed in place, they may also thus be responsive during use of the joint thereafter.

Smart RADs

In some embodiments, the implant comprises a microminiature recorder and/or transmitter. The recorder (i.e. sensor) may collect joint loading data and comprise electronics that deliver data regarding joint loading. The recorder (i.e. sensor) may collect data regarding chemical or physiologic response at the implant location, such as the presence and composition of various biologic fluids at the sensor site. The sensor may be able to detect inflammatory responses in the joint. The sensor may be able to detect the spacing of the various joint components over time or at a particular time—such as the distance between the tibia and femur during a normal gait. The implant may comprise electronics that deliver data regarding joint loading or the other aspects of the joint sensed as listed herein or otherwise that could be sensed. The transmitters may provide feedback to the patient or to a caregiver. The feedback may be real-time, or may be uploaded periodically, or may be uploaded upon request. The feedback may be provided wirelessly. The transmitters may provide a patient an ongoing feedback and ability to adjust the joint use based to the feedback from the transmitter. For example, the transmitter might signal to the patient that he should adjust his gait to reduce the ligamentary stress in one manner or another. In another example, the transmitter might indicate to a physical therapist that a certain ligament is being stressed during normal use, and that might indicate to the therapist that the patient should strengthen a particular muscle or muscle group to compensate for and balance the stresses in the joint. In another example, the sensor and transmitters transmits information regarding positioning, ligamentary stresses and other information to a graphic display of real-time feedback, enabling a surgeon to visualize and quantify joint loading and balance during implantation. Thus, a surgeon can make an informed choice to modify implant positioning, adjust leg alignment and optimize soft tissue balance through a full range of motion.

In some embodiments, the implant may comprise spacers which can be expanded or reduced following implantation to adjust joint spacing and alignment. This expansion (or reduction) may occur days, weeks, or even years after implantation. The expansion (or reduction) may be done without need to open the joint in a surgery. The expansion (or reduction) may be done remotely. In some embodiments, sensors may be used to detect a need for adjustment of the joint spacing or cushioning. This may be in response to joint changes such as torn ligaments, other wear problems, changes in body weight and thus stress changes in the joint, or other changes, or simply due to the implant fatigue over time which is due to normal use but is not necessarily considered implant failure. In certain embodiments, the implant comprises an insert that may be activated by the patient or health care worker. For example, limb alignment may be achieved by remotely expanding (or reducing) the implant sizing (thickness or other specification) in a particular location in order to correct a varus to valgus alignment. Doing so may have beneficial effects on other parts of the body, such as in the appendicular skeleton (arms and legs) and axial skeleton (spine) given the natural symmetry. For example, a patient or care giver with their external device (such as a computer or Blackberry or iPhone) may expand or reduce, the medial knee compartment by external stimulus so that instead of being a knee with varus deformity and bone on bone (bow legged) the alignment was intentionally changed to normal 6 degree valgus (knock kneed). Nevertheless, if the patient had adjusted to his deformity for years and abruptly "corrected" it to completely normal, his back may act up with aching symptoms of 'out of alignment'. This is because the body attempts to adapt to deformity. Consequently, if a lower extremity fracture healing produces a two centimeter limb shortening, the proper treatment is not to add a 2 cm shoe lift onto the injured side, but rather to start with a one cm shoe lift. Although this may not make the limb lengths equal, it may 'balance the body' as perceived by the patient. In the case of an implant as

provided herein that could adjust or be adjusted by doctor or patient, changes can be made to alignment and joint space, and then adjustments dealt with clinically as needed. If not via phone apps, other "black boxes" or tools such as a magnet placed externally adjacent to a medial compartment implant could be used to change the spacing inside the joint with an implant as described herein.

Attachment Elements and Couplers

In some embodiments the attachment elements of the implant comprises holes through which screws or other couplers may be placed to attach the implant to an attachment site (or connection site) in the bone of the knee. In some embodiments the attachment elements are also or alternatively called fixation elements or couplers. In some embodiments, the holes are created arthroscopically. In some embodiments the holes are pre-fabricated in the implant. In some embodiments, the holes may be made prior to implantation based on the patient's particular anatomy. In some embodiments, the holes are reinforced by a reinforcing material of the implant. The reinforcing material may be a polymer of sufficient durometer and/or tear resistance to reinforce the screw hole. The reinforcing material may comprise metal. In some embodiments, there is no preformed hole, but rather screws (or another coupler) secure the attachment tabs (which may be a non-balloon portion of the implant) to the joint component (bone, etc) by creating their own hole when implanted. In some embodiments, the implant may comprise tabs that are adapted to receive staples or other couplers described elsewhere herein. In some embodiments, the elasticity of the implant may allow it to stretch over the joint end and hook or snap into place, with the tendency of the material to contract acting to hold it in place (in part or wholly).

The implants described herein may comprise attachment elements (or tabs) which may then by attached or coupled to tissue of a component of the joint (whether to a bone or a ligament or a tendon or other joint component) by a coupling device. Coupling devices (or couplers) may comprise at least one of screws, snaps, washers, pins, sutures, suture anchors (metal and/or biodegradable), rivets, staples (with and/or without teeth), stabilizers, glues, hooks of cylindrical wire or flattened sheet metal into bone holes or slots respectively. The coupling devices may be resorbable or not. Also, the coupling devices may comprise at least one of strings (i.e. drawstrings), reigns, lassos, sutures, and lanyards. The strings, reigns, lassos, sutures, and/or lanyards may join with themselves and/or other coupling devices. The strings, reigns, lassos, sutures and/or lanyards may be directed not only into bone with or without anchors, but also through ligaments, tendons or loose segments of cartilage that the surgeon intends to preserve.

The posterior of the knee can be difficult to access without disturbing joint components (or in order to minimize such disturbance) such as tendons, ligaments, etc. Thus, in some embodiments, the implant comprises strings, reigns, lassos, and/or lanyards that may pass from the posterior of the implant via the intercondylar notch anteriorly to join with themselves and/or other coupling devices. These couplers may be pre-coupled to the implant, and the implant and its couplers may be configured to be pulled (or cinched) from the anterior of the implant once the implant is in its general location relative to the condyle in order to finally position the implant about the condyle—in particular in order to cinch the implant about the posterior of the condyle. Likewise, in some embodiments where the implant is pre-molded, the coupler as described are adapted to move the implant to its final position with conformity to the condyle's posterior with minimal disturbance to the joint structures at the joint's posterior (minimal cutting, minimal moving, and or minimal detachment, for non-limiting example).

In some embodiments, the implant comprises a skirt (or sleeve) that conforms to the contours of the bone (whether a condyle of the femur, a patella, or a tibia) as a coupler.

In some embodiments, a screw through tab having reinforced center holes may be part of the implant. For example, the implant may comprise polymer covered metal washer holes. The screw may go through the holes. Another embodiment may comprise a staple having spikes as shown in FIGS. **13**A-**13**D. FIGS. **13**A-**13**D depict multiple views of a staple adapted to couple an implant to a bone of the joint. FIG. **13**A depicts an embodiment of an implant **20** having a tab **10***a* that is coupled to bone using a staple **12**. FIGS. **13**B & **13**C depict a staple **12** as described herein having teeth **18**. FIG. **13**C depicts an embodiment of a tab **10***a* that is coupled to bone using a staple **12** having teeth **18**. Combinations of spikes and screws may be used in some embodiments, or combinations of other couplers. The implant may be configured to allow a surgeon the option of several types and sizes of couplers, as each patient differs with regard to size and depth of lesion, bone stock, regrowth capability, and compliance with advised recovery, and each surgeon has his own strengths and comforts when working with such implants.

The edge of the implant may have a depending skirt to secure or anchor the implant to the end of bone (femur), but may have one or more depending tabs (or appendages) that may be employed for similar functions as are discussed in other embodiments. The skirt (and/or tabs, and/or appendages) may tightly fit about the end of the femur, or the skirt can be secured by adhesive (e.g. HydroMed, Carbopol 934p, Polycarbophil AA1, xanthum gum, hydroxypropyl cellulose). Moreover, the lower portion of the skirt may be secured by a purse string suture or a suitable strand (elastic or tied) that is tightly bound about the outside of the skirt.

FIGS. **12**A, **12**B, and/or **12**C alternatively may be used to describe a patch implant or a unicompartment knee implant described herein, having appendages **4***a*, **4***c*, extending from a balloon **6** and including holes **8***a*, **8***b*, **8***c*, and/or tabs **10***a*, **10***b*. **10***c*, **10***d*, **10***e*, **10***f*, which may be used with couplers (not shown) to couple the implant to a bone of the knee joint (which may be the femur, the tibia, or the patella). Features shown in FIGS. **12**A, **12**B, and or **12**C are common to both the unicompartment knee implant (also discussed elsewhere herein) and the patch implant (also discussed elsewhere herein), although dimensions may differ as described elsewhere herein.

FIGS. **13**A-**13**D depict multiple views of a staple **12** adapted to couple implant **14** (such as those described herein) to a bone **16** of the joint. FIG. **13**A depicts a staple **12** coupling a tab **10***a* of an appendage **4***a* to the bone **16** of the joint (wherein the portion of the staple **12** embedded in the bone **16** is shown as a dashed line). FIG. **13**B depicts a view of a staple **12** having teeth **18** to grasp the tab **10***a* of the implant **14**. Similarly, FIG. **13**C depicts a view of a staple **12** having teeth **18** to grasp the tab **10***a* of the implant **14**. FIG. **13**D depicts a staple **12** attaching the tab **10***a* of an implant to a bone **16**, the dotted lines show the portion of the tab **10***a* that is compressed by the staple **12** and teeth **18** thereof.

In some embodiments, the implant is configured such that the tabs and/or couplers of the implant couple to the bone where there is no natural cartilage. In some embodiments,

the implant may be adapted by the surgeon at the time of surgery such that the tabs are positioned where there is no natural cartilage.

In some embodiments, the implant comprises a tab and a hook that couples to the tab by wrapping around a component of the knee and securing the tab to the hook. In some embodiments, the implant comprises a tab and a hook that couples to the tab by wrapping around a condyle of the knee and securing the tab to the hook. In some embodiments, the implant is configured to wrap around a condyle of the knee and to secure a first appendage to a second appendage of the implant. In some embodiments the appendages are secured by couplers described herein. In some embodiments, the implant is pre-formed to fit to the condyle in such a wrapping manner.

In some embodiments, the implant comprises a methyl methacrylate what is placed into a balloon chamber that fits into a bone hole. Such an embodiment would generally fix the implant to the bone once the methyl methacrylate cures to a solid.

In some embodiments, the implant can be anchored with generic available sutures and suture anchors fixing and positioning material to bone with proper tensioning.

In some embodiments, fixation may comprise various methods and elements. For example the fixation to a bone (the first, the second or the third bone) may comprise any one of or a combination of a screw, a snap, a pin, a staple, bone in-growth materials, glue, a nanocomposite, and cement. The implant may comprise a snap fit option for fixation. The implant itself may be pre-molded to cup the first bone of the device, or the second bone of the device. The implant may instead have a snap-like device which fixes the device to the bone (the first, second, and/or third bone). In some embodiments, fixation comprises glue. In some embodiments, fixation comprises a nanocomposite. In some embodiments, the nanocomposite comprises a polyurethane hierarchical nanocomposite. Fixation may comprise gluing a nanocomposite to the implant. In other embodiments, fixation comprises bone in-growth materials. For example, bone in-growth may be achieved as described in Vasanji A (2012). In some embodiments the patient's preoperative x-rays, MRI, CT scan, or physical measurements are coordinated with implant custom fit options providing for translation of pathophysiological data into solid works and rapid prototypes. This may provide the forum for anatomic fit of the implant to the patient. Optionally, the implant may be selected from a set of pre-selected sizes of implants and then the device may have inherent malleability which is used to couple the implant to the bone end.

In some embodiments, the implant comprises a rim comprising metal at the edge or a portion of the edge of the implant which may comprise a hole or more than one hole through which a fixation element (snap, screw, staple, other, etc.) or more than one element can be placed to fix the implant to the bone. The rim may comprise Nitinol or another metal (memory metal or deformable).

The implant may be shaped to form a joint cap which is fixed to a first bone or a second bone or a combination thereof with a fixation element such as a screw or staple or cement or another means or combination of these or others as described herein. Cementing the implant in place is an alternative or may be used with other fixation elements (screws, snaps, ties, hooks, staples, etc). In some embodiments the implant is secured in place only by the nature of its location and placement within the joint space. That is, it may naturally be held in place by the surrounding structures (tissue, bone, ligaments) as well as its own geometry in three dimensions. In some embodiments, fixing of the implant to bone is achieved by combining autograph, allograph, xenograph, and/or prosthetic structures.

In some embodiments, the implant comprises a polymer joint cap that may be used similarly to the femoral component of a total knee replacement cement arthroplasty or like a hip resurfacing. In certain cases, cartilage may be sacrificed exposing more bone beneath the implant, and cement could be used as a traditional fixation technique. In certain embodiments, specific portions of cartilage can be removed to allow attachment of the implant undersurface with the bone by localized applications of cement, bone in-growth, tacking devices, countersunk screws, or Velcro like constructs wherein opposing surfaces are set to fix. In an implant embodiment employing a cement for fixation, the anterior cruciate ligament could still be saved maintaining joint stability and proprioception.

A snap fit fixation element ("snap") may alternatively (or additionally) be used. A snap may be a protuberance off the posterior implant surface may be used. The snap may comprise a mushroom shaped peg that may insert into predrilled bone holes. The holes in some embodiments are of corresponding shape to the peg (upside-down mushroom-shaped holes, or similarly shaped holes). The holes in some embodiments are columnar shaped holes. The holes may be at the periphery (edge) of the implant as it opposes bone, or generally located as noted herein where other fixation elements are located (e.g. see FIGS. **1-4**B, **11**, **12** at least). The snap may also fit into more central posterior implant areas. With the natural effects of joint fluid and temperature on hydrophilic polymers, the snap may be designed as to increase stability by swelling beneath the joint cortical surface in the early post operative interval. Implant removal may be facilitated by placing a cooling device over the snap site to shrink or loosen the attachment. In some embodiments the peg of the snap is one of: about 1 mm to about 10 mm in diameter, about 2 mm to about 8 mm in diameter, about 3 mm to about 6 mm in diameter, about 4 mm to about 5 mm in diameter, about 4.5 mm in diameter, 1 mm to 10 mm in diameter, 2 mm to 8 mm in diameter, 3 mm to 6 mm in diameter, 4 mm to 5 mm in diameter, and 4.5 mm in diameter. In some embodiments the mushroom head of the snap is one of: about 1 mm to about 10 mm in diameter, about 2 mm to about 8 mm in diameter, about 3 mm to about 6 mm in diameter, about 4 mm to about 5 mm in diameter, about 4.5 mm in diameter, 1 mm to 10 mm in diameter, 2 mm to 8 mm in diameter, 3 mm to 6 mm in diameter, 4 mm to 5 mm in diameter, and 4.5 mm in diameter The snap or protuberances may have a narrow base that extends perpendicularly from the tabs and/or implant posterior surface. The wider sphere as compared to the diameter of the snap columnar pedestal fits into a predrilled bone hole that matches the location to be fixed. In another embodiment, the snap may be more like anchor which expands into the bone upon insertion, much like a drywall anchor acts. Material compliance allows the distal snap to enter through cortical to cancellous bone. Exposure to joint fluid and bode temperature can expand the snap wherein the snap comprises a hydrophilic polymer to secure implant apposition. In some embodiments, a mushroom shaped protuberance off the posterior of the polymer joint implant is used, with stiff pegs that push connected spheres through a predrilled cortical bone hole. The joint implant may be cap-like holding to the bone by internal elasticity of the implant and further held by the fixation elements which may be snaps or other elements. In some embodiments, a drill into cortical hole cuts a broader cancellous swath to create a location for the ball of

the snap. For example the peg hole may be 5 mm, while the mushroom cap head hole section diameter may be 7 mm. Other sizes may be appropriate for the peg hole such as about 1 mm, about 2 mm, about 3 mm, about 4 mm, about 5 mm, about 6 mm, about 7 mm, about 8 mm. Other sizes may be appropriate for the mushroom cap head hole section, such as about 2 mm, about 3 mm, about 4 mm, about 5 mm, about 6 mm, about 7 mm, about 8 mm, and about 9 mm. A hydrophilic polymer of the snap may then swell and hold the implant into place.

Other variations of fixing an implant to a bone may be known to one of skill in the art, and may include (but is not limited to) cross pins such as those used for ACL graft fixation, whip stitches with newer strong sutures as Ortho-Cord, or combinations of the above or others noted herein.

It should also be recalled that whereas the usual location of implants is over the major surface of a joint, the minor surfaces of joints may be selected optionally or additionally for coverage by an implant depending on the clinical need. In another iteration for fixation, magnets inside pegs or protuberances can allow for size adjustment internally or externally so as to engage a locking mechanism of implant to bone end.

In-Growth Features

In addition to the general in-growth that may occur based on the implant features described herein, the implant undersurface (adjacent the femur) may comprise an in-growth matrix. In some embodiments, at least a portion of the implant adjacent to the femur comprises bone in-growth materials. Such an implant can be attached by a series of tabs with or without holes, using screws, rivets, stabilizers, staples, tacks, washers, pins, snaps, or Sutures and suture anchors, for non-limiting example. The polymer of the implant substitutes for periosteum when the implant comprises living chondrocytes (e.g. Carticel) as the in-growth matrix on a surface of the implant. The polymer of the implant substitutes for periosteum when the implant comprises living chondrocytes (e.g. Carticel) as the in-growth matrix within an implant embodiment configured to reveal and/or release said chondrocytes over time and/or upon implantation.

The bone in-growth undersurface may be used for long term fixation of the tabs or rim. That is, whereas it is important for the surgery to secure the implant to the joint surface in the most desirable corrective location, it is also important in some embodiments to prepare the anatomic undersurface of bone by abrading it, removing about 0.5 mm of cortical bone so as to expose the underlying oxygen, blood, and nutrients of the patient to the undersurface of the implant that can gradually become incorporated into the limb bone. As this healing occurs over the course of weeks and months to one year post operation, the localized tacking sites may become less relevant and potentially inert. Thus, in some embodiments, the implant may comprise a biodegradable (bioresorbable) polymer or other material. The couplers may additionally and/or alternatively be biodegradable or durable (non-bioabsorbable). Once the implant is in place, it may serve to at least one of: pad defects, cushion the joint, and restore the original damage to the joint components. The end goal is to apply minimally morbid treatment that may refurbish arthritic limb regions, leaving only the small skin scar and remote memory of the healed physical mishap.

Undersurface implant materials may involve used of the art and science from Artelon or Gore-Tex research, as each has advantages and limitations. Several implant options per joint damage area may be available to enjoy the primary surgeons manipulation to fit the clinically recovery requirements best.

In some embodiments the implant comprises an in-growth patch on at least one of the first portion configured to engage the femur, the second portion configured to engage the second bone (whether the tibia or the patella), the side portion, and the appendage. In some embodiments, tissue is removed to facilitate in-growth.

The walls of the implant embodying features of the invention may be composite structures. For example, the innermost layer may be impervious to preclude escape of inflation or other filling media, a central layer may be porous or otherwise contain treatment or cell regeneration agents, and the outer layer may be a thin, but strong layer of a thermoplastic, such as a thermoplastic polyurethane for non-limiting example, which has microporosity sufficient to allow passage or egress of treatment or cell regeneration agents from the central layer (or second layer). The degree of microporosity to enable egress of treatment or cell regeneration agents from the central layer is found in polymer layers such as Chronoflex (e.g., ChronoFlexAR®, ChronoFlex AL®, ChronoFlec C®) or BIONATE (e.g., BIONATE I, BIONATE II, BIONATE 55D, BIONATE 65D, BIONATE 75D, BIONATE 80A, BIONATE 90A, BIONATE 55 or BIONATE 80). The external wall (and/or the bone engaging surface) of the implant may be coated and/or impregnated with a latticework of polymer that is surface sprayed or layered on the outside (or bone engaging surface) of the implant to promote cartilage tissue regeneration. This most external surface coating may contain living chondrocytes (for example, as is provided in the Carticel procedure by the Genzyme company), and/or may contain stem cells with or without directed gene mutations to enhance adherence of the coating to the implant. The bone engaging surface may comprise peaks and troughs. The living cells may be imposed in between (and/or provided in the) troughs of the implant surface while the surface areas of prominence (the peaks of the surface) may be used for at least one of: space validation, traction, and cell protection.

The implant embodying features of the invention may be used in a series of treatments wherein the first treatment involves use of autologous or minimally manipulated allograph interpositional tissues or xenograph, the second treatment involves the use of the same type of tissue added to stem cells or chondrocytes and the third treatment involving deployment of the implant if the first two fail or are ineffective.

The implant may comprise materials which allow for bone in-growth following implantation. In-growth may be facilitated by having interstices (or chambers) in the implant or in the fixation elements which are in the range of at least one of: about 10 microns to about 2000 microns, about 50 microns to about 1000 microns, about 100 microns to about 500 microns, about 300 microns to about 500 microns 10 microns to 2000 microns, 50 microns to 1000 microns, 100 microns to 500 microns, and 300 microns to 500 microns. In some embodiments, the chambers are sized to mimic the latticework of trabecular bone. In some embodiments, the chambers are formed by forming the implant using beads of the sizes noted above (e.g. 300 microns to 500 microns) and thereafter dissolving or otherwise breaking the beads such that interstices are left in the implant of the size of the beads. In an alternative, the beads may comprise a pharmacologic or other active agent which is absorbed or used by the body once implanted, and over time the interstices left by the beads (now gone due to absorption or use by the body)

promote in-growth. Various methods known to one of skill in the art may be used to prepare the implant surface toward maximally effective union to bone.

Pharmacologics and Therapeutic Agents & Delivery Thereof to Various Locations

In some embodiments the implant may comprise vacuoles of pharmacologic substances. The vacuoles may be on a bone-engaging portion of the implant. In some embodiments, the implant comprises bubbles comprising an active substance such as a pharmacologic substance or other active substance. In some embodiments, the implant comprises spaces filled with an active substance such as a pharmacologic substance (pharmacologic agent) or other active substance (active agent). In some embodiments, the active substance comprises iatrogenically gene mutated cells. In some embodiments, the implant may be inserted into the vacated space following removal of an infected routine total joint replacement. Current treatment of infected prostheses range from IV antibiosis, through arthroscopic washout to single or two stage replantations. With the worst infection the joint is often debrided of the prosthetic components and old cement, and then filled with new bone cement that is impregnated with antibiotics, leaving the hardened materials in place 6-12 months. During this interval 6-12 weeks IV antibiotics are typically used. In this situation if implants as noted herein were inserted with a calculated egress of antibiotics from the polymer container, both increased concentration of local antibiotics and decreased systemic side effects can benefit the patient. Further, since the polymer is both robust and compliant, use of the infected joint being treated is more realistic and comfortable, with a "bag of antibiotics and air" as opposed to a "chunk of cement."

Similar use of implants as noted herein for localized resected bone or soft tissue tumors may allow for drug delivery. Substances that can be delivered via implants noted herein are limitless, though may include (for non-limiting example) antibiotics, anti-fungal and Tb agents, anti-gout, anti-rheumatoid, and anti-tumor. Implants in certain embodiments may specifically elute contents via one or more portals from the primary chamber, and/or from a material liner of the implant. Implants in certain embodiments may specifically elute contents via the multiple chambers (in the 1 micron to 1 mm size) which are filled with the active and/or pharmacologic agent. Alternatively, the implant may have a port to an external source (outside the body or outside the space where the implant has been placed) of therapeutic agent which then may be delivered by elution or other manner from the implant itself. Stem cells such as living chondrocytes can be disbursed immediately and/or over time for regenerative purposes to regrow joint surface cartilage. Polymer layers of the implant material, in certain embodiments, may or may not be biodegradable. Disease fighting orthobiologics, both living and laboratory, can be dispensed via the implants.

Active agent delivery with implants as noted herein may be from their reservoirs wherein the agent is encapsulated in a polymer shell. Optionally matrices with entrapped polymer can elute active agents from the network, and/or the matrix can dissolve as a planned rate.

Still other iterations are contemplated. The implant may comprise micelles can be nano-sized hydrophilic shells that make up an implant layer that protects a core agent. Cell specific targeting drugs design to attach particular molecules may be delivered via implants noted herein as from a vesicle elution or matrix diffusion. For example, Gleevac targeting a GIST tumor molecule may specific address a clinical cancerous problem. Doxorubicine, a hydrophyobic anticancer agent at be emitted via polymer deliver from either a solid or inflated material interface between joint surfaces and/or from a ballooning aspect of that interpositional arthroplasty. Membranes (or walls) of the implants can be of singular or multiple layers with various relationships to each proximate layer so as to absorb or exude drugs using electroactive polymers through controlled transport(dopants) in and out of membranes. Hydrogels can be tailored to swell releasing entrapped molecules/cells through weblike matrices of the implant. Triggers from release of substances from certain embodiments of the implant can be internal or external, involving chemical factors such as pH, electromagnetic factors as magnetic fields, temperature variables as when 37 degrees body temperature induces an additional 30% pliability to the polymer wall, or ultrasonic release of vacuole content. Calculated mechanical vacuole wall thickness in relation to predictable acute, subacute or chronic intra-articular joint forces invoked by movement and limb use can release internal substances abruptly and/or over time.

Dendritic Macromolecules may deliver agent en masse from certain embodiments of the implant. The delivery in such situations may be via controllable size and structure, and may incorporate individual agent molecules or "hubs" via covalent bonds. Any combination of the nanoscopic developments can be created or assembled into the implants described herein and can be distributed, or oozed, or leaked, or expulsed from, or absorbed into as cleansing a noxious environment, or any combination thereof. Combined alternating forces such as materials that suck up or absorb noxious leukokynins or cathepsins while released useful viscolubricants such as Synvisc, Hyalgan or Orthovisc can be constructed to accommodate clinical need consistent with physical joint damage mandates or aligned with and consider of the natural history of disease processes so as to maximize either ones anticipated inevitable chronic deterioration or to thwart the adverse affects delaying degradation from arthritic or pathophysiologic processes.

Patient Symptoms

Symptoms for the patient requiring an implant described herein may include, for non-limiting example, osteoarthritis or rheumatoid or gouty arthritis.

Total Knee Arthroplasty (Dual Compartment):

Provided herein is an implant for placement on both condyles (medial and lateral) of the distal femur. In some embodiments, this is called a dual compartment implant since it covers both condyles of the femur. Such an implant comprises at least one interior (or inflatable chamber), and in some embodiments comprises a plurality of inflatable chambers (or interiors).

In some embodiments, the implant covers the "H" distal femoral cartilage segment (made up of both femoral condyles and the trochlear groove in between). The implant may absorb diffuse force, endure the millions of annual cyclic loads of both knee joints (including the patella-femur joint and the femur-tibia joints), along with rotational and shear forces up to six times body weight, at least.

In some embodiments, the implant comprises attachment tabs or attachment elements over the sides of both condyles medially and laterally. In some embodiments, the implant comprises attachment tabs or attachment elements in the intercondylar notch (or slot). In some embodiments, the implant comprises attachment tabs or attachment elements superiorly at the distal end of the femur anteriorly. In some embodiments, posterior reigns or suture-like lanyards cinch up the implant from inside the posterior intercondylar notch toward another connection site around the femur.

The posterior of the knee can be difficult to access without disturbing joint components (or in order to minimize such disturbance) such as tendons, ligaments, etc. Thus, in some embodiments, the implant comprises strings, reigns, lassos, and/or lanyards that may pass from the posterior of the implant via the intercondylar notch anteriorly to join with themselves and/or other coupling devices. These couplers may be pre-coupled to the implant, and the implant and its couplers may be configured to be pulled (or cinched) from the anterior of the implant once the implant is in its general location relative to the condyle in order to finally position the implant about the condyle—in particular in order to cinch the implant about the posterior of the condyle. Likewise, in some embodiments where the implant is pre-molded, the coupler as described are adapted to move the implant to its final position with conformity to the condyle's posterior with minimal disturbance to the joint structures at the joint's posterior (minimal cutting, minimal moving, and or minimal detachment, for non-limiting example). In some embodiments at least a portion of the ligamentary structure of the knee is spared.

Although this description focuses on the distal femur as it articulates with the retropatellar and proximal tibial cartilages implants as described generally herein may be also and/or alternatively be used in conjunction with the tibia and/or the patella. Furthermore, separate and/or connected implant components may be inserted to restore natural function to the knee. In some embodiments whereas the implant caps the major joint surface and opposes remnant cartilage, the surgeon may elect to place the implant so that it opposes metal, polymer, or another surface reconstructive material.

Coupling devices to be used as part of the dual compartment implant may include any of those mentioned or described herein, for example. Such coupling devices may comprise at least one of strings (i.e. drawstrings), reigns, lassos, sutures, and lanyards. The strings, reigns, lassos, sutures, and/or lanyards may join with themselves and/or other coupling devices. The strings, reigns, lassos, sutures and/or lanyards may be directed not only into bone with or without anchors, but also through ligaments, tendons or loose segments of cartilage that the surgeon intends to preserve.

FIG. **1** depicts an embodiment of the implant **20** in a 2D view configured for dual condyle (distal femur) coverage. FIG. **1** depicts an embodiment of the knee implant **20** having appendages **4***a*, **4***b*, **4***c*, **4***d*, including holes **8***a*, **8***b*, **8***c*, **8***d* and tabs **10***a*, **10***b* extending from a balloon **6** and including slots **26***a*, **26***b* to accommodate ligaments (not shown) of the knee joint. Couplers as described elsewhere herein may be used to couple the implant **20** to the distal femur. In some embodiments, there may only tabs, only holes, or only appendages, or combinations thereof. In some embodiments, there may be other ways to couple the implant to the distal femur, as described elsewhere herein (sutures, drawstrings, skirts, glue, etc). In some embodiments, the tabs **10***a*, **10***b* contain holes. In some embodiments, the couplers create the holes **8***a*, **8***b*, **8***c*, **8***d*, or other holes (not shown) when the implant is placed against the distal femur **24**. In some embodiments, the holes are pre-formed in the appendage prior to implantation. In some embodiments, the holes are reinforced as described elsewhere herein. In some embodiments, the holes are within the peripheral rim of the knee implant. In some embodiments, the holes are within the region of the intercondylar notch medially and/or laterally. In some embodiments, the holes are through the polymer. In some embodiments, the holes are through a reinforced rim. As shown here, the appendages in some embodiments may be different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage **4***d* that is intended to wrap over the medial condyle may be longer and/or wider than the appendage **4***c* intended to wrap over the lateral condyle. Likewise, the slots may be different in shape and/or size and/or position to accommodate the ligaments and/or tendons of the joint or other structures and functions of the joints of the knee, and to allow for placement of the implant with minimal disturbance (cutting, manipulation, for example) of the joint components such as tendons, ligaments, and other soft or hard tissues. For example, slot **26***a* is shaped and positioned to accommodate the cruciate ligaments of the knee, at least. In some embodiments, the implant as shown in FIG. **1** can have regions **4***a*, **4***b*, **4***c*, **4***d* where no inflation exists and may be composed of solid or compliant materials. In some embodiments, the implant comprises a Dyneema® mesh. The implant may comprise Dyneema® fiber. In some instances, the implant comprises Dyneema Purity® fiber. In some embodiments, the implant comprises a Dyneema Purity® UG fiber. In some embodiments, the implant comprises a Dyneema Purity® VG fiber. The implant may comprise a fiber. The implant may comprise a polyethylene. The implant may comprise a polyethylene fiber.

FIG. **2** depicts an embodiment of the knee implant **20** having appendages **4***a*, **4***b*, **4***c*, **4***d*, including holes **8***a*, **8***b*, **8***c*, **8***d* and tabs **10***a*, **10***b* extending from a balloon **6** and including slots **26***a*, **26***b* to accommodate ligaments of the knee joint as well as side views of the same knee implant. Couplers as described elsewhere herein may be used to couple the implant **20** to the distal femur. In some embodiments, there may only tabs, only holes, or only appendages, or combinations thereof. In some embodiments, there may be other ways to couple the implant to the distal femur, as described elsewhere herein (sutures, drawstrings, skirts, glue, etc). In some embodiments, the couplers create the holes **8***a*, **8***b*, **8***c*, **8***d*, or other holes (not shown) when the implant is placed against the distal femur. In some embodiments, the holes are pre-formed in the appendage prior to implantation. In some embodiments, the holes are reinforced as described elsewhere herein. As shown here, the appendages in some embodiments are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage **4***d* that is intended to wrap over the medial condyle may be longer and/or wider than the appendage **4***c* intended to wrap over the lateral condyle. Shown in the embodiment depicted in FIG. **2** are the different hole placements from the side view, showing the differences in positioning of the holes to accommodate the differences in anatomic structure and size of the condyles. Likewise, the slots may be different in shape and/or size and/or position to accommodate the ligaments and/or tendons of the joint or other structures and functions of the joints of the knee, and to allow for placement of the implant with minimal disturbance (cutting, manipulation, for example) of the joint components such as tendons, ligaments, and other soft or hard tissues. For example, slot **26***a* is shaped and positioned to accommodate the cruciate ligaments of the knee, at least. Additionally, as shown in the side views of the embodiment shown in FIG. **2**, the balloon has a first wall **28** adapted to be adjacent the femur that is of a greater thickness than the second wall **30**. In some embodiments, the first wall **28** is configured to have therapeutic benefits (pharmacologic, healing, and/or in-growth proper-

ties) as described elsewhere herein. The second wall **30** may additionally and/or alternatively be configured to have a therapeutic effect (pharmacologic, healing, and/or in-growth properties).

Nevertheless, differing thicknesses of the first wall **28** and the second wall **30** are not necessarily required in order to impart the therapeutic benefits (pharmacologic, healing, and/or in-growth) described elsewhere herein. For example, FIG. **3** depicts an embodiment of the knee implant **20** having appendages **4***a*, **4***b*, **4***c*, **4***d*, including holes **8***a*, **8***b*, **8***c*, **8***d* and tabs **10***a*, **10***b* extending from a balloon **6** and including slots **26***a*, **26***b* to accommodate ligaments of the knee joint as well as side views of the same knee implant. Couplers as described elsewhere herein may be used to couple the implant **20** to the distal femur. In some embodiments, there may only tabs, only holes, or only appendages, or combinations thereof. In some embodiments, there may be other ways to couple the implant to the distal femur, as described elsewhere herein (sutures, drawstrings, skirts, glue, etc). In some embodiments, the couplers create the holes **8***a*, **8***b*, **8***c*, **8***d*, or other holes (not shown) when the implant is placed against the distal femur. In some embodiments, the holes are pre-formed in the appendage prior to implantation. In some embodiments, the holes are reinforced as described elsewhere herein. As shown here, the appendages in some embodiments are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage **4***d* that is intended to wrap over the medial condyle may be longer and/or wider than the appendage **4***c* intended to wrap over the lateral condyle. Shown in the embodiment depicted in FIG. **3** are the different hole placements from the side view, showing the differences in positioning of the holes to accommodate the differences in anatomic structure and size of the condyles. Likewise, the slots may be different in shape and/or size and/or position to accommodate the ligaments and/or tendons of the joint or other structures and functions of the joints of the knee, and to allow for placement of the implant with minimal disturbance (cutting, manipulation, for example) of the joint components such as tendons, ligaments, and other soft or hard tissues. For example, slot **26***a* is shaped and positioned to accommodate the cruciate ligaments of the knee, at least. Additionally, as shown in the side views of the embodiment shown in FIG. **3**, the balloon has a first wall **28** adapted to be adjacent the femur that is of approximately the same thickness than the second wall **30**. In some embodiments, the first wall **28** is configured to have therapeutic benefits (pharmacologic, healing, and/or in-growth properties) as described elsewhere herein. The second wall **30** may additionally and/or alternatively be configured to have a therapeutic effect (pharmacologic, healing, and/or in-growth properties). The balloon **6** may be singular as depicted, or in certain embodiments, include a plurality of microscopic vesicular structures.

FIG. **4**A depicts an embodiment of the knee implant **20** having appendages **4***a*-**4***d* including ten tabs **10***a*-**10***j* extending from a balloon **6** and including a slot **26***a* to accommodate components (such as ligaments or other tissues whether soft tissues, hard tissues, tendons, and/or others) of the knee joint (not shown). The tabs **10***a*-**10***j* are not shown with holes in this embodiment, however if screws are used as couplers, such holes may be pre-drilled or formed in situ by the screws. Additionally and/or alternatively, staples, washers, pins, snaps, or sutures may be used (as described elsewhere herein) in order to couple the implant to the bone (femur, for example). Other couplers as described elsewhere herein may also and/or alternatively be used in this coupling process. Furthermore, the number of tabs may be fewer or greater than the ten depicted in order to achieve optimal placement and coupling to the bone. For example, FIG. **4**B depicts an embodiment of the knee implant **20** having appendages **4***a*-**4***d* including eight tabs **10***a*-**10***h* extending from a balloon **6** and including a slot **26***a* to accommodate components (such as ligaments or other tissues whether soft tissues, hard tissues, tendons, and/or others) of the knee joint (not shown). In certain embodiments, the implant comprises 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, or 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, and/or 20 tabs. The tabs may be located on either side of the condyles, including the superior, mid, and posterior portions. Any tab may be also and/or alternatively located inside the medial and intercondylar notch.

FIG. **5** depicts an embodiment of the knee implant **32** curved to simulate curvature about the condyles of a femur, the implant having appendages **4***a*-**4***d* extending from an uninflated balloon (not shown) and including slots **26***a*, **26***b* to accommodate components (such as ligaments or other tissues whether soft tissues, hard tissues, tendons, and/or others) of the knee joint (not shown). This figure also shows an implant comprising a solid compliant material, having no balloon whatsoever. The implant may comprise additional curvatures and/or slots to accommodate other ligaments and/or tissues. In some embodiments, the implant is configured to conform about various hard and/or soft tissues of the joint, such as bone, ligaments, tendons, etc. In some embodiments, the balloon is inflated once the implant is positioned within the joint. In other embodiments, the balloon is partially inflated prior to being positioned within the joint. In other embodiments, the balloon is at least partially inflated prior to being positioned within the joint. In some embodiments, the balloon is fully inflated prior to being positioned within the joint. In some embodiments, the implant is configured to allow an operator to adjust the amount of balloon inflation in situ (whether by adding inflation medium or removing inflation medium, or both, or neither). Couplers as described elsewhere herein may be used to couple the implant **32** to the distal femur.

FIG. **6**A depicts a top-down view of an embodiment of the knee implant **32** curved to simulate curvature about the condyles of a femur, the implant having appendages **4***a*-**4***d* extending from two inflated balloons **6**, **34** and including a slot **26***a* to accommodate components of the knee joint. FIG. **6**B depicts a bottom-up or anterior oblique view of the same embodiment of the knee implant **32** curved to simulate curvature about the condyles of a femur, the implant having appendages **4***a*-**4***d* extending from two inflated balloons **6**, **32** and including a slot **26***a* to accommodate components of the knee joint. Couplers as described elsewhere herein may be used to couple the implant **32** to the distal femur. As shown in FIGS. **6**A and **6**B, the appendages **4***a*-**4***d* in some embodiments are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage **4***d* that is intended to wrap over the medial condyle may be longer and/or wider than the appendage **4***c* intended to wrap over the lateral condyle. Likewise, the dimensions of the balloon **34** that is adapted for placement over the medial condyle may be a different shape and/or size than the balloon **6** over the lateral condyle (the medial condyle being larger, thus the balloon **34** may be larger for that location) Alternatively and/or additionally, as described elsewhere herein, for various reasons such as injury, realignment needs, injury, etc, there may be a need for more reconstruction of one condyle than

needed for the other, thus the inflation medium might be different in one balloon (or a portion thereof) than in the other balloon (or another chamber within the same balloon), or there may be need for a different shaped balloon in one location than in another location. Embodiments provided herein can accommodate these requirements based on materials of fillers, appendages, balloons, walls, and dimensions and chamber options of the implant and its components.

FIG. **7** depicts a top-down view of an embodiment of the knee implant **32** curved to simulate curvature about the condyles of a femur, the implant having appendages **4***a*-**4***d* extending from an inflated balloon **6** and including slots to accommodate components of the knee joint. Couplers as described elsewhere herein may be used to couple the implant **32** to the distal femur. As shown here, the appendages **4***a*-**4***d* in some embodiments are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage **4***d* that is intended to wrap over the medial condyle may be longer and/or wider than the appendage **4***c* intended to wrap over the lateral condyle. Likewise, the dimensions of the portion of the balloon that is adapted for placement over the medial condyle may be a different shape and/or size than the portion of the balloon over the lateral condyle (the medial condyle being larger, thus the balloon may be larger for that location) Alternatively and/or additionally, as described elsewhere herein, for various reasons such as injury, realignment needs, injury, etc, there may be a need for more reconstruction of one condyle than needed for the other, thus the inflation medium might be different in a portion or chamber of an implant embodiment having a plurality of inflation chambers in a single balloon, or there may be need for a non-symmetric balloon. Embodiments provided herein can accommodate these requirements based on materials of fillers, appendages, balloons, walls, and dimensions and chamber options of the implant and its components.

FIG. **8** depicts a side view of an embodiment of the knee implant **32** curved to simulate curvature about at least one condyle of a femur, the implant having appendages **4***b*, **4***d* extending from an uninflated balloon (not shown). This depiction covers the maximum anticipated distal femoral contour; other iterations may be smaller, or shorter covering limited areas of the circumference of the femoral curvatures. This figure also provides a lateral view for a solid implant (without a chamber therein) wherein the material thickness and/or layering provide cushioning.

FIG. **9**A depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4***b*, **4***d* extending from an uninflated or minimally inflated balloon **6**. In this view, the knee is positioned essentially in extension (straight), showing the tibia **36**, fibula **38**, and patella **40** of the knee. Note that although there would be other joint structures and knee structures in a true depiction of an implant positioned in the knee, this view of the implant and bones is greatly simplified for ease of understanding of the implant and the joint relative (and approximate) positions and placement. Couplers as described elsewhere herein may be used to couple the implant **20** to the distal femur **24** and/or the condyle **22** thereof (in this image the medial condyle, at least since it is primarily a one-side view of the joint and implant). For the sake of simplicity FIG. **9**A and the implant embodiment depicted show of the femur with opposition to the other surfaces of both knee joints (between femur and tibia, and femur and patella), the areas of contact varying according to activity, forces, and range of motion. Other implant iterations may apply to opposing surfaces.

FIG. **9**B depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4***b*, **4***d* extending from an inflated balloon **6**. In this view, the knee is positioned essentially in extension (straight), showing the tibia **36**, fibula **38**, and patella **40** of the knee. Note that although there would be other joint structures and knee structures in a true depiction of an implant positioned in the knee, this view of the implant and bones is greatly simplified for ease of understanding of the implant and the joint relative (and approximate) positions and placement. Couplers as described elsewhere herein may be used to couple the implant **20** to the distal femur **24** and/or the condyle **22** thereof (in this image the medial condyle, at least since it is primarily a one-side view of the joint and implant). In FIG. **9**B wherein the balloon is inflated, as compared to FIG. **9**A wherein the balloon is not inflated or is minimally inflated, the balloon second wall **30** is closer to and/or contacting the tibial plateau **42** (articular surface) when the balloon **6** is inflated. Likewise, FIG. **9**C depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4***b*, **4***d* extending from an inflated balloon **6** and having couplers **44***a*, **44***b* (which may be, for non-limiting example, staples or screws, pins, or snaps) coupling the appendages **4***b*, **4***d* to the femur. In this view, the knee is positioned essentially in extension (straight), showing the tibia **36**, fibula **38**, and patella **40** of the knee. Where the inflated balloon as seen in FIG. **9**B may fill in existing pathologic defects of the joint surface, the medium of inflated and specific balloon location and durometry with the material of the implant may also be constructed so as to force the bones opposed, e.g. the femur and tibia, into a more natural limb alignment such as six (6) degrees valgus. However, if the patient being treated has variations from normal in the affected knee as illustrated by examining and measuring the opposite normal side, then the implant inflation and pressures or balloon location may be adjusted from the population norms thus customizing this implant to the clinical case under consideration. Fixation devices may be appropriately applied at various knee range of motion intervals from full extension (zero degrees) to full flexion (usually 135 degrees) as the knee is adjusted and the implant secured under anesthesia.

FIG. **10**A depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4***b*, **4***d* extending from an inflated balloon **6** and showing the inflation medium **46** moved anteriorly toward the patella **40** when the knee joint is slightly flexed. The dynamic nature of the implant material and/or content may be responsive to body forces as a physiological rather than rigid structure. The filling of space inside the joint may add stability to the patient and to the joint. Likewise, FIG. **10**B depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4***b*, **4***d* extending from an inflated balloon **6** and having couplers **44***a*, **44***b* (which may be, for non-limiting example, staples or screws, pins or snaps) coupling the appendages **4***b*, **4***d* to the femur **24** and showing the inflation medium **46** moved anteriorly toward the patella **40** when the knee joint is slightly flexed.

For example, FIG. **14** depicts an embodiment of the knee implant **20** having appendages **4***a*, **4***b*, **4***c*, **4***d*, including holes **8***a*, **8***b*, **8***c*, **8***d* and tabs **10***a*, **10***b* and including slots

26*a*, **26***b* to accommodate ligaments of the knee joint as well as side views of the same knee implant. Couplers as described elsewhere herein may be used to couple the implant **20** to the distal femur. In some embodiments, there may only tabs, only holes, or only appendages, or combinations thereof. In some embodiments, there may be other ways to couple the implant to the distal femur, as described elsewhere herein (sutures, drawstrings, skirts, glue, etc). In some embodiments, the couplers create the holes **8***a*, **8***b*, **8***c*, **8***d*, or other holes (not shown) when the implant is placed against the distal femur. In some embodiments, the holes are pre-formed in the appendage prior to implantation. In some embodiments, the holes are reinforced as described elsewhere herein. As shown here, the appendages in some embodiments are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage **4***d* that is intended to wrap over the medial condyle may be longer and/or wider than the appendage **4***c* intended to wrap over the lateral condyle. Shown in the embodiment depicted in FIG. **14** are the different hole placements from the side view, showing the differences in positioning of the holes to accommodate the differences in anatomic structure and size of the condyles. Likewise, the slots may be different in shape and/or size and/or position to accommodate the ligaments and/or tendons of the joint or other structures and functions of the joints of the knee, and to allow for placement of the implant with minimal disturbance (cutting, manipulation, for example) of the joint components such as tendons, ligaments, and other soft or hard tissues. For example, slot **26***a* is shaped and positioned to accommodate the cruciate ligaments of the knee, at least. Additionally, as shown in the side views of the embodiment shown in FIG. **14**, the implant has a first wall **28** adapted to be adjacent the femur that is of approximately the same thickness than the second wall **30**. In some embodiments, the first wall **28** is configured to have therapeutic benefits (pharmacologic, healing, and/or in-growth properties) as described elsewhere herein. The second wall **30** may additionally and/or alternatively be configured to have a therapeutic effect (pharmacologic, healing, and/or in-growth properties). Additionally, the thickness of the implant in certain locations is variable to add cushioning to the implant as well as to provide joint spacing. In certain embodiments, the material is not variable in thickness, but provides the same cushioning and/or joint spacing for the bones of the joint. The central region in the embodiment of FIG. **14** is thicker material to add at least one of: cushioning, buffering, joint space, restore cushioning, and to respond to clinical need.

Any of the balloons described herein with regard to any of the figures may add cushioning, padding, strength, durability, flexibility, or any other aspect noted herein, and need not be a chamber per se, nor be inflatable per se. Rather they are merely distinguishable in certain embodiments from the walls which are on either side of them in composition or function or both. In some embodiments, the balloon and its interior is not materially different in composition or function from one of the walls. In some embodiments, they are not materially different in composition or function from either of the walls.

FIGS. **15**A, **15**B, and **15**C show several views of an embodiment of an implant which has no definable chamber, rather the material of the implant itself provides the cushion to the bones of the joint (at least). The implant in **15**A, **15**B, and **15**C is generally H or V-shaped, having a slot **26***b* that is significantly smaller than as shown other embodiments (for example FIGS. **3**, **4**, **5**, **6**A, **6**B, **7**, **14**). In certain embodiments, an implant shaped generally like FIGS. **15**A, **15**B, and **15***c* may comprise a chamber which, if the implant were shown in cross section, may comprise a different material than the wall of the implant itself, or may be the same material but with different geometric or chemical or physical properties, as noted herein. FIGS. **15**A, **15**B, and **15**C depict an embodiment of the knee implant **20** having appendages **4***a*, **4***b*, **4***c*, **4***d* and tabs **10***a*, **10***b*, **10***c*, **10***d*, **10***e*, **10***f*, **10***g*, **10***h* and including slots **26***a*, **26***b* to accommodate ligaments of the knee joint. Couplers as described elsewhere herein may be used to couple the implant **20** to the distal femur. In some embodiments, there may only tabs, only holes, or only appendages, or combinations thereof. In some embodiments, there may be other ways to couple the implant to the distal femur, as described elsewhere herein (sutures, drawstrings, skirts, glue, etc). In some embodiments, the couplers create holes (not shown) when the implant is placed against the distal femur. In some embodiments, the holes are pre-formed in the appendage prior to implantation. In some embodiments, the holes are reinforced as described elsewhere herein. As shown here, the appendages in some embodiments are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage **4***d* that is intended to wrap over the medial condyle may be longer and/or wider than the appendage **4***c* intended to wrap over the lateral condyle. The slots may be different in shape and/or size and/or position to accommodate the ligaments and/or tendons of the joint or other structures and functions of the joints of the knee, and to allow for placement of the implant with minimal disturbance (cutting, manipulation, for example) of the joint components such as tendons, ligaments, and other soft or hard tissues. For example, slot **26***a* is shaped and positioned to accommodate the cruciate ligaments of the knee, at least. The thickness of the implant in certain locations is variable to add cushioning to the implant as well as to provide joint spacing. In certain embodiments, the material is not variable in thickness, but provides the same cushioning and/or joint spacing for the bones of the joint.

FIG. **16** depicts a knee implant embodiment that is generally H or V-shaped, having a slot **26***b* that is significantly smaller than other embodiments, and in this embodiment is effectively replaced with a tab **10***i* at the same location (e.g. **10***i*). FIG. **16** depicts an embodiment of the knee implant **20** having appendages **4***a*, **4***b*, **4***c*, **4***d* and tabs **10***a*, **10***b*, **10***c*, **10***d*, **10***e*, **10***f*, **10***g*, **10***h*, **10***i* and including a slots **26***a* to accommodate ligament(s) of the knee joint. Couplers as described elsewhere herein may be used to couple the implant **20** to the distal femur. Contour lines **54***a*, **54***b*, for example, are also depicted in FIG. **16**, however these are not necessarily significant other than to show contour of parts of the implant **20**, although they may be in the case where a mesh is provided in the implant. In some embodiments, there may only tabs, only holes, or only appendages, or combinations thereof. In some embodiments, there may be other ways to couple the implant to the distal femur, as described elsewhere herein (sutures, drawstrings, skirts, glue, etc). In some embodiments, the couplers create holes (not shown) when the implant is placed against the distal femur. In some embodiments, the holes are pre-formed in the appendage prior to implantation. In some embodiments, the holes are reinforced as described elsewhere herein. As shown here, the appendages in some embodiments are different in shape and/or size to accommodate the

differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage **4***d* that is intended to wrap over the medial condyle may be longer and/or wider than the appendage **4***c* intended to wrap over the lateral condyle. The slot **26***a* may be different in shape and/or size and/or position to accommodate the ligaments and/or tendons of the joint or other structures and functions of the joints of the knee, and to allow for placement of the implant with minimal disturbance (cutting, manipulation, for example) of the joint components such as tendons, ligaments, and other soft or hard tissues. For example, slot **26***a* is shaped and positioned to accommodate the cruciate ligaments of the knee, at least. The thickness of the implant in certain locations is variable to add cushioning to the implant as well as to provide joint spacing. In certain embodiments, the material is not variable in thickness, but provides the same cushioning and/or joint spacing for the bones of the joint. In certain embodiments, an implant shaped generally like FIG. **16** may or may not comprise a chamber which, if the implant were shown in cross section, may comprise a several materials which may be the same as or different from any wall of the implant itself, or may be the same material but with different geometric or chemical or physical properties, as noted herein.

FIG. **17** depicts a knee implant embodiment similar to FIG. **16** which shows a posterior view including the location (s) **50***a*-**50***d* where a fill material such as cement may be placed. The fill material may be added in any one location **50***a*, **50***b*, **50***c*, or **50***d*, or added in several of locations **50***a*, **50***b*, **50***c*, and **50***d* or likewise be added anywhere on the first or second wall of the implant which contacts the first, second, and/or third bone. The fill material may be used to both cushion (as do balloons **6** in other figures) and/or secure the device to the bone in the case of a bone cement or a combination of these functions. In the case where the cement is used as the fill material, the cement may be used in an element that may or may not have any, some, or all of tabs **10***a*-**10***i*. The cushion, thus can act as a coupler (fixation element) and/or as a cushion and/or spacer for the joint bones. The cushion (whether a fill material such as cement or another material) may also be placed adjacent to a first wall or second wall, and not necessarily between said first wall and second wall.

FIG. **18** is an anterior-posterior view of an embodiment of the implant **20** attached to a knee model. The implant here comprises chambers **52***a*, **52***b*, **53***c*, at least (in this case, nano-inflated air pockets). Although sparsely shown in this embodiment, the frequency, size, etc. could be adapted to smaller chambers, larger chambers, more frequent chambers, more concentrated in particular areas of the implant, less concentrated in particular areas of the implant, or similarly adjusted. The chambers can be diffuse, of any size, containing compressible gas (air), cells, pharmacologics, liquids, beads, metals, or other materials as noted herein.

FIG. **19** depicts an implant **20** which is more squarely cut for interface with a femur, for example, which has been cut square such as is done in certain total knee arthroplasty procedures. The implant in this situation may comprise a polymer alone (of soft or hard durometer) and/or metal. The walls may be contiguous or include a chamber that is optionally filled or fillable as noted herein. Although tabs are shown in FIG. **19**, these are optional in embodiments where another attachment element (fixation element) is used such as cement or a metal pin or screw or snap through an appendage of the device.

FIGS. **20**A and **20**B depict a knee implant embodiment that is generally V-shaped or Y-shaped, and in this embodiment the slot **26***b* of other embodiments, or the tab **10***i* of other embodiments is effectively replaced with an appendage **4***e* at the same location. FIG. **20**A depicts an embodiment of the knee implant **20** having appendages **4***c*, **4***d*, and **4***e* and holes **8***a* (not shown, in FIG. **20**B), **8***b* (not shown, in FIG. **20**B), **8***c* (not shown, in FIG. **20**B), **8***d*, **8***e*, **8***f*, **8***g*, **8***h*, **8***i*, (not shown, substantially similarly positioned as **8***e* on the same edge as **8***a*-**8***c* of FIG. **20**A), **8***j* (not shown, substantially similarly positioned as **8***d* on the same edge as **8***a*-**8***c* of FIG. **20**A), and including a slot **26***a* to accommodate ligament(s) of the knee joint. Couplers as described elsewhere herein may be used to couple the implant **20** to the distal femur through slots **8***a*-**8***j*. Contour lines are also depicted in FIGS. **20**A and **20**B, however these are not necessarily significant other than to show contour of parts of the implant **20**, although they may be in the case where a mesh is provided in the implant. In some embodiments, there may only tabs, only holes, or only appendages, or combinations thereof. In some embodiments, there may be other ways to couple the implant to the distal femur, as described elsewhere herein (sutures, drawstrings, skirts, glue, etc). In some embodiments, the tabs comprise holes. In some embodiments, the couplers create holes (not shown) when the implant is placed against the distal femur. In some embodiments, the holes are within the peripheral rim of the knee implant. In some embodiments, the holes are within the region of the intercondylar notch medially and/or laterally. In some embodiments, the holes are through the polymer. In some embodiments, the holes are through a reinforced rim. In some embodiments, the holes are pre-formed in the appendage prior to implantation. In some embodiments, the holes are reinforced as described elsewhere herein. As shown here, the appendages in some embodiments are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage **4***d* that is intended to wrap over the medial condyle may be longer and/or wider than the appendage **4***c* intended to wrap over the lateral condyle. The slot **26***a* may be different in shape and/or size and/or position to accommodate the ligaments and/or tendons of the joint or other structures and functions of the joints of the knee, and to allow for placement of the implant with minimal disturbance (cutting, manipulation, for example) of the joint components such as tendons, ligaments, and other soft or hard tissues. For example, slot **26***a* is shaped and positioned to accommodate the cruciate ligaments of the knee, at least. The thickness of the implant in certain locations is variable to add cushioning to the implant as well as to provide joint spacing. In certain embodiments, the material is not variable in thickness, but provides the same cushioning and/or joint spacing for the bones of the joint. In certain embodiments, an implant shaped generally like FIG. **20**A or **20**B may or may not comprise a chamber which, if the implant were shown in cross section, may comprise a several materials which may be the same as or different from any wall of the implant itself, or may be the same material but with different geometric or chemical or physical properties, as noted herein. As shown in FIGS. **20**A and **20**B, thickness of between the first wall (part configured to touch the femur condyle) and the second wall (part configured to touch the tibia), is shown for example in the slot **26***a* (which may be called a notch herein), thus showing a side wall as described elsewhere herein to provide the thickness to the implant at the condyle(s). This thickness may be a result of a thickness

of a material of the implant (as in where the implant comprises a compliant polymer), or due to an inflation of a balloon that resides between the first wall and the second wall and the side wall. In some embodiments, the implant comprises a Dyneema® mesh. The implant may comprise Dyneema® fiber. In some instances, the implant comprises Dyneema Purity® fiber. In some embodiments, the implant comprises a Dyneema Purity® UG fiber. In some embodiments, the implant comprises a Dyneema Purity® VG fiber. The implant may comprise a fiber. The implant may comprise a polyethylene. The implant may comprise a polyethylene fiber.

In all descriptions provided herein of the dual compartment implant, the implant may instead be configured to couple to or emerge from the tibia and/or patella. In all descriptions provided herein of the dual compartment implant, the implant may instead be configured to couple to the tibia. It is the intention and understanding that the implant is suited for this purpose in certain embodiments with adjustments to account for dimensional differences of the tibia. Most descriptions provided herein are directed to embodiments coupling the implant to the femur, however, this is primarily for ease of description and continuity, and does not preclude embodiments wherein the implant is coupled to the tibia. Likewise, as noted elsewhere herein, there are embodiments where the implant may be coupled to two bones (at least), for example to both a tibia and a femur.

Patch

Some embodiments of the implant are configured to repair isolated lesions wherein osteochondral defects as in osteonecrosis create craters in the cartilage that need 'filling in' with a patch. Various size lesions of cartilage defects can be accommodated by the implants provided herein which may have balloons of at least one of: at most about 0.5 cm in diameter, at most about 0.75 cm in diameter, at most about 1 cm in diameter, at most about 1.25 cm in diameter, at most about 1.5 cm in diameter, at most about 1.75 cm in diameter, at most about 2 cm in diameter, at most about 2.25 cm in diameter, at most about 2.5 cm in diameter, at most about 2.75 cm in diameter, at most about 3 cm in diameter, at most about 3.25 cm in diameter, at most about 3.5 cm in diameter, at most about 3.75 cm in diameter, at most about 0.5 cm in length along the longest length of the balloon, at most about 0.75 cm in length along the longest length of the balloon, at most about 1 cm in length along the longest length of the balloon, at most about 1.25 cm in length along the longest length of the balloon, at most about 1.5 cm in length along the longest length of the balloon, at most about 1.75 cm in length along the longest length of the balloon, at most about 2 cm in length along the longest length of the balloon, at most about 2.25 cm in length along the longest length of the balloon, at most about 2.5 cm in length along the longest length of the balloon, at most about 2.75 cm in length along the longest length of the balloon, at most about 3 cm in length along the longest length of the balloon, at most about 3.25 cm in length along the longest length of the balloon, at most about 3.5 cm in length along the longest length of the balloon, at most about 3.75 cm in length along the longest length of the balloon, at most about 4 cm in length along the longest length of the balloon, at most about 4.25 cm in diameter, at most about 4.5 cm in diameter, at most about 4.75 cm in diameter, at most about 5 cm in diameter, at most about 5.25 cm in diameter, at most about 5.5 cm in diameter, at most about 5.75 cm in diameter, at most about 6 cm in diameter, at most about 6.25 cm in diameter, at most about 6.5 cm in diameter, at most about 6.75 cm in diameter, at most about 7 cm in diameter, at most about 7.25 cm in diameter, at most about 7.5 cm in diameter, at most about 7.75 cm in diameter, at most about 8 cm in diameter, at most about 3 cm in length along the longest length of the balloon, at most about 3.25 cm in length along the longest length of the balloon, at most about 3.5 cm in length along the longest length of the balloon, at most about 3.75 cm in length along the longest length of the balloon, at most about 4 cm in length along the longest length of the balloon, at most about 4.25 cm in length along the longest length of the balloon, at most about 4.5 cm in length along the longest length of the balloon, at most about 4.75 cm in length along the longest length of the balloon, at most about 5 cm in length along the longest length of the balloon, at most about 5.25 cm in length along the longest length of the balloon, at most about 5.5 cm in length along the longest length of the balloon, at most about 5.75 cm in length along the longest length of the balloon, at most about 6 cm in length along the longest length of the balloon, 6.25 cm in length along the longest length of the balloon, at most about 6.5 cm in length along the longest length of the balloon, at most about 6.75 cm in length along the longest length of the balloon, at most about 7 cm in length along the longest length of the balloon, at most about 7.25 cm in length along the longest length of the balloon, at most about 7.5 cm in length along the longest length of the balloon, at most about 7.75 cm in length along the longest length of the balloon, and at most about 8 cm in length along the longest length of the balloon. As used herein with respect to balloon dimensions whether length or diameter, the term "about" means variations of at least one of 0.1 cm, 0.2 cm, 0.25 cm, 0.5 cm, and 1 cm.

Thus, provided herein is an implant configured to patch osteochondral defects. The defects may occur due to injury, stress, naturally occurring, and/or may created or enhanced by a medical professional during a medical procedure. In some embodiments, the implant may be called a patch having the balloon and an attachment element (or elements—which may be called appendages) described herein and may be sized to fit within a defect in a manhole-cover type manner. In some embodiments, the implant may comprise balloon and attachment elements described elsewhere herein and may be configured to lay over a defect (full defect or partial defect). In some embodiments the implant as described herein as used to patch or repair osteochondral defects may be called a patch or a patch implant.

In some embodiments, the size of the balloon dimensions are prechosen based on the individual patient need, and the balloon size (dimensions, geometry, length, depth, for non-limiting examples) is pre-set. In some embodiments, the balloon comprises multiple chambers which may be inflated (or deflated) selectively to fill the defect in situ or just prior to implantation in order to adjust the implant's balloon size (dimensions, length, width, depth, geometry, for non-limiting example) as needed at the time of implantation. The balloon (or any chamber thereof) of some embodiments can be secondarily inflated or deflated (or both) in situ.

FIGS. **11**A, **11**B, and/or **11**C may be used to describe a patch implant described herein, having appendages **4***a*, **4***c*, extending from a balloon **6** (not shown in FIG. **11**A) and including holes **8***a*-**8***h*, and/or tabs **10***a*-**10***f* which may be used with couplers (not shown) to couple the implant to a bone of the knee joint (which may be the femur, the tibia, or the patella). Features shown in FIGS. **11**A, **11**B, and/or **11**C are common to both the unicompartment knee implant (discussed elsewhere herein) and the patch implant, although dimensions may differ as described herein. Thus, FIGS. **11**A, **11**B, and/or **11**C may be used to describe the unicompartment knee implant and/or the patch implant. FIG.

11A depicts an embodiment of the patch implant **2** curved to simulate curvature about one condyle of a femur, the implant **2** having appendages **4***a*, **4***c*, extending from an uninflated balloon (not shown) and including tabs **10***a*-**10***f* and/or holes **8***a*-**8***h*, which may be used with couplers (not shown, described elsewhere herein) to couple the implant **2** to the femur of the knee joint. FIG. **11**B depicts an embodiment of the patch implant **2** curved to simulate curvature about one condyle of a femur, the implant **2** having appendages **4***a*, **4***c*, extending from an inflated balloon **6** and including tabs **10***a*-**10***f* and/or holes **8***a*-**8***h*, which may be used with couplers (not shown, described elsewhere herein) to couple the implant **2** to the femur of the knee joint. FIGS. **11**A and **11**B show the appearance of a compliant solid material for unicompartmental implantation. FIG. **11**C depicts a bottom-up of gliding surface view of an embodiment of the patch implant **2** curved to simulate curvature about one condyle of a femur, the implant **2** having appendages **4***a*, **4***c*, extending from an inflated balloon **6** or a padded central area of the implant and including tabs **10***a*-**10***f* and/or holes **8***a*-**8***h*, which may be used with couplers (not shown, described elsewhere herein) to couple the implant **2** to the femur of the knee joint. In some embodiments, the implant is configured to couple to a tibia. In some embodiments, the implant is configured to couple to a trochlear groove of a femur. In some embodiments, the implant is configured to couple to only a portion of a condyle of a femur.

FIGS. **12**A, **12**B, and/or **12**C may be used to describe a patch implant described herein, having appendages **4***a*, **4***c*, extending from a balloon **6** and including holes **8***a*, **8***b*, **8***c* prefabricated into an uninflated area, and/or tabs **10***a*, **10***b*. **10***c*, **10***d*, **10***e*, **10***f* which may be used with couplers (not shown) to couple the implant to a bone of the knee joint (which may be the femur, the tibia, or the patella). Features shown in FIGS. **12**A, **12**B, and/or **12**C are common to both the unicompartment knee implant (discussed elsewhere herein) and the patch implant, although dimensions may differ as described herein. Thus, FIGS. **12**A, **12**B, and/or **12**C may be used to describe the unicompartment knee implant and/or the patch implant. FIG. **12**A depicts a bottom-up view of an embodiment of the implant **2** (unicompartment or patch), the implant having appendages **4***a*, **4***c*, extending from a balloon **6** and including holes **8***a*, **8***b*, **8***c*, which may be used with couplers (not shown) to couple the implant **2** to the femur of the knee joint. FIG. **12**B depicts a bottom-up view of an embodiment of the implant **2** (unicompartment or patch), the implant having appendages **4***a*, **4***c*, extending from a balloon **6** and including tabs **10***a*, **10***b* and hole **8***a* which may be used with couplers (not shown) to couple the implant to the femur of the knee joint. FIG. **12**C depicts a bottom-up view of an embodiment of the implant **2** (unicompartment or patch), the implant having appendages **4***a*, **4***c*, extending from a balloon **6** or padded weight bearing region of the implant and including tabs **10***c*, **10***d*, **10***e*, and **10***f* and hole **8***a* which may be used with couplers (not shown) to couple the implant to the femur of the knee joint. In some embodiments, the implant is configured to couple to a tibia. In some embodiments, the implant is configured to couple to a trochlear groove of a femur. In some embodiments, the implant is configured to couple to only a portion of a condyle of a femur. In some embodiments the implant is coupled to the patella. In any embodiment the balloon **6** may extend from one surface of the implant as a focal protuberance to fill a defect, space, or to aide in alignment correct, or the balloon may be full thickness as differences in FIGS. **2** and **3** show respectively. In any embodiment there may be a singular or multiple major balloons, if off a primary surface resembling bubble wrap, and there may be microscopic balloons or vacuoles containing gas, gel, or solid in the material matrix.

In all descriptions provided herein of the patch implant, the implant may instead be configured to couple to the tibia or to the fibula or the patella. It is the intention and understanding that the implant is suited for this purpose in certain embodiments with adjustments to account for dimensional differences of these bones. Most descriptions provided herein are directed to embodiments coupling the implant to the femur, however, this is primarily for ease of description and continuity, and does not preclude embodiments wherein the implant is coupled to the tibia (or other bones). Likewise, as noted elsewhere herein, there are embodiments where the implant may be coupled to two bones (at least), for example to both a tibia and a femur.

Partial Knee Arthroplasty (Unicompartment)

In addition to the total knee-type (dual condyle) and patch implants are implants that serve to cover and adjust alignment for either the medial or lateral condyle of the femur with varus or valgus knees requiring added cushioning to recreate the natural six degrees of knee valgus.

Thus, provided herein is an implant for placement on at least one condyle of the distal femur (a unicompartment implant—named so due to their coverage of a single condyle of the femur). The implant may be configured to be placed over the lateral condyle. The implant may be configured to be placed over the medial condyle. The implant may be configured to be placed over either the medial condyle or the lateral condyle. Two unicompartment implants may be placed in the same knee, one over the medial condyle, one over the lateral condyle.

FIGS. **11**A-**12** C depict example embodiments of unicompartment implants. In some embodiments, the unicompartment implant comprises a balloon that is at least one of: at most about 1.5 cm in diameter, at most about 1.75 cm in diameter, at most about 2 cm in diameter, at most about 2.25 cm in diameter, at most about 2.5 cm in diameter, at most about 2.75 cm in diameter, at most about 3 cm in diameter, at most about 3.25 cm in diameter, at most about 3.5 cm in diameter, at most about 3.75 cm in diameter, at most about 4 cm in diameter, at most about 4.25 cm in diameter, at most about 4.5 cm in diameter, at most about 4.75 cm in diameter, at most about 5 cm in diameter, at most about 5.25 cm in diameter, at most about 5.5 cm in diameter, at most about 5.75 cm in diameter, at most about 6 cm in diameter, at most about 6.25 cm in diameter, at most about 6.5 cm in diameter, at most about 6.75 cm in diameter, at most about 7 cm in diameter, at most about 7.25 cm in diameter, at most about 7.5 cm in diameter, at most about 7.75 cm in diameter, at most about 8 cm in diameter, at most about 3 cm in length along the longest length of the balloon, at most about 3.25 cm in length along the longest length of the balloon, at most about 3.5 cm in length along the longest length of the balloon, at most about 3.75 cm in length along the longest length of the balloon, at most about 4 cm in length along the longest length of the balloon, at most about 4.25 cm in length along the longest length of the balloon, at most about 4.5 cm in length along the longest length of the balloon, at most about 4.75 cm in length along the longest length of the balloon, at most about 5 cm in length along the longest length of the balloon, at most about 5.25 cm in length along the longest length of the balloon, at most about 5.5 cm in length along the longest length of the balloon, at most about 5.75 cm in length along the longest length of the balloon, at most about 6 cm in length along the longest length of the balloon, 6.25 cm in length along the longest length of the

balloon, at most about 6.5 cm in length along the longest length of the balloon, at most about 6.75 cm in length along the longest length of the balloon, at most about 7 cm in length along the longest length of the balloon, at most about 7.25 cm in length along the longest length of the balloon, at most about 7.5 cm in length along the longest length of the balloon, at most about 7.75 cm in length along the longest length of the balloon, and at most about 8 cm in length along the longest length of the balloon. As used herein with respect to balloon dimensions whether length or diameter, the term "about" means variations of at least one of 0.1 cm, 0.2 cm, 0.25 cm, 0.5 cm, and 1 cm.

In some embodiments, the implant comprises attachment tabs or attachment elements over the anterior and/or posterior and/or medial side, and/or lateral side (and/or some combination thereof) of a condyle. In some embodiments, the implant comprises attachment tabs or attachment elements in the intercondylar notch. In some embodiments, the implant comprises attachment tabs or attachment elements superiorly at the distal end of the femur anteriorly.

The posterior of the knee can be difficult to access without disturbing joint components (or in order to minimize such disturbance) such as tendons, ligaments, etc. Thus, in some embodiments, the implant comprises strings, reigns, lassos, and/or lanyards that may pass from the posterior of the implant via the intercondylar notch anteriorly to join with themselves and/or other coupling devices. In some embodiments, posterior reigns or suture-like lanyards cinch up the implant from inside the posterior intercondylar notch toward another connection site around the femur. These couplers may be pre-coupled to the implant, and the implant and its couplers may be configured to be pulled (or cinched) from the anterior of the implant once the implant is in its general location relative to the condyle in order to finally position the implant about the condyle—in particular in order to cinch the implant about the posterior of the condyle. Likewise, in some embodiments where the implant is pre-molded, the coupler as described are adapted to move the implant to its final position with conformity to the condyle's posterior with minimal disturbance to the joint structures at the joint's posterior (minimal cutting, minimal moving, and or minimal detachment, for non-limiting example). In some embodiments at least a portion of the ligamentary structure of the knee is spared.

FIG. **10**A depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4***b*, **4***d* extending from an inflated balloon **6** and showing the inflation medium **46** moved anteriorly toward the patella **40** when the knee joint is slightly flexed. Likewise, FIG. **10**B depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4***b*, **4***d* extending from an inflated balloon **6** and having couplers **44***a*, **44***b* (which may be, for non-limiting example, staples or screws, pins or snaps) coupling the appendages **4***b*, **4***d* to the femur **24** and showing the inflation medium **46** moved anteriorly toward the patella **40** when the knee joint is slightly flexed.

FIGS. **11**A, **11**B, and/or **11**C may be used to describe a unicompartment implant **2** (or unicompartment knee implant, terms which may be used interchangeably) described herein, having appendages **4***a*, **4***c*, extending from a balloon **6** (not shown in FIG. **11**A) and including holes **8***a*-**8***h*, and/or tabs **10***a*-**10***f* which may be used with couplers (not shown) to couple the implant to a bone of the knee joint (which may be the femur, the tibia, or the patella). Features shown in FIGS. **11**A, **11**B, and/or **11**C are common to both the unicompartment knee implant and the patch implant (discussed elsewhere herein), although dimensions may differ as described herein. Thus, FIGS. **11**A, **11**B, and/or **11**C may be used to describe the unicompartment knee implant and/or the patch implant. FIG. **11**A depicts an embodiment of the unicompartment knee implant **2** curved to simulate curvature about one condyle of a femur, the implant **2** having appendages **4***a*, **4***c*, extending from an uninflated balloon (not shown) and including tabs **10***a*-**10***f* and/or holes **8***a*-**8***h*, which may be used with couplers (not shown, described elsewhere herein) to couple the implant **2** to the femur of the knee joint. FIG. **11**B depicts an embodiment of the unicompartment knee implant **2** curved to simulate curvature about one condyle of a femur, the implant having appendages **4***a*, **4***c*, extending from an inflated balloon **6** and including tabs **10***a*-**10***f* and/or holes **8***a*-**8***h*, which may be used with couplers (not shown, described elsewhere herein) to couple the implant **2** to the femur of the knee joint. FIG. **11**C depicts a bottom-up view of an embodiment of the unicompartment knee implant **2** curved to simulate curvature about one condyle of a femur, the implant **2** having appendages **4***a*, **4***c*, extending from an inflated balloon **6** and including tabs **10***a*-**10***f* and/or holes **8***a*-**8***h*, which may be used with couplers (not shown, described elsewhere herein) to couple the implant **2** to the femur of the knee joint.

In some embodiments, the unicompartment implant including attachment tabs is at least one of: at most about 15 cm in length along the longest length of the implant, at most about 15.25 cm in length along the longest length of the implant, at most about 15.5 cm in length along the longest length of the implant, at most about 15.75 cm in length along the longest length of the implant, at most about 16 cm in length along the longest length of the implant, at most about 16.25 cm in length along the longest length of the implant, at most about 16.5 cm in length along the longest length of the implant, at most about 16.75 cm in length along the longest length of the implant, at most about 17 cm in length along the longest length of the implant, at most about 17.25 cm in length along the longest length of the implant, at most about 17.5 cm in length along the longest length of the implant, at most about 17.75 cm in length along the longest length of the implant, at most about 18 cm in length along the longest length of the implant, 18.25 cm in length along the longest length of the implant, at most about 18.5 cm in length along the longest length of the implant, at most about 18.75 cm in length along the longest length of the implant, at most about 19 cm in length along the longest length of the implant, at most about 19.25 cm in length along the longest length of the implant, at most about 19.5 cm in length along the longest length of the implant, at most about 19.75 cm in length along the longest length of the implant, at most about 20 cm in length along the longest length of the implant, at most about 20.25 cm in length along the longest length of the implant, at most about 20.5 cm in length along the longest length of the implant, at most about 20.75 cm in length along the longest length of the implant, at most about 21 cm in length along the longest length of the implant, at most about 21.25 cm in length along the longest length of the implant, at most about 21.5 cm in length along the longest length of the implant, at most about 21.75 cm in length along the longest length of the implant, at most about 22 cm in length along the longest length of the implant, at most about 22.25 cm in length along the longest length of the implant, at most about 22.5 cm in length along the longest length of the implant, at most about 22.75 cm in length along the longest length of the implant, at most about 23 cm in length along the longest length of the implant, 23.25 cm in length along

the longest length of the implant, at most about 23.5 cm in length along the longest length of the implant, at most about 23.75 cm in length along the longest length of the implant, at most about 24 cm in length along the longest length of the implant, at most about 24.25 cm in length along the longest length of the implant, at most about 24.5 cm in length along the longest length of the implant, at most about 24.75 cm in length along the longest length of the implant, at most about 25 cm in length along the longest length of the implant, at most about 25.25 cm in length along the longest length of the implant, at most about 25.5 cm in length along the longest length of the implant, at most about 25.75 cm in length along the longest length of the implant, and at most about 26 cm in length along the longest length of the implant. As used herein with respect to implant length dimensions, the term "about" means variations of at least one of 0.1 cm, 0.2 cm, 0.25 cm, 0.5 cm, and 1 cm.

In some embodiments, the unicompartment implant is longer than it is wide, and the longer portion of the implant wraps from the anterior of the condyle to the posterior of the condyle. In some embodiments, the length of the implant is longer on the outer edge of the implant than on the inner edge nearest the trochlear groove (whether used on the lateral or medial condyle). In some embodiments, the trochlear groove per se rather than either the medial or lateral compartment is reconstructed with the implant anatomically to oppose the undersurface of the patella.

FIGS. **12**A, **12**B, and/or **12**C may be used to describe a unicompartment knee implant (unicompartment implant) described herein, having appendages **4***a*, **4***c*, extending from a balloon **6** and including holes **8***a*, **8***b*, **8***c*, and/or tabs **10***a*, **10***b*. **10***c*, **10***d*, **10***e*, **10***f* which may be used with couplers (not shown) to couple the implant to a bone of the knee joint (which may be the femur, the tibia, or the patella). Features shown in FIGS. **12**A, **12**B, and/or **12**C are common to both the unicompartment knee implant and the patch implant (discussed elsewhere herein), although dimensions may differ as described herein. Thus, FIGS. **12**A, **12**B, and/or **12**C may be used to describe the unicompartment knee implant and/or the patch implant. FIG. **12**A depicts a bottom-up view of an embodiment of the implant **2** (unicompartment or patch), the implant having appendages **4***a*, **4***c*, extending from a balloon **6** and including holes **8***a*, **8***b*, **8***c*, which may be used with couplers (not shown) to couple the implant **2** to the femur of the knee joint. FIG. **12**B depicts a bottom-up view of an embodiment of the implant **2** (unicompartment or patch), the implant having appendages **4***a*, **4***c*, extending from a balloon **6** and including tabs **10***a*, **10***b* and hole **8***a* which may be used with couplers (not shown) to couple the implant to the femur of the knee joint. FIG. **12**C depicts a bottom-up view of an embodiment of the implant **2** (unicompartment or patch), the implant having appendages **4***a*, **4***c*, extending from a balloon **6** and including tabs **10***c*, **10***d*, **10***e*, and **10***f* and hole **8***a* which may be used with couplers (not shown) to couple the implant to the femur of the knee joint.

In all descriptions provided herein of the unicompartment implant, the implant may instead be configured to couple to the tibia or to the fibula or the patella. It is the intention and understanding that the implant is suited for this purpose in certain embodiments with adjustments to account for dimensional differences of the particular bones. Most descriptions provided herein are directed to embodiments coupling the implant to the femur, however, this is primarily for ease of description and continuity, and does not preclude embodiments wherein the implant is coupled to the tibia (or other bones). Likewise, as noted elsewhere herein, there are embodiments where the implant may be coupled to two bones (at least), for example to both a tibia and a femur.

Meniscal Replacement or Repair, and Solid, Rigid, or Semi-Rigid Components:

Provided herein is an implant having a balloon having a first and second chamber. The implant may be any of the Dual Compartment, Unicompartment, and Patch implants described herein. The second chamber may be configured to replace and/or partially replace fibrocartilage meniscal loss. The implant may have two lobes of chambers which may be alternatively described as two superimposed balloon radii in apposition to each other. The implant may be configured to provide stability between the femur and tibia by providing a meniscus wedge. In some embodiments the implant comprises a portion configured to replace and/or partially replace fibrocartilage meniscal loss. Such an embodiment may not require a second chamber.

In some embodiments a chamber of the implant is configured to receive a solid piece configured to restore joint and/or bone alignment. In some embodiments, the chamber is configured to receive a plurality of solid pieces, each of which can be used to increase the space between a first bone and a second bone in order to restore and/or improve joint and/or bone alignment. The solid pieces may be wedge-shaped, or be provided in various sizes and/or shapes. The solid pieces may individually or together be used in a chamber or multiple chambers of the implant. The solid piece (or pieces) may be used to ratchet adjacent bones to a desired distraction and/or alignment to restore and/or improve joint and/or bone alignment. The solid piece may be put in a chamber of the implant, which may enclose or partially enclose the piece to hold the piece in place. In some embodiments, a block of biocompatible material (such as PMMA or another bone-like substitute) may be provided and may be formed (by carving or other forming method) by the surgeon to a desired shape. The formed piece may then be put in a chamber of the implant, which may enclose or partially enclose the piece to hold the piece in place.

In some embodiments, the inflation medium is a methyl methacrylate or other biocompatible hardening substance which can flow when initially put into the chamber, and hardens to become a rigid piece (or solid piece). The methyl methacrylate or other biocompatible hardening substance may conform to the shape of the chamber, or may conform to the shape of a space between bones and/or other joint structures. The methyl methacrylate or other biocompatible hardening substance may conform to a form chosen by the surgeon using tools and/or pressure to influence the final shape of the rigid piece formed by the methyl methacrylate or other biocompatible hardening substance upon hardening.

The solid piece (whether formed in situ or by a surgeon or pre-formed) may be cushioned by the implant. The implant may comprise an inflatable chamber between the solid piece and the first bone. In some embodiments, the first bone is a femur. The implant may comprise an inflatable chamber between the solid piece and the tibia. The implant may comprise an inflatable chamber between the solid piece and the patella. The implant may comprise an inflatable chamber between the solid piece and the second bone. The implant may comprise a pad between the solid piece and the first bone as a cushion. In some embodiments, the first bone is a femur. The implant may comprise a pad between the solid piece and the second bone as a cushion. In some embodiments, the second bone is a tibia. In some embodiments, the second bone is a patella.

The solid piece may provide at least one of about 1 degree of joint correction, about 2 degrees of joint correction, about

3 degrees of joint correction, about 4 degrees of joint correction, about 5 degrees of joint correction, about 6 degrees of joint correction, about 7 degrees of joint correction, about 8 degrees of joint correction, about 9 degrees of joint correction, and about 10 degrees of joint correction. With respect to degrees of joint correction, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%.

The implant can be used in a variety of joints where the implant replaces a bone on bone surface and cushions the interaction between the articular ends of any two bones, such as at the femoral tibial and patella femoral knee interfaces. The implant can be used in a variety of joints where the implant replaces a bone on bone surface and cushions the interaction between the articular ends of any two bones, such as at the femoral-acetabular interspace of a patient's hip, the humerus and glenoid scapular component in the shoulder, the replacement of talus bone in the human ankle between the tibia and calcaneus and the like. Where the implant is substituting or enhancing articular cartilage, the rigidity can be reduced or enhanced to maximize conformation changes that arise during motion as enabled by the two opposing walls and intended inner space, coupled with considerations in any joint surgical reconstruction with accommodation to or amplification of the existing joint ligaments, tendons or dearth thereof. The implant **10** may be deflated and removed by minimally invasive surgery, for example, after the implant has served its purpose of regenerating tissue or if another clinical condition warrants its removal. However, it may not be clinically necessary to remove the implant even if inflation is lost, since the two remaining functions of patching the injured cartilage, and delivering restorative cells may justify implant retention.

In many embodiments the implant (or a portion thereof, such as the balloon or balloon) is a weight bearing spacer that allows joint motions to approach normal, whether filling the space left by an entirely collapsed peripheral joint bone or the space of ablated cartilage proximate surfaces diffusely as in osteoarthritis or succinctly as in osteonecrotic defects or localized trauma. The walls may be used as a membrane for holding living cells in proximity of the osteochondral defect long enough for the cells to attach (e.g. 24 hours) or to deeply adhere (up to 28 days) or return to normal (up to one year). Weight bearing may be expected to increase as distal lower extremity joints are treated.

Additional Locations for Use

Shoulder subacromical bursa may be a target joint for an implant as described herein. Rotator cuff tears may be addressed using an implant as described herein—as adjusted for the particular features, loading profile, and geometries of the joint. In shoulders, 85% of octagenians have massive rotator cuff tears and often less than half normal upper extremity abduction and flexion capabilities. There may not be sufficient remnant supraspinatus and other rotator cuff tissues to pull together. Then the humeral head rides up, in a cephalad direction, rubbing the superior bone surface on a frequently spurred and downward sloping acromion. If a subacromial implant as described herein were implanted beneath the lateral (arthroscopically decompressed and prepared) acromion, the pain of bone on bone could be reduced, and the structural anatomy between the ball and socket (humeral head and glenoid fossa) could be improved. In essence then a shoulder implant could cover the humeral head analogous to the hip redundant membrane wherein that membrane replaces a normal subacromial bursa. Optionally, a singular bladder beneath the acromion per se could pad the ball beneath it. For virtually every joint in the body (arms and legs, at least) there are similar potential implant uses.

The distal femur of the knee, and the distal humerus of the elbow are regions that interface each with two opposite joints. That is, an implant for the knee as designed with polymer capping of the femoral condyles and trochlear groove to provide cushioning of the femorotibial and patellafemoral joints. Analogously, in the humerus the distal coverage enables padding restoration of the humeral-olecranon as well as the radio-capitellar (part of the humerus) joint interfaces. Whereas generally the implant may cover the main or primary joint surface of the surgeon's choice contributing to arthritis, consequently reducing symptoms when treated, another alternative would be that the implant can cover any singular surface entirely or partially. It is generally desired that the implant may cover one surface allowing remnant cartilages in other usually opposing or opposite surfaces to glide against the implant polymer with smooth gliding joint motion. This principle allows for retained joint linings or synovium to produce lubricating substances including enzymes for facile joint movement. It also avoids the wear debris that would accrue from polymer rubbing on polymer, as recently recognized in metal on metal prostheses. In certain embodiments, the implant can cover more than one surface in a joint, such as the radiocapitallar joint wherein the distal humerus and the radial head receive prosthetic capping or interpositional application of polymers.

The surgical techniques may be individualized to fit patient need. The implants may be combined with or comprise autologous or allograph tissues such as fascia lata. Surgeons may implant fascia lata above unreconstructable rotator cuff with consequent symptom relief. Polymers can interface with any human tissue and/or with metals or polyethylenes or polyurethanes. Living tissues that can be combined with implants provided herein for repair or reconstruction may be from the same patient (autograph), and cadaver or other member of the same species (allograph) or from another species (xenograph.) Virtually any combination of polymer interpositioning is feasible with the implant concepts provided herein, as anatomy varies among patients in need, and clinical conditions differ with each person. Therefore, although the general or most common construct is expected to cover just one singular and the primary surface of a joint with an implant, any combination of surfaces can be involved allowing versatile custom applications of this implant and method of surgery.

Additionally, whereas implants as noted herein may be available in specified sizes, the material membrane elastic deformation and resilience may allow for calculated malleability toward goodness of fit. In other iterations the fit of implant over the affected joint surface is customized as paring preoperative findings of MRI or CT or PET imaging pathophysiology with intraoperative reconstructive need. Ultimately best fit implants may serve patient restorative requirement with least morbidity.

Locations wherein implants described herein may be additionally or alternatively applicable include all the limb joints of mammals. In the shoulder mainly the glenohumeral joint, though as discussed above the subacromial space are useful loci for renewed padding when pathophysiologies warrant. In the AC or acromioclavicular joint of the shoulder, a Mumford procedure (resection of the distal clavicle) can be avoided by inserted an implant as described herein. Even the TMJ in the jaw may be amenable to therapy using the implants noted herein. Proceeding distally in the aim, the elbow has two relevant joints mentioned earlier, radiocapitellar and ulnohumeral. Depending on 'where the arthritis forms' (as from fracture or disease) the padding should be

restored toward normal. Wrist, thumb and finger joints are many and may respond to vesicular implants with better durometry and vicsolubricant delivery than tradition metal or silicon prostheses. Legs started at the hip joint have been shown via Hip implant prototypes to be amenable to polymer capping. Variations per surgeon's choice could evoke special uses as for coverage of trochanteric bursae.

Additionally, the many functions of the implants noted herein may be coupled with cosmetic aspects in order to restore bulk and soft tissue balance after scarring, injury or atrophy, or for purely cosmetic purposes. Treatment for cosmesis especially when coupled with functional or visual injury deficits can provide a reduction in physiological as well as physical pain and discomfort. Therefore the extent minimally invasive implants restore the injured or diseased patient recipient to become hole, they are being used purposefully and as intended.

The knee joint is an initial focus of the figures wherein application to the largest bone (the distal femur) accommodates padding needs for the opposing patella and tibia. The potential use of implants, however, over the contralateral surfaces is an option that should not be ruled out. In the ankle the supratalar, or tibia talar joint will be a useful location as may the subtalar area, depending on pathology present. Indications for use may depend on the patients symptoms, from the history and physical exam, based on studies such as roentgenograms, MRI or CT imaging, and may depend on test result from localized injections. For example, if a talus fracture pain were alleviated by sinus tarsi injection then implant insertion into the subtalar joint would be preferred. The talonavicular and other foot/toe joints are all amenable to renewed padding via an implant noted herein.

Pets, or other animals, such as cows, dogs, and horses, may be served better by polymer joint capping than hip replacement for congenital dysplasia. The successful treatment and rehabilitation of animals can favorably affect the implant recipient and animal's owner, as pets can provide functions necessary for activities of daily living (as a horse helping to plow a field) or an animal relieved of pain from injury or arthritis can also be a comfort to its owner.

Kits

Provided herein are kits comprising multiple implants described herein. A kit may comprise multiple sizes of a single type of implant. A kit may comprise various implant types, such as the patch, the unicompartment, and/or the dual compartment types of implants described herein. A kit may comprise various couplers, which may be selected by the surgeon depending on his comfort and expertise, and/or based on the particular patient anatomy and/or needs. The kit may further comprise any insertion tools and/or surgery tools that may uniquely assist in implanting the implant in the patient.

In addition to kits involving reparative implants, and insertional tools, there may also be included software for translation of pre-injury data and/or postoperative data collection and analysis, as well as custom implants may be provided.

Implantation Methods

Implantation of implants provided herein may depend on the size of joint surface intended for reconstruction by use of the implant. This may be based upon the nature and extent of injury, and upon the expectations of the patient and surgeon. In some embodiments, an arthroscope can be inserted in one side of the knee joint through a 0.5 cm wound, while the implant is inserted into the opposite joint line wound from 1-10 cm in size. The joint may be first inspected and debrided, performing an arthroscopic synovectomy, chondroplasty, and meniscectomy as needed. Additional distraction under general anesthesia with the knee at variable degrees of flex may allow for implant introduction, systematic peripheral attachment, balancing, and inflation, if warranted.

In some embodiments, the implant may be selectively inflatable depending on the particular needs of the patient. In some embodiments, the filler of the interior of the implant may be rigid, semi-rigid, fluid, air, or combinations thereof, as described herein. In some embodiments, the implant may be used in conjunction with fibrocartilage repair or replacement. In some embodiments, the implant may be used without fibrocartilage repair or replacement. In some embodiments, the implant may be used in conjunction with boney osteotomy. In some embodiments, the implant may be used without boney osteotomy.

The posterior of the knee can be difficult to access without disturbing joint components (or in order to minimize such disturbance) such as tendons, ligaments, etc. Thus, in some embodiments, the method comprises providing an implant comprising strings, reigns, lassos, and/or lanyards that may pass from the posterior of the implant via the intercondylar notch anteriorly to join with themselves and/or other coupling devices. In some embodiments, posterior reigns or suture-like lanyards cinch up the implant from inside the posterior intercondylar notch toward another connection site around the femur. In some embodiments, the methods comprise conforming the implant posterior to the condyle by pulling the strings (or reigns, or lassos, or lanyards or the like) of the implant. Such couplers (strings, reigns, lassos, lanyards, etc) may comprise suture materials and/or wire materials.

These couplers (i.e. strings, reigns, lassos, lanyards, etc) may be pre-coupled to the implant, and the implant and its couplers may be configured to be pulled (or cinched) from the anterior of the implant once the implant is in its general location relative to the condyle in order to finally position the implant about the condyle—in particular in order to cinch the implant about the posterior of the condyle. Likewise, in some embodiments where the implant is premolded, the coupler as described are adapted to move the implant to its final position with conformity to the condyle's posterior with minimal disturbance to the joint structures at the joint's posterior (minimal cutting, minimal moving, and or minimal detachment, for non-limiting example). In some embodiments at least a portion of the ligamentary structure of the knee is spared.

In some instances, the implant is inserted arthroscopically through a cannula about 10 mm in diameter with the implant in the deflated construct, and once inside the prepared joint space and secured therein by the skirt or tabs, the implant is distended or inflated with gas, gel, fluid or fluid that becomes a resilient solid to fill the original natural space of about 0.5 cm between the bones of the joint (between at least two bones of the joint). If the implant is not inserted through a cannula, it may be inserted through an open incision from one to forty centimeters in length at the surgeon's discretion. Tensioning may be by the surgeon's sense of proper pressure application aided by a gauged syringe for insertion of viscolubricants such as Synvisc, Hyalgan, Supartz and/or analgesics such as lidocaine gel. The insertion of liquids to the joint per se may be directly, through a cannula to the joint space previously in place for debridement, and or via a cannula or tube that is not part of the original implant assembly. Once the joint is cleaned, the implant is inserted and appropriately fixed to avoid extrusion or dislocation

thereof. This may be via attachment of the implant tabs and/or by a combination of tab use plus intended friction created by implant surface coverings (analogous to Velcro) or a draw string at the smaller base of the implant.

In some embodiments the attachment tabs are positioned on the implant to both secure the implant to the joint components, and to enable a physician to ensure the implant has a minimum amount of slack that could create wrinkles or loose areas to avoid unnecessary friction and/or wear of the implant of the patient's anatomy. Figures depicted herein show examples of properly situated attachment tabs configured for these dual purposes. In some embodiments, fewer tabs are needed to achieve these goals.

In some embodiments, where slack or voids exist, the balloon under compression may fill such areas. The implant in some embodiments is configured to allow hyaline and/or cartilage cells to fill any irregularities or craters in the joint components and grow to refurbish natural joint contour. When the implant implantation is combined with, for example, movement of the treated joint in a constant passive motion machine for 12 hrs a day for 6 weeks after surgery implanting the implant, cell growth may create renewed hyaline cartilage, and/or blood/fibrin and scar to create fibrocartilage filler material.

Each attachment tab insert site may be clinically determined centripitally around the implant during surgery, driving slots or holes sequentially with an osteotome or drill immediately followed by insertion of the triangled tab extension into the bone slots or screw respectively. For example, if the implant were viewed like a clockface the first tab could be tacked/tapped in a 2 o'clock, then 7, 10, 4, 11, 5, 12, 6 (wherein #2, 7, 10, 4 are over the bilateral femurs superior/inferior to collateral ligaments, 11, 12 are superior at the distal anterior femur beneath the upper patella, and 5, 6 are inside the intercondylar notch anterior to cruciates). This can be like putting a saddle on a horse, going around the knee end with a grasper, to tug the polymer toward fit, tapping a slot over the side of the femur with a thin one-half inch osteotome, angling cuts distally, one by one, as if to pull the implant (or saddle) into its angle of repose, seating ideally over the condyles and ridings nicely in the trochlear groove.

In some embodiments, the metal clips could be set angled at about 120 degrees, as greater than 90 can favorably distract/hold the implant to tighter fit analogous to a mylar compliant balloon or stretch sock fitting over a protuberance as opposed to a piece of (non-compliant) paper that results is wrinkles and areas of incongruence between the implant and bone end. Reducing dislodgement tendency and snugging the polymer once stretched to best fit may avoid the failure history as illustrated in the Danish Polymer hip cap solid crescent shaped hip resurfacing implants which lacked inflation, surface stability, accommodation, and fixation.

Inflation may also be specified by clinical need, and modifications in the implant multi-cell (multi-compartment) construction allows for selective inflation with substances ranging from gas to solid, including gels or semi-solids that can as part of material layered integrity either provide calculated hardness (durometer) to overcome and resist limb adjacent bone mal-alignment, and/or to deliver new regenerative tissues for restoration of natural anatomy of time. That is, certain sections of the implant may be electively inflated of left without expansion, to adjust to fit as matching a normal or uninjured contralateral limb for the involved patient.

Indeed, patient interaction and feedback may be sought so as to bring to orthopedic conceived art and science the individual's own needs and concerns. It is said that for patients who have anterior cruciate injuries, one third require reconstruction for knee joint stabilizer, one third do not—living with a reduced activity level, and one third deliberate extensively until a choice between the two continuum options is made.

A goal of embodiments of implants described herein is to maintain remnant living tissue by using minimally invasive technologies, smaller incisions when they serve the patient equally to larger, sacrificing the least normal tissue as possible. Implants described herein assist and improve on current treatment options available by avoiding as much as possible the ablative bone and cartilage resecting, ligament removing total knee arthroplasty and instead to restore the padding lost in injury or disease or surgery.

Examples from within the techniques include electing to repair rather than reconstruct anterior cruciate ligaments in certain situations, proved warranted and effective at a $p<0.3$ statistical level. Whereas Carticel chondrocyte implantation is useful to enable articular surface regrowth with hyaline, rather than scar/fibrocartilage from picking/drilling, the massive morbidity from periosteal harvesting is unnecessary. This is because it takes only 24 hours for the cartilage cloned chondrocytes to attach to the prepared joint surface, and the polymer membrane (patch implant described herein, for example, or use of chondrocytes on surfaces of the dual compartment implant or the unicompartment implant) over the prepared defect (like a manhole cover) can adeptly substitute for periosteum.

With these concepts in mind in is the overall intent to do what is necessary to restore function and nothing more in order to spare the patient removal of injured tissues that may recover or regrow, by implementing a common sense approach to limb repair and reconstruction with the implant and methods of use thereof. In animals as horses and dogs, where recovery instructions are even less likely to be followed than with humans, implanting secure restorative implants for joint surface refurbishment may offer renewed function and save lives that would have otherwise been sacrificed.

Rehabilitation of knee implant treated patients may engage prudent early motion. The amount of weight bearing allowed may be analogous to the procedures written by this primary surgery for Carticel implanted cases, following the principles that excessive amounts and repetitions of stress upon reconstructed areas should be avoided for 6-12 weeks after surgery. However, the knee implant surgeries per se are expected to take less than one hour, involve less than 1 cc blood loss, require wounds less than or equal to 10 cm overall (depending on the embodiment of the implant), and the end result intends to permit early full weight bearing. Zealous sports activities may be restricted until the bone in-growth and cartilage renewal is reasonably expected, between 2 and 12 months after surgery depending upon the amount of joint tissue replaced.

In some situations, the removal of the implant may be needed, and embodiments of the implants described herein are configured for removal arthroscopically, and with the allowance to perform all regular older routine accepted techniques ranging from joint debridement to drilling, partial or total replacement. In some embodiments the implant is configured for removal and replacement with a replacement implant—either immediately (within a week), or after a period of longer time (for example, after about 6 weeks to 1 year in the case of infection once all foreign bodies are removed and depending upon the surgeon's and/or infectious disease consultant's opinion

Specific surgical decisions related to size matching, fixation and or concomitant osteotomy warranted reconstruction are left to the primary surgeon and patient in each case.

The implant is inserted by minimally invasive surgery, in some embodiments; however, in other embodiments, the implant may not be inserted by minimally invasive surgery. In some embodiments, the implant is delivered through an incision that is about 0.5 inches long. In some embodiments, the implant is delivered through an incision that is about 1 centimeter long. In some embodiments, the implant is delivered through an incision that is at most about 1 inch long. In some embodiments, the implant is delivered non-arthroscopically through an incision that is at least 1 centimeter long. In some embodiments, the implant is delivered through an incision that is at most about 0.75 inches long. In some embodiments, the implant is delivered through an incision that is at most about 0.5 inches long. In some embodiments, the implant is delivered through an incision that is about 8 centimeters long. In some embodiments, the implant is delivered through an incision that is about 9 centimeters long. In some embodiments, the implant is delivered through an incision that is about 10 centimeters long. In some embodiments, the implant is delivered through an incision that is about 11 centimeters long. In some embodiments, the implant is delivered through an incision that is about 12 centimeters long. In some embodiments, the implant is delivered through an incision that is over about 10 centimeters long. In some embodiments, the implant is delivered through an incision that is at up to about 40 centimeters long. In some embodiments, the implant is delivered through multiple incisions. In some embodiments, the implant is delivered non-arthroscopically. In other embodiments, the implant is delivered arthroscopically. With respect to incision length, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%.

In some embodiments the implant is configured to be delivered to the joint arthroscopically. In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most about 10 millimeters. In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most about 9 millimeters. In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most about 5 millimeters. With respect to cannula distal end inner diameter, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%.

In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most about 10 millimeters. In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most about 9 millimeters. In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most about 5 millimeters. With respect to cannula distal end inner diameter, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%.

In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most about 10 millimeters. In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most about 9 millimeters. In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most about 5 millimeters. With respect to cannula distal end inner diameter, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%.

In some embodiments the implant may be provided as a deflated balloon for insertion into the joint space. In some embodiments the implant may be provided as folded balloon that may be collapsed like an umbrella for insertion into the joint space. In some embodiments the implant may be provided as collapsed balloon that is of an irregular folded pattern to minimize its folded (or collapsed) size for insertion into the joint space. In some embodiments, the implant is configured to blow up (or expand) to take the form of the expanded, distracted, debrided joint.

In some embodiments, the implant replaces periosteum.

In some embodiments, the implant is implanted to preserve bone as compared to a typical arthroplasty procedure of the joint. In some embodiments, the implant is implanted to preserve cartilage as compared to a typical arthroplasty procedure of the joint. In some embodiments, the implant is implanted with minimal soft tissue dissection as compared to a typical arthroplasty procedure of the joint. In some embodiments, the implant is implanted without joint dislocation. In some embodiments, once implanted, the joint is adaptable to revision surgery. In some embodiments once implanted, the joint retains at least one of: about 90% of normal joint function, about 95% of normal joint function, about 85% of normal joint function, about 80% of normal joint function, about 75% of normal joint function, about 70% of normal joint function, about 65% of normal joint function, about 60% of normal joint function, about 55% of normal joint function, about 50% of normal joint function, at least 95% of normal joint function, at least 90% of normal joint function, at least 85% of normal joint function, at least 80% of normal joint function, at least 75% of normal joint function, at least 70% of normal joint function, at least 65% of normal joint function, at least 60% of normal joint function, at least 55% of normal joint function, at least 50% of normal joint function, about 50%-about 75% of normal joint function, about 50%-about 70% of normal joint function, about 60-about 70% of normal joint function, about 70%-about 80% of normal joint function, about 70%-about 90% of normal joint function, about 80%-about 95% of normal joint function, about 80%-about 90% of normal joint function, and about 90%-about 95% of normal joint function. As used herein with respect to percentage of normal joint function, the term "about" can be ranges of 1%, 5%, 10%, or 25%. For example, a range of 1% with respect to about 90% of normal joint function covers 89% to 90% of normal joint function.

In an example of a hip implant, an upper portion of the implant has a first wall, a second wall and a side wall which define at least in part the interior. A skirt depends from the first wall and secures the first wall to the end of the patient's femur. An upper portion may be configured to engage the corresponding acetabulum of the patient's pelvic bone. The skirt surrounds the head of the patient's femur and secures the implant thereto. In this embodiment, the upper portion of the implant creates overlapping layers, like a redundant membrane, in the side wall between the first and second walls and to accommodate the normal movement of the first or second. This provides greater motion between the femur and the acetabulum and also provides implant stabilization over the head of the femur. This structure also accommodates variation in individual joints that occur from patient to patient.

In an embodiment, the first wall does not extend across the entire end of the patient's femur. However, the implant

may be designed so that first wall may extend over the head of the femur. The second wall and the side wall tend to roll as the femur moves within the acetabulum.

In some embodiments, prior to deploying the implant embodying features of the invention, the cartilage lining the joint is prepared by removing hyaline or fibro cartilage flaps or tears, and areas of chondral advanced fissuring are excised or debrided to create precisely defined defects surrounded by stable normal remnant hyaline cartilage with vertical edges in relation to the damaged surface. It is these defects of the cartilage previously normal surface into which new living cells may be injected or otherwise inserted, and allowed to aggregate by the implant interpositional arthroplasty proximate expanded compressive external wall material. Synovitis invading the joint periphery may be vaporized and extracted conventionally or by the use of steam. Areas of greater cartilage damage are removed for subsequent regeneration and the less afflicted areas having stable cracks are treated to seal or weld the cracks. Areas where the tugor or consistency or minimally damaged cartilage can be preserved are intentionally saved rather than destroyed so as to support the normal spacing and gliding opportunity of the more normal joint interface. Thus, normal cartilage is left behind and abnormal cartilage is removed with the implant making up for the deficiencies. With the present invention, it is preferred in some embodiments to avoid joint dislocation so as to preserve natural innervations and vascularity and thus preserving the blood supply.

Joint preparation is usually performed under a brief general anesthetic of outpatient surgery. A muscle relaxant combined with traction (e.g. 60 pounds force for a hip implant) may be employed to opens the joint wider to permit improved visualization for joint preparation and implant installation, increasing the space between the remnant cartilage from about 3 up to about 12 mm. Increasing the joint space may be necessary and allows the surgeon to wash out noxious enzymes, to remove invasive synovitis, to remove loose bodies, to prepare osteochondral defects ideally and otherwise prepare the joint for the implant. Partial or complete inflation of the implant may precede release of traction in some embodiments. In some embodiments, regeneration agents or cells are inserted with the implant or as a fluid or 3-D template prior to release of traction and wound closure. It is preferred, in some embodiments, to perform joint debridement, implant deployment and application of cell regeneration agent, e.g. stem cell application, under the same anesthetic. As described by several companies in the Stem Cell Summit held in New York, N.Y. on Feb. 17, 2009, it is desirable to obtain an aspiration of the patient's bone marrow from the iliac crest after anesthesia sterilely at the beginning of the operation. The intraoperative technologist may "dial in the cells" to regenerate areas of maximum pathophysiology while the surgeon debrides or otherwise prepares the joint and inserts the implant, placing the cells at the best time. Cell implantation may also occur as a secondary or tertiary reconstructive treatment adjunct. An example resilient implant may be deployed within a patient's hip structure comprising the head of the patient's femur and the acetabulum of the patient's pelvic hip bone. The resilient implant embodying features of the invention is disposed within the space between the femur and the acetabulum. The implant is shaped like a half an orange rind or a hemisphere for a hip joint. The implant has a first wall which is secured to the head of the femur by a plurality of depending tabs (or appendages). The tabs may be attached to the femur by a suitable adhesive or mechanically such as by a screw or pin or snap. The second wall the implant engages the acetabulum, but it also may be provided with tabs and the like for securing the second wall the acetabulum.

The side wall extends between the first and second walls to form an interior which receives filling material through tube (also called a conduit herein, or may be called an inflation port). The implant would also be appropriate for the humeral head in the shoulder or one condyle of the knee or of the humerus, but other shapes may be desired for other joint configurations whether relatively flat as in the thumb base, or more inflated toward a ballooning construct as in the ankle when the talus bone is collapsed.

In many embodiments the implant (or a portion thereof, such as the balloon) is a weight bearing spacer that allows joint motions to approach normal, whether filling the space left by an entirely collapsed peripheral joint bone or the space of ablated cartilage proximate surfaces diffusely as in osteoarthritis or succinctly as in osteonecrotic defects or localized trauma. The walls may be used as a membrane for holding living cells in proximity of the osteochondral defect long enough for the cells to attach (e.g. motion is believed to be primarily between the spaced walls (or portions) of the implant peripherally secured to joint structures, although some motion may occur between the implant and the joint surfaces (as with current bipolar hip hemiarthroplasties)). The implant may be provided with a slot extending from the periphery of the implant to a centrally located passage through the implant to accommodate the ligament of the head of the femur for hip implants. Knee implants may have two slots leading to separate passages for receiving the anterior and posterior cruciate ligaments. Implants for other locations may have similar variable structures to accommodate anatomical features. Implant walls should have sufficient inherent flexibility to mold to the existing deformities imposed by either natural ligament, bone, tendon or remaining cartilage deformities of the internal joint space, and thus filled as a cushion. A separate portal or tube (not shown) or the existing conduit (tube or valve), may be used to extract noxious inflammatory enzymes that can be aspirated at appropriate clinical intervals. Viscolubricants can be injected into the interior of the resilient arthroplasty device through existing conduit or through a long needle to aide in distension, expansion, and/or lubrication (with predetermined microporosity).

The ankle version of the arthroplasty implant of the present invention comprises a square transverse cross-section that must take into account supratalar ankle dorsi/plantar flexion, subtalar eversion/inversion motions, ligament fixation-needs, and the accommodation to existing bony architecture as implant variables accounting for the ipsilateral joint pathophysiology. The implant has a first wall, a second wall and a side wall which extends between the first and second wall. The exterior of the implant may have a mesh material with a plurality of chords (or appendages) for securing the implant to adjacent bones or to remnant ligaments which are attached to adjacent bones.

The implant may be inflated with gas and/or liquid to open wider the space between the tibia above and the calcaneus below to accommodate collapse of the talus bone as in the flattening which succeeds talus fracture with avascular necrosis, or it may be filled with a liquid that becomes a resilient solid. The instant center of the implant's rotation will be constantly changing, with the talus implant mainly stable and with the tibia moving over it. Deformation with weight bearing during the average human's 10,000 daily steps or 2-4 million annual gait cycles required by the stance and walking of normal activities of daily living, must be balanced between sufficient solidarity of the implant to

maintain axial load, avoiding circumferential stress, and shear forces imposed by the tibia distal plafond on the dorsal ankle implant allowing stance and gait of the patient while avoiding implant migration or failure. Further accommodation to lateral forces imposed by the boney medial and lateral malleoli need to be endured through the cyclic load of walking, while collapsing with enough give to absorb shock and to match the shape of surrounding structures of bone and ligament tissue. Whereas the axial load between the distal tibia through the talar implant to the dorsal calcaneus may be loaded during stance and especially while walking on a level plane for supratalar motion, the lateral forces may be loaded particularly with subtalar motion while walking on an uneven plane or with inversion/eversion.

In some embodiments, the first inflation medium imparts rigidity in the implant. In some embodiments, the first inflation medium imparts cushion in the implant. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium aligns the joint. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium aligns the bones of the joint. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium changes the bone alignment. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium improves joint alignment. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium restores, at least in part, joint alignment. In some embodiments, individual chambers of the interior are selectively inflated with a first inflation medium and/or a second inflation medium. In some embodiments, individual chambers of the interior are selectively inflated with a first inflation medium and/or a second inflation medium in order to reconstruct the joint and/or bones of the joint.

In some embodiments, the interior comprises a honeycomb structure. In some embodiments, the interior comprises a mesh structure. In some embodiments, the interior comprises a sponge structure.

The dimensions of the various implant walls may vary depending upon the material properties thereof as well as the needs for a particular joint. The spacing between the first and second wall within the interior can vary from about 0.5 mm to about 5 mm for most joints (except for the implant for an ankle when an entire collapsed bone space is being replaced), preferably about one to five centimeters to fill between the tibia and calcaneus. In the ankle invention version of the implant, the amount of inflation of the implant per se may be directly proportional to the amount of talus bone collapse between the distal tibia and proximal calcaneus—thus as much as 5 cm implant distension or expansion may be required to be maintained between superior and inferior surfaces of the talus, while as much as 10 cm anterior and posterior expansion may be required for the ankle implant between the posterior soft tissues such including the Achilles tendon and the anterior navicular bone as relates to the talus.

The method of insertion for the hip joint invention may be a minimally invasive approach, ideally arthroscopically facilitated, as long as the surgical timing and result quality permit smaller incisions. The hip patient may be placed in the lateral decubitus position (lying non-operative side down on the operating table) with a stabilizing operating table pole and pad apparatus positioned to fix the pelvis. The external stabilizing table and attachments may include a padded metal pole beneath the pubis or pelvic bone from posterior to anterior, along with other external anterior and posterior pelvic stabilizing paddles. The affected leg may be attached beneath the knee with a distracting mechanism that applies about 60 pounds of distal force to open the hip joint about 1 cm once the patient is under general anesthesia. The hip joint is arthroscopically debrided through at least one anterior 0.5 cm incision and one posterior 0.5 cm incision, to remove from the femoral head acetabular (ball and socket) joint arthritic debris such as synovitis, loose bodies and noxious inflammatory enzymes. In certain cases a larger open incision may be needed. A smoothing or electronic/ultrasonic/steam or other chondroplasty method may be performed to make the remaining cartilage smoother to better accommodate the hip implant, and protuberant osteophytes or lateral bone overgrowths may be arthroscopically removed or if needed by open excision. A lateral hip incision may be required between 2 and 10 centimeters in length to deal with deformities and/or to insert the implant. In cases of major deformities appropriate reconstruction may add to the basic procedure.

Once the joint is open and cleared, the hip implant may be inserted laterally and fixed via the skirt or tabs or at least one appendage to the adjacent structures including the peripheral femoral head and/or acetabular rim. Preferably, the implant is inserted arthroscopically through a cannula about 10 mm in diameter with the implant in the deflated construct, and once inside the prepared joint space and secured therein by the skirt or tabs, the implant may be distended or inflated with gas, gel, fluid or fluid that becomes a resilient solid to fill the original natural space of about 0.5 cm between the upper acetabulum and lower femoral head, covering as much of the upper hip joint as required as the implant expands to fit the space.

The method of insertion of the ankle implant generally may be through an anterior surgical ankle approach or tendon separating incision from the distal tibia to the proximal talus (or calcaneus if the talus is absent), removing and reconstructing portions of the superior and inferior ankle extensor retinacula only to the extent required to gain access to the cleared tibiotalar space. Analogous to the hip joint insertional method, the ankle joint may be prepared arthroscopically under general anesthesia, and may benefit from distal distraction as in total ankle joint replacement surgeries with the DePuy Agility technique pinning above and below the ankle joint and then distracting it. The degree of distraction required in all joints to which this invention is applied, including but not limited to those of all appendicular skeletal structures such as the shoulder, elbow, wrist, phalanges, hip, knee, and ankle, may depend both on the nature anatomy and located pathophysiology that must be accommodated on a case by case basis and said distraction may be a combination of body position using gravitational forces and/or superimposed distracting devices. In the ankle, the surgeon may be developing the interval between the extensor hallucis longus and anterior tibial tendons. Injury tissue is removed, and the implant inserted fitting as preplanned. The implant surface may be provided with roughness, e.g. external mesh, to control movement by friction as

described above for the hip joint, and/or attached fixation cords or tabs to connect to proximate ligaments or adjacent boney structures may be used at the surgeon's discretion to balance implant location stability and integrity, with the need for functional joint movements.

Provided herein is a method for restoring a joint comprising: providing an implant configured for deployment between a first bone and at least one second bone of a joint, the implant further comprising a balloon comprising a first portion that is configured to engage the first bone of the joint, a second portion that is configured to engage at least one second bone of the joint, a side portion connecting the first portion and the second portion, in which the side portion facilitates relative motion between the first portion and the second portion, and an interior that is optionally inflatable with a first inflation medium; and coupling a first appendage of the balloon to the first bone of the joint. In the case of a knee device, the first bone may be one of a tibia, a femur and a patella. In the case of a knee device, the second bone may be one of a tibia, a patella and a femur.

In some embodiments, at least two of first portion, the second portion, and the side portion are contiguous. In some embodiments, the first portion comprises a first wall, the second portion comprises a second wall, and the side portion comprises a side wall.

In some embodiments the method comprises providing an in-growth patch on at least one of the first portion configured to engage the first bone (e.g. a femur, a tibia, or a patella, in the case of the knee device), the second portion configured to engage the second bone, the side portion, and the appendage. The in-growth patch may be configured to encourage and/or promote tissue in-growth, such as bone in-growth, for non-limiting example. The patch may be as large as the portion itself (whether the first portion the second portion, the side portion, or the appendage) or may be smaller than the portion (such as in the shape of a strip or other shaped patch). The in-growth patch may comprise a surface irregularity or roughness. The in-growth patch may be Velcro-like. In some embodiments the implant comprises an in-growth patch on the first portion and/or the second portion, from (and in some embodiments including) a first appendage to a second appendage. In some embodiments, wherein the appendages loosen from attachment from the bone (by design and/or from wear and/or over time), the in-growth patch aids in securing the implant to the bone. In some embodiments, the in-growth patch comprises beads and/or bead-like elements attached to the implant. Such an in-growth patch may be configured to simulate trabecular bone space of a normally cancellous latticework. In some embodiments, the beads are sintered beads of various sizes. In some embodiments, the beads are sintered beads about 400 microns in size. With respect to bead size, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%. In some embodiments, the first bone and/or the second bone is roughened to acquire a bleeding bone to facilitate in-growth. In some embodiments, about 0.5 mm of cortical tissue is removed to facilitate in-growth.

In some embodiments, the method comprises coupling a second appendage of the balloon to the first bone of the joint. In some embodiments, the method comprises coupling a second appendage of the balloon to at least one second bone of the joint. In some embodiments, the method comprises coupling a second appendage of at least one of the first portion, the second portion, and the side portion to at least one of the first bone and at least one second bone of the joint. In some embodiments, coupling at least one of the first appendage and the second appendage provides ligamentary-like support to the first bone and at least one second bone of the joint. In some embodiments, coupling at least one of the first appendage and the second appendage provides ligamentary-like support to the joint. In some embodiments, the first appendage and the second appendage are configured to provide tendon-like support to the first bone and the at least one second bone of the joint. In some embodiments, the first appendage and the second appendage are configured to provide tendon-like support to the joint.

In some embodiments, the method comprises providing an inflation port in communication with the interior of the balloon for inflation of the interior of the balloon with the first inflation medium. In some embodiments, the method comprises using an inflation port of the implant that is in communication with the interior of the balloon to inflate the interior of the balloon with the first inflation medium. In some embodiments, the method comprises puncturing the balloon to inflate the interior of the balloon with the first inflation medium. In some embodiments, the method comprises providing a balloon having self-sealing capability. In some embodiments, the method comprises providing a balloon having self-sealing capability upon inflation of the interior of the balloon with the first inflation medium. In some embodiments, the method comprises providing a balloon comprising a seal capable of closing the interior of the balloon.

In some embodiments, the method comprises providing a balloon having an interior comprising a plurality of inflatable chambers. In some embodiments, the interior comprises a plurality of individually inflatable chambers. In some embodiments, the method comprises inflating a first chamber of the plurality of inflatable chambers with a first inflation medium. In some embodiments, the first chamber and the inflation medium is selected based on the particular needs of the patient. For non-limiting example, if the patient has bone loss due to an injury, the chamber may be selected at the location of the missing bone, and may be filled with a rigid inflation medium (or one that becomes rigid once in the chamber) in order to replace the missing and/or damaged bone. Alternatively, or in addition, a chamber may be chosen to restore alignment of the joint, and inflated with an appropriate inflation medium to impart both alignment and cushion to the joint. In some embodiments, the method comprises inflating a second chamber of the plurality of individually inflatable chambers with a second inflation medium.

In some embodiments, the balloon is a composite structure. In some embodiments, the balloon comprises layers of porous and/or non-porous materials, or otherwise contains treatment or cell regeneration agents. In some embodiments, a first layer of the balloon is a thin, but strong layer of a thermoplastic, such as a thermoplastic polyurethane, for non-limiting example, which has microporosity sufficient to allow passage or egress of treatment or cell regeneration agents from a second layer. The second layer may be a central layer (which lies between the first layer and a third layer or a fourth layer or more layers). The first layer may comprise a bone engaging surface in some embodiments. The degree of microporosity to enable egress of treatment or cell regeneration agents from the second layer is found in polymer layers such as Chronoflex (e.g., ChronoFlexAR®, ChronoFlex AL®, ChronoFlec C®) or BIONATE (e.g., BIONATE I, BIONATE II, BIONATE 55D, BIONATE 65D, BIONATE 75D, BIONATE 80A, BIONATE 90A, BIONATE 55 or BIONATE 80). The bone engaging surface of the implant may be coated and/or impregnated with a latticework of polymer that is surface sprayed or layered on the

bone engaging surface of the implant to promote cartilage tissue regeneration. This bone engaging surface coating may contain living chondrocytes (for example, as is provided in the Carticel procedure by the Genzyme company), and/or may contain stem cells with directed gene mutations to enhance adherence of the coating to the implant. The bone engaging surface may comprise peaks and troughs. The living cells may be provided in troughs while the surface peaks may be used for at least one of: space validation, traction, and cell protection.

In some embodiments, the first inflation medium imparts rigidity in the implant. In some embodiments, the first inflation medium imparts cushion in the implant. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium aligns the joint. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium aligns the bones of the joint. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium changes the bone alignment. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium improves joint alignment. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium restores, at least in part, joint alignment. In some embodiments, individual chambers of the interior are selectively inflated with a first inflation medium and/or a second inflation medium. In some embodiments, individual chambers of the interior are selectively inflated with a first inflation medium and/or a second inflation medium in order to reconstruct the joint and/or in order to reconstruct bones of the joint.

Over time, in-growth of repair tissue aids in fixation and stability externally to the implant, while the soft cushioning implant interior may absorb forces across the joint surfaces and permit proper motion. The turgor or wall tension of the implant as well as the inside distension of the implant per se can be adjusted by adding or removing the inflation substance to the implant's interior space.

Accordingly, the present invention provides a new approach to arthroplasty that involves a resilient implant deployed between bones of the knee joint. In some instances, a joint is comprised of the interface between (a) a first bone and a first cartilage; and (b) a second bone and a second cartilage, wherein the first cartilage is separated from the second cartilage by a space (e.g., joint space) and the cushion expands to fit the joint space. In some instances, where the first cartilage and/or second cartilage is damaged or absent, the cushion expands to fit the joint space between the first bone and second cartilage or the first bone and second bone. In certain joint spaces such as the knee, the cushion expands to fit the spaces of the "knee joint" or "knee joints". For example, the cushion may expand to fit the spaces of the femoral tibial involved on standing or walking on a level plane, and the cushion may expand to fit the spaces of the patella femoral bones of the knee more involved on stair ascent and descent. For example, pressures behind the knee cap or patella when lying are zero, when standing are 0.7 times body weight, and when going up and down the patella femoral pressures are 3-4 times body weight. Thus, in some instances, the implants accommodate some or all of the normal body functional pressures and complex space movements, as described above, and can also be used in other joints such as the elbow, ankle, or hip. When in the hip joint, the normal flexion up to 120 degrees, extension of 20 degrees, abduction of 50 degrees, internal and external rotation of 45 degrees may produce variable axial, shear, and cyclic loads which the implant by design may accommodate and endure as up to 6 times body weight, consistent with a tire on a car that allows for cyclic loads different when driving straight or turning corners. The implant embodying features of the present invention provides more physiologic motion and shock absorption within the joint and has combined characteristics of anatomic design symmetry, balanced rigidity with sufficient attachment connections to adjacent normal structures, and durability that meet the needs of joint reconstruction.

The opposing internal surfaces of the first and second walls of the invention may either move together in synchrony or in opposite directions from one another (e.g. the superior wall moving medially in the hip and the inferior wall moving laterally). Optionally, the implant may be fixed to a concave surface of the joint (e.g., the acetabular hip cup) or to a convex surface of the joint (e.g. the dorsal femoral head surface), to both, or to neither (e.g., having an interference fit within the joint with an expanding balloon or cushion that fills the existing space). The implant may be inserted arthroscopically like a deflated balloon and then inflated through a cannula into the ankle or hip (or other joint structure) to act as a cushion or renewed interface for painless and stable limb motion. When feasible, joint capsular and adjacent ligament tissue as well as bone may be left in place to preserve the natural body, unless interfering with reconstructed limb function.

The application of steam in addition to removing damaged debris, can smooth out and reform the joint surface. The high temperature of the steam tends to weld cracks or fissures which can be present in the cartilage surface of a damaged joint. Smoothing of joint surface cartilage with steam welds or seals existing cracks or flaps in the cartilage, especially superficially as the lamina splendors, which melt together to provide a white shiny gliding joint surface. In cases where bone is exposed, the steam can be used to stabilize the periphery of the defect in the joint surface via capsulorrhaphy or joint tightening. Open mechanical and chemical debridement may also be employed to prepare the surfaces for the implant.

Once the implant is secured to the femur by means of the skirt or tabs or using other couplers, an impregnated transfer medium or cell template may be used, as described by Histogenics and Tygenix chondrocytes delivery systems wherein the position of concentrated cells is mechanically placed about the implant at areas of greatest cartilage damage to promote regrowth, or as in Carticel wherein watery cells are implanted beneath a periosteal membrane (a wall of the implant serving as the membrane), prior to completion of the inflation or expansion of the implant. A syringe or gauged device with measured screw-home pressure is used to inflate the implant.

Once the joint is ready to receive the implant, the deflated implant is advanced through the diaphragm of a delivery cannula (such as the Acufex from Smith & Nephew) or through the open incision site into the joint. It can be inflated by the attached cannula using a common syringe, inserting several cc's of filler material. Inserted contents and locations of cell placements depend on areas of need and joint size. In

some embodiments of the methods several cc's of filler material and a viscolubricant in the interior of the implant allows distension, cushioning, and gliding movements. Cell regeneration agents are placed in the areas of greatest need.

Methods of living cell (e.g., stem cell, differentiated cell, pluripotent cell, post-mitotic cell) or chondrocyte placement depend on the lesions and specific implant construct. Direct infusion into the joint with completion of implant inflation may press the cells into the hyaline surface, whereupon they attach within the first 24 hours. As a result, the patient may be forced to remain sedentary and the joint where the implant is deployed, non-weight bearing for the first day after surgery. Deeper osteochondral defects can be treated by 'hyper-perfusion of cells' via either 3-D cell transfer templates, or microneedle injection as used in treatment of diabetic patients for blood sugar testing and insulin/transdermal drug delivery. In cases of osteochondritis dissecans or localized both cartilage and bone lose, bone graft may be packed into the base of the defect followed by addition of a cell/tissue application. The cannula attached to the implant may be sealed and detached, or left in place for periodic aspiration of noxious enzymes as for the Cox-1, Cox-2, and 5-Lox systems, followed by reinsertion of activated substances including viscolubricants, or even more cells (e.g., stem cells, differentiated cells, pluripotent cells, post-mitotic cells).

Implants embodying features of the invention may be designed for permanent or temporary deployment within a joint structure. Moreover, the implant may be formed of suitable bioabsorbable materials so that the implant may be absorbed within a particular predetermined time frame. Suitable bioabsorbable materials include polylactic acid, polyglycolic acid, polycaprolactone, copolymers, blends and variants thereof. One present method of forming the implant is to apply numerous layers of polymer such as ChronoFlex (e.g., ChronoFlexAR®, ChronoFlex AL®, ChronoFlec C®), ChronoPrene™, ChronoSil®, ChronoThane P™, ChronoThane T™, HydroMed™, HydroThane™, or PolyBlend™ in a solvent and evaporating the solvent after applying each layer.

The coupling aspects (couplers) including but not limited to skirting or fixation tabs of the present implant prevent joint migration during use.

In some embodiments, the implant is adapted to restore natural joint function. In some embodiments, the implant is adapted to preserve viable joint tissue. In some embodiments, the implant is adapted to be placed with minimal surgery as compared to joint replacement therapy currently marketed. In some embodiments, the implant is adapted to permit weight bearing post surgery within at least one of: about 1 week, within about 1 day, within about 2 days, within about 3 days, within about 4 days, within about 5 days, within about 6 days, within about 10 days, within about 2 weeks, within about 3 weeks, within about 4 weeks, within about 5 weeks, within about 6 weeks. In some embodiments, the implant is adapted to permit weight bearing post surgery after about 1 day wherein full weight bearing is allowed in about 6 weeks. As used herein with respect to weight bearing timing, the term "about" can be a range of 1 day, 2 days, or 3 days, in some embodiments. In some embodiments, the implant is adapted to allow for faster recovery and resumption of normal activities as compared to joint replacement therapy currently marketed.

In some embodiments, the balloon (or a portion thereof) is adapted to conform to the patient's anatomy. In some embodiments, the implant (or a portion thereof) is adapted to conform to the patient's anatomy. In some embodiments, the inflation medium is adapted to absorb a force (or forces) exerted on the joint. In some embodiments, the inflation medium is adapted to absorb a force (or forces) exerted on the bones of the joint. In some embodiments, the inflation medium is adapted to absorb a force (or forces) exerted on at least one bone of the joint. In some embodiments, the balloon is adapted to absorb shocks exerted on at least one of a bone, multiple bones, a ligament of the joint, ligaments of the joint, a tendon of the joint, tendons of the joint, and the joint in general. In some embodiments, the implant is adapted to restore natural cartilage cushion with cells (e.g., stem cells, differentiated cells, pluripotent cells, post-mitotic cells). In some embodiments, the implant is adapted to restore natural cartilage cushion with stem cells.

In some embodiments, the balloon (or a portion thereof) is adapted to renew joint space. In some embodiments, the balloon (or a portion thereof) is adapted to reduce pain as compared to the pain felt prior to the implantation of the implant. In some embodiments, the balloon (or a portion thereof) is adapted to restore joint function. In some embodiments, the implant (or a portion thereof) is adapted to renew joint space. In some embodiments, the implant (or a portion thereof) is adapted to reduce pain as compared to the pain felt prior to the implantation of the implant. In some embodiments, the implant (or a portion thereof) is adapted to restore joint function.

In some embodiments, the implant is adapted to reverse arthritis in the joint. In some embodiments, the implant is adapted to prevent, reduce, or ameliorate arthritis in the joint. In some embodiments, the implant is adapted to reduce pain associated with arthritis in the joint.

In some embodiments, the balloon (or a portion thereof) is adapted to be placed into a debrided limb joint arthroscopically. In some embodiments, the balloon is adapted to pad cartilage defects. In some embodiments, the balloon is inflated to cushion the joint. In some embodiments the implant is adapted to deliver stem cells to at least one of the joint and a bone of the joint. In some embodiments the implant is adapted to deliver living chondrocytes to at least one of the joint and a bone of the joint. In some embodiments, the implant is adapted to deliver cells to at least one of the joint and a bone of the joint. In some embodiments, the cells are at least one of stem cells, differentiated cells, pluripotent cells, and post-mitotic cells. In some embodiments, the implant is adapted to provide a new articular surface for the joint. In some embodiments, the implant is adapted to act as a spacer in the joint. In some embodiments, the implant is adapted to space the bones of the joint apart for proper joint articulation. In some embodiments, the implant is adapted to space the bones of the joint apart for reduced bone-on-bone rubbing.

In some embodiments, the implant is configured to at least one of: pad cartilage, cushion the joint, deliver a pharmacologic substance, remove noxious enzymes, debride upon implantation, debride the joint following implantation, deliver a therapeutic substance, deliver a biologic substance, and deliver living stem cells. In some embodiments, the implant is configured to deliver a chemotherapeutic agent to a bone or other surrounding tissues. In some embodiments, the implant is configured to deliver an anti-infectious medication to a bone or other surrounding tissues. In some embodiments, the implant is configured to deliver at least one of an antibiotic, antifungals, and analgesics agent.

In some embodiments, the implant is configured to be selectively inflated to realign limbs.

Provided herein is a method comprising: implanting a knee implant as described herein into a subject, wherein the

implant reverses arthritis in the subject. Provided herein is a method comprising: implanting a knee implant as described herein into a subject, wherein the implant prevents, reduces, or ameliorates arthritis in the subject. Provided herein is a method comprising: implanting a knee implant as described herein into a subject, wherein the implant reduces pain associated with arthritis in the subject.

Provided herein is a method comprising: implanting a knee implant as described herein into a knee joint of a subject and treating a component of the knee joint of the subject with at least one of an allograph tissue, an autograph tissue, and an xenograph tissue. In some embodiments, the tissue comprises a cell. In some embodiments, the tissue comprises a plurality of cells. In some embodiments, the cell is a stem cell, differentiated cell, pluripotent cell, or post-mitotic cell. In some embodiments, the implanting step is at least one of: prior to the treating step, simultaneous with the treating step, and following the treating step.

Provided herein is a method comprising: implanting a knee implant as described herein into a subject, wherein the implant is configured to at least one of: restore joint function and control arthopathies. In some embodiments, the implanting spares existing anatomy.

Provided herein is a method comprising: debriding a femur condyle of a knee joint of a subject, and implanting a knee implant as described herein into the knee joint of the subject, whereby the implant is configured to anneal to the cartilage of the subject. In some embodiments, the debriding is achieved by steam application.

Provided herein is a method comprising implanting a knee implant as described herein into a joint previously treated with a joint replacement. In some embodiments, the method comprises removing the joint replacement prior to implanting the knee implant. In some embodiments, the method comprises clearing infectious matter from the joint and/or surrounding tissues. In some embodiments, the method comprises implanting a second implant of any implant described herein following removing the implant previously implanted in the joint. In some embodiments, the method comprises replacing the joint of the subject following removing the implant previously implanted in the joint. In some embodiments, the method comprises debriding the bone of the joint, and implanting an implant of any implant described herein. In some embodiments, the method comprises repeating the debriding and implanting steps.

The surgical techniques may be individualized to fit patient need. The implants may be combined with or comprise autologous or allograph tissues such as fascia lata. Surgeons may implant fascia lata above unreconstructable rotator cuff with consequent symptom relief Polymers can interface with any human tissue and/or with metals or polyethylenes or polyurethanes. Living tissues that can be combined with implants provided herein for repair or reconstruction may be from the same patient (autograph), and cadaver or other member of the same species (allograph) or from another species (xenograph.) Virtually any combination of polymer interpositioning is feasible with the implant concepts provided herein, as anatomy varies among patients in need, and clinical conditions differ with each person. Therefore, although the general or most common construct is expected to cover just one singular and the primary surface of a joint with an implant, any combination of surfaces can be involved allowing versatile custom applications of this implant and method of surgery.

Additionally, whereas implants may be available in specified sizes, the material membrane elastic deformation and resilience may allow for calculated malleability toward goodness of fit. In other iterations the fit of implant over the affected joint surface can be customized as paring preoperative findings of MRI or CT or PET imaging pathophysiology with intraoperative reconstructive need. Ultimately best fit implants may serve patient restorative requirement with least morbidity.

The implants may be implanted typically during an outpatient surgery, wherein the joint is first arthroscopically debrided and cartilage prepared, similar to the methods used in a Carticel procedure. Cartilage or osteochondral size defects and alignment problems are studied, and measurements taken. Considerations to materials stretch are acknowledged as polyurethanes gain 50% pliability with 100 hours exposure to serum, and 30% additional malleability by heating to 37 degrees C. Thus, implant presentation in the OR may aim for best fit and accommodate patient need.

Intraoperative hyaline cartilage biopsy acquiring e.g. 400 mg of normal hyaline articular tissue from the intercondylar notch (as would be wasted with notchplasty) or from the joint periphery (outside articulating regions) may allow for chondrocytes autologous acquisition. Currently such specimens may be sent to Genzyme Corp. for 2-4 weeks cloning of cells whereupon 2-3 bottles containing e.g. 1 cc of cells, 93% viability, 12 million cells per bottle, are delivered on an exact day to the operating room for placement in the Carticel cartilage regenerative procedure securing the liquid cells beneath a harvested periosteal membrane. In implant surgery contemplated in certain embodiments, the polymer may substitute for the periosteum thus reducing surgical morbidity markedly and changing an otherwise major open procedure into an arthroscopically facilitated outpatient treatment option through a small arthrotomy.

With outpatient surgeries the intraoperative biopsy may be given to the technician in the operating room in early surgery, for insertion into the stem cells generation machine. In 30-40 minutes living autologous chondrocytes may be 'spun down' and separated, then returning the living cells to the primary surgeon. By this time, the implant has been pulled up over the prepared defects and sufficient fixation sites have been locked into place so that the implant is secure in its general location over the distal femoral surface, for example. An unattached portion of the implant is lifted, the newly procured cells inserted potentially on a soft matrix to hold cells inside the prepared defect, and the implantation is completed sealing the living cells for the purpose of articular surface regeneration. After 24 hours the cells are fixed as the aggregate to the surface of the defect into which they were introduced. This begins a one year period of regrowth of the new joint surface. Concurrently the arthritis osteochondral defect so treated is padded by the implant, and the joint cushioned is mechanically restored. Said cushioning is by nano and/or macro inflation and/or by use of polymers with variable compliance. Immediate fixation and the opportunity for a regenerated joint are thus accomplished in the operating room. This may use either the implant matched to size by preoperative planning via X-rays considering the magnification factors, by using one of the other scanning methods available, or by custom generation ultimately of implant partial or entire coverage options in the same surgery.

Once the implant is secured circumferentially and solidly in place with multiple fixation sites verified as patent, one or two forms of orthobiologic activity proceed. Specifically, if chondrocytes were implanted (autologous or potentially allograph) they may mature and in the course of a year the durometry may come to resemble normal hyaline articular cartilage. The other biologic activity promoted during

implantation surgery is the bone in-growth onto the tab undersurface and/or periphery. This fixation at the secondary level in proposed to decrease the probability of loosening of the prosthetic implant, one of the two most common causes of implant failure. With the normal 10,000 steps people take per day during normal gait, or 2-4 million cycles per annum, the compressive and shear forces, and cyclic loads can cause micromotion between the implant and natural underlying tissue. This may lead to implant shift, dislocation, and/or hardware backing out if not appropriately secured to the bones. In the implant technique the immediate fixation is achieved through multiple robust circumferential fixation of implant tabs to bone. Each screw and washer secures the mechanically adequate implant tab to bone at over 300 pounds force to failure. Since, depending on the embodiment, there may be ten (10) tab sites intended the sum of 3000 pounds. In some embodiments, fixation comprises bone in-growth. In some embodiments, the fixation comprises bone in-growth as described in Vasanji A, In vivo bone growth assessment in preclinical studies and clinical trials, Bonezone, 2012, p. 12-17, herein incorporated by reference in its entirety.

The methods of surgery may have certain constants and other variables mandated by materials and fixation management versus altering anatomies and joint forces. In each joint a standardized implant method of surgery may be recommended with variations to be determined by the responsible surgeon.

While particular forms of the invention have been illustrated and described herein, it will be apparent that various modifications and improvements can be made to the invention. One alternative implant construction involves the use of an upper portion of the implant having a net-like construction and filled with balls or ball bearing like elements that are larger than the openings in the netting. The balls or ball bearing like elements provide motion to the implant. The netting and ball bearing like elements may include regeneration agents as previously discussed, and the bearing construction may be directed toward favorable implant movement balanced with content disbursement.

The invention is intended primarily for human use but may be extended to mammalian use. Examples of mammals include, but are not limited to, cats, dogs, sheep, horses, pigs, goats, cows, mice, and rats. To the extent not otherwise disclosed herein, materials and structure may be of conventional design.

Moreover, individual features of embodiments of the invention may be shown in some drawings and not in others, but those skilled in the art will recognize that individual features of one embodiment of the invention can be utilized in another embodiment. Moreover, individual features of one embodiment may be combined with any or all the features of another embodiment. Accordingly, it is not intended that the invention be limited to the specific embodiments illustrated. It is therefore intended that this invention be defined by the scope of the appended claims as broadly as the prior art will permit.

Terms such as "element", "member", "component", "device", "means", "portion", "section", "steps" and words of similar import when used herein shall not be construed as invoking the provisions of 35 U.S.C §112(6) unless the following claims expressly use the terms "means for" or "step for" followed by a particular function without reference to a specific structure or a specific action. All patents and all patent applications referred to above are hereby incorporated by reference in their entirety.

While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

What is claimed is:

1. An implant configured for deployment between a femur and a tibia of a knee joint, the implant comprising

a first portion that is configured to directly engage a medial condyle and a lateral condyle of the femur of the knee joint,

a second portion that is configured to directly engage the tibia of the knee joint,

a first appendage configured to couple the first portion to a first condyle of the femur of the knee joint, the first appendage having a pre-set curvature configured to simulate curvature of the first condyle,

a second appendage configured to couple the first portion to a second condyle of the femur of the knee joint, the second appendage having a pre-set curvature configured to simulate curvature of the second condyle,

a slot between the first appendage and the second appendage, and

a cushioning element within the implant configured to provide a cushion for the femur and tibia, the cushioning element comprising a mesh sheet or inflatable chamber, and

wherein the first portion, the second portion, the first appendage, and the second appendage together comprise a single contiguous polymer sheet.

2. The implant of claim **1**, wherein the second appendage further couples the first portion to the tibia of the joint.

3. The implant of claim **1**, further comprising an in-growth matrix on at least a portion of the implant adjacent the femur.

4. The implant of claim **3**, wherein the in-growth matrix comprises living chondrocytes.

5. The implant of claim **4**, wherein the implant is configured to release the chondrocytes over time.

6. The implant of claim **4**, wherein the polymer is configured to release the chondrocytes over time.

7. The implant of claim **4**, wherein the polymer is configured to release the chondrocytes over time, and wherein the polymer is not bioabsorbable.

8. The implant of claim **4**, wherein the in-growth matrix comprises at least one of: autologous cells, allograph cells, and xenograph cells to restore an articular surface of the femur.

9. The implant of claim **4**, wherein the in-growth matrix comprises at least one of: autologous cells, allograph cells, and xenograph cells to repair an articular surface of the femur.

10. The implant claim **1**, further comprising a bioabsorbable coupler.

11. The implant of claim **1**, wherein the coupler is at least one of: a screw, a washer, a suture, a suture anchor, a snap, a rivet, a staple, a staple having teeth, a stabilizer, a glue, a hook, a wire, a string, a lasso, a lanyard, a spike, and combinations thereof.

12. The implant of claim 1, further comprising a pharmacologic agent.

13. The implant claim 12, wherein the pharmacologic agent is on a surface of the implant adjacent the femur.

14. The implant claim 12, wherein the pharmacologic agent is released from the implant over time.

15. The implant of claim 1, wherein at least a portion of the implant is configured to anneal to a periphery of a cartilage defect.

16. The implant of claim 1, wherein the implant comprises vacuoles of pharmacologic substances.

17. The implant of claim 1, wherein the single contiguous polymer sheet is configured so that there is no separation between the first portion and the second portion.

18. The implant of claim 1, wherein the cushioning element is an inflatable chamber.

19. The implant of claim 1, wherein the single contiguous polymer sheet is configured to be the only device implanted in the knee joint having at least one surface configured to directly slidably engage an opposing bone surface.

20. The implant of claim 19, wherein the opposing bone surface is located on the tibia of the knee joint.

21. The implant of claim 1, wherein the cushioning element is a mesh sheet.

22. An implant configured for deployment between a femur and a patella of a knee joint, the implant comprising

a first portion that is configured to directly engage at a trochlear groove of the femur of the knee joint,

a second portion that is configured to directly engage the patella of the knee joint,

a first appendage configured to couple the first portion to a first condyle of the femur of the knee joint, the first appendage having a pre-set curvature configured to simulate curvature of the first condyle,

a second appendage configured to couple the first portion to a second condyle of the femur of the knee joint, the second appendage having a pre-set curvature configured to simulate curvature of the second condyle, and

a slot between the first appendage and the second appendage, and

a cushioning element within the implant configured to cushion the femur and patella the cushioning element comprising a mesh sheet or inflatable chamber, and

wherein the first portion, the second portion, the first appendage, and the second appendage together comprise a single contiguous polymer sheet.

23. The implant of claim 22, wherein the single contiguous polymer sheet is configured to be the only device implanted in the knee joint having at least one surface configured to directly slidably engage an opposing bone surface.

24. The implant of claim 23, wherein the opposing bone surface is located on the patella of the knee joint.

25. An implant configured for deployment between a tibia and a patella of a knee joint, the implant comprising

a first portion that is configured to directly engage at the tibia of the knee joint,

a second portion that is configured to directly engage the patella of the knee joint,

a first appendage configured to couple the first portion to a first condyle of the tibia of the knee joint, the first appendage having a pre-set curvature configured to simulate curvature of the first condyle,

a second appendage configured to couple the first portion to a second condyle of the tibia of the knee joint, the second appendage having a pre-set curvature configured to simulate curvature of the second condyle, and

a slot between the first appendage and the second appendage, and

a cushioning element within the implant configured to cushion the tibia and patella the cushioning element comprising a mesh sheet or inflatable chamber, and

wherein the first portion, the second portion, the first appendage, and the second appendage together comprise a single contiguous polymer sheet.

26. The implant of claim 25, wherein the single contiguous polymer sheet is configured to be the only device implanted in the knee joint having at least one surface configured to directly slidably engage an opposing bone surface.

27. The implant of claim 26, wherein the opposing bone surface is located on the patella of the knee joint.

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(12) **United States Patent**
Grotz

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(54) **RESILIENT ARTHROPLASTY DEVICE**

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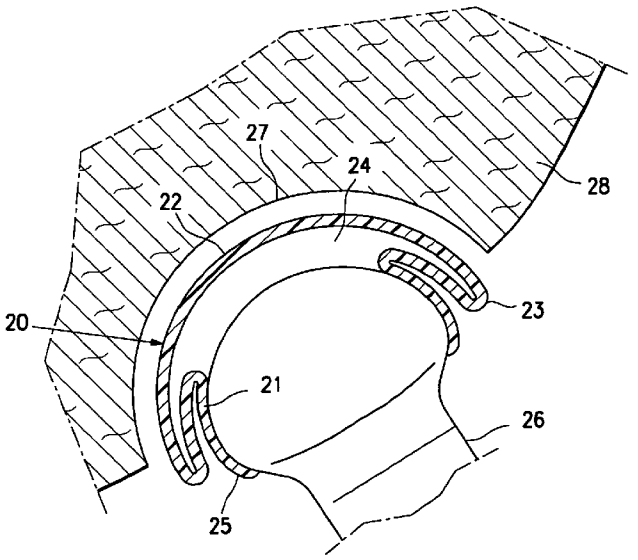
(57) **ABSTRACT**

The disclosure is directed to a resilient implant for implantation into human or animal joints to act as a cushion allowing for renewed joint motion. The implant endures variable joint forces and cyclic loads while reducing pain and improving function after injury or disease to repair, reconstruct, and regenerate joint integrity. The implant is deployed in a prepared debrided joint space, secured to at least one of the joint bones and expanded in the space, molding to surrounding structures with sufficient stability to avoid extrusion or dislocation. The implant has opposing walls that move in varied directions, and an inner space filled with suitable filler to accommodate motions which mimic or approximate normal joint motion. The implant pads the damaged joint surfaces, restores cushioning immediately and may be employed to restore cartilage to normal by delivering regenerative cells.

25 Claims, 9 Drawing Sheets



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See application file for complete search history.

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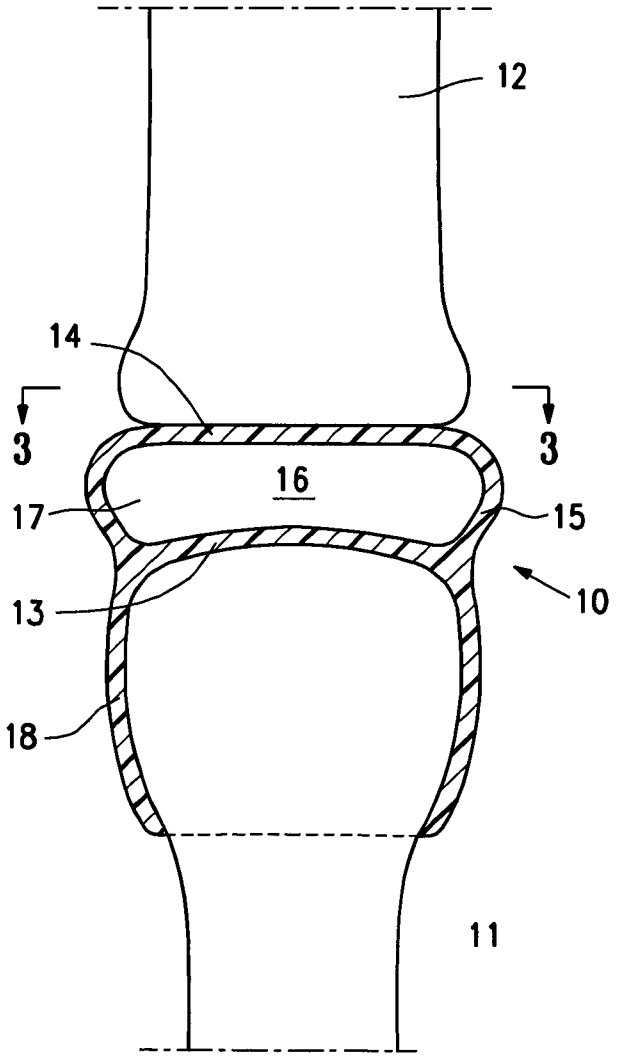


FIG. 1

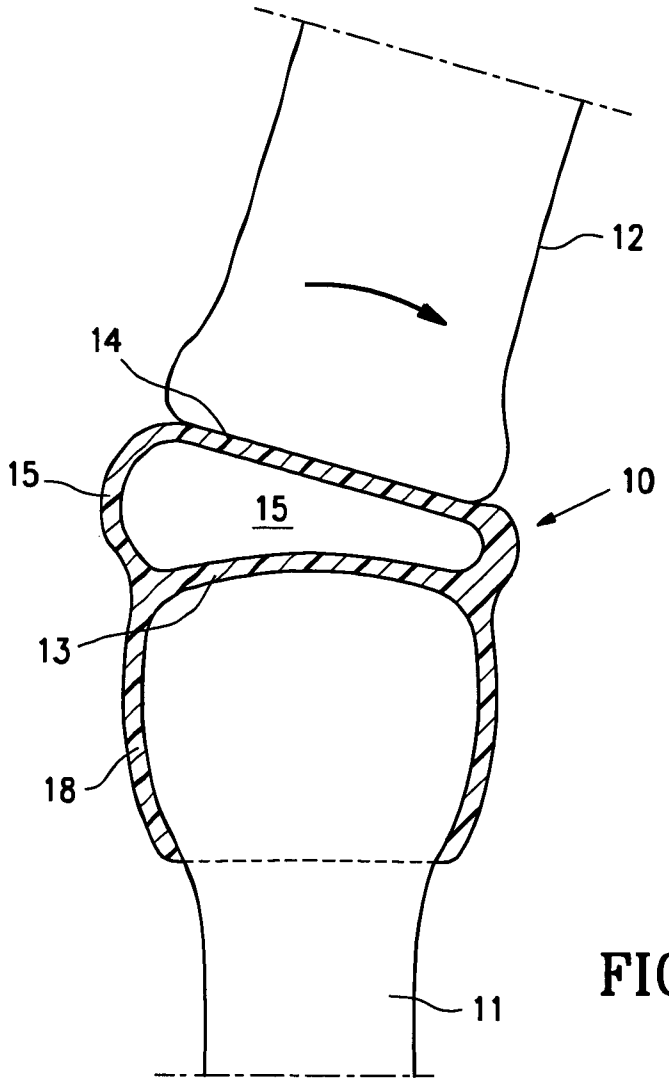


FIG. 2

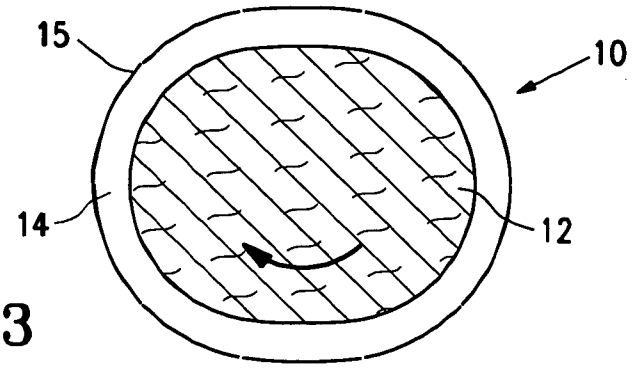


FIG. 3

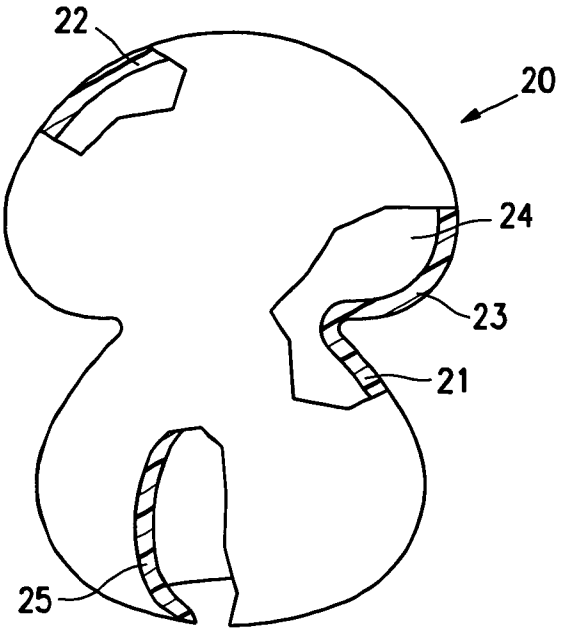


FIG. 4

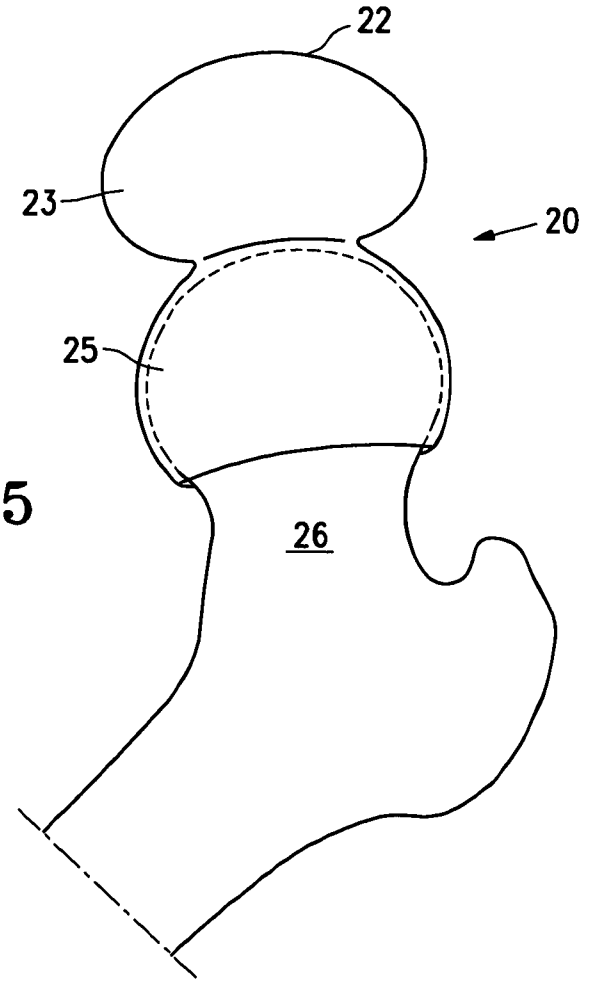
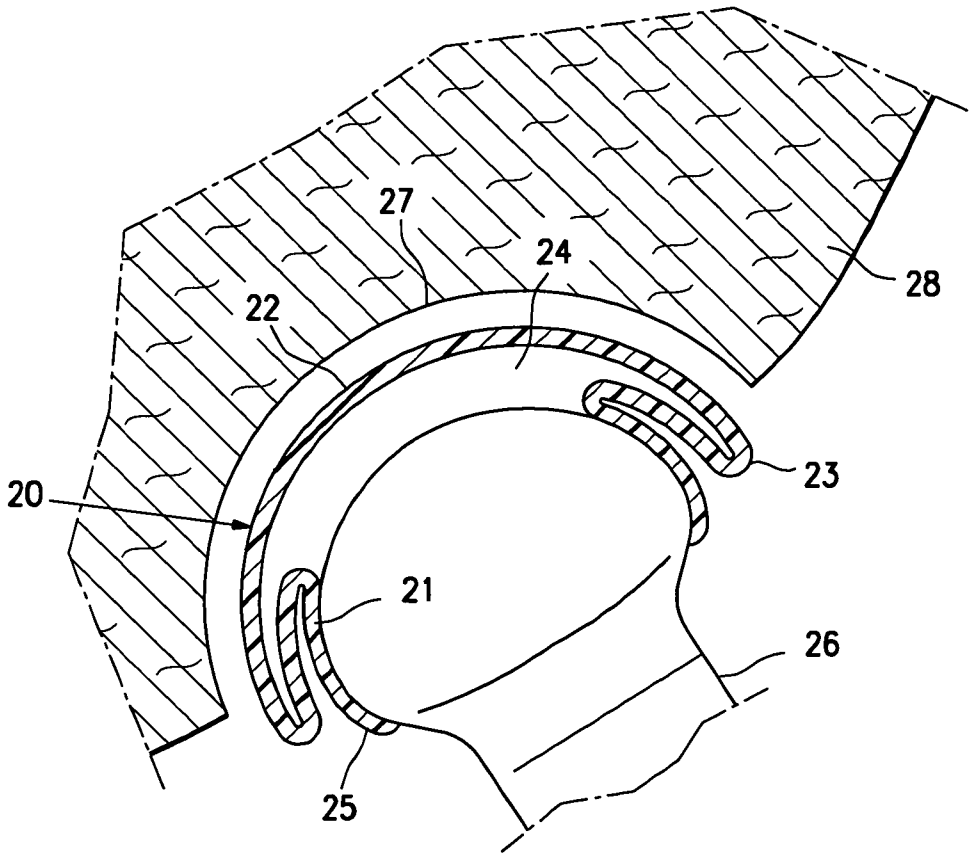


FIG. 5



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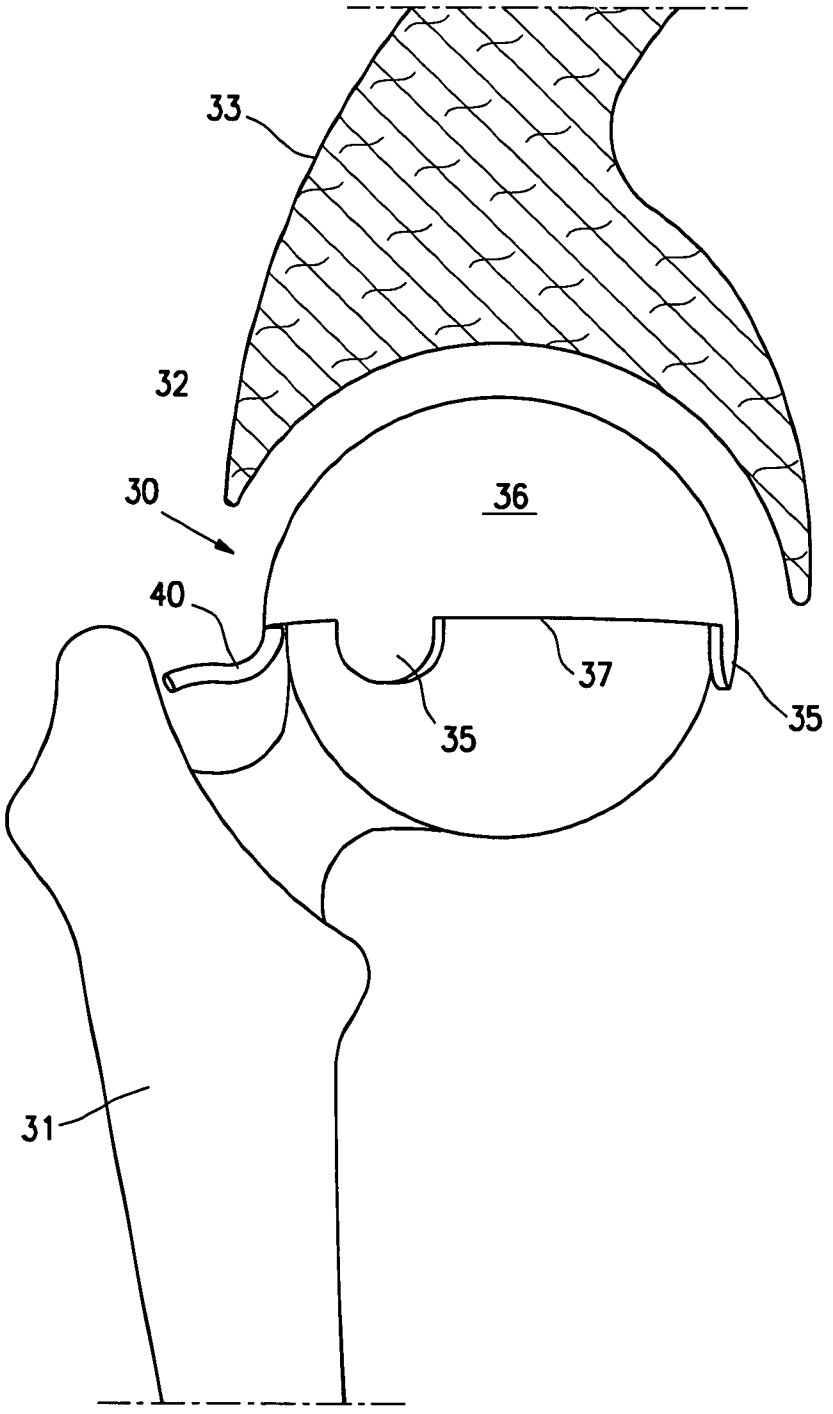

FIG. 7

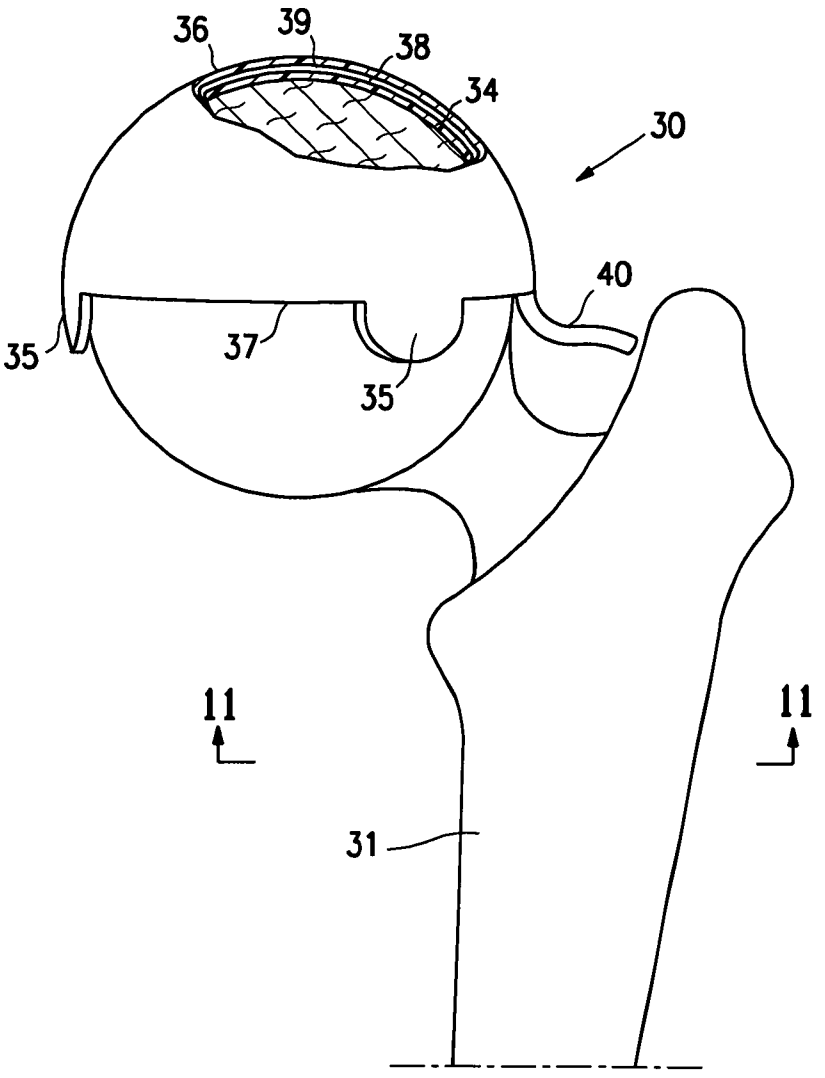

FIG. 8

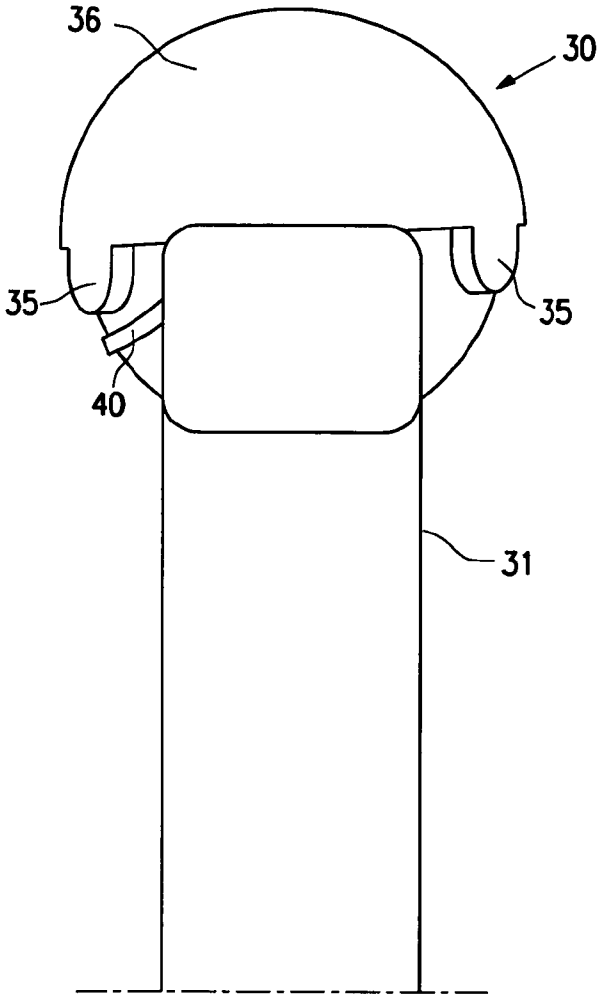

FIG. 9

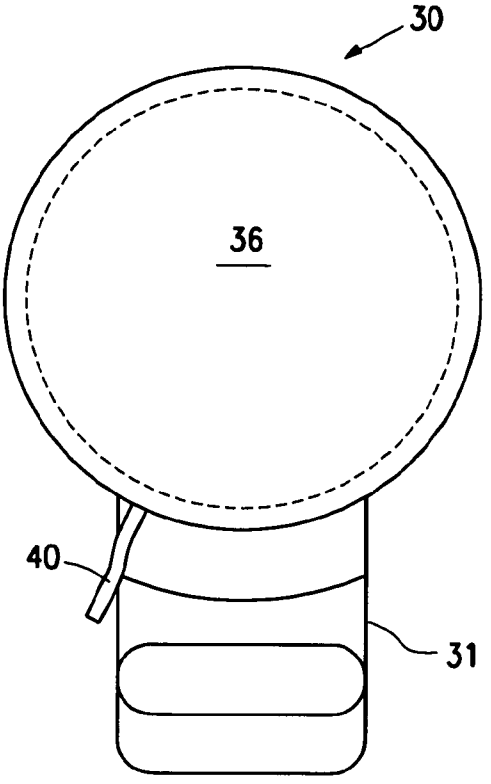

FIG.10

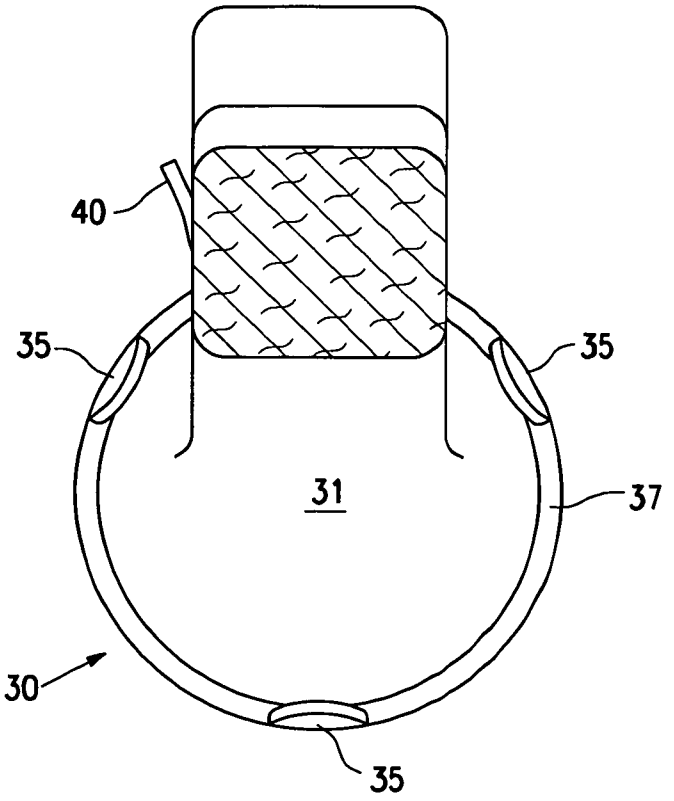

FIG. 11

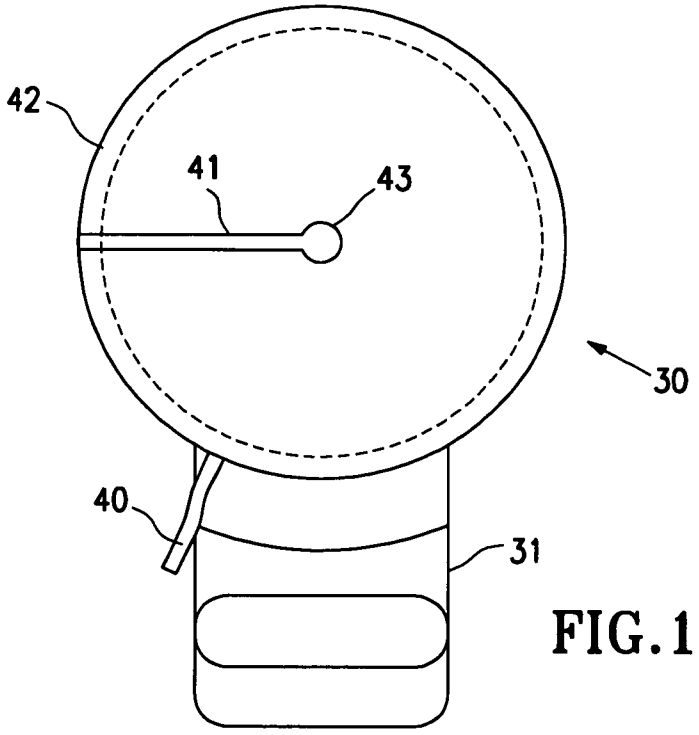

FIG. 12

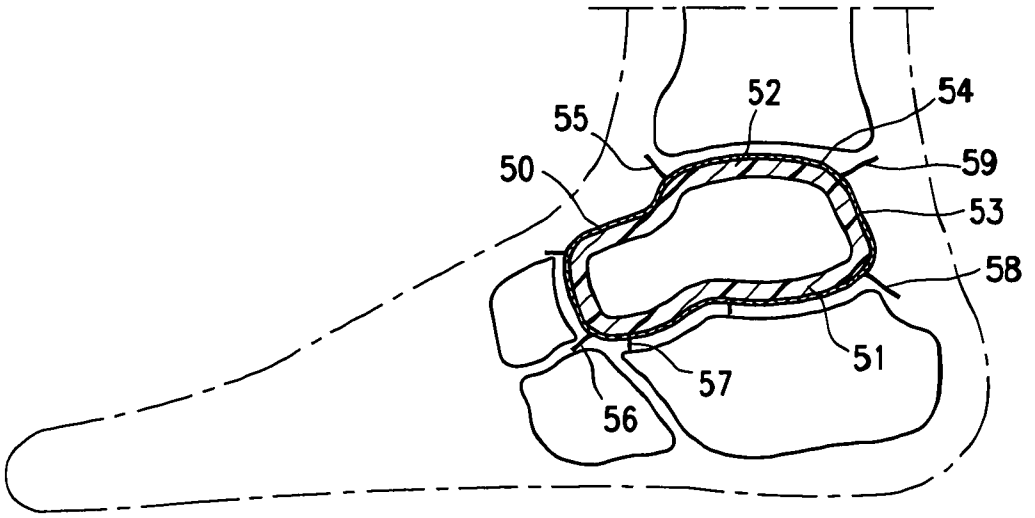

FIG. 13

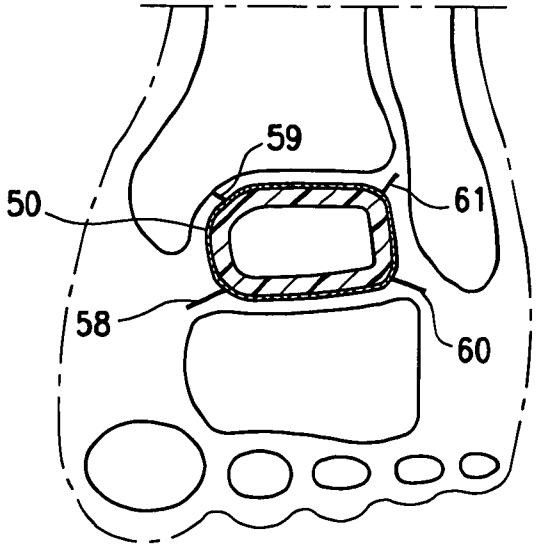

FIG. 14

RESILIENT ARTHROPLASTY DEVICE

RELATED APPLICATIONS

This application is related to provisional application Ser. No. 61/135,820, filed on Jul. 24, 2008, which is incorporated herein in its entirety and which is relied upon for priority.

BACKGROUND OF THE INVENTION

This invention relates to arthroplasty, and more particularly, to an implant for use in arthroplasty. When hyaline articular cartilage is damaged, it breaks down and joint space is lost. Inflammatory enzymes such as from the Cox-1, Cox-2 and/or 5-Lox systems, are released and loose bodies form adding to the degradation of joint function. Such joint damage is conventionally treated by physical therapy, analgesics, pain medication and injections. When these treatments fail, the traditionally accepted treatment option is arthroplasty implantation or replacing the joint with an artificial joint construct. Current arthroplasty techniques typically use "plastic and metal" implants that are rigid and which ultimately fail due to loosening or infection. Conventional materials for the artificial joint components include chrome-cobalt-molybdenum alloy (metal) and high molecular weight polyethylene (plastic). Each is often fixed by a cement-like mixture of methyl methacrylate to the ends of the bones that define the joint that is the subject of the arthroplasty, or coated with a surface that enables bone ingrowth. Current hip joint replacements typically last about 10-15 years and knee replacements typically last about 5-10 years. Ankle joint replacements, on the other hand, are not very successful, and often fail in the first several years after surgery.

Conditions requiring arthroplasty include traumatic arthritis, osteoarthritis, rheumatoid arthritis, osteonecrosis, and failed surgical procedures.

SUMMARY OF THE INVENTION

The present invention is directed to an orthopedic implant configured for deployment between opposing members of a joint structure that addresses many of the shortcomings of prior artificial joints. The arthroplasty implants embodying features of the invention are configured to preserve joint motions while removing the pain and dysfunction following the development of arthritis or joint injury. The arthroplasty implant in accordance with the present invention achieves improved physiologic motion and shock absorption during gait and acts as a resilient spacer between moving bones during limb movement. The combined characteristics of the implant include anatomic design symmetry, balanced rigidity with variable attachment connections to at least one of adjacent normal structures, and durability which addresses and meets the needs for repair or reconstruction thus far missed in the prior art. The implant should be secured to at least one of the bones of the joint structure.

More specifically, the resilient implant embodying features of the invention has a first wall configured to be secured to a first bone of the joint structure by one or more appendages such as a skirt or one or more tabs and a second wall configured to engage a second and usually opposing bone of the joint structure. A side wall extends between the first and second walls of the implant and together with the first and second walls preferably defines at least in part an inner chamber or space between the first and second walls. The implant is configured to provide linear or curvilinear

and/or rotational motion between the first and second bones which mimics or approximates the natural motion between these bones. The inner chamber or space is configured to maintain a filler material therein such as an inflation fluid or a resilient material and preferably to maintain spacing and provide support between the interior of the first and second walls to avoid significant contact therebetween. The walls of the implant are preferably sealed about the periphery thereof to maintain the interior chamber in a sealed condition to avoid loss of inflation fluid or filling media. The side wall or walls may be formed from the edges or periphery of the first and second walls. The properties of the implant walls and the interior are controlled to provide the particular resiliency desired for the joint in which the implant is to be placed as well as any desired motion between the first and second walls. A conduit may extend from a source of inflation fluid or other filling medium to the interior of the implant to facilitate expansion of the implant after deployment within the joint. The inflation fluid may be a gas, a liquid, a gel or a slurry, or a fluid that becomes a suitable resilient solid such as a curable polymer. Selection of the inflation or interior filling medium may depend upon the nature of the joint structure in which the implant is to be deployed, its anatomy, pathophysiology, and the properties of the implant material.

There may be several alternative embodiments depending upon the site in which the implant is to be deployed. For example, the polymer forming the side wall may be semi-compliant or elastic and the inflation fluid may be incompressible (e.g., a liquid). Alternatively, the polymer forming the side wall may be non-compliant (non-elastic) and the inflation fluid or filling medium may be compressible, e.g., a gas or a resilient polymeric foam or sponge-like solid that may have a closed cell structure. The first and second walls of the implant need not have the same properties as the side wall. For example, parts of the implant such as the side wall portion may be compliant and the first and second wall portions in contact with the bone or other joint structure may be non-compliant. Additionally, the various walls or portions thereof may also be reinforced with non-compliant or semi-compliant polymer strands, beads or gel coating such as biologic or polymer latticework. The thicknesses of the first, second and side walls may be varied to accommodate for the needs of the joint structure from the standpoint of strength, elasticity and wear resistance. Moreover, the walls of the implant may be provided with joint tissue regeneration agents that rebuild the joint structure in which the implant is deployed. The regeneration agent may be incorporated into the wall of the implant prior to delivery or placed between the surface of the implant and the joint structure which it contacts after delivery. All or part of the walls of the implant may also be made of a biodegradable polymer, by minimally manipulated autograph, allograph or xenograph tissues, or a combination thereof. The method of surgery may incorporate a progressive application of the implant embodiments depending upon clinical needs.

The implant is preferably formed of suitable biocompatible polymeric materials, such as Chronoflex, which is a family of thermoplastic polyurethanes based on a polycarbonate structure (Al, the aliphatic version, Ar, the aromatic version and C, the casting version) available from AdvanSource Biomaterials, Corp. Other polymers include Bionate 80, 90A, 55 or 56, which are also thermoplastic polyurethane polycarbonate copolymers, available from PTG Medical LLC., an affiliate of the Polymer Technology Group located in Berkeley, Calif. Other commercially available polymers include Purisil 20 80A which is a thermoplastic silicone polyether urethane, Carbosil 20 90A which is a

thermoplastic silicone polycarbonate urethane and Biospan which is a segmented polyurethane. These polymers are available as tubing, molded or dipped components, solution, pellets, as a casting and as a cast film for the side and first and second walls. The implant may be formed by casting, blow molding or by joining sheets of polymeric material by adhesives, laser welding and the like. Other methods of forming the implant may also be suitable. The walls may also be provided with reinforcing strands which are located on the surface of the walls or incorporated within the walls. The implant material should be biocompatible, non-toxic, and non-carcinogenic and should be resistant to particulation.

The present invention provides an improved joint implant which is designed to endure variable joint forces and cyclic loads enabling reduced pain and improved function. Depending upon the particular joint involved there may be linear or curvilinear motion between the first and second walls, rotational motion between the first and second walls or both linear and curvilinear motion and rotation motion between the first and second walls. Preferably, a space is maintained between the inner surfaces of the first and second walls to avoid erosion and wear therebetween.

The resilient arthroplasty implant embodying features of the invention is preferably deployed as a minimally invasive procedure to deliver the implant into a prepared space in a preselected joint structure, where upon it is inflated to create a cushion, to cover damaged or arthritic cartilage and to be employed to deliver stem cells or living chondrocytes or other tissue regeneration agents. The goal of such deployment is to reduce pain and improve function, to reverse arthritis, to fill in osteochondral defects succinctly, thereby avoiding living with both dysfunctional and ablative metal/plastic prostheses or the pathophysiologic state necessitating the procedure. The operative plan is simple, systematic, and productive of new joint space with regrowth potential involving joint debridement by routine arthroscopic methods or steam application, followed by implantation of the implant. The implant provides three things, namely a covering or patch for the damaged or worn joint surface, an inflated cushion to pad gait as in normal walking in the lower extremity, and delivery of regenerative cells on the cartilage remnant surface. The stem cells may be injected as the implant is being expanded and/or directed into the adjacent hyaline cartilage via an implant coating or perfused cell template. Viscolubricants such as Synvisc or Hyalgan, analgesics such as Lidoderm, anti-inflammatory and/or antibiotic coatings as well as those stimulating cell growth may accompany the composite external implant. The implant is left in place as long as feasible, at least until regenerative cells can attach to the adjacent natural joint surface (usually in about 24 hours), or until wound healing (which may take up to 28 days or more depending on the joint structure). Preferably, the implant is designed stay within the joint structure for years, providing inert padding, cushioning and a new cell source. The implant may be used in weight bearing and non-weight bearing interfaces. Animal usage of the implant, such as in horses and dogs, will benefit following hip and knee injuries. The implant is intended primarily for mammalian use.

These and other advantages of the invention will become more apparent from the following detailed description and the attached exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic cross-sectional view of an idealized joint structure having first and second bones with an implant having features of the invention disposed within the space between the opposing bones of the joint structures.

FIG. **2** is similar to FIG. **1** illustrating curvilinear movement between the two opposing bones.

FIG. **3** is a transverse cross sectional view taken along the lines **3-3** in FIG. **1** illustrating rotational movement between the two opposing bones.

FIG. **4** is a perspective view, partially in section, of an implant embodying features of the invention with an enlarged upper portion prior to implantation.

FIG. **5** is an elevational view of the implant shown in FIG. **4** mounted on the head of a patient's femur.

FIG. **6** is a cross-sectional view of the implant shown in FIGS. **4** and **5** deployed between the head of a patient's femur and acetabulum after release of traction to allow for the bones to settle into their natural albeit pathologic angles of repose.

FIG. **7** is an elevational view of a resilient arthroplasty implant with a smaller upper portion than that shown in FIGS. **4-6** that has been deployed between the head of patient's femur and the acetabulum of the pubic bone.

FIG. **8** is an elevational anterior view of a left proximal femur with an implant placed over the femoral head portion of the hip joint as shown in FIG. **7**, in partial cross section, to illustrate details thereof.

FIG. **9** is a lateral elevational view of a femur with the implant shown in FIG. **6**, as viewed from the "side of the body" or lateral hip aspect.

FIG. **10** is a superior view of a femur with the implant shown in FIG. **7**.

FIG. **11** is an inferior view of the hip joint invention iteration or implant in FIG. **10**.

FIG. **12** is a superior or cephalad view of a patient's hip with a resilient implant having features of the invention, viewed from the head of the patient or from a cephalad to caudad direction.

FIG. **13** is a lateral view of the patient's ankle having a resilient arthroplasty device implant which embodies features of the invention between opposing joint structures.

FIG. **14** is a mortise (30 degree oblique AP) view of the patient's left ankle with implant shown in FIG. **13**.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

The present invention is directed to arthroplasty implants and procedures for a wide variety of joints such as, for example, hips, knees, shoulders, ankles, elbows, wrists, fingers, toes, temporomandibular joints and the like, but for clarity, as well as brevity, the discussion herein will focus on an implant for a hip joint and an implant for replacing the talus bone of a patient's ankle.

FIG. **1** is a highly schematic idealized view of an implant **10** embodying features of the invention that is deployed within a joint structure having a first bone **11** and a second bone **12**. The implant **10** has a first wall **13**, a second wall **14**, and a side wall **15** which define the implant interior **16** which contains filling material **17**. The first wall **13** is secured to the end of the first bone **11** by the skirt **18** that extends from the first wall **13** and the second wall **14** engages the end surface of the second bone **12** and may also be secured thereto. The side wall **15** extending between the first and second walls **13** and **14** defines at least in part the implant interior **16** which is filled with filling material **17**. The inner surfaces of wall **13** and skirt **18** preferably conform to the particular surface of the head of the patient's first bone **11**. The outer surface of the second wall **14** is

preferably configured to conform to the end surface of the second bone **12**. The drawings are highly schematic and do not depict details of the joint surface features such as of the end of the first bone **11** or the end of the second bone **12**, since human pathology and variation reflects both the patient's immediate and evolving pathophysiology.

The edge of the implant **10** shown in FIG. **1** has a depending skirt **18** to secure or anchor the implant to the end of bone **11**, but may have one or more depending tabs that may be employed for similar functions as will be discussed in other embodiments. The skirt **18** (and/or tabs) may tightly fit about the end of the first bone **11** as shown, or the skirt can be secured by adhesive (e.g. methyl methacrylate, bone ingrowth) to the supporting bone structure or be mechanically connected by staples, screws and the like. Moreover, the lower portion of the skirt **18** may be secured by a purse string suture or a suitable strand (elastic or tied) that is tightly bound about the outside of the skirt.

As shown in FIG. **1**, the implant interior **16** between the wall **13** and the wall **14** is filled with filler material which aids in maintaining the desired implant dynamics within the joint structure. The nature of the filler material such as a fluid and the characteristics of the walls **13**, **14** and **15** may be selected to maintain a desired spacing between the walls in order to accommodate the pressure applied by the bones of the joint structure to the implant **10** and to allow suitable motion between the first and second walls **13** and **14** of the implant **10** which facilitate bone motion which mimics or approximates normal movement for the joint members involved such as shown in FIGS. **2** and **3**. Alternatively, as mentioned above, the inner chamber may be filled with resilient material to provide the desired spacing, pressure accommodation, while allowing desired physiologic motion between implant layers. The implant **10** is preferably configured to be shaped like the joint space and bone surfaces being replaced or to fill the void produced by injury or disease so that the natural joint spacing and cushioning of the joint interface is restored toward normal physiologic appearance and function. Fluids such as saline, mineral oil and the like may be employed to inflate the implant.

Linear or curvilinear movement between the first and second walls **13** and **14** as a result of movement of the first and second bones **11** and **12** is illustrated by the arrow shown in FIG. **2**. Rotational movement about the bone axis between the first and second walls **13** and **14** as a result of axial rotation between the first and second bones **11** and **12** is illustrated by the arrow shown in FIG. **3**. While not shown in the drawings, there may be slippage between the second bone and the second wall in addition to wall movements within the implant per se to provide desired joint movements. The skirt **18** is designed to secure the general implant to the joint structure so as to avoid dislocation of the implant. Movement of the joint with the implant **10** in place will be a shared function of both the moving opposing walls **13** and **14** of the implant but also a function of the movement of the wall **14** which may be less attached to the joint members. There may be slight movement between the skirt **18**, wall **13** and the first bone **11**. As shown in FIG. **2** one side of the side wall **15** is in compression and the other is stretched to accommodate bone interface movement. The walls **13** and **14** may be thicker is some areas to accommodate particular loads and the side wall **15** may be thinner and more elastic to accommodate rolling and stretching thereof.

The interior **16** of implant **10** is adjustably filled by the physician from an appropriate source thereof after the implant is deployed to ensure that the pathologic joint space becomes a resilient cushion again which aids restoration of worn or damaged cartilage interfaces in the joint by covering cartilage defects with the implant material, cushioning the joint and defects therein and delivering cell regeneration agents. In one embodiment, the arthroplasty implant comprises a bio-compatible inflatable member that is filled with a biocompatible fill material such as a gas, liquid, gel or slurry, or fluid that becomes a resilient solid to provide relative movement between the first and second walls **13** and **14**. The filling or inflation media may be inserted through an injection valve site leading to the cannula which delivers the material into the interior of the implant. In an alternative embodiment, the implant may be filled with or have an interior formed of biologically compatible resilient material, e.g. a closed cell sponge filled with suitable fluid that is inserted into the interior of the implant prior to the implant's deployment or injected into the interior after the implant is deployed at the joint site. The interior of the implant may be provided with lubricious material to facilitate movement between the inner wall surfaces and to minimize contact wear therebetween. The polymeric walls of the implant may be impregnated with or otherwise carry tissue regeneration agents such as stem cells, living chondrocytes, and/or genes to repair joint surfaces.

The implant can be used in a variety of joints where the implant replaces a bone on bone surface and cushions the interaction between the articular ends of any two bones, such as at the femoral-acetabular interspace of a patient's hip, the humerus and glenoid scapular component in the shoulder, the femoral tibial and patella femoral knee interfaces, the replacement of talus bone in the human ankle between the tibia and calcaneus and the like. Where the implant is substituting or enhancing articular cartilage, the rigidity can be reduced or enhanced to maximize conformation changes that arise during motion as enabled by the two opposing walls and intended inner space, coupled with considerations in any joint surgical reconstruction with accommodation to or amplification of the existing joint ligaments, tendons or dearth thereof. The implant **10** may be deflated and removed by minimally invasive surgery, for example after the implant has served its purpose of regenerating tissue or if another clinical condition warrants its removal. However, it may not be clinically necessary to remove the implant even if inflation is lost, since the two remaining functions of patching the injured cartilage, and delivering restorative cells may justify implant retention.

FIG. **4** is a perspective view, partially in section, illustrating a hip implant **20**, similar to that shown in FIG. **1**, but with a much larger upper portion. The large upper portion of the implant **20** has a first wall **21**, a second wall **22** and a side wall **23** which define at least in part the interior **24**. Skirt **25** depends from the first wall **21** and secures the first wall **21** to the end of the patient's femur **26** as best shown in FIGS. **5** and **6**. FIG. **6** illustrates the implant mounted on the head of the femur **26** with the second wall **22** of the filled upper portion configured to engage the corresponding acetabulum **27** of the patient's pelvic bone **28**. The skirt **25** surrounds the head of the patient's femur **26** and secures the implant **20** thereto. In this embodiment, the enlarged upper portion of the implant creates overlapping layers. The overlapping layers are directed in opposite directions relative to the interior portion of the implant such that an overlapping layer is directed towards the interior portion and an overlapping layer is directed away from the interior portion of the implant, like a redundant membrane, in the side wall **23** between the first and second walls **21** and **22** to accommodate the normal movement of the first or second. This provides greater motion between the femur and the acetabu-

lum and also provides implant stabilization over the head of the femur **26**. This structure also accommodates variation in individual joints that occur from patient to patient.

In the embodiment shown in FIGS. **4-6** the first wall **21** does not extend across the entire end of the patient's femur as in the embodiment shown in FIGS. **1-3**. However, the implant **20** may be designed so that first wall **21** may extend over the head of the femur as shown in FIGS. **1-3** (and FIGS. **7-12** discussed hereinafter). The second wall **22** and the side wall **23** tend to roll as the femur **26** moves within the acetabulum **27**.

Prior to deploying the implant embodying features of the invention, the cartilage lining the joint is prepared by removing hyaline or fibro cartilage flaps or tears, and areas of chondral advanced fissuring are excised or debrided to create precisely defined defects surrounded by stable normal remnant hyaline cartilage with vertical edges in relation to the damaged surface. It is these defects of the cartilage previously normal surface into which new living cells may be injected or otherwise inserted, and allowed to aggregate by the implant interpositional arthroplasty proximate expanded compressive external wall material. Synovitis invading the joint periphery may be vaporized and extracted conventionally or by the use of steam. Areas of greater cartilage damage are removed for subsequent regeneration and the less afflicted areas having stable cracks are treated to seal or weld the cracks. Areas where the tugor or consistency or minimally damaged cartilage can be preserved are intentionally saved rather than destroyed so as to support the normal spacing and gliding opportunity of the more normal joint interface. Thus, normal cartilage is left behind and abnormal cartilage is removed with the implant making up for the deficiencies. With the present invention, it is preferred to avoid joint dislocation so as to preserve natural innervations and vascularity and thus preserving the blood supply afforded by the medial and lateral circumflex arteries for the hip joint to the femoral head.

Joint preparation is usually performed under a brief general anesthetic of outpatient surgery. A muscle relaxant combined with traction (e.g. 60 pounds force for a hip implant) opens the joint wider to permit improved visualization for joint preparation and implant installation, increasing the space between the remnant cartilage from about 3 up to about 12 mm. Increasing the space allows the surgeon to wash out noxious enzymes, to remove invasive synovitis, to remove loose bodies, to prepare osteochondral defects ideally and otherwise prepare the joint for the implant. Partial or complete inflation of the implant will usually precede release of traction. Regeneration agents or cells are inserted with the implant or as a fluid or 3-D template prior to release of traction and wound closure. It is preferred to perform joint debridement, implant deployment and application of cell regeneration agent, e.g. stem cell application, under the same anesthetic. As described by several companies in the Stem Cell Summit held in New York, N.Y. on Feb. 17, 2009, it is desirable to obtain an aspiration of the patient's bone marrow from the iliac crest after anesthesial sterilely at the beginning of the operation. The intraoperative technologist will "dial in the cells" to regenerate areas of maximum pathophysiology while the surgeon debrides or otherwise prepares the joint and inserts the implant, placing the cells at the best time. Cell implantation may also occur as a secondary or tertiary reconstructive treatment adjunct.

FIG. **7** is an elevational view, partially in section, of an alternative resilient implant **30** deployed within a patient's hip structure comprising the head of the patient's femur **31** and the acetabulum **32** of the patient's pelvic hip bone **33**. The upper portion of the implant **30** is smaller than that shown in FIGS. **4-6**. Details of the interior of the joint are not provided such as cartilage, ligaments and the like for the purpose of clarity. The resilient implant **30** embodying features of the invention is disposed within the space between the femur **31** and the acetabulum **32**. FIGS. **7-11** illustrates the implant **30** mounted on the head of femur **31** without the pressure from the acetabulum **32** for purposes of clarity.

The implant **30** shown in FIGS. **7-12** is shaped like a half an orange rind or a hemisphere for a hip joint. The implant **30** has a first wall **34** seen in FIG. **8** which is secured to the head of the femur **31** by a plurality of depending tabs **35**. The tabs **35** may be attached to the femur **31** by a suitable adhesive or mechanically such as by a screw or pin. The second wall **36** of the implant engages the acetabulum **32**, but it also may be provided with tabs and the like for securing the second wall the acetabulum **32**.

The side wall **37** extends between the first and second walls **34** and **36** to form an interior **38** which receives filling material **39** through tube **40**. The implant **30** would also be appropriate for the humeral head in the shoulder or one condyle of the knee or of the humerus, but other shapes may be desired for other joint configurations whether relatively flat as in the thumb base, or more inflated toward a ballooning construct as in the ankle when the talus bone is collapsed. In many embodiments the implant **30** is a weight bearing spacer that will allow joint motions to approach normal, whether filling the space left by an entirely collapsed peripheral joint bone or the space of ablated cartilage proximate surfaces diffusely as in osteoarthritis or succinctly as in osteonecrotic defects or localized trauma. The walls **34** and **36** may be used as a membrane for holding living cells in proximity of the osteochondral defect long enough for the cells to attach (e.g. 24 hours) or to deeply adhere (up to 28 days) or return to normal (up to one year). Weight bearing will be expected to increase as distal lower extremity joints are treated.

Motion is believed to be primarily between the spaced walls of the implant peripherally secured to joint structures, although some motion may occur between the implant and the joint surfaces (as with current bipolar hip hemiarthroplasties). As shown in FIG. **12**, the implant **30** may be provided with a slot **41** extending from the periphery **42** of the implant to a centrally located passage **43** through the implant to accommodate the ligament of the head of the femur for hip implants. Knee implants (not shown) may have two slots leading to separate passages for receiving the anterior and posterior cruciate ligaments. Implants for other locations may have similar variable structures to accommodate anatomical features. Implant walls **34** and **36** should have sufficient inherent flexibility to mold to the existing deformities imposed by either natural ligament, bone, tendon and remaining cartilage deformities of the internal joint space filled as a cushion. The wall exteriors may be flat or formed with random or specific patterns for purposes of glide or trends for traction against adjacent surfaces, or as sulci or venues for cell delivery materials.

A separate portal or tube (not shown) or the existing conduit **40**, may be used to extract noxious inflammatory enzymes that can be aspirated at appropriate clinical intervals. Inflammatory enzymes in the COX1, COX2 and or 5LOX pathways can be extracted. Viscolubricants can be injected into the interior of the resilient arthroplasty device

through existing conduit **40** or through a long needle to aide in distension, expansion, lubrication (with predetermined microporosity).

The ankle version of the arthroplasty implant **50** of the present invention shown in FIGS. **13** and **14** has basically a square transverse cross-section that must take into account supratalar ankle dorsi/plantar flexion, subtalar eversion/inversion motions, ligament fixation-needs, and the accommodation to existing bony architecture as implant variables accounting for the ipsilateral joint pathophysiology. The implant **50** has a first wall **51**, a second wall **52** and a side wall **53** which extends between the first and second wall. The exterior of the implant **50** may have a mesh material **54** with a plurality of chords **55-61** for securing the implant **50** to adjacent bones or to remnant ligaments which are attached to adjacent bones.

The implant **50** may be inflated with gas and/or liquid to open wider the space between the tibia above and the calcaneus below to accommodate collapse of the talus bone as in the flattening which succeeds talus fracture with avascular necrosis, or it may be filled with a liquid that becomes a resilient solid. The instant center of the implant's rotation will be constantly changing, with the talus implant mainly stable and with the tibia moving over it. Deformation with weight bearing during the average human's. 10,000 daily steps or 2-4 million annual gait cycles required by the stance and walking of normal activities of daily living, must be balanced between sufficient solidarity of the implant to maintain axial load, avoiding circumferential stress, and shear forces imposed by the tibia distal plafond on the dorsal ankle implant allowing stance and gait of the patient while avoiding implant migration or failure. Further accommodation to lateral forces imposed by the boney medial and lateral malleoli, need to be endured through the cyclic load of walking, while collapsing with enough give to absorb shock and to match the shape of surrounding structures of bone and ligament tissue. Whereas the axial load between the distal tibia through the talar implant to the dorsal calcaneus will be loaded during stance and especially while walking on a level plane for supratalar motion, the lateral forces will be loaded particularly with subtalar motion while walking on an uneven plane or with inversion/eversion.

The dimensions of the various implant walls will vary depending upon the material properties thereof as well as the needs for a particular joint. Additionally, the first and second walls may require a thickness different from the side wall. Generally, the implant may have a wall thicknesses of about 0.125 mm to about 3 mm, preferably about 0.5 mm to about 1.5 mm. The spacing between the first and second wall within the interior can vary from about 0.5 mm to about 5 mm for most joints (except for the implant for an ankle when an entire collapsed bone space is being replaced), preferably about one to five centimeters to fill between the tibia and calcaneus. In the ankle invention version of the implant, the amount of inflation of the implant per se will be directly proportional to the amount of talus bone collapse between the distal tibia and proximal calcaneus—thus as much as 5 cm implant distension or expansion may be required to be maintained between superior and inferior surfaces in FIG. **13** of the talus, while as much as 10 cm anterior and posterior expansion may be required for the ankle implant between the posterior soft tissues such including the Achilles tendon and the anterior navicular bone as relates to the talus as seen in FIG. **13**.

The method of insertion for the hip joint invention will be a minimally invasive approach, ideally arthroscopically facilitated, as long as the surgical timing and result quality permit smaller incisions. The hip patient will be placed in the lateral decubitus position (lying non-operative side down on the operating table) with a stabilizing operating table pole and pad apparatus positioned to fix the pelvis. The external stabilizing table and attachments will include a padded metal pole beneath the pubis or pelvic bone from posterior to anterior, along with other external anterior and posterior pelvic stabilizing paddles. The affected leg will be attached beneath the knee with a distracting mechanism that applies about 60 pounds of distal force to open the hip joint about 1 cm once the patient is under general anesthesia. The hip joint is arthroscopically debrided through at least one anterior 0.5 cm incision and one posterior 0.5 cm incision, to remove from the femoral head acetabular (ball and socket) joint arthritic debris such as synovitis, loose bodies and noxious inflammatory enzymes. In certain cases a larger open incision may be needed. A smoothing or electronic/ultrasonic/steam or other chondroplasty method may be performed to make the remaining cartilage smoother to better accommodate the hip implant, and protuberant osteophytes or lateral bone overgrowths may be arthroscopically removed or if needed by open excision. A lateral hip incision may be required between 2 and 10 centimeters in length to deal with deformities and/or to insert the implant. In cases of major deformities appropriate reconstruction will add to the basic procedure.

Once the joint is open and cleared, the hip implant will be inserted laterally and fixed via the skirt or tabs to the adjacent structures including the peripheral femoral head and/or acetabular rim. Preferably, the implant is inserted arthroscopically through a cannula about 10 mm in diameter with the implant in the deflated construct, and once inside the prepared joint space and secured therein by the skirt or tabs, the implant will be distended or inflated with gas, gel, fluid or fluid that becomes a resilient solid to fill the original natural space of about 0.5 cm between the upper acetabulum and lower femoral head, covering as much of the upper hip joint as required as the implant expands to fit the space. Tensioning will be by the surgeon's sense of proper pressure application aided by a gauged syringe for insertion of viscolubricants such as Synvisc, Hyalgan, Supartz and/or analgesics such as lidocaine gel. The insertion of liquids to the joint per se may be directly, through a cannula to the joint space previously in place for debridement, and or via a cannula or tube that is not part of the original implant assembly. Once the joint is cleaned, the implant is inserted and appropriately fixed to avoid extrusion or dislocation thereof. This may be via attachment of the implant tabs and/or by a combination of tab use plus intended friction created by implant surface coverings (analogous to Velcro) or a draw string at the smaller base of the implant.

The walls of the implant embodying features of the invention may be composite structures. For example, the innermost layer may be impervious to preclude escape of inflation or other filling media, a central layer may be porous or otherwise contain treatment or cell regeneration agents, and the outer layer may be a thin, but strong layer of a thermoplastic such as a thermoplastic polyurethane which has microporosity sufficient to allow passage or egress of treatment or cell regeneration agents from the central layer. The degree of microporosity to enable egress of treatment or cell regeneration agents from the central layer is found in polymer layers such as Chronoflex or Bionate 55. The external wall of the implant may be coated and/or impregnated with a latticework of polymer surface sprayed or layered on the outside of the implant to promote cartilage tissue regeneration. This most external surface coating may

contain living chondrocytes as in the Carticel procedure by the Genzyme company, and/or may contain stem cells with directed gene mutations to enhance adherence of the coating to the implant. The living cells may be imposed in between troughs while the surface areas of prominence may be used for space validation, traction, and cell protection.

The implant embodying features of the invention may be used in a series of treatments wherein the first treatment involves use of autologous or minimally manipulated allograph interpositional tissues or xenograph, the second treatment involves the use of the same type of tissue added to stem cells or chondrocytes and the third treatment involving deployment of the implant if the first two fail or are ineffective.

The implant may be provided with latticework or other reinforcing strands, preferably on the exterior or within the wall thereof to control the maximum expansion of the implant when deployed at the orthopedic site.

The method of insertion of the ankle implant generally will be through an anterior surgical ankle approach or tendon separating incision from the distal tibia to the proximal talus (or calcaneus if the talus is absent), removing and reconstructing portions of the superior and inferior ankle extensor retinacula only to the extent required to gain access to the cleared tibiotalar space. Analogous to the hip joint insertional method, the ankle joint will be prepared arthroscopically under general anesthesia, and may benefit from distal distraction as in total ankle joint replacement surgeries with the DePuy Agility technique pinning above and below the ankle joint and then distracting it. The degree of distraction required in all joints to which this invention is applied, including but not limited to those of all appendicular skeletal structures such as the shoulder, elbow, wrist, phalanges, hip, knee, and ankle, will depend both on the nature anatomy and located pathophysiology that must be accommodated on a case by case basis and said distraction may be a combination of body position using gravitational forces and/or superimposed distracting devices. In the ankle, the surgeon will be developing the interval between the extensor hallucis longus and anterior tibial tendons. Injury tissue is removed, and the implant inserted fitting as preplanned. The implant surface may be provided with roughness, e.g. external mesh, to control movement by friction as described above for the hip joint, and/or attached fixation cords or tabs to connect to proximate ligaments or adjacent boney structures may be used at the surgeon's discretion to balance implant location stability and integrity, with the need for functional joint movements.

Over time, ingrowth of repair tissue aids in fixation and stability externally to the implant, while the soft cushioning implant interior will absorb forces across the joint surfaces and permit proper motion. The tugor or wall tension of the implant as well as the inside distension of the implant per se can be adjusted by adding or removing the inflation substance to the implant's interior space.

Accordingly, the present invention provides a new approach to arthroplasty that involves a resilient implant device deployed between bones of the joint. Whereas a joint is comprised of the interface between bone cartilage space cartilage bone, in certain joint spaces such as the knee, the invention cushion may expand to fit the spaces between both "knee joints"—the femoral tibial involved on standing or walking on a level plane, and the patella femoral bones of the knee more involved on stair ascent and decent. For example, pressures behind the knee cap or patella when lying are zero, when standing are 0.7 times body weight, and when going up and down the patella femoral pressures are 3-4 times body weight. Thus, the implants will need to accommodate all the normal body functional pressures and complex space movements, as described above also in the ankle. When in the hip joint, the normal flexion up to 120 degrees, extension of 20 degrees, abduction of 50 degrees, internal and external rotation of 45 degrees will produce variable axial, shear, and cyclic loads which the implant by design will accommodate and endure as up to 6 times body weight, consistent with a tire on a car that allows for cyclic loads different when driving straight or turning corners. The implant embodying features of the present invention provides more physiologic motion and shock absorption within the joint and has combined characteristics of anatomic design symmetry, balanced rigidity with sufficient attachment connections to adjacent normal structures, and durability that meet the needs of joint reconstruction.

The opposing internal surfaces of the first and second walls of the invention may either move together in synchrony or in opposite directions from one another (e.g. the superior wall moving medially in the hip and the inferior wall moving laterally). Optionally, the implant may be fixed to a concave surface of the joint (e.g., the acetabular hip cup) or to a convex surface of the joint (e.g. the dorsal femoral head surface), to both, or to neither (e.g., having an interference fit within the joint with an expanding balloon or cushion that fills the existing space). The implant may be inserted arthroscopically like a deflated balloon and then inflated through a cannula into the ankle or hip (or other joint structure) to act as a cushion or renewed interface for painless and stable limb motion. When feasible joint capsular and adjacent ligament tissue as well as bone will be left in place to preserve the natural body, unless interfering with reconstructed limb function.

The application of steam in addition to removing damaged debris, can smooth out and reform the joint surface. The high temperature of the steam tends to weld cracks or fissures which can be present in the cartilage surface of a damaged joint. Smoothing of joint surface cartilage with steam welds or seals existing cracks or flaps in the cartilage, especially superficially as the lamina splendors, which melt together to provide a white shiny gliding joint surface. In cases where bone is exposed, the steam can be used to stabilize the periphery of the defect in the joint surface via capsulorrhaphy or joint tightening. Open mechanical and chemical debridement may also be employed to prepare the surfaces for the implant.

Once the implant is secured to the femoral head by means of the skirt or tabs, an impregnated transfer medium or cell template may be used, as described by Histogenics and Tygenix chondrocytes delivery systems wherein the position of concentrated cells is mechanically placed about the implant at areas of greatest cartilage damage to promote regrowth, or as in Carticel wherein watery cells are implanted beneath a periosteal membrane (a wall of the implant serving as the membrane), prior to completion of the inflation or expansion of the implant. At syringe or gauged device with measured screw-home pressure is used to inflate the implant.

Once the joint is ready to receive the implant, the deflated implant is advanced through the diaphragm of a delivery cannula (such as the Acufex from Smith & Nephew) and into the joint. It can be inflated by the attached cannula using a common syringe, inserting several cc's of filler material. Inserted contents and locations of cell placements depend on areas of need and joint size. In the hip implant several cc's of filler material and a viscolubricant in the interior of the

implant will allow distension, cushioning, and gliding movements. Cell regeneration agents are placed in the areas of greatest need.

Methods of living stem cell or chondrocyte placement depend on the lesions and specific implant construct. Direct infusion into the joint with completion of implant inflation will press the cells into the hyaline surface, whereupon they attach within the first 24 hours. As a result, the patient should remain sedentary and the joint where the implant is deployed, non-weight bearing for the first day after surgery. Deeper osteochondral defects can be treated by 'hyper-perfusion of cells' via either 3-D cell transfer templates, or microneedle injection as used in treatment of diabetic patients for blood sugar testing and insulin/transdermal drug delivery. The cannula attached to the implant may be sealed and detached, or left in place for periodic aspiration of noxious enzymes as for the Cox-1, Cox-2, and 5-Lox systems, followed by reinsertion of activated substances including viscolubricants, or even more cells.

Implants embodying features of the invention may be designed for permanent or temporary deployment within a joint structure. Moreover, the implant may be formed of suitable bioabsorbable materials so that the implant may be absorbed within a particular predetermined time frame. Suitable bioabsorbable materials include polylactic acid, polyglycolic acid, polycaprolactone, copolymers, blends and variants thereof. One present method of forming the implant is to apply numerous layers of polymer such as ChronoFlex AR in a solvent and evaporating the solvent after applying each layer.

The skirting or fixation tabs of the present implant prevent joint migration during use. This is in contradistinction with prior solid polymer implants that tended toward dislocation and poor post operative function.

While particular forms of the invention have been illustrated and described herein, it will be apparent that various modifications and improvements can be made to the invention. One alternative implant construction involves the use of an upper portion of the implant having a net-like construction and filled with balls or ball bearing like elements that are larger than the openings in the netting. The balls or ball bearing like elements provide motion to the implant. The netting and ball bearing like elements may include regeneration agents as previously discussed, and the bearing construction may be directed toward favorable implant movement balanced with content disbursement.

The invention is intended primarily for human use but may be extended to mammalian use. To the extent not otherwise disclosed herein, materials and structure may be of conventional design.

Moreover, individual features of embodiments of the invention may be shown in some drawings and not in others, but those skilled in the art will recognize that individual features of one embodiment of the invention can be utilized in another embodiment. Moreover, individual features of one embodiment may be combined with any or all the features of another embodiment. Accordingly, it is not intended that the invention be limited to the specific embodiments illustrated. It is therefore intended that this invention be defined by the scope of the appended claims as broadly as the prior art will permit.

Terms such as "element", "member", "component", "device", "means", "portion", "section", "steps" and words of similar import when used herein shall not be construed as invoking the provisions of 35 U.S.C §112(6) unless the following claims expressly use the terms "means for" or "step for" followed by a particular function without reference to a specific structure or a specific action. All patents and all patent applications referred to above are hereby incorporated by reference in their entirety.

What is claimed is:

1. A resilient orthopedic implant comprising:

a. a first wall configured to engage an articulating end of an acetabulum of a pelvic bone;

b. a second wall configured to conform around a portion of a femoral head, the second wall having one or more appendages configured to secure the second wall to the femoral head;

c. a side wall extending between the first wall and the second wall and configured to facilitate relative motion between the first and second walls; and

d. an interior portion configured to be directly enclosed by the first wall the side wall, and a proximal end of the femoral head;

wherein some length of the first wall overlaps some length of the second wall creating a fold in the implant such that some length of an exterior surface of the side wall has a concave shape at the fold; and

wherein the implant is configured for deployment between the femoral head and the acetabulum of the pelvic bone when neither the femoral head nor the pelvic bone is resected.

2. The implant of claim **1** wherein the one or more appendages is a skirt.

3. The implant of claim **1** wherein the one or more appendages are tabs.

4. The implant of claim **1** wherein the one or more appendages are chords.

5. The implant of claim **1** wherein the relative motion between the first and second walls is rotational motion.

6. The implant of claim **1** wherein the relative motion between the first and second walls is linear or curvilinear motion.

7. The implant of claim **1** wherein the relative motion is rotational motion and linear or curvilinear motion.

8. The implant of claim **1** wherein the one or more appendages are configured to be secured to the femur by an adhesive.

9. The implant of claim **1** wherein the first wall has an exterior surface with a convex shape which is configured to contact the acetabulum.

10. The implant of claim **1** wherein the implant comprises a resilient material.

11. The implant of claim **10** wherein the resilient material is a biodurable thermoplastic polyurethane.

12. The implant of claim **10** wherein the resilient material is bioabsorbable.

13. The implant of claim **1** wherein one or more of the walls comprise a plurality of layers.

14. The implant of claim **13** wherein at least one of the layers is porous.

15. The implant of claim **1** wherein the side wall of the implant has reinforcing strands to control expansion upon compression of the implant.

16. The implant of claim **1** wherein the interior portion is configured to be filled with an inflation medium.

17. The implant of claim **16** wherein the inflation medium is a resilient material.

18. The implant of claim **1** wherein a lubricious material is maintained between the first and second walls to facilitate relative motion between the first and second walls.

19. The implant of claim **1**, wherein the first wall or the second wall is composed of biocompatible polymeric materials.

20. The implant of claim **1**, wherein the first wall, second wall, or side wall comprises numerous layers of one or more polymers.

21. The implant of claim **1**, wherein the first wall, second wall, or side wall comprises biocompatible polymeric materials.

22. The implant of claim **1**, wherein at least one of the first wall, second wall, or side wall incorporates a lattice.

23. The implant of claim **22**, wherein the lattice is configured to hold a therapeutic agent in proximity of an osteochondral defect.

24. The implant of claim **22**, wherein the lattice comprises a biocompatible polymer.

25. The implant of claim **1**, further comprising a conduit the conduit configured to provide access to the interior portion for injection of a biomaterial into the interior portion while the second wall is fixed to the portion of the femoral head.

* * * * *

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(12) **United States Patent**
Grotz

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(54) **UNIVERSALLY EXPANDING CAGE**

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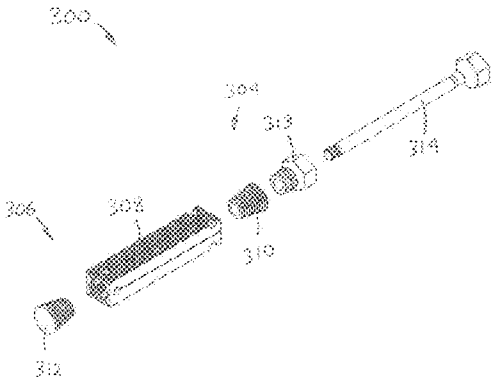
(57) **ABSTRACT**

An expandable medical implant is provided with an implantable cage body. Methods for stabilizing and correcting the alignment of a spine with an expandable medical implant are provided. The proximal and distal ends of the cage body may each be provided with a tapered or cam portion. The implant may further include a proximal flexure, a distal flexure, a proximal plug member having a tapered portion configured to mate with the tapered portion of the proximal end of the cage body, and a distal plug member having a tapered portion configured to mate with the tapered portion of the distal end of the cage body. The proximal plug member may be configured to move longitudinally such that the distal flexure moves and the circumference of the proximal end of the cage body resiliently expands. The distal plug member may be configured to move longitudinally such that the proximal flexure moves and the circumference of the distal end of the cage body resiliently expands.

20 Claims, 28 Drawing Sheets



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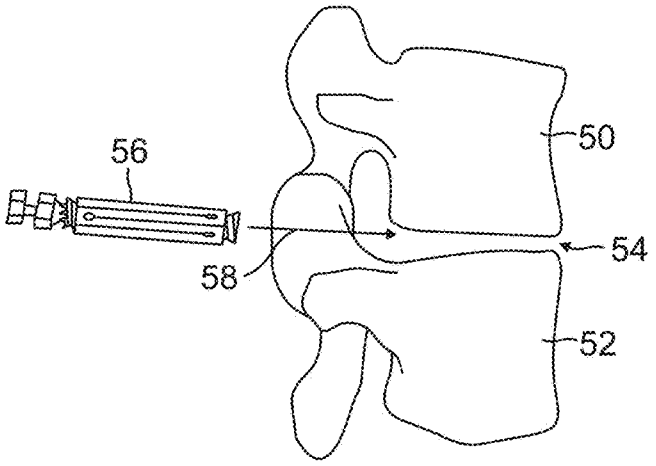

FIG. 1

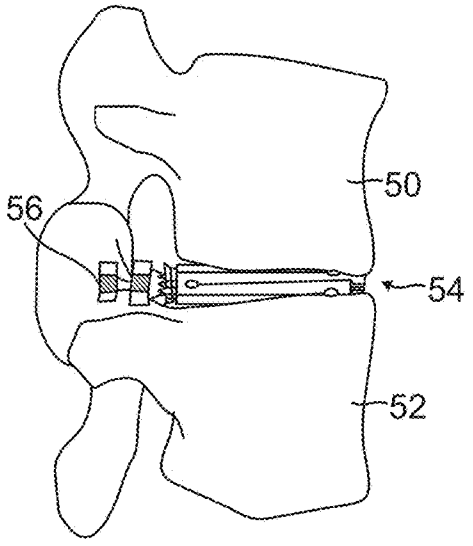

FIG. 2

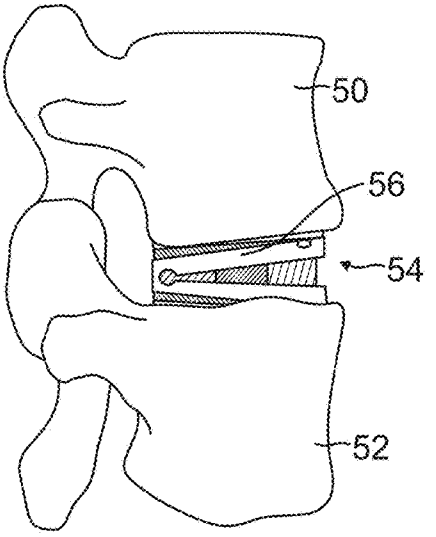

FIG. 3

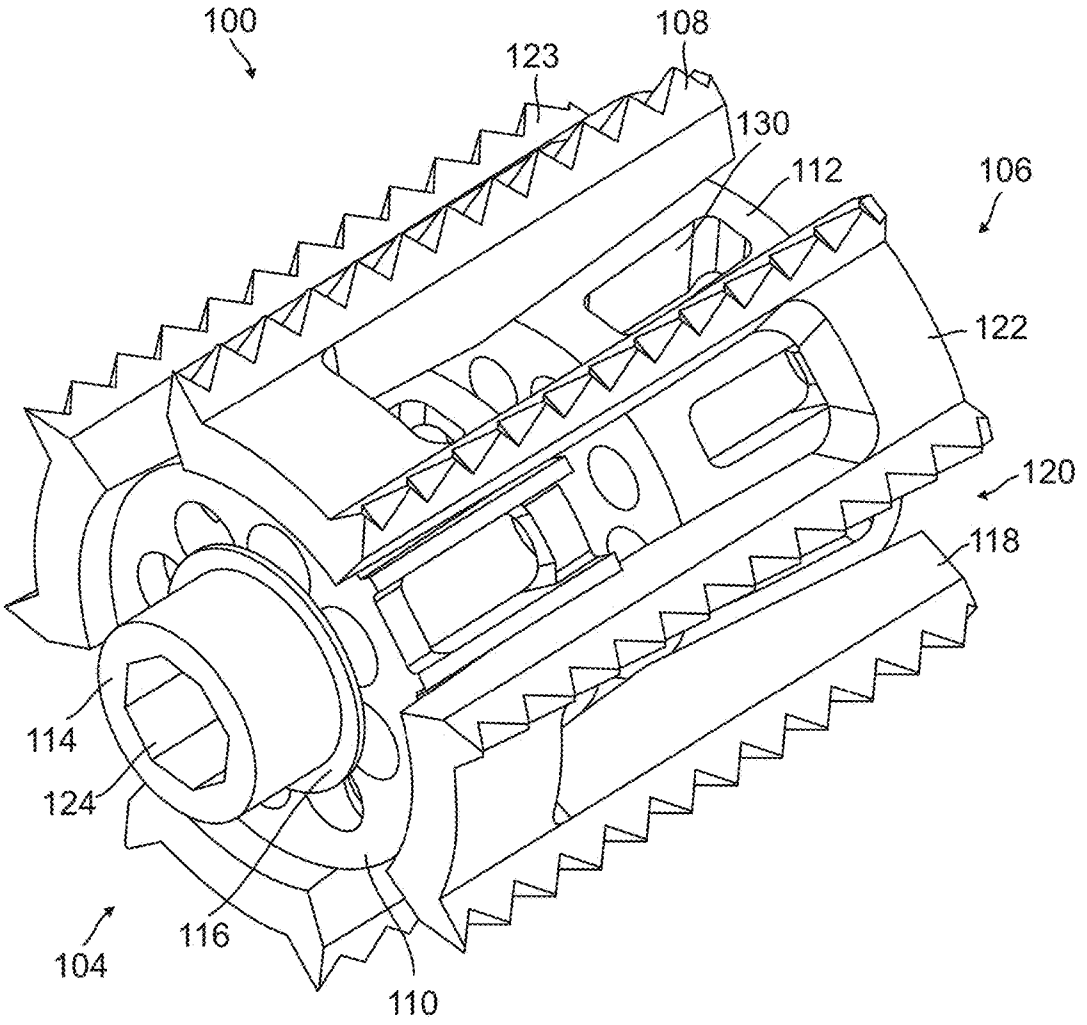

FIG. 4

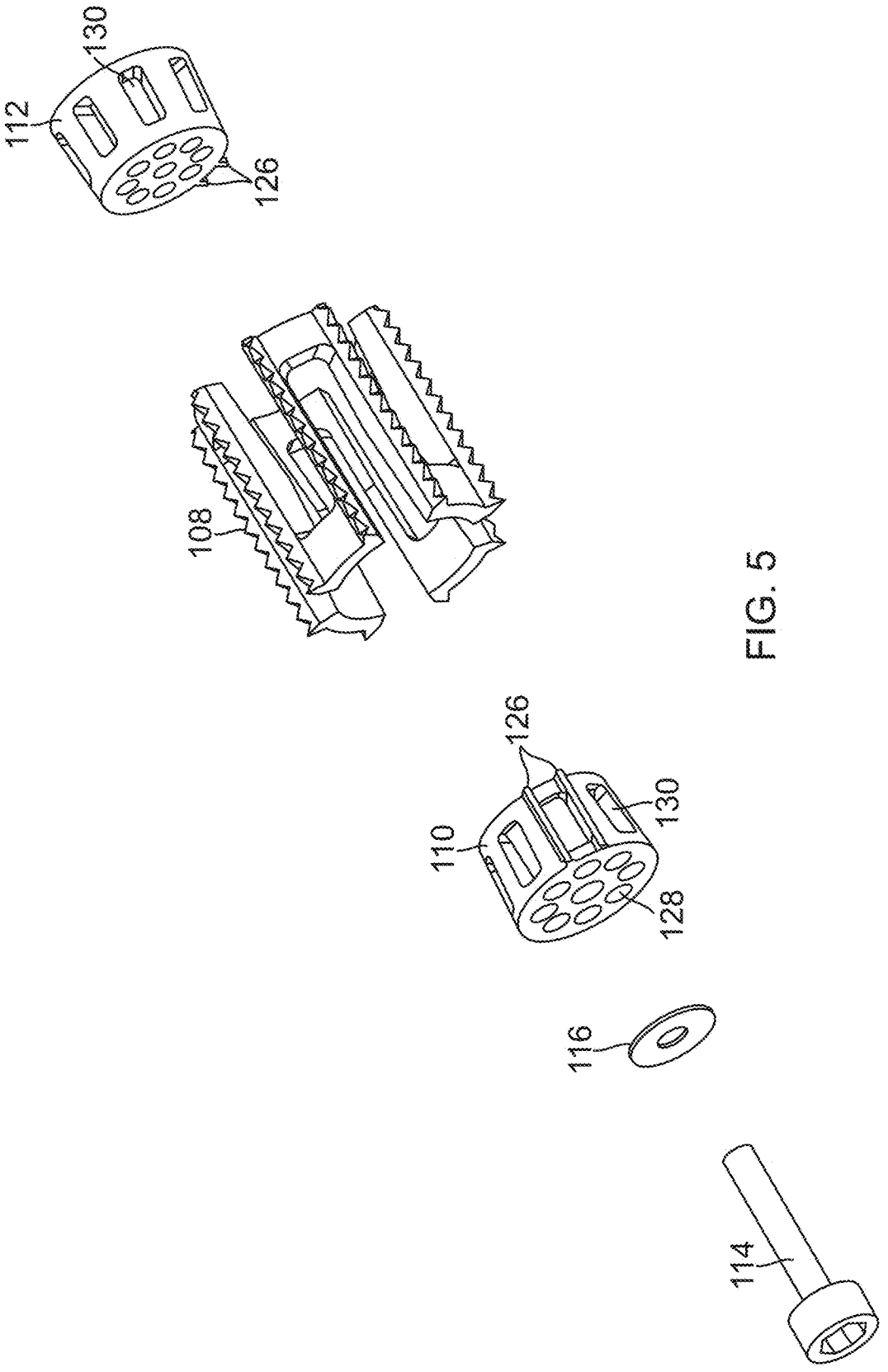

FIG. 5

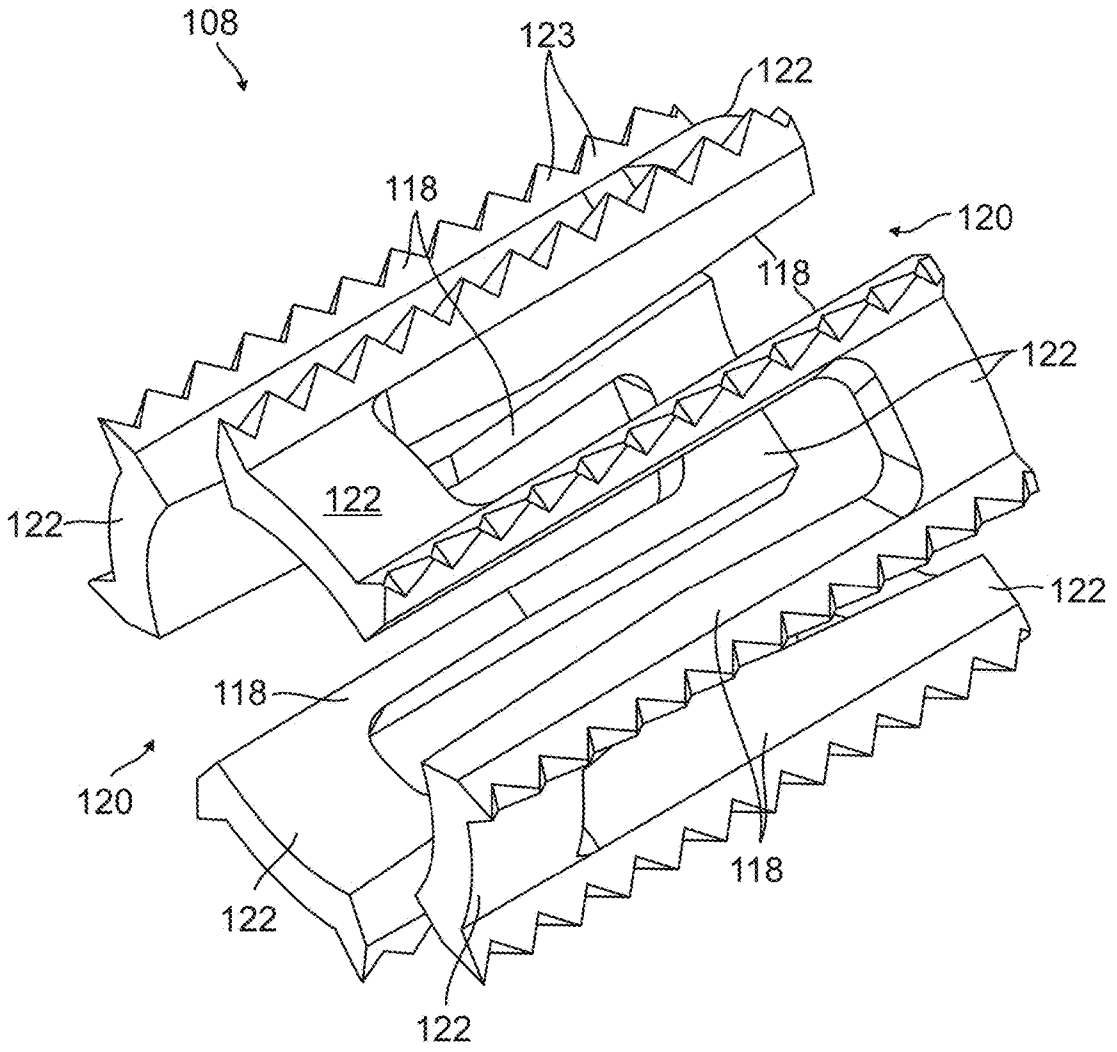

FIG. 6

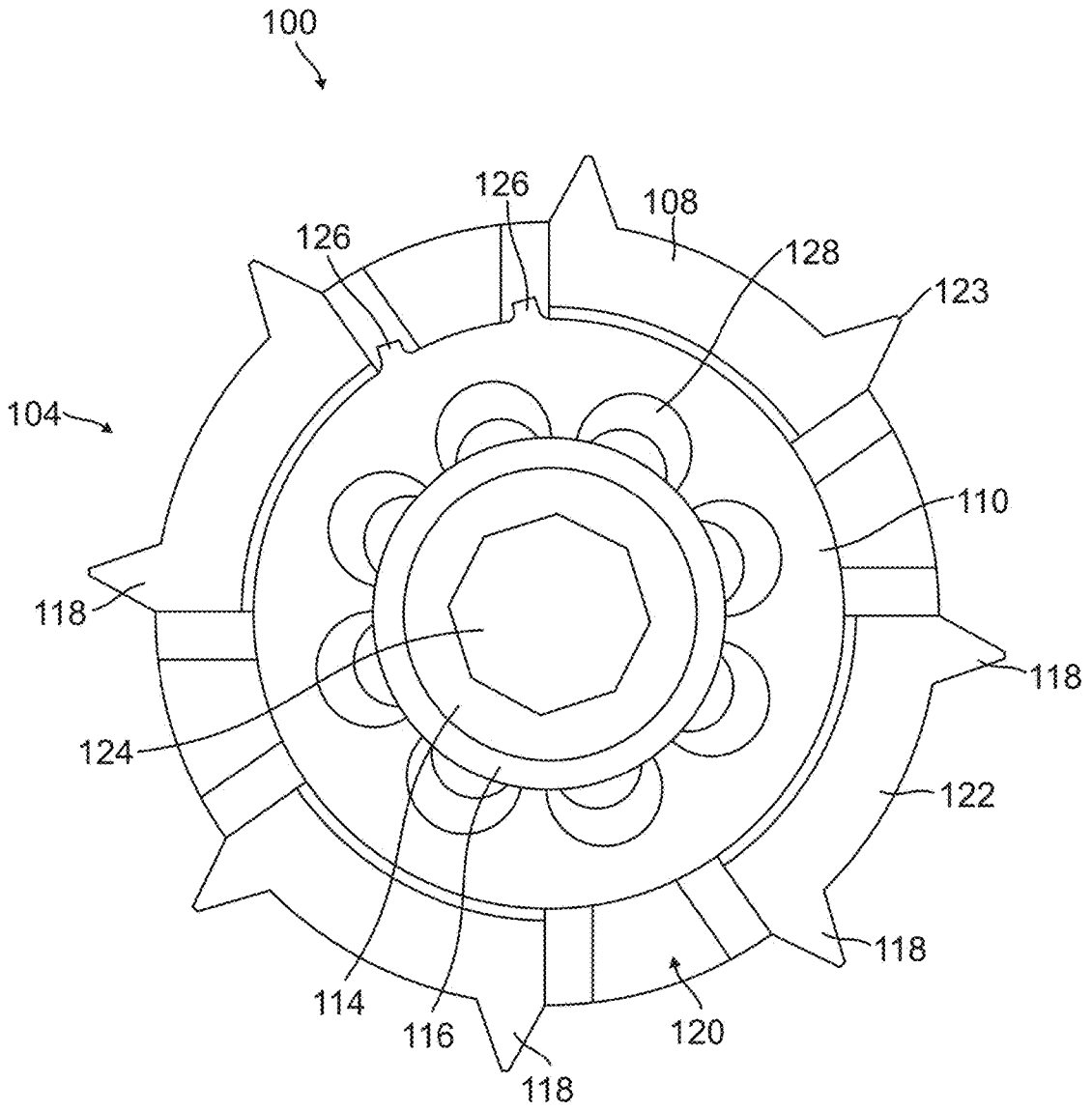
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FIG. 7

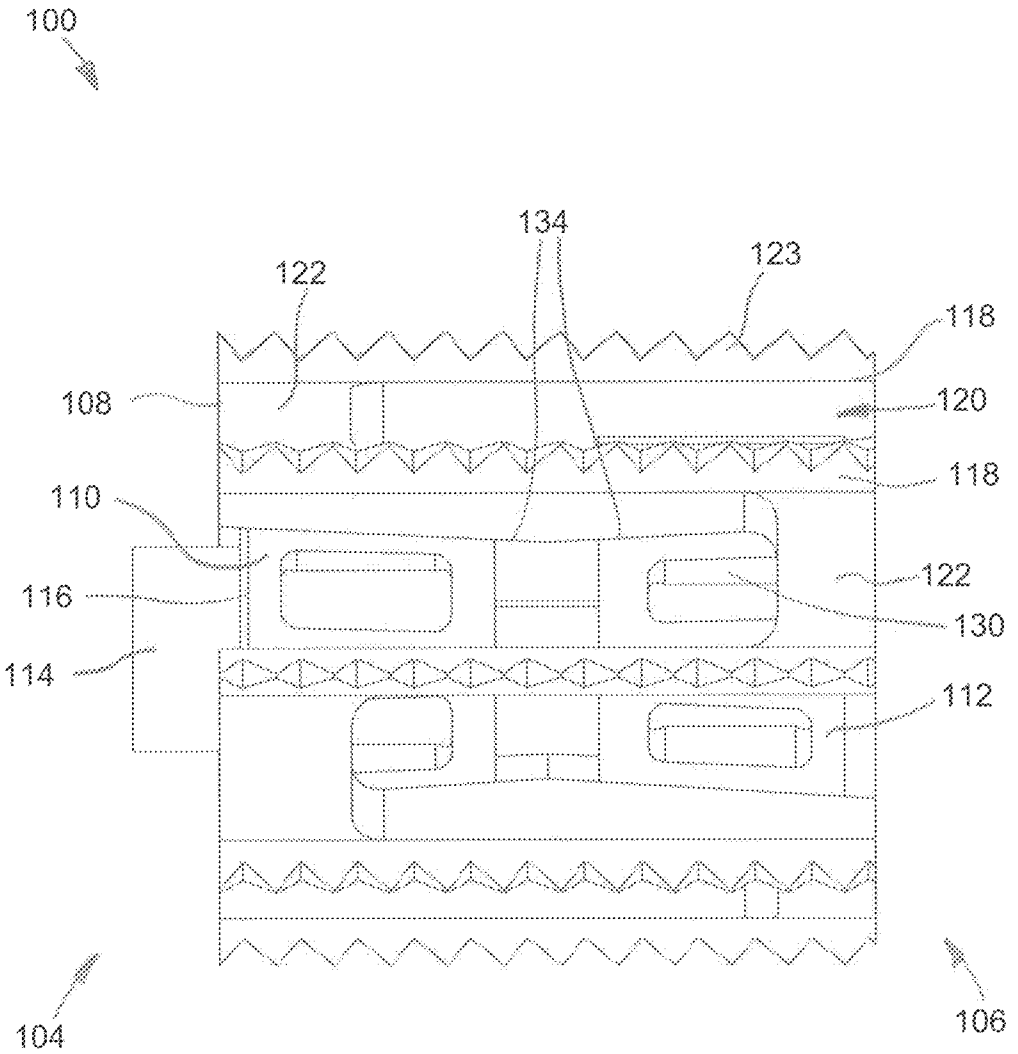

FIG. 8

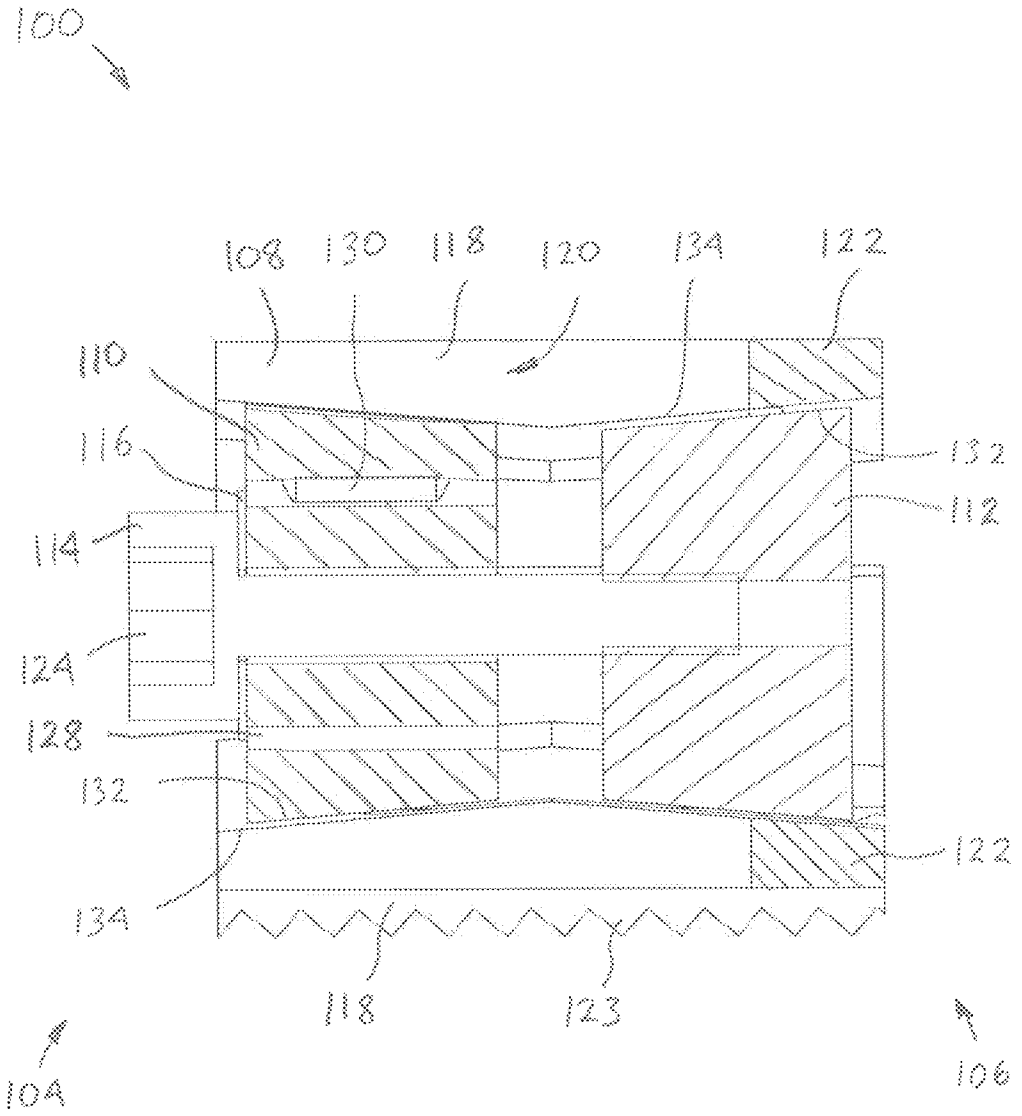
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FIG. 9

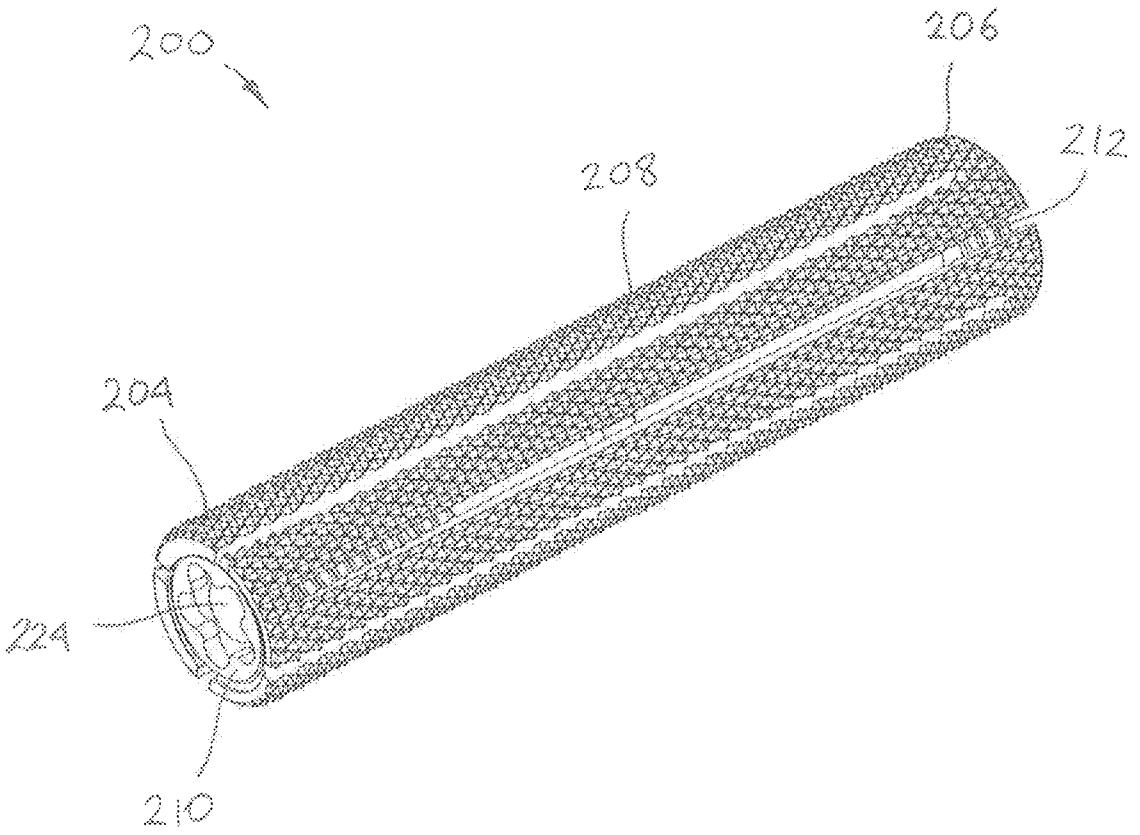

FIG. 10

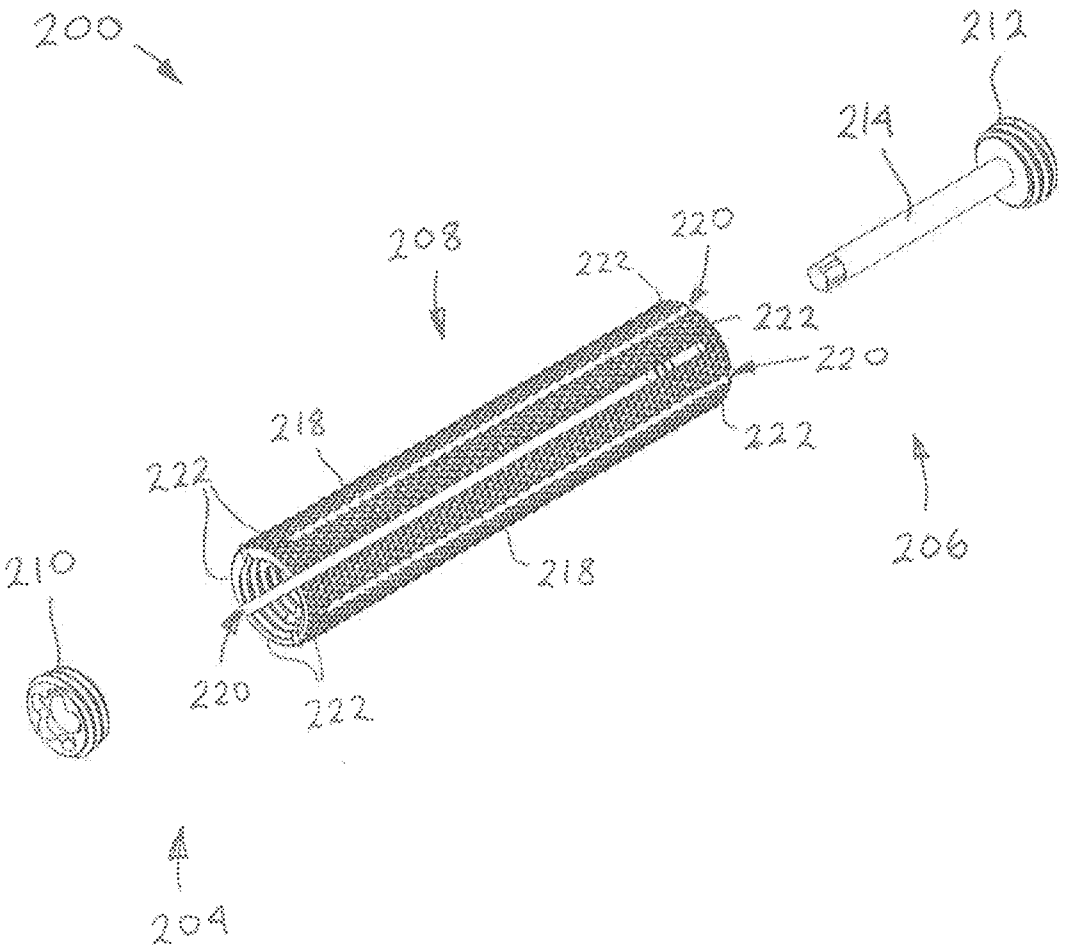
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FIG. 11

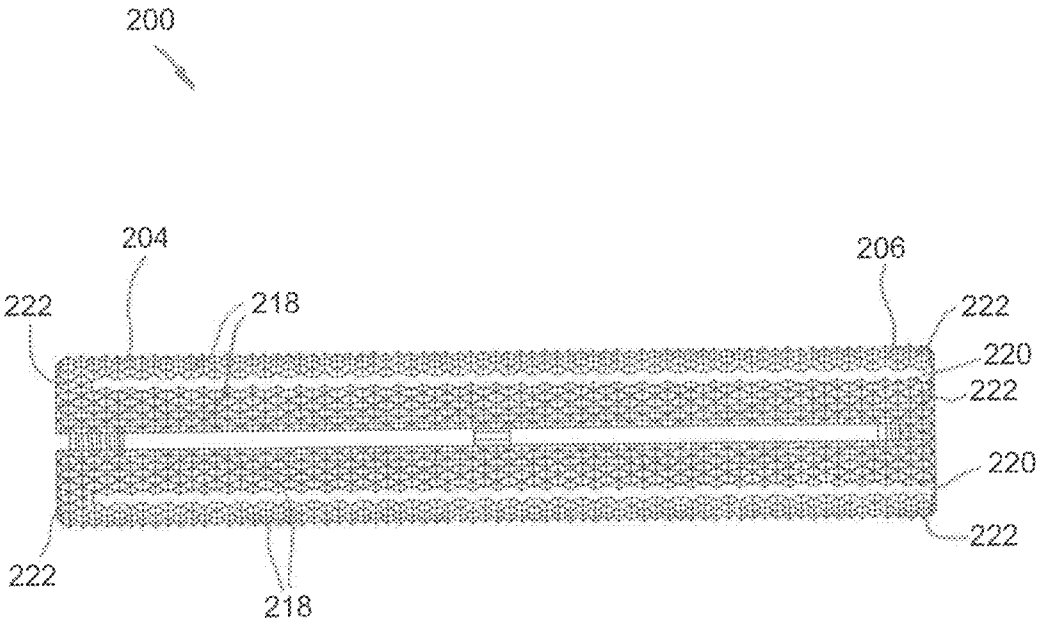

FIG. 12

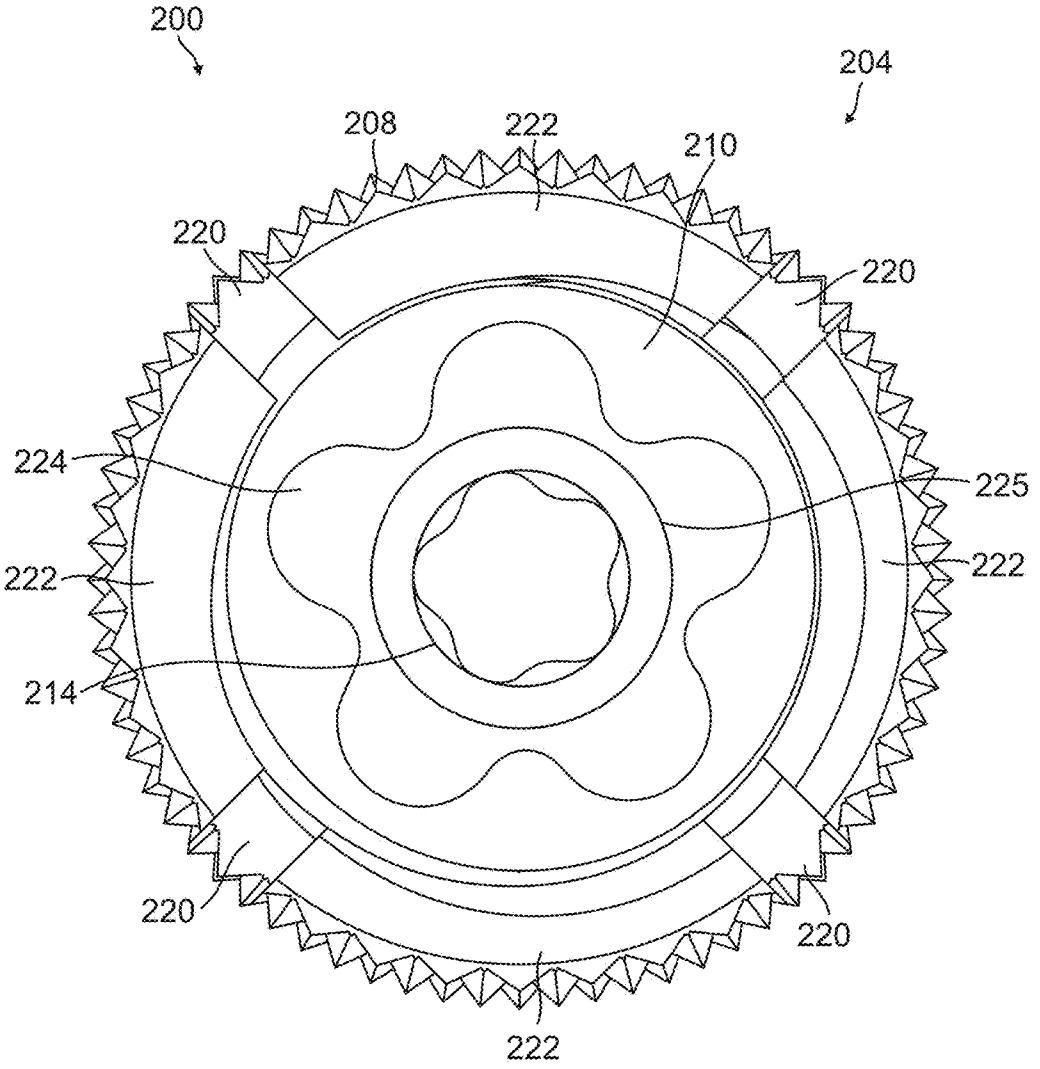

FIG. 13

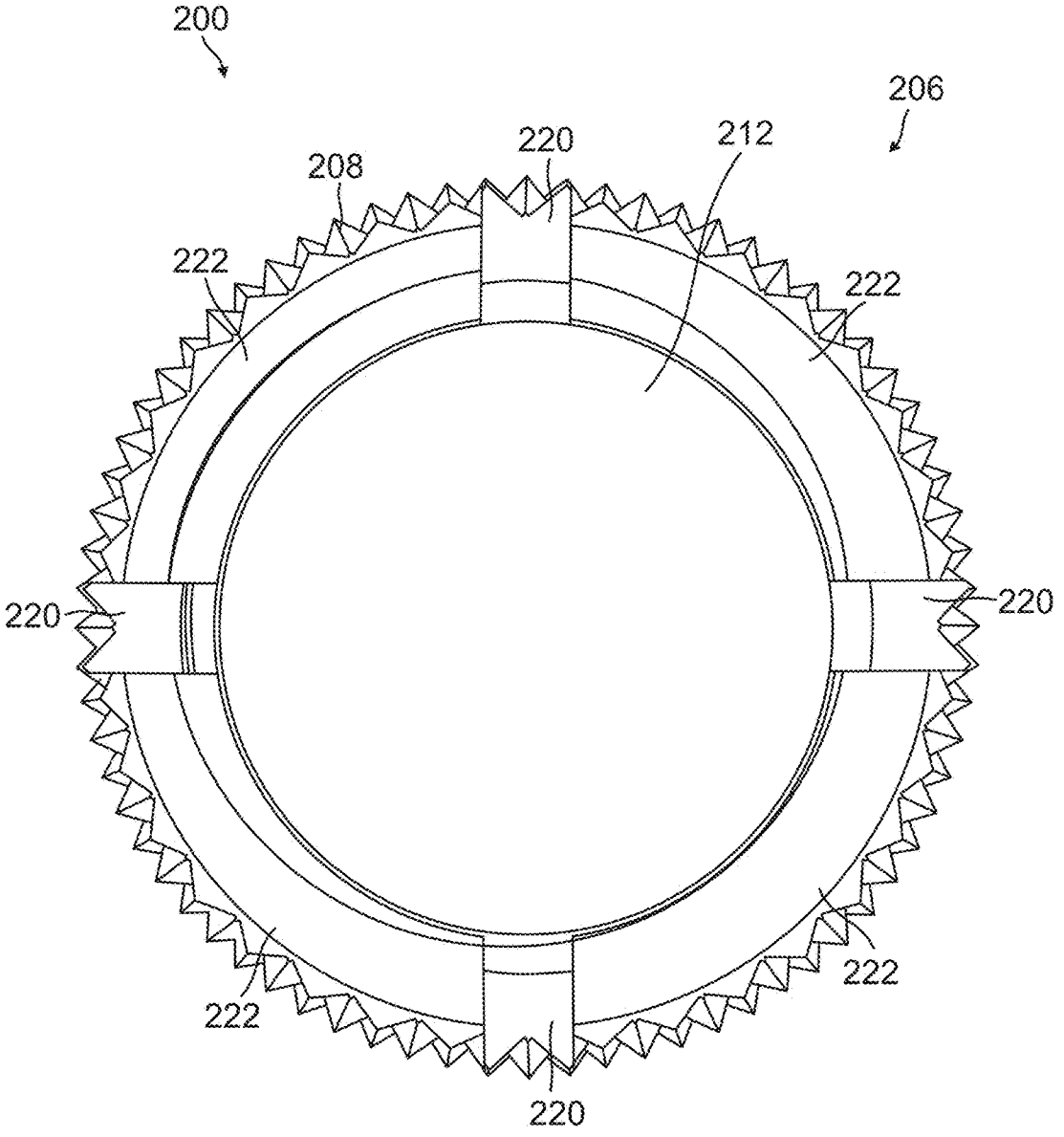

FIG. 14

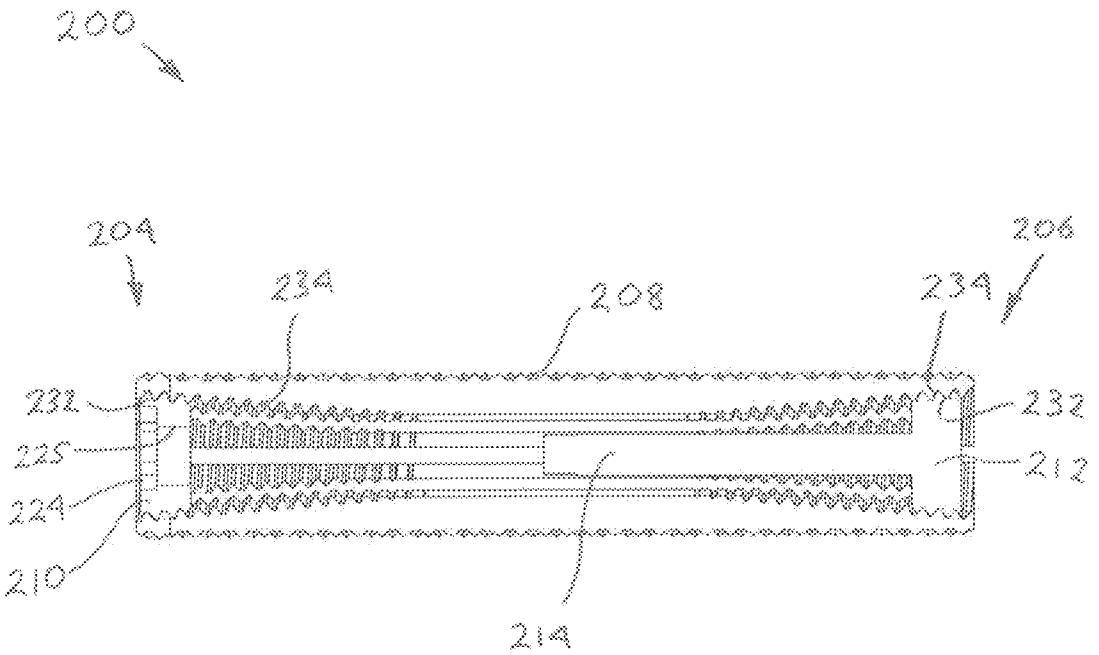

FIG. 15

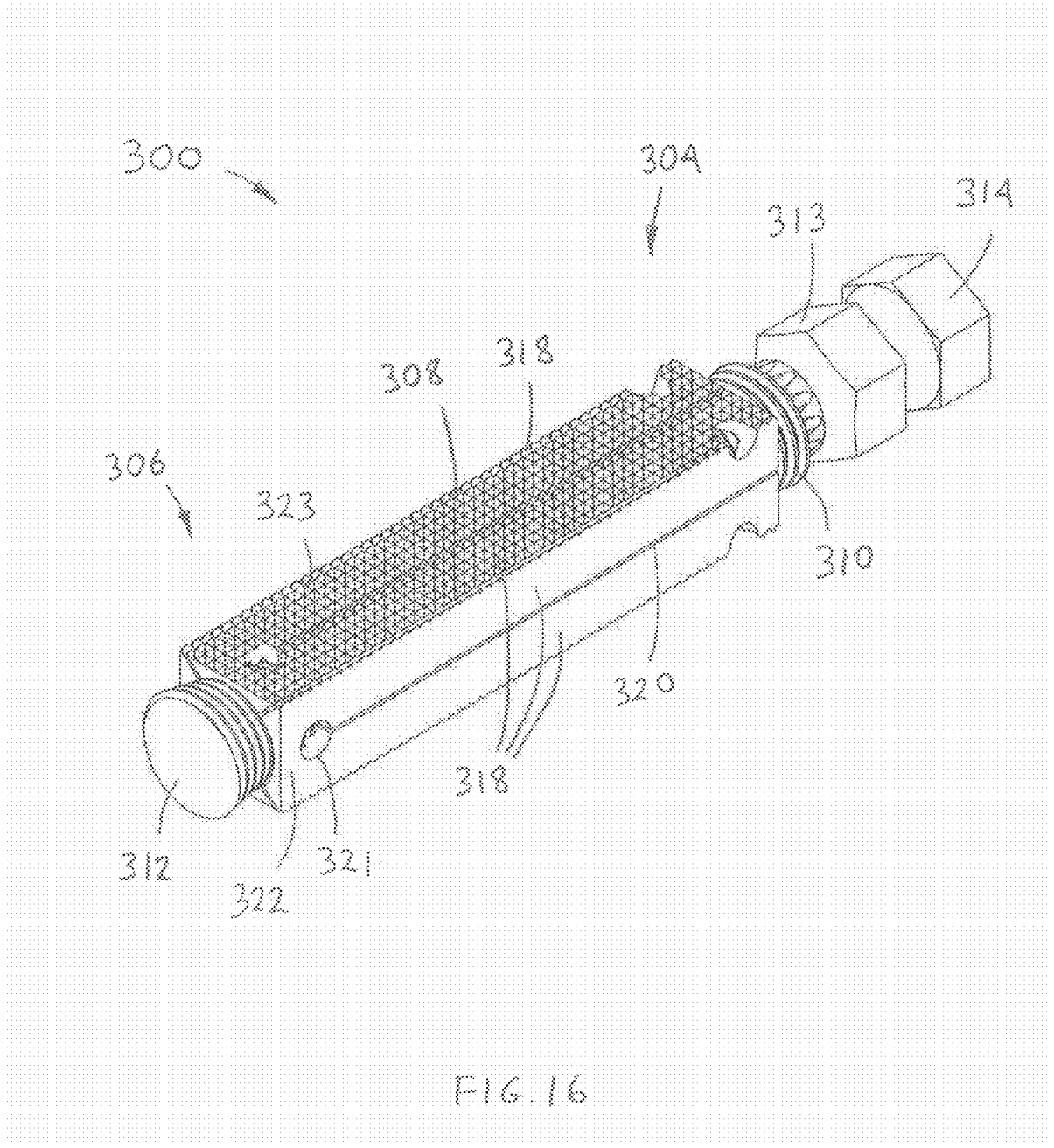

FIG. 16

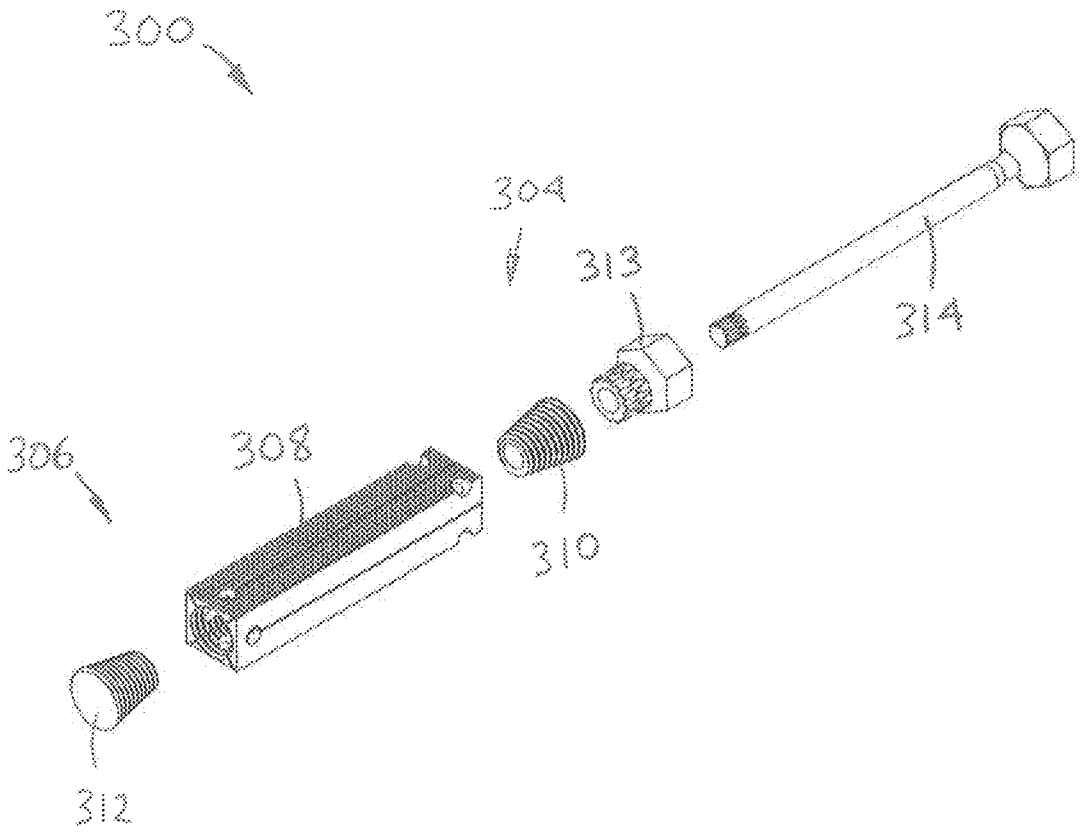

FIG. 17

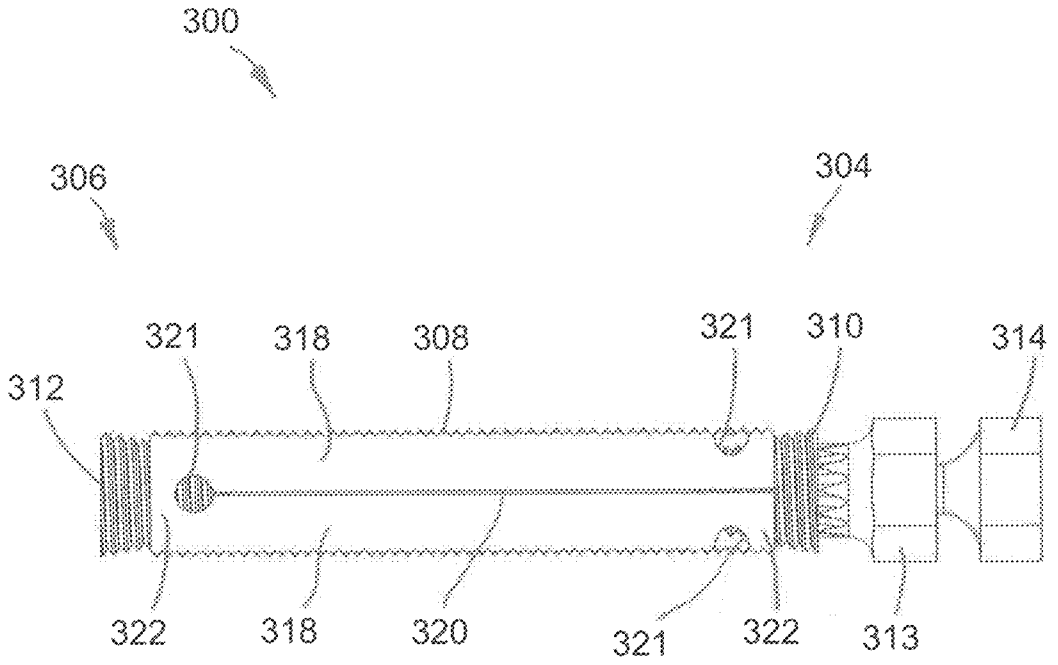

FIG. 18

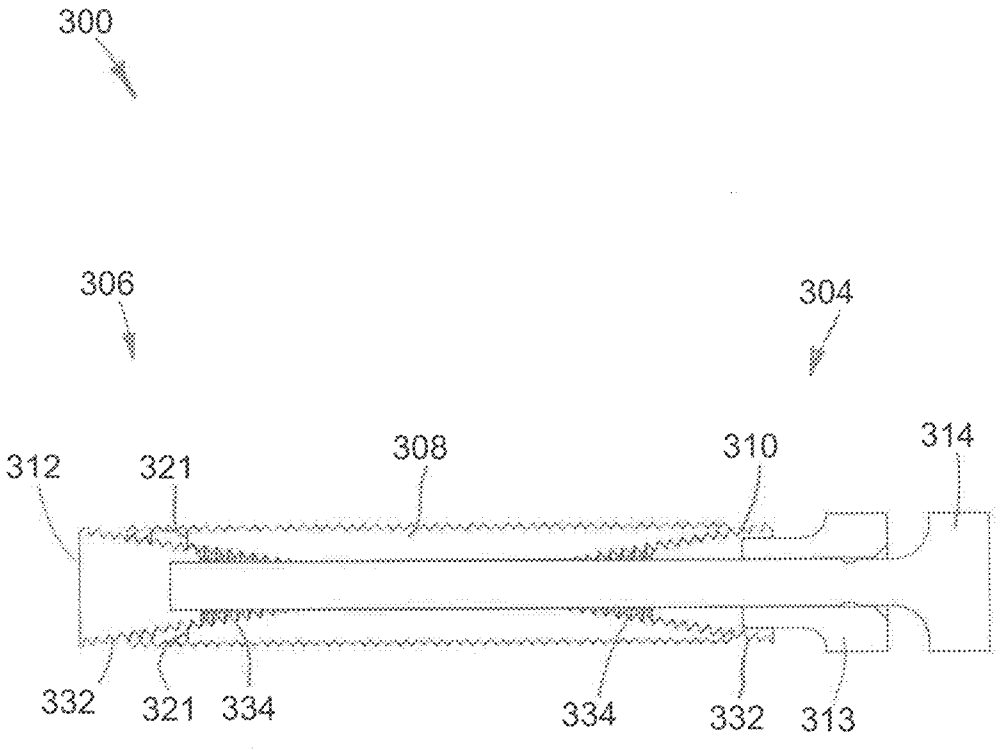

FIG. 19A

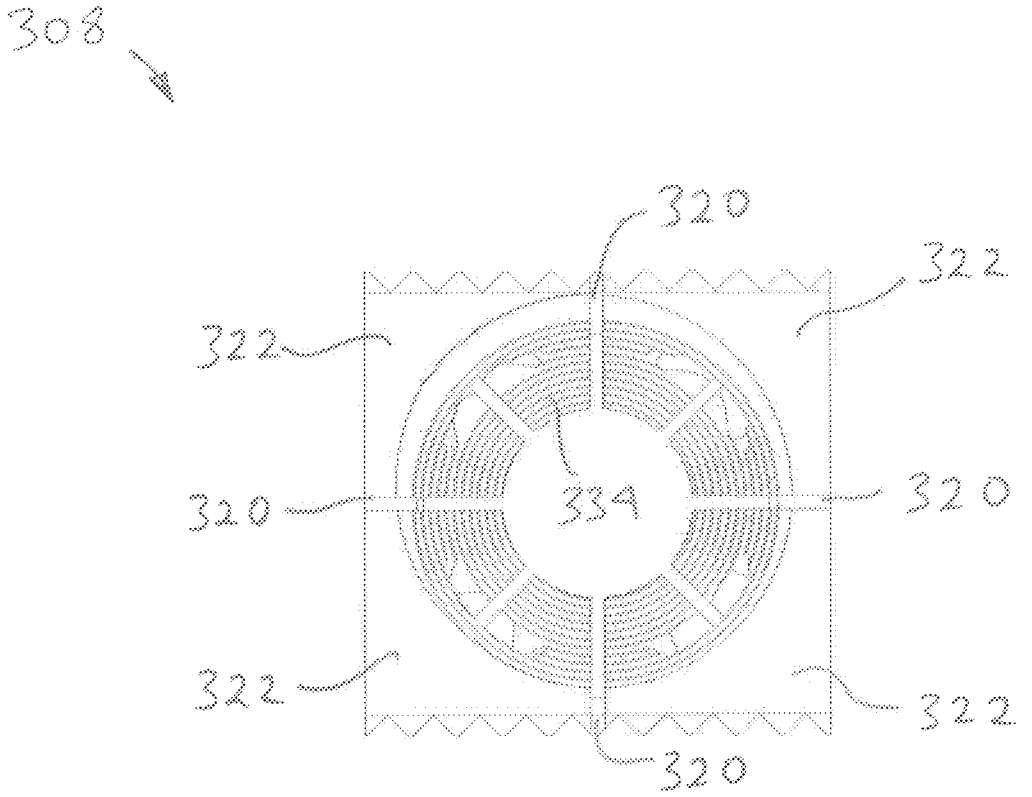

FIG 19B

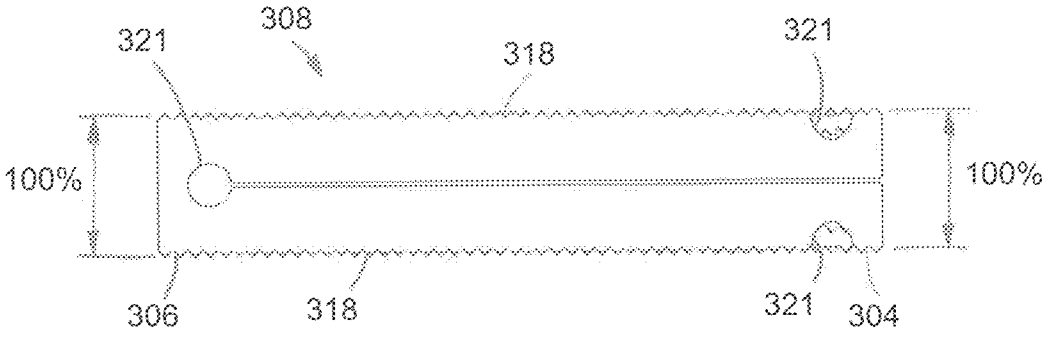

FIG. 20A

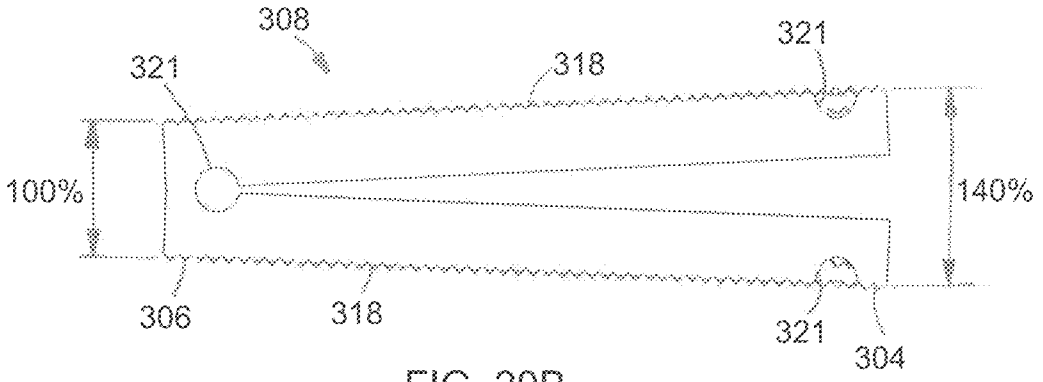

FIG. 20B

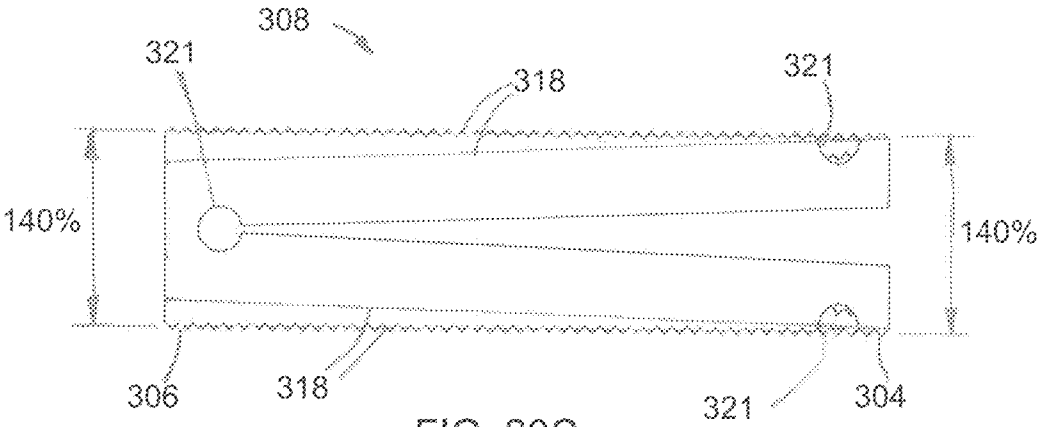

FIG. 20C

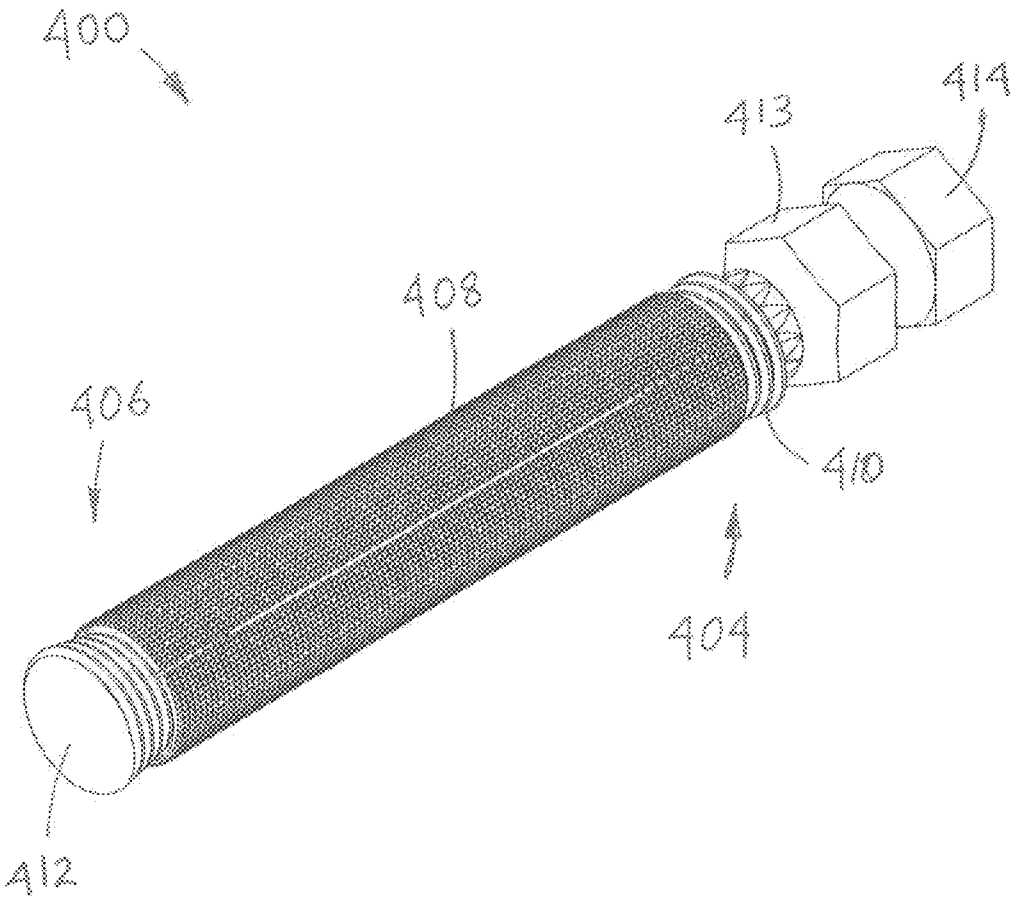

FIG 21

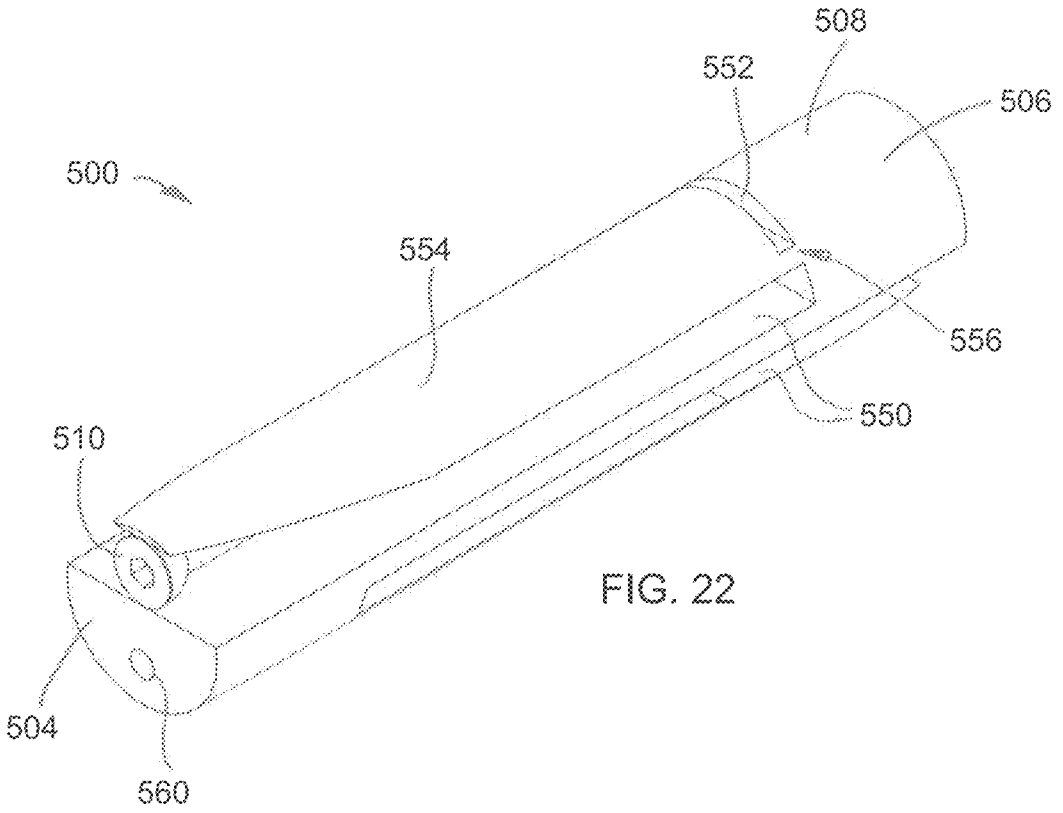
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FIG. 22

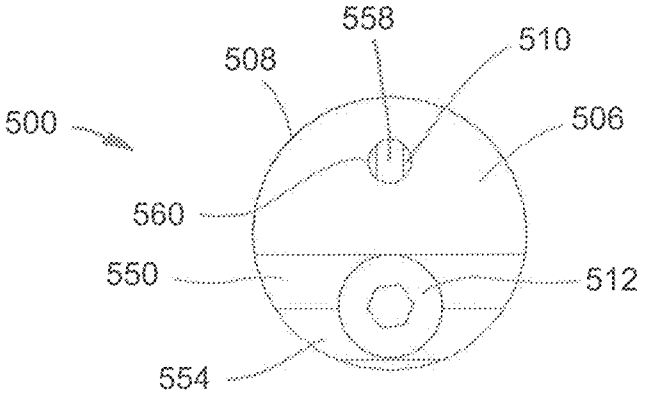
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FIG. 23

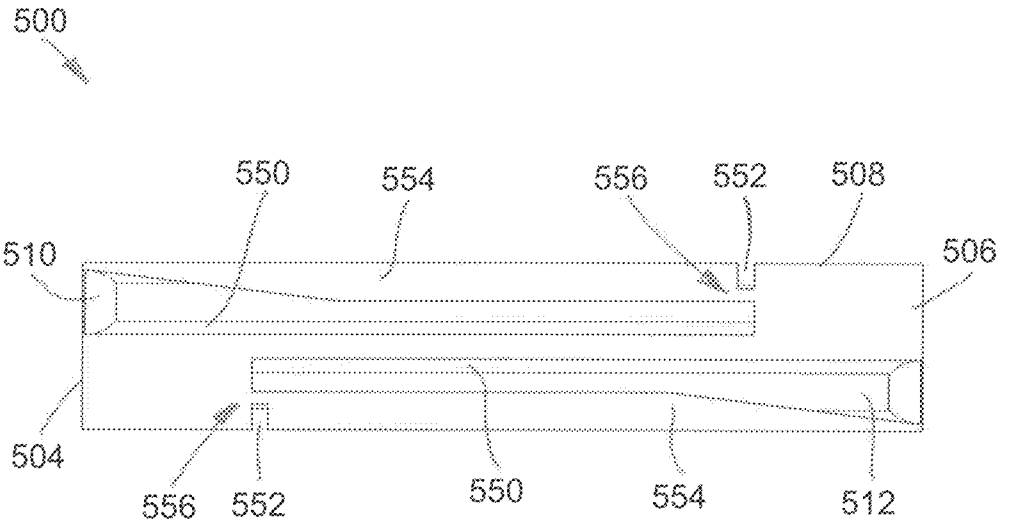
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FIG. 24

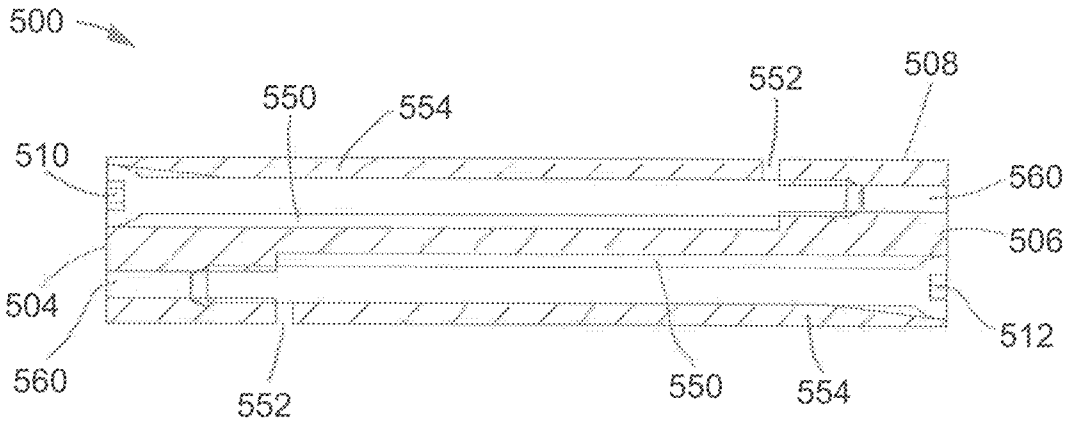
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FIG. 25

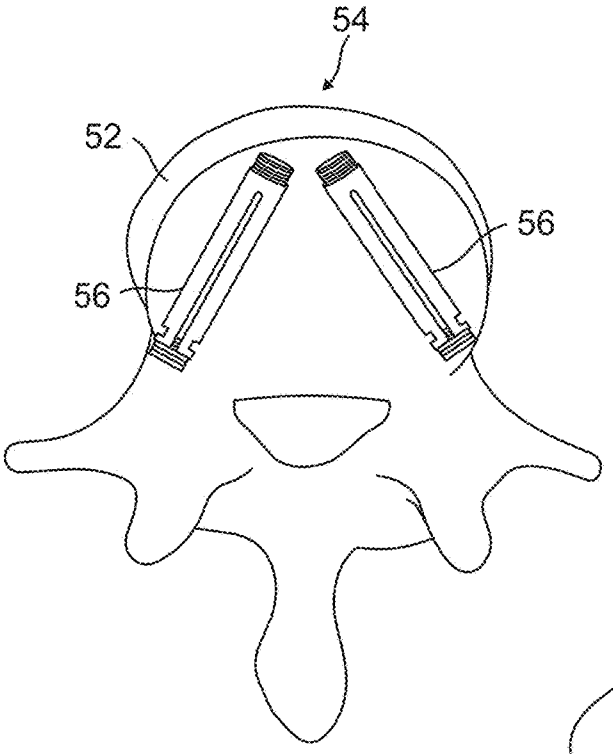

FIG. 26

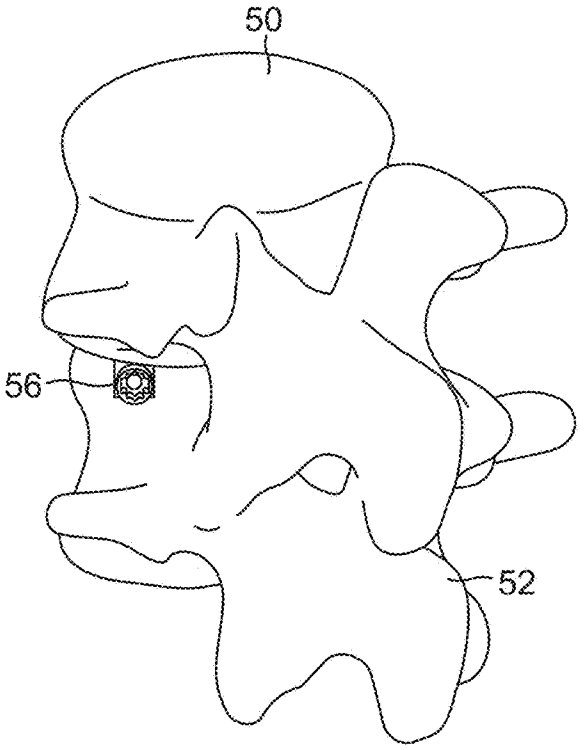

FIG. 27

Fine control over vertebral spacing
Rotate in two axis
Translate in one axis

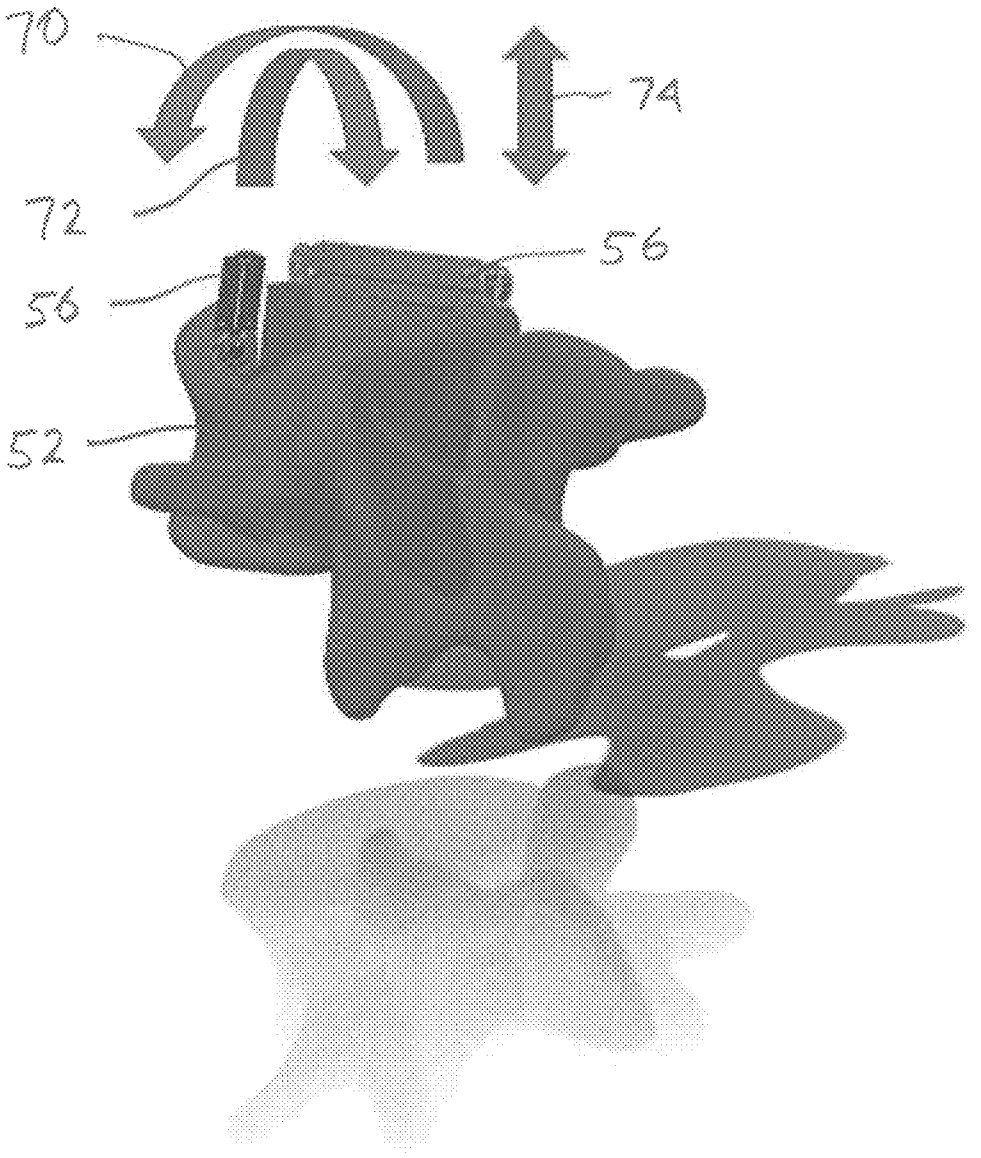

FIG. 28

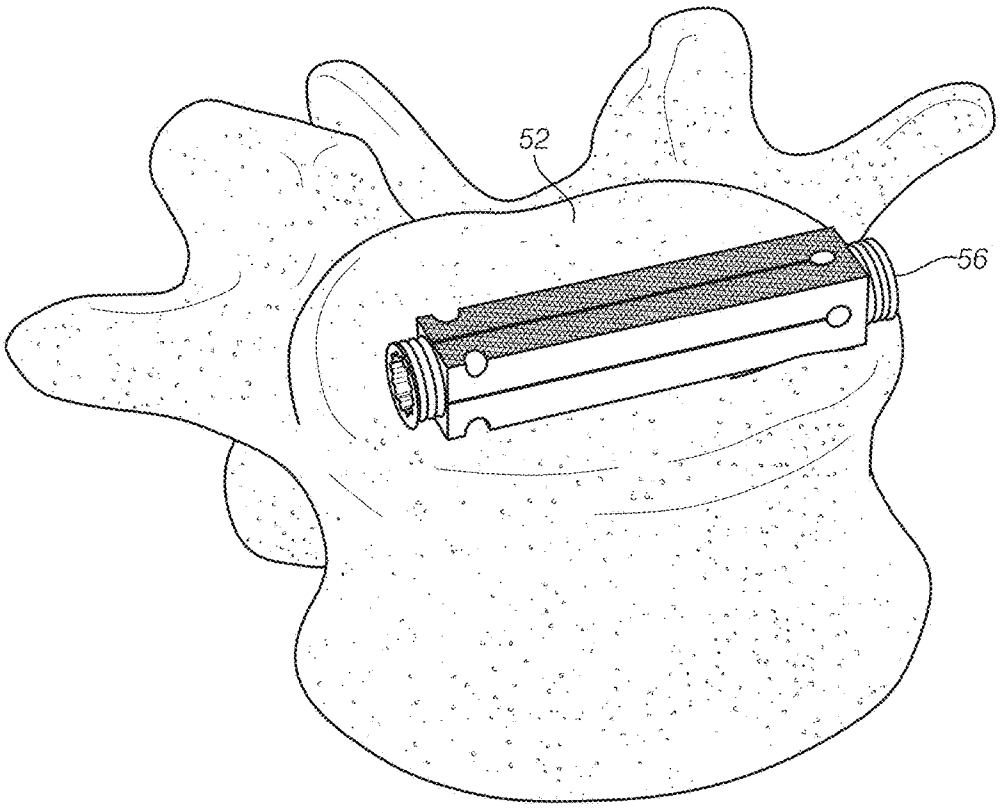

FIG. 29

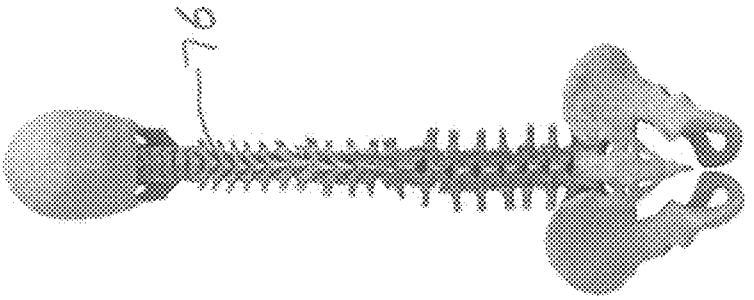

FIG. 31

Scoliosis Correction

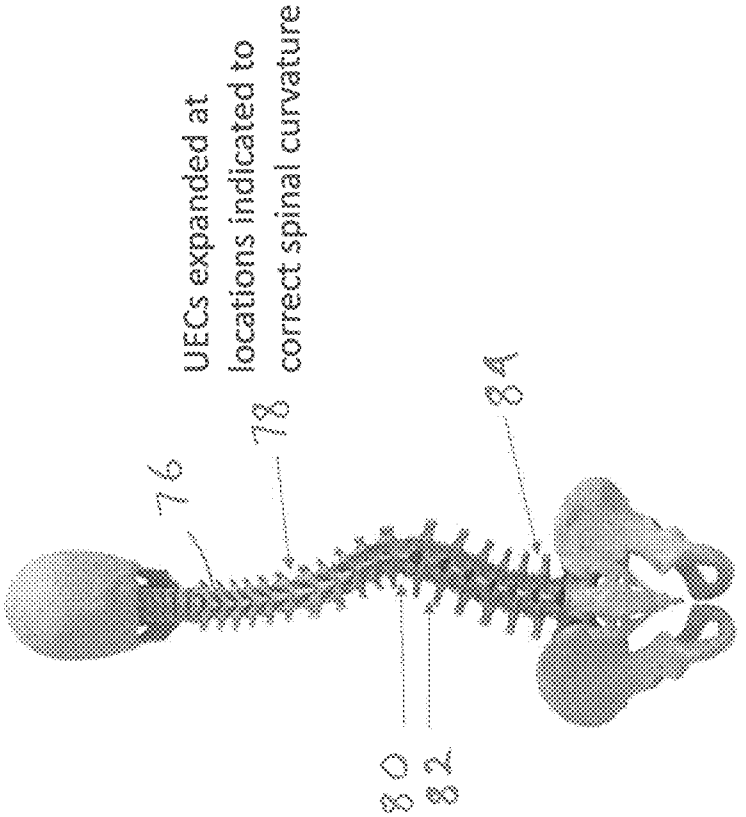

FIG. 30

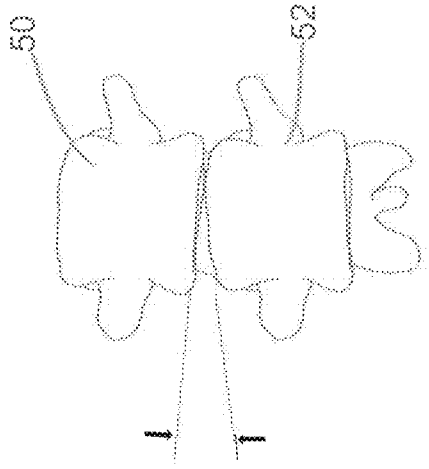

FIG. 32A

Misalignments

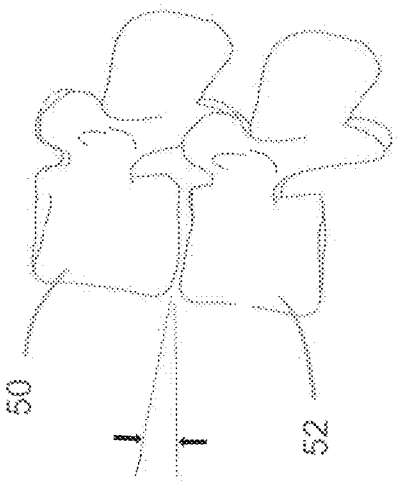

FIG. 32B

Uneven Spacing

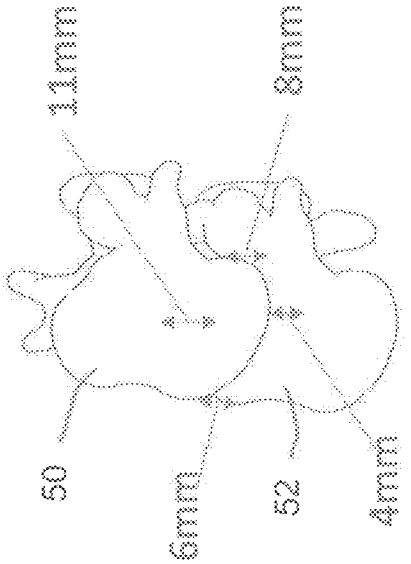

FIG. 32C

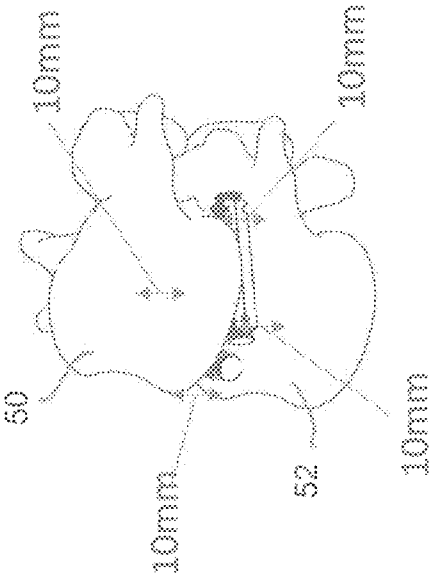

FIG. 33C

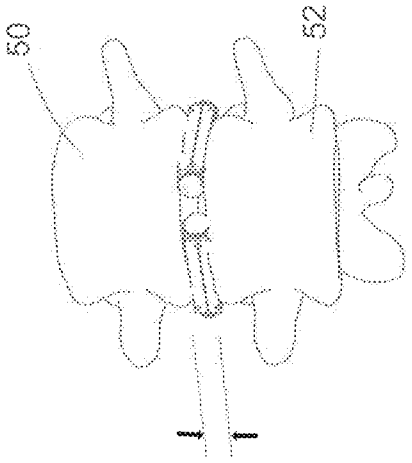

FIG. 33A

Alignment Restored

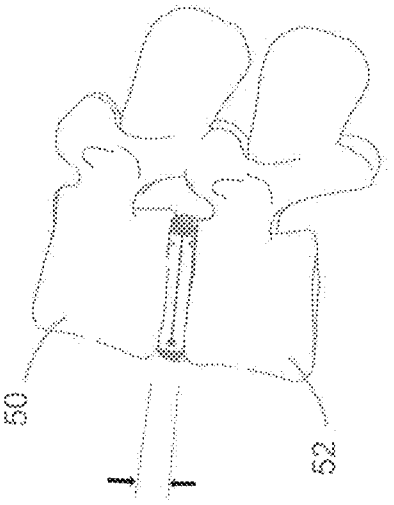

FIG. 33B

UNIVERSALLY EXPANDING CAGE

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims benefit of U.S. Non-provisional patent application Ser. No. 15/485,131 filed Apr. 11, 2017 which claims the benefit of U.S. non-provisional patent application Ser. No. 14/939,905 filed Nov. 12, 2015, now U.S. Pat. No. 9,622,878 which claims the benefit of U.S. Provisional Application No. 62/078,850 filed Nov. 12, 2014, all of which are incorporated herein by reference in their entirety.

INCORPORATION BY REFERENCE

All publications and patent applications mentioned in this specification are herein incorporated by reference in their entirety to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

FIELD

The present disclosure generally relates to medical devices for stabilizing the vertebral motion segment or other bone segments. More particularly, the field of the disclosure relates to a universally expanding cage (UEC) and method of use for providing controlled spinal correction or other bond segment spacing and/or alignment.

BACKGROUND

Conventional spine cages or implants are typically characterized by a kidney bean-shaped body comprising a hydroxyapatite-coated surface provided on the exterior surface for contact with adjacent vertebral segments or endplates which are shown in FIG. **1**. A conventional spine cage with flat endplates is typically inserted posterolaterally proximate to the neuroforamen of the distracted spine after a trial implant creates a pathway. Optionally two parallel externally threaded conduits are inserted anteriorly to achieve lumbar arthrodesis. The implants are often of constant diameter whereas the L5-S1 disc space is trapezoidal, thus a 'flat back' syndrome may be iatrogenically created. Generally spine intradiscal implants are for lumbar fusion or cervical motion preservation, while a separate system of rods and screws corrects alignment.

With the novel UECs disclosed herein, additional options include fusion throughout the spinal column, and deformity angular correction.

Existing devices for interbody stabilization have important and significant limitations. Among the limitations are an inability to expand and distract the endplates. Consequently, if a cage that is "to small" is inserted it can 'rattle around and never heal'. If the static cage is too big, it can injure adjacent nerves or destabilize the spine via end plate resection or subsidence.

Current devices for interbody stabilization include static spacers composed of titanium, PEEK, and high performance thermoplastic polymer produced by VICTREX, (Victrex USA Inc, 3A Caledon Court, Greenville, S.C. 29615), carbon fiber, or resorbable polymers. Current interbody spacers may not maintain interbody lordosis and can contribute to the formation of a straight or even kyphotic segments and the clinical problem of "flatback syndrome." Separation of the endplates increases space available for the neural elements, specifically the neural foramen. Existing static cages do not reliably improve space for the neural elements. Therefore, what is needed is an expanding cage that will increase space for the neural elements posteriorly between the vertebral bodies, or at least maintain the natural bone contours to avoid neuropraxia (nerve stretch) or encroachment.

U.S. Pat. No. 7,985,256, filed Sep. 26, 2006 and titled "Selectively Expanding Spine Cage, Hydraulically Controllable in Three Dimensions for Enhanced Spinal Fusion", and U.S. Pat. No. 7,819,921, filed Oct. 31, 2007 and titled "Linearly expanding spine cage for enhanced spinal fusion", both provide detailed background on expanding spine cages.

The cages disclosed in U.S. Pat. No. 7,985,256 above are restricted to use with hydraulics, and lumbar fusion. The cage disclosed in U.S. Pat. No. 7,819,921 allows for trapezoidal linear expanding, not uniform expansion, thus a trapezoidal L5 cage as disclosed therein will preserve natural lumbar lordosis. The disclosed cage was never developed. It is intended for use as two (2) parallel linearly expanding split conduits inserted anteriorly for lumbar fusion.

In contrast, the UEC cages disclosed herein expands either uniformly, or at either end proximally or distally. Given the adjustment option the surgeon can correct angulation deformity with the novel UEC.

Another problem with conventional devices of interbody stabilization includes poor interface between bone and biomaterial. Conventional static interbody spacers form a weak interface between bone and biomaterial. Although the surface of such implants is typically provided with a series of ridges or coated with hydroxyapetite, the ridges may be in parallel with applied horizontal vectors or side-to-side motion. That is, the ridges or coatings offer little resistance to movement applied to either side of the endplates. Thus, nonunion is common in allograft, titanium and polymer spacers, due to motion between the implant and host bone. Conventional devices typically do not expand between adjacent vertebrae. Since the UEC expands under surgeon control, the visible, palpable 'goodness of fit' setting can ideal lock opposing vertebral endplates at the time of surgery. As healing accrues, the implants become inert. Since no motion equates with no pain, clinical results are improved with UECs.

Therefore, what is needed is a way to expand an implant to develop immediate fixation forces that can exceed the ultimate strength at healing, with improved abilities to enable disc space fixation solidarity while correcting spine angular deformity. Such an expandable implant ideally will maximize stability of the interface and enhance stable fixation. The immediate fixation of such an expandable interbody implant advantageously will provide stability that is similar to that achieved at the time of healing. Such an implant will have valuable implications enhancing early post-operative rehabilitation for the patient.

Another problem of conventional interbody spacers is their large diameter requiring wide exposure. Existing devices used for interbody spacers include structural allograft, threaded cages, cylindrical cages, and boomerang-shaped cages. Conventional devices have significant limitation with regard to safety and efficacy. Regarding safety of the interbody spacers, injury to neural and aortic elements may occur with placement from an anterior or posterior approach. A conventional spine cage lacks the ability to expand, diminishing its fixation capabilities. Prior attempts to preserve lumbar motion have failed by extrusion of the implant after implantation. The risks to neural elements are

primarily due to the disparity between the large size of the cage required to adequately support the interbody space, and the small space available for insertion of the device, especially when placed from a posterior or transforaminal approach. Existing boomerang cages are shaped like a partially flattened kidney bean. Their implantation requires a wide exposure and potential compromise of vascular and neural structures, both because of their inability to enter small and become larger, and due to the fact that their insertion requires mechanical manipulation during insertion and expanding of the implant. Once current boomerang implants are prepared for insertion via a trial spacer to make a pathway toward the anterior spinal column, the existing static cage is shoved toward the end point with the hope that it will reach a desired anatomic destination. Given the proximity of nerve roots and vascular structures to the insertion site, and the solid, relatively large size of conventional devices, such constraints predispose a patient to foraminal (nerve passage site) encroachment, and possible neural and vascular injury.

Therefore, what is needed is a minimally invasive expanding spine cage that is capable of insertion with minimal invasion into a smaller aperture. Such a minimally invasive spine cage advantageously could be expanded with completely positional control or adjustment in three dimensions. What is also needed is a smaller expanding spine cage that is easier to operatively insert into a patient with minimal surgical trauma in contrast to conventional, relatively large devices that create the needless trauma to nerve roots in the confined space of the vertebral region. Existing interbody implants have limited space available for bone graft. Adequate bone graft or bone graft substitute is critical for a solid interbody arthrodesis. It would be desirable to provide an expandable interbody cage that will permit a large volume of bone graft material to be placed within the cage and around it, to fill the intervertebral space. Additionally, conventional interbody implants lack the ability to stabilize endplates completely and prevent them from moving. Therefore, what is also needed is an expanding spine cage wherein the vertebral end plates are subject to forces that both distract them apart, and hold them from moving. Such an interbody cage would be capable of stabilization of the motion segment, thereby reducing micromotion, and discouraging pseudoarthrosis (incomplete fusion) and pain.

Ideally, what is needed is a spine cage or implant that is capable of increasing its expansion in height and angle, spreading to a calculated degree. Furthermore, what is needed is a spine cage that can adjust the amount of not only overall anterior posterior expansion, but also medial and lateral variable expansion so that both the normal lordotic curve is maintained, and adjustments can be made for scoliosis or bone defects. Such a spine cage or implant would permit restoration of normal spinal alignment after surgery and hold the spine segments together rigidly, mechanically, until healing occurs.

What is also needed is an expanding cage or implant that is capable of holding the vertebral or joint sections with increased pullout strength to minimize the chance of implant fixation loss during the period when the implant is becoming incorporated into the arthrodesis bone block.

SUMMARY OF THE DISCLOSURE

According to some aspects of the disclosure, an expandable medical implant is provided with an implantable cage body having a proximal end and a distal end. In some embodiments, the proximal and distal ends of the cage body are each provided with a tapered or cam portion. The cage body further has a longitudinal axis extending between the proximal end and the distal end of the cage body. The implant may further comprise at least one proximal flexure at least partially located adjacent to the proximal end of the cage body and configured to allow a circumference of the distal end of the cage body to resiliently expand. The implant may further comprise at least one distal flexure at least partially located adjacent to the distal end of the cage body and configured to allow a circumference of the proximal end of the cage body to resiliently expand. The implant may further comprise a proximal plug member having a tapered portion configured to mate with the tapered portion of the proximal end of the cage body. The proximal plug member may be configured to move longitudinally relative to the cage body from a first position to a second position such that the at least one distal flexure moves and the circumference of the proximal end of the cage body resiliently expands. The proximal plug member may also be configured to move from the second position to the first position such that the circumference of the proximal end resiliently contracts. The implant may further comprise a distal plug member having a tapered portion configured to mate with the tapered portion of the distal end of the cage body. The distal plug member may be configured to move longitudinally relative to the cage body from a third position to a fourth position such that the at least one proximal flexure moves and the circumference of the distal end of the cage body resiliently expands. The distal plug member may also be configured to move from the fourth position to the third position such that the circumference of the distal end resiliently contracts.

In some embodiments, the cage body further comprises a first tapered bore at the proximal end configured to slidably receive the proximal plug member, and a second tapered bore at the distal end configured to slidably receive the distal plug member. The first tapered bore may threadably engage the proximal plug member such that when the proximal plug member is rotated relative to the cage body, the proximal plug member advances in a longitudinal direction relative to the cage body. The second tapered bore may threadably engage the distal plug member such that when the distal plug member is rotated relative to the cage body, the distal plug member advances in a longitudinal direction relative to the cage body.

In some embodiments, the at least one proximal flexure comprises a generally circular and open ended aperture and a pair of generally flexible beam portions extending longitudinally from the aperture. The at least one proximal flexure may include a pair of longitudinally extending beam portions separated by a longitudinally extending gap, wherein the at least one proximal flexure further comprises a connector portion interconnecting proximal ends of the beam portions. The at least one proximal flexure may include a plurality of circumferentially spaced proximal flexures, and the at least one distal flexure may include a plurality of circumferentially spaced distal flexures. The plurality of proximal flexures may be rotationally staggered from the plurality of distal flexures.

In some embodiments, each of the proximal flexures includes a pair of longitudinally extending beam portions separated by a longitudinally extending gap and bridged together by a connector portion interconnecting only proximal ends of the beam portions. Each of the distal flexures may include a pair of longitudinally extending beam portions separated by a longitudinally extending gap and bridged together by a connector portion interconnecting only distal ends of the beam portions. Each of the proximal

flexures can share a beam portion with two of the distal flexures that are adjacent to each proximal flexure, thereby forming a continuous serpentine pattern along the cage body.

In some embodiments, the implant includes a first adjustment member coupled to at least the proximal plug member such that when the first adjustment member is rotated, the proximal plug member is caused to move longitudinally. The implant may further include a second adjustment member coupled to the distal plug member such that when the second adjustment member is rotated, the distal plug member is caused to move longitudinally, thereby allowing the proximal and the distal ends of the cage body to be expanded and contracted independent from one another. The first and the second adjustment members may be coaxially nested one within the other and independently rotatable. In some embodiments, the first and the second adjustment members each have knobs axially spaced but adjacent to one another such that the knobs may alternately be rotated in unison or individually. At least one of the first and the second adjustment members may have a keyed end configured to slidably mate and rotationally couple with its associated plug member such that the at least one adjustment member can be removed from the expandable medical implant.

In some embodiments, the cage body has a square or circular cross-section transverse to the longitudinal axis.

In some embodiments, an expandable medical implant includes an implantable cage, a plurality of proximal flexures, a plurality of distal flexures, a proximal plug member, a distal plug member, and first and second adjustment members. In these embodiments, the implantable cage body has a proximal end and a distal end each provided with a threaded and tapered bore. The cage body has a longitudinal axis extending between the proximal end and the distal end of the cage body. The plurality of proximal flexures are circumferentially spaced and each is at least partially located adjacent to the proximal end of the cage body and configured to allow a circumference of the distal end of the cage body to resiliently expand. Each of the proximal flexures comprises a pair of longitudinally extending beam portions separated by a longitudinally extending gap and bridged together by a connector portion interconnecting only proximal ends of the beam portions. The plurality of distal flexures are circumferentially spaced and each is at least partially located adjacent to the distal end of the cage body and configured to allow a circumference of the proximal end of the cage body to resiliently expand. Each of the distal flexures comprises a pair of longitudinally extending beam portions separated by a longitudinally extending gap and bridged together by a connector portion interconnecting only distal ends of the beam portions. Each of the proximal flexures shares a beam portion with two of the distal flexures that are adjacent to each proximal flexure, thereby forming a continuous serpentine pattern along the cage body. The proximal plug member has a threaded and tapered circumference configured to mate with the threaded and tapered bore of the proximal end of the cage body. The proximal plug member is configured to move along the longitudinal axis relative to the cage body from a first position to a second position such that the plurality of distal flexures move and the circumference of the proximal end of the cage body resiliently expands. The proximal plug member is also configured to move from the second position to the first position such that the circumference of the proximal end resiliently contracts. The distal plug member has a threaded and tapered circumference configured to mate with the threaded and tapered bore of the distal end of the cage body. The distal plug member is configured to move along the longitudinal axis relative to the cage body from a third position to a fourth position such that the plurality of proximal flexures move and the circumference of the distal end of the cage body resiliently expands. The distal plug member is also configured to move from the fourth position to the third position such that the circumference of the distal end resiliently contracts. The first adjustment member is rotationally coupled to the proximal plug member such that when the first adjustment member is rotated, the proximal plug member is caused to move along the longitudinal axis. The second adjustment member rotationally coupled to the distal plug member such that when the second adjustment member is rotated, the distal plug member is caused to move longitudinally, thereby allowing the proximal and the distal ends of the cage body to be expanded and contracted independent from one another. The first and the second adjustment members are coaxially nested one within the other and independently rotatable. The first and the second adjustment members each have knobs axially spaced but adjacent to one another such that the knobs may alternately be rotated in unison or individually. At least one of the first and the second adjustment members may have a keyed end configured to slidably mate and rotationally couple with its associated plug member such that the at least one adjustment member can be removed from the expandable medical implant.

According to some aspects of the disclosure, a method of distracting adjacent bone segments having opposing surfaces is provided. The method comprises the steps of inserting an expandable medical implant as described above between the opposing surfaces of the bone segments, and moving the proximal and the distal plug members longitudinally and independently from one another such that the proximal and the distal ends of the cage body expand independently to alter the distance and the angle between the opposing surfaces of the bone segments. In some embodiments, the method further includes the step of removing at least one adjustment member from the medical implant after the adjustment member has been used to move at least one of the proximal and distal plug members. In some embodiments, the bone segments are adjacent vertebrae, and the opposing surfaces are end plates of the adjacent vertebrae.

BRIEF DESCRIPTION OF THE DRAWINGS

For the purpose of illustrating concepts of the disclosure, the drawings show aspects of one or more embodiments. However, it should be understood that the present disclosure is not limited to the precise arrangements and instrumentalities shown in the drawings, wherein:

FIGS. **1-3** are a series of lateral representations of two vertebral bodies, wherein FIG. **1** depicts the insertion of an exemplary Universally Expanding Cage (UEC) in its unexpanded state, FIG. **2** depicts the UEC in place between the vertebral bodies and still in its unexpanded state, and FIG. **3** depicts the inserted UEC in its expanded state.

FIG. **4** is a perspective view of a first embodiment of a UEC in an unexpanded state according to aspects of the disclosure.

FIG. **5** is an exploded perspective view showing the UEC of FIG. **4**.

FIG. **6** is a perspective view showing the cage body of the UEC of FIG. **4**.

FIG. **7** is a proximal end view of the UEC of FIG. **4**.

FIG. **8** is a side view of the UEC of FIG. **4**.

FIG. **9** is a side cross-sectional view of the UEC of FIG. **4**.

FIG. **10** is a perspective view of a second embodiment of a UEC in an unexpanded state according to aspects of the disclosure.

FIG. **11** is an exploded perspective view showing the UEC of FIG. **10**.

FIG. **12** is a side view showing the UEC of FIG. **10**.

FIG. **13** is a proximal end view showing the UEC of FIG. **10**.

FIG. **14** is a distal end view showing the UEC of FIG. **10**.

FIG. **15** is a side cross-sectional view showing the UEC of FIG. **10**.

FIG. **16** is a perspective view of a third embodiment of a UEC in an unexpanded state according to aspects of the disclosure.

FIG. **17** is an exploded perspective view showing the UEC of FIG. **16**.

FIG. **18** is a side view showing the UEC of FIG. **16**.

FIG. **19**A is a side cross-sectional view showing the UEC of FIG. **16**.

FIG. **19**B is an end cross-sectional view showing the UEC of FIG. **16**.

FIGS. **20**A-**20**C are a series of side views showing the progressive expansion of the UEC of FIG. **16**, wherein FIG. **20**A shows both ends of the UEC in the unexpanded state, FIG. **20**B shows only one end expanded, and FIG. **20**C shows both ends expanded.

FIG. **21** is a perspective view of a fourth embodiment of a UEC in an unexpanded state according to aspects of the disclosure.

FIG. **22** is a perspective view of a fifth embodiment of a UEC in an unexpanded state according to aspects of the disclosure.

FIG. **23** is a distal end view showing the UEC of FIG. **22**.

FIG. **24** is a side view showing the UEC of FIG. **22**.

FIG. **25** is a side cross-sectional view showing the UEC of FIG. **22**.

FIG. **26** is a cranial to caudal view showing the insertion sites of dual UECs on a vertebral body in one example implementation.

FIG. **27** is an oblique posterolateral view showing one of the insertion sites of the implementation of FIG. **26**.

FIG. **28** is an oblique posterolateral view showing the axes of adjustment provided by the implementation of FIG. **26**.

FIG. **29** is an oblique anterior view showing an anterior column implant.

FIG. **30** is a posterior view showing a human spine exhibiting scoliosis.

FIG. **31** is a posterior view showing the spine of FIG. **29** after being corrected according to aspects of the disclosure.

FIGS. **32**A-**32**C are anterior, lateral and oblique views, respectively, showing adjacent vertebral bodies having misalignments/uneven spacing.

FIGS. **33**A-**33**C are anterior, lateral and oblique views, respectively, showing the vertebral bodies of FIGS. **32**A-**32**C with the misalignments/uneven spacing corrected according to aspects of the disclosure.

DETAILED DESCRIPTION

Referring to FIG. **1-3**, a series of lateral views of vertebral segments **50** and **52** are shown, depicting the insertion and expansion of one embodiment of UEC (Universally Expanding Cage). The depicted vertebral bodies **50** and **52** have an average 8 mm gap between vertebral end plates, representing an average intervertebral space **54**. In a typical implementation, a complete discectomy is performed prior to the insertion of the UEC **56**. The intervertebral disc occupying space **54** is removed using standard techniques including rongeur, curettage, and endplate preparation to bleeding subcondral bone. The posterior longitudinal ligament is divided to permit expansion of the intervertebral space.

The intervertebral space **54** may be distracted to about 10 mm using a rotating spatula (not shown). This is a well-known device that looks like a wide screw driver that can be placed into the disc space horizontally and turned 90 degrees to separate the endplates. A novel feature of the UEC is that after intervertebral disc space expansion and preparation (by curetting or ideally arthroscopically facilitated disc material removal), the UEC implant per se can be inserted through any orifice or angle that does not cause injury to nerves or other structures, positioned at the immediate implant location and consequent expansion platform to yield both the best fusion and angular correction results.

In the example implementation depicted in FIGS. **1-3**, UEC **56** is inserted posteriorly (in the direction of arrow **58**) between vertebral bodies **50** and **52**, as shown in FIG. **1**. The vertebral space **54** depicted is meant to represent any vertebral space in which it is desired to insert the UEC (sacral, lumbar, thoracic and/or cervical), and from any direction permitted by the surrounding anatomy. In accordance with an aspect of the disclosure, the UEC is reduced to a small size in its unexpanded state to enable it to be inserted through into the intervertebral space **54** as shown in FIG. **1**. FIG. **2** shows UEC **56** inserted between vertebral bodies **50** and **52**, with UEC **56** still in its unexpanded state. In one exemplary embodiment, dimensions of an unexpanded UEC are: 10-12 mm wide, 10 mm high and 28 mm long to facilitate insertion and thereby minimize trauma to the patient and risk of injury to nerve roots. These dimensions may accommodate the flat external surfaces. Once in place, the exemplary UEC **56** may be expanded to 140 percent of its unexpanded size (as shown in FIG. **3**), enabling 20 degrees or more of spinal correction depending on the 3D clinical pre-operation anatomic analysis.

It should be noted that while the exemplary UEC **56** depicted in FIGS. **1-3** is an implant intended to ideally fill the warranted space, other shapes of implants such as those shown in later figures and/or described herein may be used. In various embodiments, the implants may have a transverse cross-section that is circular, oval, elliptical, square, rectangular, trapezoidal, or other shape suited to fill the implant site and transmit the required loads. The implants may straight, curved, bean-shaped, and/or include other shapes and aspect ratios. Additionally, the external surfaces may be smooth, spiked, threaded, coated and/or further adapted as subsequently described in more detail. The UEC can be used at any spinal level the surgeon deems in need of fusion, and may be placed at any position and angle relative to the vertebral endplates as may be needed. One, two, or more UECs may be placed at any particular level to achieve the desired height and angles between vertebral bodies. As will be later described, multiple UECs may be used to adjust the overall cranio-caudal height, the anterior-posterior angle, and the medio-lateral angle between adjacent vertebral bodies UECs may be implanted at multiple levels to obtain or restore the desired three dimensional curvature and positioning of the spine.

Referring to FIGS. **4-9**, a first embodiment of an exemplary UEC **100** according to aspects of the disclosure is shown. FIG. **4** is an enlarged perspective view which shows details of UEC **100**. For ease of understanding, a proximal end **104** and a distal end **106** of UEC **100** can be defined as shown in FIG. **4**. It should be noted that while the distal end

106 of UEC 100 is typically inserted first into a patient and proximal end 104 is typically closest to the surgeon, other orientations of this exemplary device and other devices described herein may be adopted in certain procedures despite the distal and proximal nomenclature being used.

Referring to FIG. 5, an exploded perspective view shows the individual components of UEC 100. In this first embodiment, UEC 100 includes a cylindrically-shaped cage body 108, a proximal plug 110, a distal plug 112, a threaded actuator 114, and a washer 116. The terms "plug" and "plug member" are used interchangeably herein. Actuator 114 has a shank sized to slidably pass through a central bore within proximal plug 110 when UEC 100 is assembled. Actuator 114 also has threads on its distal end for engaging with a threaded central bore within distal plug 112. Proximal plug 110 and distal plug 112 each have outer surfaces that are inwardly tapered to match inwardly tapered surfaces within cage body 108 (as best seen in FIG. 9) With this arrangement, actuator 114 may be rotated in a first direction to draw distal plug 112 toward proximal plug 110 to outwardly expand cage body 108, as will be subsequently described in more detail.

Referring to FIG. 6, this perspective view shows details of cage body 108 of the first exemplary embodiment of UEC 100. In this embodiment, cage body 108 includes eight longitudinally extending beam portions 118, each separated from an adjacent beam portion 118 by a longitudinally extending gap 120. In other embodiments (not shown), the cage body may include fewer or more than eight beam portions, and/or beam portions having a different or varying cross-section or shape. Cage body 108 of the current embodiment also includes eight circumferentially extending connector portions 122. The connector portions 122 interconnect the ends of the beam portions 118. Four of the connector portions 122 are located at the proximal end 104 of cage body 108, and the other four connector portions 122 are located at the distal end 106. The connector portions 122 located at the proximal end 104 are staggered in relation to the connector portions 122 located at the distal end 106 such that each pair of adjacent beam portions 118 are connected at only one end by a connector portion 122. With this arrangement the beam portions 118 and connector portions 122 form a continuous serpentine or repeating S-shaped pattern. The beam portions 118 and or the connector portions 122 are configured to resiliently flex to allow the cage body 108 to increase in diameter when urged radially outward by plugs 110 and 112 (shown in FIG. 4). When plugs 110 and 112 are not urging cage body 108 radially outward, the resiliency of beam portions 118 and or connector portions 122 allows cage body 108 to return to its original reduced diameter. It can be appreciated that as beam portions 118 and or connector portions 122 flex outwardly, gaps 120 become wider at their open ends opposite connector portions 122. The outwardly facing surfaces of beam portions 118 may each be provided with one or more points or spikes 123 as shown, to permit cage body 108 to grip the end plates of the vertebral bodies.

Referring to FIG. 7, an end view of the proximal end 104 of UEC 100 is shown. The enlarged head at the proximal end of actuator 114 may be provided with a recessed socket 124 as shown for removably receiving a tool for turning actuator 114. Proximal plug 110 (and distal plug 112, not shown) may be provided with radially outwardly extending protuberances 126 that reside in one or more gaps 120 and abut against the side of beam portions 118. This arrangement prevents plugs 110 and 112 from rotating when actuator 114 is turned, thereby constraining plugs 110 and 112 to only move axially toward or away from each other. Proximal plug 110 (and distal plug 112) may be provided with through holes and or recesses 128 to allow for bony ingrowth from the vertebral bodies for more solidly healing/fusing UEC 100 in place. Longitudinally extending slots 130 (shown in FIG. 4) may also be provided for this purpose, and or for packing plugs 110 and 112 with autograft, allograft, and/or other materials for promoting healing/fusion.

Referring to FIGS. 8 and 9, a side view and side cross-sectional view, respectively, are shown. In operation, UEC 100 is expanded by inserting a tool such as a hex key wrench or driver (not shown) into the recessed socket 124 at the proximal end of actuator 114 and turning it clockwise. As best seen in FIG. 9, the distal end of actuator 114 is threaded into the central bore of distal plug 112. Turning actuator 114 clockwise causes the distal end of actuator 114 to pull distal plug 112 towards the center of cage body 108 while the enlarged head at the proximal and of actuator 114 pushes proximal plug 110 towards the center. This movement in turn causes the ramped surfaces 132 of plugs 110 and 112 to slide inwardly along the ramped surfaces 134 located along the inside of beam portions 118 and connector portions 122 to cause these elements to flex and expand radially outward as previously described. This process may be reversed by turning actuator 114 counterclockwise. The resilient inward forces from the beam portions 118 and or connector portions 122 (and or the compressive forces from adjacent vertebral bodies) against plugs 110 and 112 causes the two plugs to separate axially, thereby allowing UEC 100 to return to its non-expanded state.

Referring to FIGS. 10-15, a second embodiment of an exemplary UEC 200 according to aspects of the disclosure is shown. FIG. 10 is a perspective view which shows details of UEC 200. UEC 200 includes a proximal end 204 and a distal end 206, and shares many of the same features of previously described UEC 100, which are identified with similar reference numerals.

Referring to FIG. 11, an exploded perspective view shows the individual components of UEC 200. In this second embodiment, UEC 200 includes an elongated cylindrical cage body 208, a proximal plug 210, and a distal plug 212. Distal plug 212 includes an integrally formed actuator rod 214 that extends along the internal central axis of cage body 208 towards proximal plug 210 when UEC 200 is assembled. Proximal plug 210 and distal plug 212 each have outer surfaces that are threaded and inwardly tapered to match threaded and inwardly tapered surfaces within cage body 208 (as best seen in FIG. 15). With this arrangement, each plug 210 and 212 may be independently rotated to move the particular plug axially toward the middle of cage body 208 to outwardly expand that particular end 204 or 206 of cage body 208, as will be subsequently described in more detail.

As shown in FIGS. 11 and 12, cage body 208 includes eight longitudinally extending beam portions 218, each separated from an adjacent beam portion 218 by a longitudinally extending gap 220. In other embodiments (not shown), the cage body may include fewer or more than eight beam portions, and/or beam portions having a different or varying cross-section or shape. Cage body 208 of the current embodiment also includes eight circumferentially extending connector portions 222. The connector portions 222 interconnect the ends of the beam portions 218. Four of the connector portions 222 are located at the proximal end 204 of cage body 208, and the other four connector portions 222 are located at the distal end 206. The connector portions 222 located at the proximal end 204 are staggered in relation to

the connector portions **222** located at the distal end **206** such that each pair of adjacent beam portions **218** are connected at only one end by a connector portion **222**. With this arrangement the beam portions **218** and connector portions **222** form a continuous serpentine or repeating S-shaped pattern. The beam portions **218** and or the connector portions **222** are configured to resiliently flex to allow the cage body **208** to increase in diameter when urged radially outward by plugs **210** and **212**. When plugs **210** and **212** are not urging cage body **208** radially outward, the resiliency of beam portions **218** and or connector portions **222** allows cage body **208** to return to its original reduced diameter. It can be appreciated that as beam portions **218** and or connector portions **222** flex outwardly, gaps **220** become wider at their open ends opposite connector portions **222**. The outwardly facing surfaces of beam portions **218** may each be provided with one or more points or spikes **223** as shown, to permit cage body **208** to grip the end plates of the vertebral bodies.

Referring to FIG. **13**, an end view of the proximal end **204** of UEC **200** is shown. The proximal plug **210** may be provided with a recessed socket **224** as shown for removably receiving a tool for turning proximal plug **210** in either direction, such as a five-lobed driver (not shown). Alternatively, other suitable types of recessed sockets, slots, protruding and/or keyed features may be utilized with a mating driver. The proximal end of actuator shaft **214** (which extends proximally from distal plug **212** inside cage body **208**) may be accessed through a central bore **225** in proximal plug **210**. The proximal end of actuator shaft **214** may be shaped as shown to be received within a mating driver socket (such as a five-lobed socket, not shown), which can be removably extended into the center of cage body **208** through central bore **225**. With this arrangement, both the proximal plug **210** and the distal plug **212** can be independently accessed and rotated from the proximal end of UEC **200** so that the proximal end **204** and the distal end **206** of UEC **200** can be expanded or contracted independently.

Referring to FIG. **14**, an end view of the distal end **206** of UEC **200** is shown. By comparing FIGS. **13** and **14**, it can be appreciated that connector portions **222** at the proximal end **204** of UEC **200** are staggered (i.e. rotated 45°) in relation to the connector portions **222** at the distal end **206** of UEC **200**.

Referring to FIG. **15**, a side cross-sectional view of UEC **200** is shown. In operation, the proximal end **204** of UEC **200** may be independently expanded by inserting a tool such as a five-lobed driver (not shown) into the recessed socket **224** of proximal plug **210** and turning it clockwise. Turning proximal plug **210** clockwise causes the threaded ramped surfaces **232** of plug **210** to translate inwardly (to the right in FIG. **15**) along the threaded ramped surfaces **234** located along the inside of beam portions **218** and connector portions **222** to cause these elements to flex and expand radially outward as previously described. This process may be reversed by turning proximal plug **210** counterclockwise, thereby allowing the proximal end **204** of UEC **200** to return to its non-expanded state. Similarly, the distal end **206** of UEC **200** may be independently expanded by inserting a tool such as a five-lobed socket (not shown) through the central bore **225** in proximal plug **210** until it engages with the proximal end of actuator **214**, which is attached to distal plug **212**. Turning distal plug **212** counterclockwise (from the perspective of the proximal end) causes the threaded ramped surfaces **232** of plug **212** to translate inwardly (to the left in FIG. **15**) along the threaded ramped surfaces **234** located along the inside of beam portions **218** and connector portions **222** to cause these elements to flex and expand radially outward as previously described. This process may be reversed by turning distal plug **212** clockwise, thereby allowing the distal end **206** of UEC **200** to return to its non-expanded state.

The adjustment tools described above (not shown) for turning proximal plug **210** and distal plug **212** may be inserted one at a time into UEC **200**. Alternatively, the two tools may be nested together, with the tool for turning the distal plug **212** passing through a central bore in the tool for turning the proximal plug, as will be subsequently shown and described in relation to other embodiments. With this arrangement, both tools may be turned simultaneously or individually. In some embodiments, both proximal plug **210** and distal plug **212** are provided with right-handed threads, so that when both tools are simultaneously turned in the same direction, one end of UEC **200** expands while the other end contracts, thereby changing the outer surface angle of UEC **200** without substantially changing its overall diameter (i.e. without substantially changing the diameter or height of the midpoint of UEC **200**.) For example, by turning the two tools in the same direction, the lordotic angle between two vertebral bodies can be changed by UEC **200** without substantially changing the height between the two vertebral bodies.

In other embodiments, one of the plugs **210** or **212** may be provides with a right-handed thread and the other plug provided with a left-handed thread. In these embodiments, when both adjustment tools are simultaneously turned in the same direction, both ends **204** and **206** of UEC **200** expand or contract together without substantially changing the outer surface angle of UEC **200**. For example, by turning the two tools in the same direction, the height between the two vertebral bodies can be changed by UEC **200** without substantially changing the lordotic angle between two vertebral bodies.

In some embodiments, plugs **210** and **212** may each be provided with threads having a different pitch from the other. Such an arrangement allows both the height and the angle between adjacent vertebral bodies to be adjusted simultaneously in a predetermined relationship when both adjustment tools are turned together in unison. For example, proximal plug **210** may be provided with right-handed threads of a particular pitch while distal plug **212** may be provided with finer, left-handed threads having half the pitch of the proximal plug threads. In this embodiment, when both adjustment tools are turned together in a clockwise direction, both ends of UEC **200** expand at the same time but the proximal end **204** expands at twice the rate of the distal end **206**. This allows the surgeon to increase the height between adjacent vertebral bodies and at the same time angle the bodies away from him or her. One or both of the tools may then be turned individually to more finely adjust the height and angle between the vertebral bodies.

In some embodiments the above-described adjustment tools may be removed from UEC **200** before the surgical procedure is completed. In some embodiments the above adjustment tools may remain in place after the procedure is completed.

In some embodiments, UEC **200** is 50 mm long, has an unexpanded diameter of 10 mm, and an expanded diameter of 14 mm. In other embodiments, the UEC may be configured to expand to about 11, 12, or 13 mm, or more than 14 mm. In still other embodiments, the UEC may be configured with dimensions larger or smaller than these to conform to a particular anatomy or procedure.

Referring to FIGS. **16-20**, a third embodiment of an exemplary UEC **300** according to aspects of the disclosure is shown. FIG. **16** is a perspective view which shows details of UEC **300**. UEC **300** includes a proximal end **304** and a distal end **306**, and shares many of the same features of previously described UECs **100** and **200**, which are identified with similar reference numerals.

Referring to FIG. **17**, an exploded perspective view shows the individual components of UEC **300**. In this third embodiment, UEC **300** includes a rectangular cage body **308**, a proximal plug **310**, a distal plug **312**, a proximal plug adjustment tool **313**, and a distal plug adjustment tool **314**. As in the previously described UEC **200**, both plugs **310** and **312** are threaded and tapered, and each end of cage body **308** is provided with an inwardly tapered and threaded bore configured to receive one of the plugs **310** or **312**. Adjustment tools **313** and **314** are similar in construction and operation to the adjustment tools previously described (but not shown) in reference to UEC **200**. Proximal plug **310** includes a mating recess on its proximal end (not shown) configured to removably receive the splined distal end of proximal plug adjustment tool **313** for rotating proximal plug **310**. Distal plug **312** includes a smaller mating recess on its proximal end (not shown) configured to removably receive the smaller splined distal end of distal plug adjustment tool **314** for rotating distal plug **312**. Both proximal plug adjustment tool **313** and proximal plug **312** are provided with central bores that permit the distal end of distal plug adjustment tool **314** to pass therethrough, through the center of cage body **308**, and partially into distal plug **312**. In this exemplary embodiment, the proximal ends of adjustment tools **313** and **314** each have a hexagonally-shaped head that permits them to be turned together in unison or individually (as previously described in relation to UEC **200**), using wrench(es), socket(s) (not shown) and/or by hand.

As shown in FIGS. **16** and **17**, cage body **308** includes eight longitudinally extending beam portions **318**, each separated from an adjacent beam portion **318** by a longitudinally extending gap **320**. In other embodiments (not shown), the cage body may include fewer or more than eight beam portions, and/or beam portions having a different or varying cross-section or shape. It can be seen that in this embodiment, four of the gaps **320** are formed through the middle of the four faces of cage body **308**, and the other four gaps **320** are formed along the corner edges of cage body **308**. Cage body **308** also includes eight circumferentially extending connector portions **322**. The connector portions **322** interconnect the ends of the beam portions **318**. Circular apertures **321** may be provided as shown between the ends of gaps **320** and the connector portions **322** to relieve stress concentrations at those locations as connector portions **322** flex. Four of the connector portions/flexures **322** are located at the proximal end **304** of cage body **308** (across the corner edges of cage body **308**), and the other four connector portions/flexures **322** are located at the distal end **306** (across the distal end of the faces of cage body **308**.) The connector portions **322** located at the proximal end **304** are staggered in relation to the connector portions **322** located at the distal end **306** such that each pair of adjacent beam portions **318** are connected at only one end by a connector portion **322**. As with previously described embodiments, the beam portions **318** and connector portions **322** form a continuous serpentine or repeating S-shaped pattern. The beam portions **318** and or the connector portions **322** are configured to resiliently flex to allow the cage body **308** to increase in circumference when urged radially outward by plugs **310** and **312**. When plugs **310** and **312** are not urging cage body **308** radially outward, the resiliency of beam portions **318** and or connector portions **322** allows cage body **308** to return to its original reduced circumference. It can be appreciated that as beam portions **318** and or connector portions **322** flex outwardly, gaps **320** become wider at their open ends opposite connector portions **322**. The outwardly facing surfaces of beam portions **318** may each be provided with one or more points or spikes **323** as shown, to permit cage body **308** to grip the end plates of the vertebral bodies. In this exemplary embodiment, spiked or knurled surfaces are provided along the top and bottom of UEC **300** while the side surfaces are left smooth.

Referring to FIGS. **18** and **19**, a side view and a side cross-sectional view, respectively, of UEC **300** are shown. In operation, the proximal end **304** of UEC **300** may be independently expanded by inserting proximal plug adjustment tool **313** into the mating recessed socket of proximal plug **310** (as shown in FIG. **19**) and turning it clockwise. Turning proximal plug **310** clockwise causes the threaded ramped surfaces **332** of plug **310** to translate inwardly (to the left in FIGS. **18** and **19**) along the threaded ramped surfaces **334** located along the inside of beam portions **318** and connector portions **322** to cause these elements to flex and expand radially outward as previously described. This process may be reversed by turning proximal plug **310** counterclockwise, thereby allowing the proximal end **304** of UEC **300** to return to its non-expanded state. Similarly, the distal end **306** of UEC **300** may be independently expanded by inserting a tool such as a five-lobed socket (not shown) through the central bore **325** in proximal plug **310** until it engages with the proximal end of actuator **314**, which is attached to distal plug **312**. Turning distal plug **312** counterclockwise (from the perspective of the proximal end) causes the threaded ramped surfaces **332** of plug **312** to translate inwardly (to the right in FIGS. **18** and **19**) along the threaded ramped surfaces **334** located along the inside of beam portions **318** and connector portions **322** to cause these elements to flex and expand radially outward as previously described. This process may be reversed by turning distal plug **312** clockwise, thereby allowing the distal end **306** of UEC **300** to return to its non-expanded state.

Referring to FIGS. **20**A-**20**C, a series of side views depicts the progression from a fully retracted and a fully expanded UEC **300**. In FIG. **20**A, cage body **308** is shown in a fully retracted position. In this figure, the height of each end of cage body **308** is labeled as 100% of retracted cage height. In FIG. **20**B, the proximal end **304** of cage body **308** has been fully expanded while the distal end **306** remains fully retracted. In this exemplary embodiment, each end is capable of being expanded to a height (and therefore also a width) that is 140% of the fully retracted height, as shown. In FIG. **20**C, the distal end **306** has also been expanded by 40%.

In some embodiments, UEC **300** has a cage length of 50 mm, an unexpanded cage height of 10 mm, and an expanded cage height of 14 mm. The overall length of UEC **300** with adjustment tools **313** and **314** in place and in the unexpanded state may be 75 mm. In other embodiments, the UEC may be configured to expand to about 11, 12, or 13 mm, or more than 14 mm. In still other embodiments, the UEC may be configured with dimensions larger or smaller than these to conform to a particular anatomy or procedure. In some embodiments, the UEC can form an included angle between its top and bottom surfaces of at least 20 degrees.

Referring to FIG. **21**, a fourth embodiment of an exemplary UEC **400** according to aspects of the disclosure is

shown. FIG. **21** is a perspective view which shows details of UEC **400**. UEC **400** includes a proximal end **404**, a distal end **406**, cage body **408**, proximal plug **410**, distal plug **412**, proximal plug adjusting tool **413**, and distal plug adjusting tool **414**. Other than cage body **408** having a circular cross-section rather than a square cross-section, UEC **400** is essentially identical in construction and operation to previously described UEC **300**. In other embodiments (not shown), the UEC may have a cross-section transverse to the central longitudinal axis that is rectangular, trapezoidal, oval, elliptical or other shape.

Referring to FIGS. **22-25**, a fifth embodiment of an exemplary UEC **500** according to aspects of the disclosure is shown. FIG. **16** is a perspective view which shows details of UEC **500**. UEC **500** includes a proximal end **504** and a distal end **506**, and shares many of the same features of previously described UECs **100-400**, which are identified with similar reference numerals.

UEC **500** includes three components: a generally cylindrical, unitary cage body **508**; a proximal actuator screw **510**; and a distal actuator screw **512**. The heads of actuator screws **510** and **512** may be referred to as plug members. Cage body **508** includes two longitudinal, off-center slots **550** which each extend about three-quarters of the length of cage body **508**, and emanate from opposite ends and opposite sides of cage body **508**. Cage body **508** is also provided with two transverse slots **552**, each located adjacent to the closed end of one of the longitudinal slots **550**. Each transverse slot **552** extends from the outer circumference of cage body **508** and approaches the base of a longitudinal slot **550**. Each of the two pairings of a longitudinal slot **550** with a transverse slot **552** defines a cantilevered arm **554** that is connected with the remainder of the cage body **508** by a living hinge **556** near the closed ends of the two slots **550** and **552**. Each living hinge **556** allows its associated arm **554** to flex outwardly against a vertebral body.

The open ends of longitudinal slots **550** are outwardly tapered to receive the enlarged, tapered heads of an actuator screw **510** or **512**, as best seen in FIG. **24**. The opposite ends of actuator screws **510** and **512** extend through longitudinal slots **550** and thread into the opposite ends of cage body **508**. With this arrangement, each actuator screw **510** and **512** may be turned independently of the other, causing the screw to move axially relative to bone cage **508**. This axial movement causes the head of the screw to urge the tapered tip of the associated arm **554** outward, or allowing it to flex back inward when the screw is turned in the opposite direction. If both actuator screws **510** and **512** are turned in the same direction the same amount, UEC **500** expands uniformly and increases the height between adjacent vertebral bodies. If one of the two actuator screws **510** or **512** is turned more than the other, the surgeon is able to change the angle between the vertebral bodies.

As best seen in FIG. **23**, a slot **558** or other suitable feature may be provided in the end of each actuator screw **510** and **512** at the opposite end from the screw head. A hole **560** may also be provided through each end of cage body **508** to allow access to each of the two slots **558**. This arrangement allows both of the actuator screws **510** and **512** to be turned from either end **504** and/or **506** of cage body **508**.

Referring to FIGS. **26-28**, an example implementation utilizing two UECs **56** in tandem is shown. Each UEC **56** may be inserted as previously described in relation to FIGS. **1-3**. In this implementation, UECs **56** are placed non-parallel to one another. As best seen in FIG. **28**, this arrangement allows the surgeon to adjust the angle between the vertebrae about two different axes, and also translate the vertebrae with respect to one another about another axis.

FIG. **29** is an oblique anterior view showing placement of an anterior column implant **56** on a vertebral body **52**. In this implementation, implant **56** is placed laterally across the vertebral body **52**, forward of the lateral midline. After adjustment of implant **56**, its plugs are flush with or recessed within the outer perimeter of the endplate of vertebral body **52** so as not to impinge upon adjacent tissue.

Referring to FIG. **30**, a human spine **76** is shown that exhibits scoliosis. According to aspects of the disclosure, dual UECs may be placed at various levels of the spine to treat the condition. For example, a single UEC or pairs of UECs may be implanted at the levels depicted by reference numerals **78**, **80**, **82** and **84** shown in FIG. **30**. By using the adjustments described above relative to FIG. **28**, the curvature of the spine may be adjusted in three dimensions at these four levels to a correct alignment, as shown in FIG. **31**.

FIGS. **32A-32C** are anterior, lateral and oblique views, respectively, showing adjacent vertebral bodies **50** and **52** having misalignments/uneven spacing.

FIGS. **33A-33C** are anterior, lateral and oblique views, respectively, showing the vertebral bodies **50** and **52** of FIGS. **32A-32C** with the misalignments/uneven spacing corrected according to aspects of the disclosure.

The implants can be made of, for example, such materials as titanium, 64 titanium, or an alloy thereof, 316 or 321 stainless steel, biodegradable and biologically active materials, e.g. stem cells, and polymers, such as semi-crystalline, high purity polymers comprised of repeating monomers of two ether groups and a ketone group, e.g. polyaryetheretherketone (PEEK)™, or Teflon™.

To prevent movement of proximal and distal plugs or actuators after implantation, in some implementations a biocompatible adhesive or thread locking compound may be applied to one or more of the moving parts. In some embodiments (not shown) a pin may be inserted radially or axially between the plug/actuator and the cage body to lock the parts in place post operatively. In some embodiments, a ratchet, spring loaded decent, or other locking mechanism may be provided for this purpose.

In general, as disclosed in the above embodiments, the cage body is cut with openings at every other end of each slot, like a sine wave, allowing expansion when the center of the cage becomes occupied with a cone or mandrill shaped unit. The cage body's series of alternating slots allows the expansion to take place while keeping the outside of the UEC one single piece. The slots plus the teeth on the surface allow for a solid grip on the bone surfaces and plenty of opportunities for good bone ingrowth. Also, by allowing the surgeon to make one end of the UEC thicker than the other, the effects of the cone (mandrill) introduction vary from uniform to selective conduit expansion. The UEC expansion mechanism is adaptable to both fixed fusion and mobile 'motion preservation' implants, with exteriors of the expanding implant per surgeon's choice (round, flat, custom, etc.) As such, in some implementations, relative motion may be preserved between the vertebral bodies adjacent the implanted UEC(s). In other implementations, it may be desirable to fuse the adjacent vertebral bodies around the implanted UEC(s).

To provide motion preservation between adjacent vertebrae, robust compressible materials may be used between the UEC and one or both of the vertebral endplates, and/or one or more components of the UEC may comprise such materials. These materials may replicate the load distributing and shock absorbing functions of the annulus and

nucleus of a natural disk. For example, in some embodiments the UEC may be provided with tapered plugs made of a resilient polymer to allow the UEC to compress and expand to accommodate relative motion of the adjacent vertebrae. Examples of biocompatible materials suitable for some UEC embodiments include Bionate®, a thermoplastic polycarbonate-urethane (PCU) provided by DSM Biomedical in Exton, Pa., and ChronoFlex®, a PCU provided by AdvanSource Biomaterials in Wilmington, Mass.

The UEC provides advantages over currently existing technology that include correction of coronal plane deformity; introduction of interbody lordosis and early stabilization of the interbody space with rigidity that is greater than present spacer devices. This early stability may improve post-operative pain, preclude the need for posterior implants including pedicle screws, and improve the rate of successful arthrodesis. Importantly, the UEC provides improvement of space available for the neural elements while improving lordosis. Traditional implants are limited to spacer effects, as passive fillers of the intervertebral disc locations awaiting eventual fusion if and when bone graft in and around the implant fuses. By expanding and morphing into the calculated shape which physiologically corrects spine angulation, the UEC immediately fixes the spine in its proper, painless, functional position. As infused osteoinductive/osteoconductive bone graft materials heal, the patient becomes well and the implant becomes inert and quiescent, embedded in bone, and no longer needed.

In some embodiments, the external surface of the UEC may be 3D printed to not only fit into the intervertebral space per se, but to match the surface topography at each insertion location. In other words, a 3D printed endplate may be utilized, computer calculated to fit and expand the disc space of the individual patient, resulting in both best 'goodness of fit' for fusion, and improved axial skeletal alignment.

By creating to 'maps' that fit e.g. as a precisely congruent superior and inferior surface to fit into a particular patients disc space, and placing these UEC end plates on either side the novel UEC expansion mechanism, a patient's disc space AND overall spine alignment will be ideally treated toward best fusion (or motion preservation) and alignment.

"Method of Surgery" instructions may recommend the surgeon and/or robotic unit deploy expansion as programmed to insert the UEC into a particular disc level of pathology, to achieve best results. For example, preoperative patient scans/films can predict ideal UEC surgeon use, such as "turn Knob A a certain number of rotations clockwise," to maximize visible, palpable, and roentgenographic 'Goodness of Fit'. With this approach, post activation, the UEC implant fits the location, entering at the predetermined best angle (in 3 axes) using the proprietary Method of Surgery and UEC insertion tools provided.

In some embodiments, the UEC may be coated with hydroxyapatite. In some embodiments, toothed or 400 μm beaded surfaces may be utilized to promote bony ingrowth. Inflatable chambers may be provided within the endplate that can expand after being implanted. This approach addresses the 3-D congruence to proximate disc pathology. It can also allow for intervertebral arthrodesis or arthroplasty treatment and overall improved spinal alignment, integrating the internal proprietary expansion with the variable external endplate shapes and their contents. UEC inflatable endplates of polymer may be employed, such as tiny vacuoles, "bubblewrap", and multiple or singular bladder constructs. If a portion of the disk space were collapsed, that region could be aptly elevated or expanded by the UEC endplate variation in material and/or inflation. The inflatable chambers may contain compressible gas (such as air), granules as pharmacologics, and/or stem cells that are delivered via liquids. In cases where the UEC is compressible or force absorbing, the material and/or chamber could be used as a cushion or to 'selectively direct and protect chondrocytes' toward improvement of existing pathophysiology via best drug use or regeneration.

The 'preparation' of the UEC insertion site will vary per surgeon. In some implementations, an arthroscopic burr may be advisable for removing 0.5 mm of cortical bone along with all aberrant disc contents under digital arthroscopic camera control. In other implementations, the surgeon may just carefully curette the intervertebral space to 'clean it out' in preparation for the UEC implant insertion.

The UEC may be inserted directly into the insertion site, or may be inserted through proprietary or commercially available insertion tube. The insertion tube typically will have a blunt distal tip so that it can be inserted through an incision without causing tissue damage. The tube can be used with or without additional tissue retractors. The UEC may be preloaded into the insertion tube, or placed into the tube after the tube has been introduced into the insertion site. A pusher rod or other device may be utilized to deploy the UEC from the insertion tube into the insertion site. In some procedures, the placement of the UEC may be arthroscopically assisted.

Note that regardless of the endplate preparation, in the deformed, aging, pathologic spine there will be pathology to correct. According to various aspects of the present disclosure, the UECs provided herein may accomplish this in several ways as pertains to the external implant composition. For example, the UEC can expand as an externally threaded conduit, either uniformly end to end resulting in same diameters at each end post-operatively (such as 40% overall expansion), or precisely at either end, thus creating an overall conical albeit expanded UEC. Also, the UEC can be flat superiorly and inferiorly as shown in the above drawings, thus more likely matching the rather flat vertebral body end plates. However, according to further aspects of the present disclosure, special care should be taken to consider both the peripheral end plate boney rim as thicker more prominent cortical bone at the vertebral end plates with a sunken or concave thinner interior (thus subject to potential subsidence). The UEC MOS (Method of Surgery) contemplated herein considers the preoperative findings (e.g. MRI, 3D CT scan, X-rays) to integrate information on bone density, specific disc space and longitudinal spine anatomy, topography and alignment.

The various expanding cages disclosed herein and variations thereof are not limited to use in the spinal column but may be used between other bone segments throughout the human or animal body. For example, a UEC can be used during arthrodesis of a metatarsal joint. The UEC can aid in setting the orientation of the toe to a desired angle before fusion of the apposing bone segments occurs. Similarly, a UEC may be utilized in the knee, elbow or other body joints, or between two or more bone segments that have been fractured by trauma.

According to various aspects of the disclosure:

1) the UEC corrects spine surgical pathology both locally via horizontal (disc) and longitudinal vertical axial (scoliotic/kyphotic) spine deformity improvements.
2) the UEC is applicable cervical through lumbar for
A) arthrodesis (fusion) or
B) arthroplasty (motion preservation) or
C) drug/cell therapy delivery

3) the UEC can expand uniformly throughout implant length, and/or expand only proximally (toward the surgical incision) or distally, thus enabling clinical adjustments favorable to spine diseased or injured patients for local and overall spondylopathies.

4) the UEC can be surgically inserted via outpatient MIS (Minimally Invasive—outpatient Surgery) as safe, efficacious implants "doing no harm" applying advantages from

A) materials thicknesses for height differentials or

B) expansion adjustments surgically controlled (before/during or after implantation) or via prefabricated portals or injections—programing implant 'mapped' corrections using

C) polymers durometrically calculated with variable compressions, permanent or biodegradable activations at will.

D) inflation of the implant as via UEC surface chambers or bladder(s).

E) adding endplate biologics, foam, or other adaptables for best results.

F) UEC expansion can adapt to expand variable external surface parameters including flat, round, or customized external maximally congruent surfaces to interface as with proximate endplates.

5) Delivery either via UEC materials per se (eluding substances—cells or pharmacologics) or through extrusion from a UEC container or delivery vesicle/depot/chamber/portal will enable not only immediate surgically correction but long term enhanced bone in growth and local/general therapeutic and/or regenerative clinical benefits.

While the disclosure has been described in connection with example embodiments, it is to be understood that the disclosure is not limited to the disclosed embodiments and alternatives as set forth above, but on the contrary is intended to cover various modifications and equivalent arrangements included within the claim scope.

What is claimed is:

1. A method of adjusting a spine comprising, implanting at least one adjustable medical implant between a first vertebral bone endplate and a second vertebral bone endplate, the implant comprising, a proximal end, a distal end, a first adjustment tool and a second adjustment tool wherein the first adjustment tool adjusts one of the proximal end or the distal end of the implant and the second adjustment tool adjusts the other of the proximal end of the implant or the distal end of the implant wherein the first adjustment tool and the second adjustment tool are located at the proximal end of the implant and the first adjustment tool and the second adjustment tool are coaxially nested one within the other and independently rotatable, and performing the step of (a) actuating the first adjustment tool, (b) actuating the second adjustment tool or (c) independently actuating both the first adjustment tool and second adjustment tool, such that when any of steps (a), (b) or (c) are taken the proximal end of the implant and the distal end of the implant are independently adjusted.

2. The method of claim **1**, wherein the actuating causes an expansion or contraction of the proximal end of the implant.

3. The method of claim **1**, wherein the actuating causes an expansion or contraction of the distal end of the implant.

4. The method of claim **1**, wherein the actuating independently causes an expansion or contraction of both the proximal end of the implant and the distal end of the implant.

5. The method of claim **1**, wherein the actuating independently causes an expansion of both the proximal end of the implant and the distal end of the implant.

6. The method of claim **1**, wherein the actuating independently causes a contraction of both the proximal end of the implant and the distal end of the implant.

7. The method of claim **1**, wherein the actuating independently causes a contraction of the proximal end of the implant and an expansion of the distal end of the implant.

8. The method of claim **1**, wherein the actuating independently causes a contraction of the distal end of the implant and an expansion of the proximal end of the implant.

9. The method of claim **1**, further comprising implanting a second adjustable medical implant between the first vertebral bone endplate and the second vertebral bone endplate.

10. The method of claim **1**, further comprising implanting at least one adjustable medical implant between a third vertebral bone endplate and a fourth vertebral bone endplate.

11. The method of claim **1**, further comprising implanting at least one adjustable medical implant between a fifth vertebral bone endplate and a sixth vertebral bone endplate.

12. The method of claim **1**, wherein the implant further comprises a cage body, at least one proximal flexure and at least one distal flexure such that the proximal flexure shares a beam portion of the cage body with a distal flexure to form a continuous serpentine pattern along the cage body.

13. A method of altering the distance between two opposing vertebral bone end plates independently from altering the angle between two opposing vertebral bone end plates comprising, implanting at least one expandable medical implant comprising a cage body wherein the cage body has an expandable proximal end and an expandable distal end and performing the step of (a) adjusting the expansion or contraction of the proximal end, (b) adjusting the expansion or contraction of the distal end, or (c) independently adjusting the expansion or contraction of both the proximal end and distal end, such that when any of steps (a), (b) or (c) are taken the distance between two opposing vertebral bone end plates is altered independently from the angle between two opposing vertebral bone end plates, wherein the proximal end and the distal end are proximally actuated.

14. The method of claim **13**, wherein either the distance between two opposing vertebral bone end plates is altered or the angle between two opposing vertebral bone end plates is altered.

15. The method of claim **13**, further comprising implanting at least one additional expandable medical implant between the two opposing vertebral bone end plates.

16. A method of independently altering the distance and angle between two opposing vertebral bone end plates comprising, implanting adjacent to two opposing vertebral bone end plates an expandable medical implant comprising a cage body wherein the cage body has an expandable proximal end and an expandable distal end and altering the distance between the two opposing vertebral bone end plates and/or altering the angle between the two opposing vertebral bone end plates by independently adjusting the expansion of the proximal end and the distal end such that the proximal end and the distal end of the cage body expand independently to alter the distance and/or the angle between the two opposing vertebral bone end plates, and wherein the proximal end and the distal end are independently proximally actuated.

17. The method of claim **16**, wherein the distance is altered and the angle is not altered.

18. The method of claim **16**, wherein the distance is not altered and the angle is altered.

19. The method of claim **16**, wherein the angle is sloped anteriorly.

20. The method of claim **16**, wherein the angle is sloped posteriorly.

* * * * *

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Grotz

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(54) **UNIVERSALLY EXPANDING CAGE**

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(58) **Field of Classification Search**
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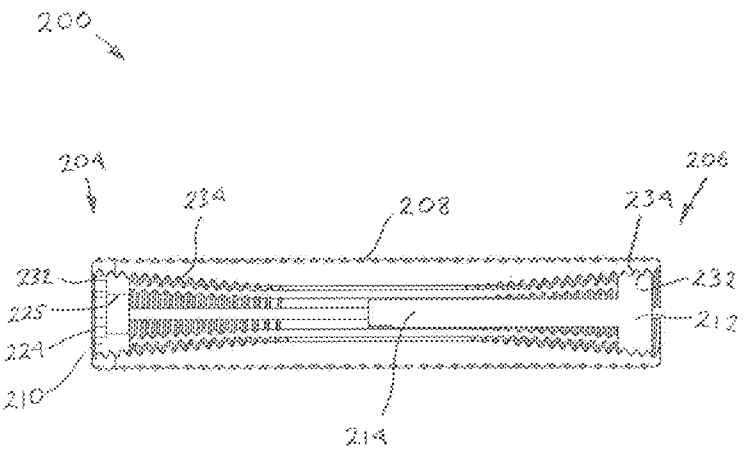
(57) **ABSTRACT**

An expandable medical implant is provided with an implantable cage body. The proximal and distal ends of the cage body may each be provided with a tapered or cam portion. The implant may further include a proximal flexure, a distal flexure, a proximal plug member having a tapered portion configured to mate with the tapered portion of the proximal end of the cage body, and a distal plug member having a tapered portion configured to mate with the tapered portion of the distal end of the cage body. The proximal plug member may be configured to move longitudinally such that the distal flexure moves and the circumference of the proximal end of the cage body resiliently expands. The distal plug member may be configured to move longitudinally such that the proximal flexure moves and the circumference of the distal end of the cage body resiliently expands. Methods are also disclosed.

15 Claims, 28 Drawing Sheets



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CPC .. ***A61F 2/4637*** (2013.01); *A61F 2002/30408* (2013.01); *A61F 2002/30411* (2013.01); *A61F 2002/30507* (2013.01); *A61F 2002/30538* (2013.01); *A61F 2002/30545* (2013.01); *A61F 2002/30556* (2013.01); *A61F 2002/30579* (2013.01); *A61F 2002/30841* (2013.01); *A61F 2002/448* (2013.01); *A61F 2002/4642* (2013.01)

(58) **Field of Classification Search**
CPC .. A61F 2002/30411; A61F 2002/30538; A61F 2002/30556; A61F 2002/30545; A61F 2002/30579; A61F 2002/30841; A61F 2002/448
USPC 606/246–249, 279, 313, 90; 623/17.11, 623/17.13, 17.15, 17.16
See application file for complete search history.

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2014/0180419	A1	6/2014	Dmuschewsky	

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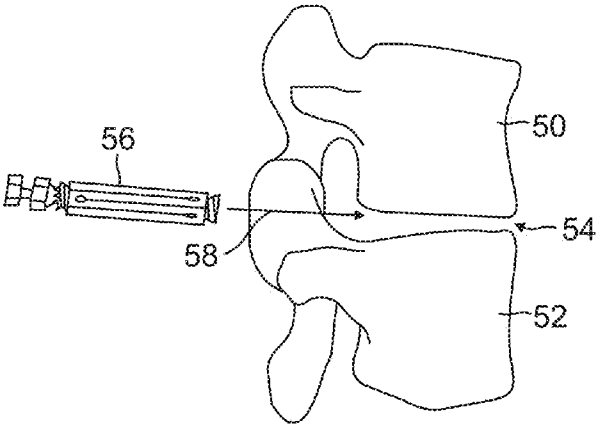

FIG. 1

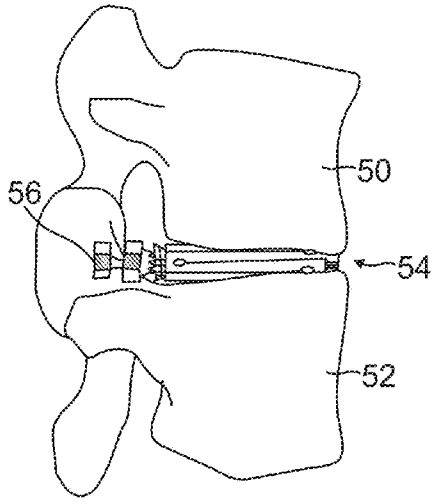

FIG. 2

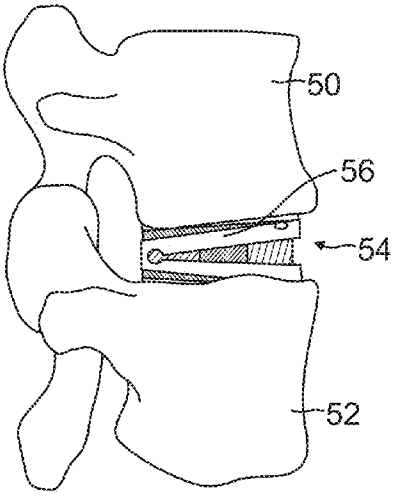

FIG. 3

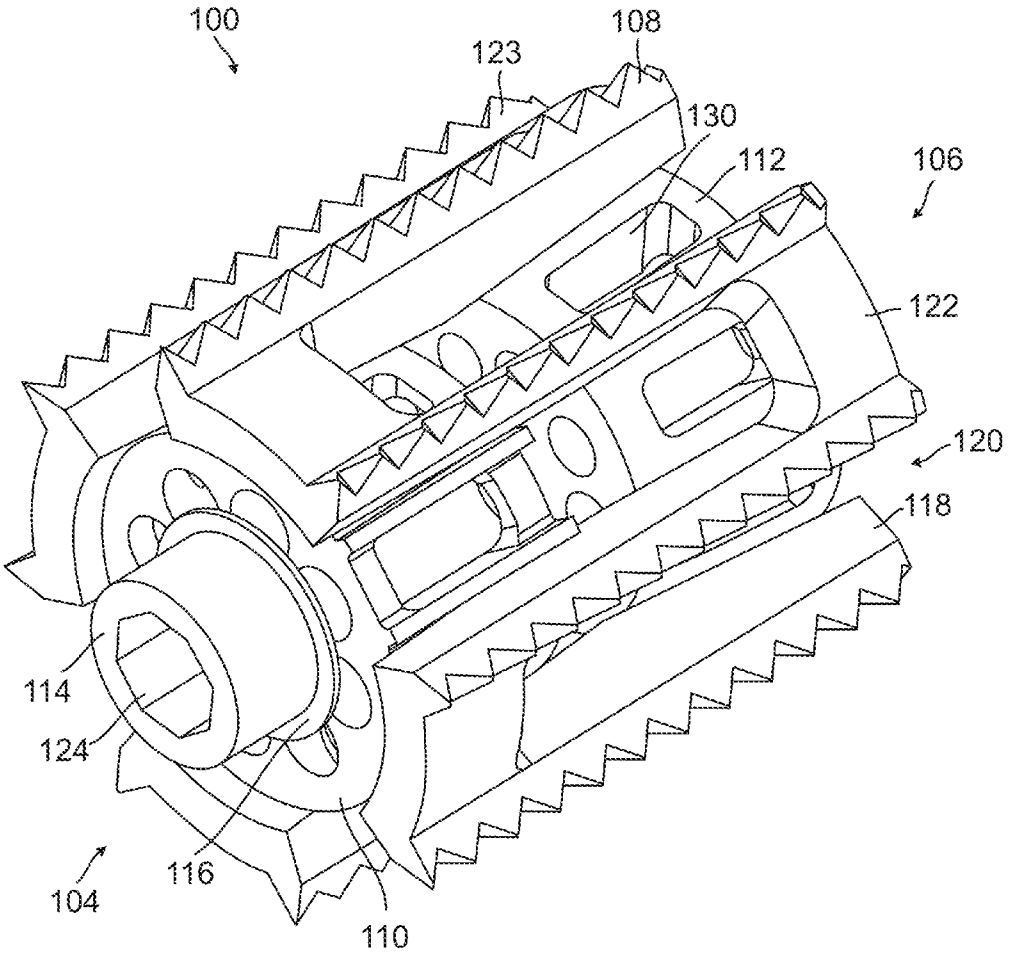

FIG. 4

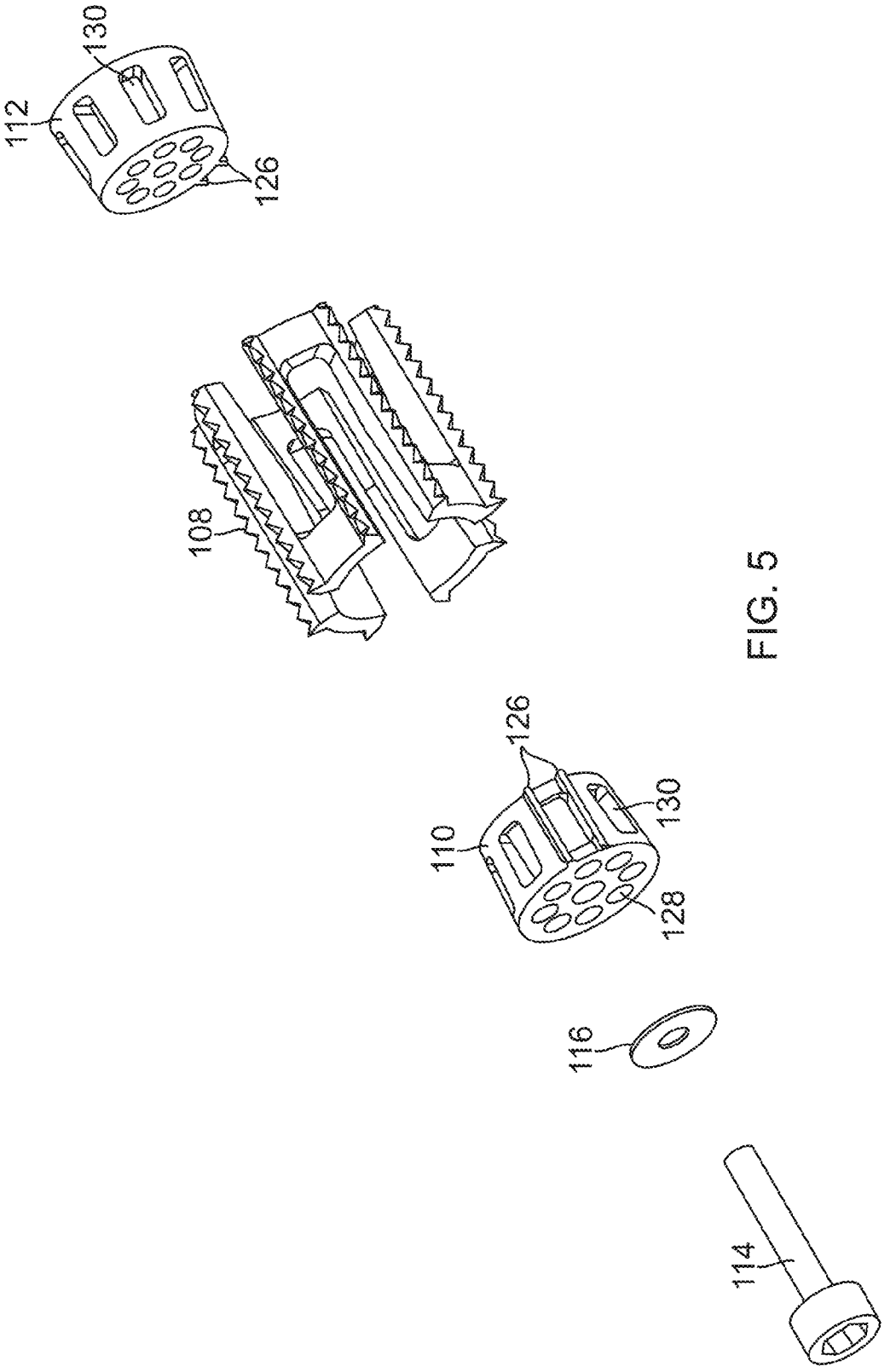

FIG. 5

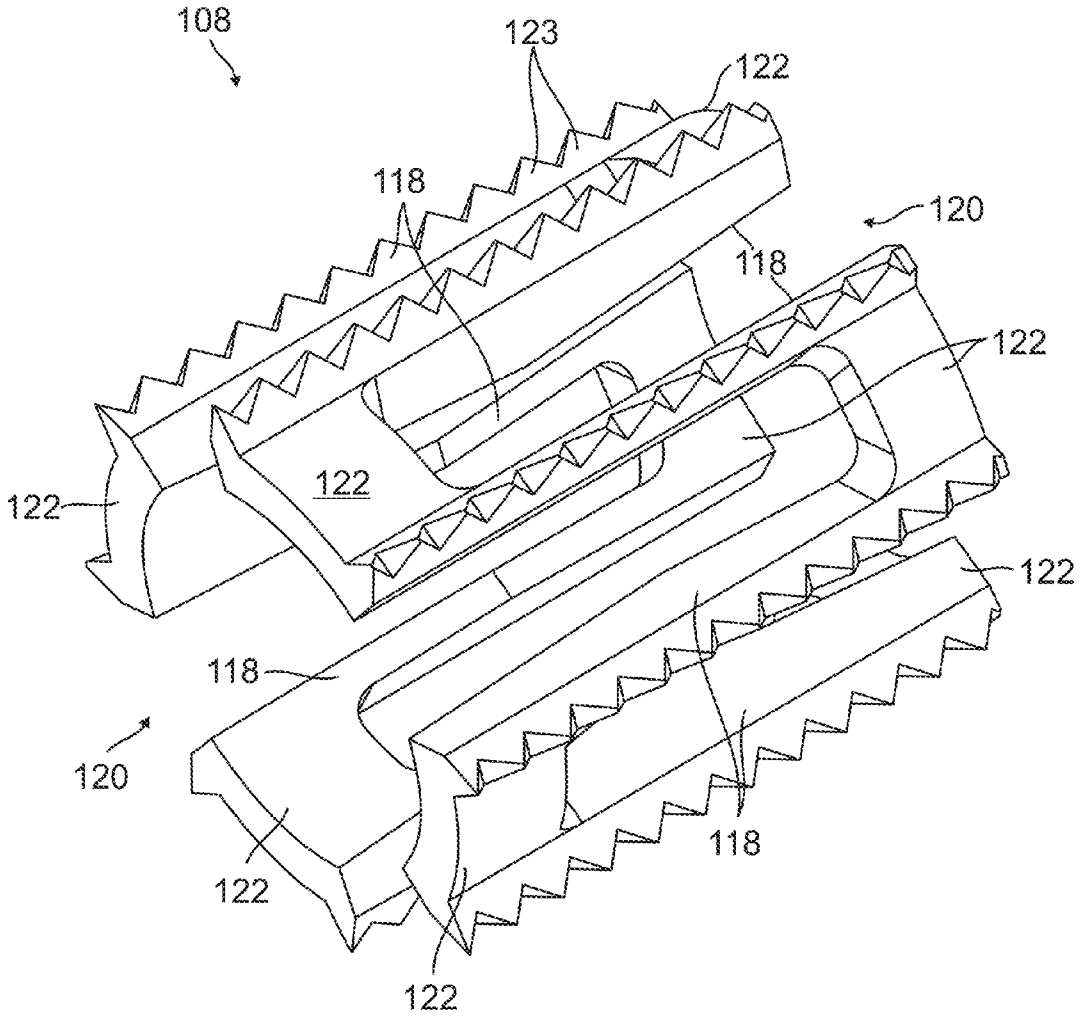

FIG. 6

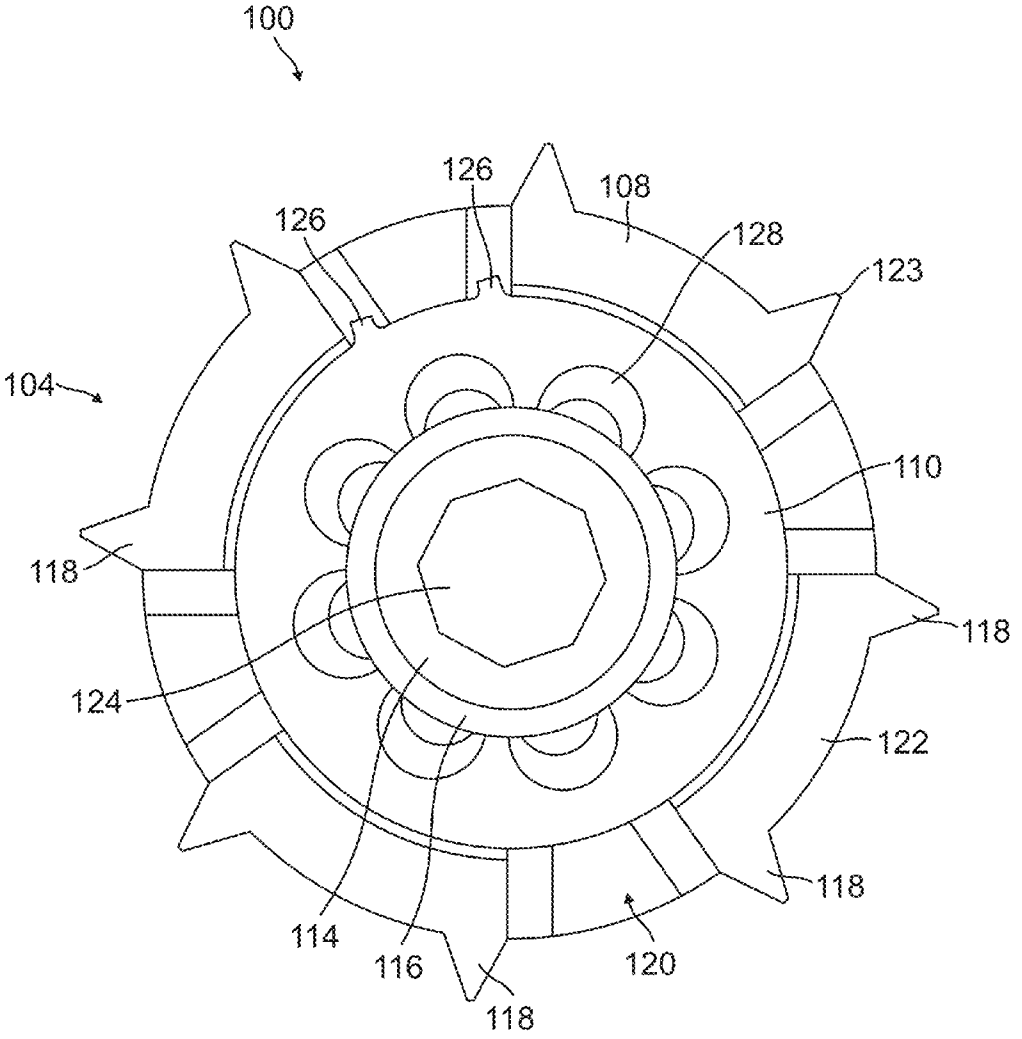
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FIG. 7

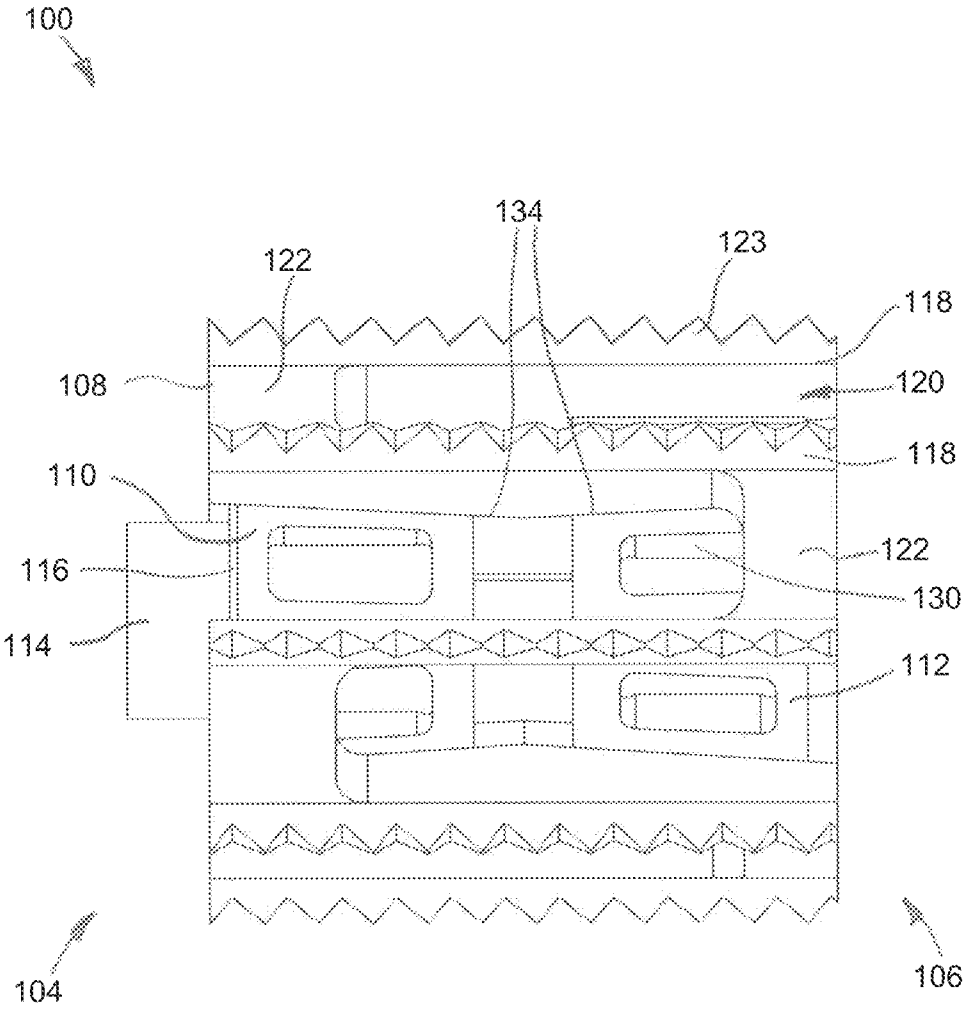

FIG. 8

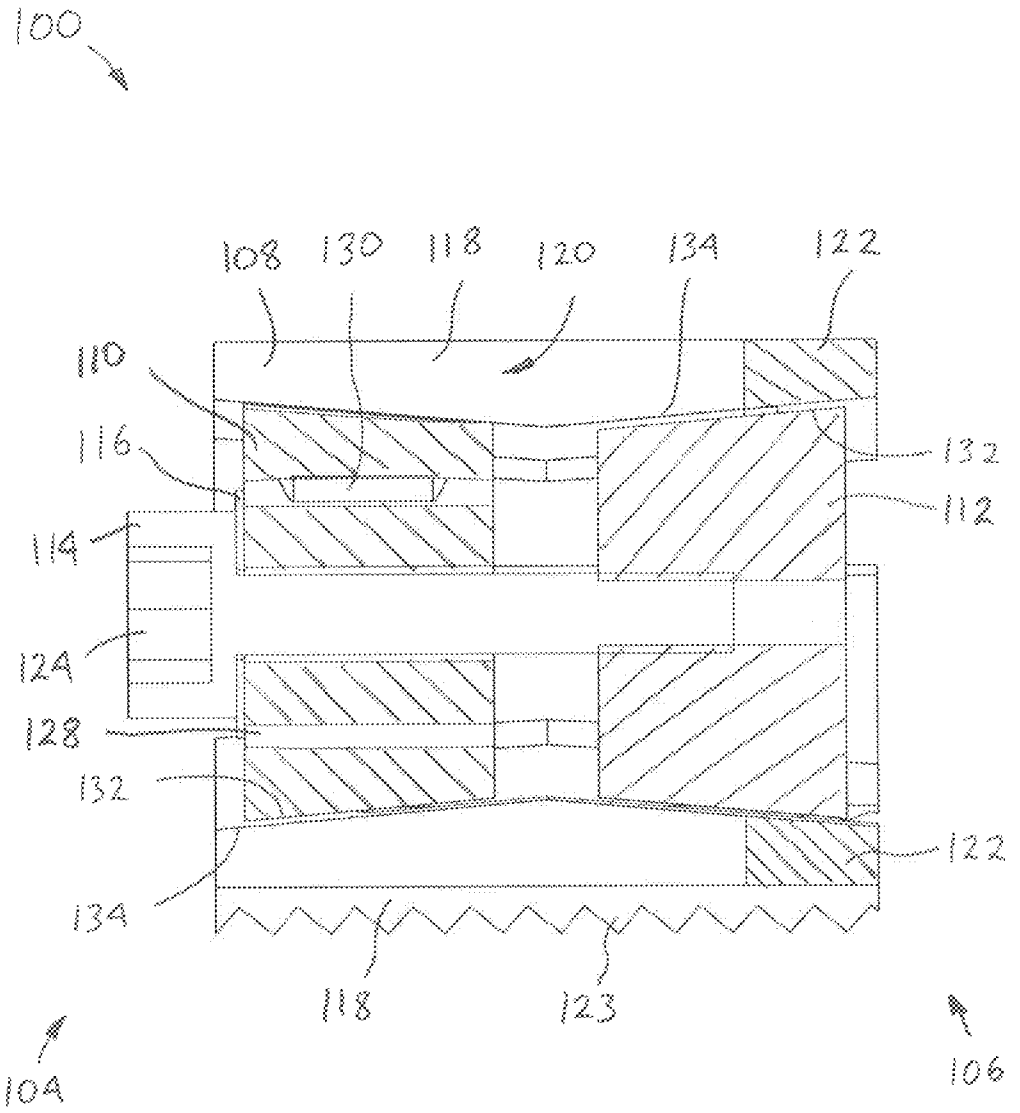
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FIG. 9

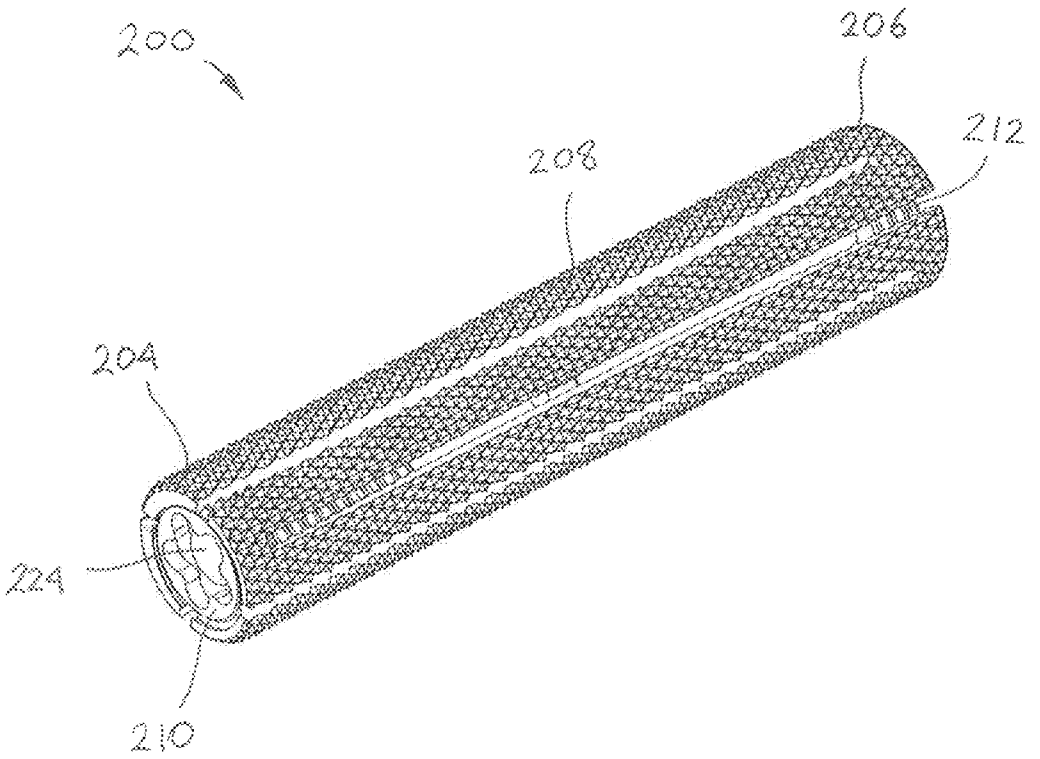

FIG. 10

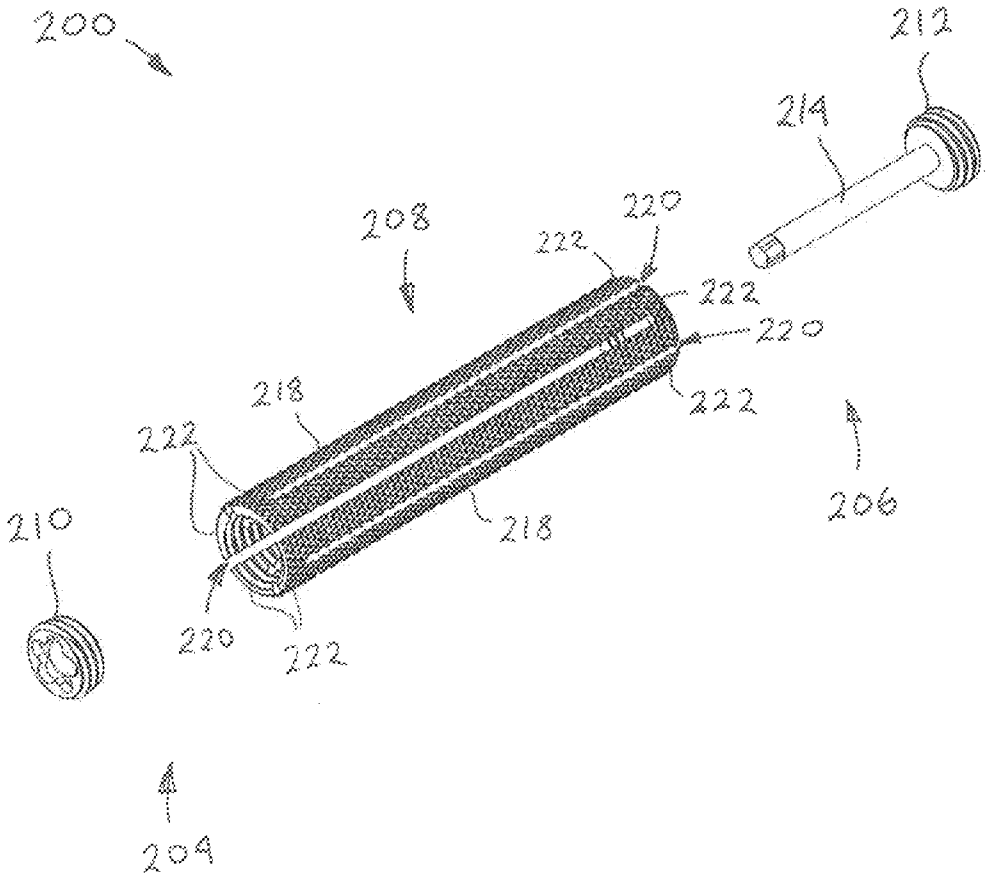
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FIG. 11

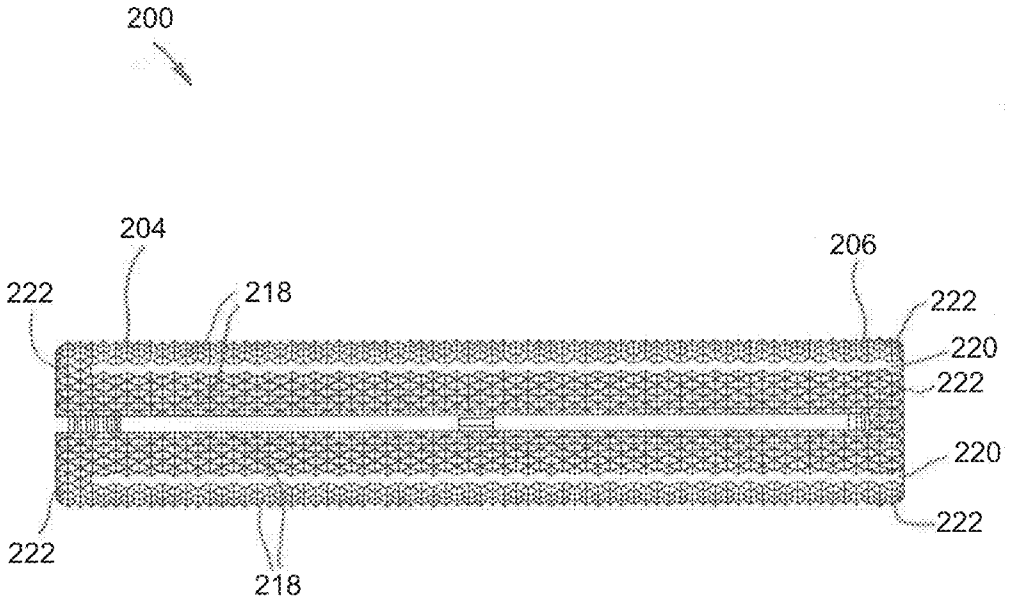

FIG. 12

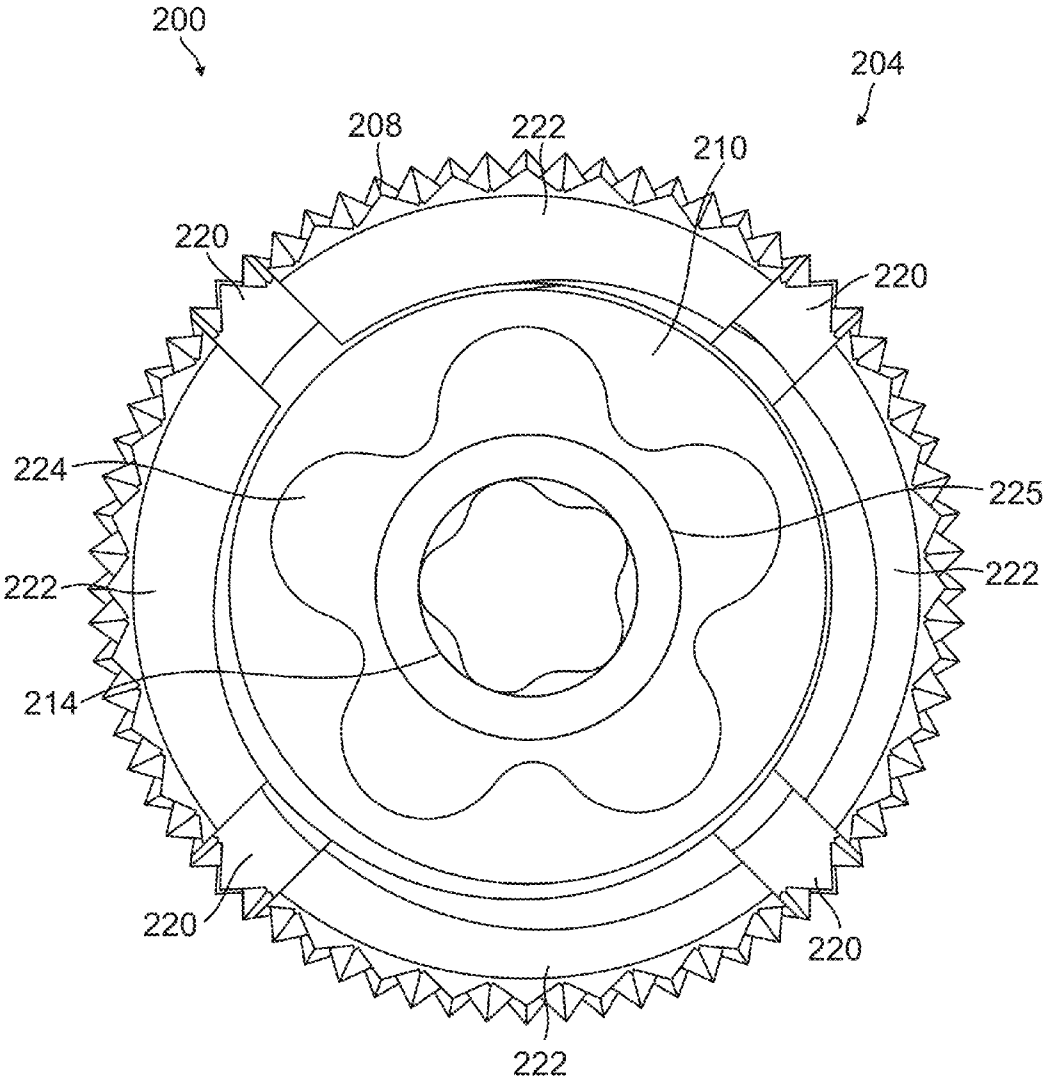

FIG. 13

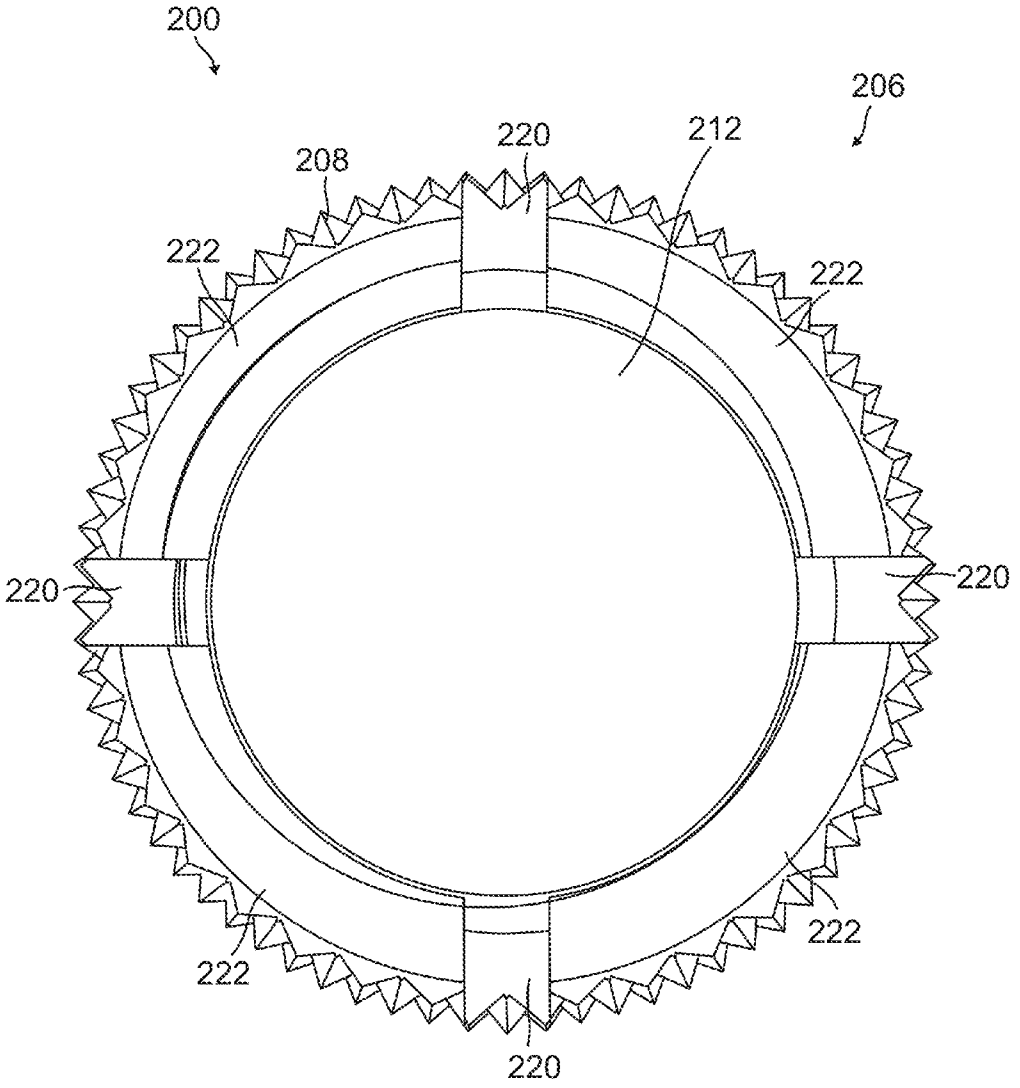

FIG. 14

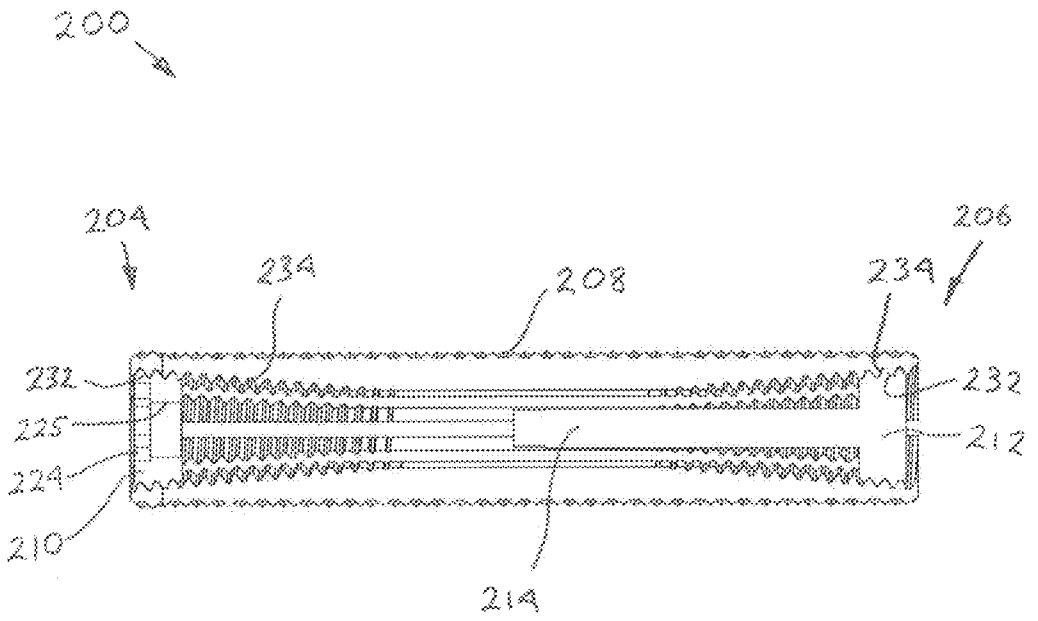

FIG. 15

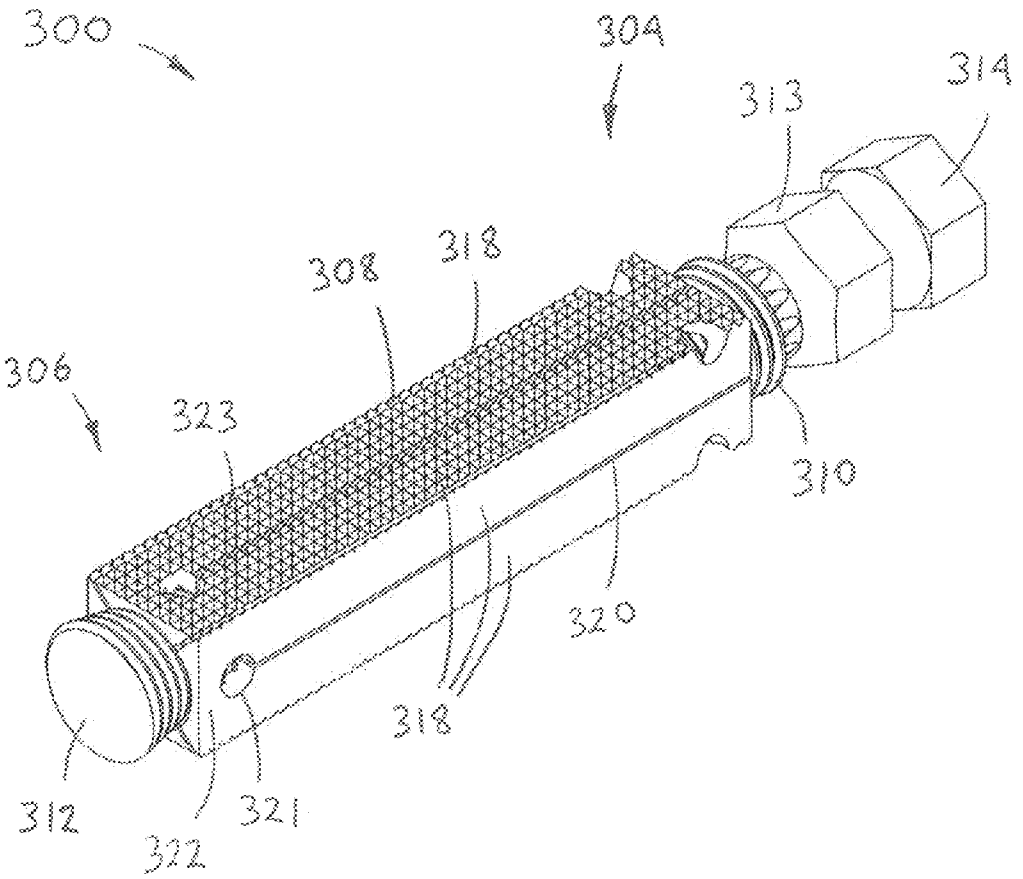

FIG. 16

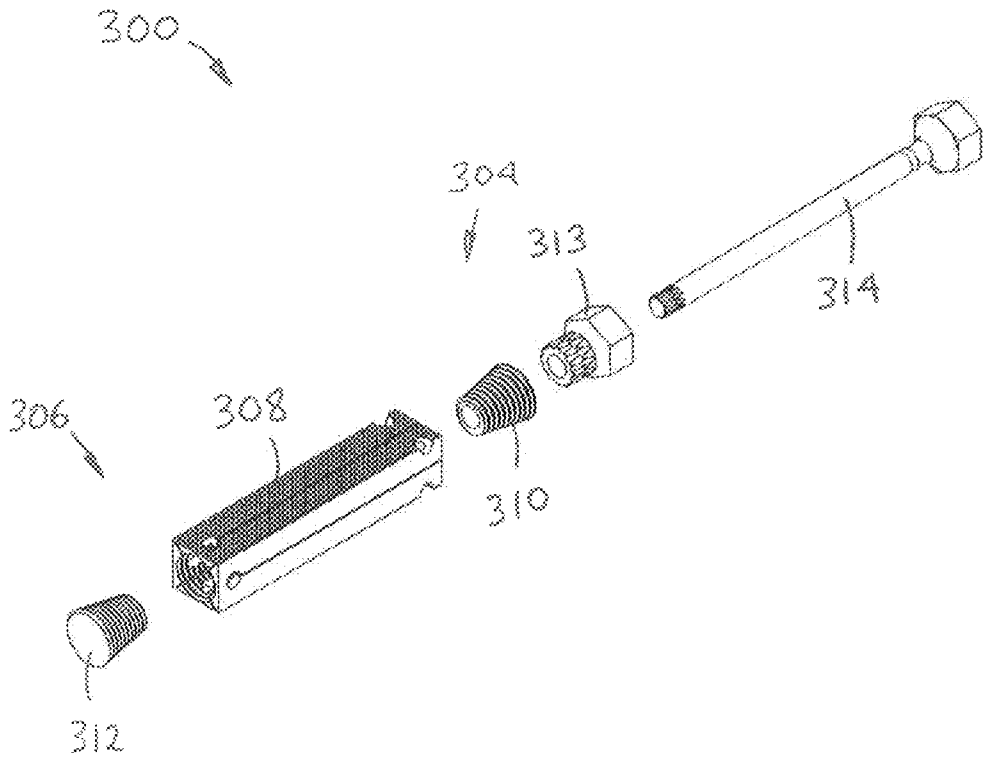

FIG. 17

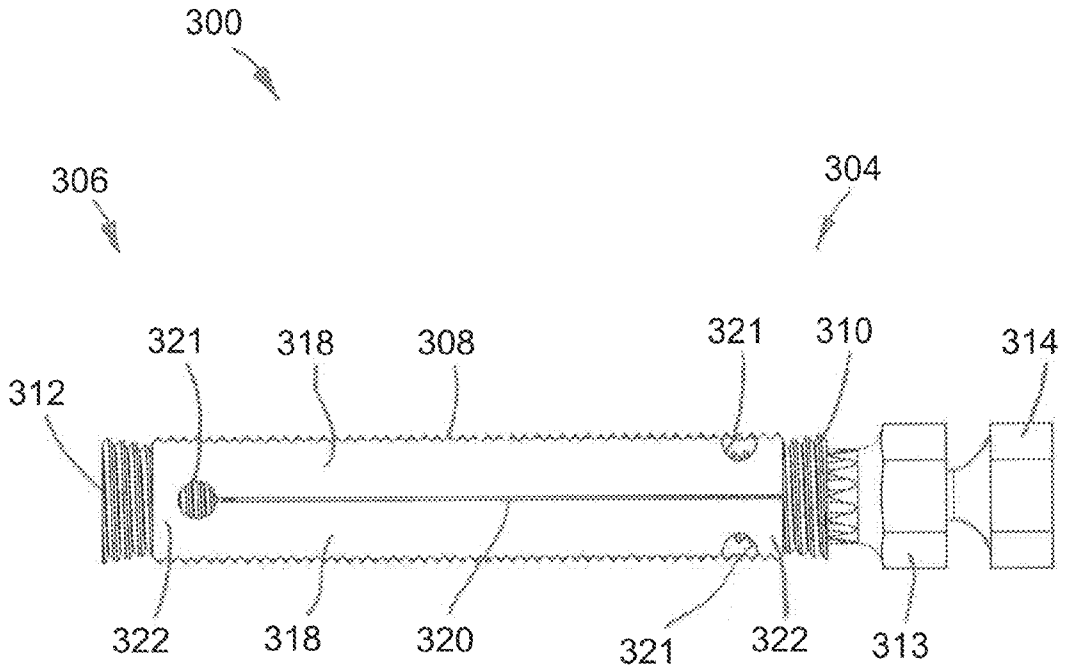

FIG. 18

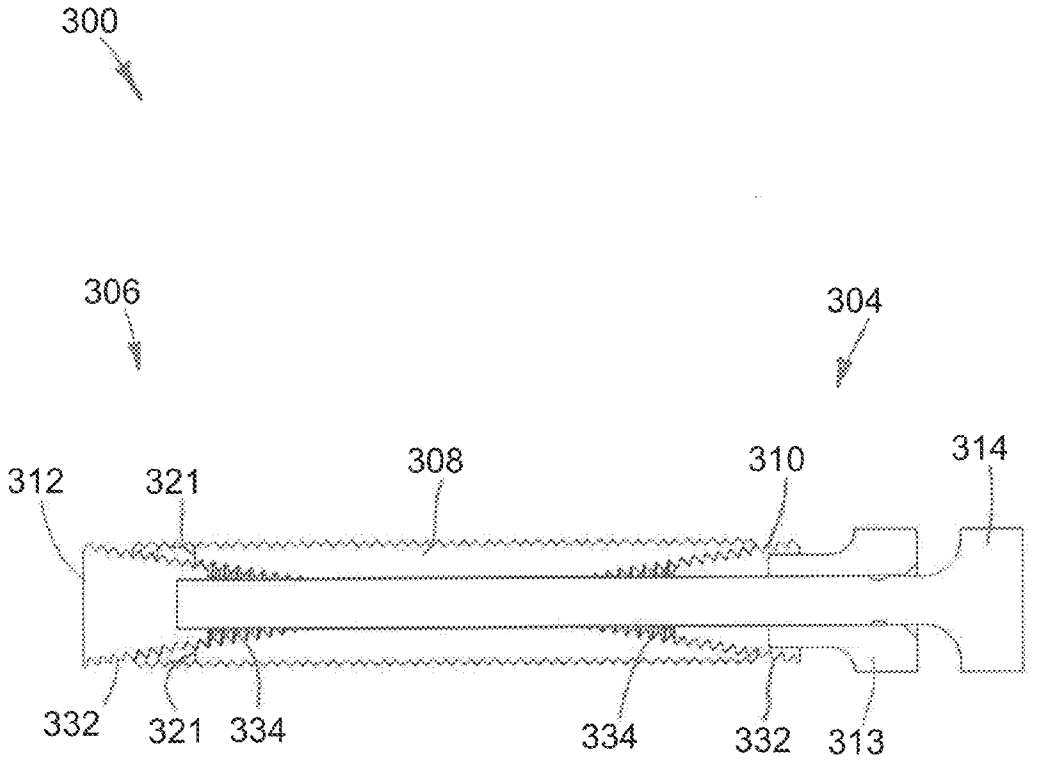

FIG. 19A

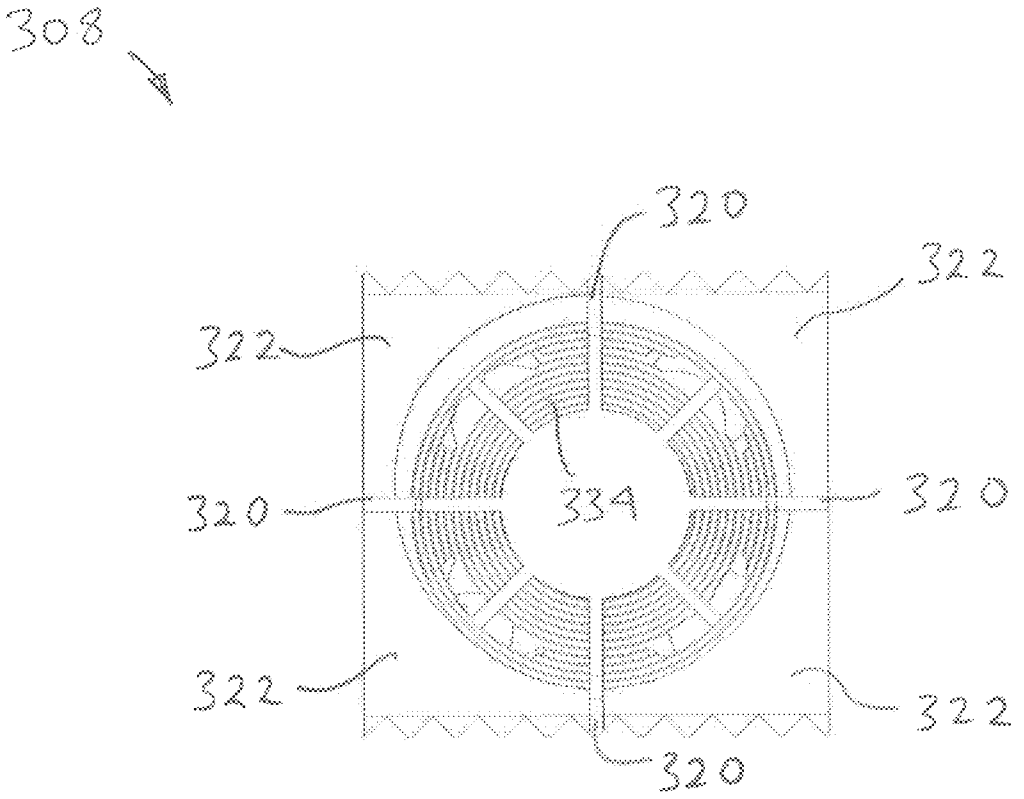

FIG 19B

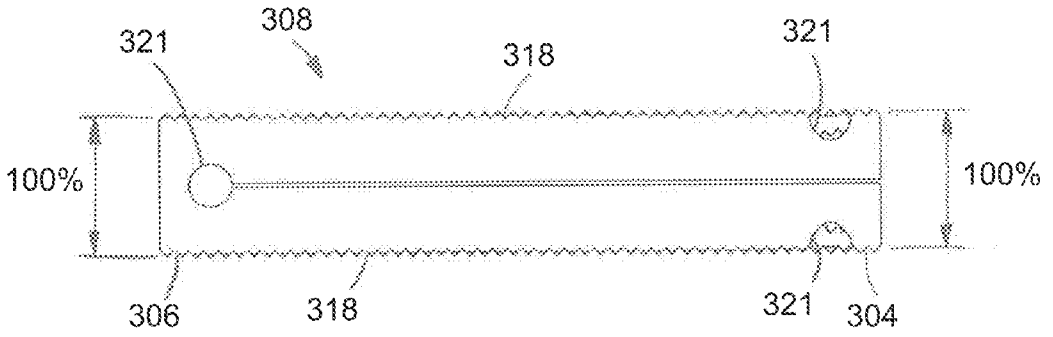

FIG. 20A

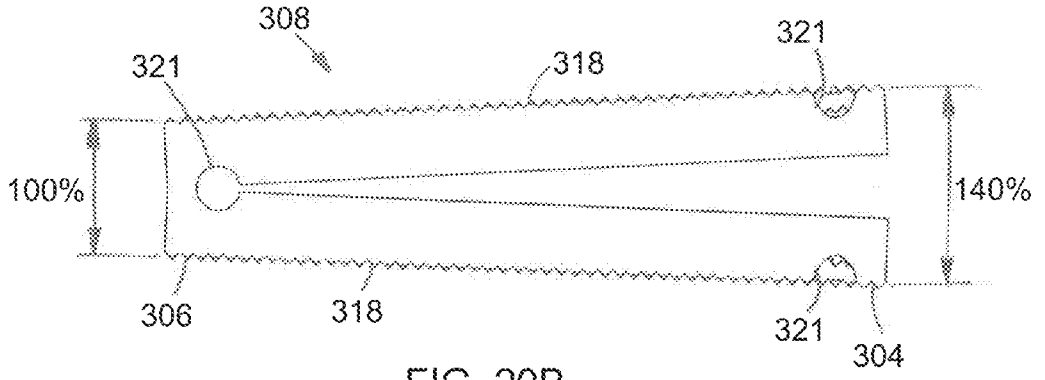

FIG. 20B

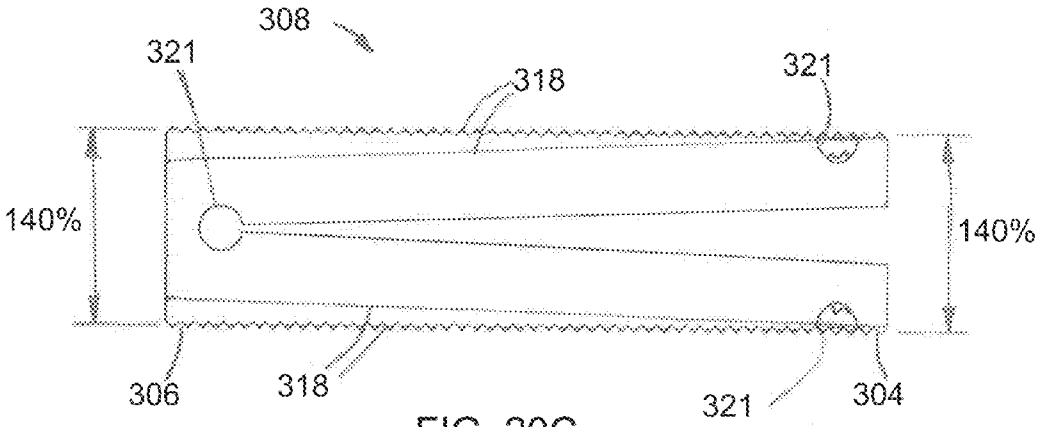

FIG. 20C

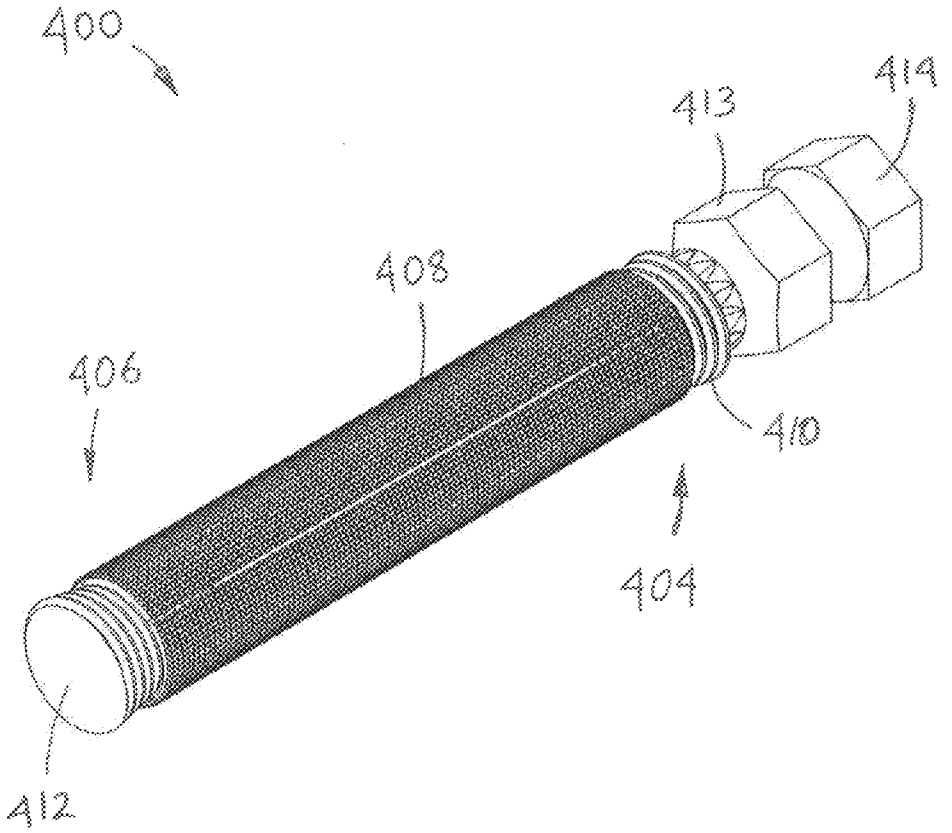

FIG 21

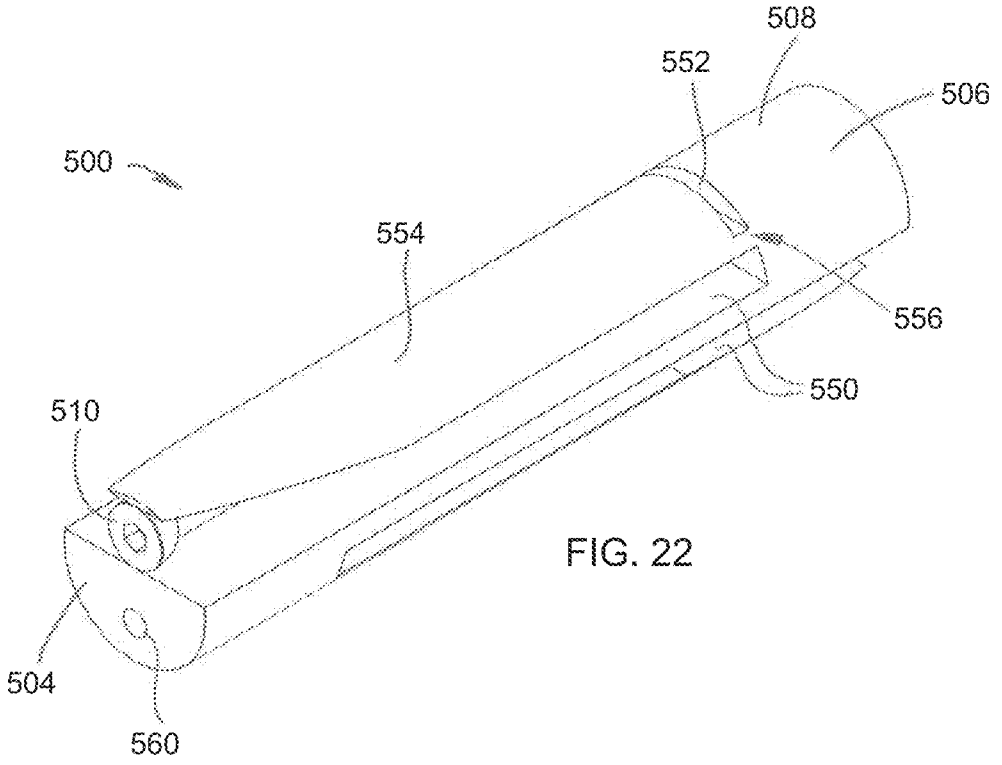
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FIG. 22

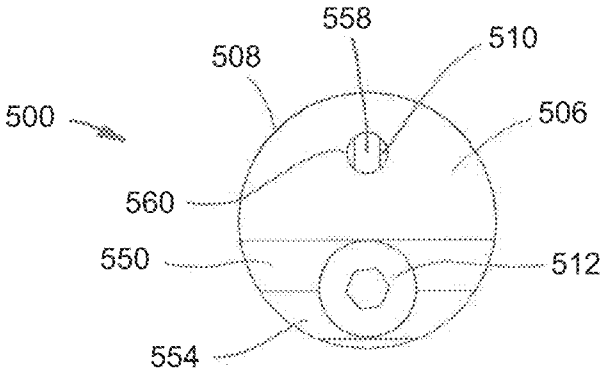
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FIG. 23

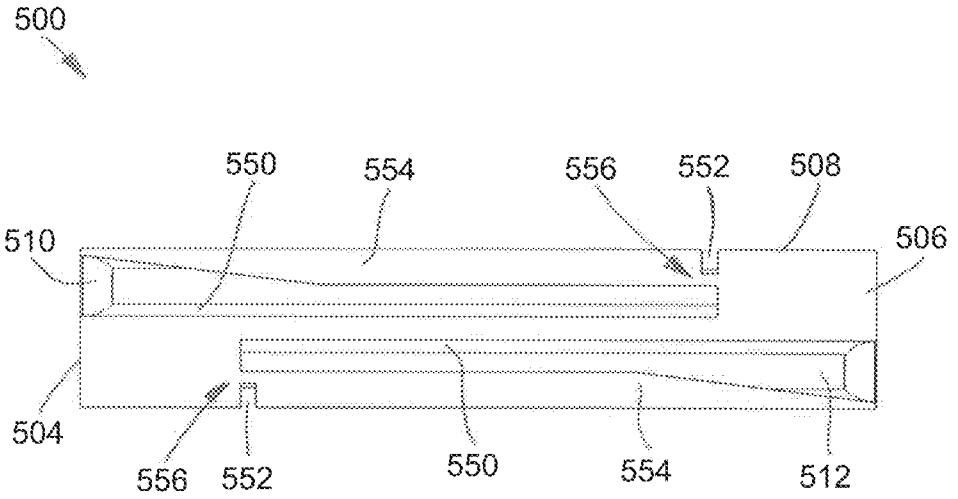
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FIG. 24

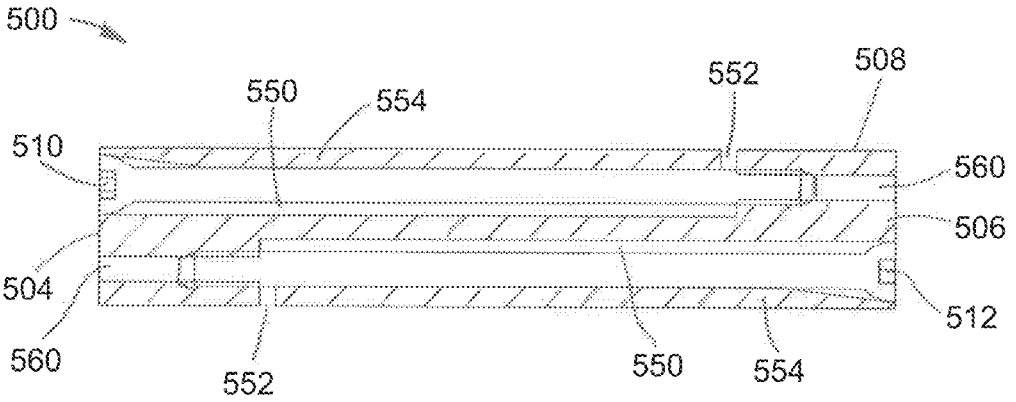
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FIG. 25

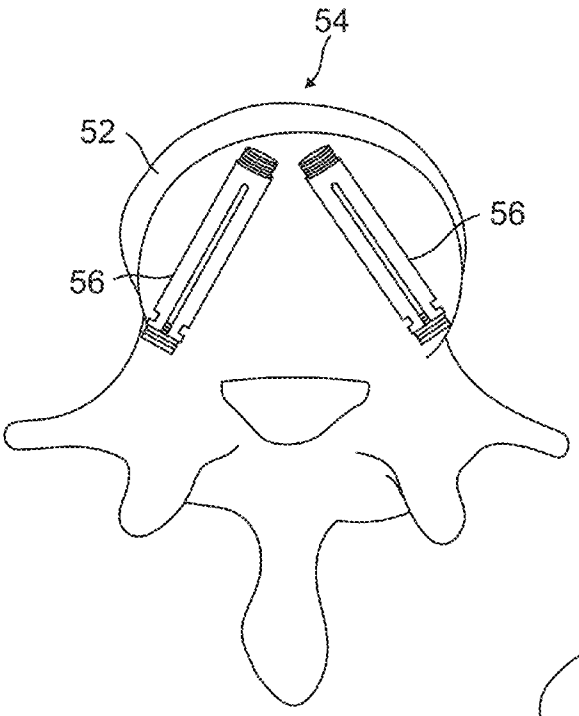

FIG. 26

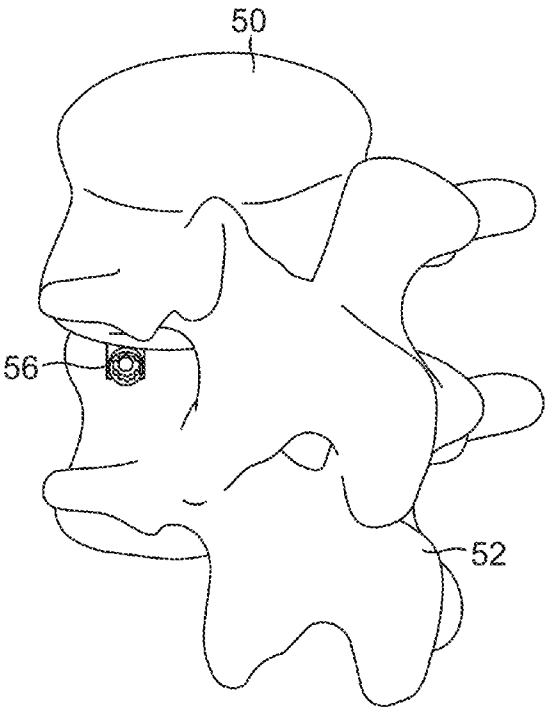

FIG. 27

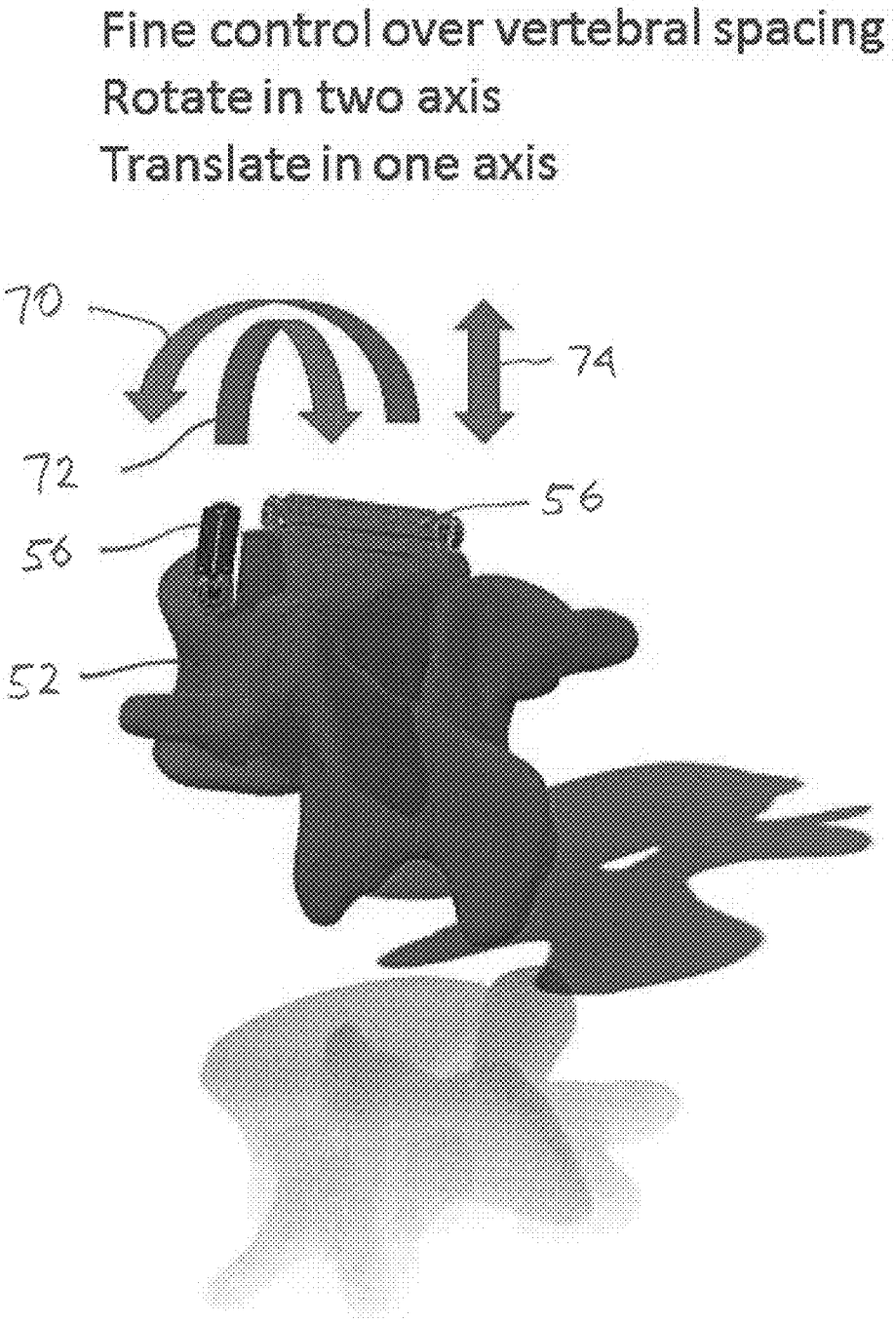
Fine control over vertebral spacing
Rotate in two axis
Translate in one axis
70
74
72
56
56
52

FIG. 28

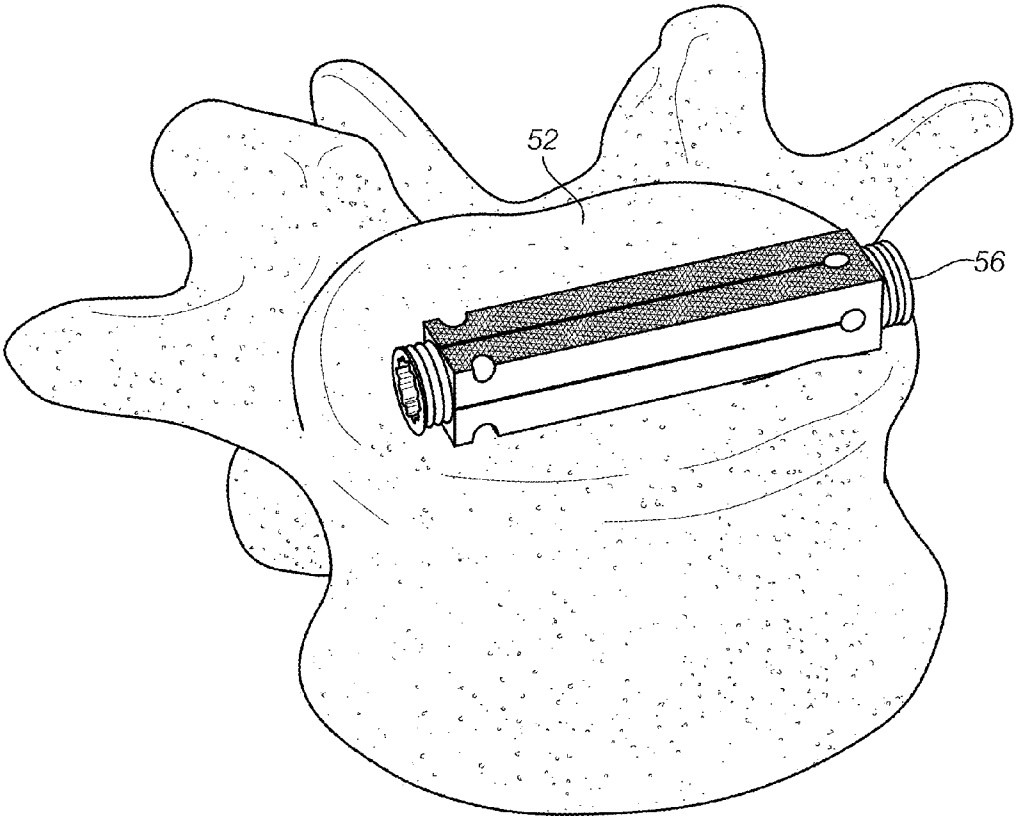

FIG. 29

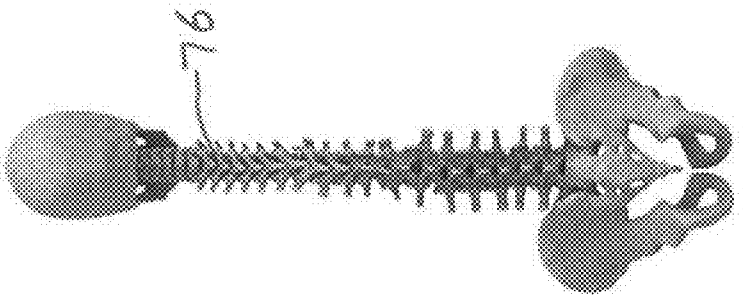

FIG. 31

Scoliosis Correction

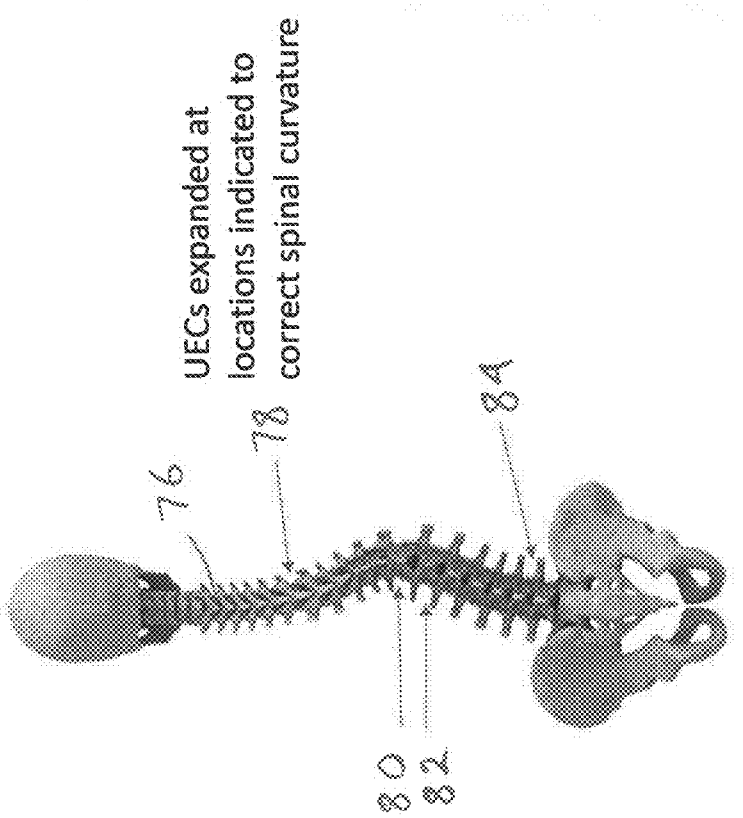

FIG. 30

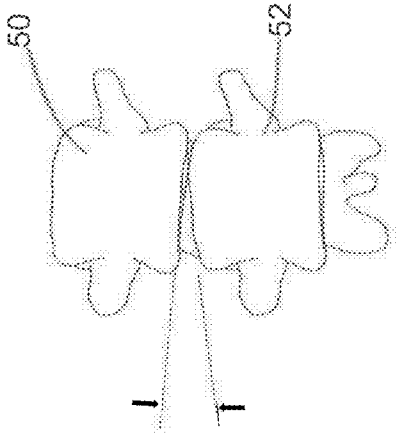

FIG. 32A

Misalignments

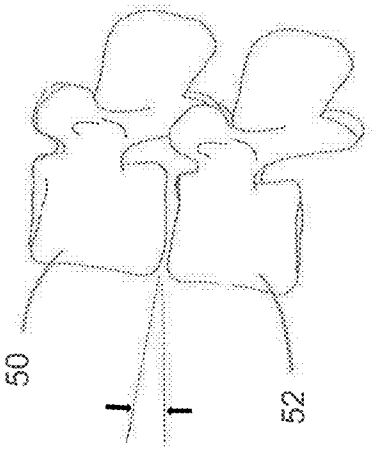

FIG. 32B

Uneven Spacing

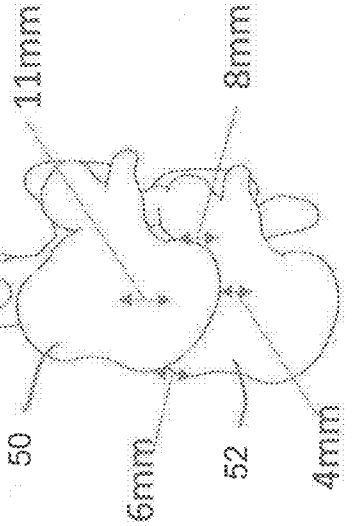

FIG. 32C

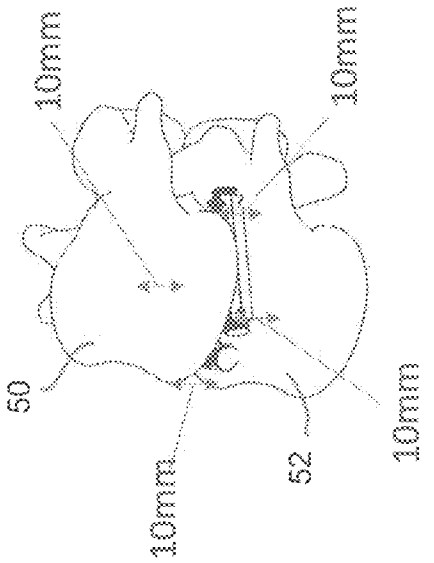

FIG. 33C

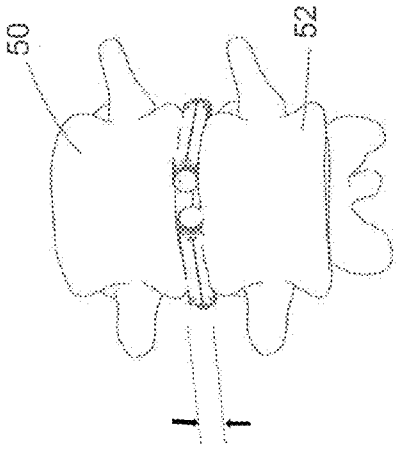

FIG. 33A

Alignment Restored

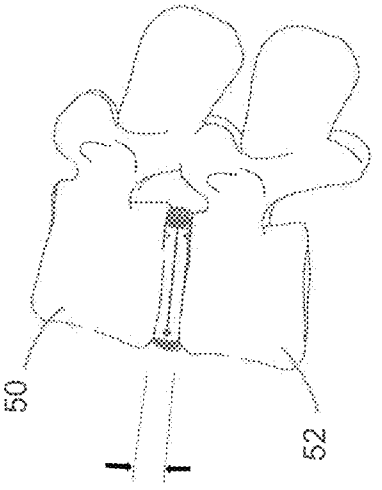

FIG. 33B

UNIVERSALLY EXPANDING CAGE

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 14/939,905 filed Nov. 12, 2015 which claims the benefit of U.S. Provisional Application No. 62/078,850 filed Nov. 12, 2014.

INCORPORATION BY REFERENCE

All publications and patent applications mentioned in this specification are herein incorporated by reference in their entirety to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

FIELD

The present disclosure generally relates to medical devices for stabilizing the vertebral motion segment or other bone segments. More particularly, the field of the disclosure relates to a universally expanding cage (UEC) and method of use for providing controlled spinal correction or other bond segment spacing and/or alignment.

BACKGROUND

Conventional spine cages or implants are typically characterized by a kidney bean-shaped body comprising a hydroxyapatite-coated surface provided on the exterior surface for contact with adjacent vertebral segments or endplates which are shown in FIG. **1**. A conventional spine cage with flat endplates is typically inserted posterolaterally proximate to the neuroforamen of the distracted spine after a trial implant creates a pathway. Optionally two parallel externally threaded conduits are inserted anteriorly to achieve lumbar arthrodesis. The implants are often of constant diameter whereas the L5-S1 disc space is trapezoidal, thus a 'flat back' syndrome may be iatrogenically created. Generally spine intradiscal implants are for lumbar fusion or cervical motion preservation, while a separate system of rods and screws corrects alignment.

With the novel UECs disclosed herein, additional options include fusion throughout the spinal column, and deformity angular correction.

Existing devices for interbody stabilization have important and significant limitations. Among the limitations are an inability to expand and distract the endplates. Consequently, if a cage that is "to small" is inserted it can 'rattle around and never heal'. If the static cage is too big, it can injure adjacent nerves or destabilize the spine via end plate resection or subsidence.

Current devices for interbody stabilization include static spacers composed of titanium, PEEK, and high performance thermoplastic polymer produced by VICTREX, (Victrex USA Inc, 3A Caledon Court, Greenville, S.C. 29615), carbon fiber, or resorbable polymers. Current interbody spacers may not maintain interbody lordosis and can contribute to the formation of a straight or even kyphotic segments and the clinical problem of "flatback syndrome." Separation of the endplates increases space available for the neural elements, specifically the neural foramen. Existing static cages do not reliably improve space for the neural elements. Therefore, what is needed is an expanding cage that will increase space for the neural elements posteriorly between

the vertebral bodies, or at least maintain the natural bone contours to avoid neuropraxia (nerve stretch) or encroachment.

U.S. Pat. No. 7,985,256, filed Sep. 26, 2006 and titled "Selectively Expanding Spine Cage, Hydraulically Controllable in Three Dimensions for Enhanced Spinal Fusion", and U.S. Pat. No. 7,819,921, filed Oct. 31, 2007 and titled "Linearly expanding spine cage for enhanced spinal fusion", both provide detailed background on expanding spine cages.

The cages disclosed in U.S. Pat. No. 7,985,256 above are restricted to use with hydraulics, and lumbar fusion. The cage disclosed in U.S. Pat. No. 7,819,921 allows for trapezoidal linear expanding, not uniform expansion, thus a trapezoidal L5 cage as disclosed therein will preserve natural lumbar lordosis. The disclosed cage was never developed. It is intended for use as two (2) parallel linearly expanding split conduits inserted anteriorly for lumbar fusion.

In contrast, the UEC cages disclosed herein expands either uniformly, or at either end proximally or distally. Given the adjustment option the surgeon can correct angulation deformity with the novel UEC.

Another problem with conventional devices of interbody stabilization includes poor interface between bone and biomaterial. Conventional static interbody spacers form a weak interface between bone and biomaterial. Although the surface of such implants is typically provided with a series of ridges or coated with hydroxyapetite, the ridges may be in parallel with applied horizontal vectors or side-to-side motion. That is, the ridges or coatings offer little resistance to movement applied to either side of the endplates. Thus, nonunion is common in allograft, titanium and polymer spacers, due to motion between the implant and host bone. Conventional devices typically do not expand between adjacent vertebrae. Since the UEC expands under surgeon control, the visible, palpable 'goodness of fit' setting can ideal lock opposing vertebral endplates at the time of surgery. As healing accrues, the implants become inert. Since no motion equates with no pain, clinical results are improved with UECs.

Therefore, what is needed is a way to expand an implant to develop immediate fixation forces that can exceed the ultimate strength at healing, with improved abilities to enable disc space fixation solidarity while correcting spine angular deformity. Such an expandable implant ideally will maximize stability of the interface and enhance stable fixation. The immediate fixation of such an expandable interbody implant advantageously will provide stability that is similar to that achieved at the time of healing. Such an implant will have valuable implications enhancing early post-operative rehabilitation for the patient.

Another problem of conventional interbody spacers is their large diameter requiring wide exposure. Existing devices used for interbody spacers include structural allograft, threaded cages, cylindrical cages, and boomerang-shaped cages. Conventional devices have significant limitation with regard to safety and efficacy. Regarding safety of the interbody spacers, injury to neural and aortic elements may occur with placement from an anterior or posterior approach. A conventional spine cage lacks the ability to expand, diminishing its fixation capabilities. Prior attempts to preserve lumbar motion have failed by extrusion of the implant after implantation. The risks to neural elements are primarily due to the disparity between the large size of the cage required to adequately support the interbody space, and the small space available for insertion of the device, especially when placed from a posterior or transforaminal

approach. Existing boomerang cages are shaped like a partially flattened kidney bean. Their implantation requires a wide exposure and potential compromise of vascular and neural structures, both because of their inability to enter small and become larger, and due to the fact that their insertion requires mechanical manipulation during insertion and expanding of the implant. Once current boomerang implants are prepared for insertion via a trial spacer to make a pathway toward the anterior spinal column, the existing static cage is shoved toward the end point with the hope that it will reach a desired anatomic destination. Given the proximity of nerve roots and vascular structures to the insertion site, and the solid, relatively large size of conventional devices, such constraints predispose a patient to foraminal (nerve passage site) encroachment, and possible neural and vascular injury.

Therefore, what is needed is a minimally invasive expanding spine cage that is capable of insertion with minimal invasion into a smaller aperture. Such a minimally invasive spine cage advantageously could be expanded with completely positional control or adjustment in three dimensions. What is also needed is a smaller expanding spine cage that is easier to operatively insert into a patient with minimal surgical trauma in contrast to conventional, relatively large devices that create the needless trauma to nerve roots in the confined space of the vertebral region. Existing interbody implants have limited space available for bone graft. Adequate bone graft or bone graft substitute is critical for a solid interbody arthrodesis. It would be desirable to provide an expandable interbody cage that will permit a large volume of bone graft material to be placed within the cage and around it, to fill the intervertebral space. Additionally, conventional interbody implants lack the ability to stabilize endplates completely and prevent them from moving. Therefore, what is also needed is an expanding spine cage wherein the vertebral end plates are subject to forces that both distract them apart, and hold them from moving. Such an interbody cage would be capable of stabilization of the motion segment, thereby reducing micromotion, and discouraging pseudoarthrosis (incomplete fusion) and pain.

Ideally, what is needed is a spine cage or implant that is capable of increasing its expansion in height and angle, spreading to a calculated degree. Furthermore, what is needed is a spine cage that can adjust the amount of not only overall anterior posterior expansion, but also medial and lateral variable expansion so that both the normal lordotic curve is maintained, and adjustments can be made for scoliosis or bone defects. Such a spine cage or implant would permit restoration of normal spinal alignment after surgery and hold the spine segments together rigidly, mechanically, until healing occurs.

What is also needed is an expanding cage or implant that is capable of holding the vertebral or joint sections with increased pullout strength to minimize the chance of implant fixation loss during the period when the implant is becoming incorporated into the arthrodesis bone block.

SUMMARY OF THE DISCLOSURE

According to some aspects of the disclosure, an expandable medical implant is provided with an implantable cage body having a proximal end and a distal end. In some embodiments, the proximal and distal ends of the cage body are each provided with a tapered or cam portion. The cage body further has a longitudinal axis extending between the proximal end and the distal end of the cage body. The implant may further comprise at least one proximal flexure at least partially located adjacent to the proximal end of the cage body and configured to allow a circumference of the distal end of the cage body to resiliently expand. The implant may further comprise at least one distal flexure at least partially located adjacent to the distal end of the cage body and configured to allow a circumference of the proximal end of the cage body to resiliently expand. The implant may further comprise a proximal plug member having a tapered portion configured to mate with the tapered portion of the proximal end of the cage body. The proximal plug member may be configured to move longitudinally relative to the cage body from a first position to a second position such that the at least one distal flexure moves and the circumference of the proximal end of the cage body resiliently expands. The proximal plug member may also be configured to move from the second position to the first position such that the circumference of the proximal end resiliently contracts. The implant may further comprise a distal plug member having a tapered portion configured to mate with the tapered portion of the distal end of the cage body. The distal plug member may be configured to move longitudinally relative to the cage body from a third position to a fourth position such that the at least one proximal flexure moves and the circumference of the distal end of the cage body resiliently expands. The distal plug member may also be configured to move from the fourth position to the third position such that the circumference of the distal end resiliently contracts.

In some embodiments, the cage body further comprises a first tapered bore at the proximal end configured to slidably receive the proximal plug member, and a second tapered bore at the distal end configured to slidably receive the distal plug member. The first tapered bore may threadably engage the proximal plug member such that when the proximal plug member is rotated relative to the cage body, the proximal plug member advances in a longitudinal direction relative to the cage body. The second tapered bore may threadably engage the distal plug member such that when the distal plug member is rotated relative to the cage body, the distal plug member advances in a longitudinal direction relative to the cage body.

In some embodiments, the at least one proximal flexure comprises a generally circular and open ended aperture and a pair of generally flexible beam portions extending longitudinally from the aperture. The at least one proximal flexure may include a pair of longitudinally extending beam portions separated by a longitudinally extending gap, wherein the at least one proximal flexure further comprises a connector portion interconnecting proximal ends of the beam portions. The at least one proximal flexure may include a plurality of circumferentially spaced proximal flexures, and the at least one distal flexure may include a plurality of circumferentially spaced distal flexures. The plurality of proximal flexures may be rotationally staggered from the plurality of distal flexures.

In some embodiments, each of the proximal flexures includes a pair of longitudinally extending beam portions separated by a longitudinally extending gap and bridged together by a connector portion interconnecting only proximal ends of the beam portions. Each of the distal flexures may include a pair of longitudinally extending beam portions separated by a longitudinally extending gap and bridged together by a connector portion interconnecting only distal ends of the beam portions. Each of the proximal flexures can share a beam portion with two of the distal flexures that are adjacent to each proximal flexure, thereby forming a continuous serpentine pattern along the cage body.

In some embodiments, the implant includes a first adjustment member coupled to at least the proximal plug member such that when the first adjustment member is rotated, the proximal plug member is caused to move longitudinally. The implant may further include a second adjustment member coupled to the distal plug member such that when the second adjustment member is rotated, the distal plug member is caused to move longitudinally, thereby allowing the proximal and the distal ends of the cage body to be expanded and contracted independent from one another. The first and the second adjustment members may be coaxially nested one within the other and independently rotatable. In some embodiments, the first and the second adjustment members each have knobs axially spaced but adjacent to one another such that the knobs may alternately be rotated in unison or individually. At least one of the first and the second adjustment members may have a keyed end configured to slidably mate and rotationally couple with its associated plug member such that the at least one adjustment member can be removed from the expandable medical implant.

In some embodiments, the cage body has a square or circular cross-section transverse to the longitudinal axis.

In some embodiments, an expandable medical implant includes an implantable cage, a plurality of proximal flexures, a plurality of distal flexures, a proximal plug member, a distal plug member, and first and second adjustment members. In these embodiments, the implantable cage body has a proximal end and a distal end each provided with a threaded and tapered bore. The cage body has a longitudinal axis extending between the proximal end and the distal end of the cage body. The plurality of proximal flexures are circumferentially spaced and each is at least partially located adjacent to the proximal end of the cage body and configured to allow a circumference of the distal end of the cage body to resiliently expand. Each of the proximal flexures comprises a pair of longitudinally extending beam portions separated by a longitudinally extending gap and bridged together by a connector portion interconnecting only proximal ends of the beam portions. The plurality of distal flexures are circumferentially spaced and each is at least partially located adjacent to the distal end of the cage body and configured to allow a circumference of the proximal end of the cage body to resiliently expand. Each of the distal flexures comprises a pair of longitudinally extending beam portions separated by a longitudinally extending gap and bridged together by a connector portion interconnecting only distal ends of the beam portions. Each of the proximal flexures shares a beam portion with two of the distal flexures that are adjacent to each proximal flexure, thereby forming a continuous serpentine pattern along the cage body. The proximal plug member has a threaded and tapered circumference configured to mate with the threaded and tapered bore of the proximal end of the cage body. The proximal plug member is configured to move along the longitudinal axis relative to the cage body from a first position to a second position such that the plurality of distal flexures move and the circumference of the proximal end of the cage body resiliently expands. The proximal plug member is also configured to move from the second position to the first position such that the circumference of the proximal end resiliently contracts. The distal plug member has a threaded and tapered circumference configured to mate with the threaded and tapered bore of the distal end of the cage body. The distal plug member is configured to move along the longitudinal axis relative to the cage body from a third position to a fourth position such that the plurality of proximal flexures move and the circumference of the distal end of the cage body resiliently expands. The distal plug member is also configured to move from the fourth position to the third position such that the circumference of the distal end resiliently contracts. The first adjustment member is rotationally coupled to the proximal plug member such that when the first adjustment member is rotated, the proximal plug member is caused to move along the longitudinal axis. The second adjustment member rotationally coupled to the distal plug member such that when the second adjustment member is rotated, the distal plug member is caused to move longitudinally, thereby allowing the proximal and the distal ends of the cage body to be expanded and contracted independent from one another. The first and the second adjustment members are coaxially nested one within the other and independently rotatable. The first and the second adjustment members each have knobs axially spaced but adjacent to one another such that the knobs may alternately be rotated in unison or individually. At least one of the first and the second adjustment members may have a keyed end configured to slidably mate and rotationally couple with its associated plug member such that the at least one adjustment member can be removed from the expandable medical implant.

According to some aspects of the disclosure, a method of distracting adjacent bone segments having opposing surfaces is provided. The method comprises the steps of inserting an expandable medical implant as described above between the opposing surfaces of the bone segments, and moving the proximal and the distal plug members longitudinally and independently from one another such that the proximal and the distal ends of the cage body expand independently to alter the distance and the angle between the opposing surfaces of the bone segments. In some embodiments, the method further includes the step of removing at least one adjustment member from the medical implant after the adjustment member has been used to move at least one of the proximal and distal plug members. In some embodiments, the bone segments are adjacent vertebrae, and the opposing surfaces are end plates of the adjacent vertebrae.

BRIEF DESCRIPTION OF THE DRAWINGS

For the purpose of illustrating concepts of the disclosure, the drawings show aspects of one or more embodiments. However, it should be understood that the present disclosure is not limited to the precise arrangements and instrumentalities shown in the drawings, wherein:

FIGS. **1-3** are a series of lateral representations of two vertebral bodies, wherein FIG. **1** depicts the insertion of an exemplary Universally Expanding Cage (UEC) in its unexpanded state, FIG. **2** depicts the UEC in place between the vertebral bodies and still in its unexpanded state, and FIG. **3** depicts the inserted UEC in its expanded state.

FIG. **4** is a perspective view of a first embodiment of a UEC in an unexpanded state according to aspects of the disclosure.

FIG. **5** is an exploded perspective view showing the UEC of FIG. **4**.

FIG. **6** is a perspective view showing the cage body of the UEC of FIG. **4**.

FIG. **7** is a proximal end view of the UEC of FIG. **4**.

FIG. **8** is a side view of the UEC of FIG. **4**.

FIG. **9** is a side cross-sectional view of the UEC of FIG. **4**.

FIG. **10** is a perspective view of a second embodiment of a UEC in an unexpanded state according to aspects of the disclosure.

FIG. **11** is an exploded perspective view showing the UEC of FIG. **10**.

FIG. **12** is a side view showing the UEC of FIG. **10**.

FIG. **13** is a proximal end view showing the UEC of FIG. **10**.

FIG. **14** is a distal end view showing the UEC of FIG. **10**.

FIG. **15** is a side cross-sectional view showing the UEC of FIG. **10**.

FIG. **16** is a perspective view of a third embodiment of a UEC in an unexpanded state according to aspects of the disclosure.

FIG. **17** is an exploded perspective view showing the UEC of FIG. **16**.

FIG. **18** is a side view showing the UEC of FIG. **16**.

FIG. **19**A is a side cross-sectional view showing the UEC of FIG. **16**.

FIG. **19**B is an end cross-sectional view showing the UEC of FIG. **16**.

FIGS. **20**A-**20**C are a series of side views showing the progressive expansion of the UEC of FIG. **16**, wherein FIG. **20**A shows both ends of the UEC in the unexpanded state, FIG. **20**B shows only one end expanded, and FIG. **20**C shows both ends expanded.

FIG. **21** is a perspective view of a fourth embodiment of a UEC in an unexpanded state according to aspects of the disclosure.

FIG. **22** is a perspective view of a fifth embodiment of a UEC in an unexpanded state according to aspects of the disclosure.

FIG. **23** is a distal end view showing the UEC of FIG. **22**.

FIG. **24** is a side view showing the UEC of FIG. **22**.

FIG. **25** is a side cross-sectional view showing the UEC of FIG. **22**.

FIG. **26** is a cranial to caudal view showing the insertion sites of dual UECs on a vertebral body in one example implementation.

FIG. **27** is an oblique posterolateral view showing one of the insertion sites of the implementation of FIG. **26**.

FIG. **28** is an oblique posterolateral view showing the axes of adjustment provided by the implementation of FIG. **26**.

FIG. **29** is an oblique anterior view showing an anterior column implant.

FIG. **30** is a posterior view showing a human spine exhibiting scoliosis.

FIG. **31** is a posterior view showing the spine of FIG. **29** after being corrected according to aspects of the disclosure.

FIGS. **32**A-**32**C are anterior, lateral and oblique views, respectively, showing adjacent vertebral bodies having misalignments/uneven spacing.

FIGS. **33**A-**33**C are anterior, lateral and oblique views, respectively, showing the vertebral bodies of FIGS. **32**A-**32**C with the misalignments/uneven spacing corrected according to aspects of the disclosure.

DETAILED DESCRIPTION

Referring to FIG. **1-3**, a series of lateral views of vertebral segments **50** and **52** are shown, depicting the insertion and expansion of one embodiment of UEC (Universally Expanding Cage). The depicted vertebral bodies **50** and **52** have an average 8 mm gap between vertebral end plates, representing an average intervertebral space **54**. In a typical implementation, a complete discectomy is performed prior to the insertion of the UEC **56**. The intervertebral disc occupying space **54** is removed using standard techniques including rongeur, curettage, and endplate preparation to bleeding subcondral bone. The posterior longitudinal ligament is divided to permit expansion of the intervertebral space.

The intervertebral space **54** may be distracted to about 10 mm using a rotating spatula (not shown). This is a well-known device that looks like a wide screw driver that can be placed into the disc space horizontally and turned 90 degrees to separate the endplates. A novel feature of the UEC is that after intervertebral disc space expansion and preparation (by curetting or ideally arthroscopically facilitated disc material removal), the UEC implant per se can be inserted through any orifice or angle that does not cause injury to nerves or other structures, positioned at the immediate implant location and consequent expansion platform to yield both the best fusion and angular correction results.

In the example implementation depicted in FIGS. **1-3**, UEC **56** is inserted posteriorly (in the direction of arrow **58**) between vertebral bodies **50** and **52**, as shown in FIG. **1**. The vertebral space **54** depicted is meant to represent any vertebral space in which it is desired to insert the UEC (sacral, lumbar, thoracic and/or cervical), and from any direction permitted by the surrounding anatomy. In accordance with an aspect of the disclosure, the UEC is reduced to a small size in its unexpanded state to enable it to be inserted through into the intervertebral space **54** as shown in FIG. **1**. FIG. **2** shows UEC **56** inserted between vertebral bodies **50** and **52**, with UEC **56** still in its unexpanded state. In one exemplary embodiment, dimensions of an unexpanded UEC are: 10-12 mm wide, 10 mm high and 28 mm long to facilitate insertion and thereby minimize trauma to the patient and risk of injury to nerve roots. These dimensions may accommodate the flat external surfaces. Once in place, the exemplary UEC **56** may be expanded to 140 percent of its unexpanded size (as shown in FIG. **3**), enabling 20 degrees or more of spinal correction depending on the 3D clinical pre-operation anatomic analysis.

It should be noted that while the exemplary UEC **56** depicted in FIGS. **1-3** is an implant intended to ideally fill the warranted space, other shapes of implants such as those shown in later figures and/or described herein may be used. In various embodiments, the implants may have a transverse cross-section that is circular, oval, elliptical, square, rectangular, trapezoidal, or other shape suited to fill the implant site and transmit the required loads. The implants may straight, curved, bean-shaped, and/or include other shapes and aspect ratios. Additionally, the external surfaces may be smooth, spiked, threaded, coated and/or further adapted as subsequently described in more detail. The UEC can be used at any spinal level the surgeon deems in need of fusion, and may be placed at any position and angle relative to the vertebral endplates as may be needed. One, two, or more UECs may be placed at any particular level to achieve the desired height and angles between vertebral bodies. As will be later described, multiple UECs may be used to adjust the overall cranio-caudal height, the anterior-posterior angle, and the medio-lateral angle between adjacent vertebral bodies. UECs may be implanted at multiple levels to obtain or restore the desired three dimensional curvature and positioning of the spine.

Referring to FIGS. **4-9**, a first embodiment of an exemplary UEC **100** according to aspects of the disclosure is shown. FIG. **4** is an enlarged perspective view which shows details of UEC **100**. For ease of understanding, a proximal end **104** and a distal end **106** of UEC **100** can be defined as shown in FIG. **4**. It should be noted that while the distal end **106** of UEC **100** is typically inserted first into a patient and proximal end **104** is typically closest to the surgeon, other orientations of this exemplary device and other devices

described herein may be adopted in certain procedures despite the distal and proximal nomenclature being used.

Referring to FIG. **5**, an exploded perspective view shows the individual components of UEC **100**. In this first embodiment, UEC **100** includes a cylindrically-shaped cage body **108**, a proximal plug **110**, a distal plug **112**, a threaded actuator **114**, and a washer **116**. The terms "plug" and "plug member" are used interchangeably herein. Actuator **114** has a shank sized to slidably pass through a central bore within proximal plug **110** when UEC **100** is assembled. Actuator **114** also has threads on its distal end for engaging with a threaded central bore within distal plug **112**. Proximal plug **110** and distal plug **112** each have outer surfaces that are inwardly tapered to match inwardly tapered surfaces within cage body **108** (as best seen in FIG. **9**) With this arrangement, actuator **114** may be rotated in a first direction to draw distal plug **112** toward proximal plug **110** to outwardly expand cage body **108**, as will be subsequently described in more detail.

Referring to FIG. **6**, this perspective view shows details of cage body **108** of the first exemplary embodiment of UEC **100**. In this embodiment, cage body **108** includes eight longitudinally extending beam portions **118**, each separated from an adjacent beam portion **118** by a longitudinally extending gap **120**. In other embodiments (not shown), the cage body may include fewer or more than eight beam portions, and/or beam portions having a different or varying cross-section or shape. Cage body **108** of the current embodiment also includes eight circumferentially extending connector portions **122**. The connector portions **122** interconnect the ends of the beam portions **118**. Four of the connector portions **122** are located at the proximal end **104** of cage body **108**, and the other four connector portions **122** are located at the distal end **106**. The connector portions **122** located at the proximal end **104** are staggered in relation to the connector portions **122** located at the distal end **106** such that each pair of adjacent beam portions **118** are connected at only one end by a connector portion **122**. With this arrangement the beam portions **118** and connector portions **122** form a continuous serpentine or repeating S-shaped pattern. The beam portions **118** and or the connector portions **122** are configured to resiliently flex to allow the cage body **108** to increase in diameter when urged radially outward by plugs **110** and **112** (shown in FIG. **4**). When plugs **110** and **112** are not urging cage body **108** radially outward, the resiliency of beam portions **118** and or connector portions **122** allows cage body **108** to return to its original reduced diameter. It can be appreciated that as beam portions **118** and or connector portions **122** flex outwardly, gaps **120** become wider at their open ends opposite connector portions **122**. The outwardly facing surfaces of beam portions **118** may each be provided with one or more points or spikes **123** as shown, to permit cage body **108** to grip the end plates of the vertebral bodies.

Referring to FIG. **7**, an end view of the proximal end **104** of UEC **100** is shown. The enlarged head at the proximal end of actuator **114** may be provided with a recessed socket **124** as shown for removably receiving a tool for turning actuator **114**. Proximal plug **110** (and distal plug **112**, not shown) may be provided with radially outwardly extending protuberances **126** that reside in one or more gaps **120** and abut against the side of beam portions **118**. This arrangement prevents plugs **110** and **112** from rotating when actuator **114** is turned, thereby constraining plugs **110** and **112** to only move axially toward or away from each other. Proximal plug **110** (and distal plug **112**) may be provided with through holes and or recesses **128** to allow for bony ingrowth from the vertebral bodies for more solidly healing/fusing UEC **100** in place. Longitudinally extending slots **130** (shown in FIG. **4**) may also be provided for this purpose, and or for packing plugs **110** and **112** with autograft, allograft, and/or other materials for promoting healing/fusion.

Referring to FIGS. **8** and **9**, a side view and side cross-sectional view, respectively, are shown. In operation, UEC **100** is expanded by inserting a tool such as a hex key wrench or driver (not shown) into the recessed socket **124** at the proximal end of actuator **114** and turning it clockwise. As best seen in FIG. **9**, the distal end of actuator **114** is threaded into the central bore of distal plug **112**. Turning actuator **114** clockwise causes the distal end of actuator **114** to pull distal plug **112** towards the center of cage body **108** while the enlarged head at the proximal and of actuator **114** pushes proximal plug **110** towards the center. This movement in turn causes the ramped surfaces **132** of plugs **110** and **112** to slide inwardly along the ramped surfaces **134** located along the inside of beam portions **118** and connector portions **122** to cause these elements to flex and expand radially outward as previously described. This process may be reversed by turning actuator **114** counterclockwise. The resilient inward forces from the beam portions **118** and or connector portions **122** (and or the compressive forces from adjacent vertebral bodies) against plugs **110** and **112** causes the two plugs to separate axially, thereby allowing UEC **100** to return to its non-expanded state.

Referring to FIGS. **10-15**, a second embodiment of an exemplary UEC **200** according to aspects of the disclosure is shown. FIG. **10** is a perspective view which shows details of UEC **200**. UEC **200** includes a proximal end **204** and a distal end **206**, and shares many of the same features of previously described UEC **100**, which are identified with similar reference numerals.

Referring to FIG. **11**, an exploded perspective view shows the individual components of UEC **200**. In this second embodiment, UEC **200** includes an elongated cylindrical cage body **208**, a proximal plug **210**, and a distal plug **212**. Distal plug **212** includes an integrally formed actuator rod **214** that extends along the internal central axis of cage body **208** towards proximal plug **210** when UEC **200** is assembled. Proximal plug **210** and distal plug **212** each have outer surfaces that are threaded and inwardly tapered to match threaded and inwardly tapered surfaces within cage body **208** (as best seen in FIG. **15**). With this arrangement, each plug **210** and **212** may be independently rotated to move the particular plug axially toward the middle of cage body **208** to outwardly expand that particular end **204** or **206** of cage body **208**, as will be subsequently described in more detail.

As shown in FIGS. **11** and **12**, cage body **208** includes eight longitudinally extending beam portions **218**, each separated from an adjacent beam portion **218** by a longitudinally extending gap **220**. In other embodiments (not shown), the cage body may include fewer or more than eight beam portions, and/or beam portions having a different or varying cross-section or shape. Cage body **208** of the current embodiment also includes eight circumferentially extending connector portions **222**. The connector portions **222** interconnect the ends of the beam portions **218**. Four of the connector portions **222** are located at the proximal end **204** of cage body **208**, and the other four connector portions **222** are located at the distal end **206**. The connector portions **222** located at the proximal end **204** are staggered in relation to the connector portions **222** located at the distal end **206** such that each pair of adjacent beam portions **218** are connected at only one end by a connector portion **222**. With this

arrangement the beam portions **218** and connector portions **222** form a continuous serpentine or repeating S-shaped pattern. The beam portions **218** and or the connector portions **222** are configured to resiliently flex to allow the cage body **208** to increase in diameter when urged radially outward by plugs **210** and **212**. When plugs **210** and **212** are not urging cage body **208** radially outward, the resiliency of beam portions **218** and or connector portions **222** allows cage body **208** to return to its original reduced diameter. It can be appreciated that as beam portions **218** and or connector portions **222** flex outwardly, gaps **220** become wider at their open ends opposite connector portions **222**. The outwardly facing surfaces of beam portions **218** may each be provided with one or more points or spikes **223** as shown, to permit cage body **208** to grip the end plates of the vertebral bodies.

Referring to FIG. **13**, an end view of the proximal end **204** of UEC **200** is shown. The proximal plug **210** may be provided with a recessed socket **224** as shown for removably receiving a tool for turning proximal plug **210** in either direction, such as a five-lobed driver (not shown). Alternatively, other suitable types of recessed sockets, slots, protruding and/or keyed features may be utilized with a mating driver. The proximal end of actuator shaft **214** (which extends proximally from distal plug **212** inside cage body **208**) may be accessed through a central bore **225** in proximal plug **210**. The proximal end of actuator shaft **214** may be shaped as shown to be received within a mating driver socket (such as a five-lobed socket, not shown), which can be removably extended into the center of cage body **208** through central bore **225**. With this arrangement, both the proximal plug **210** and the distal plug **212** can be independently accessed and rotated from the proximal end of UEC **200** so that the proximal end **204** and the distal end **206** of UEC **200** can be expanded or contracted independently.

Referring to FIG. **14**, an end view of the distal end **206** of UEC **200** is shown. By comparing FIGS. **13** and **14**, it can be appreciated that connector portions **222** at the proximal end **204** of UEC **200** are staggered (i.e. rotated 45°) in relation to the connector portions **222** at the distal end **206** of UEC **200**.

Referring to FIG. **15**, a side cross-sectional view of UEC **200** is shown. In operation, the proximal end **204** of UEC **200** may be independently expanded by inserting a tool such as a five-lobed driver (not shown) into the recessed socket **224** of proximal plug **210** and turning it clockwise. Turning proximal plug **210** clockwise causes the threaded ramped surfaces **232** of plug **210** to translate inwardly (to the right in FIG. **15**) along the threaded ramped surfaces **234** located along the inside of beam portions **218** and connector portions **222** to cause these elements to flex and expand radially outward as previously described. This process may be reversed by turning proximal plug **210** counterclockwise, thereby allowing the proximal end **204** of UEC **200** to return to its non-expanded state. Similarly, the distal end **206** of UEC **200** may be independently expanded by inserting a tool such as a five-lobed socket (not shown) through the central bore **225** in proximal plug **210** until it engages with the proximal end of actuator **214**, which is attached to distal plug **212**. Turning distal plug **212** counterclockwise (from the perspective of the proximal end) causes the threaded ramped surfaces **232** of plug **212** to translate inwardly (to the left in FIG. **15**) along the threaded ramped surfaces **234** located along the inside of beam portions **218** and connector portions **222** to cause these elements to flex and expand radially outward as previously described. This process may be reversed by turning distal plug **212** clockwise, thereby allowing the distal end **206** of UEC **200** to return to its non-expanded state.

The adjustment tools described above (not shown) for turning proximal plug **210** and distal plug **212** may be inserted one at a time into UEC **200**. Alternatively, the two tools may be nested together, with the tool for turning the distal plug **212** passing through a central bore in the tool for turning the proximal plug, as will be subsequently shown and described in relation to other embodiments. With this arrangement, both tools may be turned simultaneously or individually. In some embodiments, both proximal plug **210** and distal plug **212** are provided with right-handed threads, so that when both tools are simultaneously turned in the same direction, one end of UEC **200** expands while the other end contracts, thereby changing the outer surface angle of UEC **200** without substantially changing its overall diameter (i.e. without substantially changing the diameter or height of the midpoint of UEC **200**.) For example, by turning the two tools in the same direction, the lordotic angle between two vertebral bodies can be changed by UEC **200** without substantially changing the height between the two vertebral bodies.

In other embodiments, one of the plugs **210** or **212** may be provides with a right-handed thread and the other plug provided with a left-handed thread. In these embodiments, when both adjustment tools are simultaneously turned in the same direction, both ends **204** and **206** of UEC **200** expand or contact together without substantially changing the outer surface angle of UEC **200**. For example, by turning the two tools in the same direction, the height between the two vertebral bodies can be changed by UEC **200** without substantially changing the lordotic angle between two vertebral bodies.

In some embodiments, plugs **210** and **212** may each be provided with threads having a different pitch from the other. Such an arrangement allows both the height and the angle between adjacent vertebral bodies to be adjusted simultaneously in a predetermined relationship when both adjustment tools are turned together in unison. For example, proximal plug **210** may be provided with right-handed threads of a particular pitch while distal plug **212** may be provided with finer, left-handed threads having half the pitch of the proximal plug threads. In this embodiment, when both adjustment tools are turned together in a clockwise direction, both ends of UEC **200** expand at the same time but the proximal end **204** expands at twice the rate of the distal end **206**. This allows the surgeon to increase the height between adjacent vertebral bodies and at the same time angle the bodies away from him or her. One or both of the tools may then be turned individually to more finely adjust the height and angle between the vertebral bodies.

In some embodiments the above-described adjustment tools may be removed from UEC **200** before the surgical procedure is completed. In some embodiments the above adjustment tools may remain in place after the procedure is completed.

In some embodiments, UEC **200** is 50 mm long, has an unexpanded diameter of 10 mm, and an expanded diameter of 14 mm. In other embodiments, the UEC may be configured to expand to about 11, 12, or 13 mm, or more than 14 mm. In still other embodiments, the UEC may be configured with dimensions larger or smaller than these to conform to a particular anatomy or procedure.

Referring to FIGS. **16-20**, a third embodiment of an exemplary UEC **300** according to aspects of the disclosure is shown. FIG. **16** is a perspective view which shows details

of UEC **300**. UEC **300** includes a proximal end **304** and a distal end **306**, and shares many of the same features of previously described UECs **100** and **200**, which are identified with similar reference numerals.

Referring to FIG. **17**, an exploded perspective view shows the individual components of UEC **300**. In this third embodiment, UEC **300** includes a rectangular cage body **308**, a proximal plug **310**, a distal plug **312**, a proximal plug adjustment tool **313**, and a distal plug adjustment tool **314**. As in the previously described UEC **200**, both plugs **310** and **312** are threaded and tapered, and each end of cage body **308** is provided with an inwardly tapered and threaded bore configured to receive one of the plugs **310** or **312**. Adjustment tools **313** and **314** are similar in construction and operation to the adjustment tools previously described (but not shown) in reference to UEC **200**. Proximal plug **310** includes a mating recess on its proximal end (not shown) configured to removably receive the splined distal end of proximal plug adjustment tool **313** for rotating proximal plug **310**. Distal plug **312** includes a smaller mating recess on its proximal end (not shown) configured to removably receive the smaller splined distal end of distal plug adjustment tool **314** for rotating distal plug **312**. Both proximal plug adjustment tool **313** and proximal plug **312** are provided with central bores that permit the distal end of distal plug adjustment tool **314** to pass therethrough, through the center of cage body **308**, and partially into distal plug **312**. In this exemplary embodiment, the proximal ends of adjustment tools **313** and **314** each have a hexagonally-shaped head that permits them to be turned together in unison or individually (as previously described in relation to UEC **200**), using wrench(es), socket(s) (not shown) and/or by hand.

As shown in FIGS. **16** and **17**, cage body **308** includes eight longitudinally extending beam portions **318**, each separated from an adjacent beam portion **318** by a longitudinally extending gap **320**. In other embodiments (not shown), the cage body may include fewer or more than eight beam portions, and/or beam portions having a different or varying cross-section or shape. It can be seen that in this embodiment, four of the gaps **320** are formed through the middle of the four faces of cage body **308**, and the other four gaps **320** are formed along the corner edges of cage body **308**. Cage body **308** also includes eight circumferentially extending connector portions **322**. The connector portions **322** interconnect the ends of the beam portions **318**. Circular apertures **321** may be provided as shown between the ends of gaps **320** and the connector portions **322** to relieve stress concentrations at those locations as connector portions **322** flex. Four of the connector portions/flexures **322** are located at the proximal end **304** of cage body **308** (across the corner edges of cage body **308**), and the other four connector portions/flexures **322** are located at the distal end **306** (across the distal end of the faces of cage body **308**.) The connector portions **322** located at the proximal end **304** are staggered in relation to the connector portions **322** located at the distal end **306** such that each pair of adjacent beam portions **318** are connected at only one end by a connector portion **322**. As with previously described embodiments, the beam portions **318** and connector portions **322** form a continuous serpentine or repeating S-shaped pattern. The beam portions **318** and or the connector portions **322** are configured to resiliently flex to allow the cage body **308** to increase in circumference when urged radially outward by plugs **310** and **312**. When plugs **310** and **312** are not urging cage body **308** radially outward, the resiliency of beam portions **318** and or connector portions **322** allows cage body **308** to return to its original reduced circumference. It can be appreciated that as beam portions **318** and or connector portions **322** flex outwardly, gaps **320** become wider at their open ends opposite connector portions **322**. The outwardly facing surfaces of beam portions **318** may each be provided with one or more points or spikes **323** as shown, to permit cage body **308** to grip the end plates of the vertebral bodies. In this exemplary embodiment, spiked or knurled surfaces are provided along the top and bottom of UEC **300** while the side surfaces are left smooth.

Referring to FIGS. **18** and **19**, a side view and a side cross-sectional view, respectively, of UEC **300** are shown. In operation, the proximal end **304** of UEC **300** may be independently expanded by inserting proximal plug adjustment tool **313** into the mating recessed socket of proximal plug **310** (as shown in FIG. **19**) and turning it clockwise. Turning proximal plug **310** clockwise causes the threaded ramped surfaces **332** of plug **310** to translate inwardly (to the left in FIGS. **18** and **19**) along the threaded ramped surfaces **334** located along the inside of beam portions **318** and connector portions **322** to cause these elements to flex and expand radially outward as previously described. This process may be reversed by turning proximal plug **310** counterclockwise, thereby allowing the proximal end **304** of UEC **300** to return to its non-expanded state. Similarly, the distal end **306** of UEC **300** may be independently expanded by inserting a tool such as a five-lobed socket (not shown) through the central bore **325** in proximal plug **310** until it engages with the proximal end of actuator **314**, which is attached to distal plug **312**. Turning distal plug **312** counterclockwise (from the perspective of the proximal end) causes the threaded ramped surfaces **332** of plug **312** to translate inwardly (to the right in FIGS. **18** and **19**) along the threaded ramped surfaces **334** located along the inside of beam portions **318** and connector portions **322** to cause these elements to flex and expand radially outward as previously described. This process may be reversed by turning distal plug **312** clockwise, thereby allowing the distal end **306** of UEC **300** to return to its non-expanded state.

Referring to FIGS. **20**A-**20**C, a series of sides views depicts the progression from a fully retracted and a fully expanded UEC **300**. In FIG. **20**A, cage body **308** is shown in a fully retracted position. In this figure, the height of each end of cage body **308** is labeled as 100% of retracted cage height. In FIG. **20**B, the proximal end **304** of cage body **308** has been fully expanded while the distal end **306** remains fully retracted. In this exemplary embodiment, each end is capable of being expanded to a height (and therefore also a width) that is 140% of the fully retracted height, as shown. In FIG. **20**C, the distal end **306** has also been expanded by 40%.

In some embodiments, UEC **300** has a cage length of 50 mm, an unexpanded cage height of 10 mm, and an expanded cage height of 14 mm. The overall length of UEC **300** with adjustment tools **313** and **314** in place and in the unexpanded state may be 75 mm. In other embodiments, the UEC may be configured to expand to about 11, 12, or 13 mm, or more than 14 mm. In still other embodiments, the UEC may be configured with dimensions larger or smaller than these to conform to a particular anatomy or procedure. In some embodiments, the UEC can form an included angle between its top and bottom surfaces of at least 20 degrees.

Referring to FIG. **21**, a fourth embodiment of an exemplary UEC **400** according to aspects of the disclosure is shown. FIG. **21** is a perspective view which shows details of UEC **400**. UEC **400** includes a proximal end **404**, a distal end **406**, cage body **408**, proximal plug **410**, distal plug **412**,

proximal plug adjusting tool **413**, and distal plug adjusting tool **414**. Other than cage body **408** having a circular cross-section rather than a square cross-section, UEC **400** is essentially identical in construction and operation to previously described UEC **300**. In other embodiments (not shown), the UEC may have a cross-section transverse to the central longitudinal axis that is rectangular, trapezoidal, oval, elliptical or other shape.

Referring to FIGS. **22-25**, a fifth embodiment of an exemplary UEC **500** according to aspects of the disclosure is shown. FIG. **16** is a perspective view which shows details of UEC **500**. UEC **500** includes a proximal end **504** and a distal end **506**, and shares many of the same features of previously described UECs **100-400**, which are identified with similar reference numerals.

UEC **500** includes three components: a generally cylindrical, unitary cage body **508**; a proximal actuator screw **510**; and a distal actuator screw **512**. The heads of actuator screws **510** and **512** may be referred to as plug members. Cage body **508** includes two longitudinal, off-center slots **550** which each extend about three-quarters of the length of cage body **508**, and emanate from opposite ends and opposite sides of cage body **508**. Cage body **508** is also provided with two transverse slots **552**, each located adjacent to the closed end of one of the longitudinal slots **550**. Each transverse slot **552** extends from the outer circumference of cage body **508** and approaches the base of a longitudinal slot **550**. Each of the two pairings of a longitudinal slot **550** with a transverse slot **552** defines a cantilevered arm **554** that is connected with the remainder of the cage body **508** by a living hinge **556** near the closed ends of the two slots **550** and **552**. Each living hinge **556** allows its associated arm **554** to flex outwardly against a vertebral body.

The open ends of longitudinal slots **550** are outwardly tapered to receive the enlarged, tapered heads of an actuator screw **510** or **512**, as best seen in FIG. **24**. The opposite ends of actuator screws **510** and **512** extend through longitudinal slots **550** and thread into the opposite ends of cage body **508**. With this arrangement, each actuator screw **510** and **512** may be turned independently of the other, causing the screw to move axially relative to bone cage **508**. This axial movement causes the head of the screw to urge the tapered tip of the associated arm **554** outward, or allowing it to flex back inward when the screw is turned in the opposite direction. If both actuator screws **510** and **512** are turned in the same direction the same amount, UEC **500** expands uniformly and increases the height between adjacent vertebral bodies. If one of the two actuator screws **510** or **512** is turned more than the other, the surgeon is able to change the angle between the vertebral bodies.

As best seen in FIG. **23**, a slot **558** or other suitable feature may be provided in the end of each actuator screw **510** and **512** at the opposite end from the screw head. A hole **560** may also be provided through each end of cage body **508** to allow access to each of the two slots **558**. This arrangement allows both of the actuator screws **510** and **512** to be turned from either end **504** and/or **506** of cage body **508**.

Referring to FIGS. **26-28**, an example implementation utilizing two UECs **56** in tandem is shown. Each UEC **56** may be inserted as previously described in relation to FIGS. **1-3**. In this implementation, UECs **56** are placed non-parallel to one another. As best seen in FIG. **28**, this arrangement allows the surgeon to adjust the angle between the vertebrae about two different axes, and also translate the vertebrae with respect to one another about another axis.

FIG. **29** is an oblique anterior view showing placement of an anterior column implant **56** on a vertebral body **52**. In this implementation, implant **56** is placed laterally across the vertebral body **52**, forward of the lateral midline. After adjustment of implant **56**, its plugs are flush with or recessed within the outer perimeter of the endplate of vertebral body **52** so as not to impinge upon adjacent tissue.

Referring to FIG. **30**, a human spine **76** is shown that exhibits scoliosis. According to aspects of the disclosure, dual UECs may be placed at various levels of the spine to treat the condition. For example, a single UEC or pairs of UECs may be implanted at the levels depicted by reference numerals **78**, **80**, **82** and **84** shown in FIG. **30**. By using the adjustments described above relative to FIG. **28**, the curvature of the spine may be adjusted in three dimensions at these four levels to a correct alignment, as shown in FIG. **31**.

FIGS. **32A-32C** are anterior, lateral and oblique views, respectively, showing adjacent vertebral bodies **50** and **52** having misalignments/uneven spacing.

FIGS. **33A-33C** are anterior, lateral and oblique views, respectively, showing the vertebral bodies **50** and **52** of FIGS. **32A-32C** with the misalignments/uneven spacing corrected according to aspects of the disclosure.

The implants can be made of, for example, such materials as titanium, 64 titanium, or an alloy thereof, 316 or 321 stainless steel, biodegradeable and biologically active materials, e.g. stem cells, and polymers, such as semi-crystalline, high purity polymers comprised of repeating monomers of two ether groups and a ketone group, e.g. polyaryetheretherketone (PEEK)™, or Teflon™.

To prevent movement of proximal and distal plugs or actuators after implantation, in some implementations a biocompatible adhesive or thread locking compound may be applied to one or more of the moving parts. In some embodiments (not shown) a pin may be inserted radially or axially between the plug/actuator and the cage body to lock the parts in place post operatively. In some embodiments, a ratchet, spring loaded detent, or other locking mechanism may be provided for this purpose.

In general, as disclosed in the above embodiments, the cage body is cut with openings at every other end of each slot, like a sine wave, allowing expansion when the center of the cage becomes occupied with a cone or mandrill shaped unit. The cage body's series of alternating slots allows the expansion to take place while keeping the outside of the UEC one single piece. The slots plus the teeth on the surface allow for a solid grip on the bone surfaces and plenty of opportunities for good bone ingrowth. Also, by allowing the surgeon to make one end of the UEC thicker than the other, the effects of the cone (mandrill) introduction vary from uniform to selective conduit expansion. The UEC expansion mechanism is adaptable to both fixed fusion and mobile 'motion preservation' implants, with exteriors of the expanding implant per surgeon's choice (round, flat, custom, etc.) As such, in some implementations, relative motion may be preserved between the vertebral bodies adjacent the implanted UEC(s). In other implementations, it may be desirable to fuse the adjacent vertebral bodies around the implanted UEC(s).

To provide motion preservation between adjacent vertebrae, robust compressible materials may be used between the UEC and one or both of the vertebral endplates, and/or one or more components of the UEC may comprise such materials. These materials may replicate the load distributing and shock absorbing functions of the annulus and nucleus of a natural disk. For example, in some embodiments the UEC may be provided with tapered plugs made of a resilient polymer to allow the UEC to compress and expand to accommodate relative motion of the adjacent

vertebrae. Examples of biocompatible materials suitable for some UEC embodiments include Bionate®, a thermoplastic polycarbonate-urethane (PCU) provided by DSM Biomedical in Exton, Pa., and ChronoFlex®, a PCU provided by AdvanSource Biomaterials in Wilmington, Mass.

The UEC provides advantages over currently existing technology that include correction of coronal plane deformity; introduction of interbody lordosis and early stabilization of the interbody space with rigidity that is greater than present spacer devices. This early stability may improve post-operative pain, preclude the need for posterior implants including pedicle screws, and improve the rate of successful arthrodesis. Importantly, the UEC provides improvement of space available for the neural elements while improving lordosis. Traditional implants are limited to spacer effects, as passive fillers of the intervertebral disc locations awaiting eventual fusion if and when bone graft in and around the implant fuses. By expanding and morphing into the calculated shape which physiologically corrects spine angulation, the UEC immediately fixes the spine in its proper, painless, functional position. As infused osteoinductive/osteoconductive bone graft materials heal, the patient becomes well and the implant becomes inert and quiescent, embedded in bone, and no longer needed.

In some embodiments, the external surface of the UEC may be 3D printed to not only fit into the intervertebral space per se, but to match the surface topography at each insertion location. In other words, a 3D printed endplate may be utilized, computer calculated to fit and expand the disc space of the individual patient, resulting in both best 'goodness of fit' for fusion, and improved axial skeletal alignment.

By creating to 'maps' that fit e.g. as a precisely congruent superior and inferior surface to fit into a particular patients disc space, and placing these UEC end plates on either side the novel UEC expansion mechanism, a patient's disc space AND overall spine alignment will be ideally treated toward best fusion (or motion preservation) and alignment.

"Method of Surgery" instructions may recommend the surgeon and/or robotic unit deploy expansion as programmed to insert the UEC into a particular disc level of pathology, to achieve best results. For example, preoperative patient scans/films can predict ideal UEC surgeon use, such as "turn Knob A a certain number of rotations clockwise," to maximize visible, palpable, and roentgenographic 'Goodness of Fit'. With this approach, post activation, the UEC implant fits the location, entering at the predetermined best angle (in 3 axes) using the proprietary Method of Surgery and UEC insertion tools provided.

In some embodiments, the UEC may be coated with hydroxyapatite. In some embodiments, toothed or 400 μm beaded surfaces may be utilized to promote bony ingrowth. Inflatable chambers may be provided within the endplate that can expand after being implanted. This approach addresses the 3-D congruence to proximate disc pathology. It can also allow for intervertebral arthrodesis or arthroplasty treatment and overall improved spinal alignment, integrating the internal proprietary expansion with the variable external endplate shapes and their contents. UEC inflatable endplates of polymer may be employed, such as tiny vacuoles, "bubblewrap", and multiple or singular bladder constructs. If a portion of the disk space were collapsed, that region could be aptly elevated or expanded by the UEC endplate variation in material and/or inflation. The inflatable chambers may contain compressible gas (such as air,) granules as pharmacologics, and/or stem cells that are delivered via liquids. In cases where the UEC is compressible or force absorbing, the material and/or chamber could be used as a cushion or to 'selectively direct and protect chondrocytes' toward improvement of existing pathophysiology via best drug use or regeneration.

The 'preparation' of the UEC insertion site will vary per surgeon. In some implementations, an arthroscopic burr may be advisable for removing 0.5 mm of cortical bone along with all aberrant disc contents under digital arthroscopic camera control. In other implementations, the surgeon may just carefully curette the intervertebral space to 'clean it out' in preparation for the UEC implant insertion.

The UEC may be inserted directly into the insertion site, or may be inserted through proprietary or commercially available insertion tube. The insertion tube typically will have a blunt distal tip so that it can be inserted through an incision without causing tissue damage. The tube can be used with or without additional tissue retractors. The UEC may be preloaded into the insertion tube, or placed into the tube after the tube has been introduced into the insertion site. A pusher rod or other device may be utilized to deploy the UEC from the insertion tube into the insertion site. In some procedures, the placement of the UEC may be arthroscopically assisted.

Note that regardless of the endplate preparation, in the deformed, aging, pathologic spine there will be pathology to correct. According to various aspects of the present disclosure, the UECs provided herein may accomplish this in several ways as pertains to the external implant composition. For example, the UEC can expand as an externally threaded conduit, either uniformly end to end resulting in same diameters at each end post-operatively (such as 40% overall expansion), or precisely at either end, thus creating an overall conical albeit expanded UEC. Also, the UEC can be flat superiorly and inferiorly as shown in the above drawings, thus more likely matching the rather flat vertebral body end plates. However, according to further aspects of the present disclosure, special care should be taken to consider both the peripheral end plate boney rim as thicker more prominent cortical bone at the vertebral end plates with a sunken or concave thinner interior (thus subject to potential subsidence). The UEC MOS (Method of Surgery) contemplated herein considers the preoperative findings (e.g. MRI, 3D CT scan, X-rays) to integrate information on bone density, specific disc space and longitudinal spine anatomy, topography and alignment.

The various expanding cages disclosed herein and variations thereof are not limited to use in the spinal column but may be used between other bone segments throughout the human or animal body. For example, a UEC can be used during arthrodesis of a metatarsal joint. The UEC can aid in setting the orientation of the toe to a desired angle before fusion of the apposing bone segments occurs. Similarly, a UEC may be utilized in the knee, elbow or other body joints, or between two or more bone segments that have been fractured by trauma.

According to various aspects of the disclosure:

1) the UEC corrects spine surgical pathology both locally via horizontal (disc) and longitudinal vertical axial (scoliotic/kyphotic) spine deformity improvements.

2) the UEC is applicable cervical through lumbar for

A) arthrodesis (fusion) or

B) arthroplasty (motion preservation)

C) drug/cell therapy delivery

3) the UEC can expand uniformly throughout implant length, and/or expand only proximally (toward the surgical incision) or distally, thus enabling clinical adjustments favorable to spine diseased or injured patients for local and overall spondylopathies.

4) the UEC can be surgically inserted via outpatient MIS (Minimally Invasive—outpatient Surgery) as safe, efficacious implants "doing no harm" applying advantages from

A) materials thicknesses for height differentials or

B) expansion adjustments surgically controlled (before/during or after implantation) or via prefabricated portals or injections—programing implant 'mapped' corrections using

C) polymers durometrically calculated with variable compressions, permanent or biodegradable activations at will.

D) inflation of the implant as via UEC surface chambers or bladder(s).

E) adding endplate biologics, foam, or other adaptables for best results.

F) UEC expansion can adapt to expand variable external surface parameters including flat, round, or customized external maximally congruent surfaces to interface as with proximate endplates.

5) Delivery either via UEC materials per se (eluding substances—cells or pharmacologics) or through extrusion from a UEC container or delivery vesicle/depot/chamber/portal will enable not only immediate surgically correction but long term enhanced bone in growth and local/general therapeutic and/or regenerative clinical benefits.

While the disclosure has been described in connection with example embodiments, it is to be understood that the disclosure is not limited to the disclosed embodiments and alternatives as set forth above, but on the contrary is intended to cover various modifications and equivalent arrangements included within the claim scope.

What is claimed as the invention is:

1. An expandable medical implant comprising:

an implantable cage body having a proximal end provided with a first tapered portion and a distal end provided with a second tapered portion, the first and second tapered portions being tapered in opposite directions, the cage body further having a longitudinal axis extending between the proximal end and the distal end of the cage body;

at least one proximal flexure at least partially located adjacent to the proximal end of the cage body and configured to allow a circumference of the distal end of the cage body to resiliently expand;

at least one distal flexure at least partially located adjacent to the distal end of the cage body and configured to allow a circumference of the proximal end of the cage body to resiliently expand;

a proximal plug member having a tapered portion configured to mate with the first tapered portion of the proximal end of the cage body, the proximal plug member being configured to move longitudinally relative to the cage body from a first position to a second position such that the at least one distal flexure moves and the circumference of the proximal end of the cage body resiliently expands, and from the second position to the first position such that the circumference of the proximal end resiliently contracts;

a distal plug member having a tapered portion configured to mate with the second tapered portion of the distal end of the cage body, the distal plug member being configured to move longitudinally relative to the cage body from a third position to a fourth position such that the at least one proximal flexure moves and the circumference of the distal end of the cage body resiliently expands, and from the fourth position to the third position such that the circumference of the distal end resiliently contracts;

a first adjustment member configured to be coupled to at least the proximal plug member such that when the first adjustment member is rotated, the proximal plug member is caused to move longitudinally; and

a second adjustment member configured to be coupled to the distal plug member such that when the second adjustment member is rotated, the distal plug member is caused to move longitudinally, thereby allowing the proximal and the distal ends of the cage body to be expanded and contracted independent from one another,

wherein the first and the second adjustment members are independently rotatable and operable from a single end of the cage body.

2. The expandable medical implant of claim **1**, wherein the first tapered portion comprises a first tapered bore at the proximal end configured to slidably receive the proximal plug member, and the second tapered portion comprises a second tapered bore at the distal end configured to slidably receive the distal plug member.

3. The expandable medical implant of claim **2**, wherein the first tapered bore threadably engages the proximal plug member such that when the proximal plug member is rotated relative to the cage body, the proximal plug member advances in a longitudinal direction relative to the cage body, and wherein the second tapered bore threadably engages the distal plug member such that when the distal plug member is rotated relative to the cage body, the distal plug member advances in a longitudinal direction relative to the cage body.

4. The expandable medical implant of claim **1**, wherein the at least one proximal flexure comprises a generally circular and open ended aperture and a pair of generally flexible beam portions extending longitudinally from the aperture.

5. The expandable medical implant of claim **1**, wherein the at least one proximal flexure comprises a pair of longitudinally extending beam portions separated by a longitudinally extending gap, wherein the at least one proximal flexure further comprises a connector portion interconnecting proximal ends of the beam portions.

6. The expandable medical implant of claim **1**, wherein the at least one proximal flexure comprises a plurality of circumferentially spaced proximal flexures, and wherein the at least one distal flexure comprises a plurality of circumferentially spaced distal flexures.

7. The expandable medical implant of claim **6**, wherein the plurality of proximal flexures are rotationally staggered from the plurality of distal flexures.

8. The expandable medical implant of claim **7**, wherein each of the proximal flexures comprises a pair of longitudinally extending beam portions separated by a longitudinally extending gap and bridged together by a connector portion interconnecting only proximal ends of the beam portions, wherein each of the distal flexures comprises a pair of longitudinally extending beam portions separated by a longitudinally extending gap and bridged together by a connector portion interconnecting only distal ends of the beam portions, and wherein each of the proximal flexures shares a beam portion with two of the distal flexures that are adjacent to each proximal flexure, thereby forming a continuous serpentine pattern along the cage body.

9. The expandable medical implant of claim **1**, wherein the first and the second adjustment members each have

knobs axially spaced but adjacent to one another such that the knobs may alternately be rotated in unison or individually.

10. The expandable medical implant of claim **1**, wherein at least one of the first and the second adjustment members has a keyed end configured to slidably mate and rotationally couple with its associated plug member such that the at least one adjustment member can be removed from the expandable medical implant.

11. The expandable medical implant of claim **1**, wherein the cage body has a square cross-section transverse to the longitudinal axis.

12. The expandable medical implant of claim **1**, wherein the cage body has a circular cross-section transverse to the longitudinal axis.

13. A method of distracting adjacent bone segments having opposing surfaces, the method comprising:

inserting the expandable medical implant of claim **1** between the opposing surfaces;

moving the proximal and the distal plug members longitudinally and independently from one another such that the proximal and the distal ends of the cage body expand independently to alter the distance and the angle between the opposing surfaces of the bone segments.

14. The method of claim **13**, further comprising;

removing at least one adjustment member from the medical implant after the adjustment member has been used to move at least one of the proximal and distal plug members.

15. The method of claim **14**, wherein the bone segments are adjacent vertebrae, and the opposing surfaces are end plates of the adjacent vertebrae.

* * * * *

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(54) **UNIVERSALLY EXPANDING CAGE**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days. days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **15/831,192**

(22) Filed: **Dec. 4, 2017**

Related U.S. Application Data

(63) Continuation of application No. 15/668,650, filed on Aug. 3, 2017, now Pat. No. 9,861,494, which is a (Continued)

(51) **Int. Cl.**
A61F 2/44 (2006.01)
A61F 2/46 (2006.01)
A61F 2/30 (2006.01)

(52) **U.S. Cl.**
CPC ***A61F 2/4425*** (2013.01); ***A61F 2/446*** (2013.01); ***A61F 2/447*** (2013.01); ***A61F 2/4611*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61F 2/446; A61F 2/447; A61F 2/4611; A61F 2/4425; A61F 2/4637;
(Continued)

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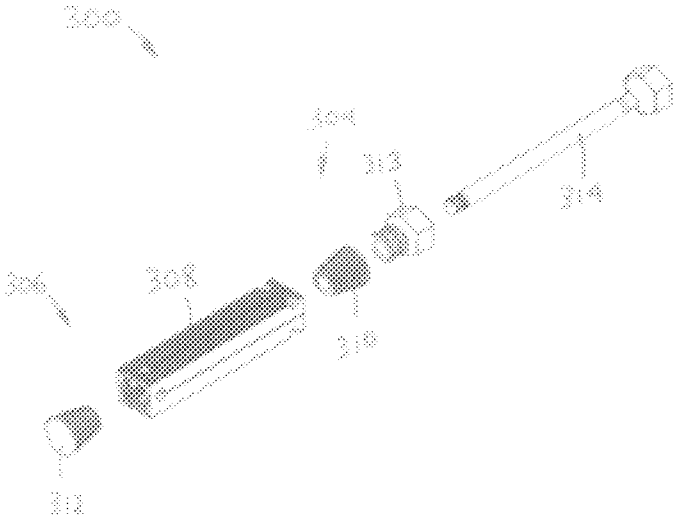
Primary Examiner — Pedro Philogene
Assistant Examiner — David C Comstock
(74) *Attorney, Agent, or Firm* — Michel Graffeo

(57) **ABSTRACT**

An expandable medical implant is provided with an implantable cage body. Methods for stabilizing and correcting the alignment of a spine with an expandable medical implant are provided. The proximal and distal ends of the cage body may each be provided with a tapered or cam portion. The implant may further include a proximal flexure, a distal flexure, a proximal plug member having a tapered portion configured to mate with the tapered portion of the proximal end of the cage body, and a distal plug member having a tapered portion configured to mate with the tapered portion of the distal end of the cage body. The proximal plug member may be configured to move longitudinally such that the distal flexure moves and the circumference of the proximal end of the cage body resiliently expands. The distal plug member may be configured to move longitudinally such that the proximal flexure moves and the circumference of the distal end of the cage body resiliently expands.

12 Claims, 23 Drawing Sheets



Related U.S. Application Data

continuation of application No. 15/485,131, filed on Apr. 11, 2017, now Pat. No. 9,872,778, which is a continuation of application No. 14/939,905, filed on Nov. 12, 2015, now Pat. No. 9,622,878.

(60) Provisional application No. 62/078,850, filed on Nov. 12, 2014.

(52) **U.S. Cl.**
CPC .. ***A61F 2/4637*** (2013.01); *A61F 2002/30408* (2013.01); *A61F 2002/30411* (2013.01); *A61F 2002/30507* (2013.01); *A61F 2002/30538* (2013.01); *A61F 2002/30545* (2013.01); *A61F 2002/30556* (2013.01); *A61F 2002/30579* (2013.01); *A61F 2002/30841* (2013.01); *A61F 2002/448* (2013.01); *A61F 2002/4642* (2013.01)

(58) **Field of Classification Search**
CPC .. A61F 2002/30408; A61F 2002/30411; A61F 2002/30507; A61F 2002/30538; A61F 2002/30556; A61F 2002/30545; A61F 2002/30579; A61F 2002/30841; A61F 2002/448; A61F 2002/4642
USPC 606/246–249, 313, 90; 623/17.11, 17.13, 623/17.15, 17.16
See application file for complete search history.

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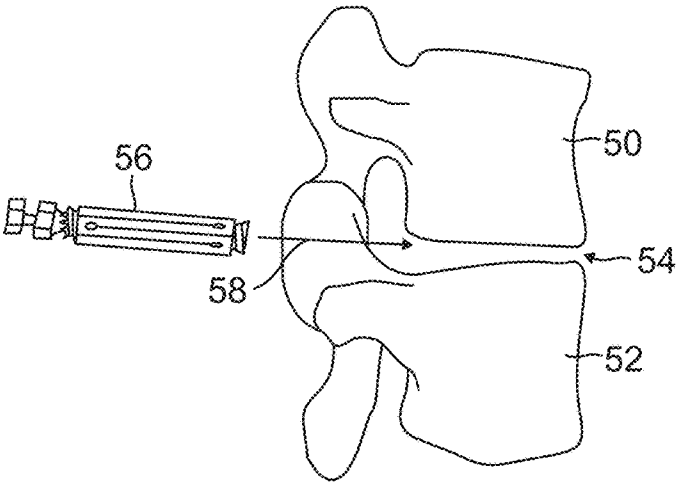


FIG. 1

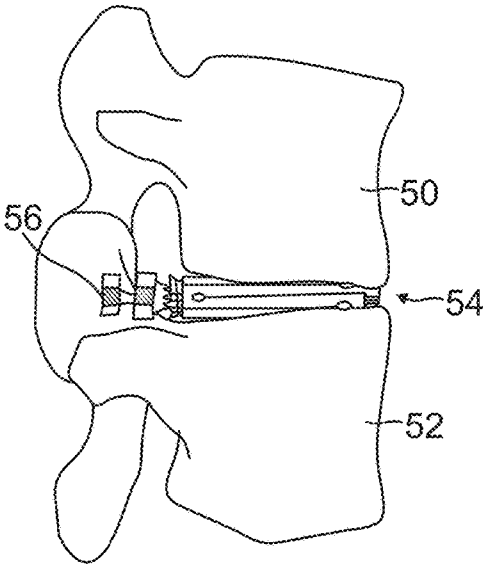


FIG. 2

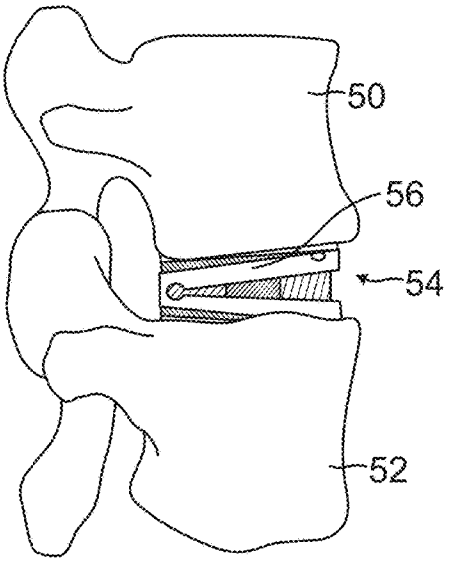
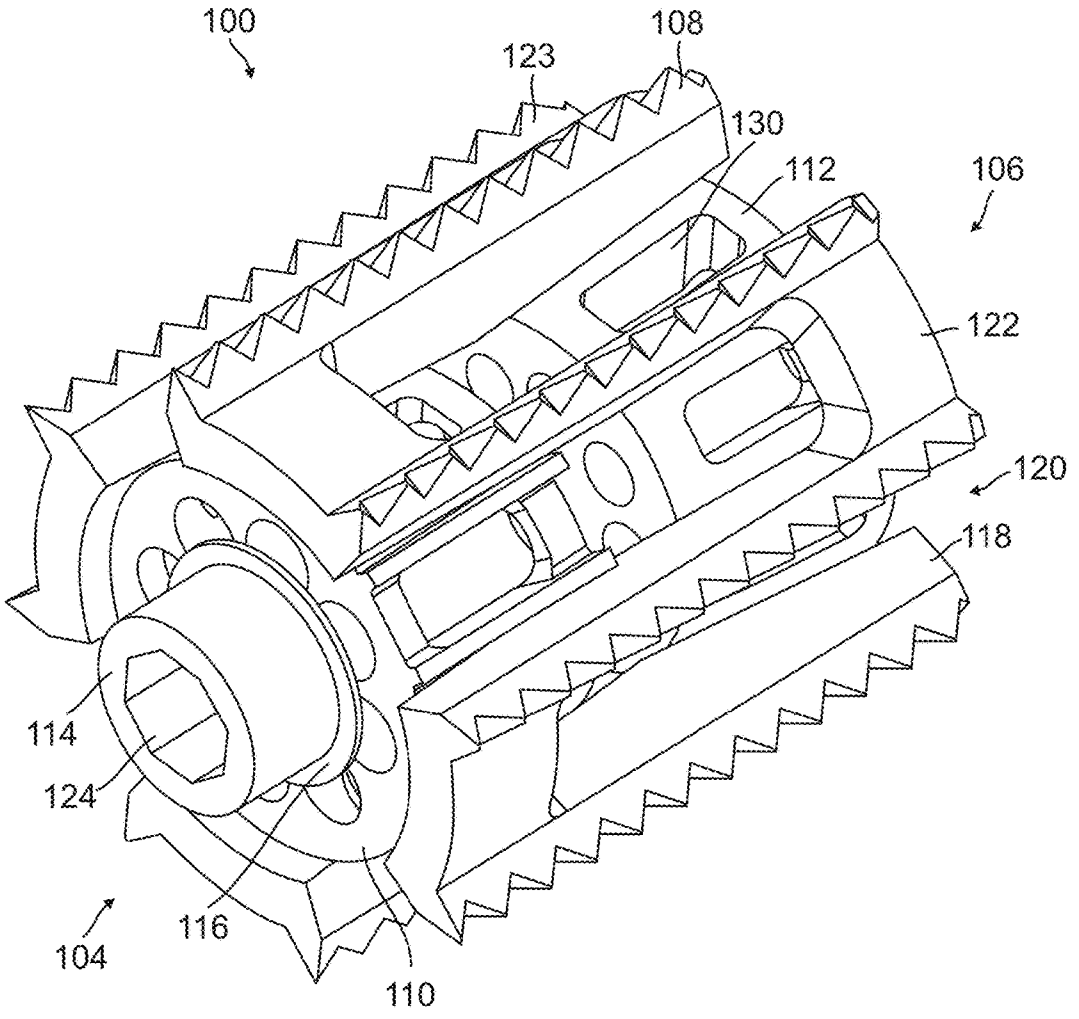


FIG. 3



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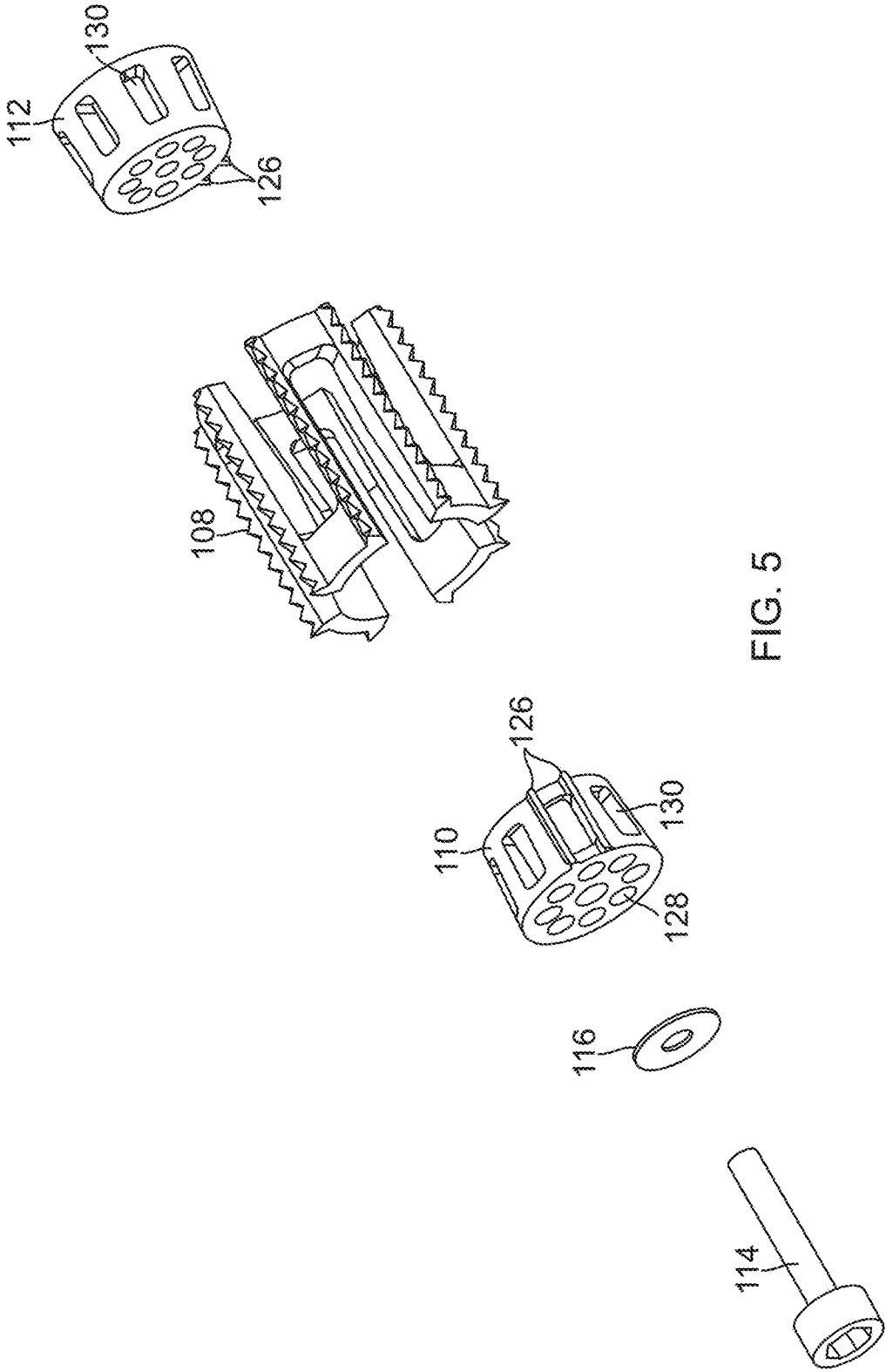

FIG. 5

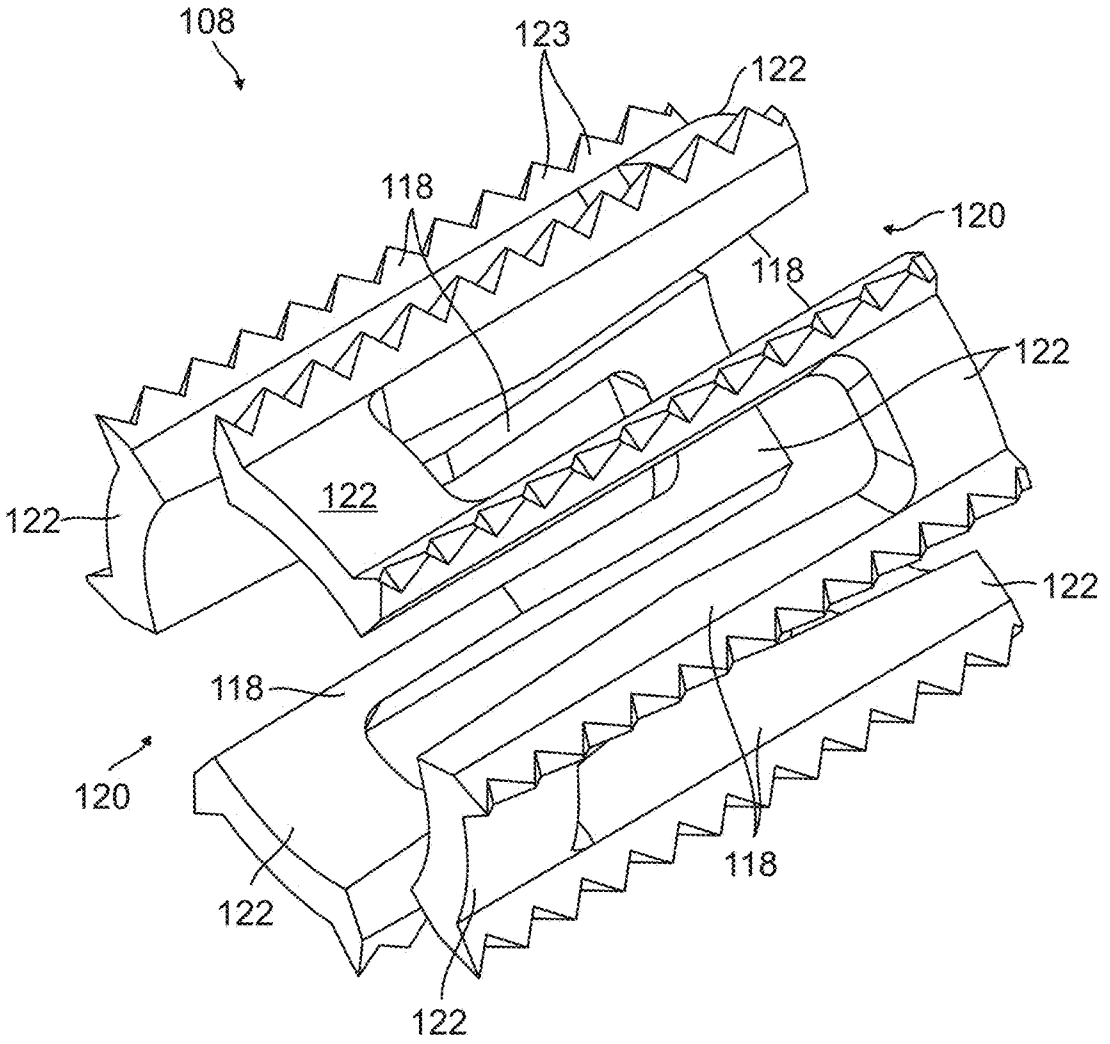

FIG. 6

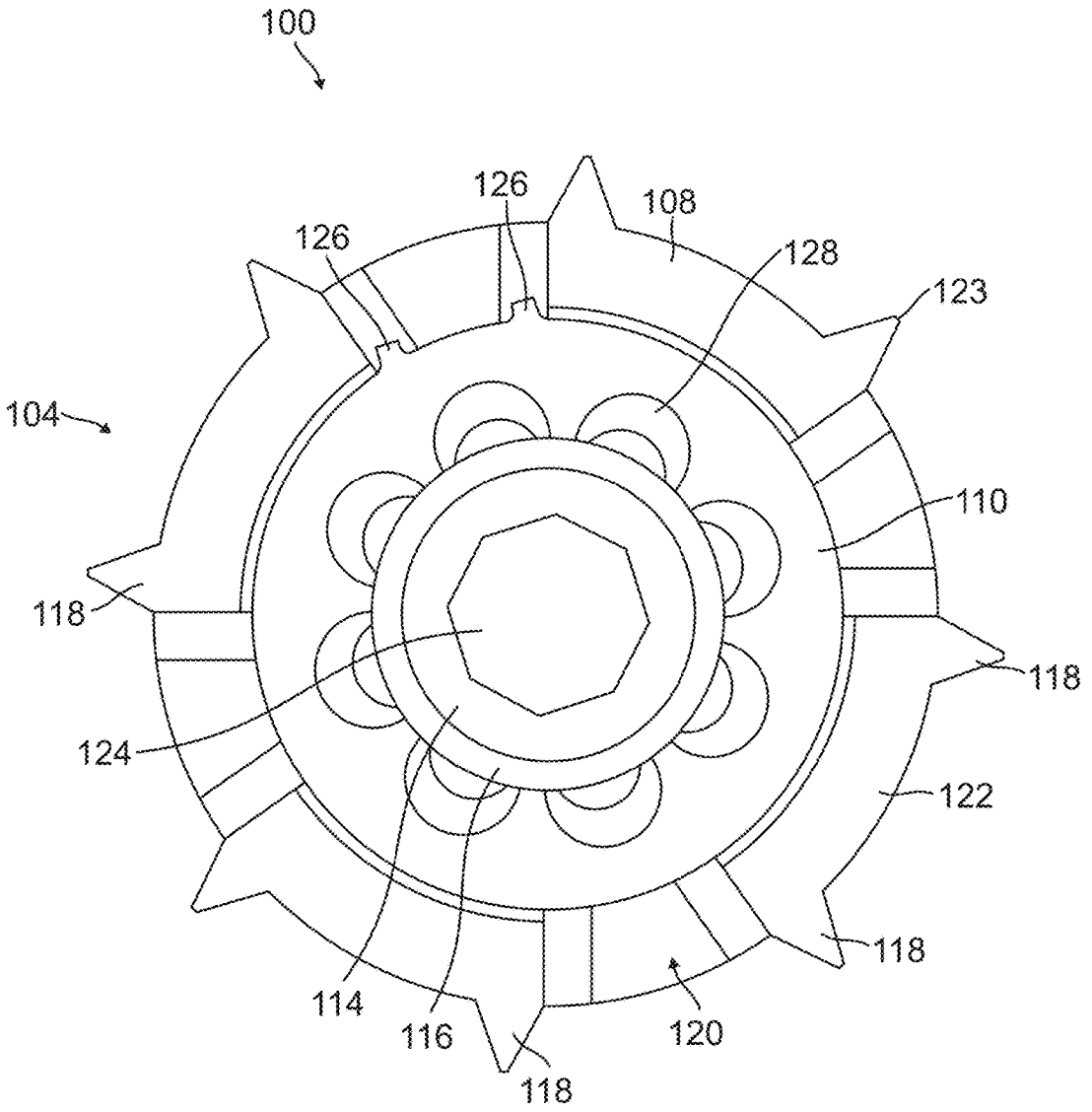
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FIG. 7

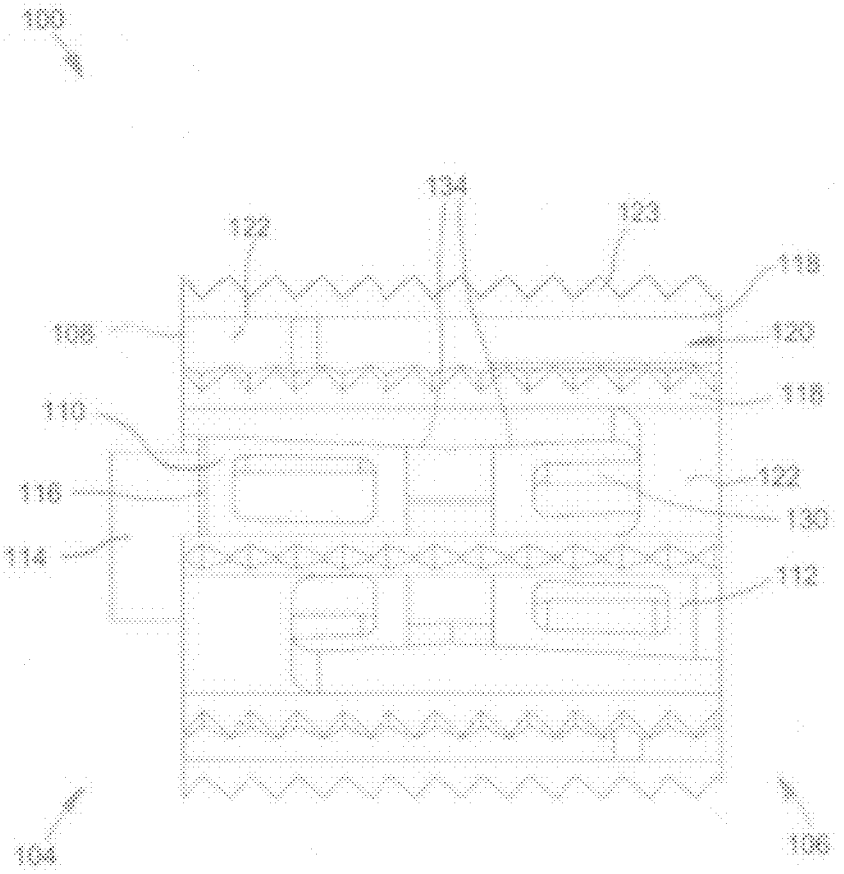

FIG. 8

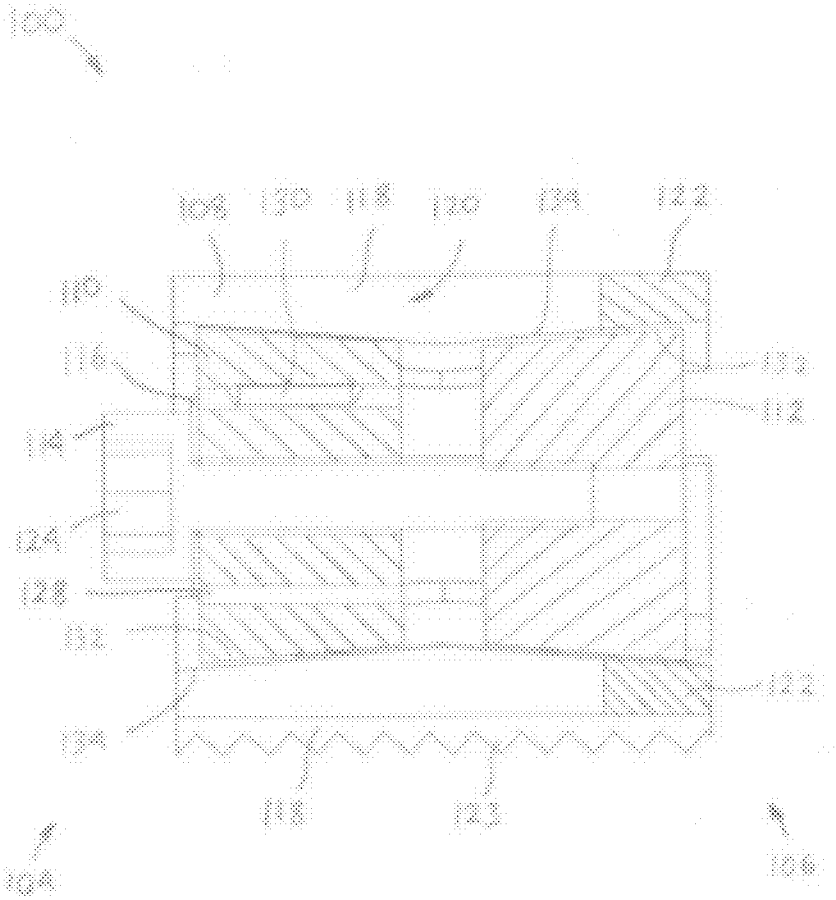
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FIG. 9

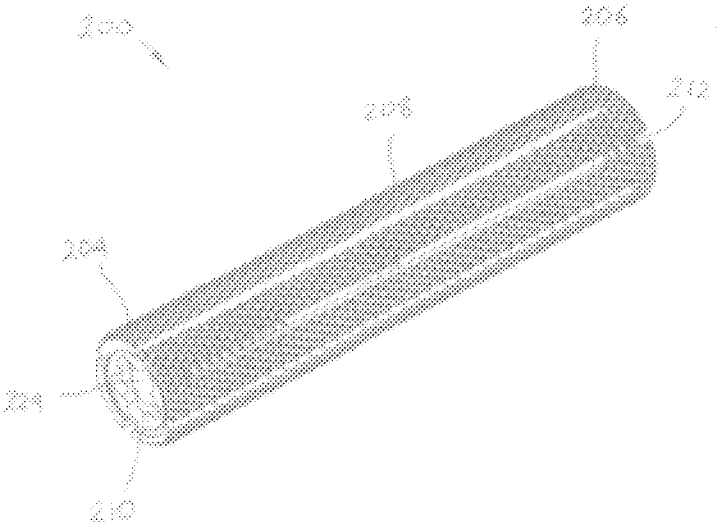

FIG. 14

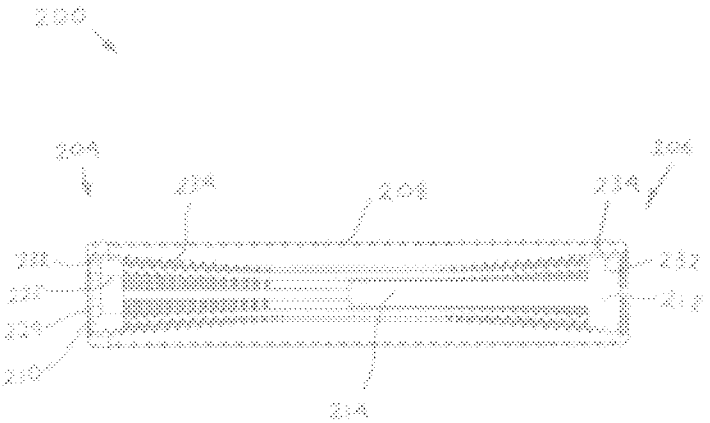

FIG. 15

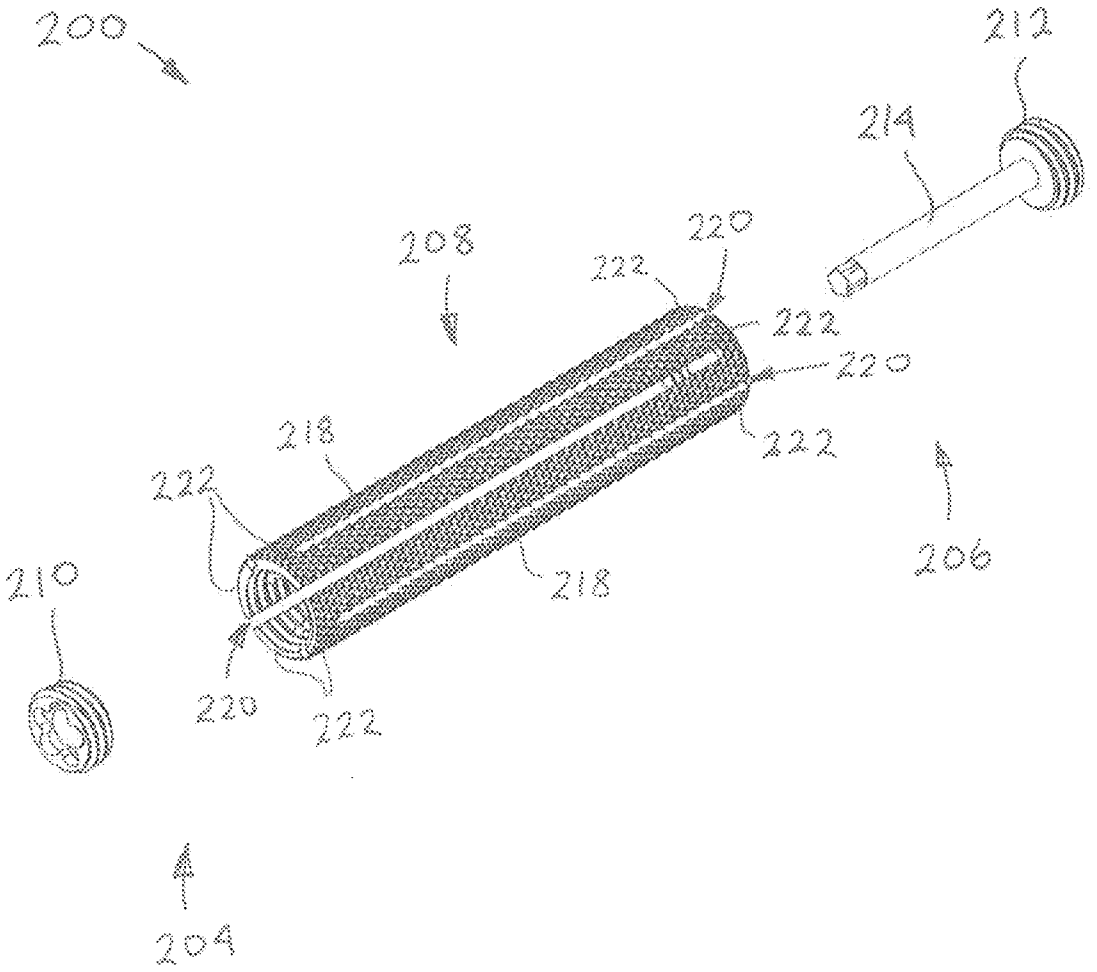
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FIG. 11

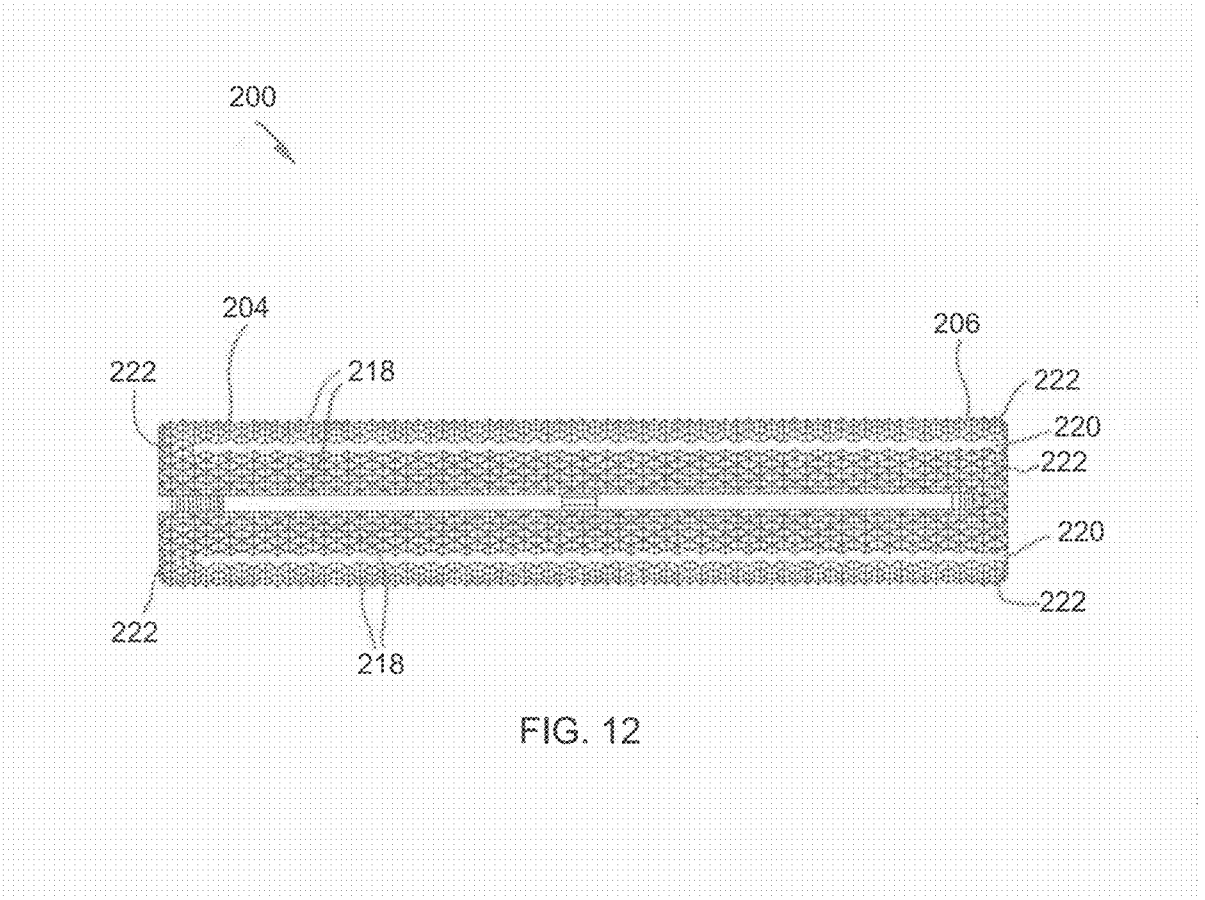

FIG. 12

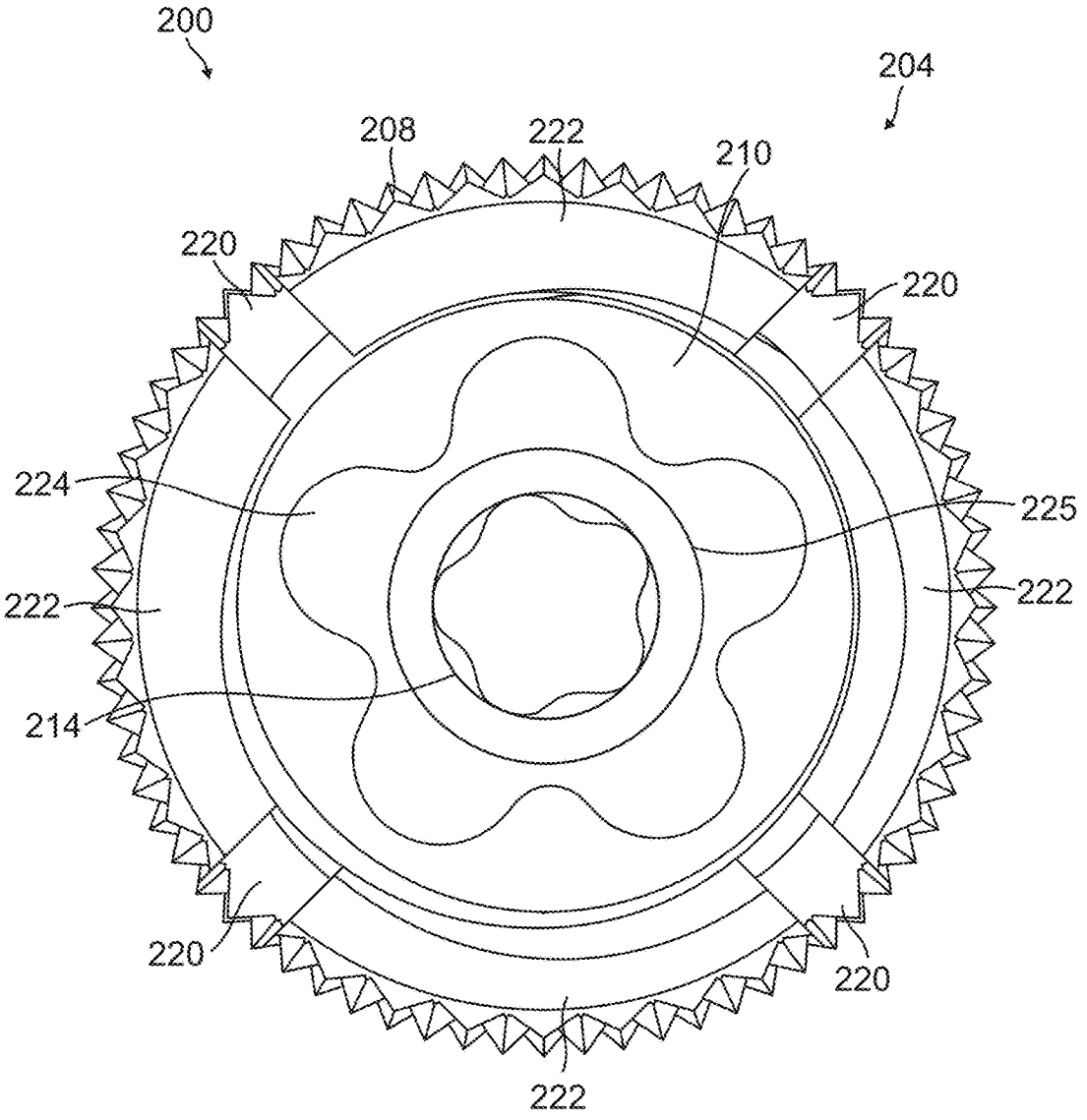

FIG. 13

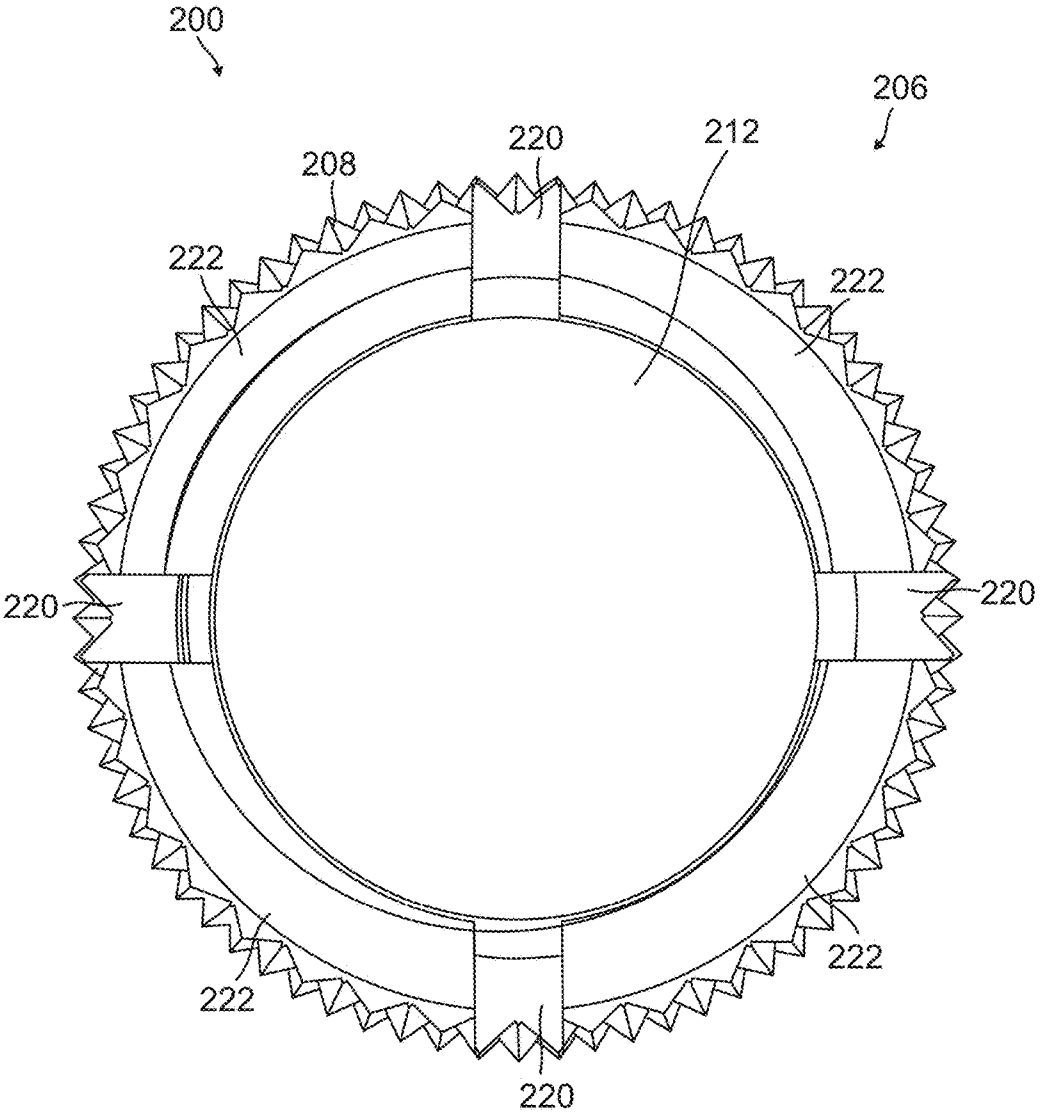

FIG. 14

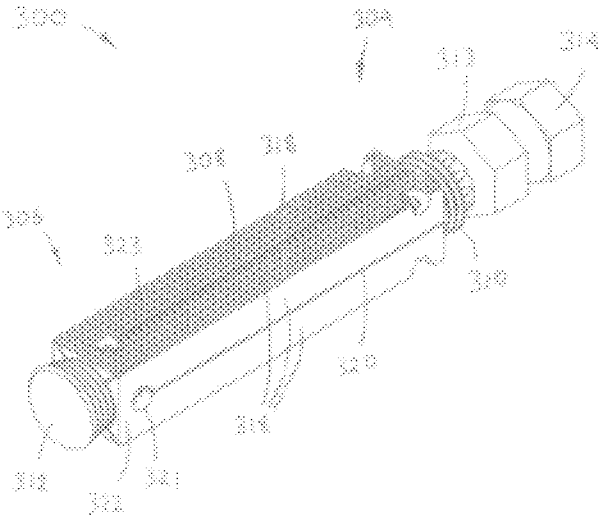

FIG. 16

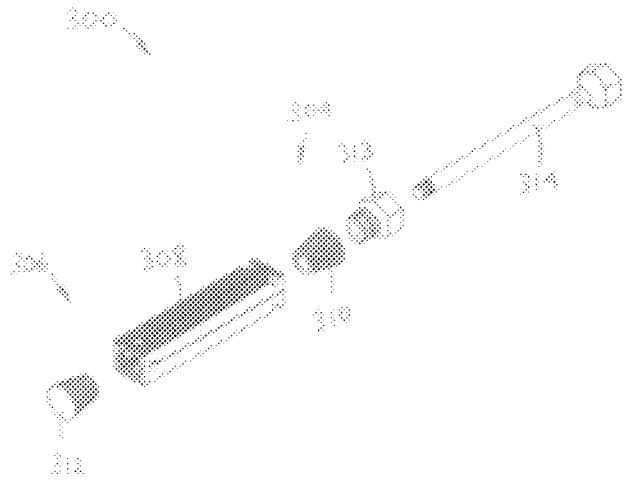

FIG. 17

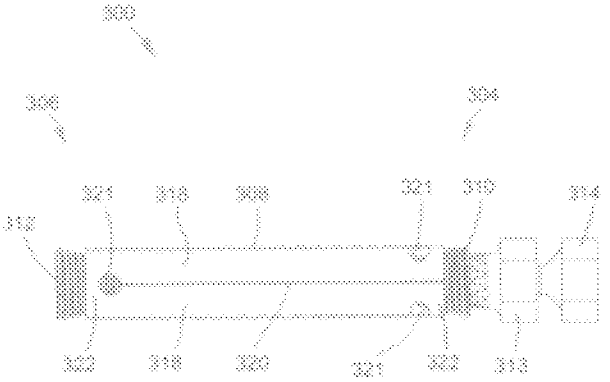

FIG. 18

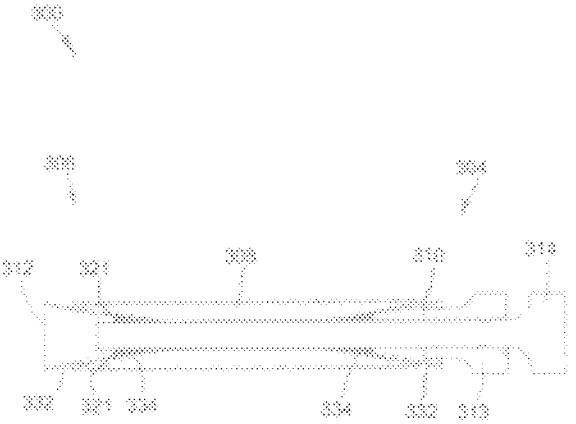

FIG. 18A

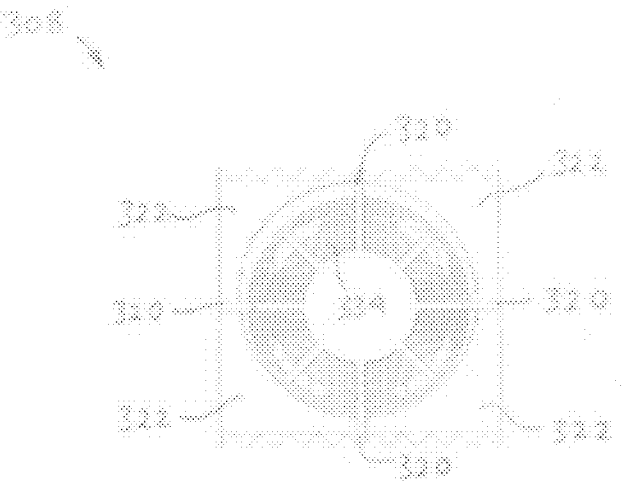

FIG. 19B

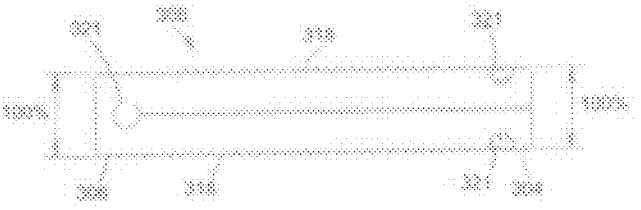

FIG. 20A

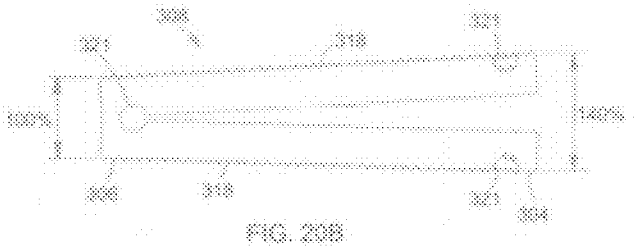

FIG. 20B

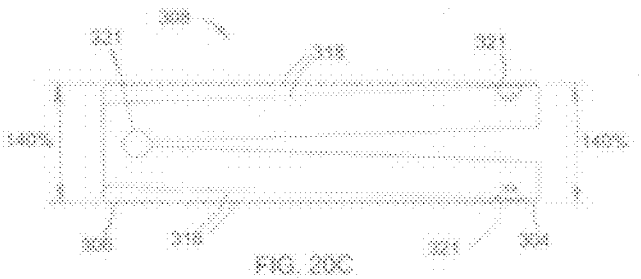

FIG. 20C

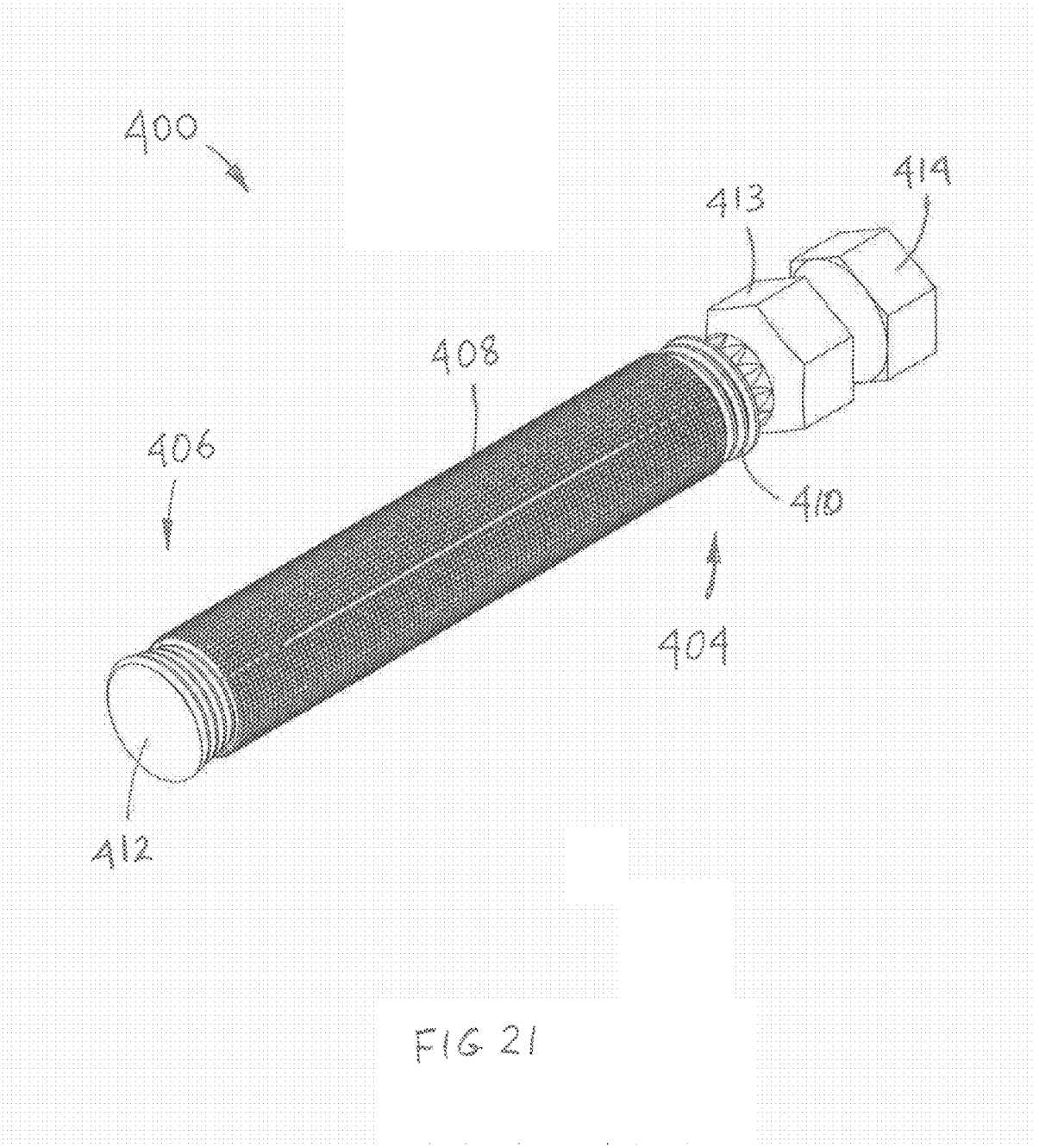

FIG 21

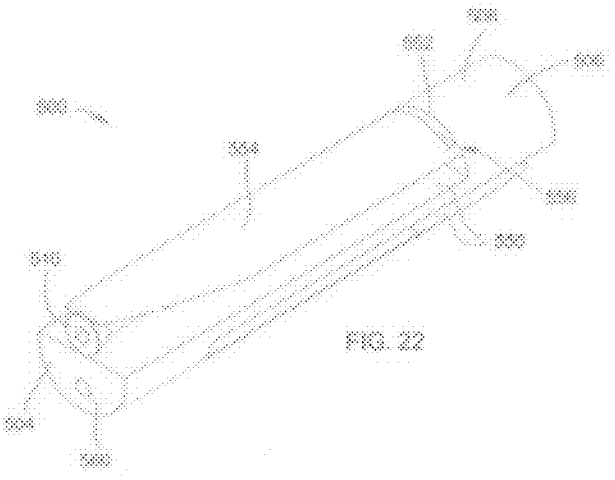

FIG. 22

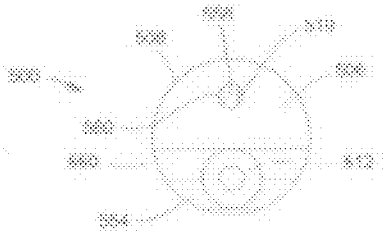

FIG. 23

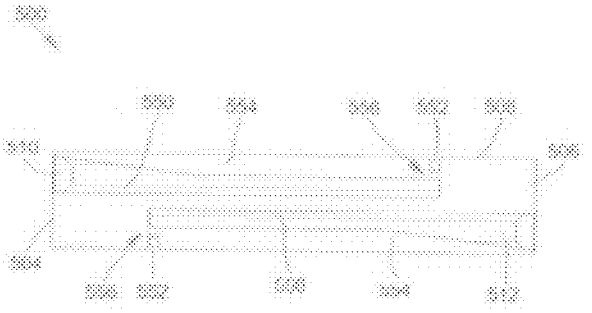

FIG. 24

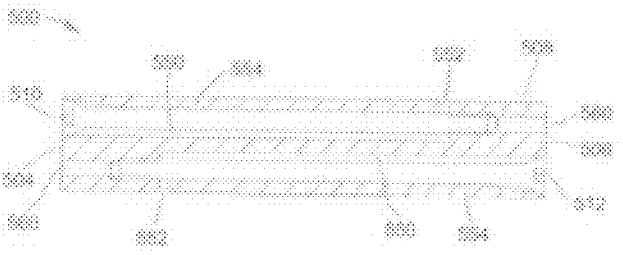

FIG. 25

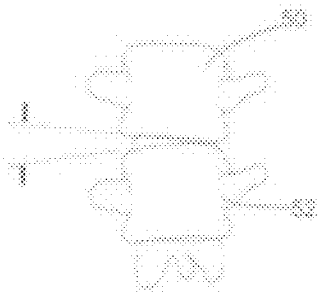

FIG. 32A

Misalignments

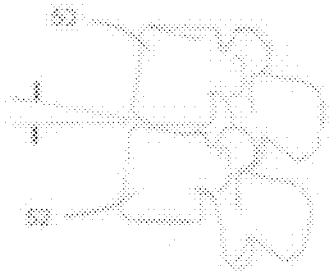

FIG. 32B

Uneven Spacing

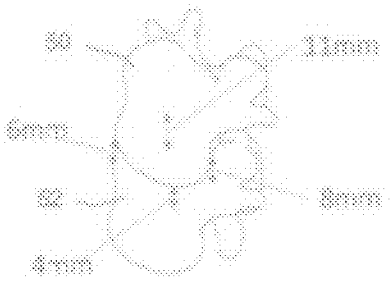

FIG. 32C

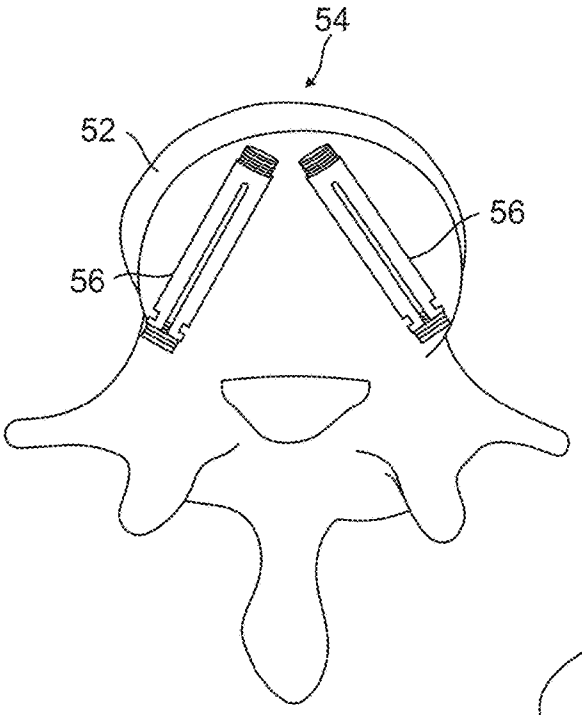

FIG. 26

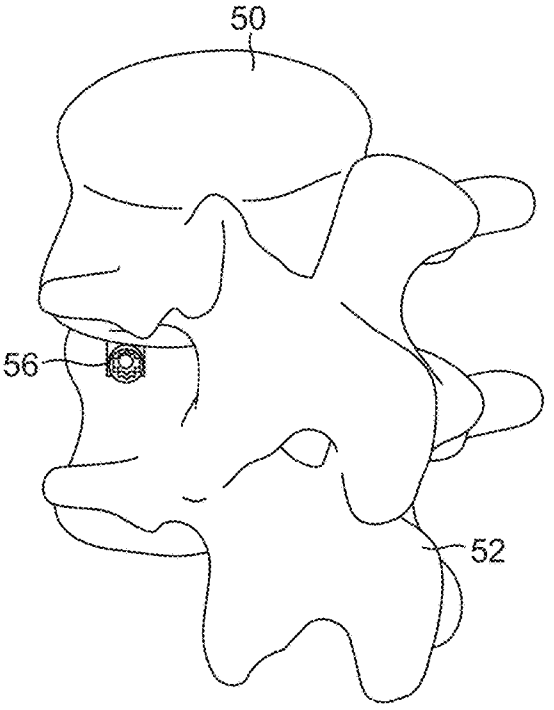

FIG. 27

Fine control over vertebral spacing
Rotate in two axis
Translate in one axis

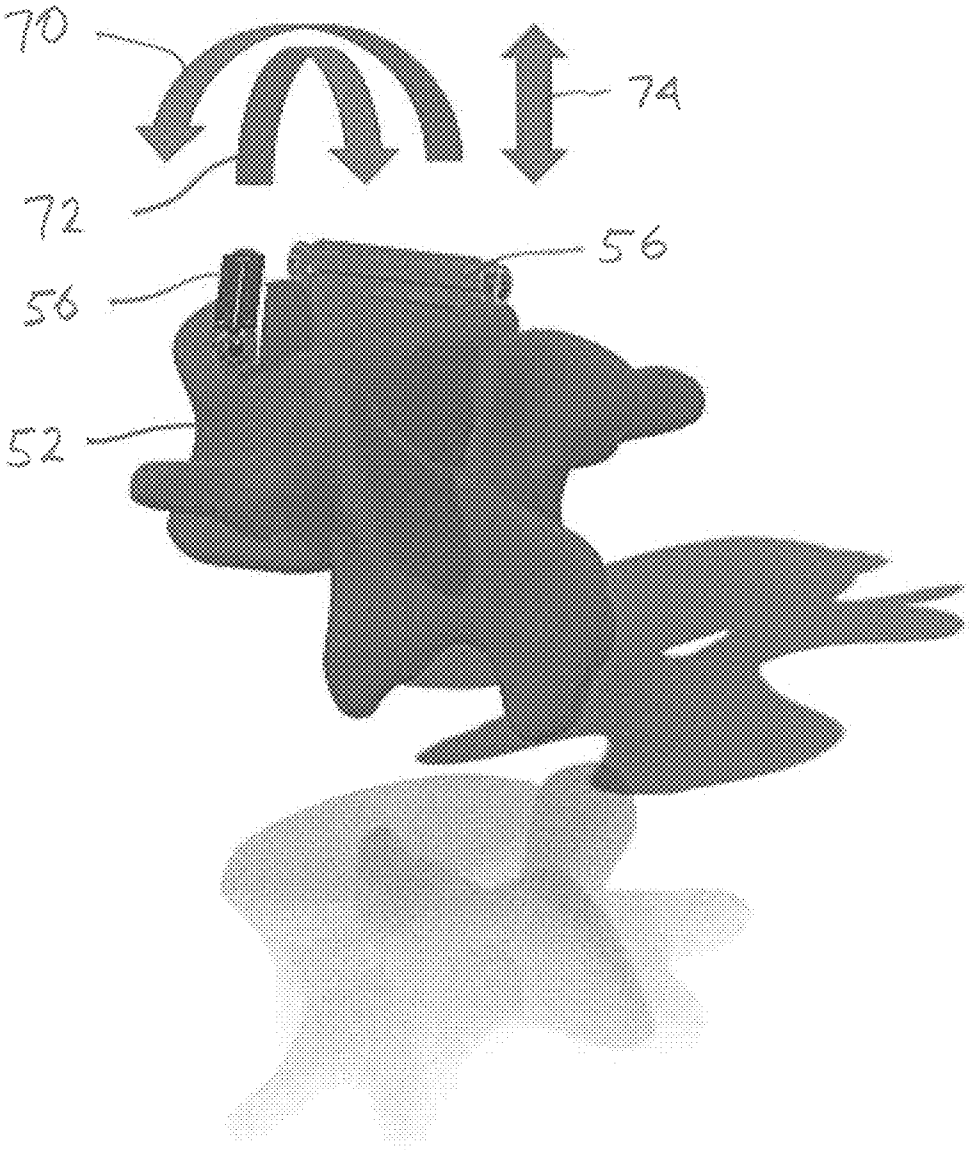

FIG. 28

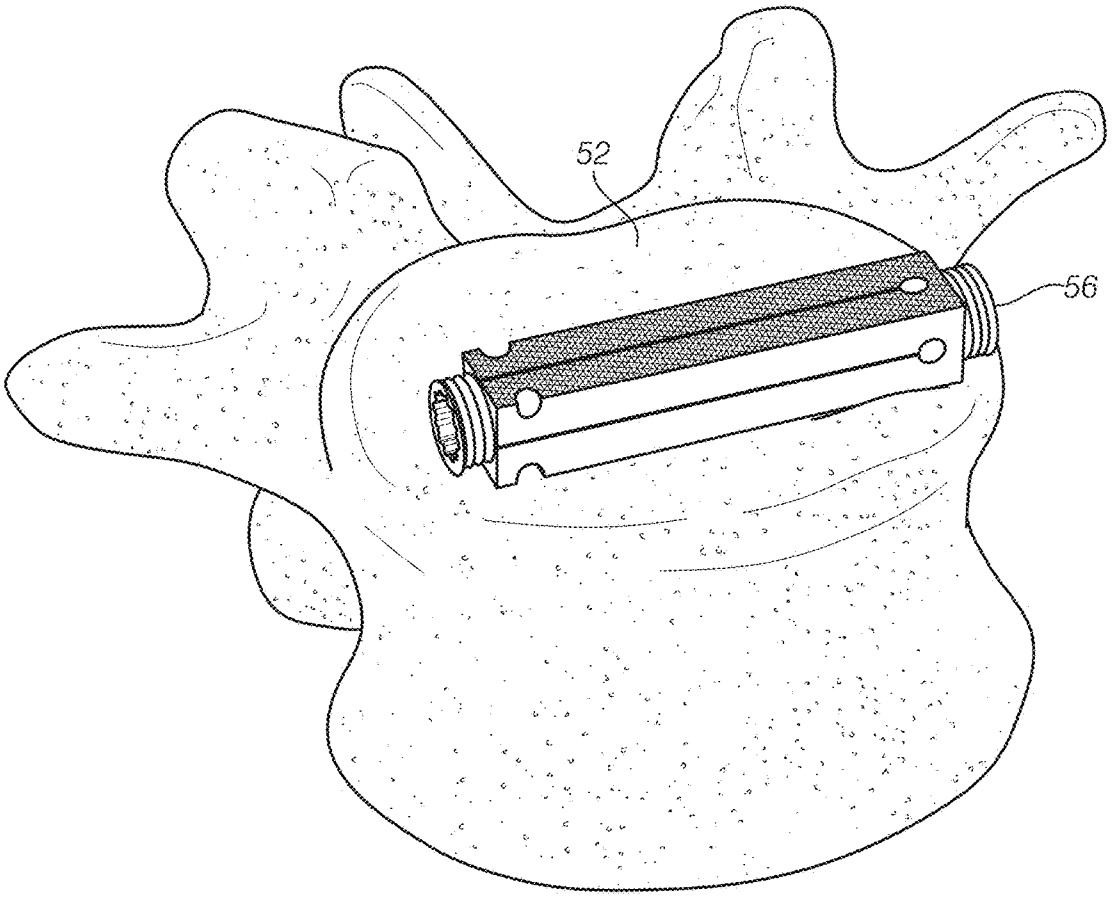

FIG. 29

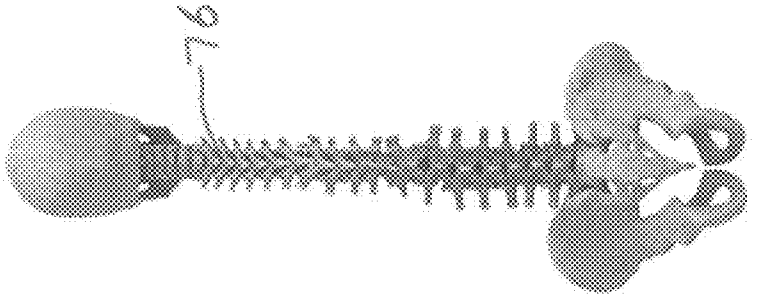

FIG. 31

Scoliosis Correction

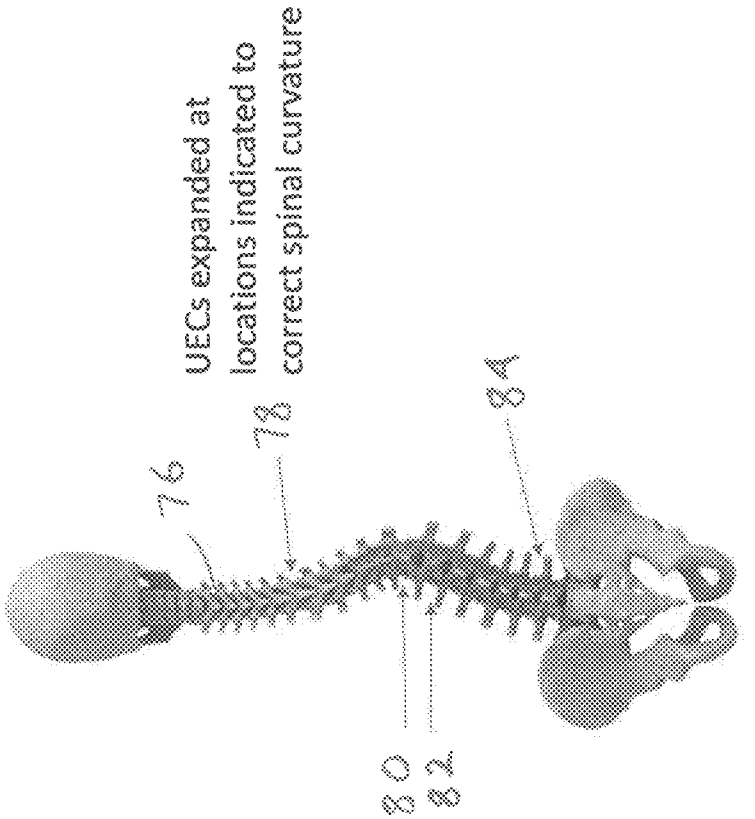

FIG. 30

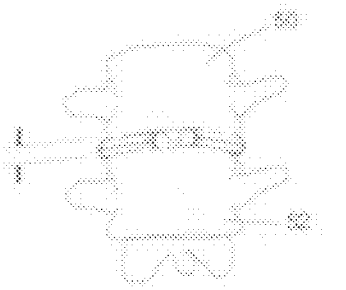

FIG. 33A

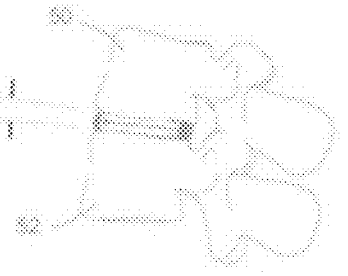

FIG. 33B

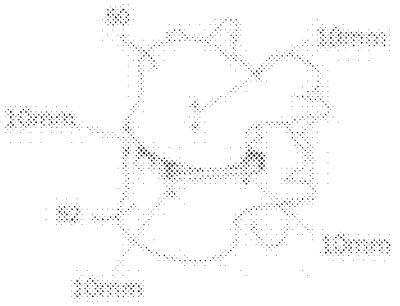

FIG. 33C

UNIVERSALLY EXPANDING CAGE

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims benefit of U.S. Non-provisional patent application Ser. No. 15/668,650 filed Aug. 3, 2017, which claims the benefit of U.S. Non-provisional patent application Ser. No. 15/485,131 filed Apr. 11, 2017, which claims the benefit of U.S. non-provisional patent application Ser. No. 14/939,905 filed Nov. 12, 2015, now U.S. Pat. No. 9,622,878 which claims the benefit of U.S. Provisional Application No. 62/078,850 filed Nov. 12, 2014, all of which are incorporated herein by reference in their entirety.

INCORPORATION BY REFERENCE

All publications and patent applications mentioned in this specification are herein incorporated by reference in their entirety to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

FIELD

The present disclosure generally relates to medical devices for stabilizing the vertebral motion segment or other bone segments. More particularly, the field of the disclosure relates to a universally expanding cage (UEC) and method of use for providing controlled spinal correction or other bond segment spacing and/or alignment.

BACKGROUND

Conventional spine cages or implants are typically characterized by a kidney bean-shaped body comprising a hydroxyapatite-coated surface provided on the exterior surface for contact with adjacent vertebral segments or endplates which are shown in FIG. **1**. A conventional spine cage with flat endplates is typically inserted posterolaterally proximate to the neuroforamen of the distracted spine after a trial implant creates a pathway. Optionally two parallel externally threaded conduits are inserted anteriorly to achieve lumbar arthrodesis. The implants are often of constant diameter whereas the L5-S1 disc space is trapezoidal, thus a 'flat back' syndrome may be iatrogenically created. Generally spine intradiscal implants are for lumbar fusion or cervical motion preservation, while a separate system of rods and screws corrects alignment.

With the novel UECs disclosed herein, additional options include fusion throughout the spinal column, and deformity angular correction.

Existing devices for interbody stabilization have important and significant limitations. Among the limitations are an inability to expand and distract the endplates. Consequently, if a cage that is "to small" is inserted it can 'rattle around and never heal'. If the static cage is too big, it can injure adjacent nerves or destabilize the spine via end plate resection or subsidence.

Current devices for interbody stabilization include static spacers composed of titanium, PEEK, and high performance thermoplastic polymer produced by VICTREX, (Victrex USA Inc, 3A Caledon Court, Greenville, S.C. 29615), carbon fiber, or resorbable polymers. Current interbody spacers may not maintain interbody lordosis and can contribute to the formation of a straight or even kyphotic segments and the clinical problem of "flatback syndrome." Separation of

the endplates increases space available for the neural elements, specifically the neural foramen. Existing static cages do not reliably improve space for the neural elements. Therefore, what is needed is an expanding cage that will increase space for the neural elements posteriorly between the vertebral bodies, or at least maintain the natural bone contours to avoid neuropraxia (nerve stretch) or encroachment.

U.S. Pat. No. 7,985,256, filed Sep. 26, 2006 and titled "Selectively Expanding Spine Cage, Hydraulically Controllable in Three Dimensions for Enhanced Spinal Fusion", and U.S. Pat. No. 7,819,921, filed Oct. 31, 2007 and titled "Linearly expanding spine cage for enhanced spinal fusion", both provide detailed background on expanding spine cages.

The cages disclosed in U.S. Pat. No. 7,985,256 above are restricted to use with hydraulics, and lumbar fusion. The cage disclosed in U.S. Pat. No. 7,819,921 allows for trapezoidal linear expanding, not uniform expansion, thus a trapezoidal L5 cage as disclosed therein will preserve natural lumbar lordosis. The disclosed cage was never developed. It is intended for use as two (2) parallel linearly expanding split conduits inserted anteriorly for lumbar fusion.

In contrast, the UEC cages disclosed herein expands either uniformly, or at either end proximally or distally. Given the adjustment option the surgeon can correct angulation deformity with the novel UEC.

Another problem with conventional devices of interbody stabilization includes poor interface between bone and biomaterial. Conventional static interbody spacers form a weak interface between bone and biomaterial. Although the surface of such implants is typically provided with a series of ridges or coated with hydroxyapetite, the ridges may be in parallel with applied horizontal vectors or side-to-side motion. That is, the ridges or coatings offer little resistance to movement applied to either side of the endplates. Thus, nonunion is common in allograft, titanium and polymer spacers, due to motion between the implant and host bone. Conventional devices typically do not expand between adjacent vertebrae. Since the UEC expands under surgeon control, the visible, palpable 'goodness of fit' setting can ideal lock opposing vertebral endplates at the time of surgery. As healing accrues, the implants become inert. Since no motion equates with no pain, clinical results are improved with UECs.

Therefore, what is needed is a way to expand an implant to develop immediate fixation forces that can exceed the ultimate strength at healing, with improved abilities to enable disc space fixation solidarity while correcting spine angular deformity. Such an expandable implant ideally will maximize stability of the interface and enhance stable fixation. The immediate fixation of such an expandable interbody implant advantageously will provide stability that is similar to that achieved at the time of healing. Such an implant will have valuable implications enhancing early post-operative rehabilitation for the patient.

Another problem of conventional interbody spacers is their large diameter requiring wide exposure. Existing devices used for interbody spacers include structural allograft, threaded cages, cylindrical cages, and boomerang-shaped cages. Conventional devices have significant limitation with regard to safety and efficacy. Regarding safety of the interbody spacers, injury to neural and aortic elements may occur with placement from an anterior or posterior approach. A conventional spine cage lacks the ability to expand, diminishing its fixation capabilities. Prior attempts to preserve lumbar motion have failed by extrusion of the

implant after implantation. The risks to neural elements are primarily due to the disparity between the large size of the cage required to adequately support the interbody space, and the small space available for insertion of the device, especially when placed from a posterior or transforaminal approach. Existing boomerang cages are shaped like a partially flattened kidney bean. Their implantation requires a wide exposure and potential compromise of vascular and neural structures, both because of their inability to enter small and become larger, and due to the fact that their insertion requires mechanical manipulation during insertion and expanding of the implant. Once current boomerang implants are prepared for insertion via a trial spacer to make a pathway toward the anterior spinal column, the existing static cage is shoved toward the end point with the hope that it will reach a desired anatomic destination. Given the proximity of nerve roots and vascular structures to the insertion site, and the solid, relatively large size of conventional devices, such constraints predispose a patient to foraminal (nerve passage site) encroachment, and possible neural and vascular injury.

Therefore, what is needed is a minimally invasive expanding spine cage that is capable of insertion with minimal invasion into a smaller aperture. Such a minimally invasive spine cage advantageously could be expanded with completely positional control or adjustment in three dimensions. What is also needed is a smaller expanding spine cage that is easier to operatively insert into a patient with minimal surgical trauma in contrast to conventional, relatively large devices that create the needless trauma to nerve roots in the confined space of the vertebral region. Existing interbody implants have limited space available for bone graft. Adequate bone graft or bone graft substitute is critical for a solid interbody arthrodesis. It would be desirable to provide an expandable interbody cage that will permit a large volume of bone graft material to be placed within the cage and around it, to fill the intervertebral space. Additionally, conventional interbody implants lack the ability to stabilize endplates completely and prevent them from moving. Therefore, what is also needed is an expanding spine cage wherein the vertebral end plates are subject to forces that both distract them apart, and hold them from moving. Such an interbody cage would be capable of stabilization of the motion segment, thereby reducing micromotion, and discouraging pseudoarthrosis (incomplete fusion) and pain.

Ideally, what is needed is a spine cage or implant that is capable of increasing its expansion in height and angle, spreading to a calculated degree. Furthermore, what is needed is a spine cage that can adjust the amount of not only overall anterior posterior expansion, but also medial and lateral variable expansion so that both the normal lordotic curve is maintained, and adjustments can be made for scoliosis or bone defects. Such a spine cage or implant would permit restoration of normal spinal alignment after surgery and hold the spine segments together rigidly, mechanically, until healing occurs.

What is also needed is an expanding cage or implant that is capable of holding the vertebral or joint sections with increased pullout strength to minimize the chance of implant fixation loss during the period when the implant is becoming incorporated into the arthrodesis bone block.

SUMMARY OF THE DISCLOSURE

According to some aspects of the disclosure, an expandable medical implant is provided with an implantable cage body having a proximal end and a distal end. In some embodiments, the proximal and distal ends of the cage body are each provided with a tapered or cam portion. The cage body further has a longitudinal axis extending between the proximal end and the distal end of the cage body. The implant may further comprise at least one proximal flexure at least partially located adjacent to the proximal end of the cage body and configured to allow a circumference of the distal end of the cage body to resiliently expand. The implant may further comprise at least one distal flexure at least partially located adjacent to the distal end of the cage body and configured to allow a circumference of the proximal end of the cage body to resiliently expand. The implant may further comprise a proximal plug member having a tapered portion configured to mate with the tapered portion of the proximal end of the cage body. The proximal plug member may be configured to move longitudinally relative to the cage body from a first position to a second position such that the at least one distal flexure moves and the circumference of the proximal end of the cage body resiliently expands. The proximal plug member may also be configured to move from the second position to the first position such that the circumference of the proximal end resiliently contracts. The implant may further comprise a distal plug member having a tapered portion configured to mate with the tapered portion of the distal end of the cage body. The distal plug member may be configured to move longitudinally relative to the cage body from a third position to a fourth position such that the at least one proximal flexure moves and the circumference of the distal end of the cage body resiliently expands. The distal plug member may also be configured to move from the fourth position to the third position such that the circumference of the distal end resiliently contracts.

In some embodiments, the cage body further comprises a first tapered bore at the proximal end configured to slidably receive the proximal plug member, and a second tapered bore at the distal end configured to slidably receive the distal plug member. The first tapered bore may threadably engage the proximal plug member such that when the proximal plug member is rotated relative to the cage body, the proximal plug member advances in a longitudinal direction relative to the cage body. The second tapered bore may threadably engage the distal plug member such that when the distal plug member is rotated relative to the cage body, the distal plug member advances in a longitudinal direction relative to the cage body.

In some embodiments, the at least one proximal flexure comprises a generally circular and open ended aperture and a pair of generally flexible beam portions extending longitudinally from the aperture. The at least one proximal flexure may include a pair of longitudinally extending beam portions separated by a longitudinally extending gap, wherein the at least one proximal flexure further comprises a connector portion interconnecting proximal ends of the beam portions. The at least one proximal flexure may include a plurality of circumferentially spaced proximal flexures, and the at least one distal flexure may include a plurality of circumferentially spaced distal flexures. The plurality of proximal flexures may be rotationally staggered from the plurality of distal flexures.

In some embodiments, each of the proximal flexures includes a pair of longitudinally extending beam portions separated by a longitudinally extending gap and bridged together by a connector portion interconnecting only proximal ends of the beam portions. Each of the distal flexures may include a pair of longitudinally extending beam portions separated by a longitudinally extending gap and bridged together by a connector portion interconnecting only

distal ends of the beam portions. Each of the proximal flexures can share a beam portion with two of the distal flexures that are adjacent to each proximal flexure, thereby forming a continuous serpentine pattern along the cage body.

In some embodiments, the implant includes a first adjustment member coupled to at least the proximal plug member such that when the first adjustment member is rotated, the proximal plug member is caused to move longitudinally. The implant may further include a second adjustment member coupled to the distal plug member such that when the second adjustment member is rotated, the distal plug member is caused to move longitudinally, thereby allowing the proximal and the distal ends of the cage body to be expanded and contracted independent from one another. The first and the second adjustment members may be coaxially nested one within the other and independently rotatable. In some embodiments, the first and the second adjustment members each have knobs axially spaced but adjacent to one another such that the knobs may alternately be rotated in unison or individually. At least one of the first and the second adjustment members may have a keyed end configured to slidably mate and rotationally couple with its associated plug member such that the at least one adjustment member can be removed from the expandable medical implant.

In some embodiments, the cage body has a square or circular cross-section transverse to the longitudinal axis.

In some embodiments, an expandable medical implant includes an implantable cage, a plurality of proximal flexures, a plurality of distal flexures, a proximal plug member, a distal plug member, and first and second adjustment members. In these embodiments, the implantable cage body has a proximal end and a distal end each provided with a threaded and tapered bore. The cage body has a longitudinal axis extending between the proximal end and the distal end of the cage body. The plurality of proximal flexures are circumferentially spaced and each is at least partially located adjacent to the proximal end of the cage body and configured to allow a circumference of the distal end of the cage body to resiliently expand. Each of the proximal flexures comprises a pair of longitudinally extending beam portions separated by a longitudinally extending gap and bridged together by a connector portion interconnecting only proximal ends of the beam portions. The plurality of distal flexures are circumferentially spaced and each is at least partially located adjacent to the distal end of the cage body and configured to allow a circumference of the proximal end of the cage body to resiliently expand. Each of the distal flexures comprises a pair of longitudinally extending beam portions separated by a longitudinally extending gap and bridged together by a connector portion interconnecting only distal ends of the beam portions. Each of the proximal flexures shares a beam portion with two of the distal flexures that are adjacent to each proximal flexure, thereby forming a continuous serpentine pattern along the cage body. The proximal plug member has a threaded and tapered circumference configured to mate with the threaded and tapered bore of the proximal end of the cage body. The proximal plug member is configured to move along the longitudinal axis relative to the cage body from a first position to a second position such that the plurality of distal flexures move and the circumference of the proximal end of the cage body resiliently expands. The proximal plug member is also configured to move from the second position to the first position such that the circumference of the proximal end resiliently contracts. The distal plug member has a threaded and tapered circumference configured to mate with the threaded and tapered bore of the distal end of the cage body. The distal plug member is configured to move along the longitudinal axis relative to the cage body from a third position to a fourth position such that the plurality of proximal flexures move and the circumference of the distal end of the cage body resiliently expands. The distal plug member is also configured to move from the fourth position to the third position such that the circumference of the distal end resiliently contracts. The first adjustment member is rotationally coupled to the proximal plug member such that when the first adjustment member is rotated, the proximal plug member is caused to move along the longitudinal axis. The second adjustment member rotationally coupled to the distal plug member such that when the second adjustment member is rotated, the distal plug member is caused to move longitudinally, thereby allowing the proximal and the distal ends of the cage body to be expanded and contracted independent from one another. The first and the second adjustment members are coaxially nested one within the other and independently rotatable. The first and the second adjustment members each have knobs axially spaced but adjacent to one another such that the knobs may alternately be rotated in unison or individually. At least one of the first and the second adjustment members may have a keyed end configured to slidably mate and rotationally couple with its associated plug member such that the at least one adjustment member can be removed from the expandable medical implant.

According to some aspects of the disclosure, a method of distracting adjacent bone segments having opposing surfaces is provided. The method comprises the steps of inserting an expandable medical implant as described above between the opposing surfaces of the bone segments, and moving the proximal and the distal plug members longitudinally and independently from one another such that the proximal and the distal ends of the cage body expand independently to alter the distance and the angle between the opposing surfaces of the bone segments. In some embodiments, the method further includes the step of removing at least one adjustment member from the medical implant after the adjustment member has been used to move at least one of the proximal and distal plug members. In some embodiments, the bone segments are adjacent vertebrae, and the opposing surfaces are end plates of the adjacent vertebrae.

In some embodiments, the implant includes a proximal end, a distal end, a first adjustment tool and a second adjustment tool wherein the first adjustment tool adjusts one of the proximal end or the distal end of the implant and the second adjustment tool adjusts the other of the proximal end of the implant or the distal end of the implant wherein the first adjustment tool and the second adjustment tool are located at the proximal end of the implant and the first adjustment tool and the second adjustment tool are coaxially nested one within the other and independently rotatable.

In other embodiments, the first adjustment tool adjusts for expansion or contraction of the proximal end of the implant. In some embodiments, the second adjustment tool adjusts for expansion or contraction of the distal end of the implant. In other embodiments, the implant further comprises a cage body, at least one proximal flexure and at least one distal flexure such that the proximal flexure shares a beam portion of the cage body with a distal flexure to form a continuous serpentine pattern along the cage body.

In some aspects, the implant includes a proximal end which is capable of independent resilient expansion by means of a distal flexure, a distal end which is capable of independent resilient expansion by means of a proximal flexure, an expansion means that is functionally associated

with the proximal end, an expansion means that is functionally associated with the distal end, an adjustment tool interface that is located at the proximal end, wherein the proximal and distal ends are physically associated by beam portions.

In some other aspects, a first adjustment tool and a second adjustment tool wherein the first adjustment tool adjusts one of the proximal end or the distal end of the implant and the second adjustment tool adjusts the other of the proximal end of the implant or the distal end of the implant.

In other aspects, the first adjustment tool and the second adjustment tool are located at the proximal end of the implant and the first adjustment tool and the second adjustment tool are coaxially nested one within the other and independently rotatable. In some aspects, the first adjustment tool adjusts for expansion or contraction of the proximal end of the implant. In some other aspects, the first adjustment tool adjusts for expansion or contraction of the distal end of the implant. In some other aspects, the second adjustment tool adjusts for expansion or contraction of the proximal end of the implant. In other aspects, the second adjustment tool adjusts for expansion or contraction of the distal end of the implant.

In some aspects, the implant further comprises a cage body, at least one proximal flexure and at least one distal flexure such that the proximal flexure shares a beam portion of the cage body with a distal flexure to form a continuous serpentine pattern along the cage body.

BRIEF DESCRIPTION OF THE DRAWINGS

For the purpose of illustrating concepts of the disclosure, the drawings show aspects of one or more embodiments. However, it should be understood that the present disclosure is not limited to the precise arrangements and instrumentalities shown in the drawings, wherein:

FIGS. **1-3** are a series of lateral representations of two vertebral bodies, wherein FIG. **1** depicts the insertion of an exemplary Universally Expanding Cage (UEC) in its unexpanded state, FIG. **2** depicts the UEC in place between the vertebral bodies and still in its unexpanded state, and FIG. **3** depicts the inserted UEC in its expanded state.

FIG. **4** is a perspective view of a first embodiment of a UEC in an unexpanded state according to aspects of the disclosure.

FIG. **5** is an exploded perspective view showing the UEC of FIG. **4**.

FIG. **6** is a perspective view showing the cage body of the UEC of FIG. **4**.

FIG. **7** is a proximal end view of the UEC of FIG. **4**.

FIG. **8** is a side view of the UEC of FIG. **4**.

FIG. **9** is a side cross-sectional view of the UEC of FIG. **4**.

FIG. **10** is a perspective view of a second embodiment of a UEC in an unexpanded state according to aspects of the disclosure.

FIG. **11** is an exploded perspective view showing the UEC of FIG. **10**.

FIG. **12** is a side view showing the UEC of FIG. **10**.

FIG. **13** is a proximal end view showing the UEC of FIG. **10**.

FIG. **14** is a distal end view showing the UEC of FIG. **10**.

FIG. **15** is a side cross-sectional view showing the UEC of FIG. **10**.

FIG. **16** is a perspective view of a third embodiment of a UEC in an unexpanded state according to aspects of the disclosure.

FIG. **17** is an exploded perspective view showing the UEC of FIG. **16**.

FIG. **18** is a side view showing the UEC of FIG. **16**.

FIG. **19**A is a side cross-sectional view showing the UEC of FIG. **16**.

FIG. **19**B is an end cross-sectional view showing the UEC of FIG. **16**.

FIGS. **20**A-**20**C are a series of side views showing the progressive expansion of the UEC of FIG. **16**, wherein FIG. **20**A shows both ends of the UEC in the unexpanded state, FIG. **20**B shows only one end expanded, and FIG. **20**C shows both ends expanded.

FIG. **21** is a perspective view of a fourth embodiment of a UEC in an unexpanded state according to aspects of the disclosure.

FIG. **22** is a perspective view of a fifth embodiment of a UEC in an unexpanded state according to aspects of the disclosure.

FIG. **23** is a distal end view showing the UEC of FIG. **22**.

FIG. **24** is a side view showing the UEC of FIG. **22**.

FIG. **25** is a side cross-sectional view showing the UEC of FIG. **22**.

FIG. **26** is a cranial to caudal view showing the insertion sites of dual UECs on a vertebral body in one example implementation.

FIG. **27** is an oblique posterolateral view showing one of the insertion sites of the implementation of FIG. **26**.

FIG. **28** is an oblique posterolateral view showing the axes of adjustment provided by the implementation of FIG. **26**.

FIG. **29** is an oblique anterior view showing an anterior column implant.

FIG. **30** is a posterior view showing a human spine exhibiting scoliosis.

FIG. **31** is a posterior view showing the spine of FIG. **29** after being corrected according to aspects of the disclosure.

FIGS. **32**A-**32**C are anterior, lateral and oblique views, respectively, showing adjacent vertebral bodies having misalignments/uneven spacing.

FIGS. **33**A-**33**C are anterior, lateral and oblique views, respectively, showing the vertebral bodies of FIGS. **32**A-**32**C with the misalignments/uneven spacing corrected according to aspects of the disclosure.

DETAILED DESCRIPTION

Referring to FIG. **1-3**, a series of lateral views of vertebral segments **50** and **52** are shown, depicting the insertion and expansion of one embodiment of UEC (Universally Expanding Cage). The depicted vertebral bodies **50** and **52** have an average 8 mm gap between vertebral end plates, representing an average intervertebral space **54**. In a typical implementation, a complete discectomy is performed prior to the insertion of the UEC **56**. The intervertebral disc occupying space **54** is removed using standard techniques including rongeur, curettage, and endplate preparation to bleeding subcondral bone. The posterior longitudinal ligament is divided to permit expansion of the intervertebral space.

The intervertebral space **54** may be distracted to about 10 mm using a rotating spatula (not shown). This is a well-known device that looks like a wide screw driver that can be placed into the disc space horizontally and turned 90 degrees to separate the endplates. A novel feature of the UEC is that after intervertebral disc space expansion and preparation (by curetting or ideally arthroscopically facilitated disc material removal), the UEC implant per se can be inserted through any orifice or angle that does not cause injury to nerves or

other structures, positioned at the immediate implant location and consequent expansion platform to yield both the best fusion and angular correction results.

In the example implementation depicted in FIGS. **1-3**, UEC **56** is inserted posteriorly (in the direction of arrow **58**) between vertebral bodies **50** and **52**, as shown in FIG. **1**. The vertebral space **54** depicted is meant to represent any vertebral space in which it is desired to insert the UEC (sacral, lumbar, thoracic and/or cervical), and from any direction permitted by the surrounding anatomy. In accordance with an aspect of the disclosure, the UEC is reduced to a small size in its unexpanded state to enable it to be inserted through into the intervertebral space **54** as shown in FIG. **1**. FIG. **2** shows UEC **56** inserted between vertebral bodies **50** and **52**, with UEC **56** still in its unexpanded state. In one exemplary embodiment, dimensions of an unexpanded UEC are: 10-12 mm wide, 10 mm high and 28 mm long to facilitate insertion and thereby minimize trauma to the patient and risk of injury to nerve roots. These dimensions may accommodate the flat external surfaces. Once in place, the exemplary UEC **56** may be expanded to 140 percent of its unexpanded size (as shown in FIG. **3**), enabling 20 degrees or more of spinal correction depending on the 3D clinical pre-operation anatomic analysis.

It should be noted that while the exemplary UEC **56** depicted in FIGS. **1-3** is an implant intended to ideally fill the warranted space, other shapes of implants such as those shown in later figures and/or described herein may be used. In various embodiments, the implants may have a transverse cross-section that is circular, oval, elliptical, square, rectangular, trapezoidal, or other shape suited to fill the implant site and transmit the required loads. The implants may straight, curved, bean-shaped, and/or include other shapes and aspect ratios. Additionally, the external surfaces may be smooth, spiked, threaded, coated and/or further adapted as subsequently described in more detail. The UEC can be used at any spinal level the surgeon deems in need of fusion, and may be placed at any position and angle relative to the vertebral endplates as may be needed. One, two, or more UECs may be placed at any particular level to achieve the desired height and angles between vertebral bodies. As will be later described, multiple UECs may be used to adjust the overall cranio-caudal height, the anterior-posterior angle, and the medic-lateral angle between adjacent vertebral bodies. UECs may be implanted at multiple levels to obtain or restore the desired three dimensional curvature and positioning of the spine.

Referring to FIGS. **4-9**, a first embodiment of an exemplary UEC **100** according to aspects of the disclosure is shown. FIG. **4** is an enlarged perspective view which shows details of UEC **100**. For ease of understanding, a proximal end **104** and a distal end **106** of UEC **100** can be defined as shown in FIG. **4**. It should be noted that while the distal end **106** of UEC **100** is typically inserted first into a patient and proximal end **104** is typically closest to the surgeon, other orientations of this exemplary device and other devices described herein may be adopted in certain procedures despite the distal and proximal nomenclature being used.

Referring to FIG. **5**, an exploded perspective view shows the individual components of UEC **100**. In this first embodiment, UEC **100** includes a cylindrically-shaped cage body **108**, a proximal plug **110**, a distal plug **112**, a threaded actuator **114**, and a washer **116**. The terms "plug" and "plug member" are used interchangeably herein. Actuator **114** has a shank sized to slidably pass through a central bore within proximal plug **110** when UEC **100** is assembled. Actuator **114** also has threads on its distal end for engaging with a threaded central bore within distal plug **112**. Proximal plug **110** and distal plug **112** each have outer surfaces that are inwardly tapered to match inwardly tapered surfaces within cage body **108** (as best seen in FIG. **9**) With this arrangement, actuator **114** may be rotated in a first direction to draw distal plug **112** toward proximal plug **110** to outwardly expand cage body **108**, as will be subsequently described in more detail.

Referring to FIG. **6**, this perspective view shows details of cage body **108** of the first exemplary embodiment of UEC **100**. In this embodiment, cage body **108** includes eight longitudinally extending beam portions **118**, each separated from an adjacent beam portion **118** by a longitudinally extending gap **120**. In other embodiments (not shown), the cage body may include fewer or more than eight beam portions, and/or beam portions having a different or varying cross-section or shape. Cage body **108** of the current embodiment also includes eight circumferentially extending connector portions **122**. The connector portions **122** interconnect the ends of the beam portions **118**. Four of the connector portions **122** are located at the proximal end **104** of cage body **108**, and the other four connector portions **122** are located at the distal end **106**. The connector portions **122** located at the proximal end **104** are staggered in relation to the connector portions **122** located at the distal end **106** such that each pair of adjacent beam portions **118** are connected at only one end by a connector portion **122**. With this arrangement the beam portions **118** and connector portions **122** form a continuous serpentine or repeating S-shaped pattern. The beam portions **118** and or the connector portions **122** are configured to resiliently flex to allow the cage body **108** to increase in diameter when urged radially outward by plugs **110** and **112** (shown in FIG. **4**). When plugs **110** and **112** are not urging cage body **108** radially outward, the resiliency of beam portions **118** and or connector portions **122** allows cage body **108** to return to its original reduced diameter. It can be appreciated that as beam portions **118** and or connector portions **122** flex outwardly, gaps **120** become wider at their open ends opposite connector portions **122**. The outwardly facing surfaces of beam portions **118** may each be provided with one or more points or spikes **123** as shown, to permit cage body **108** to grip the end plates of the vertebral bodies.

Referring to FIG. **7**, an end view of the proximal end **104** of UEC **100** is shown. The enlarged head at the proximal end of actuator **114** may be provided with a recessed socket **124** as shown for removably receiving a tool for turning actuator **114**. Proximal plug **110** (and distal plug **112**, not shown) may be provided with radially outwardly extending protuberances **126** that reside in one or more gaps **120** and abut against the side of beam portions **118**. This arrangement prevents plugs **110** and **112** from rotating when actuator **114** is turned, thereby constraining plugs **110** and **112** to only move axially toward or away from each other. Proximal plug **110** (and distal plug **112**) may be provided with through holes and or recesses **128** to allow for bony ingrowth from the vertebral bodies for more solidly healing/fusing UEC **100** in place. Longitudinally extending slots **130** (shown in FIG. **4**) may also be provided for this purpose, and or for packing plugs **110** and **112** with autograft, allograft, and/or other materials for promoting healing/fusion.

Referring to FIGS. **8** and **9**, a side view and side cross-sectional view, respectively, are shown. In operation, UEC **100** is expanded by inserting a tool such as a hex key wrench or driver (not shown) into the recessed socket **124** at the proximal end of actuator **114** and turning it clockwise. As best seen in FIG. **9**, the distal end of actuator **114** is threaded

into the central bore of distal plug **112**. Turning actuator **114** clockwise causes the distal end of actuator **114** to pull distal plug **112** towards the center of cage body **108** while the enlarged head at the proximal and of actuator **114** pushes proximal plug **110** towards the center. This movement in turn causes the ramped surfaces **132** of plugs **110** and **112** to slide inwardly along the ramped surfaces **134** located along the inside of beam portions **118** and connector portions **122** to cause these elements to flex and expand radially outward as previously described. This process may be reversed by turning actuator **114** counterclockwise. The resilient inward forces from the beam portions **118** and or connector portions **122** (and or the compressive forces from adjacent vertebral bodies) against plugs **110** and **112** causes the two plugs to separate axially, thereby allowing UEC **100** to return to its non-expanded state.

Referring to FIGS. **10-15**, a second embodiment of an exemplary UEC **200** according to aspects of the disclosure is shown. FIG. **10** is a perspective view which shows details of UEC **200**. UEC **200** includes a proximal end **204** and a distal end **206**, and shares many of the same features of previously described UEC **100**, which are identified with similar reference numerals.

Referring to FIG. **11**, an exploded perspective view shows the individual components of UEC **200**. In this second embodiment, UEC **200** includes an elongated cylindrical cage body **208**, a proximal plug **210**, and a distal plug **212**. Distal plug **212** includes an integrally formed actuator rod **214** that extends along the internal central axis of cage body **208** towards proximal plug **210** when UEC **200** is assembled. Proximal plug **210** and distal plug **212** each have outer surfaces that are threaded and inwardly tapered to match threaded and inwardly tapered surfaces within cage body **208** (as best seen in FIG. **15**). With this arrangement, each plug **210** and **212** may be independently rotated to move the particular plug axially toward the middle of cage body **208** to outwardly expand that particular end **204** or **206** of cage body **208**, as will be subsequently described in more detail.

As shown in FIGS. **11** and **12**, cage body **208** includes eight longitudinally extending beam portions **218**, each separated from an adjacent beam portion **218** by a longitudinally extending gap **220**. In other embodiments (not shown), the cage body may include fewer or more than eight beam portions, and/or beam portions having a different or varying cross-section or shape. Cage body **208** of the current embodiment also includes eight circumferentially extending connector portions **222**. The connector portions **222** interconnect the ends of the beam portions **218**. Four of the connector portions **222** are located at the proximal end **204** of cage body **208**, and the other four connector portions **222** are located at the distal end **206**. The connector portions **222** located at the proximal end **204** are staggered in relation to the connector portions **222** located at the distal end **206** such that each pair of adjacent beam portions **218** are connected at only one end by a connector portion **222**. With this arrangement the beam portions **218** and connector portions **222** form a continuous serpentine or repeating S-shaped pattern. The beam portions **218** and or the connector portions **222** are configured to resiliently flex to allow the cage body **208** to increase in diameter when urged radially outward by plugs **210** and **212**. When plugs **210** and **212** are not urging cage body **208** radially outward, the resiliency of beam portions **218** and or connector portions **222** allows cage body **208** to return to its original reduced diameter. It can be appreciated that as beam portions **218** and or connector portions **222** flex outwardly, gaps **220** become wider at their open ends opposite connector portions **222**. The outwardly facing surfaces of beam portions **218** may each be provided with one or more points or spikes **223** as shown, to permit cage body **208** to grip the end plates of the vertebral bodies.

Referring to FIG. **13**, an end view of the proximal end **204** of UEC **200** is shown. The proximal plug **210** may be provided with a recessed socket **224** as shown for removably receiving a tool for turning proximal plug **210** in either direction, such as a five-lobed driver (not shown). Alternatively, other suitable types of recessed sockets, slots, protruding and/or keyed features may be utilized with a mating driver. The proximal end of actuator shaft **214** (which extends proximally from distal plug **212** inside cage body **208**) may be accessed through a central bore **225** in proximal plug **210**. The proximal end of actuator shaft **214** may be shaped as shown to be received within a mating driver socket (such as a five-lobed socket, not shown), which can be removably extended into the center of cage body **208** through central bore **225**. With this arrangement, both the proximal plug **210** and the distal plug **212** can be independently accessed and rotated from the proximal end of UEC **200** so that the proximal end **204** and the distal end **206** of UEC **200** can be expanded or contracted independently.

Referring to FIG. **14**, an end view of the distal end **206** of UEC **200** is shown. By comparing FIGS. **13** and **14**, it can be appreciated that connector portions **222** at the proximal end **204** of UEC **200** are staggered (i.e. rotated 45°) in relation to the connector portions **222** at the distal end **206** of UEC **200**.

Referring to FIG. **15**, a side cross-sectional view of UEC **200** is shown. In operation, the proximal end **204** of UEC **200** may be independently expanded by inserting a tool such as a five-lobed driver (not shown) into the recessed socket **224** of proximal plug **210** and turning it clockwise. Turning proximal plug **210** clockwise causes the threaded ramped surfaces **232** of plug **210** to translate inwardly (to the right in FIG. **15**) along the threaded ramped surfaces **234** located along the inside of beam portions **218** and connector portions **222** to cause these elements to flex and expand radially outward as previously described. This process may be reversed by turning proximal plug **210** counterclockwise, thereby allowing the proximal end **204** of UEC **200** to return to its non-expanded state. Similarly, the distal end **206** of UEC **200** may be independently expanded by inserting a tool such as a five-lobed socket (not shown) through the central bore **225** in proximal plug **210** until it engages with the proximal end of actuator **214**, which is attached to distal plug **212**. Turning distal plug **212** counterclockwise (from the perspective of the proximal end) causes the threaded ramped surfaces **232** of plug **212** to translate inwardly (to the left in FIG. **15**) along the threaded ramped surfaces **234** located along the inside of beam portions **218** and connector portions **222** to cause these elements to flex and expand radially outward as previously described. This process may be reversed by turning distal plug **212** clockwise, thereby allowing the distal end **206** of UEC **200** to return to its non-expanded state.

The adjustment tools described above (not shown) for turning proximal plug **210** and distal plug **212** may be inserted one at a time into UEC **200**. Alternatively, the two tools may be nested together, with the tool for turning the distal plug **212** passing through a central bore in the tool for turning the proximal plug, as will be subsequently shown and described in relation to other embodiments. With this arrangement, both tools may be turned simultaneously or individually. In some embodiments, both proximal plug **210**

and distal plug **212** are provided with right-handed threads, so that when both tools are simultaneously turned in the same direction, one end of UEC **200** expands while the other end contracts, thereby changing the outer surface angle of UEC **200** without substantially changing its overall diameter (i.e. without substantially changing the diameter or height of the midpoint of UEC **200**.) For example, by turning the two tools in the same direction, the lordotic angle between two vertebral bodies can be changed by UEC **200** without substantially changing the height between the two vertebral bodies.

In other embodiments, one of the plugs **210** or **212** may be provides with a right-handed thread and the other plug provided with a left-handed thread. In these embodiments, when both adjustment tools are simultaneously turned in the same direction, both ends **204** and **206** of UEC **200** expand or contact together without substantially changing the outer surface angle of UEC **200**. For example, by turning the two tools in the same direction, the height between the two vertebral bodies can be changed by UEC **200** without substantially changing the lordotic angle between two vertebral bodies.

In some embodiments, plugs **210** and **212** may each be provided with threads having a different pitch from the other. Such an arrangement allows both the height and the angle between adjacent vertebral bodies to be adjusted simultaneously in a predetermined relationship when both adjustment tools are turned together in unison. For example, proximal plug **210** may be provided with right-handed threads of a particular pitch while distal plug **212** may be provided with finer, left-handed threads having half the pitch of the proximal plug threads. In this embodiment, when both adjustment tools are turned together in a clockwise direction, both ends of UEC **200** expand at the same time but the proximal end **204** expands at twice the rate of the distal end **206**. This allows the surgeon to increase the height between adjacent vertebral bodies and at the same time angle the bodies away from him or her. One or both of the tools may then be turned individually to more finely adjust the height and angle between the vertebral bodies.

In some embodiments the above-described adjustment tools may be removed from UEC **200** before the surgical procedure is completed. In some embodiments the above adjustment tools may remain in place after the procedure is completed.

In some embodiments, UEC **200** is 50 mm long, has an unexpanded diameter of 10 mm, and an expanded diameter of 14 mm. In other embodiments, the UEC may be configured to expand to about 11, 12, or 13 mm, or more than 14 mm. In still other embodiments, the UEC may be configured with dimensions larger or smaller than these to conform to a particular anatomy or procedure.

Referring to FIGS. **16-20**, a third embodiment of an exemplary UEC **300** according to aspects of the disclosure is shown. FIG. **16** is a perspective view which shows details of UEC **300**. UEC **300** includes a proximal end **304** and a distal end **306**, and shares many of the same features of previously described UECs **100** and **200**, which are identified with similar reference numerals.

Referring to FIG. **17**, an exploded perspective view shows the individual components of UEC **300**. In this third embodiment, UEC **300** includes a rectangular cage body **308**, a proximal plug **310**, a distal plug **312**, a proximal plug adjustment tool **313**, and a distal plug adjustment tool **314**. As in the previously described UEC **200**, both plugs **310** and **312** are threaded and tapered, and each end of cage body **308** is provided with an inwardly tapered and threaded bore configured to receive one of the plugs **310** or **312**. Adjustment tools **313** and **314** are similar in construction and operation to the adjustment tools previously described (but not shown) in reference to UEC **200**. Proximal plug **310** includes a mating recess on its proximal end (not shown) configured to removably receive the splined distal end of proximal plug adjustment tool **313** for rotating proximal plug **310**. Distal plug **312** includes a smaller mating recess on its proximal end (not shown) configured to removably receive the smaller splined distal end of distal plug adjustment tool **314** for rotating distal plug **312**. Both proximal plug adjustment tool **313** and proximal plug **312** are provided with central bores that permit the distal end of distal plug adjustment tool **314** to pass therethrough, through the center of cage body **308**, and partially into distal plug **312**. In this exemplary embodiment, the proximal ends of adjustment tools **313** and **314** each have a hexagonally-shaped head that permits them to be turned together in unison or individually (as previously described in relation to UEC **200**), using wrench(es), socket(s) (not shown) and/or by hand.

As shown in FIGS. **16** and **17**, cage body **308** includes eight longitudinally extending beam portions **318**, each separated from an adjacent beam portion **318** by a longitudinally extending gap **320**. In other embodiments (not shown), the cage body may include fewer or more than eight beam portions, and/or beam portions having a different or varying cross-section or shape. It can be seen that in this embodiment, four of the gaps **320** are formed through the middle of the four faces of cage body **308**, and the other four gaps **320** are formed along the corner edges of cage body **308**. Cage body **308** also includes eight circumferentially extending connector portions **322**. The connector portions **322** interconnect the ends of the beam portions **318**. Circular apertures **321** may be provided as shown between the ends of gaps **320** and the connector portions **322** to relieve stress concentrations at those locations as connector portions **322** flex. Four of the connector portions/flexures **322** are located at the proximal end **304** of cage body **308** (across the corner edges of cage body **308**), and the other four connector portions/flexures **322** are located at the distal end **306** (across the distal end of the faces of cage body **308**.) The connector portions **322** located at the proximal end **304** are staggered in relation to the connector portions **322** located at the distal end **306** such that each pair of adjacent beam portions **318** are connected at only one end by a connector portion **322**. As with previously described embodiments, the beam portions **318** and connector portions **322** form a continuous serpentine or repeating S-shaped pattern. The beam portions **318** and or the connector portions **322** are configured to resiliently flex to allow the cage body **308** to increase in circumference when urged radially outward by plugs **310** and **312**. When plugs **310** and **312** are not urging cage body **308** radially outward, the resiliency of beam portions **318** and or connector portions **322** allows cage body **308** to return to its original reduced circumference. It can be appreciated that as beam portions **318** and or connector portions **322** flex outwardly, gaps **320** become wider at their open ends opposite connector portions **322**. The outwardly facing surfaces of beam portions **318** may each be provided with one or more points or spikes **323** as shown, to permit cage body **308** to grip the end plates of the vertebral bodies. In this exemplary embodiment, spiked or knurled surfaces are provided along the top and bottom of UEC **300** while the side surfaces are left smooth.

Referring to FIGS. **18** and **19**, a side view and a side cross-sectional view, respectively, of UEC **300** are shown. In

operation, the proximal end **304** of UEC **300** may be independently expanded by inserting proximal plug adjustment tool **313** into the mating recessed socket of proximal plug **310** (as shown in FIG. **19**) and turning it clockwise. Turning proximal plug **310** clockwise causes the threaded ramped surfaces **332** of plug **310** to translate inwardly (to the left in FIGS. **18** and **19**) along the threaded ramped surfaces **334** located along the inside of beam portions **318** and connector portions **322** to cause these elements to flex and expand radially outward as previously described. This process may be reversed by turning proximal plug **310** counterclockwise, thereby allowing the proximal end **304** of UEC **300** to return to its non-expanded state. Similarly, the distal end **306** of UEC **300** may be independently expanded by inserting a tool such as a five-lobed socket (not shown) through the central bore **325** in proximal plug **310** until it engages with the proximal end of actuator **314**, which is attached to distal plug **312**. Turning distal plug **312** counterclockwise (from the perspective of the proximal end) causes the threaded ramped surfaces **332** of plug **312** to translate inwardly (to the right in FIGS. **18** and **19**) along the threaded ramped surfaces **334** located along the inside of beam portions **318** and connector portions **322** to cause these elements to flex and expand radially outward as previously described. This process may be reversed by turning distal plug **312** clockwise, thereby allowing the distal end **306** of UEC **300** to return to its non-expanded state.

Referring to FIGS. **20**A-**20**C, a series of sides views depicts the progression from a fully retracted and a fully expanded UEC **300**. In FIG. **20**A, cage body **308** is shown in a fully retracted position. In this figure, the height of each end of cage body **308** is labeled as 100% of retracted cage height. In FIG. **20**B, the proximal end **304** of cage body **308** has been fully expanded while the distal end **306** remains fully retracted. In this exemplary embodiment, each end is capable of being expanded to a height (and therefore also a width) that is 140% of the fully retracted height, as shown. In FIG. **20**C, the distal end **306** has also been expanded by 40%.

In some embodiments, UEC **300** has a cage length of 50 mm, an unexpanded cage height of 10 mm, and an expanded cage height of 14 mm. The overall length of UEC **300** with adjustment tools **313** and **314** in place and in the unexpanded state may be 75 mm. In other embodiments, the UEC may be configured to expand to about 11, 12, or 13 mm, or more than 14 mm. In still other embodiments, the UEC may be configured with dimensions larger or smaller than these to conform to a particular anatomy or procedure. In some embodiments, the UEC can form an included angle between its top and bottom surfaces of at least 20 degrees.

Referring to FIG. **21**, a fourth embodiment of an exemplary UEC **400** according to aspects of the disclosure is shown. FIG. **21** is a perspective view which shows details of UEC **400**. UEC **400** includes a proximal end **404**, a distal end **406**, cage body **408**, proximal plug **410**, distal plug **412**, proximal plug adjusting tool **413**, and distal plug adjusting tool **414**. Other than cage body **408** having a circular cross-section rather than a square cross-section, UEC **400** is essentially identical in construction and operation to previously described UEC **300**. In other embodiments (not shown), the UEC may have a cross-section transverse to the central longitudinal axis that is rectangular, trapezoidal, oval, elliptical or other shape.

Referring to FIGS. **22**-**25**, a fifth embodiment of an exemplary UEC **500** according to aspects of the disclosure is shown. FIG. **16** is a perspective view which shows details of UEC **500**. UEC **500** includes a proximal end **504** and a distal end **506**, and shares many of the same features of previously described UECs **100**-**400**, which are identified with similar reference numerals.

UEC **500** includes three components: a generally cylindrical, unitary cage body **508**; a proximal actuator screw **510**; and a distal actuator screw **512**. The heads of actuator screws **510** and **512** may be referred to as plug members. Cage body **508** includes two longitudinal, off-center slots **550** which each extend about three-quarters of the length of cage body **508**, and emanate from opposite ends and opposite sides of cage body **508**. Cage body **508** is also provided with two transverse slots **552**, each located adjacent to the closed end of one of the longitudinal slots **550**. Each transverse slot **552** extends from the outer circumference of cage body **508** and approaches the base of a longitudinal slot **550**. Each of the two pairings of a longitudinal slot **550** with a transverse slot **552** defines a cantilevered arm **554** that is connected with the remainder of the cage body **508** by a living hinge **556** near the closed ends of the two slots **550** and **552**. Each living hinge **556** allows its associated arm **554** to flex outwardly against a vertebral body.

The open ends of longitudinal slots **550** are outwardly tapered to receive the enlarged, tapered heads of an actuator screw **510** or **512**, as best seen in FIG. **24**. The opposite ends of actuator screws **510** and **512** extend through longitudinal slots **550** and thread into the opposite ends of cage body **508**. With this arrangement, each actuator screw **510** and **512** may be turned independently of the other, causing the screw to move axially relative to bone cage **508**. This axial movement causes the head of the screw to urge the tapered tip of the associated arm **554** outward, or allowing it to flex back inward when the screw is turned in the opposite direction. If both actuator screws **510** and **512** are turned in the same direction the same amount, UEC **500** expands uniformly and increases the height between adjacent vertebral bodies. If one of the two actuator screws **510** or **512** is turned more than the other, the surgeon is able to change the angle between the vertebral bodies.

As best seen in FIG. **23**, a slot **558** or other suitable feature may be provided in the end of each actuator screw **510** and **512** at the opposite end from the screw head. A hole **560** may also be provided through each end of cage body **508** to allow access to each of the two slots **558**. This arrangement allows both of the actuator screws **510** and **512** to be turned from either end **504** and/or **506** of cage body **508**.

Referring to FIGS. **26**-**28**, an example implementation utilizing two UECs **56** in tandem is shown. Each UEC **56** may be inserted as previously described in relation to FIGS. **1**-**3**. In this implementation, UECs **56** are placed non-parallel to one another. As best seen in FIG. **28**, this arrangement allows the surgeon to adjust the angle between the vertebrae about two different axes, and also translate the vertebrae with respect to one another about another axis.

FIG. **29** is an oblique anterior view showing placement of an anterior column implant **56** on a vertebral body **52**. In this implementation, implant **56** is placed laterally across the vertebral body **52**, forward of the lateral midline. After adjustment of implant **56**, its plugs are flush with or recessed within the outer perimeter of the endplate of vertebral body **52** so as not to impinge upon adjacent tissue.

Referring to FIG. **30**, a human spine **76** is shown that exhibits scoliosis. According to aspects of the disclosure, dual UECs may be placed at various levels of the spine to treat the condition. For example, a single UEC or pairs of UECs may be implanted at the levels depicted by reference numerals **78**, **80**, **82** and **84** shown in FIG. **30**. By using the adjustments described above relative to **28**, the curvature of

the spine may be adjusted in three dimensions at these four levels to a correct alignment, as shown in FIG. **31**.

FIGS. **32**A-**32**C are anterior, lateral and oblique views, respectively, showing adjacent vertebral bodies **50** and **52** having misalignments/uneven spacing.

FIGS. **33**A-**33**C are anterior, lateral and oblique views, respectively, showing the vertebral bodies **50** and **52** of FIGS. **32**A-**32**C with the misalignments/uneven spacing corrected according to aspects of the disclosure.

The implants can be made of, for example, such materials as titanium, 64 titanium, or an alloy thereof, 316 or 321 stainless steel, biodegradeable and biologically active materials, e.g. stem cells, and polymers, such as semi-crystalline, high purity polymers comprised of repeating monomers of two ether groups and a ketone group, e.g. polyaryetheretherketone (PEEK)™, or Teflon™.

To prevent movement of proximal and distal plugs or actuators after implantation, in some implementations a biocompatible adhesive or thread locking compound may be applied to one or more of the moving parts. In some embodiments (not shown) a pin may be inserted radially or axially between the plug/actuator and the cage body to lock the parts in place post operatively. In some embodiments, a ratchet, spring loaded detent, or other locking mechanism may be provided for this purpose.

In general, as disclosed in the above embodiments, the cage body is cut with openings at every other end of each slot, like a sine wave, allowing expansion when the center of the cage becomes occupied with a cone or mandrill shaped unit. The cage body's series of alternating slots allows the expansion to take place while keeping the outside of the UEC one single piece. The slots plus the teeth on the surface allow for a solid grip on the bone surfaces and plenty of opportunities for good bone ingrowth. Also, by allowing the surgeon to make one end of the UEC thicker than the other, the effects of the cone (mandrill) introduction vary from uniform to selective conduit expansion. The UEC expansion mechanism is adaptable to both fixed fusion and mobile 'motion preservation' implants, with exteriors of the expanding implant per surgeon's choice (round, flat, custom, etc.) As such, in some implementations, relative motion may be preserved between the vertebral bodies adjacent the implanted UEC(s). In other implementations, it may be desirable to fuse the adjacent vertebral bodies around the implanted UEC(s).

To provide motion preservation between adjacent vertebrae, robust compressible materials may be used between the UEC and one or both of the vertebral endplates, and/or one or more components of the UEC may comprise such materials. These materials may replicate the load distributing and shock absorbing functions of the annulus and nucleus of a natural disk. For example, in some embodiments the UEC may be provided with tapered plugs made of a resilient polymer to allow the UEC to compress and expand to accommodate relative motion of the adjacent vertebrae. Examples of biocompatible materials suitable for some UEC embodiments include Bionate®, a thermoplastic polycarbonate-urethane (PCU) provided by DSM Biomedical in Exton, Pa., and ChronoFlex®, a PCU provided by AdvanSource Biomaterials in Wilmington, Mass.

The UEC provides advantages over currently existing technology that include correction of coronal plane deformity; introduction of interbody lordosis and early stabilization of the interbody space with rigidity that is greater than present spacer devices. This early stability may improve post-operative pain, preclude the need for posterior implants including pedicle screws, and improve the rate of successful arthrodesis. Importantly, the UEC provides improvement of space available for the neural elements while improving lordosis. Traditional implants are limited to spacer effects, as passive fillers of the intervertebral disc locations awaiting eventual fusion if and when bone graft in and around the implant fuses. By expanding and morphing into the calculated shape which physiologically corrects spine angulation, the UEC immediately fixes the spine in its proper, painless, functional position. As infused osteoinductive/osteoconductive bone graft materials heal, the patient becomes well and the implant becomes inert and quiescent, embedded in bone, and no longer needed.

In some embodiments, the external surface of the UEC may be 3D printed to not only fit into the intervertebral space per se, but to match the surface topography at each insertion location. In other words, a 3D printed endplate may be utilized, computer calculated to fit and expand the disc space of the individual patient, resulting in both best 'goodness of fit' for fusion, and improved axial skeletal alignment.

By creating to 'maps' that fit e.g., as a precisely congruent superior and inferior surface to fit into a particular patients disc space, and placing these UEC end plates on either side the novel UEC expansion mechanism, a patient's disc space AND overall spine alignment will be ideally treated toward best fusion (or motion preservation) and alignment.

"Method of Surgery" instructions may recommend the surgeon and/or robotic unit deploy expansion as programmed to insert the UEC into a particular disc level of pathology, to achieve best results. For example, preoperative patient scans/films can predict ideal UEC surgeon use, such as "turn Knob A a certain number of rotations clockwise," to maximize visible, palpable, and roentgenographic 'Goodness of Fit'. With this approach, post activation, the UEC implant fits the location, entering at the predetermined best angle (in 3 axes) using the proprietary Method of Surgery and UEC insertion tools provided.

In some embodiments, the UEC may be coated with hydroxyapatite. In some embodiments, toothed or 400 μm beaded surfaces may be utilized to promote bony ingrowth, Inflatable chambers may be provided within the endplate that can expand after being implanted. This approach addresses the 3-D congruence to proximate disc pathology. It can also allow for intervertebral arthrodesis or arthroplasty treatment and overall improved spinal alignment, integrating the internal proprietary expansion with the variable external endplate shapes and their contents. UEC inflatable endplates of polymer may be employed, such as tiny vacuoles, "bubblewrap", and multiple or singular bladder constructs. If a portion of the disk space were collapsed, that region could be aptly elevated or expanded by the UEC endplate variation in material and/or inflation. The inflatable chambers may contain compressible gas (such as air), granules as pharmacologics, and/or stem cells that are delivered via liquids. In cases where the UEC is compressible or force absorbing, the material and/or chamber could be used as a cushion or to 'selectively direct and protect chondrocytes' toward improvement of existing pathophysiology via best drug use or regeneration.

The 'preparation' of the UEC insertion site will vary per surgeon. In some implementations, an arthroscopic burr may be advisable for removing 0.5 mm of cortical bone along with all aberrant disc contents under digital arthroscopic camera control. In other implementations, the surgeon may just carefully curette the intervertebral space to 'clean it out' in preparation for the UEC implant insertion.

The UEC may be inserted directly into the insertion site, or may be inserted through proprietary or commercially

available insertion tube. The insertion tube typically will have a blunt distal tip so that it can be inserted through an incision without causing tissue damage. The tube can be used with or without additional tissue retractors. The UEC may be preloaded into the insertion tube, or placed into the tube after the tube has been introduced into the insertion site. A pusher rod or other device may be utilized to deploy the UEC from the insertion tube into the insertion site. In some procedures, the placement of the UEC may be arthroscopically assisted.

Note that regardless of the endplate preparation, in the deformed, aging, pathologic spine there will be pathology to correct. According to various aspects of the present disclosure, the UECs provided herein may accomplish this in several ways as pertains to the external implant composition. For example, the UEC can expand as an externally threaded conduit, either uniformly end to end resulting in same diameters at each end post-operatively (such as 40% overall expansion), or precisely at either end, thus creating an overall conical albeit expanded UEC. Also, the UEC can be flat superiorly and inferiorly as shown in the above drawings, thus more likely matching the rather flat vertebral body end plates. However, according to further aspects of the present disclosure, special care should be taken to consider both the peripheral end plate honey rim as thicker more prominent cortical bone at the vertebral end plates with a sunken or concave thinner interior (thus subject to potential subsidence). The UEC MOS (Method of Surgery) contemplated herein considers the preoperative findings (e.g. MRI, 3D CT scan, X-rays) to integrate information on bone density, specific disc space and longitudinal spine anatomy, topography and alignment.

The various expanding cages disclosed herein and variations thereof are not limited to use in the spinal column but may be used between other bone segments throughout the human or animal body. For example, a UEC can be used during arthrodesis of a metatarsal joint. The UEC can aid in setting the orientation of the toe to a desired angle before fusion of the apposing bone segments occurs. Similarly, a UEC may be utilized in the knee, elbow or other body joints, or between two or more bone segments that have been fractured by trauma.

According to various aspects of the disclosure:

1) the UEC corrects spine surgical pathology both locally via horizontal (disc) and longitudinal vertical axial (scoliotic/kyphotic) spine deformity improvements.

2) the UEC is applicable cervical through lumbar for
- A) arthrodesis (fusion) or
- B) arthroplasty (motion preservation) or
- C) drug/cell therapy delivery

3) the UEC can expand uniformly throughout implant length, and/or expand only proximally (toward the surgical incision) or distally, thus enabling clinical adjustments favorable to spine diseased or injured patients for local and overall spondylopathies.

4) the UEC can be surgically inserted via outpatient MIS (Minimally Invasive—outpatient Surgery) as safe, efficacious implants "doing no harm" applying advantages from
A) materials thicknesses for height differentials or
B) expansion adjustments surgically controlled (before/during or after implantation) or via prefabricated portals or injections—programing implant 'mapped' corrections using
C) polymers durometrically calculated with variable compressions, permanent or biodegradable activations at will.
D) inflation of the implant as via UEC surface chambers or bladder(s).
E) adding endplate biologics, foam, or other adaptables for best results.
F) UEC expansion can adapt to expand variable external surface parameters including flat, round, or customized external maximally congruent surfaces to interface as with proximate endplates.

5) Delivery either via UEC materials per se (eluding substances—cells or pharmacologics) or through extrusion from a UEC container or delivery vesicle/depot/chamber/portal will enable not only immediate surgically correction but long term enhanced bone in growth and local/general therapeutic and/or regenerative clinical benefits.

While the disclosure has been described in connection with example embodiments, it is to be understood that the disclosure is not limited to the disclosed embodiments and alternatives as set forth above, but on the contrary is intended to cover various modifications and equivalent arrangements included within the claim scope.

What is claimed is:

1. An expandable medical implant comprising: a proximal end, a distal end, a first adjustment tool and a second adjustment tool wherein the first adjustment tool adjusts one of the proximal end or the distal end of the implant and the second adjustment tool adjusts the other of the proximal end of the implant or the distal end of the implant wherein the first adjustment tool and the second adjustment tool are located at the proximal end of the implant and the first adjustment tool and the second adjustment tool are coaxially nested one within the other and independently rotatable.

2. The expandable medical implant of claim **1**, wherein the first adjustment tool adjusts for expansion or contraction of the proximal end of the implant.

3. The expandable medical implant of claim **1**, wherein the second adjustment tool adjusts for expansion or contraction of the distal end of the implant.

4. The expandable medical implant of claim **1**, wherein the implant further comprises a cage body, at least one proximal flexure and at least one distal flexure such that the proximal flexure shares a beam portion of the cage body with a distal flexure to form a continuous serpentine pattern along the cage body.

5. A resiliently expandable medical implant comprising:
- a proximal end which is capable of independent resilient expansion by means of a distal flexure,
- a distal end which is capable of independent resilient expansion by means of a proximal flexure,
- an expansion means that is functionally associated with the proximal end,
- an expansion means that is functionally associated with the distal end,
- an adjustment tool interface that is located at the proximal end,
- wherein the proximal and distal ends are physically associated by beam portions.

6. The resiliently expandable medical implant of claim **5**, further comprising: a first adjustment tool and a second adjustment tool wherein the first adjustment tool adjusts one of the proximal end or the distal end of the implant and the second adjustment tool adjusts the other of the proximal end of the implant or the distal end of the implant.

7. The expandable medical implant of claim **6**, wherein the first adjustment tool adjusts for expansion or contraction of the proximal end of the implant.

8. The expandable medical implant of claim **6**, wherein the first adjustment tool adjusts for expansion or contraction of the distal end of the implant.

9. The expandable medical implant of claim 6, wherein the second adjustment tool adjusts for expansion or contraction of the proximal end of the implant.

10. The expandable medical implant of claim 6, wherein the second adjustment tool adjusts for expansion or contraction of the distal end of the implant.

11. The resiliently expandable medical implant of claim 5, wherein the first adjustment tool and the second adjustment tool are located at the proximal end of the implant and the first adjustment tool and the second adjustment tool are coaxially nested one within the other and independently rotatable.

12. The expandable medical implant of claim 5, wherein the implant further comprises a cage body, at least one proximal flexure and at least one distal flexure such that the proximal flexure shares a beam portion of the cage body with a distal flexure to form a continuous serpentine pattern along the cage body.

* * * * *

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(12) **United States Patent**
Grotz

(10) **Patent No.: US 10,004,605 B2**
(45) **Date of Patent: Jun. 26, 2018**

(54) **RESILIENT KNEE IMPLANT AND METHODS**

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(72) Inventor: **R. Thomas Grotz**, Las Vegas, NV (US)

(73) Assignee: **IORTHOPEDICS, INC.**, Las Vegas, NV (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days. days.

(21) Appl. No.: **15/608,885**

(22) Filed: **May 30, 2017**

(65) **Prior Publication Data**

US 2017/0266012 A1 Sep. 21, 2017

Related U.S. Application Data

(60) Division of application No. 14/289,431, filed on May 28, 2014, now Pat. No. 9,662,218, which is a (Continued)

(51) **Int. Cl.**
A61F 2/38 (2006.01)
A61B 17/064 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61F 2/3859*** (2013.01); ***A61B 17/0642*** (2013.01); ***A61B 17/562*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC .. A61F 2/38; A61F 2/28; A61F 2/3859; A61F 2220/0025
See application file for complete search history.

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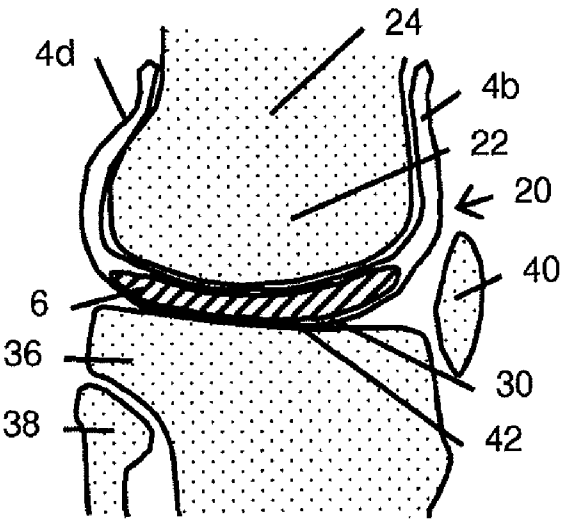
Primary Examiner — Jason-Dennis Stewart
(74) *Attorney, Agent, or Firm* — Michel Graffeo

(57) **ABSTRACT**

This disclosure is directed to a resilient interpositional arthroplasty implant for application into a knee joint to pad cartilage defects, cushion a joint, and replace or restore the articular surface, which may preserve joint integrity, reduce pain and improve function. The implant may endure variable joint compressive and shear forces and cyclic loads. The implant may repair, reconstruct, and regenerate joint anatomy, and thereby improve upon joint replacement alternatives. Rather than using periosteal harvesting for cell containment in joint resurfacing, the walls of this invention may capture, distribute and hold living cells until aggregation and hyaline cartilage regrowth occurs. The implant may be deployed into debrided joint spaces, molding and conforming to surrounding structures with sufficient stability to avoid extrusion or dislocation. Appendages of the implant may repair or reconstruct tendons or ligaments, and an interior of the implant that is inflatable may accommodate motions which mimic or approximate normal joint motion.

9 Claims, 7 Drawing Sheets



Related U.S. Application Data

continuation of application No. 13/574,499, filed as application No. PCT/US2011/021674 on Jan. 19, 2011, now Pat. No. 8,771,363.

(60) Provisional application No. 61/297,698, filed on Jan. 22, 2010.

(51) **Int. Cl.**

A61B 17/56	(2006.01)
A61L 27/18	(2006.01)
A61L 27/38	(2006.01)
A61L 27/54	(2006.01)
A61F 2/30	(2006.01)

(52) **U.S. Cl.**

CPC ***A61L 27/18*** (2013.01); ***A61L 27/3817*** (2013.01); ***A61L 27/54*** (2013.01); *A61B 2017/561* (2013.01); *A61F 2/38* (2013.01); *A61F 2/3872* (2013.01); *A61F 2002/30563* (2013.01); *A61F 2002/30583* (2013.01); *A61F 2002/30586* (2013.01); *A61F 2002/30677* (2013.01); *A61F 2002/30754* (2013.01); *A61F 2002/3863* (2013.01); *A61L 2300/402* (2013.01); *A61L 2300/404* (2013.01); *A61L 2300/406* (2013.01); *A61L 2300/414* (2013.01); *A61L 2300/416* (2013.01); *A61L 2300/452* (2013.01); *A61L 2300/64* (2013.01)

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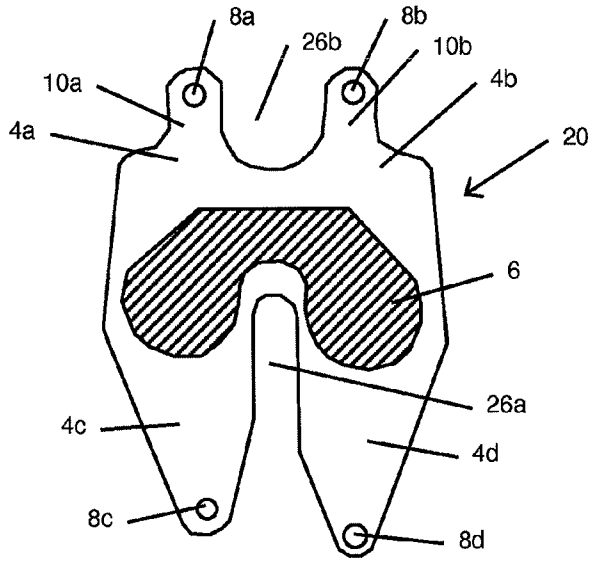

FIG. 1

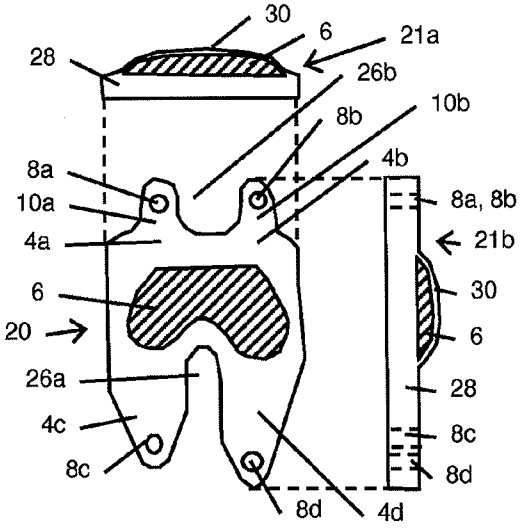

FIG. 2

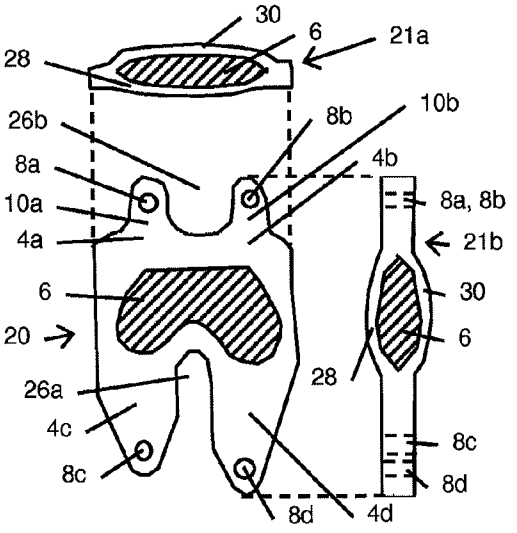

FIG. 3

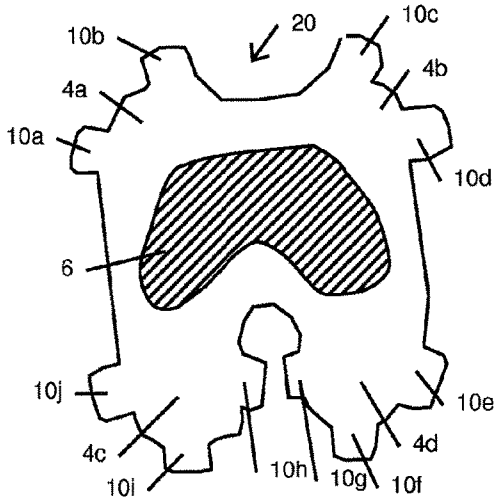

FIG 4A

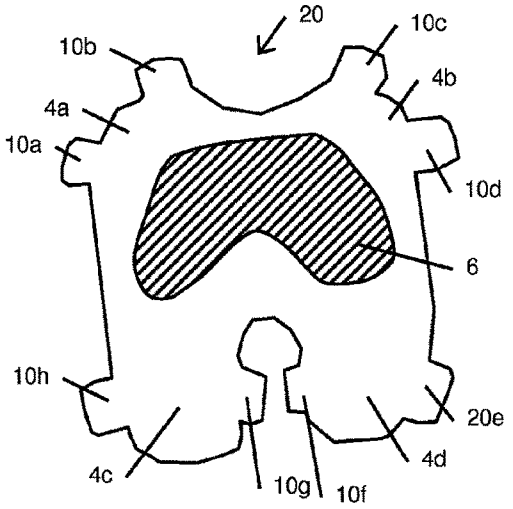

FIG 4B

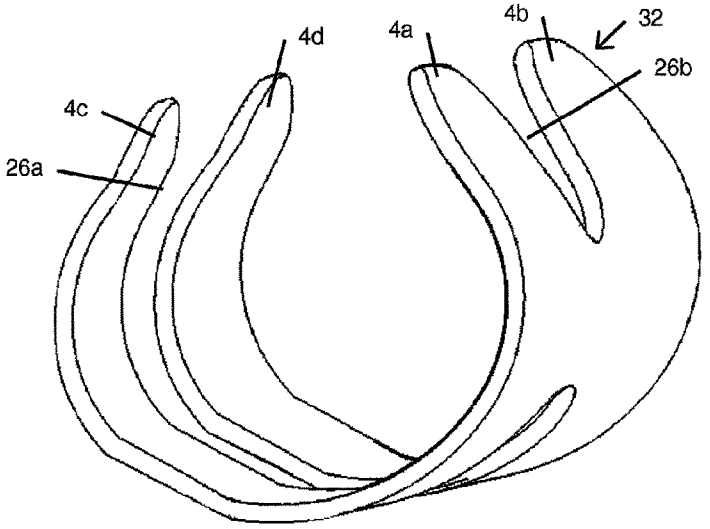

FIG 5

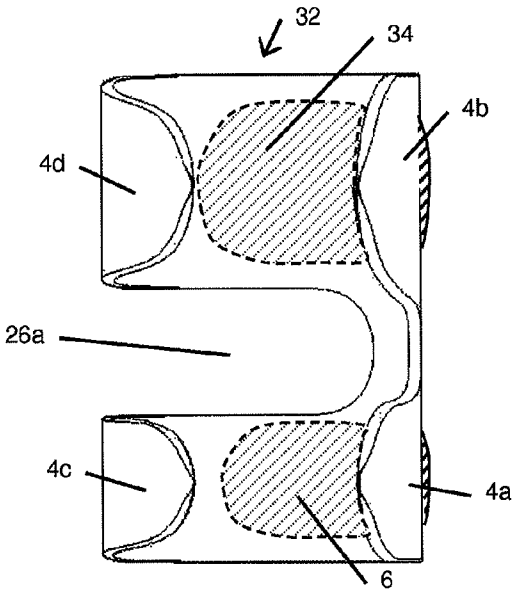

FIG 6A

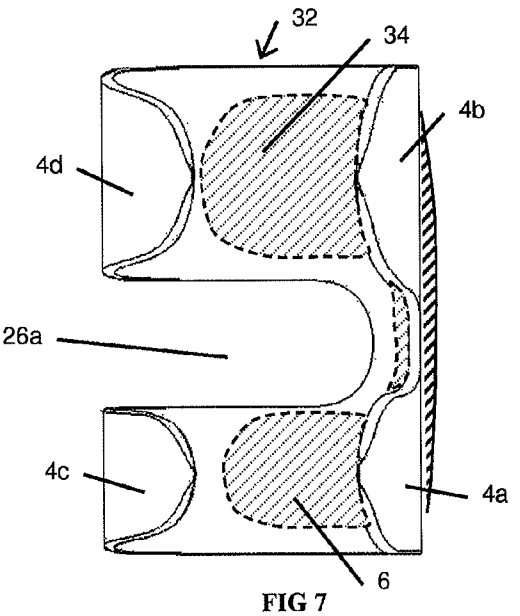

FIG 7

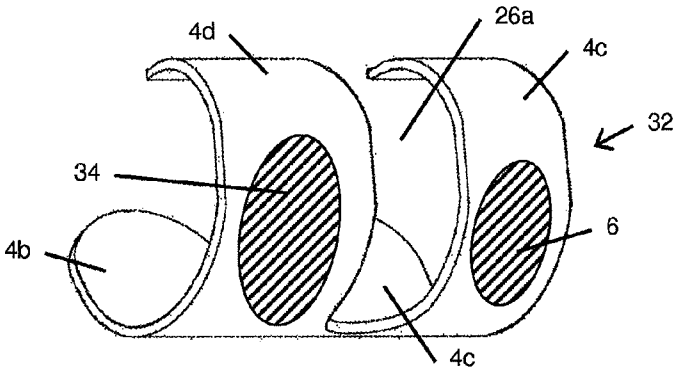

FIG 6B

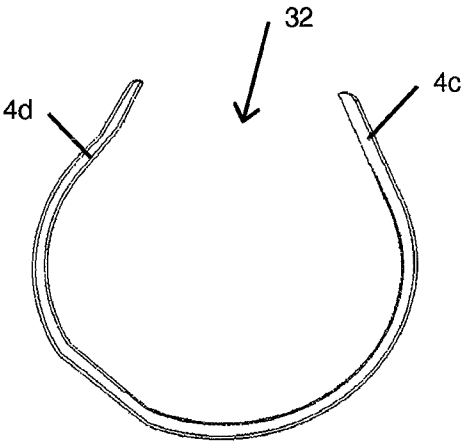

FIG 8

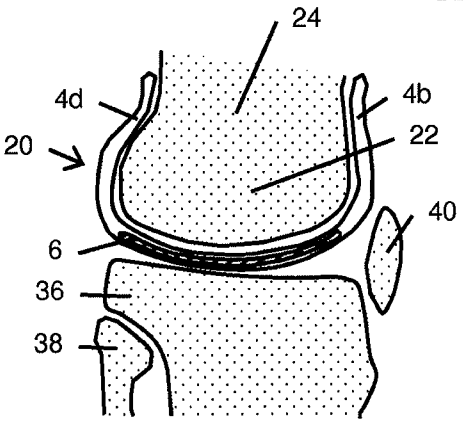

FIG 9A

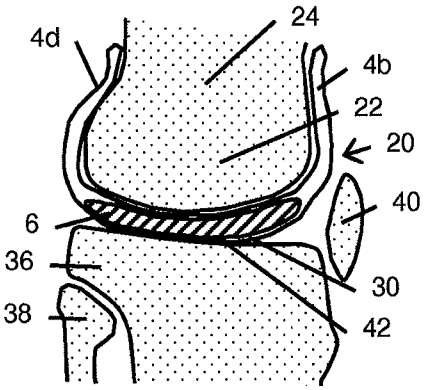

FIG 9B

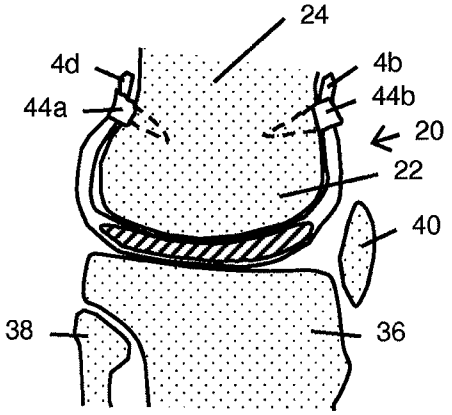

FIG 9C

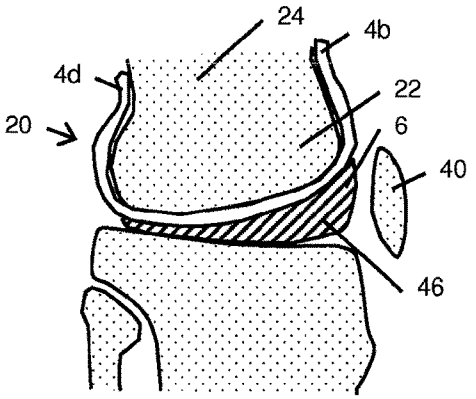

FIG 10A

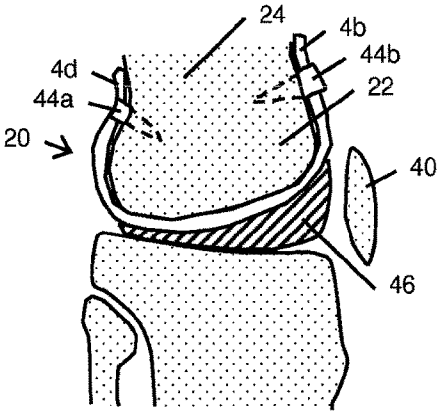

FIG 10B

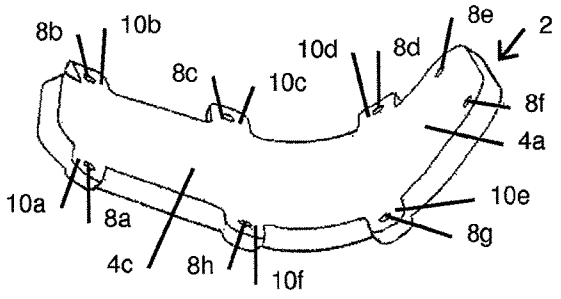

FIG 11A

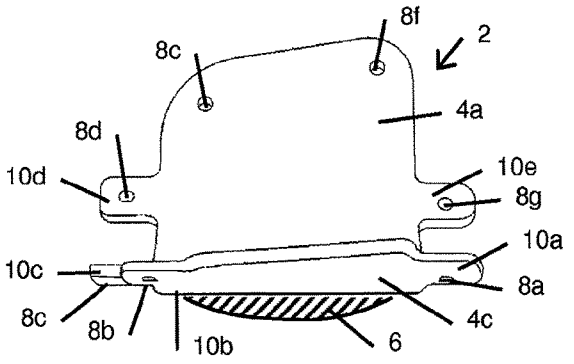

FIG 11B

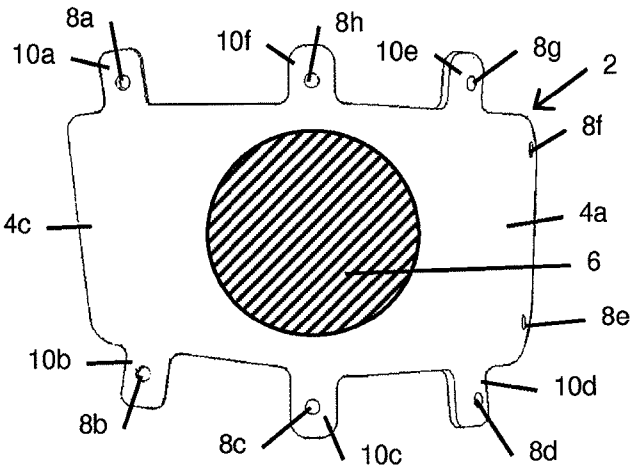

FIG 11C

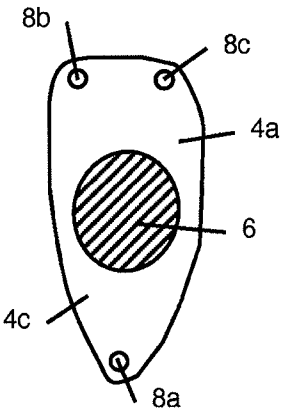

FIG 12A

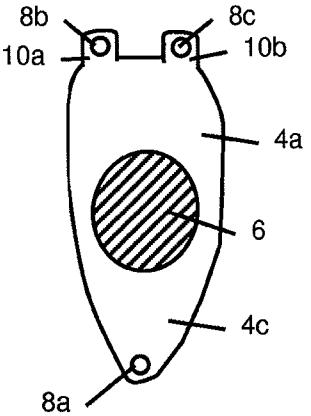

FIG 12B

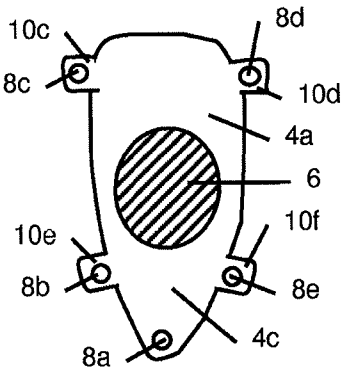

FIG 12C

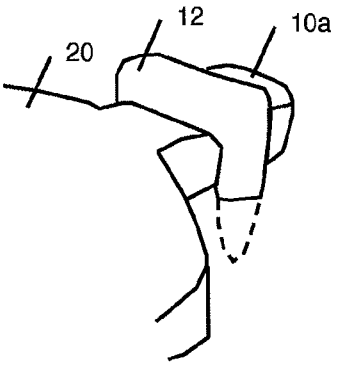

FIG 13A

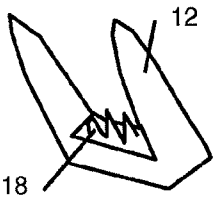

FIG 13B

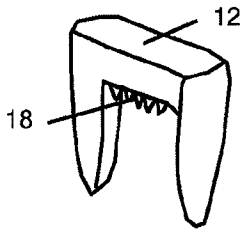

FIG 13C

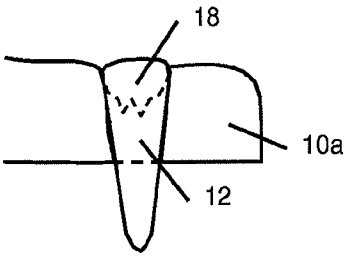

FIG 13D

RESILIENT KNEE IMPLANT AND METHODS

CROSS REFERENCE

This application is a divisional of U.S. patent application Ser. No. 14/289,431, filed on May 28, 2014, now U.S. Pat. No. 9,662,218, which is a continuation of U.S. patent application Ser. No. 13/574,499, filed on Oct. 8, 2012, now U.S. Pat. No. 8,771,363, which is a U.S. National Phase Entry of PCT Application No. PCT/US2011/021674, filed on Jan. 19, 2011, which claims the benefit of U.S. Provisional Application No. 61/297,698, filed on Jan. 22, 2010; the entire contents of each of the above listed patents and applications are incorporated herein by reference.

BACKGROUND OF THE INVENTION

This invention relates to arthroplasty, and more particularly, to an implant for use in arthroplasty when hyaline articular cartilage is damaged, it breaks down and joint space is lost. Inflammatory enzymes such as from the Cox-1, Cox-2 and/or 5-Lox systems, are released and loose bodies form adding to the degradation of joint function. Such joint damage is conventionally treated by physical therapy, analgesics, pain medication and injections. When these treatments fail, the traditionally accepted treatment option is arthroplasty implantation or replacing the joint with an artificial joint construct. Current arthroplasty techniques typically use "plastic and metal" implants that are rigid and which ultimately fail due to loosening or infection. Conventional materials for the artificial joint components include chrome-cobalt-molybdenum alloy (metal) and high molecular weight polyethylene (plastic). Each is often fixed by a cement-like mixture of methyl methacrylate to the ends of the bones that define the joint that is the subject of the arthroplasty, or coated with a surface that enables bone ingrowth. Replacement surgeries are known to fail in a number of years.

Conditions requiring arthroplasty include traumatic arthritis, osteoarthritis, rheumatoid arthritis, osteonecrosis, and failed surgical procedures.

SUMMARY OF THE INVENTION

The present invention is directed to an orthopedic implant configured for deployment between opposing members of a joint structure that addresses many of the shortcomings of prior artificial joints. The arthroplasty implants embodying features of the invention are configured to preserve joint motions while removing the pain and dysfunction following the development of arthritis or joint injury. The arthroplasty implant in accordance with the present invention achieves improved physiologic motion and shock absorption during gait and acts as a resilient spacer between moving bones during limb movement. The combined characteristics of the implant include anatomic design symmetry, balanced rigidity with variable attachment connections to at least one of adjacent normal structures, and durability which addresses and meets the needs for repair or reconstruction thus far missed in the prior art. The implant should be secured to at least one of the bones of the joint structure.

Provided herein is an implant configured for deployment between a femur and a tibia of a knee joint, the implant comprising a balloon comprising a first portion that is configured to engage a medial condyle and a lateral condyle of the femur of the knee joint, a second portion that is configured to engage the tibia of the knee joint, a side portion connecting the first portion and the second portion, in which the side portion facilitates relative motion between the first portion and the second portion, and an interior that is optionally inflatable with a first inflation medium; and a first appendage configured to couple the balloon to the femur of the knee joint.

In some embodiments, the implant comprises at least one attachment element in the intercondylar notch. In some embodiments, the implant comprises at least one attachment element superiorly at the distal end of the femur anteriorly. In some embodiments, the implant comprises at least one posterior reign configured to cinch up the implant from inside a posterior intercondylar notch toward a connection site around the femur. In some embodiments, the implant comprises at least one suture-like lanyard configured to cinch up the implant from inside a posterior intercondylar notch toward a connection site around the femur.

In some embodiments, the first portion comprises a first wall, the second portion comprises a second wall, and the side portion comprises a side wall.

In some embodiments, the implant comprises an inflation port in communication with the interior of the balloon for inflation of the interior of the balloon with the first inflation medium. In some embodiments, the interior comprises a plurality of inflatable chambers. In some embodiments, a first chamber of the plurality of individually inflatable chambers is adapted to be inflated with the first inflation medium, and a second chamber of the plurality of individually inflatable chambers is adapted to be inflated with a second inflation medium. In some embodiments, the first inflation medium imparts at least one of rigidity in the implant and cushion in the implant.

In some embodiments, the implant comprises a second appendage coupling the balloon to at least one of: the femur of the joint and the tibia of the joint.

Provided herein is an implant configured for deployment between a femur and a tibia of a knee joint, the implant comprising a balloon comprising a first portion that is configured to engage at least one condyle of the femur of the knee joint, a second portion that is configured to engage the tibia of the knee joint, a side portion connecting the first portion and the second portion, in which the side portion facilitates relative motion between the first portion and the second portion, and an interior that is optionally inflatable with a first inflation medium; and a first appendage configured to couple the balloon to the femur of the knee joint.

In some embodiments, the at least one condyle is the medial condyle. In some embodiments, the at least one condyle is the lateral condyle.

In some embodiments, the balloon is at least one of: at most about 1.5 cm in diameter, at most about 1.75 cm in diameter, at most about 2 cm in diameter, at most about 2.25 cm in diameter, at most about 2.5 cm in diameter, at most about 2.75 cm in diameter, at most about 3 cm in diameter, at most about 3.25 cm in diameter, at most about 3.5 cm in diameter, at most about 3.75 cm in diameter, at most about 4 cm in diameter, at most about 4.25 cm in diameter, at most about 4.5 cm in diameter, at most about 4.75 cm in diameter, at most about 5 cm in diameter, at most about 5.25 cm in diameter, at most about 5.5 cm in diameter, at most about 5.75 cm in diameter, at most about 6 cm in diameter, at most about 6.25 cm in diameter, at most about 6.5 cm in diameter, at most about 6.75 cm in diameter, at most about 7 cm in diameter, at most about 7.25 cm in diameter, at most about 7.5 cm in diameter, at most about 7.75 cm in diameter, at most about 8 cm in diameter, at most about 3 cm in length

along the longest length of the balloon, at most about 3.25 cm in length along the longest length of the balloon, at most about 3.5 cm in length along the longest length of the balloon, at most about 3.75 cm in length along the longest length of the balloon, at most about 4 cm in length along the longest length of the balloon, at most about 4.25 cm in length along the longest length of the balloon, at most about 4.5 cm in length along the longest length of the balloon, at most about 4.75 cm in length along the longest length of the balloon, at most about 5 cm in length along the longest length of the balloon, at most about 5.25 cm in length along the longest length of the balloon, at most about 5.5 cm in length along the longest length of the balloon, at most about 5.75 cm in length along the longest length of the balloon, at most about 6 cm in length along the longest length of the balloon, 6.25 cm in length along the longest length of the balloon, at most about 6.5 cm in length along the longest length of the balloon, at most about 6.75 cm in length along the longest length of the balloon, at most about 7 cm in length along the longest length of the balloon, at most about 7.25 cm in length along the longest length of the balloon, at most about 7.5 cm in length along the longest length of the balloon, at most about 7.75 cm in length along the longest length of the balloon, and at most about 8 cm in length along the longest length of the balloon.

In some embodiments, the first portion comprises a first wall, the second portion comprises a second wall, and the side portion comprises a side wall.

In some embodiments, the implant comprises an inflation port in communication with the interior of the balloon for inflation of the interior of the balloon with the first inflation medium. In some embodiments, the interior comprises a plurality of inflatable chambers. In some embodiments, a first chamber of the plurality of individually inflatable chambers is adapted to be inflated with the first inflation medium, and a second chamber of the plurality of individually inflatable chambers is adapted to be inflated with a second inflation medium. In some embodiments, the first inflation medium imparts at least one of rigidity in the implant and cushion in the implant.

In some embodiments, the implant comprises a second appendage coupling the balloon to at least one of: the femur of the joint and the tibia of the joint. In some embodiments, the implant comprises at least one attachment element in the intercondylar notch. The In some embodiments, the implant comprises at least one attachment element superiorly at the distal end of the femur anteriorly. In some embodiments, the implant comprises at least one posterior reign configured to cinch up the implant from inside a posterior intercondylar notch toward a connection site around the femur. In some embodiments, the implant comprises at least one suture-like lanyard configured to cinch up the implant from inside a posterior intercondylar notch toward a connection site around the femur.

Provided herein is an implant configured for patch a defect of a bone of a knee joint, the implant comprising a balloon configured to engage the defect of the bone of the knee joint and comprising an interior that is optionally inflatable with a first inflation medium; and a first appendage configured to couple the balloon to the bone of the knee joint.

In some embodiments, at least one of the appendage and the balloon are configured to replace cartilage.

In some embodiments, the balloon is at least one of: at most about 0.5 cm in diameter, at most about 0.75 cm in diameter, at most about 1 cm in diameter, at most about 1.25 cm in diameter, at most about 1.5 cm in diameter, at most about 1.75 cm in diameter, at most about 2 cm in diameter, at most about 2.25 cm in diameter, at most about 2.5 cm in diameter, at most about 2.75 cm in diameter, at most about 3 cm in diameter, at most about 3.25 cm in diameter, at most about 3.5 cm in diameter, at most about 3.75 cm in diameter, at most about 0.5 cm in length along the longest length of the balloon, at most about 0.75 cm in length along the longest length of the balloon, at most about 1 cm in length along the longest length of the balloon, at most about 1.25 cm in length along the longest length of the balloon, at most about 1.5 cm in length along the longest length of the balloon, at most about 1.75 cm in length along the longest length of the balloon, at most about 2 cm in length along the longest length of the balloon, at most about 2.25 cm in length along the longest length of the balloon, at most about 2.5 cm in length along the longest length of the balloon, at most about 2.75 cm in length along the longest length of the balloon, at most about 3 cm in length along the longest length of the balloon, at most about 3.25 cm in length along the longest length of the balloon, at most about 3.5 cm in length along the longest length of the balloon, at most about 3.75 cm in length along the longest length of the balloon, and at most about 4 cm in length along the longest length of the balloon.

In some embodiments, the size of the balloon size is pre-set. In some embodiments, the balloon comprises multiple chambers which may be selectively inflated. In some embodiments, the balloon comprises multiple chambers which may be selectively deflated. In some embodiments, the balloon comprises multiple chambers which may be selectively inflated in situ to fill the defect. In some embodiments, the balloon comprises multiple chambers which may be selectively inflated just prior to implantation.

In some embodiments, the balloon or a chamber thereof may be secondarily inflated, deflated, or a combination thereof in situ.

In some embodiments, the implant comprises an ingrowth matrix on at least a portion of the implant adjacent the femur. In some embodiments, the ingrowth matrix comprises living chondrocytes. In some embodiments, the implant is configured to release the chondrocytes over time. In some embodiments, the implant comprises a bioabsorbable polymer configured to release the chondrocytes over time. In some embodiments, the implant comprises a polymer configured to release the chondrocytes over time, wherein the polymer is not bioabsorbable. In some embodiments, the ingrowth matrix comprises at least one of: autologous cells, allograph cells, and xenograph cells to restore an articular surface of the femur. In some embodiments, the ingrowth matrix comprises at least one of: autologous cells, allograph cells, and xenograph cells to repair an articular surface of the femur.

In some embodiments, the implant comprises couplers that couple the appendage to the femur. In some embodiments, the coupler is bioabsorbable. In some embodiments, the coupler is at least one of: a screw, a washer, a suture, a suture anchor, a rivot, a staple, a staple having teeth, a stabilizer, a glue, a hook, a wire, a string, a lasso, a lanyard, a spike, and combinations thereof. The implant may also and/or alternatively be attached via bone ingrowth.

In some embodiments, the implant comprises a pharmacologic agent. In some embodiments, the pharmacologic agent is on a surface of the implant adjacent the femur. In some embodiments, the pharmacologic agent is released from the implant over time. In some embodiments, the pharmacologic agent is released from within the implant over time. In some embodiments, the pharmacologic agent is released from within the balloon over time.

In some embodiments, the inflation medium is compressible. In some embodiments, the inflation medium comprises a viscolubricant. In some embodiments, the inflation medium comprises an NSAID. In some embodiments, the inflation medium comprises chondrocytes.

In some embodiments, at least a portion of the implant is configured to anneal to a periphery of a cartilage defect.

In some embodiments, the implant comprises vacuoles of pharmacologic substances. In some embodiments, the vacuoles may be on a bone-engaging portion of the implant. In some embodiments, the implant comprises bubbles comprising an active substance such as a pharmacologic substance or other active agent. In some embodiments, the active agent comprises at least one of: stem cells, growth factors, antibiotics, and viscolubricants. In some embodiments, the active agent comprises iatrigenically gene mutated cells.

In some embodiments, the implant comprises enzyme absorptive microscopic sponges that could be sucked out or evacuated at or around the time of implant delivery to the joint.

In some embodiments, the implant comprises spaces filled with an active substance such as a pharmacologic substance or other active substance. In some embodiments, the implant is configured to deliver by dissolution of the implant material In some embodiments, the implant is configured to deliver by release through pores of the implant. In some embodiments, the implant is configured to deliver by fracture of a vacuole by a catalyst such as ultrasound or pressure or other fracturing catalyst.

In some embodiments, the implant is configured to at least one of: pad cartilage, cushion the joint, deliver a pharmacologic substance, remove noxious enzymes, debride upon implantation, debride the joint following implantation, deliver a therapeutic substance, deliver a biologic substance, and deliver living stem cells. In some embodiments, the implant is configured to deliver a chemotherapeutic agent to a bone or other surrounding tissues. In some embodiments, the implant is configured to deliver an anti-infectious medication to a bone or other surrounding tissues. In some embodiments, the implant is configured to deliver at least one of an antibiotic, antifungals, and analgesics agent.

In some embodiments, the implant is configured to be selectively inflated to realign limbs.

Provided herein is a method comprising: implanting a knee implant as described herein into a subject, wherein the implant reverses arthritis in the subject.

Provided herein is a method comprising: implanting a knee implant as described herein into a knee joint of a subject and treating a component of the knee joint of the subject with at least one of an allograph tissue, an autograph tissue, and an xenograph tissue. In some embodiments, the implanting step is at least one of: prior to the treating step, simultaneous with the treating step, and following the treating step.

Provided herein is a method comprising: implanting a knee implant as described herein into a subject, wherein the implant at least one of: restores joint function and controls arthropathies. In some embodiments, the implanting spares existing anatomy.

Provided herein is a method comprising: debriding a femur condyle of a knee joint of a subject, and implanting a knee implant as described herein into the knee joint of the subject, whereby the implant is configured to anneal to the cartilage of the subject. In some embodiments, the debriding is achieved by steam application.

Provided herein is a method comprising implanting a knee implant as described herein into a joint previously treated with a joint replacement. In some embodiments, the method comprises removing the joint replacement prior to implanting the knee implant. In some embodiments, the method comprises clearing infectious matter from the joint and/or surrounding tissues. In some embodiments, the method comprises implanting a second implant of any implant described herein following removing the implant previously implanted in the joint. In some embodiments, the method comprises replacing the joint of the subject following removing the implant previously implanted in the joint. In some embodiments, the method comprises debriding the bone of the joint, and implanting an implant of any implant described herein. In some embodiments, the method comprises repeating the debriding and implanting steps.

These and other advantages of the invention will become more apparent from the following detailed description and the attached exemplary drawings.

INCORPORATION BY REFERENCE

All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

FIG. **1** depicts an embodiment of the knee implant having appendages including holes and tabs extending from a balloon and including slots to accommodate ligaments of the knee joint.

FIG. **2** depicts an embodiment of the knee implant having appendages including holes and tabs extending from a balloon and including slots to accommodate ligaments of the knee joint as well as side views of the same knee implant.

FIG. **3** depicts an embodiment of the knee implant having appendages including holes and tabs extending from a balloon and including slots to accommodate ligaments of the knee joint as well as side views of the same knee implant.

FIG. **4**A depicts an embodiment of the knee implant having appendages including ten tabs extending from a balloon and including a slot to accommodate components of the knee joint.

FIG. **4**B depicts an embodiment of the knee implant having appendages including eight tabs extending from a balloon and including a slot to accommodate components of the knee joint.

FIG. **5** depicts an embodiment of the knee implant curved to simulate curvature about the condyles of a femur, the implant having appendages extending from an uninflated balloon (not shown) and including slots to accommodate ligaments of the knee joint.

FIG. **6**A depicts a top-down view of an embodiment of the knee implant curved to simulate curvature about the condyles of a femur, the implant having appendages extending from two inflated balloons and including slots to accommodate components of the knee joint.

FIG. **6**B depicts a bottom-up view of an embodiment of the knee implant curved to simulate curvature about the condyles of a femur, the implant having appendages extending from two inflated balloons and including slots to accommodate components of the knee joint.

FIG. **7** depicts a top-down view of an embodiment of the knee implant curved to simulate curvature about the condyles of a femur, the implant having appendages extending from an inflated balloon and including slots to accommodate components of the knee joint.

FIG. **8** depicts a side view of an embodiment of the knee implant curved to simulate curvature about at least one condyle of a femur, the implant having appendages extending from an uninflated balloon (not shown).

FIG. **9**A depicts a side view of an embodiment of the knee implant curved about at least one condyle of a femur, the implant having appendages extending from an uninflated or minimally inflated balloon.

FIG. **9**B depicts a side view of an embodiment of the knee implant curved about at least one condyle of a femur, the implant having appendages extending from an inflated balloon.

FIG. **9**C depicts a side view of an embodiment of the knee implant curved about at least one condyle of a femur, the implant having appendages extending from an inflated balloon and having staples or screws coupling the appendages to the femur.

FIG. **10**A depicts a side view of an embodiment of the knee implant curved about at least one condyle of a femur, the implant having appendages extending from an inflated balloon and showing the inflation medium moved anteriorly toward the patella when the knee joint is flexed. FIG. **10**B depicts a side view of an embodiment of the knee implant curved about at least one condyle of a femur, the implant having appendages extending from an inflated balloon and having staples or screws coupling the appendages to the femur and showing the inflation medium moved anteriorly toward the patella when the knee joint is flexed.

FIG. **11**A depicts an embodiment of the unicompartment knee implant curved to simulate curvature about one condyle of a femur, the implant having appendages extending from an uninflated balloon (not shown) and including tabs and holes which may be used with couplers to couple the implant to the femur of the knee joint.

FIG. **11**B depicts an embodiment of the unicompartment knee implant curved to simulate curvature about one condyle of a femur, the implant having appendages extending from an inflated balloon and including tabs and holes which may be used with couplers to couple the implant to the femur of the knee joint.

FIG. **11**C depicts a bottom-up view of an embodiment of the unicompartment knee implant curved to simulate curvature about one condyle of a femur, the implant having appendages extending from an inflated balloon and including tabs and holes which may be used with couplers to couple the implant to the femur of the knee joint.

FIG. **12**A depicts a bottom-up view of an embodiment of the unicompartment knee implant or patch implant, the implant having appendages, extending from a balloon and including holes, which may be used with couplers (not shown) to couple the implant to the femur of the knee joint.

FIG. **12**B depicts a bottom-up view of an embodiment of the unicompartment knee implant or patch implant, the implant having appendages, extending from a balloon and including tabs and a hole which may be used with couplers (not shown) to couple the implant to the femur of the knee joint.

FIG. **12**C depicts a bottom-up view of an embodiment of the unicompartment knee implant or patch implant, the implant having appendages, extending from a balloon and including tabs and a hole which may be used with couplers (not shown) to couple the implant to the femur of the knee joint.

FIGS. **13**A-**13**D depict multiple views of a staple adapted to couple an implant to a bone of the joint.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is directed to arthroplasty implants and procedures for a knee.

Knee interpositional arthroplasty can replace existing total joint metal/plastic technology. It intends to fill the gap (literally in some embodiments of the implant) in cases where arthroscopic debridement fails to provide cure, since we can only 'polish arthritis' and 'clean up the joints' to date. The polymer medically inflatable implants may physiologically restore joint function. Padding is provided where cartilage is damaged, cushioning to both the femoral tibial and patella femoral joints when narrowed or pathologic. The implant in some embodiments is adapted to deliver cells, autologous (from the patient), allograph (from another member of the same species) or xenograph (from another species) that restore articular surfaces. Since cartilage is an immunologically privileged tissue, the antigens are buried in the cartilage matrix and antibodies do not reject the refurbished surface coating.

The gap (or gaps) filled by the balloon or balloons of the implant will provide compliance between opposing joint surfaces (the femoral condyle or condyles and tibial plateau). The femur may have some portion (of not all) of the retropatellar rounded facet "V" shape of hyaline, normally about 5 mm thick, or it may not have such hyaline when the implant is inserted. The tibial plateau may have some portion of meniscal fibrocartilages, including all of said fibrocartilages, none of said fibrocartilages, or some portion thereof. When the knee is extended (straight) the implant buffers the femoro-tibial joint. When the knee is flexed, the implant balloon apposition is more between the trochlear groove portion of the anterior distal femur (groove between the condyles on the 'front of the knee') and the patella.

The knee anatomy is unique to other joint anatomies and thus has a unique set of challenges that are addressed by the implant embodiments described herein. For example, the knee is not a ball and socket joint like a hip; it is a combination of two joints—the femoral-tibial joint and the patellar-femoral joint. The bones of the knee have facets and irregularities that must be accommodated by a conformable implant directed to the particular shapes of the bones without impeding the joints' functions and movements, and/or which minimizes impedence to such function and movement. Not only do the joints of the knee work together to allow extension and flexion of the knee, but the knee is also designed to allow rotational movement in a screw-like manner. That is, as the tibia is twisted relative to the femur, the joints are uniquely designed to allow this twist, but to limit the twist as well. Furthermore, the knee joints are able to withstand forces that vary depending on the particular movement of the individual, not only in force strength, but in direction as well. Thus, the implants as described herein are uniquely designed to account for these factors and result in a knee having preserved natural tissues as well as pre-

served function and movement as compared to typical arthroplasty procedures (such as partial or full knee replacements).

As described herein, embodiments of the implant conform to the patient's own joint features not only in that it can be pre-molded and/or adapted to couple to the contours of the patient's bone (condyle, etc), but in that it has a balloon having an inflation medium that is conformable to the joint anatomy and allow freedom of joint movement much like natural joint while preserving the joint and bone natural tissues as much as possible. With the ability to fill various chambers of the balloon with varying materials, and to add rigid and/or semi-rigid pieces to the implant, the implant can additionally have leveling capabilities and alignment capabilities.

Diagnoses:

Patients may complain of pain and knee joint dysfunction signaled by locking, clicking, or giving way. Knees may be swollen, maligned or show crepitus (palpable crunching on movement.) Instability of ligaments whether anterior/posterior cruciates, or medial/lateral conlaterals, are treated by techniques separate for those entities via allowance for healing (as for collaterals) or via cruciate repair or reconstruction.

Indications for use of implants provided herein may be those patients recognizing greater than or equal to 2 Sq cm of 3-4+/4 traumatic arthritis (ala Carticel). In such cases, the cartilage defect is often precisely locally symptomatic, with point tenderness, clicking if a loose cartilage flap exists, and may be visible on MRI and/or arthroscopic inspection and/or through palpation. The implants used herein may additionally and/or alternatively be appropriate when existed techniques such as 'picking', K wire drills, and/or allograph implants fail.

Patients with knee problems typically complain of pain and dysfunction. Pathognomonic symptoms for meniscal tearing include locking, clicking, giving way from wear or twisting the knee. Aching diffusely may arise from arthritis or synovitis; anterior knee pain is generally patella-femoral, increased with stair use due to magnified body weight forces. Diagnosis should be accurate as distinguished from pain through the knee actually arising in the back caused by L4 nerve root irritation. Physical Exam findings of pathologic knees include observed swelling, redness, or deformity. Palpation often aids focus on which compartments are involved. The patella inhibition test position connotes retropatellar pathology, and often tracking problems that warrant soft tissue or boney correct. Improved limb alignment will increase benefits, and can in part accrue from selective inflation of embodiments of the implants provided herein. X-rays of the knee are best evaluated in weight bearing views, and should be coupled with other data including MRI or CT. Relative compartment narrowing suggests cartilage degradation. Once an embodiment of an implant described herein has been successfully implanted and the knee adequately rehabilitated, the appearance of a knee with such implant should resemble a normal joint X-ray. Knee distension is from saline and/or air insufflation. Knee implant patients will benefit from tailored rehab programs, cautious weight bearing, early motion, and potential the use of constant passive motion machine regimens.

General Features

Implant Aspects

Provided herein is a resilient implant for implantation into knee joints to act as a cushion allowing for renewed joint motion. The implant may endure variable knee joint forces and cyclic loads while reducing pain and improving function after injury or disease to repair, reconstruct, and regenerate joint integrity. The implant may be deployed in a prepared debrided knee joint space, secured to at least one of the knee joint bones and expanded in the space, molding to surrounding structures with sufficient stability to avoid extrusion or dislocation. The implant may have has opposing walls that move in varied directions, and an inner space filled with suitable filler to accommodate motions which mimic or approximate normal knee joint motion. The implant may pad the damaged joint surfaces, restores cushioning immediately and may be employed to restore cartilage to normal by delivering regenerative cells.

Provided herein is a resilient interpositional arthroplasty implant for application into knee joints to pad cartilage defects, cushion joints, and replace or restore the articular surface, preserving joint integrity, reducing pain and improving function. The implant may endure variable knee joint compressive and shear forces, and millions of cyclic loads, after injury or disease requires intervention. The implant may repair, reconstruct, and regenerate knee joint anatomy in a minimally morbid fashion, with physiologic solutions that improve upon the rigid existing joint replacement alternatives of plastic and metal. In cases where cells have been used for joint resurfacing requiring massive periosteal harvesting for containment, the polymer walls of some embodiments of the implant can capture, distribute and hold living cells until aggregation and hyaline cartilage regrowth occurs. The implant may be deployed into a prepared debrided knee joint space, molding and conforming to surrounding structures with sufficient stability to avoid extrusion or dislocation. Appendages (or tabs) of the implant may serve to repair or reconstruct tendons or ligaments. The implant may have opposing walls that move in varied directions, and an inner space, singular or divided, filled with suitable gas, liquid, and/or complex polymer layers as force-absorbing mobile constituents, such than robust valid and reliable joint motion is enabled.

Provided herein is a resilient orthopedic implant configured for deployment between a femur and at least one second bone of a joint. The second bone may be a tibia. The second bone may be a patella. The implant further comprises a balloon comprising a first portion that is configured to engage the femur, a second portion that is configured to engage the second bone of the joint, a side portion connecting the first portion and the second portion, in which the side portion facilitates relative motion between the first portion and the second portion, and an interior that is optionally inflatable with a first inflation medium; and a first appendage configured to couple the balloon to the femur. The terms "balloon" and "bladder" may be used interchangeably throughout this disclosure to describe an implant having the features described herein.

In some embodiments, at least two of the first portion, the second portion, and the side portion are contiguous. In some embodiments, the first portion comprises a first wall, the second portion comprises a second wall, and the side portion comprises a side wall. As used herein, each of the terms the "first portion", the "second portion", and the "side portion" is used to describe a part of the balloon, and may not be separate parts in some embodiments. Rather, in some embodiments, each is named in order to indicate the general geometry and location of each portion relative to the other of the portions and/or relative to bones and/or ligaments and/or tendons of the joint. Likewise, as used herein, each of the terms the "first wall", the "second wall", and the "side wall" is used to describe a part of the balloon, and may not be separate parts of the balloon in some embodiments.

Rather, in some embodiments, each of the walls is named in order to indicate the general geometry and location of each portion relative to the other of the portions and/or relative to bones and/or ligaments and/or tendons of the joint. In some embodiments, at least two of first wall, the second wall, and the side wall are contiguous. Nevertheless, each of the walls may, in some embodiments, be separate parts of the implant that are joined to form the implant. Likewise, each of the portions may, indeed, in some embodiments, be separate parts of the implant that are joined to form the implant.

In some embodiments, the first portion is a term used interchangeably with the first wall. In some embodiments, the second portion is a term used interchangeably with the second wall. In some embodiments, the side portion is a term used interchangeably with the side wall. In some embodiments, a wall (whether a first wall, a second wall, and/or a side wall) of the implant may comprise a plurality of layers. The wall may comprise multiple materials to impart physical and/or therapeutic characteristics to the wall.

In some embodiments, the implant comprises a second appendage coupling the balloon to the first bone of the joint. In some embodiments, the implant comprises a second appendage coupling the balloon to at least one second bone of the joint. In some embodiments, the implant comprises a second appendage configured to couple at least one of the first portion, the second portion, and the side portion to at least one of the first bone and at least one second bone of the joint. In some embodiments, the first appendage and the second appendage are configured to provide ligamentary-like support to the first bone and the at least one second bone of the joint. In some embodiments, the first appendage and the second appendage are configured to provide ligamentary-like support to the joint. In some embodiments, the first appendage and the second appendage are configured to provide tendon-like support to the first bone and the at least one second bone of the joint. In some embodiments, the first appendage and the second appendage are configured to provide tendon-like support to the joint.

In some embodiments, the implant comprises an inflation port in communication with the interior of the balloon for inflation of the interior of the balloon with the first inflation medium. In some embodiments, the balloon is punctured to inflate the interior of the balloon hi the first inflation medium. In some embodiments, the balloon is self-sealing. In some embodiments, the balloon is self-sealing upon inflation of the interior of the balloon with the first inflation medium. In some embodiments, the implant comprises a seal capable of closing the interior of the balloon.

In some embodiments, the interior comprises a plurality of inflatable chambers. In some embodiments, the interior comprises a plurality of individually inflatable chambers. In some embodiments, a first chamber of the plurality of individually inflatable chambers is adapted to be inflated with the first inflation medium, and a second chamber of the plurality of individually inflatable chambers is adapted to be inflated with a second inflation medium.

In some embodiments, the interior comprises a honeycomb structure. In some embodiments, the interior comprises a mesh structure. In some embodiments, the interior comprises a sponge structure.

In many embodiments the implant (or a portion thereof, such as the balloon or balloons) is a weight bearing spacer that will allow joint motions to approach normal, whether filling the space left by an entirely collapsed joint bone or the space of ablated cartilage proximate surfaces diffusely as in osteoarthritis or succinctly as in osteonecrotic defects or localized trauma. The walls of the implant may be used as a membrane for holding living cells in proximity of the osteochondral defect long enough for the cells to attach (e.g. 24 hours) or to deeply adhere (up to 28 days) or return to normal (up to one year). Weight bearing will be expected to increase as distal lower extremity joints are treated.

Movement (whether linear or curvilinear) between the first and second walls of the implant (i.e. of the balloon) as a result of movement of the femur and the tibia is illustrated in the comparison between FIGS. **9**B and **10**A, or in the comparison between FIGS. **9**C and **10**B. In some embodiments, the implant may comprise a balloon that is configured to allow a wall of the implant rolling upon another wall (or the same wall) of the implant (e.g. the side wall rolling upon the first wall, the first wall rolling upon the second wall, the second wall rolling upon the first wall, the first wall rolling upon the side wall, the second wall rolling upon the side wall, the side wall rolling upon the second wall, the first wall rolling upon the first wall, the second wall rolling upon the second wall, and/or the side wall rolling upon the side wall). In some embodiments, the implant may comprise a balloon that is configured to allow a portion of the implant rolling upon another portion (or the same portion) of the implant (for non-limiting example, the side wall rolling upon an appendage, the first wall rolling upon an appendage, and/or the second wall rolling upon an appendage). In some embodiments, the implant may comprise a balloon that is configured to allow movement of a portion of the implant rolling upon cartilage. While not shown in the drawings, there may be slippage between the a portion of the implant (whether an appendage, a wall, or some other portion of the implant) and a joint component (whether a bone, ligament, tendon or other tissue). This slippage may be in addition to wall movements within the implant per se to provide desired joint movements. While not shown in the drawings, there may be slippage between the second bone (for example, the tibia) and the second wall in addition to wall movements within the implant per se to provide desired joint movements. The appendage (or appendages) is (are) designed to secure the implant to the knee joint structure so as to avoid dislocation of the implant. Movement of the joint with the implant in place will be a shared function of both the moving opposing walls of the implant but also a function of the movement of the wall which may be less attached to the joint members. There may be slight movement between the appendage, first wall and the femur. The walls of the balloon may compress and/or stretch to accommodate bone interface movement. Material choices, material dimensions, and implant dimensions, placement and/or coupling may be chosen to allow for the desired amount of compression, stretching relative movement of various joint and/or implant components. For non-limiting example, the walls of the implant may be thicker is some areas to accommodate particular loads and the side wall may be thinner and more elastic to accommodate rolling and stretching thereof.

Motion is believed to be primarily between the spaced walls (or portions) of the implant peripherally secured to joint structures, although some motion may occur between the implant and the joint surfaces. As shown multiple Figures (including, FIGS. **1**-**7**), the implant may be provided with a slot extending from the periphery of the implant toward the balloon of the implant to accommodate at least one ligament of the joint. Knee implants may have two slots leading to separate passages for receiving the anterior and posterior cruciate ligaments. Implant walls should have sufficient inherent flexibility to mold to the existing deformities imposed by either natural ligament, bone, tendon and remaining cartilage deformities of the internal joint space

filled as a cushion. The wall exteriors may be flat or formed with random or specific patterns for purposes of glide or trends for traction against adjacent surfaces, or as sulci or venues for cell delivery materials.

The exterior of the implant may have a mesh material with a plurality of chords (or appendages) for securing the implant to adjacent bones or to remnant ligaments which are attached to adjacent bones.

The dimensions of the various implant walls will vary depending upon the material properties thereof as well as the needs for a particular joint. Additionally, the first and second walls may require a thickness different from the side wall. Generally, the implant may have a wall thicknesses of about 0.125 mm to about 3 mm, preferably about 0.5 mm to about 1.5 mm. The spacing between the first and second wall within the interior can vary from about 0.5 mm to about 5 mm.

In some embodiments, the implant has a first wall, a second wall, and a side wall which define the implant interior (or interior) which contains filling material. In some embodiments, the filling material is an inflation medium. The first wall is secured to the end of the femur by at least one appendage that extends from the first wall and the second wall engages the end surface of the second bone (which in the case of a femoral-tibial joint implant, would be the tibia) and may also be secured thereto. The side wall extending between the first and second walls defines at least in part the implant interior which is filled with filling material (or an inflation medium). The inner surfaces of wall and appendage may conform to the particular surface femur, for example by being wider in particular locations and/or longer in particular areas. For example a dual compartment implant (described herein) may have a wider section to cover the medial condyle than the lateral condyle (as shown in FIGS. **1**, **2**, **3**, **6**A, **6**B, and **7**). In another example, the length of the implant the along the external edge may be longer than the length of the implant along the trochlear groove edge (as shown in FIGS. **11**A, **11**B and **11**C). In yet another example, the width may vary along a single condyle, such as is shown in FIGS. **12**A-**12**C, wherein the wider edge of the implant is adapted to fit over at least a portion of the anterior condyle, and the narrower portion is adapted to fit over at least a portion of the posterior condyle. In some embodiments, the inner surfaces of the first wall and appendages preferably conform to the particular surface of the patient's femur, and do so by not only dimensions of the implant (lengths, widths, balloon location and shape), but also and/or alternatively due to appendage and/or tab and/or hole and/or coupler location and/or surface contours of the first wall. The outer surface of the second wall may be configured to conform to the end surface of the second bone (which may be a tibia or a patella, for example). In some embodiments, the outer surface of the second wall is configured to conform to a surface of the second bone (which may be a tibia or a patella, for example). The figures provided herein are highly schematic and do not depict details of the joint surface features, since human pathology and variation reflects both the patient's immediate and evolving pathophysiology. Neither do the figures depict other joint features such as cartilage, tendons, ligaments and other soft tissues and fluids of the joint for ease of viewing that which is depicted.

In some embodiments, the implant is configured to resemble the shape of the natural hyaline of a normal knee. For example, the normal hyaline is typically "H" shaped, thus certain embodiments of the implant are generally "H" shaped.

Implant Materials and Material Features

In some embodiments, the implant comprises polymer. Polymers may comprise at least one of: a polyurethane (such as, for example, ChronoFlex AR), a polycarbonate urethane, a thermoplastic polycarbonate urethane (such as Bionate 55), ethylene-vinyl acetate copolymer, multiblock copolymers of poly(ethylene oxide) (PEO) and poly(butylene terephthalate) (PBT), PEG, PEO, and a polyetheylene. In some embodiments the implant comprises a 125 micron thickness thermoplastic polycarbonate urethane.

The implant may comprise to a plurality of layers of polymer (such as ChronoFlex AR) in a solvent and evaporating the solvent after applying each layer. In some embodiments, the implant comprises a polyurethane that is sprayed and dried (wherein the spraying and drying is repeated at least once) to a desired thickness.

In some embodiments, the implant is created by dip molding a mandrel having a shape of a bone of the knee joint (the medial condyle, the lateral condyle, the tibia, for non-limiting example) into a polymer solution (for non-limiting example, a urethane polymer such as Chronoflex). Following each dip, the implant is dried for a specified time, which may be, for example, about 3 seconds, about 4 seconds, about 5 seconds, about 6 seconds, about 7 seconds, about 8 seconds, about 9 seconds, about 10 seconds, about 15 seconds, about 20 seconds, about 25 seconds, about 30 seconds, about 45 seconds, about 1 minute, about 2 minutes, about 5 minutes, about 10 minutes, about 15 minutes, and over about 15 minutes. The term "about" used herein in reference to drying time of the implant can mean variations of at least one of 5%, 10%, 25%, and 50%. In some embodiments, no drying step is used. The dipping may be repeated multiple times. In some embodiments a single dip is sufficient. In some embodiments, the dipping is repeated 2 times. In some embodiments, the dipping is repeated 3 times. In some embodiments, the dipping is repeated 4 times. In some embodiments, the dipping is repeated 5 times. In some embodiments, the dipping is repeated 6 times. In some embodiments, the dipping is repeated 7 times. In some embodiments, the dipping is repeated 8 times. In some embodiments, the dipping is repeated 9 times. In some embodiments, the dipping is repeated 10 times. In some embodiments, the dipping is repeated 11 times. In some embodiments, the dipping is repeated 12 times. In some embodiments, the dipping is repeated 13 times. In some embodiments, the dipping is repeated 14 times. In some embodiments, the dipping is repeated 15 times. In some embodiments, the dipping is repeated 16 times. In some embodiments, the dipping is repeated 17 times. In some embodiments, the dipping is repeated 18 times. In some embodiments, the dipping is repeated 19 times. In some embodiments, the dipping is repeated 20 times. In some embodiments, the dipping is repeated 21 times. In some embodiments, the dipping is repeated 22 times. In some embodiments, the dipping is repeated 23 times. In some embodiments, the dipping is repeated 24 times. In some embodiments, the dipping is repeated 25 times. In some embodiments, the dipping is repeated over 25 times. In some embodiments, the dipping is repeated a sufficient number of times to create an implant that is a prescribed thickness. The thickness may vary depending on the polymer and depending on the embodiment of the implant. The thickness may be at least one of: about 25 microns thick, about 50 microns thick, about 100 microns thick, about 125 microns thick, about 150 microns thick, about 200 microns thick, about 250 microns thick, about 300 microns thick, about 350 microns thick, about 400 microns

thick, about 25-50 microns thick, about 50-100 microns thick, about 50-200 microns thick, about 100-150 microns thick, about 150-300 microns thick, about 100-300 microns thick, about 100-500 microns thick, about 200-500 microns thick, and about 200-1000 microns thick. The term "about" used herein in reference to thickness of the implant can mean variations of at least one of 5%, 10%, 25%, and 50%. The thickness may vary at different locations of the implant. In some embodiments, the implant is fabricated in two pieces, one or more of which is molded to form an interior when the two pieces are put together. In some embodiments, the implant is filled by puncturing the implant wall and sealing the puncture hole with a plug, patch or other sealant. The plug, patch, or other sealant may comprise Chronoflex material, for non-limiting example. The plug, patch, or other sealant may comprise the same material from which the implant is constructed, for non-limiting example.

The walls of the implant embodying features of the invention may be composite structures. For example, the innermost layer may be impervious to preclude escape of inflation or other filling media, a central layer may be porous or otherwise contain treatment or cell regeneration agents, and the outer layer may be a thin, but strong layer of a thermoplastic, such as a thermoplastic polyurethane for non-limiting example, which has microporosity sufficient to allow passage or egress of treatment or cell regeneration agents from the central layer (or second layer). The degree of microporosity to enable egress of treatment or cell regeneration agents from the central layer is found in polymer layers such as Chronoflex or Bionate 55.

The external wall (and/or the bone engaging surface) of the implant may be coated and/or impregnated with a latticework of polymer that is surface sprayed or layered on the outside (or bone engaging surface) of the implant to promote cartilage tissue regeneration. This most external surface coating may contain living chondrocytes (for example, as is provided in the Carticel procedure by the Genzyme company), and/or may contain stem cells with directed gene mutations to enhance adherence of the coating to the implant. The bone engaging surface may comprise peaks and troughs. The living cells may be imposed in between (and/or provided in the) troughs of the implant surface while the surface areas of prominence (the peaks of the surface) may be used for at least one of: space validation, traction, and cell protection.

The implant may be formed of suitable bioabsorbable materials so that the implant may be absorbed within a particular predetermined time frame. Suitable bioabsorbable materials include polylactic acid, polyglycolic acid, polycaprolactone, copolymers, blends and variants thereof. Suitable bioabsorbable materials may also/alternatively include poly(hydroxyalkanoate)s of the PHB-PHV class, additional poly(ester)s, and natural polymers, particularly, modified poly(saccharide)s, e.g., starch, cellulose, and chitosan. The walls of the implant may be (in whole and/or in part) bioabsorbable. The balloon may be (in whole and/or in part) bioabsorbable. As used herein the terms bioabsorbable, bioerodable, and/or bioabsorbable may be used interchangeably. The walls of the implant may release a pharmaceutical agent or an biological agent (such as stem cells, living chondrocytes, gene therapies, and the like). The release of such agents (whether biological or pharmaceutical, or a combination thereof) may occur over time, as the wall of the implant (or as the balloon) bioabsorbs in some embodiments, or as the joint is used (i.e. through pressure, for non-limiting example). In some embodiments, at least one of the implant walls is permeable to a pharmaceutical agent and/or a biological agent, such as in an embodiment wherein the inflation medium comprises the pharmaceutical agent and/or biological agent. In some embodiments, at least one of the implant walls has pores through which the pharmaceutical agent and/or the biological agent may fit, such as in an embodiment wherein the inflation medium comprises the pharmaceutical agent and/or biological agent.

The implant may be provided with latticework or other reinforcing strands, preferably on the exterior or within the wall thereof to control the maximum expansion of the implant when deployed at the orthopedic site.

In some embodiments, the implant comprises amniotic membrane (and/or a component thereof). In some embodiments, the implant comprises amniotic sac (and/or a component thereof). In some embodiments, the implant comprises amniotic tissue (and/or a component thereof). Amniotic membrane (and/or sac and/or tissue) is unique in that its mechanical properties include that it slippery on one side (lubricious, low modulus of elasticity) and sticky (adherent) on the other. In some embodiments, at least one of the first wall, the second wall and the side wall comprise amniotic membrane or a component thereof. In some embodiments, at least one of the first wall, the second wall and the side wall comprise amniotic sac or a component thereof. In some embodiments, at least one of the first wall, the second wall and the side wall comprise amniotic tissue or a component thereof. The amniotic membrane and/or amniotic sac and/or amniotic tissue may be used in conjunction with other biologic agents, pharmaceutical agents, and/or therapeutic agents. Amniotic tissue is used extensively in pluripotential cells. It qualifies as HTBP (Human Tissue Based Product) because of the short term time span on the product and origin.

In some embodiments, the balloon is a composite structure. In some embodiments, the balloon comprises layers of porous and/or non-porous materials, or otherwise contain treatment or cell regeneration agents. In some embodiments, a first layer of the balloon is a thin, but strong layer of a thermoplastic, such as a thermoplastic polyurethane, for non-limiting example, which has microporosity sufficient to allow passage or egress of treatment or cell regeneration agents from a second layer. The second layer may be a central layer (which lies between the first layer and a third layer or a fourth layer or more layers). The first layer may comprise a bone engaging surface in some embodiments. The degree of microporosity to enable egress of treatment or cell regeneration agents from the second layer is found in polymer layers such as Chronoflex or Bionate 55. The bone engaging surface of the implant may be coated and/or impregnated with a latticework of polymer that is surface sprayed or layered on the bone engaging surface of the implant to promote cartilage tissue regeneration. This bone engaging surface coating may contain living chondrocytes (for example, as is provided in the Carticel procedure by the Genzyme company), and/or may contain stem cells with directed gene mutations to enhance adherence of the coating to the implant. The bone engaging surface may comprise peaks and troughs. The living cells may be provided in troughs while the surface peaks may be used for at least one of: space validation, traction, and cell protection.

In some embodiments, the implant is pre-molded to fit about at least one condyle of the femur. In some embodiments, the implant comprises a memory plastic. In some embodiments, the implant comprises a wire frame. In some embodiments, the wire of the wire frame comprises a memory metal. In some embodiments, the memory metal comprises nitinol. In some embodiments, the wire frame is

disposed in the periphery of the implant or a portion thereof. In some embodiments, the wire frame is configured to aid in placement against the posterior of the condyle.

In some embodiments, at least a portion of the implant comprises a slippery surface. In some embodiments the slippery surface is configured to allow for relative movement between the implant (or a portion thereof) that is coupled to the femur and the tibia. In some embodiments the slippery surface is configured to allow for relative movement between the implant (or a portion thereof) that is coupled to the femur and the patella.

Inflation Medium and Inflation or Filling of the Implant Interior

In some embodiments, the implant comprises an inflation medium that is compressible. In some embodiments, the implant comprises an inflation medium that comprises a viscolubricant. In some embodiments, the implant comprises an inflation medium that comprises a parmacologic substance. In some embodiments, the implant comprises an inflation medium that comprises an NSAID. In some embodiments, the implant comprises an inflation medium that comprises chondrocytes. In some embodiments the implant is configured to anneal the outer most layer of the implant (or a portion thereof) to the peripheral of succinct cartilage defects so as to cover them, allowing for healing. In some embodiments the implant is configured to anneal the outer most layer of the implant (or a portion thereof) to the peripheral of succinct cartilage defects so as to cover them, allowing for healing once new chondrocytes have been installed.

The implant interior (balloon interior) may be inflated with gas. The implant interior (balloon interior) may be inflated with liquid. The implant interior (balloon interior) may be inflated with saline. The implant interior (balloon interior) may be inflated with suspended stem cells. The implant interior (balloon interior) may be inflated with gel. The implant interior (balloon interior) may be inflated with a viscolubricant. The inflation medium in some embodiments stays within the balloon, or a portion thereof (as where there are multiple chambers to the balloon). In some embodiments, balloon contents disburse through microporosities and/or dissolving membranes into the joint. In some embodiments, balloon contents disburse by expulsive or evacuation precipitated through an implant wall after pressure from limb use. In some embodiments, balloon contents disburse by expulsive or evacuation precipitated through an implant wall from planned osmosis. In some embodiments, balloon contents disburse by expulsive or evacuation precipitated through an implant wall from vacuole rupture (whether mechanical rupture, ultrasound, or chemical rupture, for non-limiting example). In some embodiments, balloon contents disburse by expulsive or evacuation precipitated through an implant wall thereby distributing contents of the implant interior to joints as lubricious, analgesic, anti-inflammatory and/or otherwise healing substances. In some embodiments, the implant may comprise solid beads or beads containing gel or liquid for sequential disbursement by compressive force through rupture with varied bead wall thicknesses, or the beads may be time-released (opened) chemically, pharmacologically, or by an outside ultrasound or magnetic force external knee application at appropriate clinical intervals. In some embodiments, the implant may comprise vacuoles containing gel or liquid for sequential disbursement by compressive force through rupture with varied vacuole wall thicknesses, or the vacuoles may be time-released (opened) chemically, pharmacologically, or by an outside ultrasound or magnetic force external knee application at appropriate clinical intervals.

The implant interior (or balloon interior) between the first wall and the second wall is filled with filler material (or an inflation medium) which aids in maintaining the desired implant dynamics within the joint structure. The nature of the filler material such as a fluid and the characteristics of the walls may be selected to maintain a desired spacing between the walls in order to accommodate the pressure applied by the bones of the joint structure to the implant and to allow suitable motion between the first and second walls of the implant which facilitate bone motion which mimics or approximates normal movement for the joint members involved.

Alternatively (and/or additionally), the inner chamber (interior or a portion thereof) may be filled with resilient material to provide the desired spacing, pressure accommodation, while allowing desired physiologic motion between implant layers. The implant may be configured to be shaped like the joint space and bone surfaces being replaced or to fill the void produced by injury or disease so that the natural joint spacing and cushioning of the joint interface is restored toward normal physiologic appearance and function. Fluids such as saline, mineral oil and the like may be employed to inflate the implant.

The interior of implant is adjustably filled by the physician from an appropriate source thereof after the implant is deployed to ensure that the pathologic joint space becomes a resilient cushion again which aids restoration of worn or damaged cartilage interfaces in the joint by covering cartilage defects with the implant material, cushioning the joint and defects therein and delivering cell regeneration agents. In one embodiment, the implant comprises a biocompatible inflatable member (balloon) that is filled with a biocompatible fill material (inflation medium) such as a gas, liquid, gel or slurry, or fluid that becomes a resilient solid to provide relative movement between the first and second walls. The filling or inflation media may be inserted through an injection valve site leading to the cannula which delivers the material into the interior of the implant. In an alternative embodiment, the implant may be filled with or have an interior formed of biologically compatible resilient material, e.g. a closed cell sponge filled with suitable fluid that is inserted into the interior of the implant prior to the implant's deployment or injected into the interior after the implant is deployed at the joint site. The interior of the implant may be provided with lubricious material to facilitate movement between the inner wall surfaces and to minimize contact wear therebetween. The polymeric walls of the implant may be impregnated with or otherwise carry tissue regeneration agents such as stem cells, living chondrocytes, and/or genes to repair joint surfaces.

In some embodiments, the first inflation medium imparts rigidity in the implant. In some embodiments, the first inflation medium imparts cushion in the implant. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium aligns the joint. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium aligns the bones of the joint. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium changes the bone alignment. In some

embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium improves joint alignment. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium restores, at least in part, joint alignment. In some embodiments, individual chambers of the interior may be selectively inflated with a first inflation medium and/or a second inflation medium. In some embodiments, individual chambers of the interior are selectively inflated with a first inflation medium and/or a second inflation medium in order to reconstruct the joint and/or bones of the joint.

In some embodiments the inflation medium comprises living chondrocytes.

The implant interior (balloon interior) may be inflated with methymethacrylate as a liquid that becomes a solid or semi-solid (rigid or semi-rigid). In some embodiments, the inflation medium is a methyl methacrylate or other biocompatible hardening substance which can flow when initially put into the chamber, and hardens to become a rigid piece or semi-rigid piece or solid piece. The methyl methacrylate or other biocompatible hardening substance may conform to the shape of the chamber, or may conform to the shape of a space between bones and/or other joint structures. The methyl methacrylate or other biocompatible hardening substance may conform to a form chosen by the surgeon using tools and/or pressure to influence the final shape of the rigid piece formed by the methyl methacrylate or other biocompatible hardening substance upon hardening.

The side wall extends between the first and second walls to form an interior which receives filling material through tube (also called a conduit herein, or may be called an inflation port). In some embodiments, the inflation port is not a tube, but is a valve which may or may not extend from a wall of the implant. The valve may be part of a wall of the implant, or part of the balloon or a portion thereof. The implant would also be appropriate for one condyle of the knee, but other shapes may be desired for other joint configurations whether relatively flat or more inflated toward a ballooning construct. In some embodiments, the inner diameter of the inflation port (or tube) is 5 millimeters maximum. In some embodiments, the inner diameter of the inflation port is about 1 millimeter. In some embodiments, the inner diameter of the inflation port is about 2 millimeters. In some embodiments, a needle (of typical needle sizes) may be used to inflate the implant.

A separate portal or tube (not shown) or the existing conduit (tube or valve), may be used to extract noxious inflammatory enzymes that can be aspirated at appropriate clinical intervals. Inflammatory enzymes in the COX1, COX2 and or 5LOX pathways can be extracted. Viscolubricants can be injected into the interior of the resilient arthroplasty implant through existing conduit or through a long needle to aide in distension, expansion, lubrication (with predetermined microporosity).

In some embodiments, an inflation medium that generates heat (by means of a catalyst reaction or other means) may be used to deliver heat to a joint structure. The heat may aide hyaline cartilage annealing. Thermal effects of the implant materials are calculated accordingly to benefit and protect the joint surface analogous to a dry suit or wet suit for a scuba diver exposed to temperature extremes. Embodiments of the implant generally seek to avoid head from friction via lubricious coatings whether allograph as amniotic membrane or polymer, for non-limiting example.

The implant in some embodiments is inserted arthroscopically through a cannula about 10 mm in diameter with the implant in the deflated construct, and once inside the prepared joint space and secured therein by the appendages or tabs, the implant will be distended or inflated with gas, gel, fluid or fluid that becomes a resilient solid to fill the original natural space of a bone of the joint (whether the tibia, femur or patella). Tensioning will be by the surgeon's sense of proper pressure application aided by a gauged syringe for insertion of viscolubricants such as Synvisc, Hyalgan, Supartz and/or analgesics such as lidocaine gel. The insertion of liquids to the joint per se may be directly, through a cannula to the joint space previously in place for debridement, and or via a cannula or tube that is not part of the original implant assembly. Once the joint is cleaned, the implant is inserted and appropriately fixed to avoid extrusion or dislocation thereof. This may be via attachment of the implant tabs and/or by a combination of tab use plus intended friction created by implant surface coverings (analogous to Velcro) or a draw string at the smaller base of the implant.

Attachment Elements and Couplers

In some embodiments the attachment elements of the implant comprises holes through which screws or other couplers may be placed to attach the implant to an attachment site (or connection site) in the bone of the knee. In some embodiments, the holes are created arthroscopically. In some embodiments the holes are pre-fabricated in the implant. In some embodiments, the holes may be made prior to implantation based on the patient's particular anatomy. In some embodiments, the holes are reinforced by a reinforcing material of the implant. The reinforcing material may be a polymer of sufficient durometer and/or tear resistance to reinforce the screw hole. The reinforcing material may be comprise metal. In some embodiments, there is no preformed hole, but rather screws (or another coupler) secure the attachment tabs (which may be a non-balloon portion of the implant) to the joint component (bone, etc) by creating their own hole when implanted. In some embodiments, the implant may comprise tabs that are adapted to receive staples or other couplers described elsewhere herein.

The implants described herein may comprise attachment elements (or tabs) which may then by attached or coupled to tissue of a component of the joint (whether to a bone or a ligament or a tendon or other joint component) by a coupling device. Coupling devices (or couplers) may comprise at least one of screws, washers, sutures, suture anchors (metal and/or biodegradable), rivots, staples (with and/or without teeth), stabilizers, glues, hooks of cylindrical wire or flattened sheet metal into bone holes or slots respectively. The coupling devices may be resorbable or not. Also, the coupling devices may comprise at least one of strings (i.e. drawstrings), reigns, lassos, sutures, and lanyards. The strings, reigns, lassos, sutures, and/or lanyards may join with themselves and/or other coupling devices. The strings, reigns, lassos, sutures and/or lanyards may be directed not only into bone with or without anchors, but also through ligaments, tendons or loose segments of cartilage that the surgeon intends to preserve.

The posterior of the knee can be difficult to access without disturbing joint components (or in order to minimize such disturbance) such as tendons, ligaments, etc. Thus, in some embodiments, the implant comprises strings, reigns, lassos, and/or lanyards that may pass from the posterior of the implant via the intercondylar notch anteriorly to join with

themselves and/or other coupling devices. These couplers may be pre-coupled to the implant, and the implant and its couplers may be configured to be pulled (or cinched) from the anterior of the implant once the implant is in its general location relative to the condyle in order to finally position the implant about the condyle—in particular in order to cinch the implant about the posterior of the condyle. Likewise, in some embodiments where the implant is pre-molded, the coupler as described are adapted to move the implant to its final position with conformity to the condyle's posterior with minimal disturbance to the joint structures at the joint's posterior (minimal cutting, minimal moving, and or minimal detachment, for non-limiting example).

In some embodiments, the implant comprises a skirt (or sleeve) that conforms to the contours of the bone (whether a condyle of the femur, a patella, or a tibia) as a coupler.

In some embodiments, a screw through tab having reinforced center holes may be part of the implant. For example, the implant may comprise polymer covered metal washer holes. The screw may go through the holes. Another embodiment may comprise a staple having spikes as shown in FIGS. **13**A-**13**D. FIGS. **13**A-**13**D depict multiple views of a staple adapted to couple an implant to a bone of the joint. FIG. **13**A depicts an embodiment of an implant **20** having a tab **10***a* that is coupled to bone using a staple **12**. FIGS. **13**B & **13**C depict a staple **12** as described herein having teeth **18**. FIG. **13**C depicts an embodiment of a tab **10***a* that is coupled to bone using a staple **12** having teeth **18**. Combinations of spikes and screws may be used in some embodiments, or combinations of other couplers. The implant may be configured to allow a surgeon the option of several types and sizes of couplers, as each patient differs with regard to size and depth of lesion, bone stock, regrowth capability, and compliance with advised recovery, and each surgeon has his own strengths and comforts when working with such implants.

The edge of the implant may have a depending skirt to secure or anchor the implant to the end of bone (femur), but may have one or more depending tabs (or appendages) that may be employed for similar functions as will be discussed in other embodiments. The skirt (and/or tabs, and/or appendages) may tightly fit about the end of the femur, or the skirt can be secured by adhesive (e.g. methyl methacrylate, bone ingrowth) to the supporting bone structure or be mechanically connected by staples, screws and the like. Moreover, the lower portion of the skirt may be secured by a purse string suture or a suitable strand (elastic or tied) that is tightly bound about the outside of the skirt.

FIGS. **12**A, **12**B, and/or **12**C alternatively may be used to describe a patch implant or a unicompartment knee implant described herein, having appendages **4***a*, **4***c*, extending from a balloon **6** and including holes **8***a*, **8***b*, **8***c*, and/or tabs **10***a*, **10***b*. **10***c*. **10***d*, **10***e*, **10***f*, which may be used with couplers (not shown) to couple the implant to a bone of the knee joint (which may be the femur, the tibia, or the patella). Features shown in FIG. **12**A, **12**B, and or **12**C are common to both the unicompartment knee implant (also discussed elsewhere herein) and the patch implant (also discussed elsewhere herein), although dimensions may differ as described elsewhere herein.

FIGS. **13**A-**13**D depict multiple views of a staple **12** adapted to couple implant **14** (such as those described herein) to a bone **16** of the joint. FIG. **13**A depicts a staple **12** coupling a tab **10***a* of an appendage **4***a* to the bone **16** of the joint (wherein the portion of the staple **12** embedded in the bone **16** is shown as a dashed line). FIG. **13**B depicts a view of a staple **12** having teeth **18** to grasp the tab **10***a* of the implant **14**. Similarly, FIG. **13**C depicts a view of a staple **12** having teeth **18** to grasp the tab **10***a* of the implant **14**. FIG. **13**D depicts a staple **12** attaching the tab **10***a* of an implant to a bone **16**, the dotted lines show the portion of the tab **10***a* that is compressed by the staple **12** and teeth **18** thereof.

In some embodiments, the implant is configured such that the tabs and/or couplers of the implant couple to the bone where there is no natural cartilage. In some embodiments, the implant may be adapted by the surgeon at the time of surgery such that the tabs are positioned where there is no natural cartilage.

In some embodiments, the implant comprises a tab and a hook that couples to the tab by wrapping around a component of the knee and securing the tab to the hook. In some embodiments, the implant comprises a tab and a hook that couples to the tab by wrapping around a condyle of the knee and securing the tab to the hook. In some embodiments, the implant is configured to wrap around a condyle of the knee and to secure a first appendage to a second appendage of the implant. In some embodiments the appendages are secured by couplers described herein. In some embodiments, the implant is pre-formed to fit to the condyle in such a wrapping manner.

In some embodiments, the implant comprises a methymethacrylate what is placed into a balloon chamber that fits into a bone hole. Such an embodiment would generally fix the implant to the bone once the methymethacrylate cures to a solid.

In some embodiments, the implant can be anchored with generic available sutures and suture anchors fixing and positioning material to bone with proper tensioning.

Ingrowth Features

In addition to the general ingrowth that may occur based on the implant features described herein, the implant undersurface (adjacent the femur) may comprise an ingrowth matrix. In some embodiments, at least a portion of the implant adjacent to the femur comprises bone ingrowth materials. Such an implant can be attached by a series of tabs with or without holes, using screws, rivots, stabilizers, staples, tacks, or Sutures and suture anchors, for non-limiting example. The polymer of the implant substitutes for periosteum when the implant comprises living chondrocytes (e.g. Carticel) as the ingrowth matrix on a surface of the implant. The polymer of the implant substitutes for periosteum when the implant comprises living chondrocytes (e.g. Carticel) as the ingrowth matrix within an implant embodiment configured to reveal and/or release said chondrocytes over time and/or upon implantation.

The bone ingrowth undersurface may be used for long term fixation of the tabs or rim. That is, whereas it is important for the surgery to secure the implant to the joint surface in the most desirable corrective location, it is also important in some embodiments to prepare the anatomic undersurface of bone by abraiding it, removing about 0.5 mm of cortical bone so as to expose the underlying oxygen, blood, and nutrients of the patient to the undersurface of the implant that can gradually become incorporated into the limb bone. As this healing occurs over the course of weeks and months to one year post operation, the localized tacking sites may become less relevant and potentially inert. Thus, in some embodiments, the implant may comprise a biodegradable (bioresorbable) polymer or other material. The couplers may additionally and/or alternatively be biodegradable. Once the implant is in place, it will serve to at least one of: pad defects, cushion the joint, and restore the original damage to the joint components. The end goal is to apply

minimally morbid treatment that will refurbish arthritic limb regions, leaving only the small skin scar and remote memory of the healed physical mishap.

Undersurface implant materials may involve used of the art and science from Artelon or Gore-Tex research, as each has advantages and limitations. Several implant options per joint damage area may be available to enjoy the primary surgeons manipulation to fit the clinically recovery requirements best.

In some embodiments the implant comprises an ingrowth patch on at least one of the first portion configured to engage the femur, the second portion configured to engage the second bone (whether the tibia or the patella), the side portion, and the appendage. The ingrowth patch may be configured to encourage and/or promote tissue ingrowth, such as bone ingrowth, for non-limiting example. The patch may be as large as the portion itself (whether the first portion the second portion, the side portion, or the appendage) or may be smaller than the portion (such as in the shape of a strip or other shaped patch). The ingrowth patch may comprise a surface irregularity or roughness. The ingrowth patch may be Velcro-like. In some embodiments the implant comprises an ingrowth patch on the first portion and/or the second portion, from (and in some embodiments including) a first appendage to a second appendage. In some embodiments, wherein the appendages loosen from attachment from the bone (by design and/or from wear and/or over time), the ingrowth patch aids in securing the implant to the bone. In some embodiments, the ingrowth patch comprises beads and/or bead-like elements attached to the implant. Such an ingrowth patch may be configured to simulate trabecular bone space of a normally cancellous latticework. In some embodiments, the beads are sintered beads of various sizes. In some embodiments, the beads are sintered beads about 400 microns in size. With respect to bead size, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%. In some embodiments, the first bone and/or the second bone is roughened to acquire a bleeding bone to facilitate ingrowth. In some embodiments, tissue is removed to facilitate ingrowth.

The walls of the implant embodying features of the invention may be composite structures. For example, the innermost layer may be impervious to preclude escape of inflation or other filling media, a central layer may be porous or otherwise contain treatment or cell regeneration agents, and the outer layer may be a thin, but strong layer of a thermoplastic, such as a thermoplastic polyurethane for non-limiting example, which has microporosity sufficient to allow passage or egress of treatment or cell regeneration agents from the central layer (or second layer). The degree of microporosity to enable egress of treatment or cell regeneration agents from the central layer is found in polymer layers such as Chronoflex or Bionate 55. The external wall (and/or the bone engaging surface) of the implant may be coated and/or impregnated with a latticework of polymer that is surface sprayed or layered on the outside (or bone engaging surface) of the implant to promote cartilage tissue regeneration. This most external surface coating may contain living chondrocytes (for example, as is provided in the Carticel procedure by the Genzyme company), and/or may contain stem cells with or without directed gene mutations to enhance adherence of the coating to the implant. The bone engaging surface may comprise peaks and troughs. The living cells may be imposed in between (and/or provided in the) troughs of the implant surface while the surface areas of prominence (the peaks of the surface) may be used for at least one of: space validation, traction, and cell protection.

The implant embodying features of the invention may be used in a series of treatments wherein the first treatment involves use of autologous or minimally manipulated allograph interpositional tissues or xenograph, the second treatment involves the use of the same type of tissue added to stem cells or chondrocytes and the third treatment involving deployment of the implant if the first two fail or are ineffective.

Pharmacologics and Therapeutic Agents

In some embodiments the implant may comprise vacuoles of pharmacologic substances. The vacuoles may be on a bone-engaging portion of the implant. In some embodiments, the implant comprises bubbles comprising an active substance such as a pharmacologic substance or other active substance. In some embodiments, the implant comprises spaces filled with an active substance such as a pharmacologic substance (pharmacologic agent) or other active substance (active agent). The implant may deliver by dissolution of the implant material (i.e. a biodegradable polymer which releases the active substance), and/or by release through pores of the implant (wherein the polymer is permeable to the active substance), and/or by fracture of the vacuole (or bubble, or space) by a catalyst such as ultrasound or pressure or other fracturing catalyst. The implant may deliver the active substance at a time after the actual implanting of the implant into the joint, for example an hour later, less than a day later, a day later, less than a week later, a week later, less than a month later, and/or a month later. In some embodiments, stem cells that are percolating in the bubble (or vacuole, or space) may be delivered to the joint space (or a constituent of the joint) after the implant is inserted into the joint. Active agents may, for non-limiting example, include stem cells, growth factors, antibiotics, and/or viscolubricants. In some embodiments, the implant may comprise enzyme absorptive 'microscopic sponges' that could be sucked out or evacuated at or around the time of implant delivery to the joint. In some embodiments, the active substance comprises iatrigenically gene mutated cells.

Patient Symptoms

Symptoms for the patient requiring an implant described herein may include, for non-limiting example, osteoarthritis or rheumatoid or gouty arthritis.

Total Knee Arthroplasty (Dual Compartment):

Provided herein is an implant for placement on both condyles (medial and lateral) of the distal femur. In some embodiments, this is called a dual compartment implant since it covers both condyles of the femur. Such an implant comprises at least one interior (or inflatable chamber), and in some embodiments comprises a plurality of inflatable chambers (or interiors).

In some embodiments, the implant will cover the "H" distal femoral cartilage segment (made up of both femoral condyles and the trochlear groove in between). The implant may absorb diffuse force, endure the millions of annual cyclic loads of both knee joints (including the patella-femur joint and the femur-tibia joints), along with rotational and shear forces up to six times body weight, at least.

In some embodiments, the implant comprises attachment tabs or attachment elements over the sides of both condyles medially and laterally. In some embodiments, the implant comprises attachment tabs or attachment elements in the intercondylar notch (or slot). In some embodiments, the implant comprises attachment tabs or attachment elements superiorly at the distal end of the femur anteriorly. In some

embodiments, posterior reigns or suture-like lanyards cinch up the implant from inside the posterior intercondylar notch toward another connection site around the femur.

The posterior of the knee can be difficult to access without disturbing joint components (or in order to minimize such disturbance) such as tendons, ligaments, etc. Thus, in some embodiments, the implant comprises strings, reigns, lassos, and/or lanyards that may pass from the posterior of the implant via the intercondylar notch anteriorly to join with themselves and/or other coupling devices. These couplers may be pre-coupled to the implant, and the implant and its couplers may be configured to be pulled (or cinched) from the anterior of the implant once the implant is in its general location relative to the condyle in order to finally position the implant about the condyle in particular in order to cinch the implant about the posterior of the condyle. Likewise, in some embodiments where the implant is pre-molded, the coupler as described are adapted to move the implant to its final position with conformity to the condyle's posterior with minimal disturbance to the joint structures at the joint's posterior (minimal cutting, minimal moving, and or minimal detachment, for non-limiting example). In some embodiments at least a portion of the ligamentary structure of the knee is spared.

Although this application focuses on the distal femur as it articulates with the retropatellar and proximal tibial cartilages implants as described generally herein may be also and/or alternatively be used in conjunction with the tibia and/or the patella. Furthermore, separate and/or connected implant components may be inserted to restore natural function to the knee.

Coupling devices to be used as part of the dual compartment implant may include any of those mentioned or described herein, for example. Such coupling devices may comprise at least one of strings (i.e. drawstrings), reigns, lassos, sutures, and lanyards. The strings, reigns, lassos, sutures, and/or lanyards may join with themselves and/or other coupling devices. The strings, reigns, lassos, sutures and/or lanyards may be directed not only into bone with or without anchors, but also through ligaments, tendons or loose segments of cartilage that the surgeon intends to preserve.

FIG. **1** depicts an embodiment of the implant **20** in a 2D view configured for dual condyle (distal femur) coverage. FIG. **1** depicts an embodiment of the knee implant **20** having appendages **4***a*, **4***b*, **4***c*, **4***d*, including holes **8***a*, **8***b*, **8***c*, **8***d* and tabs **10***a*, **10***b* extending from a balloon **6** and including slots **26***a*, **26***b* to accommodate ligaments (not shown) of the knee joint. Couplers as described elsewhere herein may be used to couple the implant **20** to the distal femur. In some embodiments, there may only tabs, only holes, or only appendages, or combinations thereof. In some embodiments, there may be other ways to couple the implant to the distal femur, as described elsewhere herein (sutures, drawstrings, skirts, glue, etc). In some embodiments, the couplers create the holes **8***a*, **8***b*, **8***c*, **8***d*, or other holes (not shown) when the implant is placed against the distal femur **24**. In some embodiments, the holes are pre-formed in the appendage prior to implantation. In some embodiments, the holes are reinforced as described elsewhere herein. As shown here, the appendages in some embodiments be different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage **4***d* that is intended to wrap over the medial condyle may be longer and/or wider than the appendage **4***c* intended to wrap over the lateral condyle. Likewise, the slots may be different in shape and/or size and/or position to accommodate the ligaments and/or tendons of the joint or other structures and functions of the joints of the knee, and to allow for placement of the implant with minimal disturbance (cutting, manipulation, for example) of the joint components such as tendons, ligaments, and other soft or hard tissues. For example, slot **26***a* is shaped and positioned to accommodate the cruciate ligaments of the knee, at least.

FIG. **2** depicts an embodiment of the knee implant **20** having appendages **4***a*, **4***b*, **4***c*, **4***d*, including holes **8***a*, **8***b*, **8***c*, **8***d* and tabs **10***a*, **10***b* extending from a balloon **6** and including slots **26***a*, **26***b* to accommodate ligaments of the knee joint as well as side views of the same knee implant. Couplers as described elsewhere herein may be used to couple the implant **20** to the distal femur. In some embodiments, there may only tabs, only holes, or only appendages, or combinations thereof. In some embodiments, there may be other ways to couple the implant to the distal femur, as described elsewhere herein (sutures, drawstrings, skirts, glue, etc). In some embodiments, the couplers create the holes **8***a*, **8***b*, **8***c*, **8***d*, or other holes (not shown) when the implant is placed against the distal femur. In some embodiments, the holes are pre-formed in the appendage prior to implantation. In some embodiments, the holes are reinforced as described elsewhere herein. As shown here, the appendages in some embodiments are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage **4***d* that is intended to wrap over the medial condyle may be longer and/or wider than the appendage **4***c* intended to wrap over the lateral condyle. Shown in the embodiment depicted in FIG. **2** are the different hole placements from the side view, showing the differences in positioning of the holes to accommodate the differences in anatomic structure and size of the condyles. Likewise, the slots may be different in shape and/or size and/or position to accommodate the ligaments and/or tendons of the joint or other structures and functions of the joints of the knee, and to allow for placement of the implant with minimal disturbance (cutting, manipulation, for example) of the joint components such as tendons, ligaments, and other soft or hard tissues. For example, slot **26***a* is shaped and positioned to accommodate the cruciate ligaments of the knee, at least. Additionally, as shown in the side views of the embodiment shown in FIG. **2**, the balloon has a first wall **28** adapted to be adjacent the femur that is of a greater thickness than the second wall **30**. In some embodiments, the first wall **28** is configured to have therapeutic benefits (pharmacologic, healing, and/or ingrowth properties) as described elsewhere herein. The second wall **30** may additionally and/or alternatively be configured to have a therapeutic effect (pharmacologic, healing, and/or ingrowth properties).

Nevertheless, differing thicknesses of the first wall **28** and the second wall **30** are not necessarily required in order to impart the therapeutic benefits (pharmacologic, healing, and/or ingrowth) described elsewhere herein. For example, FIG. **3** depicts an embodiment of the knee implant **20** having appendages **4***a*, **4***b*, **4***c*, **4***d*, including holes **8***a*, **8***b*, **8***c*, **8***d* and tabs **10***a*, **10***b* extending from a balloon **6** and including slots **26***a*, **26***b* to accommodate ligaments of the knee joint as well as side views of the same knee implant. Couplers as described elsewhere herein may be used to couple the implant **20** to the distal femur. In some embodiments, there may only tabs, only holes, or only appendages, or combinations thereof. In some embodiments, there may be other ways to couple the implant to the distal femur, as described

elsewhere herein (sutures, drawstrings, skirts, glue, etc). In some embodiments, the couplers create the holes **8***a*, **8***b*, **8***c*, **8***d*, or other holes (not shown) when the implant is placed against the distal femur. In some embodiments, the holes are pre-formed in the appendage prior to implantation. In some embodiments, the holes are reinforced as described elsewhere herein. As shown here, the appendages in some embodiments are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage **4***d* that is intended to wrap over the medial condyle may be longer and/or wider than the appendage **4***c* intended to wrap over the lateral condyle. Shown in the embodiment depicted in FIG. **3** are the different hole placements from the side view, showing the differences in positioning of the holes to accommodate the differences in anatomic structure and size of the condyles. Likewise, the slots may be different in shape and/or size and/or position to accommodate the ligaments and/or tendons of the joint or other structures and functions of the joints of the knee, and to allow for placement of the implant with minimal disturbance (cutting, manipulation, for example) of the joint components such as tendons, ligaments, and other soft or hard tissues. For example, slot **26***a* is shaped and positioned to accommodate the cruciate ligaments of the knee, at least. Additionally, as shown in the side views of the embodiment shown in FIG. **3**, the balloon has a first wall **28** adapted to be adjacent the femur that is of approximately the same thickness than the second wall **30**. In some embodiments, the first wall **28** is configured to have therapeutic benefits (pharmacologic, healing, and/or ingrowth properties) as described elsewhere herein. The second wall **30** may additionally and/or alternatively be configured to have a therapeutic effect (pharmacologic, healing, and/or ingrowth properties).

FIG. **4**A depicts an embodiment of the knee implant **20** having appendages **4***a*-**4***d* including ten tabs **10***a*-**10***j* extending from a balloon **6** and including a slot **26***a* to accommodate components (such as ligaments or other tissues whether soft tissues, hard tissues, tendons, and/or others) of the knee joint (not shown). The tabs **10***a*-**10***j* are not shown with holes in this embodiment, however if screws are used as couplers, such holes may be pre-drilled or formed in situ by the screws. Additionally and/or alternatively, staples or sutures may be used (as described elsewhere herein) in order to couple the implant to the bone (femur, for example). Other couplers as described elsewhere herein may also and/or alternatively be used in this coupling process. Furthermore, the number of tabs may be fewer or greater than the ten depicted in order to achieve optimal placement and coupling to the bone. For example, FIG. **4**B depicts an embodiment of the knee implant **20** having appendages **4***a*-**4***d* including eight tabs **10***a*-**10***h* extending from a balloon **6** and including a slot **26***a* to accommodate components (such as ligaments or other tissues whether soft tissues, hard tissues, tendons, and/or others) of the knee joint (not shown).

FIG. **5** depicts an embodiment of the knee implant **32** curved to simulate curvature about the condyles of a femur, the implant having appendages **4***a*-**4***d* extending from an uninflated balloon (not shown) and including slots **26***a*, **26***b* to accommodate components (such as ligaments or other tissues whether soft tissues, hard tissues, tendons, and/or others) of the knee joint (not shown). The implant may comprise additional curvatures and/or slots to accommodate other ligaments and/or tissues. In some embodiments, the implant is configured to conform about various hard and/or soft tissues of the joint, such as bone, ligaments, tendons, etc. In some embodiments, the balloon is inflated once the implant is positioned within the joint. In other embodiments, the balloon is partially inflated prior to being positioned within the joint. In other embodiments, the balloon is at least partially inflated prior to being positioned within the joint. In some embodiments, the balloon is fully inflated prior to being positioned within the joint. In some embodiments, the implant is configured to allow an operator to adjust the amount of balloon inflation in situ (whether by adding inflation medium or removing inflation medium, or both, or neither). Couplers as described elsewhere herein may be used to couple the implant **32** to the distal femur.

FIG. **6**A depicts a top-down view of an embodiment of the knee implant **32** curved to simulate curvature about the condyles of a femur, the implant having appendages **4***a*-**4***d* extending from two inflated balloons **6**, **34** and including a slot **26***a* to accommodate components of the knee joint. FIG. **6**B depicts a bottom-up or anterior oblique view of the same embodiment of the knee implant **32** curved to simulate curvature about the condyles of a femur, the implant having appendages **4***a*-**4***d* extending from two inflated balloons **6**, **32** and including a slot **26***a* to accommodate components of the knee joint. Couplers as described elsewhere herein may be used to couple the implant **32** to the distal femur. As shown in FIGS. **6**A and **6**B, the appendages **4***a*-**4***d* in some embodiments are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage **4***d* that is intended to wrap over the medial condyle may be longer and/or wider than the appendage **4***c* intended to wrap over the lateral condyle. Likewise, the dimensions of the balloon **34** that is adapted for placement over the medial condyle may be a different shape and/or size than the balloon **6** over the lateral condyle (the medial condyle being larger, thus the balloon **34** may be larger for that location) Alternatively and/or additionally, as described elsewhere herein, for various reasons such as injury, realignment needs, injury, etc, there may be a need for more reconstruction of one condyle than needed for the other, thus the inflation medium might be different in one balloon (or a portion thereof) than in the other balloon (or another chamber within the same balloon), or there may be need for a different shaped balloon in one location than in another location. Embodiments provided herein can accommodate these requirements based on materials of fillers, appendages, balloons, walls, and dimensions and chamber options of the implant and its components.

FIG. **7** depicts a top-down view of an embodiment of the knee implant **32** curved to simulate curvature about the condyles of a femur, the implant having appendages **4***a*-**4***d* extending from an inflated balloon **6** and including slots to accommodate components of the knee joint. Couplers as described elsewhere herein may be used to couple the implant **32** to the distal femur. As shown here, the appendages **4***a*-**4***d* in some embodiments are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage **4***d* that is intended to wrap over the medial condyle may be longer and/or wider than the appendage **4***c* intended to wrap over the lateral condyle. Likewise, the dimensions of the portion of the balloon that is adapted for placement over the medial condyle may be a different shape and/or size than the portion of the balloon over the lateral condyle (the medial condyle being larger, thus the balloon may be larger for that location) Alternatively and/or additionally, as described elsewhere herein, for various reasons such as injury, realignment needs,

injury, etc, there may be a need for more reconstruction of one condyle than needed for the other, thus the inflation medium might be different in a portion or chamber of an implant embodiment having a plurality of inflation chambers in a single balloon, or there may be need for a non-symmetric balloon. Embodiments provided herein can accommodate these requirements based on materials of fillers, appendages, balloons, walls, and dimensions and chamber options of the implant and its components.

FIG. **8** depicts a side view of an embodiment of the knee implant **32** curved to simulate curvature about at least one condyle of a femur, the implant having appendages **4***b*, **4***d* extending from an uninflated balloon (not shown). This depiction covers the maximum anticipated distal femoral contour; other iterations may be smaller, or shorter covering limited areas of the circumference of the femoral curvatures.

FIG. **9**A depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4***b*, **4***d* extending from an uninflated or minimally inflated balloon **6**. In this view, the knee is positioned essentially in extension (straight), showing the tibia **36**, fibula **38**, and patella **40** of the knee. Note that although there would be other joint structures and knee structures in a true depiction of an implant positioned in the knee, this view of the implant and bones is greatly simplified for ease of understanding of the implant and the joint relative (and approximate) positions and placement. Couplers as described elsewhere herein may be used to couple the implant **20** to the distal femur **24** and/or the condyle **22** thereof (in this image the medial condyle, at least since it is primarily a one-side view of the joint and implant). For the sake of simplicity FIG. **9**A and the implant embodiment depicted show of the femur with opposition to the other surfaces of both knee joints (between femur and tibia, and femur and patella), the areas of contact varying according to activity, forces, and range of motion. Other implant iterations may apply to opposing surfaces.

FIG. **9**B depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4***b*, **4***d* extending from an inflated balloon **6**. In this view, the knee is positioned essentially in extension (straight), showing the tibia **36**, fibula **38**, and patella **40** of the knee. Note that although there would be other joint structures and knee structures in a true depiction of an implant positioned in the knee, this view of the implant and bones is greatly simplified for ease of understanding of the implant and the joint relative (and approximate) positions and placement. Couplers as described elsewhere herein may be used to couple the implant **20** to the distal femur **24** and/or the condyle **22** thereof (in this image the medial condyle, at least since it is primarily a one-side view of the joint and implant). In FIG. **9**B wherein the balloon is inflated, as compared to FIG. **9**A wherein the balloon is not inflated or is minimally inflated, the balloon second wall **30** is closer to and/or contacting the tibial plateau **42** (articular surface) when the balloon **6** is inflated. Likewise, FIG. **9**C depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4***b*, **4***d* extending from an inflated balloon **6** and having couplers **44***a*, **44***b* (which may be, for non-limiting example, staples or screws) coupling the appendages **4***b*, **4***d* to the femur. In this view, the knee is positioned essentially in extension (straight), showing the tibia **36**, fibula **38**, and patella **40** of the knee. Where the inflated balloon as seen in FIG. **9**B may fill in existing pathologic defects of the joint surface, the medium of inflated and specific balloon location and durometry with the material of the implant may also be constructed so as to force the bones opposed, e.g. the femur and tibia, into a more natural limb alignment such as six (6) degrees valgus. However, if the patient being treated has variations from normal in the affected knee as illustrated by examining and measuring the opposite normal side, then the implant inflation and pressures or balloon location may be adjusted from the population norms thus customizing this implant to the clinical case under consideration. Fixation devices may be appropriately applied at various knee range of motion intervals from full extension (zero degrees) to full flexion (usually 135 degrees) as the knee is adjusted and the implant secured under anesthesia.

FIG. **10**A depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4***b*, **4***d* extending from an inflated balloon **6** and showing the inflation medium **46** moved anteriorly toward the patella **40** when the knee joint is slightly flexed. Likewise, FIG. **10**B depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4***b*, **4***d* extending from an inflated balloon **6** and having couplers **44***a*, **44***b* (which may be, for non-limiting example, staples or screws) coupling the appendages **4***b*, **4***d* to the femur **24** and showing the inflation medium **46** moved anteriorly toward the patella **40** when the knee joint is slightly flexed.

In all descriptions provided herein of the dual compartment implant, the implant may instead be configured to couple to or emerge from the tibia and/or patella. In all descriptions provided herein of the dual compartment implant, the implant may instead be configured to couple to the tibia. It is the intention and understanding that the implant is suited for this purpose in certain embodiments with adjustments to account for dimensional differences of the tibia. Most descriptions provided herein are directed to embodiments coupling the implant to the femur, however, this is primarily for ease of description and continuity, and does not preclude embodiments wherein the implant is coupled to the tibia. Likewise, as noted elsewhere herein, there are embodiments where the implant may be coupled to two bones (at least), for example to both a tibia and a femur.

Patch

Some embodiments of the implant are configured to repair isolated lesions wherein osteochondral defects as in osteonecrosis create craters in the cartilage that need 'filling in' with a patch. Various size lesions of cartilage defects can be accommodated by the implants provided herein which may have balloons of at least one of: at most about 0.5 cm in diameter, at most about 0.75 cm in diameter, at most about 1 cm in diameter, at most about 1.25 cm in diameter, at most about 1.5 cm in diameter, at most about 1.75 cm in diameter, at most about 2 cm in diameter, at most about 2.25 cm in diameter, at most about 2.5 cm in diameter, at most about 2.75 cm in diameter, at most about 3 cm in diameter, at most about 3.25 cm in diameter, at most about 3.5 cm in diameter, at most about 3.75 cm in diameter, at most about 0.5 cm in length along the longest length of the balloon, at most about 0.75 cm in length along the longest length of the balloon, at most about 1 cm in length along the longest length of the balloon, at most about 1.25 cm in length along the longest length of the balloon, at most about 1.5 cm in length along the longest length of the balloon, at most about 1.75 cm in length along the longest length of the balloon, at most about 2 cm in length along the longest length of the balloon, at most about 2.25 cm in length along the longest length of the balloon, at most about 2.5 cm in length along the longest

length of the balloon, at most about 2.75 cm in length along the longest length of the balloon, at most about 3 cm in length along the longest length of the balloon, at most about 3.25 cm in length along the longest length of the balloon, at most about 3.5 cm in length along the longest length of the balloon, at most about 3.75 cm in length along the longest length of the balloon, at most about 4 cm in length along the longest length of the balloon, at most about 4.25 cm in diameter, at most about 4.5 cm in diameter, at most about 4.75 cm in diameter, at most about 5 cm in diameter, at most about 5.25 cm in diameter, at most about 5.5 cm in diameter, at most about 5.75 cm in diameter, at most about 6 cm in diameter, at most about 6.25 cm in diameter, at most about 6.5 cm in diameter, at most about 6.75 cm in diameter, at most about 7 cm in diameter, at most about 7.25 cm in diameter, at most about 7.5 cm in diameter, at most about 7.75 cm in diameter, at most about 8 cm in diameter, at most about 3 cm in length along the longest length of the balloon, at most about 3.25 cm in length along the longest length of the balloon, at most about 3.5 cm in length along the longest length of the balloon, at most about 3.75 cm in length along the longest length of the balloon, at most about 4 cm in length along the longest length of the balloon, at most about 4.25 cm in length along the longest length of the balloon, at most about 4.5 cm in length along the longest length of the balloon, at most about 4.75 cm in length along the longest length of the balloon, at most about 5 cm in length along the longest length of the balloon, at most about 5.25 cm in length along the longest length of the balloon, at most about 5.5 cm in length along the longest length of the balloon, at most about 5.75 cm in length along the longest length of the balloon, at most about 6 cm in length along the longest length of the balloon, 6.25 cm in length along the longest length of the balloon, at most about 6.5 cm in length along the longest length of the balloon, at most about 6.75 cm in length along the longest length of the balloon, at most about 7 cm in length along the longest length of the balloon, at most about 7.25 cm in length along the longest length of the balloon, at most about 7.5 cm in length along the longest length of the balloon, at most about 7.75 cm in length along the longest length of the balloon, and at most about 8 cm in length along the longest length of the balloon. As used herein with respect to balloon dimensions whether length or diameter, the term "about" means variations of at least one of 0.1 cm, 0.2 cm, 0.25 cm, 0.5 cm, and 1 cm.

Thus, provided herein is an implant configured to patch osteochondral defects. The defects may occur due to injury, stress, naturally occurring, and/or may created or enhanced by a medical professional during a medical procedure. In some embodiments, the implant may be called a patch having the balloon and an attachment element (or elements which may be called appendages) described herein and may be sized to fit within a defect in a manhole-cover type manner. In some embodiments, the implant may comprise balloon and attachment elements described elsewhere herein and may be configured to lay over a defect (full defect or partial defect). In some embodiments the implant as described herein as used to patch or repair osteochondral defects may be called a patch or a patch implant.

In some embodiments, the size of the balloon dimensions are prechosen based on the individual patient need, and the balloon size (dimensions, geometry, length, depth, for non-limiting examples) is pre-set. In some embodiments, the balloon comprises multiple chambers which may be inflated (or deflated) selectively to fill the defect in situ or just prior to implantation in order to adjust the implant's balloon size (dimensions, length, width, depth, geometry, for non-limiting example) as needed at the time of implantation. The balloon (or any chamber thereof) of some embodiments can be secondarily inflated or deflated (or both) in situ.

FIGS. **11**A, **11**B, and/or **11**C may be used to describe a patch implant described herein, having appendages **4***a*, **4***c*, extending from a balloon **6** (not shown in FIG. **11**A) and including holes **8***a*-**8***h*, and/or tabs **10***a*-**10***f* which may be used with couplers (not shown) to couple the implant to a bone of the knee joint (which may be the femur, the tibia, or the patella). Features shown in FIGS. **11**A, **11**B, and/or **11**C are common to both the unicompartment knee implant (discussed elsewhere herein) and the patch implant, although dimensions may differ as described herein. Thus, FIGS. **11**A, **11**B, and/or **11**C may be used to describe the unicompartment knee implant and/or the patch implant. FIG. **11**A depicts an embodiment of the patch implant **2** curved to simulate curvature about one condyle of a femur, the implant **2** having appendages **4***a*, **4***c*, extending from an uninflated balloon (not shown) and including tabs **10***a*-**10***f* and/or holes **8***a*-**8***h*, which may be used with couplers (not shown, described elsewhere herein) to couple the implant **2** to the femur of the knee joint. FIG. **11**B depicts an embodiment of the patch implant **2** curved to simulate curvature about one condyle of a femur, the implant **2** having appendages **4***a*, **4***c*, extending from an inflated balloon **6** and including tabs **10***a*-**10***f* and/or holes **8***a*-**8***h*, which may be used with couplers (not shown, described elsewhere herein) to couple the implant **2** to the femur of the knee joint. FIG. **11**C depicts a bottom-up of gliding surface view of an embodiment of the patch implant **2** curved to simulate curvature about one condyle of a femur, the implant **2** having appendages **4***a*, **4***c*, extending from an inflated balloon **6** and including tabs **10***a*-**10***f* and/or holes **8***a*-**8***h*, which may be used with couplers (not shown, described elsewhere herein) to couple the implant **2** to the femur of the knee joint. In some embodiments, the implant is configured to couple to a tibia. In some embodiments, the implant is configured to couple to a trochlear groove of a femur. In some embodiments, the implant is configured to couple to only a portion of a condyle of a femur.

FIGS. **12**A, **12**B, and/or **12**C may be used to describe a patch implant described herein, having appendages **4***a*, **4***c*, extending from a balloon **6** and including holes **8***a*, **8***b*, **8***c*, and/or tabs **10***a*, **10***b*. **10***c*, **10***d*, **10***e*, **10***f* which may be used with couplers (not shown) to couple the implant to a bone of the knee joint (which may be the femur, the tibia, or the patella). Features shown in FIGS. **12**A, **12**B, and/or **12**C are common to both the unicompartment knee implant (discussed elsewhere herein) and the patch implant, although dimensions may differ as described herein. Thus, FIGS. **12**A, **12**B, and/or **12**C may be used to describe the unicompartment knee implant and/or the patch implant. FIG. **12**A depicts a bottom-up view of an embodiment of the implant **2** (unicompartment or patch), the implant having appendages **4***a*, **4***c*, extending from a balloon **6** and including holes **8***a*, **8***b*, **8***c*, which may be used with couplers (not shown) to couple the implant **2** to the femur of the knee joint. FIG. **12**B depicts a bottom-up view of an embodiment of the implant **2** (unicompartment or patch), the implant having appendages **4***a*, **4***c*, extending from a balloon **6** and including tabs **10***a*, **10***b* and hole **8***a* which may be used with couplers (not shown) to couple the implant to the femur of the knee joint. FIG. **12**C depicts a bottom-up view of an embodiment of the implant **2** (unicompartment or patch), the implant having appendages **4***a*, **4***c*, extending from a balloon **6** and including tabs **10***c*, **10***d*, **10***e*, and **10***f* and hole **8***a* which may be used with couplers (not shown) to couple the implant to the femur

of the knee joint. In some embodiments, the implant is configured to couple to a tibia. In some embodiments, the implant is configured to couple to a trochlear groove of a femur. In some embodiments, the implant is configured to couple to only a portion of a condyle of a femur. In some embodiments the implant is coupled to the patella. In any embodiment the balloon **6** may extend from one surface of the implant as a focal protuberance to fill a defect, space, or to aide in alignment correct, or the balloon may be full thickness as differences in FIGS. **2** and **3** show respectively. In any embodiment there may be a singular or multiple major balloons, if off a primary surface resembling bubble wrap, and there may be microscopic balloons or vacuoles containing gas, gel, or solid in the material matrix.

In all descriptions provided herein of the patch implant, the implant may instead be configured to couple to the tibia or to the fibula or the patella. It is the intention and understanding that the implant is suited for this purpose in certain embodiments with adjustments to account for dimensional differences of these bones. Most descriptions provided herein are directed to embodiments coupling the implant to the femur, however, this is primarily for ease of description and continuity, and does not preclude embodiments wherein the implant is coupled to the tibia (or other bones). Likewise, as noted elsewhere herein, there are embodiments where the implant may be coupled to two bones (at least), for example to both a tibia and a femur.

Partial Knee Arthroplasty (Unicompartment)

In addition to the total knee-type (dual condyle) and patch implants are implants that serve to cover and adjust alignment for either the medial or lateral condyle of the femur with varus or valgus knees requiring added cushioning to recreate the natural six degrees of knee valgus.

Thus, provided herein is an implant for placement on at least one condyle of the distal femur (a unicompartment implant—named so due to their coverage of a single condyle of the femur). The implant may be configured to be placed over the lateral condyle. The implant may be configured to be placed over the medial condyle. The implant may be configured to be placed over either the medial condyle or the lateral condyle. Two unicompartment implants may be placed in the same knee, one over the medial condyle, one over the lateral condyle.

FIGS. **11**A-**12** C depict example embodiments of unicompartment implants. In some embodiments, the unicompartment implant comprises a balloon that is at least one of: at most about 1.5 cm in diameter, at most about 1.75 cm in diameter, at most about 2 cm in diameter, at most about 2.25 cm in diameter, at most about 2.5 cm in diameter, at most about 2.75 cm in diameter, at most about 3 cm in diameter, at most about 3.25 cm in diameter, at most about 3.5 cm in diameter, at most about 3.75 cm in diameter, at most about 4 cm in diameter, at most about 4.25 cm in diameter, at most about 4.5 cm in diameter, at most about 4.75 cm in diameter, at most about 5 cm in diameter, at most about 5.25 cm in diameter, at most about 5.5 cm in diameter, at most about 5.75 cm in diameter, at most about 6 cm in diameter, at most about 6.25 cm in diameter, at most about 6.5 cm in diameter, at most about 6.75 cm in diameter, at most about 7 cm in diameter, at most about 7.25 cm in diameter, at most about 7.5 cm in diameter, at most about 7.75 cm in diameter, at most about 8 cm in diameter, at most about 3 cm in length along the longest length of the balloon, at most about 3.25 cm in length along the longest length of the balloon, at most about 3.5 cm in length along the longest length of the balloon, at most about 3.75 cm in length along the longest length of the balloon, at most about 4 cm in length along the longest length of the balloon, at most about 4.25 cm in length along the longest length of the balloon, at most about 4.5 cm in length along the longest length of the balloon, at most about 4.75 cm in length along the longest length of the balloon, at most about 5 cm in length along the longest length of the balloon, at most about 5.25 cm in length along the longest length of the balloon, at most about 5.5 cm in length along the longest length of the balloon, at most about 5.75 cm in length along the longest length of the balloon, at most about 6 cm in length along the longest length of the balloon, 6.25 cm in length along the longest length of the balloon, at most about 6.5 cm in length along the longest length of the balloon, at most about 6.75 cm in length along the longest length of the balloon, at most about 7 cm in length along the longest length of the balloon, at most about 7.25 cm in length along the longest length of the balloon, at most about 7.5 cm in length along the longest length of the balloon, at most about 7.75 cm in length along the longest length of the balloon, and at most about 8 cm in length along the longest length of the balloon. As used herein with respect to balloon dimensions whether length or diameter, the term "about" means variations of at least one of 0.1 cm, 0.2 cm, 0.25 cm, 0.5 cm, and 1 cm.

In some embodiments, the implant comprises attachment tabs or attachment elements over the anterior and/or posterior and/or medial side, and/or lateral side (and/or some combination thereof) of a condyle. In some embodiments, the implant comprises attachment tabs or attachment elements in the intercondylar notch. In some embodiments, the implant comprises attachment tabs or attachment elements superiorly at the distal end of the femur anteriorly.

The posterior of the knee can be difficult to access without disturbing joint components (or in order to minimize such disturbance) such as tendons, ligaments, etc. Thus, in some embodiments, the implant comprises strings, reigns, lassos, and/or lanyards that may pass from the posterior of the implant via the intercondylar notch anteriorly to join with themselves and/or other coupling devices. In some embodiments, posterior reigns or suture-like lanyards cinch up the implant from inside the posterior intercondylar notch toward another connection site around the femur. These couplers may be pre-coupled to the implant, and the implant and its couplers may be configured to be pulled (or cinched) from the anterior of the implant once the implant is in its general location relative to the condyle in order to finally position the implant about the condyle—in particular in order to cinch the implant about the posterior of the condyle. Likewise, in some embodiments where the implant is pre-molded, the coupler as described are adapted to move the implant to its final position with conformity to the condyle's posterior with minimal disturbance to the joint structures at the joint's posterior (minimal cutting, minimal moving, and or minimal detachment, for non-limiting example). In some embodiments at least a portion of the ligamentary structure of the knee is spared.

FIG. **10**A depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4***b*, **4***d* extending from an inflated balloon **6** and showing the inflation medium **46** moved anteriorly toward the patella **40** when the knee joint is slightly flexed. Likewise, FIG. **10**B depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4***b*, **4***d* extending from an inflated balloon **6** and having couplers **44***a*, **44***b* (which may be, for non-limiting example, staples or screws) coupling the

appendages **4***b*, **4***d* to the femur **24** and showing the inflation medium **46** moved anteriorly toward the patella **40** when the knee joint is slightly flexed.

FIGS. **11**A, **11**B, and/or **11**C may be used to describe a unicompartment implant **2** (or unicompartment knee implant, terms which may be used interchangeably) described herein, having appendages **4***a*, **4***c*, extending from a balloon **6** (not shown in FIG. **11**A) and including holes **8***a*-**8***h*, and/or tabs **10***a*-**10***f* which may be used with couplers (not shown) to couple the implant to a bone of the knee joint (which may be the femur, the tibia, or the patella). Features shown in FIGS. **11**A, **11**B, and/or **11**C are common to both the unicompartment knee implant and the patch implant (discussed elsewhere herein), although dimensions may differ as described herein. Thus, FIGS. **11**A, **11**B, and/or **11**C may be used to describe the unicompartment knee implant and/or the patch implant. FIG. **11**A depicts an embodiment of the unicompartment knee implant **2** curved to simulate curvature about one condyle of a femur, the implant **2** having appendages **4***a*, **4***c*, extending from an uninflated balloon (not shown) and including tabs **10***a*-**10***f* and/or holes **8***a*-**8***h*, which may be used with couplers (not shown, described elsewhere herein) to couple the implant **2** to the femur of the knee joint. FIG. **11**B depicts an embodiment of the unicompartment knee implant **2** curved to simulate curvature about one condyle of a femur, the implant having appendages **4***a*, **4***c*, extending from an inflated balloon **6** and including tabs **10***a*-**10***f* and/or holes **8***a*-**8***h*, which may be used with couplers (not shown, described elsewhere herein) to couple the implant **2** to the femur of the knee joint. FIG. **11**C depicts a bottom-up view of an embodiment of the unicompartment knee implant **2** curved to simulate curvature about one condyle of a femur, the implant **2** having appendages **4***a*, **4***c*, extending from an inflated balloon **6** and including tabs **10***a*-**10***f* and/or holes **8***a*-**8***h*, which may be used with couplers (not shown, described elsewhere herein) to couple the implant **2** to the femur of the knee joint.

In some embodiments, the unicompartment implant including attachment tabs is at least one of: at most about 15 cm in length along the longest length of the implant, at most about 15.25 cm in length along the longest length of the implant, at most about 15.5 cm in length along the longest length of the implant, at most about 15.75 cm in length along the longest length of the implant, at most about 16 cm in length along the longest length of the implant, at most about 16.25 cm in length along the longest length of the implant, at most about 16.5 cm in length along the longest length of the implant, at most about 16.75 cm in length along the longest length of the implant, at most about 17 cm in length along the longest length of the implant, at most about 17.25 cm in length along the longest length of the implant, at most about 17.5 cm in length along the longest length of the implant, at most about 17.75 cm in length along the longest length of the implant, at most about 18 cm in length along the longest length of the implant, 18.25 cm in length along the longest length of the implant, at most about 18.5 cm in length along the longest length of the implant, at most about 18.75 cm in length along the longest length of the implant, at most about 19 cm in length along the longest length of the implant, at most about 19.25 cm in length along the longest length of the implant, at most about 19.5 cm in length along the longest length of the implant, at most about 19.75 cm in length along the longest length of the implant, at most about 20 cm in length along the longest length of the implant, at most about 20.25 cm in length along the longest length of the implant, at most about 20.5 cm in length along the longest length of the implant, at most about 20.75 cm in length along the longest length of the implant, at most about 21 cm in length along the longest length of the implant, at most about 21.25 cm in length along the longest length of the implant, at most about 21.5 cm in length along the longest length of the implant, at most about 21.75 cm in length along the longest length of the implant, at most about 22 cm in length along the longest length of the implant, at most about 22.25 cm in length along the longest length of the implant, at most about 22.5 cm in length along the longest length of the implant, at most about 22.75 cm in length along the longest length of the implant, at most about 23 cm in length along the longest length of the implant, 23.25 cm in length along the longest length of the implant, at most about 23.5 cm in length along the longest length of the implant, at most about 23.75 cm in length along the longest length of the implant, at most about 24 cm in length along the longest length of the implant, at most about 24.25 cm in length along the longest length of the implant, at most about 24.5 cm in length along the longest length of the implant, at most about 24.75 cm in length along the longest length of the implant, at most about 25 cm in length along the longest length of the implant, at most about 25.25 cm in length along the longest length of the implant, at most about 25.5 cm in length along the longest length of the implant, at most about 25.75 cm in length along the longest length of the implant, and at most about 26 cm in length along the longest length of the implant. As used herein with respect to implant length dimensions, the term "about" means variations of at least one of 0.1 cm, 0.2 cm, 0.25 cm, 0.5 cm, and 1 cm.

In some embodiments, the unicompartment implant is longer than it is wide, and the longer portion of the implant wraps from the anterior of the condyle to the posterior of the condyle. In some embodiments, the length of the implant is longer on the outer edge of the implant than on the inner edge nearest the trochlear groove (whether used on the lateral or medial condyle).

FIGS. **12**A, **12**B, and/or **12**C may be used to describe a unicompartment knee implant (unicompartment implant) described herein, having appendages **4***a*, **4***c*, extending from a balloon **6** and including holes **8***a*, **8***b*, **8***c*, and/or tabs **10***a*, **10***b*. **10***c*, **10***d*, **10***e*, **10***f* which may be used with couplers (not shown) to couple the implant to a bone of the knee joint (which may be the femur, the tibia, or the patella). Features shown in FIGS. **12**A, **12**B, and/or **12**C are common to both the unicompartment knee implant and the patch implant (discussed elsewhere herein), although dimensions may differ as described herein. Thus, FIGS. **12**A, **12**B, and/or **12**C may be used to describe the unicompartment knee implant and/or the patch implant. FIG. **12**A depicts a bottom-up view of an embodiment of the implant **2** (unicompartment or patch), the implant having appendages **4***a*, **4***c*, extending from a balloon **6** and including holes **8***a*, **8***b*, **8***c*, which may be used with couplers (not shown) to couple the implant **2** to the femur of the knee joint. FIG. **12**B depicts a bottom-up view of an embodiment of the implant **2** (unicompartment or patch), the implant having appendages **4***a*, **4***c*, extending from a balloon **6** and including tabs **10***a*, **10***b* and hole **8***a* which may be used with couplers (not shown) to couple the implant to the femur of the knee joint. FIG. **12**C depicts a bottom-up view of an embodiment of the implant **2** (unicompartment or patch), the implant having appendages **4***a*, **4***c*, extending from a balloon **6** and including tabs **10***c*, **10***d*, **10***e*, and **10***f* and hole **8***a* which may be used with couplers (not shown) to couple the implant to the femur of the knee joint.

In all descriptions provided herein of the unicompartment implant, the implant may instead be configured to couple to

the tibia or to the fibula or the patella. It is the intention and understanding that the implant is suited for this purpose in certain embodiments with adjustments to account for dimensional differences of the particular bones. Most descriptions provided herein are directed to embodiments coupling the implant to the femur, however, this is primarily for ease of description and continuity, and does not preclude embodiments wherein the implant is coupled to the tibia (or other bones). Likewise, as noted elsewhere herein, there are embodiments where the implant may be coupled to two bones (at least), for example to both a tibia and a femur.

Meniscal Replacement or Repair, and Solid, Rigid, or Semi-Rigid Components:

Provided herein is an implant having a balloon having a first and second chamber. The implant may be any of the Dual Compartment, Unicompartment, and Patch implants described herein. The second chamber may be configured to replace and/or partially replace fibrocartilage meniscal loss. The implant may have two lobes of chambers which may be alternatively described as two superimposed balloon radii in apposition to each other. The implant may be configured to provide stability between the femur and tibia by providing a meniscus wedge. In some embodiments the implant comprises a portion configured to replace and/or partially replace fibrocartilage meniscal loss. Such an embodiment may not require a second chamber.

In some embodiments a chamber of the implant is configured to receive a solid piece configured to restore joint and/or bone alignment. In some embodiments, the chamber is configured to receive a plurality of solid pieces, each of which can be used to increase the space between a first bone and a second bone in order to restore and/or improve joint and/or bone alignment. The solid pieces may be wedge-shaped, or be provided in various sizes and/or shapes. The solid pieces may individually or together be used in a chamber or multiple chambers of the implant. The solid piece (or pieces) may be used to ratchet adjacent bones to a desired distraction and/or alignment to restore and/or improve joint and/or bone alignment. The solid piece may be put in a chamber of the implant, which may enclose or partially enclose the piece to hold the piece in place. In some embodiments, a block of biocompatible material (such as PMMA or another bone-like substitute) may be provided and may be formed (by carving or other forming method) by the surgeon to a desired shape. The formed piece may then be put in a chamber of the implant, which may enclose or partially enclose the piece to hold the piece in place.

In some embodiments, the inflation medium is a methyl methacrylate or other biocompatible hardening substance which can flow when initially put into the chamber, and hardens to become a rigid piece (or solid piece). The methyl methacrylate or other biocompatible hardening substance may conform to the shape of the chamber, or may conform to the shape of a space between bones and/or other joint structures. The methyl methacrylate or other biocompatible hardening substance may conform to a form chosen by the surgeon using tools and/or pressure to influence the final shape of the rigid piece formed by the methyl methacrylate or other biocompatible hardening substance upon hardening.

The solid piece (whether formed in situ or by a surgeon or pre-formed) may be cushioned by the implant. The implant may comprise an inflatable chamber between the solid piece and the femur. The implant may comprise an inflatable chamber between the solid piece and the tibia. The implant may comprise an inflatable chamber between the solid piece and the patella. The implant may comprise an inflatable chamber between the solid piece and the second bone. The implant may comprise a pad between the solid piece and the femur as a cushion. The implant may comprise a pad between the solid piece and the tibia as a cushion. The implant may comprise a pad between the solid piece and the patella as a cushion.

The solid piece may provide at least one of about 1 degree of joint correction, about 2 degrees of joint correction, about 3 degrees of joint correction, about 4 degrees of joint correction, about 5 degrees of joint correction, about 6 degrees of joint correction, about 7 degrees of joint correction, about 8 degrees of joint correction, about 9 degrees of joint correction, and about 10 degrees of joint correction. With respect to degrees of joint correction, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%.

The implant can be used in a variety of joints where the implant replaces a bone on bone surface and cushions the interaction between the articular ends of any two bones, such as at the femoral tibial and patella femoral knee interfaces. Where the implant is substituting or enhancing articular cartilage, the rigidity can be reduced or enhanced to maximize conformation changes that arise during motion as enabled by the two opposing walls and intended inner space, coupled with considerations in any joint surgical reconstruction with accommodation to or amplification of the existing joint ligaments, tendons or dearth thereof. The implant **10** may be deflated and removed by minimally invasive surgery, for example, after the implant has served its purpose of regenerating tissue or if another clinical condition warrants its removal. However, it may not be clinically necessary to remove the implant even if inflation is lost, since the two remaining functions of patching the injured cartilage, and delivering restorative cells may justify implant retention.

In many embodiments the implant (or a portion thereof, such as the balloon or balloon) is a weight bearing spacer that will allow joint motions to approach normal, whether filling the space left by an entirely collapsed peripheral joint bone or the space of ablated cartilage proximate surfaces diffusely as in osteoarthritis or succinctly as in osteonecrotic defects or localized trauma. The walls may be used as a membrane for holding living cells in proximity of the osteochondral defect long enough for the cells to attach (e.g. 24 hours) or to deeply adhere (up to 28 days) or return to normal (up to one year). Weight bearing will be expected to increase as distal lower extremity joints are treated.

Kits

Provided herein are kits comprising multiple implants described herein. A kit may comprise multiple sizes of a single type of implant. A kit may comprise various implant types, such as the patch, the unicompartment, and/or the dual compartment types of implants described herein. A kit may comprise various couplers, which may be selected by the surgeon depending on his comfort and expertise, and/or based on the particular patient anatomy and/or needs. The kit may further comprise any insertion tools and/or surgery tools that may uniquely assist in implanting the implant in the patient.

Implantation Methods

Implantation of implants provided herein will depend on the size of joint surface intended for reconstruction by use of the implant. In some embodiments, an arthroscope can be inserted in one side of the knee joint through a 0.5 cm wound, while the implant is inserted into the opposite joint line wound from 1-10 cm in size. The joint may be first inspected and debrided, performing an arthroscopic synovectomy, chondroplasty, and meniscectomy as needed. Additional distraction under general anesthesia with the

knee at variable degrees of flex may allow for implant introduction, systematic peripheral attachment, balancing, and inflation.

In some embodiments, the implant may be selectively inflatable depending on the particular needs of the patient. In some embodiments, the filler of the interior of the implant may be rigid, semi-rigid, fluid, air, or combinations thereof, as described herein. In some embodiments, the implant may be used in conjunction with fibrocartilage repair or replacement. In some embodiments, the implant may be used without fibrocartilage repair or replacement. In some embodiments, the implant may be used in conjunction with boney osteotomy. In some embodiments, the implant may be used without boney osteotomy.

The posterior of the knee can be difficult to access without disturbing joint components (or in order to minimize such disturbance) such as tendons, ligaments, etc. Thus, in some embodiments, the method comprises providing an implant comprising strings, reigns, lassos, and/or lanyards that may pass from the posterior of the implant via the intercondylar notch anteriorly to join with themselves and/or other coupling devices. In some embodiments, posterior reigns or suture-like lanyards cinch up the implant from inside the posterior intercondylar notch toward another connection site around the femur. In some embodiments, the methods comprise conforming the implant posterior to the condyle by pulling the strings (or reigns, or lassos, or lanyards or the like) of the implant. Such couplers (strings, reigns, lassos, lanyards, etc) may comprise suture materials and/or wire materials.

These couplers (i.e. strings, reigns, lassos, lanyards, etc) may be pre-coupled to the implant, and the implant and its couplers may be configured to be pulled (or cinched) from the anterior of the implant once the implant is in its general location relative to the condyle in order to finally position the implant about the condyle—in particular in order to cinch the implant about the posterior of the condyle. Likewise, in some embodiments where the implant is pre-molded, the coupler as described are adapted to move the implant to its final position with conformity to the condyle's posterior with minimal disturbance to the joint structures at the joint's posterior (minimal cutting, minimal moving, and or minimal detachment, for non-limiting example). In some embodiments at least a portion of the ligamentary structure of the knee is spared.

The implant is inserted arthroscopically through a cannula about 10 mm in diameter with the implant in the deflated construct, and once inside the prepared joint space and secured therein by the skirt or tabs, the implant will be distended or inflated with gas, gel, fluid or fluid that becomes a resilient solid to fill the original natural space of about 0.5 cm between the bones of the joint (between at least two bones of the joint). If the implant is not inserted through a cannula, it may be inserted through an open incision from one to forty centimeters in length at the surgeons discretion. Tensioning will be by the surgeon's sense of proper pressure application aided by a gauged syringe for insertion of viscolubricants such as Synvisc, Hyalgan, Supartz and/or analgesics such as lidocaine gel. The insertion of liquids to the joint per se may be directly, through a cannula to the joint space previously in place for debridement, and or via a cannula or tube that is not part of the original implant assembly. Once the joint is cleaned, the implant is inserted and appropriately fixed to avoid extrusion or dislocation thereof. This may be via attachment of the implant tabs and/or by a combination of tab use plus intended friction created by implant surface coverings (analogous to Velcro) or a draw string at the smaller base of the implant.

In some embodiments the attachment tabs are positioned on the implant to both secure the implant to the joint components, and to enable a physician to ensure the implant has a minimum amount of slack that could create wrinkles or loose areas to avoid unnecessary friction and/or wear of the implant of the patient's anatomy. Figures depicted herein show examples of properly situated attachment tabs configured for these dual purposes. In some embodiments, fewer tabs are needed to achieve these goals.

In some embodiments, where slack or voids exist, the balloon under compression may fill such areas. The implant in some embodiments is configured to allow hyaline and/or cartilage cells to fill any irregularities or craters in the joint components and grow to refurbish natural joint contour. When the implant implantation is combined with, for example, movement of the treated joint in a constant passive motion machine for 12 hrs a day for 6 weeks after surgery implanting the implant, cell growth will create renewed hyaline cartilage, and/or blood/fibrin and scar to create fibrocartilage filler material.

Each attachment tab insert site may be clinically determined centripitally around the implant during surgery, driving slots or holes sequentially with an osteotome or drill immediately followed by insertion of the triangled tab extension into the bone slots or screw respectively. For example, if the implant were viewed like a clockface the first tab could be tacked/tapped in a 2 o'clock, then 7, 10, 4 11, 5, 12, 6 (wherein #2, 7, 10, 4 are over the bilateral femurs superior/inferior to collateral ligaments, 11, 12 are superior at the distal anterior femur beneath the upper patella, and 5, 6 are inside the intercondylar notch anterior to cruciates.) This can be like putting a saddle on a horse, going around the knee end with a grasper, to tug the polymer toward fit, tapping a slot over the side of the femur with a thin one-half inch osteotome, angling cuts distally, one by one, as if to pull the implant (or saddle) into its angle of repose, seating ideally over the condyles and ridings nicely in the trochlear groove.

In some embodiments, the metal clips could be set angled at about 120 degrees, as greater than 90 will favorably distract/hold the implant to tighter fit analogous to a mylar compliant balloon or stretch sock fitting over a protuberance as opposed to a piece of (non-compliant) paper that results is wrinkles and areas of incongruence between the implant and bone end. Reducing dislodgement tendency and snugging the polymer once stretched to best fit may avoid the failure history as illustrated in the Danish Polymer hip cap solid crescent shaped hip resurfacing implants which lacked inflation, surface stability, accommodation, and fixation.

Inflation may also be specified by clinical need, and modifications in the implant multi-cell (multi-compartment) construction allows for selective inflation with substances ranging from gas to solid, including gels or semi-solids that can as part of material layered integrity either provide calculated hardness (durometer) to overcome and resist limb adjacent bone mal-alignment, and/or to deliver new regenerative tissues for restoration of natural anatomy of time. That is, certain sections of the implant may be electively inflated of left without expansion, to adjust to fit as matching a normal or uninjured contralateral limb for the involved patient.

Indeed, patient interaction and feedback may be sought so as to bring to orthopedic conceived art and science the individual's own needs and concerns. It is said that for patients who have anterior cruciate injuries, one third require

reconstruction for knee joint stabilizer, one third do not—living with a reduced activity level, and one third deliberate extensively until a choice between the two continuum options is made.

A goal of embodiments of implants described herein is to maintain remnant living tissue by using minimally invasive technologies, smaller incisions when they serve the patient equally to larger, sacrificing the least normal tissue as possible. Implants described herein assist and improve on current treatment options available by avoiding as much as possible the ablative bone and cartilage resecting, ligament removing total knee arthroplasty and instead to restore the padding lost in injury or disease or surgery.

Examples from within the techniques include electing to repair rather than reconstruct anterior cruciate ligaments in certain situations, proved warranted and effective at a $p<0.3$ statistical level. Whereas Carticel chondrocyte implantation is useful to enable articular surface regrowth with hyaline, rather than scar/fibrocartilage from picking/drilling, the massive morbidity from periosteal harvesting is unnecessary. This is because it takes only 24 hours for the cartilage cloned chondrocytes to attach to the prepared joint surface, and the polymer membrane (patch implant described herein, for example, or use of chondrocytes on surfaces of the dual compartment implant or the unicompartment implant) over the prepared defect (like a manhole cover) will adeptly substitute for periosteum.

With these concepts in mind in is the overall intent to do what is necessary to restore function and nothing more in order to spare the patient removal of injured tissues that may recover or regrow, by implementing a common sense approach to limb repair and reconstruction with the implant and methods of use thereof. In animals as horses and dogs, where recovery instructions are even less likely to be followed than with humans, implanting secure restorative implants for joint surface refurbishment may offer renewed function and save lives that would have otherwise been sacrificed.

Rehabilitation of knee implant treated patients will engage prudent early motion. The amount of weight bearing allowed with be analogous to the procedures written by this primary surgery for Carticel implanted cases, following the principles that excessive amounts and repetitions of stress upon reconstructed areas should be avoided for 6-12 weeks after surgery. However, the knee implant surgeries per se are expected to take less than one hour, involve less than 1 cc blood loss, require wounds less than or equal to 10 cm overall (depending on the embodiment of the implant), and the end result intends to permit early full weight bearing. Zealous sports activities may be restricted until the bone ingrowth and cartilage renewal is reasonably expected, between 2 and 12 months after surgery depending upon the amount of joint tissue replaced.

In some situations, the removal of the implant may be needed, and embodiments of the implants described herein are configured for removal arthroscopically, and with the allowance to perform all regular older routine accepted techniques ranging from joint debridement to drilling, partial or total replacement. In some embodiments the implant is configured for removal and replacement with a replacement implant—either immediately (within a week), or after a period of longer time (for example, after about 6 weeks to 1 year in the case of infection once all foreign bodies are removed and depending upon the surgeon's and/or infectious disease consultant's opinion

Specific surgical decisions related to size matching, fixation and or concomitant osteotomy warranted reconstruction are left to the primary surgeon and patient in each case.

The implant is inserted by minimally invasive surgery, in some embodiments, however, in other embodiments, the implant may not be inserted by minimally invasive surgery. In some embodiments, the implant is delivered through an incision that is about 0.5 inches long. In some embodiments, the implant is delivered through an incision that is about 1 centimeter long. In some embodiments, the implant is delivered through an incision that is at most about 1 inch long. In some embodiments, the implant is delivered non-arthroscopically through an incision that is at least 1 centimeter long. In some embodiments, the implant is delivered through an incision that is at most about 0.75 inches long. In some embodiments, the implant is delivered through an incision that is at most about 0.5 inches long. In some embodiments, the implant is delivered through an incision that is about 8 centimeters long. In some embodiments, the implant is delivered through an incision that is about 9 centimeters long. In some embodiments, the implant is delivered through an incision that is about 10 centimeters long. In some embodiments, the implant is delivered through an incision that is about 11 centimeters long. In some embodiments, the implant is delivered through an incision that is about 12 centimeters long. In some embodiments, the implant is delivered through an incision that is over about 10 centimeters long. In some embodiments, the implant is delivered through an incision that is at up to about 40 centimeters long. In some embodiments, the implant is delivered through multiple incisions. With respect to incision length, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%.

In some embodiments the implant is configured to be delivered to the joint arthroscopically. In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most 10 millimeters. In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most 9 millimeters. In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most 5 millimeters.

In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end, inner diameter of at most 10 millimeters. In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most 9 millimeters. In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most 5 millimeters.

In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most 10 millimeters. In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most 9 millimeters. In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most 5 millimeters.

In some embodiments the implant is configured to be delivered to the joint arthroscopically. In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most about 10 millimeters. In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most about 9 millimeters. In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most about 5

millimeters. With respect to cannula distal end inner diameter, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%.

In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most about 10 millimeters. In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most about 9 millimeters. In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most about 5 millimeters. With respect to cannula distal end inner diameter, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%.

In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most about 10 millimeters. In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most about 9 millimeters. In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most about 5 millimeters. With respect to cannula distal end inner diameter, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%.

In some embodiments the implant may be provided as a deflated balloon for insertion into the joint space. In some embodiments the implant may be provided as folded balloon that may be collapsed like an umbrella for insertion into the joint space. In some embodiments the implant may be provided as collapsed balloon that is of an irregular folded pattern to minimize its folded (or collapsed) size for insertion into the joint space. In some embodiments, the implant is configured to blow up (or expand) to take the form of the expanded, distracted, debrided joint.

In some embodiments, the implant replaces periosteum.

In some embodiments, the implant is implanted to preserve bone as compared to a typical arthroplasty procedure of the joint. In some embodiments, the implant is implanted to preserve cartilage as compared to a typical arthroplasty procedure of the joint. In some embodiments, the implant is implanted with minimal soft tissue dissection as compared to a typical arthroplasty procedure of the joint. In some embodiments, the implant is implanted without joint dislocation. In some embodiments, once implanted, the joint is adaptable to revision surgery. In some embodiments once implanted, the joint retains at least one of: about 90% of normal joint function, about 95% of normal joint function, about 85% of normal joint function, about 80% of normal joint function, about 75% of normal joint function, about 70% of normal joint function, about 65% of normal joint function, about 60% of normal joint function, about 55% of normal joint function, about 50% of normal joint function, at least 95% of normal joint function, at least 90% of normal joint function, at least 85% of normal joint function, at least 80% of normal joint function, at least 75% of normal joint function, at least 70% of normal joint function, at least 65% of normal joint function, at least 60% of normal joint function, at least 55% of normal joint function, at least 50% of normal joint function, about 50%-about 75% of normal joint function, about 50%-about 70% of normal joint function, about 60-about 70% of normal joint function, about 70%-about 80% of normal joint function, about 70%-about 90% of normal joint function, about 80%-about 95% of normal joint function, about 80%-about 90% of normal joint function, and about 90%-about 95% of normal joint function. As used herein with respect to percentage of normal joint function, the term "about" can be ranges of 1%, 5%, 10%, or 25%. For example, a range of 1% with respect to about 90% of normal joint function covers 89% to 90% of normal joint function.

In some embodiments, prior to deploying the implant embodying features of the invention, the cartilage lining the joint is prepared by removing hyaline or fibro cartilage flaps or tears, and areas of chondral advanced fissuring are excised or debrided to create precisely defined defects surrounded by stable normal remnant hyaline cartilage with vertical edges in relation to the damaged surface. It is these defects of the cartilage previously normal surface into which new living cells may be injected or otherwise inserted, and allowed to aggregate by the implant interpositional arthroplasty proximate expanded compressive external wall material. Synovitis invading the joint periphery may be vaporized and extracted conventionally or by the use of steam. Areas of greater cartilage damage are removed for subsequent regeneration and the less afflicted areas having stable cracks are treated to seal or weld the cracks. Areas where the tugor or consistency or minimally damaged cartilage can be preserved are intentionally saved rather than destroyed so as to support the normal spacing and gliding opportunity of the more normal joint interface. Thus, normal cartilage is left behind and abnormal cartilage is removed with the implant making up for the deficiencies. With the present invention, it is preferred in some embodiments to avoid joint dislocation so as to preserve natural innervations and vascularity and thus preserving the blood supply.

Joint preparation is usually performed under a brief general anesthetic of outpatient surgery. Increasing the joint space may be necessary and allows the surgeon to wash out noxious enzymes, to remove invasive synovitis, to remove loose bodies, to prepare osteochondral defects ideally and otherwise prepare the joint for the implant. Partial or complete inflation of the implant may precede release of traction in some embodiments. In some embodiments, regeneration agents or cells are inserted with the implant or as a fluid or 3-D template prior to release of traction and wound closure. It is preferred, in some embodiments, to perform joint debridement, implant deployment and application of cell regeneration agent, e.g. stem cell application, under the same anesthetic. As described by several companies in the Stem Cell Summit held in New York, N.Y. on Feb. 17, 2009, it is desirable to obtain an aspiration of the patient's bone marrow from the iliac crest after anesthesia) sterilely at the beginning of the operation. The intraoperative technologist will "dial in the cells" to regenerate areas of maximum pathophysiology while the surgeon debrides or otherwise prepares the joint and inserts the implant, placing the cells at the best time. Cell implantation may also occur as a secondary or tertiary reconstructive treatment adjunct.

Provided herein is a method for restoring a joint comprising: providing an implant configured for deployment between a femur and at least one second bone of a joint, the implant comprising a balloon comprising a first portion that is configured to engage the femur of the joint, a second portion that is configured to engage at least one second bone of the joint, a side portion connecting the first portion and the second portion, in which the side portion facilitates relative motion between the first portion and the second portion, and an interior that is optionally inflatable with a first inflation medium; and coupling a first appendage of the balloon to the femur of the joint. Provided herein is a method for restoring a joint comprising: providing an implant configured for deployment between a tibia and at least one second bone of a joint, the implant comprising a balloon comprising a first portion that is configured to engage the tibia of the joint, a

second portion that is configured to engage at least one second bone of the joint, a side portion connecting the first portion and the second portion, in which the side portion facilitates relative motion between the first portion and the second portion, and an interior that is optionally inflatable with a first inflation medium; and coupling a first appendage of the balloon to the tibia of the joint.

In some embodiments, at least two of first portion, the second portion, and the side portion are contiguous. In some embodiments, the first portion comprises a first wall, the second portion comprises a second wall, and the side portion comprises a side wall.

In some embodiments the method comprises providing an ingrowth patch on at least one of the first portion configured to engage the femur, the second portion configured to engage the second bone, the side portion, and the appendage. In some embodiments the method comprises providing an ingrowth patch on at least one of the first portion configured to engage the tibia, the second portion configured to engage the second bone, the side portion, and the appendage. The ingrowth patch may be configured to encourage and/or promote tissue ingrowth, such as bone ingrowth, for non-limiting example. The patch may be as large as the portion itself (whether the first portion the second portion, the side portion, or the appendage) or may be smaller than the portion (such as in the shape of a strip or other shaped patch). The ingrowth patch may comprise a surface irregularity or roughness. The ingrowth patch may be Velcro-like. In some embodiments the implant comprises an ingrowth patch on the first portion and/or the second portion, from (and in some embodiments including) a first appendage to a second appendage. In some embodiments, wherein the appendages loosen from attachment from the bone (by design and/or from wear and/or over time), the ingrowth patch aids in securing the implant to the bone. In some embodiments, the ingrowth patch comprises beads and/or bead-like elements attached to the implant. Such an ingrowth patch may be configured to simulate trabecular bone space of a normally cancellous latticework. In some embodiments, the beads are sintered beads of various sizes. In some embodiments, the beads are sintered beads about 400 microns in size. With respect to bead size, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%. In some embodiments, the first bone and/or the second bone is roughened to acquire a bleeding bone to facilitate ingrowth. In some embodiments, about 0.5 mm of cortical tissue is removed to facilitate ingrowth.

In some embodiments, the method comprises coupling a second appendage of the balloon to the femur of the joint. In some embodiments, the method comprises coupling a second appendage of the balloon to the tibia of the joint. In some embodiments, the method comprises coupling a second appendage of the balloon to at least one second bone of the joint. In some embodiments, the method comprises coupling a second appendage of at least one of the first portion, the second portion, and the side portion to at least one of the femur and at least one second bone of the joint. In some embodiments, the method comprises coupling a second appendage of at least one of the first portion, the second portion, and the side portion to at least one of the tibia and at least one second bone of the joint. In some embodiments, coupling at least one of the first appendage and the second appendage provides ligamentary-like support to the femur and the at least one second bone of the joint. In some embodiments, coupling at least one of the first appendage and the second appendage provides ligamentary-like support to the tibia and the at least one second bone of the joint. In some embodiments, coupling at least one of the first appendage and the second appendage provides ligamentary-like support to the joint. In some embodiments, the first appendage and the second appendage are configured to provide tendon-like support to the femur and the at least one second bone of the joint. In some embodiments, the first appendage and the second appendage are configured to provide tendon-like support to the tibia and the at least one second bone of the joint. In some embodiments, the first appendage and the second appendage are configured to provide tendon-like support to the joint.

In some embodiments, the method comprises providing an inflation port in communication with the interior of the balloon for inflation of the interior of the balloon with the first inflation medium. In some embodiments, the method comprises using an inflation port of the implant that is in communication with the interior of the balloon to inflate the interior of the balloon with the first inflation medium. In some embodiments, the method comprises puncturing the balloon to inflate the interior of the balloon with the first inflation medium. In some embodiments, the method comprises providing a balloon having self-sealing capability. In some embodiments, the method comprises providing a balloon having self-sealing capability upon inflation of the interior of the balloon with the first inflation medium. In some embodiments, the method comprises providing a balloon comprising a seal capable of closing the interior of the balloon.

In some embodiments, the method comprises providing a balloon having an interior comprising a plurality of inflatable chambers. In some embodiments, the interior comprises a plurality of individually inflatable chambers. In some embodiments, the method comprises inflating a first chamber of the plurality of inflatable chambers with a first inflation medium. In some embodiments, the first chamber and the inflation medium is selected based on the particular needs of the patient. For non-limiting example, if the patient has bone loss due to an injury, the chamber may be selected at the location of the missing bone, and may be filled with a rigid inflation medium (or one that becomes rigid once in the chamber) in order to replace the missing and/or damaged bone. Alternatively, or in addition, a chamber may be chosen to restore alignment of the joint, and inflated with an appropriate inflation medium to impart both alignment and cushion to the joint. In some embodiments, the method comprises inflating a second chamber of the plurality of individually inflatable chambers with a second inflation medium.

In some embodiments, the balloon is a composite structure. In some embodiments, the balloon comprises layers of porous and/or non-porous materials, or otherwise contain treatment or cell regeneration agents. In some embodiments, a first layer of the balloon is a thin, but strong layer of a thermoplastic, such as a thermoplastic polyurethane, for non-limiting example, which has microporosity sufficient to allow passage or egress of treatment or cell regeneration agents from a second layer. The second layer may be a central layer (which lies between the first layer and a third layer or a fourth layer or more layers). The first layer may comprise a bone engaging surface in some embodiments. The degree of microporosity to enable egress of treatment or cell regeneration agents from the second layer is found in polymer layers such as Chronoflex or Bionate 55. The bone engaging surface of the implant may be coated and/or impregnated with a latticework of polymer that is surface sprayed or layered on the bone engaging surface of the implant to promote cartilage tissue regeneration. This bone

engaging surface coating may contain living chondrocytes (for example, as is provided in the Carticel procedure by the Genzyme company), and/or may contain stem cells with directed gene mutations to enhance adherence of the coating to the implant. The bone engaging surface may comprise peaks and troughs. The living cells may be provided in troughs while the surface peaks may be used for at least one of: space validation, traction, and cell protection.

In some embodiments, the first inflation medium imparts rigidity in the implant. In some embodiments, the first inflation medium imparts cushion in the implant. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium aligns the joint. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium aligns the bones of the joint. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium changes the bone alignment. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium improves joint alignment. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium restores, at least in part, joint alignment. In some embodiments, individual chambers of the interior are selectively inflated with a first inflation medium and/or a second inflation medium. In some embodiments, individual chambers of the interior are selectively inflated with a first inflation medium and/or a second inflation medium in order to reconstruct the joint and/or in order to reconstruct bones of the joint.

Over time, ingrowth of repair tissue aids in fixation and stability externally to the implant, while the soft cushioning implant interior will absorb forces across the joint surfaces and permit proper motion. The turgor or wall tension of the implant as well as the inside distension of the implant per se can be adjusted by adding or removing the inflation substance to the implant's interior space.

Accordingly, the present invention provides a new approach to arthroplasty that involves a resilient implant deployed between bones of the knee joint. Whereas a joint is comprised of the interface between bone cartilage space cartilage bone, in certain joint spaces such as the knee, the invention cushion may expand to fit the spaces between both "knee joints"—the femoral tibial involved on standing or walking on a level plane, and the patella femoral bones of the knee more involved on stair ascent and decent. For example, pressures behind the knee cap or patella when lying are zero, when standing are 0.7 times body weight, and when going up and down the patella femoral pressures are 3-4 times body weight. Thus, the implants will need to accommodate all the normal body functional pressures and complex space movements. The implant embodying features of the present invention provides more physiologic motion and shock absorption within the joint and has combined characteristics of anatomic design symmetry, balanced rigidity with sufficient attachment connections to adjacent normal structures, and durability that meet the needs of joint reconstruction.

The opposing internal surfaces of the first and second walls of the invention may either move together in synchrony or in opposite directions from one another (e.g. the superior wall moving medially in the hip and the inferior wall moving laterally). Optionally, the implant may be fixed to a concave surface of the joint or to a convex surface of the joint, to both, or to neither (e.g., having an interference fit within the joint with an expanding balloon or cushion that fills the existing space). The implant may be inserted arthroscopically like a deflated balloon and then inflated through a cannula into the joint structure) to act as a cushion or renewed interface for painless and stable limb motion. When feasible joint capsular and adjacent ligament tissue as well as bone will be left in place to preserve the natural body, unless interfering with reconstructed limb function.

The application of steam in addition to removing damaged debris, can smooth out and reform the joint surface. The high temperature of the steam tends to weld cracks or fissures which can be present in the cartilage surface of a damaged joint. Smoothing of joint surface cartilage with steam welds or seals existing cracks or flaps in the cartilage, especially superficially as the lamina splendors, which melt together to provide a white shiny gliding joint surface. In cases where bone is exposed, the steam can be used to stabilize the periphery of the defect in the joint surface via capsulorrhaphy or joint tightening. Open mechanical and chemical debridement may also be employed to prepare the surfaces for the implant.

Once the implant is secured to the femur by means of the skirt or tabs or using other couplers, an impregnated transfer medium or cell template may be used, as described by Histogenics and Tygenix chondrocytes delivery systems wherein the position of concentrated cells is mechanically placed about the implant at areas of greatest cartilage damage to promote regrowth, or as in Carticel wherein watery cells are implanted beneath a periosteal membrane (a wall of the implant serving as the membrane), prior to completion of the inflation or expansion of the implant. At syringe or gauged device with measured screw-home pressure is used to inflate the implant.

Once the joint is ready to receive the implant, the deflated implant is advanced through the diaphragm of a delivery cannula (such as the Acufex from Smith & Nephew) or through the open incision site into the joint. It can be inflated by the attached cannula using a common syringe, inserting several cc's of filler material. Inserted contents and locations of cell placements depend on areas of need and joint size. In some embodiments of the methods several cc's of filler material and a viscolubricant in the interior of the implant will allow distension, cushioning, and gliding movements. Cell regeneration agents are placed in the areas of greatest need.

Methods of living stem cell or chondrocyte placement depend on the lesions and specific implant construct. Direct infusion into the joint with completion of implant inflation will press the cells into the hyaline surface, whereupon they attach within the first 24 hours. As a result, the patient may be forced to remain sedentary and the joint where the implant is deployed, non-weight bearing for the first day after surgery. Deeper osteochondral defects can be treated by 'hyper-perfusion of cells' via either 3-D cell transfer templates, or microneedle injection as used in treatment of diabetic patients for blood sugar testing and insulin/transdermal drug delivery. In cases of osteochondritis dissecans or localized both cartilage and bone lose, bone graft may be packed into the base of the defect followed by addition cell/tissue application. The cannula attached to the implant

may be sealed and detached, or left in place for periodic aspiration of noxious enzymes as for the Cox-1, Cox-2, and 5-Lox systems, followed by reinsertion of activated substances including viscolubricants, or even more cells.

Implants embodying features of the invention may be designed for permanent or temporary deployment within a joint structure. Moreover, the implant may be formed of suitable bioabsorbable materials so that the implant may be absorbed within a particular predetermined time frame. Suitable bioabsorbable materials include polylactic acid, polyglycolic acid, polycaprolactone, copolymers, blends and variants thereof. One present method of forming the implant is to apply numerous layers of polymer such as ChronoFlex AR in a solvent and evaporating the solvent after applying each layer.

The coupling aspects (couplers) including but not limited to skirting or fixation tabs of the present implant prevent joint migration during use.

In some embodiments, the implant is adapted to restore natural joint function. In some embodiments, the implant is adapted to preserve viable joint tissue. In some embodiments, the implant is adapted to be placed with minimal surgery as compared to joint replacement therapy currently marketed. In some embodiments, the implant is adapted to permit weight bearing post surgery within at least one of: about 1 week, within about 1 day, within about 2 days, within about 3 days, within about 4 days, within about 5 days, within about 6 days, within about 10 days, within about 2 weeks, within about 3 weeks, within about 4 weeks, within about 5 weeks, within about 6 weeks. In some embodiments, the implant is adapted to permit weight bearing post surgery after about 1 day wherein full weight bearing is allowed in about 6 weeks. As used herein with respect to weight bearing timing, the term "about" can be a range of 1 day, 2 days, or 3 days, in some embodiments. In some embodiments, the implant is adapted to be allow for faster recovery and resumption of normal activities as compared to joint replacement therapy currently marketed.

In some embodiments, the balloon (or a portion thereof) is adapted to conform to the patient's anatomy. In some embodiments, the implant (or a portion thereof) is adapted to conform to the patient's anatomy. In some embodiments, the inflation medium is adapted to absorb a force (or forces) exerted on the joint. In some embodiments, the inflation medium is adapted to absorb a force (or forces) exerted on the bones of the joint. In some embodiments, the inflation medium is adapted to absorb a force (or forces) exerted on at least one bone of the joint. In some embodiments, the balloon is adapted to absorb shocks exerted on at least one of a bone, multiple bones, a ligament of the joint, ligaments of the joint, a tendon of the joint, tendons of the joint, and the joint in general. In some embodiments, the implant is adapted to restore natural cartilage cushion with stem cells.

In some embodiments, the balloon (or a portion thereof) is adapted to renew joint space. In some embodiments, the balloon (or a portion thereof) is adapted to reducing pain as compared to the pain felt prior to the implantation of the implant. In some embodiments, the balloon (or a portion thereof) is adapted to restore joint function. In some embodiments, the implant (or a portion thereof) is adapted to renew joint space. In some embodiments, the implant (or a portion thereof) is adapted to reducing pain as compared to the pain felt prior to the implantation of the implant. In some embodiments, the implant (or a portion thereof) is adapted to restore joint function.

In some embodiments, the implant is adapted to reverse arthritis in the joint.

In some embodiments, the balloon (or a portion thereof) is adapted to be placed into a debrided limb joint arthroscopically. In some embodiments, the balloon is adapted to pad cartilage defects. In some embodiments, the balloon is inflated to cushion the joint. In some embodiments the implant is adapted to deliver stem cells to at least one of the joint and a bone of the joint. In some embodiments the implant is adapted to deliver living chondrocytes to at least one of the joint and a bone of the joint. In some embodiments, the implant is adapted to provide a new articular surface for the joint. In some embodiments, the implant is adapted to act as a spacer in the joint. In some embodiments, the implant is adapted to space the bones of the joint apart for proper joint articulation. In some embodiments, the implant is adapted to space the bones of the joint apart for reduced bone-on-bone rubbing.

In some embodiments, the implant is configured to at least one of: pad cartilage, cushion the joint, deliver a pharmacologic substance, remove noxious enzymes, debride upon implantation, debride the joint following implantation, deliver a therapeutic substance, deliver a biologic substance, and deliver living stem cells. In some embodiments, the implant is configured to deliver a chemotherapeutic agent to a bone or other surrounding tissues. In some embodiments, the implant is configured to deliver an anti-infectious medication to a bone or other surrounding tissues. In some embodiments, the implant is configured to deliver at least one of an antibiotic, antifungals, and analgesics agent.

In some embodiments, the implant is configured to be selectively inflated to realign limbs.

Provided herein is a method comprising: implanting a knee implant as described herein into a subject, wherein the implant reverses arthritis in the subject.

Provided herein is a method comprising: implanting a knee implant as described herein into a knee joint of a subject and treating a component of the knee joint of the subject with at least one of an allograph tissue, an autograph tissue, and an xenograph tissue. In some embodiments, the implanting step is at least one of: prior to the treating step, simultaneous with the treating step, and following the treating step.

Provided herein is a method comprising: implanting a knee implant as described herein into a subject, wherein the implant at least one of: restores joint function and controls arthropathies. In some embodiments, the implanting spares existing anatomy.

Provided herein is a method comprising: debriding a femur condyle of a knee joint of a subject, and implanting a knee implant as described herein into the knee joint of the subject, whereby the implant is configured to anneal to the cartilage of the subject. In some embodiments, the debriding is achieved by steam application.

Provided herein is a method comprising implanting a knee implant as described herein into a joint previously treated with a joint replacement. In some embodiments, the method comprises removing the joint replacement prior to implanting the knee implant. In some embodiments, the method comprises clearing infectious matter from the joint and/or surrounding tissues. In some embodiments, the method comprises implanting a second implant of any implant described herein following removing the implant previously implanted in the joint. In some embodiments, the method comprises replacing the joint of the subject following removing the implant previously implanted in the joint. In some embodiments, the method comprises debriding the bone of the joint, and implanting an implant of any implant

described herein. In some embodiments, the method comprises repeating the debriding and implanting steps.

While particular forms of the invention have been illustrated and described herein, it will be apparent that various modifications and improvements can be made to the invention. One alternative implant construction involves the use of an upper portion of the implant having a net-like construction and filled with balls or ball bearing like elements that are larger than the openings in the netting. The balls or ball bearing like elements provide motion to the implant. The netting and ball bearing like elements may include regeneration agents as previously discussed, and the bearing construction may be directed toward favorable implant movement balanced with content disbursement.

The invention is intended primarily for human use but may be extended to mammalian use. To the extent not otherwise disclosed herein, materials and structure may be of conventional design.

Moreover, individual features of embodiments of the invention may be shown in some drawings and not in others, but those skilled in the art will recognize that individual features of one embodiment of the invention can be utilized in another embodiment. Moreover, individual features of one embodiment may be combined with any or all the features of another embodiment. Accordingly, it is not intended that the invention be limited to the specific embodiments illustrated. It is therefore intended that this invention be defined by the scope of the appended claims as broadly as the prior art will permit.

Terms such as "element", "member", "component", "device", "means", "portion", "section", "steps" and words of similar import when used herein shall not be construed as invoking the provisions of 35 U.S.C § 112(6) unless the following claims expressly use the terms "means for" or "step for" followed by a particular function without reference to a specific structure or a specific action. All patents and all patent applications referred to above are hereby incorporated by reference in their entirety.

While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

What is claimed is:

1. A knee implant comprising:

a balloon comprising:

a polymer comprising a first layer configured to engage a bone surface, and a second layer positioned beneath the first layer wherein at least one of a pharmacologic agent and an active agent is located between the first layer and the second layer, wherein delivery of at least one of a pharmacologic agent and an active agent comprises release of the at least one of the pharmacologic agent and the active agent through micropores in the first layer, and wherein the rate of the delivery of at least one of the pharmacologic agent and the active agent is controlled by the degree of microporosity of the first layer;

a first surface configured to engage a condyle of the knee;

a second surface configured to be oriented towards at least one of the tibia of the knee and the patella of the knee; and

an interior that is optionally inflatable with an inflation medium.

2. The knee implant of claim **1**, further comprising a metal frame comprising a surface.

3. The knee implant of claim **2**, wherein the metal frame comprises a memory metal.

4. The knee implant of claim **3**, wherein the memory metal comprises nitinol.

5. The knee implant of claim **1**, wherein at least one of the first surface and the second surface comprises a plurality of vacuoles containing at least one of a pharmacologic agent and an active agent.

6. The knee implant of claim **5**, wherein the active agent comprises at least one of stem cells and chondrocytes.

7. The knee implant of claim **1**, wherein the inflation medium comprises at least one of a pharmacologic agent and an active agent.

8. The knee implant of claim **7**, wherein the active agent comprises at least one of stem cells and chondrocytes.

9. The knee implant of claim **1**, wherein the polymer comprises either Bionate 55 or Chronoflex.

* * * * *

US010045851B2

(12) **United States Patent**
Grotz

(10) **Patent No.: US 10,045,851 B2**
(45) **Date of Patent: Aug. 14, 2018**

(54) **RESILIENT INTERPOSITIONAL ARTHROPLASTY DEVICE**

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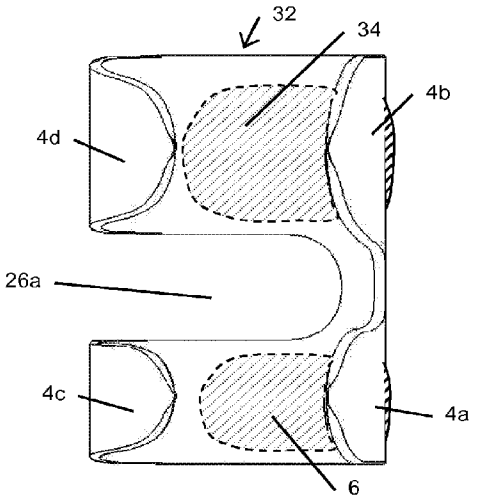
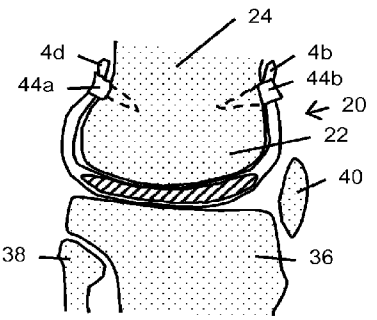
(57) **ABSTRACT**

This disclosure is directed to restoring joints by deploying a resilient interpositional arthroplasty implant. Such implants function to pad cartilage defects, cushion, and replace or restore the articular surface, which may preserve joint integrity, reduce pain and improve function. The implant may endure variable joint compressive and shear forces and cyclic loads. The implant may repair, reconstruct, and regenerate joint anatomy, and thereby improve upon joint replacement alternatives. The walls of this invention may capture, distribute and hold living cells until aggregation and hyaline cartilage regrowth occurs. The implant may be deployed into debrided joint spaces, molding and conforming to surrounding structures with sufficient stability so as to enable immediate limb use after outpatient surgery. Appendages of the implant may repair or reconstruct tendons or ligaments, and menisci by interpositional inflatable or compliant polymer arthroplasties that promote anatomic joint motion.

20 Claims, 14 Drawing Sheets





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See application file for complete search history.

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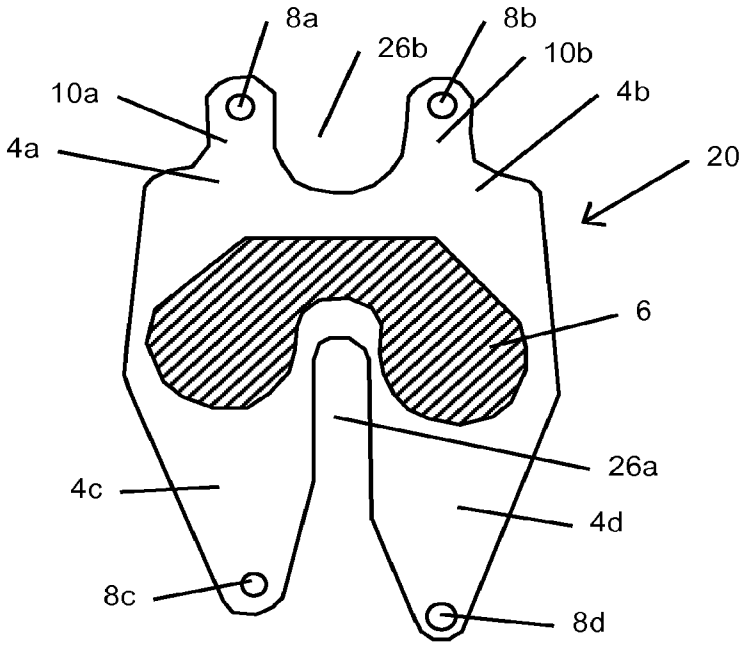
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10b
10a
4b
4a
20
6
26a
4c
4d
8c
8d

FIG. 1

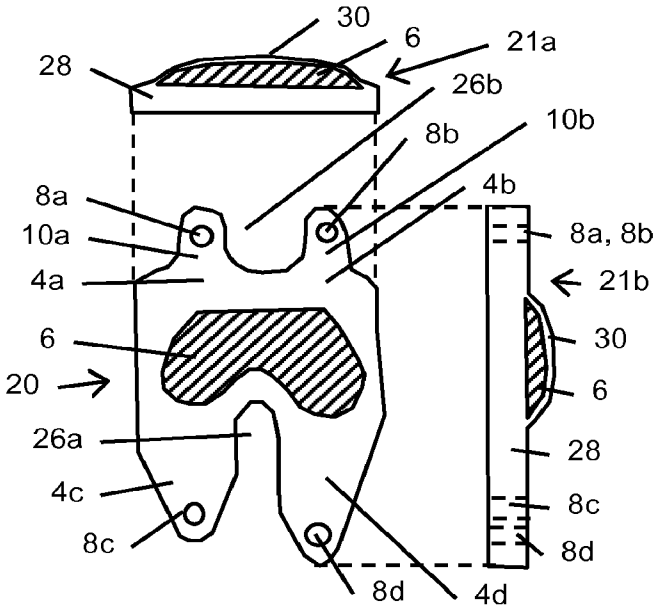
30
6
21a
28
26b
8b
10b
4b
8a
10a
8a, 8b
4a
21b
6
30
20
6
26a
28
4c
8c
8c
8d
8d
4d

FIG. 2

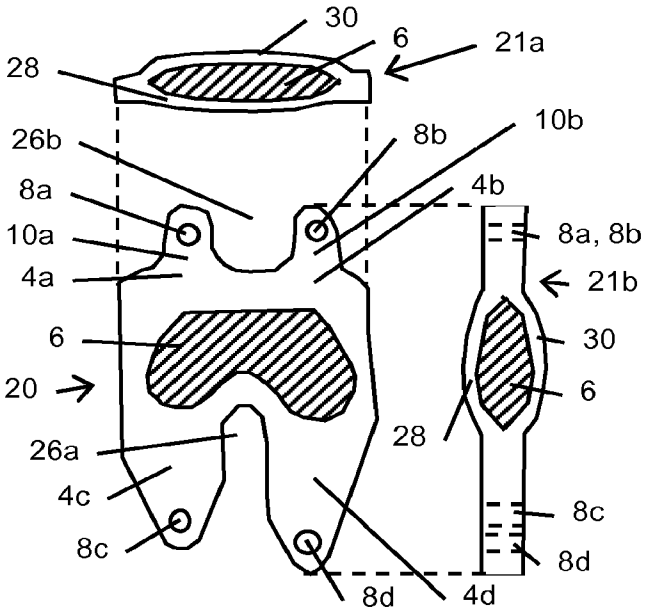
30
6
21a
28
26b
8b
10b
8a
4b
10a
8a, 8b
4a
21b
6
30
20
6
28
26a
4c
8c
8c
8d
8d
4d

FIG. 3

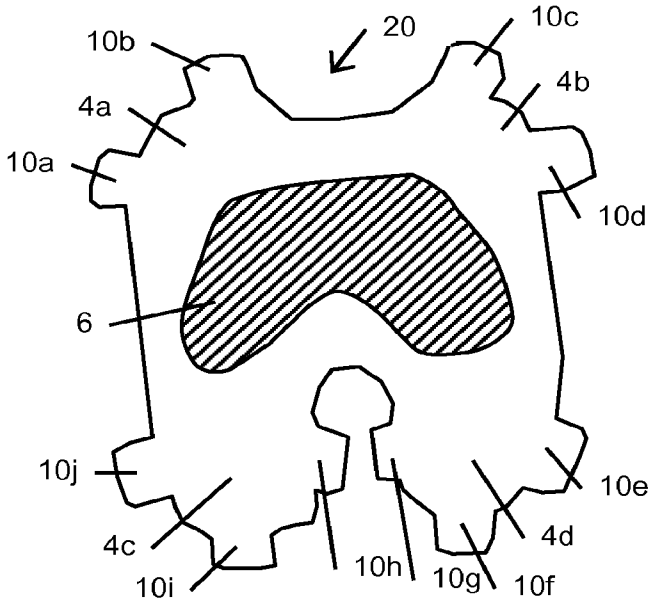
20
10c
10b
4b
4a
10a
10d
6
10j
10e
4c
4d
10h
10g
10i
10f

FIG 4A

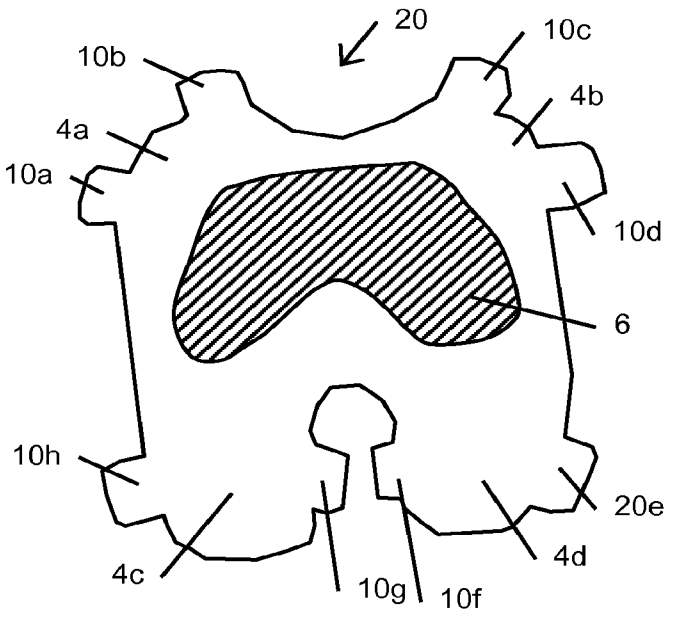
20
10b
10c
4b
4a
10a
10d
6
10h
20e
4c
4d
10g
10f

FIG 4B

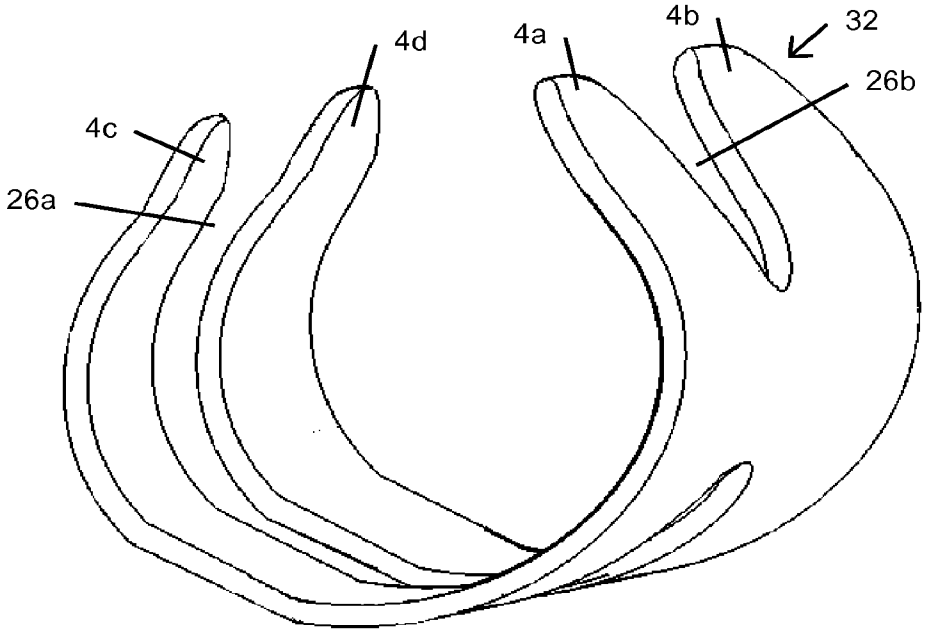
4d
4a
4b
32
26b
4c
26a

FIG 5

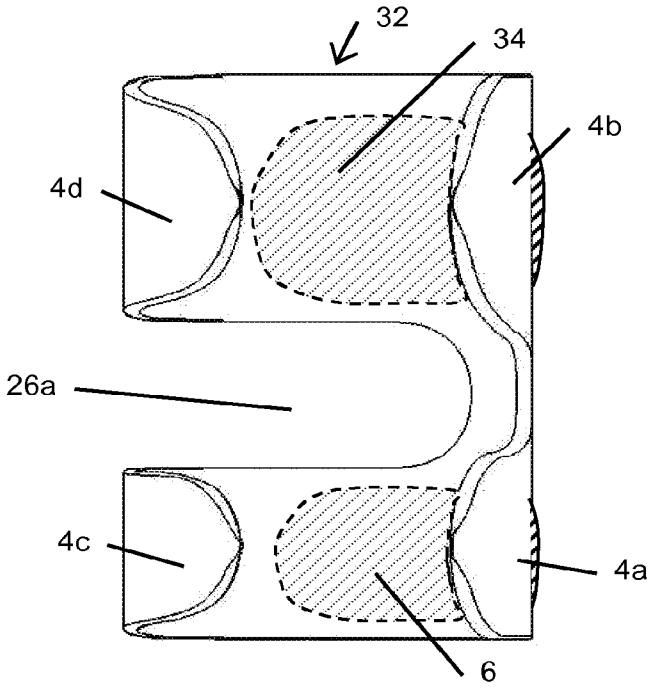

FIG. 6A

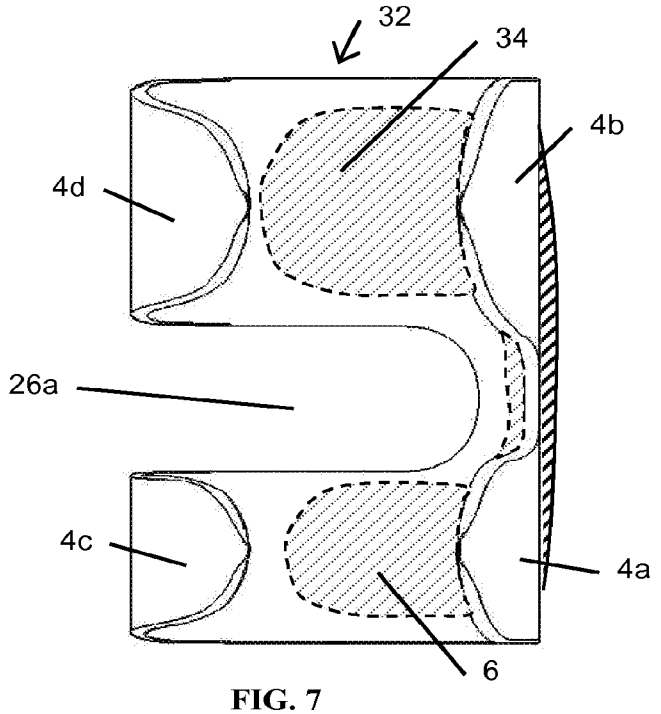

FIG. 7

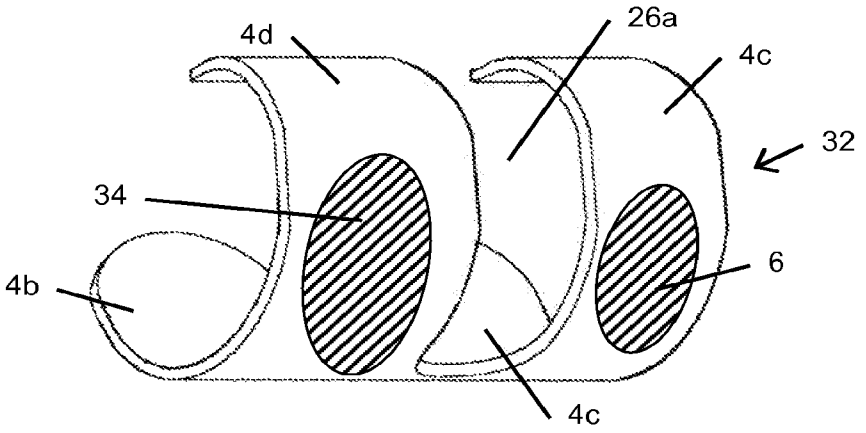

FIG 6B

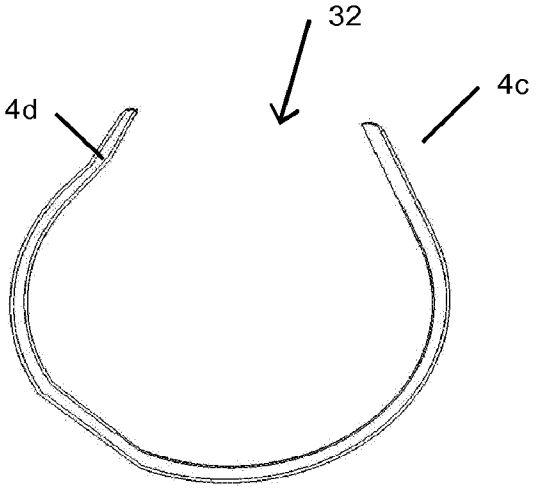

FIG 8

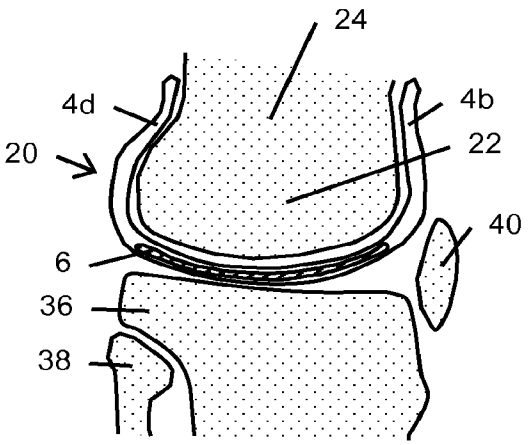

FIG 9A

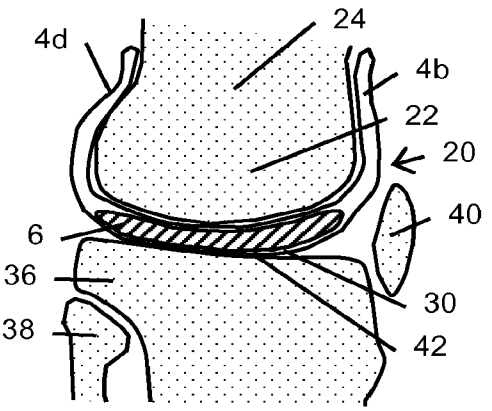

FIG 9B

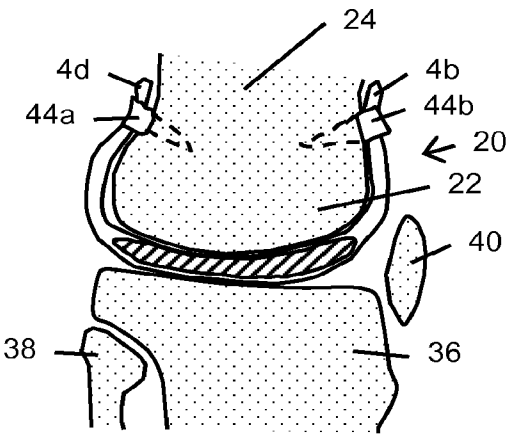

FIG 9C

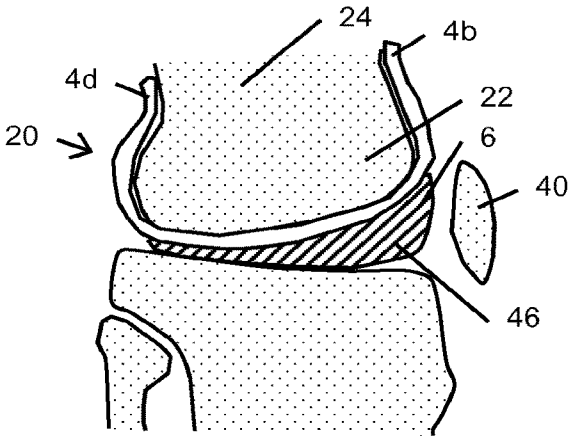

FIG 10A

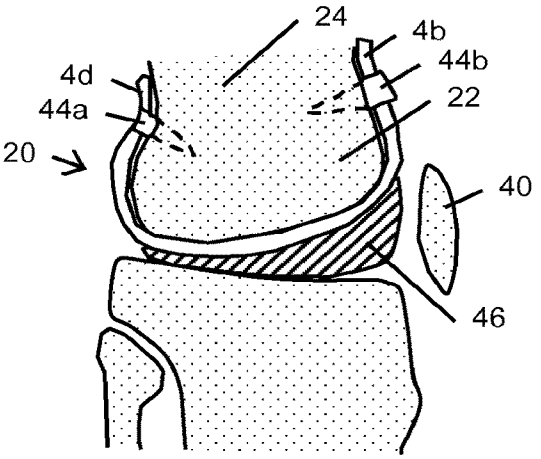

FIG 10B

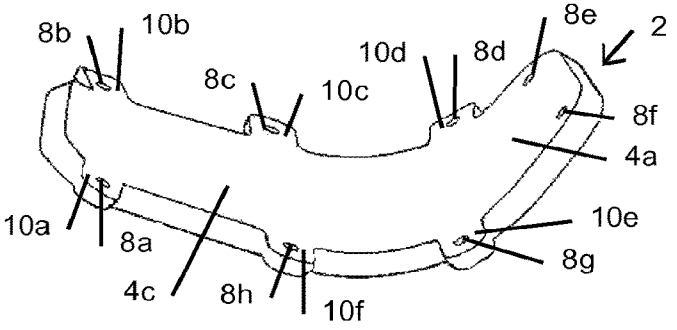

FIG 11A

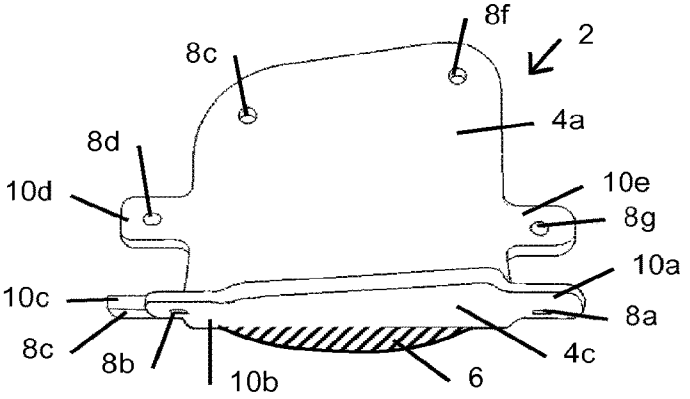

FIG 11B

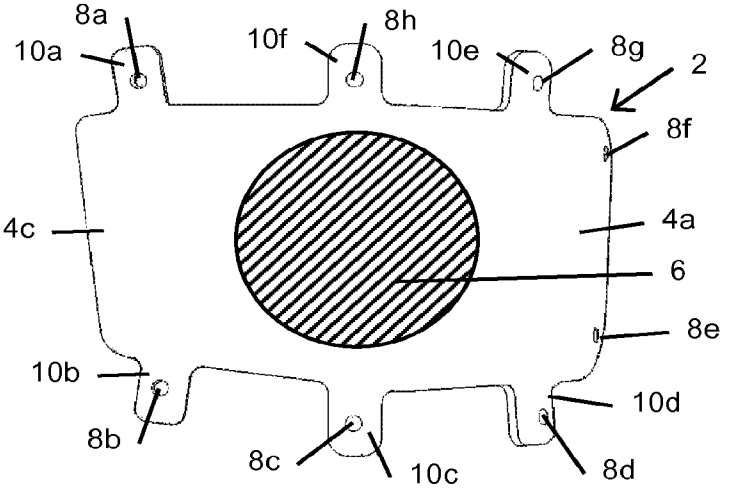

FIG 11C

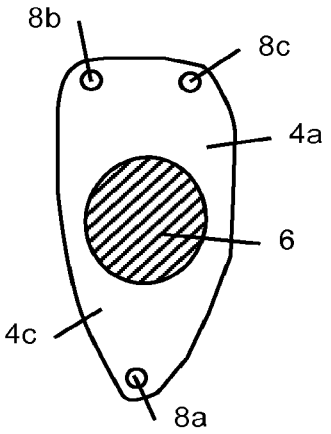

FIG 12A

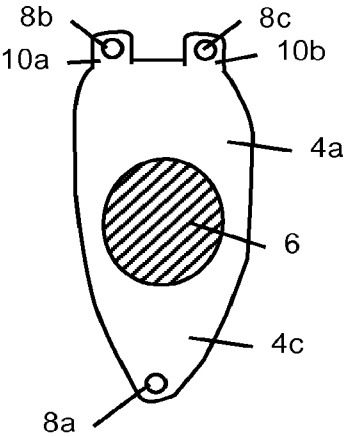

FIG 12B

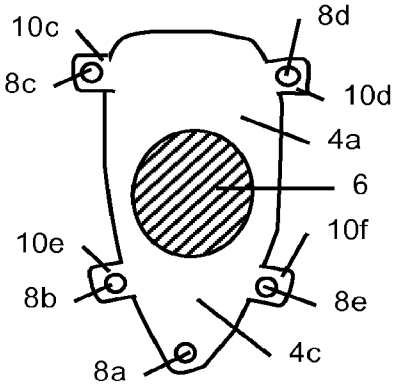

FIG 12C

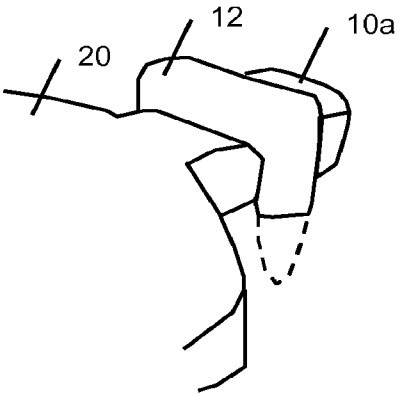

FIG 13A

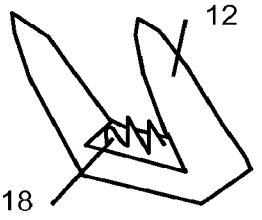

FIG 13B

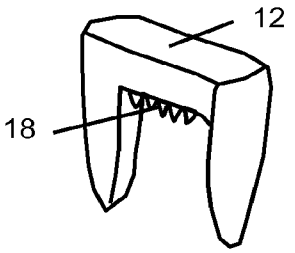

FIG 13C

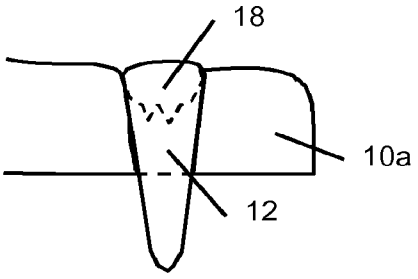

FIG 13D

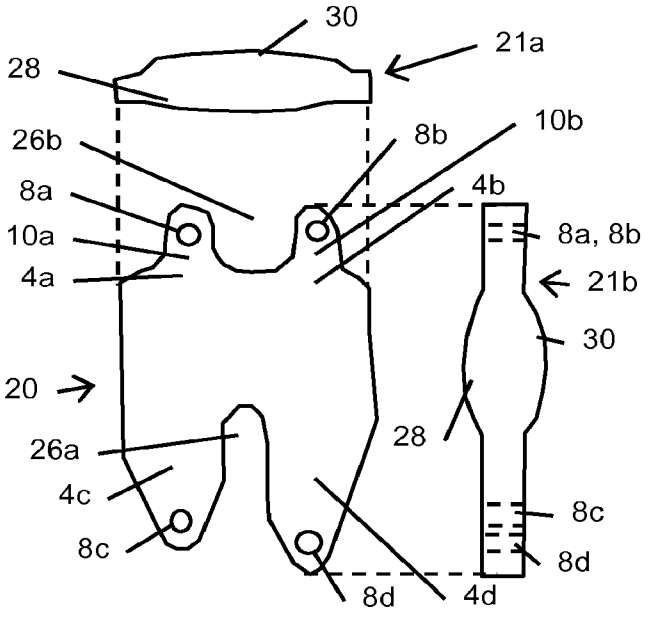

FIG 14

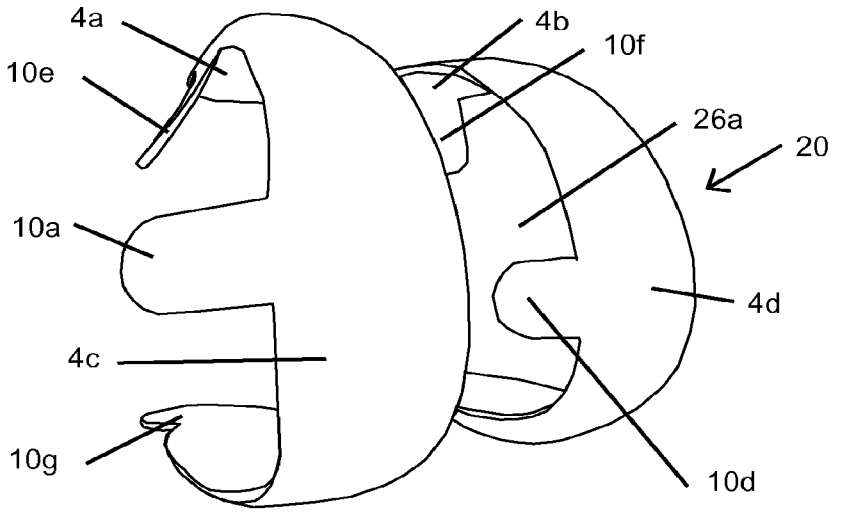

FIG 15A

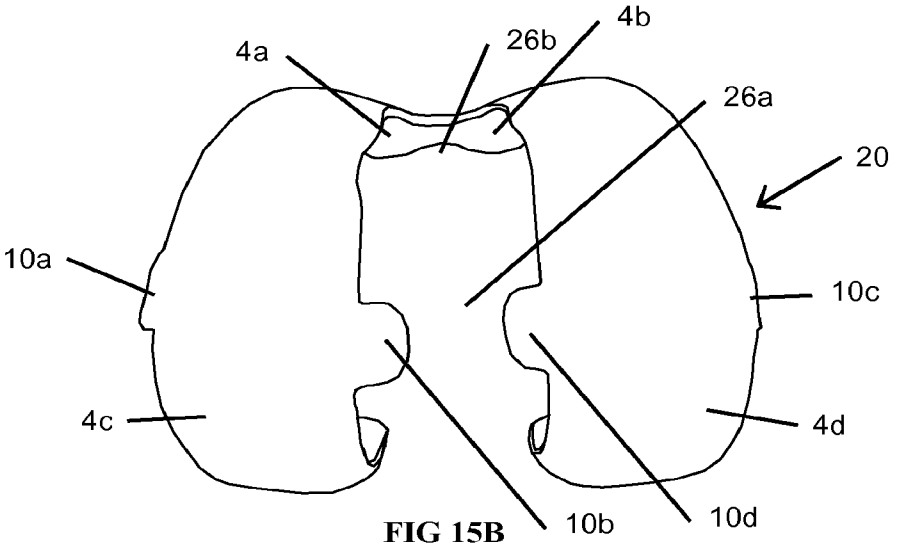

FIG 15B

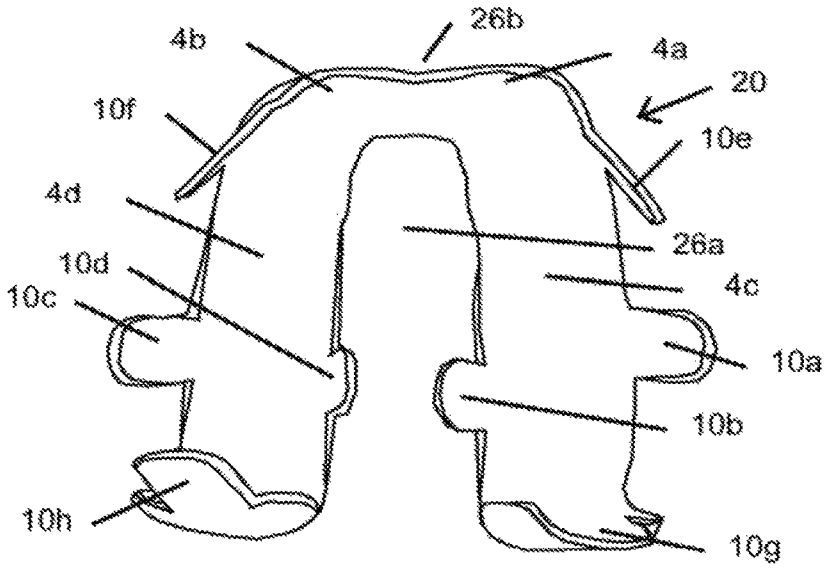

FIG 15C

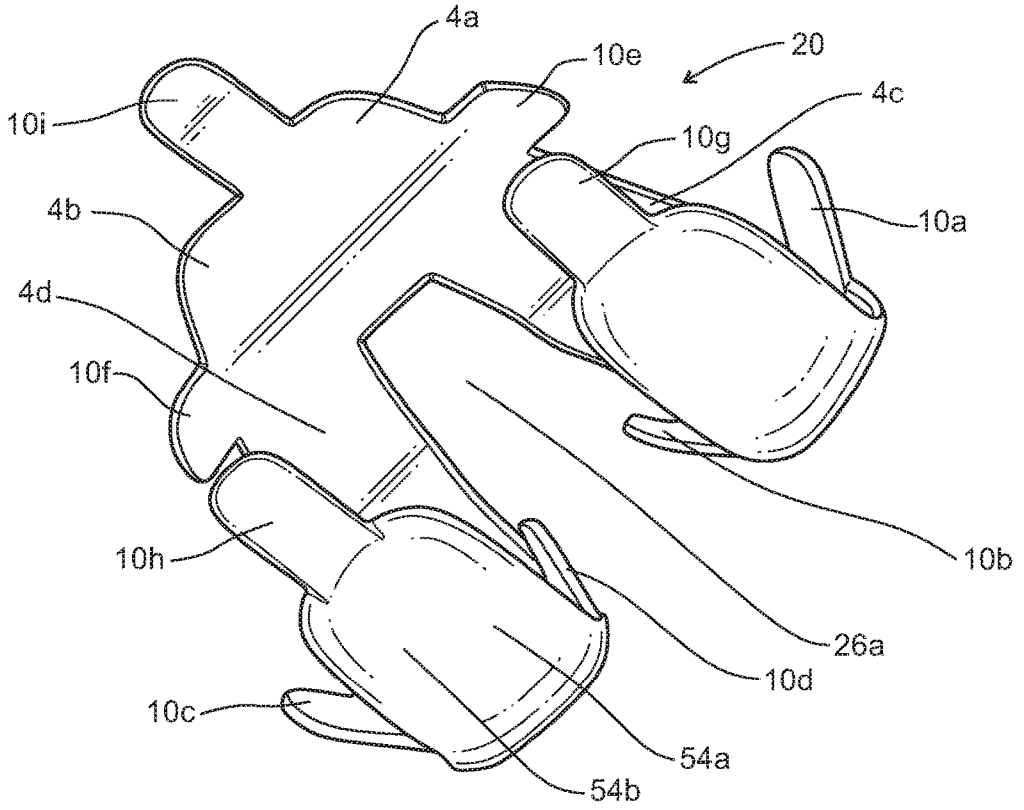

FIG 16

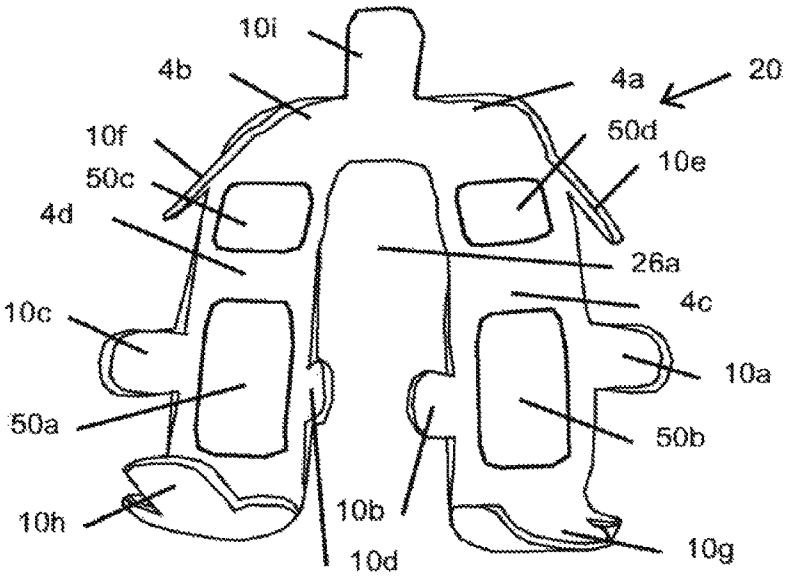
10i
4b
4a
20
10f
50d
50c
10e
4d
26a
4c
10c
10a
50a
50b
10h
10b
10d
10g

FIG 17

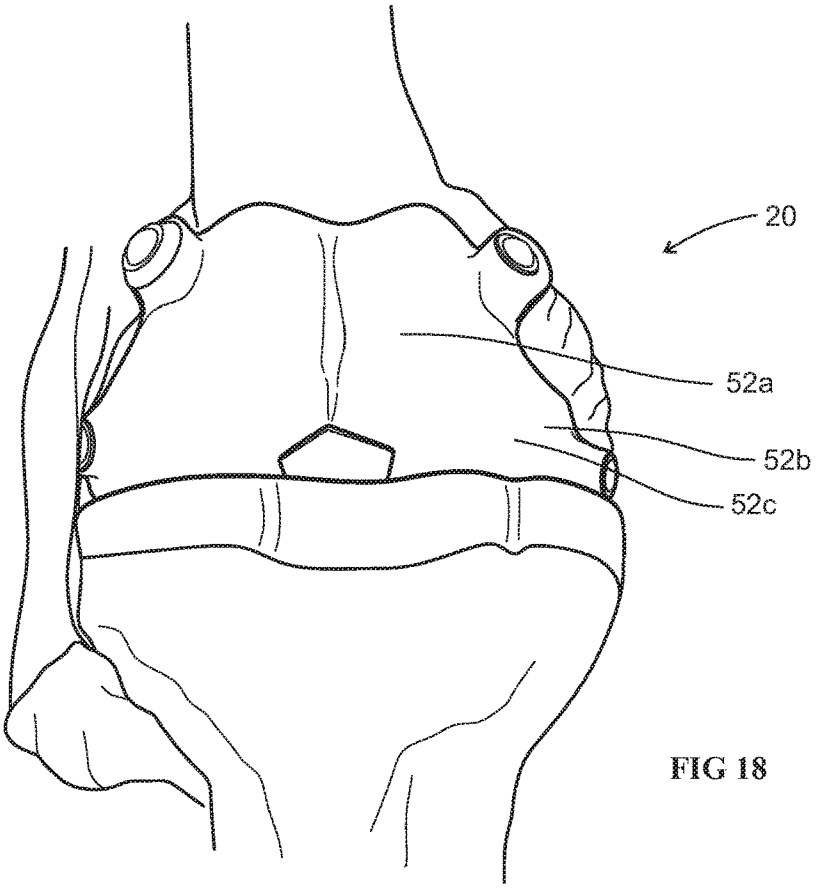
20
52a
52b
52c

FIG 18

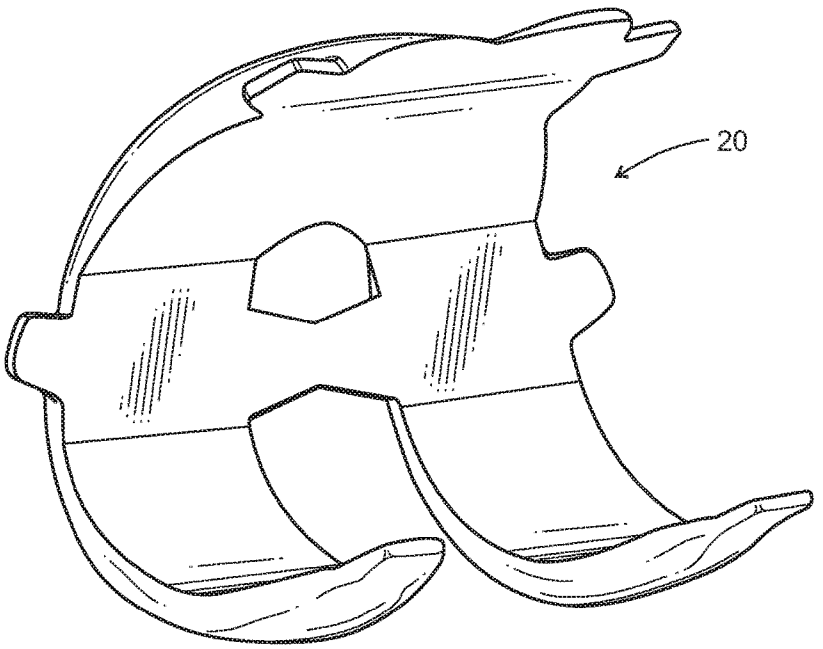

FIG 19

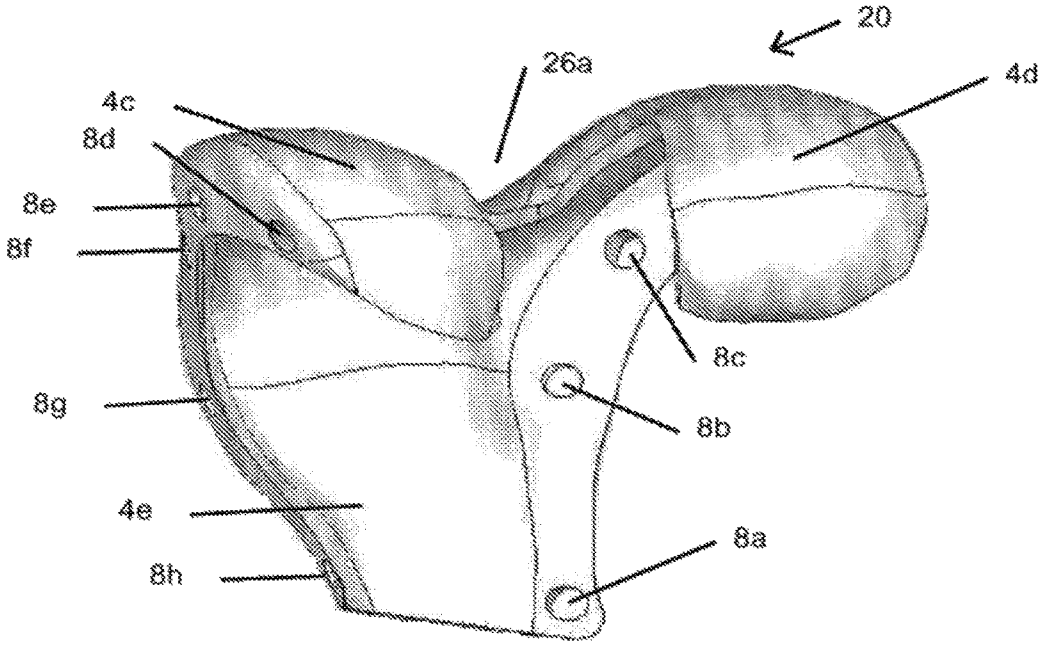

FIG 20A

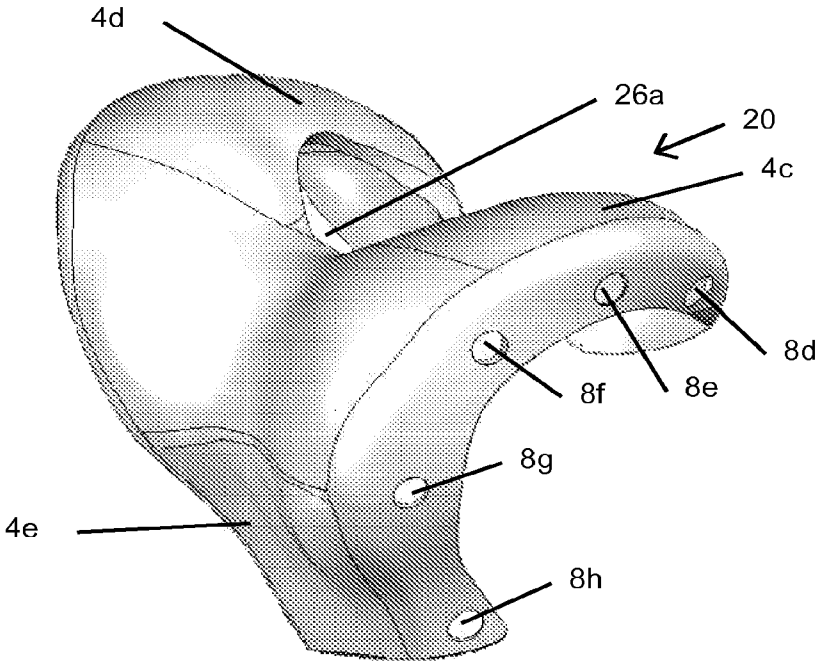

FIG 20B

RESILIENT INTERPOSITIONAL ARTHROPLASTY DEVICE

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Non-provisional Ser. No. 14/239,992 filed on Jun. 5, 2014, which is the National Stage of International Application No. PCT/US12/053207, filed on Aug. 30, 2012, which claims the benefit of U.S. Provisional Application No. 61/530,324 filed on Sep. 1, 2011, all of which are incorporated herein by reference in their entirety.

BACKGROUND OF THE INVENTION

This invention relates to arthroplasty, and more particularly, to an implant for use in arthroplasty when hyaline articular cartilage is damaged, it breaks down and joint space is lost. Inflammatory enzymes such as from the Cox-1, Cox-2 and/or 5-Lox systems are released and loose bodies form adding to the degradation of joint function. Such joint damage is conventionally treated by physical therapy, analgesics, pain medication and injections. When these treatments fail, the traditionally accepted treatment option is arthroplasty implantation or replacing the joint with an artificial joint construct. Current arthroplasty techniques typically use "plastic and metal" implants that are rigid and which ultimately fail due to loosening or infection or debris from wear. Conventional materials for the artificial joint components include chrome-cobalt-molybdenum alloy (metal) and high molecular weight polyethylene (plastic). Each is often fixed by a cement-like mixture of methyl methacrylate to the ends of the bones that define the joint that is the subject of the arthroplasty, or coated with a surface that enables bone in-growth. Current hip joint replacements typically last about 10-15 years and knee replacements typically last about 5-10 years. Ankle joint replacements, on the other hand, are not very successful, and often fail in the first several years after surgery.

Conditions requiring arthroplasty include traumatic arthritis, osteoarthritis, rheumatoid arthritis, osteonecrosis, and failed surgical procedures.

SUMMARY OF THE INVENTION

The present invention is directed to an orthopedic implant configured for deployment between opposing members of a joint structure that addresses many of the shortcomings of prior artificial joints. The arthroplasty implants embodying features of the invention are configured to preserve joint motions while removing the pain and dysfunction following the development of arthritis or joint injury. The arthroplasty implant in accordance with the present invention achieves improved physiologic motion and shock absorption during gait and acts as a resilient spacer between moving bones during limb movement. The combined characteristics of the implant include anatomic design symmetry, balanced rigidity with variable attachment connections to at least one of adjacent normal structures, and durability which addresses and meets the needs for repair or reconstruction thus far missed in the prior art. The implant should be secured to at least one of the bones of the joint structure.

Provided herein is a resilient implant for implantation into human or animal joints to act as a cushion allowing for renewed joint motion. The implant may endure variable joint forces and cyclic loads while reducing pain and improving function after injury or disease to repair, reconstruct, and regenerate joint integrity. The implant may be deployed in a prepared debrided joint space, secured to at least one of the joint bones and expanded in the space, molding to surrounding structures with sufficient stability to avoid extrusion or dislocation. The implant may have opposing walls that move in varied directions, and an inner space filled with suitable filler to accommodate motions which mimic or approximate normal joint motion. The implant may pad the damaged joint surfaces, may restore cushioning immediately and may be employed to restore cartilage to normal by delivering regenerative cells.

Provided herein is a resilient interpositional arthroplasty implant for application into human or animal joints to pad cartilage defects, cushion joints, and replace or restore the articular surface, preserving joint integrity, reducing pain and improving function. The implant may endure variable joint compressive and shear forces, and millions of cyclic loads, after injury or disease requires intervention. The implant may repair, reconstruct, and regenerate joint anatomy in a minimally morbid fashion, with physiologic solutions that improve upon the rigid existing joint replacement alternatives of plastic and metal. In cases where cells have been used for joint resurfacing requiring massive periosteal harvesting for containment, the polymer walls of some embodiments of the implant can capture, distribute and hold living cells until aggregation and hyaline cartilage regrowth occurs. The implant may be deployed into a prepared debrided joint space, molding and conforming to surrounding structures with sufficient stability to avoid extrusion or dislocation. Appendages of the implant may serve to repair or reconstruct tendons or ligaments. Appendages of the implant may serve to repair or reconstruct fibrocartilage as in menisci, or the labrum tissues of hips or shoulders. The implant may have opposing walls that move in varied directions, and an inner space, singular or divided, filled with suitable gas, liquid, and/or complex polymer layers as force-absorbing mobile constituents, such than robust valid and reliable joint motion is enabled.

Provided herein is a resilient orthopedic implant configured for deployment between a first bone and at least one second bone of a joint, the implant comprising a balloon comprising a first portion that is configured to engage the first bone of the joint, a second portion that is configured to engage at least one second bone of the joint, a side portion connecting the first portion and the second portion, in which the side portion facilitates relative motion between the first portion and the second portion, and an interior that is optionally inflatable with a first inflation medium; and a first appendage configured to couple the balloon to the first bone of the joint. As used herein a balloon may also and/or alternatively be called a balloon. In the embodiments wherein the balloon is not inflated, the uninflated balloon may accommodate movement between portions of the balloon wall or a first wall of the balloon and a second wall of the balloon. Alternatively or additionally, the uninflated balloon may provide the opportunity for later inflation following implantation. In some embodiments, the materials of the implant allow for internal expansion. In other embodiments, material layers may be fixed in apposition so as to encourage strength and anti-creep, as with a mesh. In certain embodiments, the fixed layer itself has pockets containing gas or gel (e.g. viscolubricants) or liquid or a pharmacologic. In other embodiments, the implant walls are contiguous having no discernable pockets, vacuoles or chambers.

Provided herein is a resilient orthopedic implant configured for deployment between a femur and a tibia of a knee

joint, the implant comprising a balloon comprising a first portion that is configured to engage a medial condyle and a lateral condyle of the femur of the knee joint, a second portion that is configured to engage the tibia of the knee joint, a side portion connecting the first portion and the second portion, in which the side portion facilitates relative motion between the first portion and the second portion, and an interior that is optionally inflatable with a first inflation medium; and a first appendage configured to couple the balloon to the femur of the knee joint.

In some embodiments, the implant comprises at least one attachment element in the intercondylar notch. In some embodiments, the implant comprises at least one attachment element in the medial region of the intercondylar notch. In some embodiments, the implant comprises at least one attachment element in the lateral region of the intercondylar notch. In some embodiments, the implant comprises at least one attachment element superiorly at the distal end of the femur anteriorly. In some embodiments, the implant comprises at least one posterior reign configured to cinch up the implant from inside a posterior intercondylar notch toward a connection site around the femur. In some embodiments, the implant comprises at least one suture-like lanyard configured to cinch up the implant from inside a posterior intercondylar notch toward a connection site around the femur.

In some embodiments, at least two of first portion, the second portion, and the side portion are contiguous. In some embodiments, the first portion comprises a first wall, the second portion comprises a second wall, and the side portion comprises a side wall.

In some embodiments, the implant comprises an inflation port in communication with the interior of the balloon for inflation of the interior of the balloon with the first inflation medium. In some embodiments, the interior comprises a plurality of inflatable chambers. In some embodiments, a first chamber of the plurality of individually inflatable chambers is adapted to be inflated with the first inflation medium, and a second chamber of the plurality of individually inflatable chambers is adapted to be inflated with a second inflation medium. In some embodiments, the first inflation medium imparts at least one of rigidity in the implant and cushion in the implant. In some embodiments, there is no inflatable chamber and the cushioning is a result of compliant materials of the walls themselves

In some embodiments, the implant comprises a second appendage coupling the balloon to at least one of: the femur of the joint and the tibia of the joint.

Provided herein is an implant configured for deployment between a femur and a tibia of a knee joint, the implant comprising a balloon comprising a first portion that is configured to engage at least one condyle of the femur of the knee joint, a second portion that is configured to engage the tibia of the knee joint, a side portion connecting the first portion and the second portion, in which the side portion facilitates relative motion between the first portion and the second portion, and an interior that is optionally inflatable with a first inflation medium; and a first appendage configured to couple the balloon to the femur of the knee joint.

In some embodiments, the at least one condyle is the medial condyle. In some embodiments, the at least one condyle is the lateral condyle. In some embodiments, the retropatellar surface could be the anatomic region padded. In some embodiments, the tibia-medial or lateral or both is capped. In certain knee implant embodiments, the implant articulates against cartilage of the first bone, second bone, and/or the third bone

In some embodiments, the balloon is at least one of: at most about 1.5 cm in diameter, at most about 1.75 cm in diameter, at most about 2 cm in diameter, at most about 2.25 cm in diameter, at most about 2.5 cm in diameter, at most about 2.75 cm in diameter, at most about 3 cm in diameter, at most about 3.25 cm in diameter, at most about 3.5 cm in diameter, at most about 3.75 cm in diameter, at most about 4 cm in diameter, at most about 4.25 cm in diameter, at most about 4.5 cm in diameter, at most about 4.75 cm in diameter, at most about 5 cm in diameter, at most about 5.25 cm in diameter, at most about 5.5 cm in diameter, at most about 5.75 cm in diameter, at most about 6 cm in diameter, at most about 6.25 cm in diameter, at most about 6.5 cm in diameter, at most about 6.75 cm in diameter, at most about 7 cm in diameter, at most about 7.25 cm in diameter, at most about 7.5 cm in diameter, at most about 7.75 cm in diameter, at most about 8 cm in diameter, at most about 3 cm in length along the longest length of the balloon, at most about 3.25 cm in length along the longest length of the balloon, at most about 3.5 cm in length along the longest length of the balloon, at most about 3.75 cm in length along the longest length of the balloon, at most about 4 cm in length along the longest length of the balloon, at most about 4.25 cm in length along the longest length of the balloon, at most about 4.5 cm in length along the longest length of the balloon, at most about 4.75 cm in length along the longest length of the balloon, at most about 5 cm in length along the longest length of the balloon, at most about 5.25 cm in length along the longest length of the balloon, at most about 5.5 cm in length along the longest length of the balloon, at most about 5.75 cm in length along the longest length of the balloon, at most about 6 cm in length along the longest length of the balloon, 6.25 cm in length along the longest length of the balloon, at most about 6.5 cm in length along the longest length of the balloon, at most about 6.75 cm in length along the longest length of the balloon, at most about 7 cm in length along the longest length of the balloon, at most about 7.25 cm in length along the longest length of the balloon, at most about 7.5 cm in length along the longest length of the balloon, at most about 7.75 cm in length along the longest length of the balloon, and at most about 8 cm in length along the longest length of the balloon.

In some embodiments, the first portion comprises a first wall, the second portion comprises a second wall, and the side portion comprises a side wall.

In some embodiments, the implant comprises an inflation port in communication with the interior of the balloon for inflation of the interior of the balloon with the first inflation medium. In some embodiments, the balloon is punctured to inflate the interior of the balloon with the first inflation medium. In some embodiments, the balloon is self-sealing. In some embodiments, the balloon is self-sealing upon inflation of the interior of the balloon with the first inflation medium. In some embodiments, the implant comprises a seal capable of closing the interior of the balloon. In some embodiments, there is no balloon and inflation into a wall of the implant expands the implant with a compressible material. In some embodiments, inflation is achieved via a needle or cannula that delivers the inflation medium such as lubricating materials or medications or a combination thereof, or other inflation mediums. In some embodiments, despite addition of an inflation medium, there is no ballooning effect or change in thickness in the device, as the inflation medium itself fills empty spaces in the wall (or walls) into which it is delivered. In some embodiments, the implant comprises an inflation port in communication with the interior of the balloon for inflation of the interior of the balloon with the

first inflation medium. In some embodiments, the interior comprises a plurality of inflatable chambers. In some embodiments, a first chamber of the plurality of individually inflatable chambers is adapted to be inflated with the first inflation medium, and a second chamber of the plurality of individually inflatable chambers is adapted to be inflated with a second inflation medium. In some embodiments, the first inflation medium imparts at least one of rigidity in the implant and cushion in the implant. In some embodiments the chambers are constructed as part of a trabecular polymer framework or honeycomb or foam or alveolar network. The chambers may be adapted to increase the surface area of available polymer for disbursement or absorption.

In some embodiments, the implant comprises a second appendage coupling the balloon to at least one of: the femur of the joint and the tibia of the joint. In some embodiments, the implant comprises at least one attachment element in the intercondylar notch. In some embodiments, the implant comprises at least one attachment element in the medial region of the intercondylar notch. In some embodiments, the implant comprises at least one attachment element in the lateral region of the intercondylar notch. In some embodiments, the implant comprises at least one attachment element superiorly at the distal end of the femur anteriorly. In some embodiments, the implant comprises at least one posterior reign configured to cinch up the implant from inside a posterior intercondylar notch toward a connection site around the femur. In some embodiments, the implant comprises at least one suture-like lanyard configured to cinch up the implant from inside a posterior intercondylar notch toward a connection site around the femur.

In some embodiments, the implant is fabricated to resemble a certain anatomic region over which the implant is stretched or pulled into place. The implant then may settle into its angle of repose via inherent elasticity. In some embodiments the ambient environment of the joint via exposure to serum or temperature or acidity has a specified effect on the implant materials such as increasing the implant malleability that affects implant performance.

Provided herein is an implant configured to patch a defect of a bone of a knee joint, the implant comprising a balloon configured to engage the defect of the bone of the knee joint and comprising an interior that is optionally inflatable with a first inflation medium; and a first appendage configured to couple the balloon to the bone of the knee joint.

In some embodiments, at least one of the appendage and the balloon are configured to replace cartilage.

In some embodiments, the balloon is at least one of: at most about 0.5 cm in diameter, at most about 0.75 cm in diameter, at most about 1 cm in diameter, at most about 1.25 cm in diameter, at most about 1.5 cm in diameter, at most about 1.75 cm in diameter, at most about 2 cm in diameter, at most about 2.25 cm in diameter, at most about 2.5 cm in diameter, at most about 2.75 cm in diameter, at most about 3 cm in diameter, at most about 3.25 cm in diameter, at most about 3.5 cm in diameter, at most about 3.75 cm in diameter, at most about 0.5 cm in length along the longest length of the balloon, at most about 0.75 cm in length along the longest length of the balloon, at most about 1 cm in length along the longest length of the balloon, at most about 1.25 cm in length along the longest length of the balloon, at most about 1.5 cm in length along the longest length of the balloon, at most about 1.75 cm in length along the longest length of the balloon, at most about 2 cm in length along the longest length of the balloon, at most about 2.25 cm in length along the longest length of the balloon, at most about 2.5 cm in length along the longest length of the balloon, at most about 2.75 cm in length along the longest length of the balloon, at most about 3 cm in length along the longest length of the balloon, at most about 3.25 cm in length along the longest length of the balloon, at most about 3.5 cm in length along the longest length of the balloon, at most about 3.75 cm in length along the longest length of the balloon, and at most about 4 cm in length along the longest length of the balloon.

In some embodiments, the interior comprises a plurality of inflatable chambers. In some embodiments, the interior comprises a plurality of individually inflatable chambers. In some embodiments, a first chamber of the plurality of individually inflatable chambers is adapted to be inflated with the first inflation medium, and a second chamber of the plurality of individually inflatable chambers is adapted to be inflated with a second inflation medium.

In some embodiments, the balloon or a chamber thereof may be secondarily inflated, deflated, or a combination thereof in situ.

In some embodiments, the implant comprises an in-growth matrix on at least a portion of the implant adjacent the femur. In some embodiments, the in-growth matrix comprises living chondrocytes. In some embodiments, the implant is configured to release the chondrocytes over time. In some embodiments, the implant comprises a bioabsorbable polymer configured to release the chondrocytes over time. In some embodiments, the implant comprises a polymer configured to release the chondrocytes over time, wherein the polymer is not bioabsorbable. In some embodiments, the in-growth matrix comprises cells. In some embodiments, the in-growth matrix comprises at least one of: stem cells, differentiated cells, pluripotent cells, post-mitotic cells. In some embodiments, the cells restore an articular surface of the femur. In other embodiments, the cells repair an articular surface of the femur. In some embodiments, the implant comprises a bioabsorbable polymer configured to release the cells over time. In some embodiments, the implant comprises a polymer configured to release the cells over time, wherein the polymer is not bioabsorbable. In some embodiments, the in-growth matrix comprises at least one of: autologous cells, allograph cells, and xenograph cells to restore an articular surface of the femur. In some embodiments, the in-growth matrix comprises at least one of: autologous cells, allograph cells, and xenograph cells to repair an articular surface of the femur. In some embodiments, the in-growth matrix comprises a pharmacologic substance. In some embodiments, the patch implant comprises a matrix that is coated with a hydrophilic or a hydrophobic polymer. In some embodiments the patch is vessicular with or without matrices in the wall components. In certain embodiments, the patch is a solid compliant material. In some embodiments, the walls or material construct is responsive or performs in a dynamic fashion to exogenous joint forces. For non-limiting example, in bone under normal physiologic stress of bearing weight, calcification yields sufficient bone density so as to deter fracture. However, in circumstances wherein prolonged dearth of weight bearing stress is produced by immobilization the bone becomes osteoporotic and pathologic. The implant herein may have smart features to adjust to stimulate healing and tissue regeneration. In some embodiments such materials can be composed of macromolecules or dendritic connections that regulate permeability and transfer of adjacent media.

In some embodiments, the implant comprises couplers that couple the appendage to the femur. In some embodiments, the coupler is bioabsorbable. In some embodiments, the coupler is at least one of: a screw, a snap, a washer, a

suture, a suture anchor, a rivet, a staple, a staple having teeth, a magnet, an electromagnet, a microminiature transmitter that regulates implant fixation or performance responsive to patient need as perceived by the patient or a care giver, a stabilizer, a glue, a hook, a wire, a string, a lasso, a lanyard, a spike, and combinations thereof. The implant may also and/or alternatively be attached via bone in-growth. In some embodiments, the implant is attached via bone in-growth as described in Vasanji A, In vivo bone growth assessment in preclinical studies and clinical trials, Bonezone, 2012, p. 12-17, herein incorporated by reference in its entirety.

In some embodiments, the implant comprises a pharmacologic agent. In some embodiments, the pharmacologic agent is on a surface of the implant adjacent the femur. In some embodiments, the pharmacologic agent is released from the implant over time. In some embodiments, the pharmacologic agent is released from within the implant over time. In some embodiments, the pharmacologic agent is released from within the balloon over time. In some embodiments, the agent is released as a combination of vessicular and matrix origins using internal or external stimuli from normal or exogenous sources.

In some embodiments, the first inflation medium imparts rigidity in the implant. In some embodiments the implant comprises a bone cement. In some embodiments, the implant comprises methyl methacrylate. In some embodiments, the first inflation medium imparts cushion in the implant.

In some embodiments, the inflation medium is compressible. In some embodiments, the inflation medium comprises a viscolubricant. In some embodiments, the inflation medium comprises a pharmacologic substance. In some embodiments, the inflation medium comprises an NSAID. In some embodiments, the inflation medium comprises chondrocytes. In some embodiments, the inflation medium comprises cells.

In some embodiments, at least a portion of the implant is configured to anneal to a periphery of a cartilage defect.

In some embodiments, the implant comprises vacuoles of pharmacologic substances. In some embodiments, the vacuoles may be on a bone-engaging portion of the implant. In some embodiments, the implant comprises bubbles comprising an active substance such as a pharmacologic substance or other active agent. In some embodiments, the active agent comprises at least one of: stem cells, growth factors, antibiotics, antifungals, antituberculous, antitumor, antigout agents and viscolubricants. In some embodiments, the active agent comprises iatrigenically gene mutated cells.

In some embodiments, the implant comprises enzyme absorptive microscopic sponges that could be sucked out or evacuated at or around the time of implant delivery to the joint.

In some embodiments, the interior comprises a honeycomb structure. In some embodiments, the interior comprises a mesh structure. In some embodiments, the interior comprises a sponge structure. In some embodiments the implant comprises a sponge structure. In some embodiments the implant comprises a compliant membrane.

In some embodiments, the implant comprises spaces filled with an active substance such as a pharmacologic substance or other active substance. In some embodiments, the implant comprises spaces for deliverables (e.g., biologics, antibodies, cells, pharmacologic substances, biomolecules, molecules, compounds). In some embodiments, the implant comprises spaces for compressibles (e.g., gas, air). In some embodiments, the spaces comprise nanovesicles. In some embodiments, the nanovasicles comprise deliverables (e.g., biologics, antibodies, cells, pharmacologic substances, biomolecules, molecules, compounds). In some embodiments, the nanovesicles comprise compressibles (e.g., gas, air).

In some embodiments, the implant comprises a second appendage coupling the balloon to the first bone of the joint. In some embodiments, the implant comprises a second appendage coupling the balloon to at least one second bone of the joint. In some embodiments, the implant comprises a second appendage configured to couple at least one of the first portion, the second portion, and the side portion to at least one of the first bone and at least one second bone of the joint. In some embodiments, the first appendage and the second appendage are configured to provide ligamentary-like support to the first bone and the at least one second bone of the joint. In some embodiments, the first appendage and the second appendage are configured to provide ligamentary-like support to the joint. In some embodiments, the first appendage and the second appendage are configured to provide tendon-like support to the first bone and the at least one second bone of the joint. In some embodiments, the first appendage and the second appendage are configured to provide tendon-like support to the joint.

In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most 10 millimeters. In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most 9 millimeters. In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most 5 millimeters. In some embodiments, the implant may be configured to be introduced surgically arthroscopically as with the cannula 10 mm in diameter or may be introduced through minimal invasive surgery via a large conduit and plunger requiring a small arthrotomy several centimeters in diameter. In some embodiments routine open surgical insertion with a larger wound may be necessary depending on clinical condition, complexity and surgeon choice.

In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most 10 millimeters. In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most 9 millimeters. In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most 5 millimeters.

In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most 10 millimeters. In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most 9 millimeters. In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most 5 millimeters.

In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most 10 millimeters. In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most 9 millimeters. In some embodiments, the implant is configured to deliver by dissolution of the implant material. In some embodiments, the implant is configured to deliver by release through pores of the implant. In some embodiments, the implant is configured to deliver by release through spaces of the implant. In some embodiments, the implant is configured to deliver by release through nanovesicles of the implant. In some embodiments, the implant is configured to

deliver by fracture of a vacuole by a catalyst such as ultrasound or pressure or other fracturing catalyst. In some embodiments the release of contents may be over time as a function of normal cumulative limb use forces.

In some embodiments, the implant is configured to at least one of: pad cartilage, cushion the joint, deliver a pharmacologic substance, remove noxious enzymes, debride upon implantation, debride the joint following implantation, deliver a therapeutic substance, deliver a biologic substance, and deliver living stem cells. In some embodiments, the implant is configured to deliver a cell or tissue to a bone or surrounding tissue. In some embodiments, the cell is at least one of: stem cell, differentiated cell, pluripotent cell, and post-mitotic cell. In some embodiments, the implant is configured to deliver a chemotherapeutic agent to a bone or other surrounding tissues. In some embodiments, the implant is configured to deliver an anti-infectious medication to a bone or other surrounding tissues. In some embodiments, the implant is configured to deliver at least one of an antibiotic, antifungals, and analgesics agent. In some embodiments, the implant is configured to deliver an antibody. In some embodiments the implant is configured as a targeting structure for treatment of proximate pathophysiology. In some embodiments, the implant comprises a transmitter or a sensor that can emit or receive actionable instruction. In some embodiments, the implant comprises a sensor, for non-limiting example: a gauge, camera, fiberoptic, or other meter, to provide information of clinical relevance as it relates to proximate tissue. In some embodiments, the information received from the implant is transferred to the patient to enhance wound healing or other desired effects.

In some embodiments, the implant is configured to be selectively inflated to realign limbs.

Provided herein is a method comprising: implanting a knee implant as described herein into a subject, wherein the implant reverses arthritis in the subject.

Provided herein is a method comprising: implanting a knee implant as described herein into a knee joint of a subject and treating a component of the knee joint of the subject with at least one of an allograph tissue, an autograph tissue, and an xenograph tissue. In some embodiments, the implanting step is at least one of: prior to the treating step, simultaneous with the treating step, and following the treating step.

Provided herein is a method comprising: implanting a knee implant as described herein into a subject, wherein the implant at least one of: restores joint function and controls arthopathies. In some embodiments, the implanting spares existing anatomy.

Provided herein is a method comprising: debriding a femur condyle of a knee joint of a subject, and implanting a knee implant as described herein into the knee joint of the subject, whereby the implant is configured to anneal to the cartilage of the subject. In some embodiments, the debriding is achieved by steam application.

Provided herein is a method comprising implanting a knee implant as described herein into a joint previously treated with a joint replacement. In some embodiments, the method comprises removing the joint replacement prior to implanting the knee implant. In some embodiments, the method comprises clearing infectious matter from the joint and/or surrounding tissues. In some embodiments, the method comprises implanting a second implant of any implant described herein following removing the implant previously implanted in the joint. In some embodiments, the method comprises replacing the joint of the subject following removing the implant previously implanted in the joint. In some embodiments, the method comprises debriding the bone of the joint, and implanting an implant of any implant described herein. In some embodiments, the method comprises repeating the debriding and implanting steps.

In some embodiments, the implant is delivered non-arthroscopically through an incision that is at least 1 centimeter long. In some embodiments, the implant is delivered through an incision that is over about 10 centimeters long. In some embodiments, the implant is delivered through an incision that is at up to about 40 centimeters long.

In some embodiments, the implant replaces periosteum.

In some embodiments, the resilient implant embodying features of the invention has a first wall configured to be secured to a first bone of the joint structure by one or more appendages such as a skirt or one or more tabs and a second wall configured to engage a second and usually opposing bone of the joint structure. A side wall extends between the first and second walls of the implant and together with the first and second walls preferably defines at least in part an inner chamber or space between the first and second walls. The implant is configured to provide linear or curvilinear and/or rotational motion between the first and second bones which mimics or approximates the natural motion between these bones. The inner chamber or space is configured to maintain a filler material therein such as an inflation fluid or a resilient material and preferably to maintain spacing and provide support between the interior of the first and second walls to avoid significant contact therebetween. The walls of the implant are preferably sealed about the periphery thereof to maintain the interior chamber in a sealed condition to avoid loss of inflation fluid or filling media. The side wall or walls may be formed from the edges or periphery of the first and second walls. The properties of the implant walls and the interior are controlled to provide the particular resiliency desired for the joint in which the implant is to be placed as well as any desired motion between the first and second walls. A conduit may extend from a source of inflation fluid or other filling medium to the interior of the implant to facilitate expansion of the implant after deployment within the joint. The inflation fluid may be a gas, a liquid, a gel, a slurry, or a fluid that becomes a suitable resilient solid such as a curable polymer. Selection of the inflation or interior filling medium may depend upon the nature of the joint structure in which the implant is to be deployed, its anatomy, pathophysiology, and the properties of the implant material.

There may be several alternative embodiments depending upon the site in which the implant is to be deployed. For example, the polymer forming the side wall may be semi-compliant or elastic and the inflation fluid may be incompressible (e.g., a liquid). Alternatively, the polymer forming the side wall may be non-compliant (non-elastic) and the inflation fluid or filling medium may be compressible, e.g., a gas or a resilient polymeric foam or sponge-like solid that may have a closed cell structure. The first and second walls of the implant need not have the same properties as the side wall. For example, parts of the implant such as the side wall portion may be compliant and the first and second wall portions in contact with the bone or other joint structure may be non-compliant. Additionally, the various walls or portions thereof may also be reinforced with non-compliant or semi-compliant polymer strands, beads or gel coating such as biologic or polymer latticework. The thicknesses of the first, second and side walls may be varied to accommodate for the needs of the joint structure from the standpoint of strength, elasticity and wear resistance. Moreover, the walls of the implant may be provided with joint tissue regeneration

agents that rebuild the joint structure in which the implant is deployed. The regeneration agent may be incorporated into the wall of the implant prior to delivery or placed between the surface of the implant and the joint structure which it contacts after delivery. All or part of the walls of the implant may also be made of a biodegradable polymer, by minimally manipulated autograph, allograph or xenograph tissues, or a combination thereof. The method of surgery may incorporate a progressive application of the implant embodiments depending upon clinical needs. The walls of the implant may serve one or more functions, including but not limited to filling space, attachment, strengthening, and any physiological function.

The implant is preferably formed of suitable biocompatible polymeric materials, such as Chronoflex (e.g., ChronoFlexAR®, ChronoFlex AL®, ChronoFlec C®), which is a family of thermoplastic polyurethanes based on a polycarbonate structure (Al, the aliphatic version, Ar, the aromatic version and C, the casting version) available from AdvanSource Biomaterials, Corp. Other polymers include BIONATE 80, 80A, 90A, 75D, 65D, 55D, 55 or 56, BIONATE I, or BIONATE II, which are also thermoplastic polyurethane polycarbonate copolymers, available from PTG Medical LLC., an affiliate of the Polymer Technology Group located in Berkeley, Calif. Other commercially available polymers include PurSil® (e.g., PurSil® 10, 20, 35, 40 80A, AL-10 75A) which is a thermoplastic silicone polyether urethane, CarboSil® (e.g., CarboSil® 10 90A, 20 55D, 20 80A, 20 90A, 40 90A, 5) which is a thermoplastic silicone polycarbonate urethane, Elasthane™ (e.g., Elasthane™ 55D, 75D, 80A) which is an aromatic biomedical polymer and Biospan which is a segmented polyurethane. These polymers are available as tubing, molded or dipped components, solution, pellets, as a casting and as a cast film for the side and first and second walls. The implant may be formed by casting, blow molding or by joining sheets of polymeric material by adhesives, laser welding and the like. Other methods of forming the implant may also be suitable. Example methods include melting beads and compression molding. The walls may also be provided with reinforcing strands which are located on the surface of the walls or incorporated within the walls. The implant material should be biocompatible, nontoxic, and non-carcinogenic and should be resistant to particulation.

The present invention provides an improved joint implant which is designed to endure variable joint forces and cyclic loads enabling reduced pain and improved function. Depending upon the particular joint involved there may be linear or curvilinear motion between the first and second walls, rotational motion between the first and second walls or both linear and curvilinear motion and rotation motion between the first and second walls. Preferably, a space is maintained between the inner surfaces of the first and second walls to avoid erosion and wear there between. The walls may be opposite sides of the same solid.

The resilient arthroplasty implant embodying features of the invention is preferably deployed as a minimally invasive procedure to deliver the implant into a prepared space in a preselected joint structure, where upon it is inflated to create a cushion, to cover damaged or arthritic cartilage and to be employed to deliver stem cells or living chondrocytes or other tissue regeneration agents. The goal of such deployment is to reduce pain and improve function, to reverse arthritis, to fill in osteochondral defects succinctly, thereby avoiding living with both dysfunctional and ablative metal/plastic prostheses or the pathophysiologic state necessitating the procedure. The operative plan is simple, systematic, and productive of new joint space with regrowth potential involving joint debridement by routine arthroscopic coblation, electronic chondroplasty methods or steam application, followed by implantation of the implant. The implant provides three things, namely a covering or patch for the damaged or worn joint surface, an inflated cushion to pad gait via inflation or compliant polymer as in normal walking in the lower extremity, and delivery of regenerative cells on the cartilage remnant surface. The stem cells may be injected as the implant is being expanded and/or directed into the adjacent hyaline cartilage via an implant coating or perfused cell template. Viscolubricants such as Synvisc or Hyalgan, analgesics such as Lidoderm, anti-inflammatory and/or antibiotic coatings as well as those stimulating cell growth may accompany the composite external implant. The implant is left in place as long as feasible, at least until regenerative cells can attach to the adjacent natural joint surface (usually in about 24 hours), or until wound healing (which may take up to 28 days or more depending on the joint structure). Preferably, the implant is designed stay within the joint structure for years, providing inert padding, cushioning and a new cell source. The implant may be used in weight bearing and non-weight bearing interfaces. Animal, such as in horses and dogs, can benefit from usage of the implant following hip and knee injuries. The implant is intended primarily for mammalian use. In humans, the implant may be used in any upper or lower extremity joint and temperomandibular joint.

These and other advantages of the invention will become more apparent from the following detailed description and the attached exemplary drawings.

INCORPORATION BY REFERENCE

All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

FIG. **1** depicts an embodiment of the knee implant having appendages including holes and tabs extending from a balloon and including slots to accommodate ligaments of the knee joint.

FIG. **2** depicts an embodiment of the knee implant having appendages including holes and tabs extending from a balloon and including slots to accommodate ligaments of the knee joint as well as side views of the same knee implant.

FIG. **3** depicts an embodiment of the knee implant having appendages including holes and tabs extending from a balloon and including slots to accommodate ligaments of the knee joint as well as side views of the same knee implant.

FIG. **4**A depicts an embodiment of the knee implant having appendages including ten tabs extending from a balloon and including a slot to accommodate components of the knee joint.

FIG. **4**B depicts an embodiment of the knee implant having appendages including eight tabs extending from a balloon and including a slot to accommodate components of the knee joint.

FIG. **5** depicts an embodiment of the knee implant curved to simulate curvature about the condyles of a femur, the implant having appendages extending from an uninflated balloon (not shown) and including slots to accommodate ligaments of the knee joint.

FIG. **6**A depicts a top-down view of an embodiment of the knee implant curved to simulate curvature about the condyles of a femur, the implant having appendages extending from two inflated balloons and including slots to accommodate components of the knee joint.

FIG. **6**B depicts a bottom-up view of an embodiment of the knee implant curved to simulate curvature about the condyles of a femur, the implant having appendages extending from two inflated balloons and including slots to accommodate components of the knee joint.

FIG. **7** depicts a top-down view of an embodiment of the knee implant curved to simulate curvature about the condyles of a femur, the implant having appendages extending from an inflated balloon and including slots to accommodate components of the knee joint.

FIG. **8** depicts a side view of an embodiment of the knee implant curved to simulate curvature about at least one condyle of a femur, the implant having appendages extending from an uninflated balloon (not shown).

FIG. **9**A depicts a side view of an embodiment of the knee implant curved about at least one condyle of a femur, the implant having appendages extending from an uninflated or minimally inflated balloon.

FIG. **9**B depicts a side view of an embodiment of the knee implant curved about at least one condyle of a femur, the implant having appendages extending from an inflated balloon.

FIG. **9**C depicts a side view of an embodiment of the knee implant curved about at least one condyle of a femur, the implant having appendages extending from an inflated balloon and having staples or screws coupling the appendages to the femur.

FIG. **10**A depicts a side view of an embodiment of the knee implant curved about at least one condyle of a femur, the implant having appendages extending from an inflated balloon and showing the inflation medium moved anteriorly toward the patella when the knee joint is flexed. FIG. **10**B depicts a side view of an embodiment of the knee implant curved about at least one condyle of a femur, the implant having appendages extending from an inflated balloon and having staples or screws or snaps or pins coupling the appendages to the femur and showing the inflation medium moved anteriorly toward the patella when the knee joint is flexed.

FIG. **11**A depicts an embodiment of the unicompartment knee implant curved to simulate curvature about one condyle of a femur, the implant having appendages extending from an uninflated balloon (not shown) and including tabs and holes which may be used with couplers to couple the implant to the femur of the knee joint.

FIG. **11**B depicts an embodiment of the unicompartment knee implant curved to simulate curvature about one condyle of a femur, the implant having appendages extending from an inflated balloon and including tabs and holes which may be used with couplers to couple the implant to the femur of the knee joint.

FIG. **11**C depicts a bottom-up view of an embodiment of the unicompartment knee implant curved to simulate curvature about one condyle of a femur, the implant having appendages extending from an inflated balloon and including tabs and holes which may be used with couplers to couple the implant to the femur of the knee joint.

FIG. **12**A depicts a bottom-up view of an embodiment of the unicompartment knee implant or patch implant, the implant having appendages, extending from a balloon and including holes, which may be used with couplers (not shown) to couple the implant to the femur of the knee joint.

FIG. **12**B depicts a bottom-up view of an embodiment of the unicompartment knee implant or patch implant, the implant having appendages, extending from a balloon and including tabs and a hole which may be used with couplers (not shown) to couple the implant to the femur of the knee joint.

FIG. **12**C depicts a bottom-up view of an embodiment of the unicompartment knee implant or patch implant, the implant having appendages, extending from a balloon and including tabs and a hole which may be used with couplers (not shown) to couple the implant to the femur of the knee joint.

FIGS. **13**A-**13**D depict multiple views of a staple adapted to couple an implant to a bone of the joint.

FIG. **14** depicts an embodiment of the knee implant having appendages including holes and tabs and including slots to accommodate ligaments of the knee joint as well as side views of the same knee implant.

FIGS. **15**A, **15**B, and **15**C show several views of an embodiment of an implant which has no definable chamber, rather the material of the implant itself provides the cushion to the bones of the joint (at least).

FIG. **16** depicts a knee implant embodiment that is generally H or V-shaped, having a slot **26** *b* that is significantly smaller than other embodiments, and in this embodiment is effectively replaced with a tab **10** *i* at the same location (e.g. **10** *i*).

FIG. **17** depicts a knee implant embodiment similar to FIG. **16** which shows a posterior view including the location (s) **50** *a*-**50** *d* where a fill material such as cement may be placed.

FIG. **18** is an anterior-posterior view of an embodiment of the implant **20** attached to a knee model.

FIG. **19** depicts an implant **20** which is more squarely cut for interface with a femur, for example, which has been cut square such as is done in certain total knee arthroplasty procedures.

FIGS. **20**A and **20**B depict a knee implant embodiment that is generally V-shaped or Y-shaped, and in this embodiment the notch **26** *b* of other embodiments, or the tab **10** *i* of other embodiments is effectively replaced with an appendage **4** *e* at the same location.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is directed to arthroplasty implants and procedures for a wide variety of joints such as, for example, hips, knees, shoulders, ankles, elbows, wrists, fingers, toes, temporomandibular joints and the like, but for clarity, as well as brevity, the discussion herein will focus on an implant for a knee joint or hip joint and an implant for replacing the talus bone of a patient's ankle.

Knee interpositional arthroplasty can replace existing total joint metal/plastic technology. It intends to fill the gap (literally in some embodiments of the implant) in cases where arthroscopic debridement fails to provide cure, since we can only 'polish arthritis' and 'clean up the joints' to date.

The polymer medically inflatable implants may physiologically restore joint function. Padding is provided where cartilage is damaged, cushioning to both the femoral tibial and patella femoral joints when narrowed or pathologic. The implant in some embodiments is adapted to deliver cells, autologous (from the patient), allograph (from another member of the same species) or xenograph (from another species,) that restore articular surfaces. Since cartilage is an immunologically privileged tissue, the antigens are buried in the cartilage matrix and antibodies do not reject the refurbished surface coating.

The gap (or gaps) filled by the balloon or balloons of the implant may provide compliance between opposing joint surfaces (the femoral condyle or condyles and tibial plateau). The femur may have some portion (of not all) of the retropatellar rounded facet "V" shape of hyaline, normally about 5 mm thick, or it may not have such hyaline when the implant is inserted. The tibial plateau may have some portion of meniscal fibrocartilages, including all of said fibrocartilages, none of said fibrocartilages, or some portion thereof. When the knee is extended (straight) the implant buffers the femoro-tibial joint. When the knee is flexed, the implant balloon apposition is more between the trochlear groove portion of the anterior distal femur (groove between the condyles on the 'front of the knee') and the patella.

The knee anatomy is unique to other joint anatomies and thus has a unique set of challenges that are addressed by the implant embodiments described herein. For example, the knee is not a ball and socket joint like a hip; it is a combination of two joints—the femoral-tibial joint and the patellar-femoral joint. The bones of the knee have facets and irregularities that must be accommodated by a conformable implant directed to the particular shapes of the bones without impeding the joints' functions and movements, and/or which minimizes impedance to such function and movement. Not only do the joints of the knee work together to allow extension and flexion of the knee, but the joints of the knee are also designed to allow rotational movement in a screw-like manner. That is, as the tibia is twisted relative to the femur, the joints are uniquely designed to allow this twist, but to limit the twist as well. Furthermore, the knee joints are able to withstand forces that vary depending on the particular movement of the individual, not only in force strength, but in direction as well. Thus, the implants as described herein are uniquely designed to account for these factors and result in a knee having preserved natural tissues as well as preserved function and movement as compared to typical arthroplasty procedures (such as partial or full knee replacements).

As described herein, embodiments of the implant conform to the patient's own joint features not only in that it can be pre-molded and/or adapted to couple to the contours of the patient's bone (condyle, etc), but in that it has a balloon having an inflation medium that is conformable to the joint anatomy and allow freedom of joint movement much like natural joint while preserving the joint and bone natural tissues as much as possible. With the ability to fill various chambers of the balloon with varying materials, and to add rigid and/or semi-rigid pieces to the implant, the implant can additionally have leveling capabilities and alignment capabilities.

Diagnoses:

Patients may complain of pain and knee joint dysfunction signaled by locking, clicking, or giving way. Knees may be swollen, malaligned or show crepitus (palpable crunching on movement.) Instability of ligaments whether anterior/posterior cruciates, or medial/lateral condyles, are treated by techniques separate for those entities via allowance for healing (as for collaterals) or via cruciate repair or reconstruction.

Indications for use of implants provided herein may be those patients recognizing greater than or equal to 2 Sq cm of 3–4+/4 traumatic arthritis (ala Carticel). In such cases, the cartilage defect is often precisely locally symptomatic, with point tenderness, clicking if a loose cartilage flap exists, and may be visible on MRI and/or arthroscopic inspection and/or through palpation. The implants used herein may additionally and/or alternatively be appropriate when existing techniques such as 'picking', K wire drills, and/or allograph implants fail.

Patients with knee problems typically complain of pain and dysfunction. Pathognomonic symptoms for meniscal tearing include locking, clicking, giving way from wear or twisting the knee. Aching diffusely may arise from arthritis or synovitis; anterior knee pain is generally patella-femoral, increased with stair use due to magnified body weight forces. Diagnosis should be accurate as distinguished from pain through the knee actually arising in the back caused by L4 nerve root irritation. Physical Exam findings of pathologic knees include observed swelling, redness, or deformity. Palpation often aids focus on which compartments are involved. The patella inhibition test position connotes retropatellar pathology, and often tracking problems that warrant soft tissue or boney correct. Improved limb alignment may increase benefits, and can in part accrue from selective inflation of embodiments of the implants provided herein. X-rays of the knee are best evaluated in weight bearing views, and should be coupled with other data including MRI or CT. Relative compartment narrowing suggests cartilage degradation. Once an embodiment of an implant described herein has been successfully implanted and the knee adequately rehabilitated, the appearance of a knee with such implant should resemble a normal joint X-ray. Knee distension is from saline and/or air insufflation. Knee implant patients will benefit from tailored rehab programs, cautious weight bearing, early motion, and potential the use of constant passive motion machine regimens.

General Features

Implant Aspects

Provided herein is a resilient implant for implantation into human or animal joints to act as a cushion allowing for renewed joint motion. The implant may endure variable joint forces and cyclic loads while reducing pain and improving function after injury or disease to repair, reconstruct, and regenerate joint integrity. The implant may be deployed in a prepared debrided joint space, secured to at least one of the joint bones and expanded in the space, molding to surrounding structures with sufficient stability to avoid extrusion or dislocation. The implant may have has opposing walls that move in varied directions, and an inner space filled with suitable filler to accommodate motions which mimic or approximate normal joint motion. The implant may pad the damaged joint surfaces, restores cushioning immediately and may be employed to restore cartilage to normal by delivering regenerative cells.

The implant may be have no inflation chamber (inner space). The implant may comprise a chamber which is not inflated once implanted. The implant may have varying thicknesses at different locations. The implant may have different features at different locations. Inflation may involve singular balloons for cushioning or realignment, multiple separate or connected vesicles, or small vacuoles that contain gas, fluid, gel, fluid that becomes solid, or combinations thereof. Inflation may be invoked on either

both surfaces of the implant or any surface of the implant inside or between variable walls (which can be considered layers in certain embodiments). Cushioning while intending to address deficiencies in cartilage may accrue from inflation or the use of compliant materials without inflation (and without a balloon per se for that matter) or both.

Provided herein is a resilient interpositional arthroplasty implant for application into knee joints to pad cartilage defects, cushion joints, and replace or restore the articular surface, preserving joint integrity, reducing pain and improving function. The implant may endure variable knee joint compressive and shear forces, and millions of cyclic loads, after injury or disease requires intervention. The implant may repair, reconstruct, and regenerate knee joint anatomy in a minimally morbid fashion, with physiologic solutions that improve upon the rigid existing joint replacement alternatives of plastic and metal. In cases where cells have been used for joint resurfacing requiring massive periosteal harvesting for containment, the polymer walls of some embodiments of the implant can capture, distribute and hold living cells until aggregation and hyaline cartilage regrowth occurs. The implant may be deployed into a prepared debrided knee joint space, molding and conforming to surrounding structures with sufficient stability to avoid extrusion or dislocation. Appendages (or tabs) of the implant may serve to repair or reconstruct tendons or ligaments. The implant may have opposing walls that move in varied directions, and an inner space, singular or divided, filled with suitable gas, liquid, and/or complex polymer layers as force-absorbing mobile constituents, such than robust valid and reliable joint motion is enabled. There may be no defined inner chamber, however at a particular location in the device the implant may have different features to aid in cushion, therapeutic effect, wear resistance, defect correction, or the like.

Provided herein is a resilient orthopedic implant configured for deployment between a first bone and at least one second bone of a joint. In the case of a knee joint, the first bone may be a femur, a tibia, or a patella. In the case of a knee joint, the second bone may be a tibia, a patella or a femur. The implant may further comprise a balloon comprising a first portion that is configured to engage the first bone of the joint, a second portion that is configured to engage the second bone of the joint, a side portion connecting the first portion and the second portion, in which the side portion facilitates relative motion between the first portion and the second portion, and an interior that is optionally inflatable with a first inflation medium; and a first appendage configured to couple the balloon to the first bone of the joint. The terms "balloon" and "bladder" may be used interchangeably throughout this disclosure to describe an implant having the features described herein.

In some embodiments, at least two of the first portion, the second portion, and the side portion are contiguous. In some embodiments, the first portion comprises a first wall, the second portion comprises a second wall, and the side portion comprises a side wall. As used herein, each of the terms the "first portion", the "second portion", and the "side portion" is used to describe a part of the balloon, and may not be separate parts in some embodiments. In embodiments wherein no inflation is used, a first portion may be one side and the second portion another side of the same implant. In some embodiments, each portion or wall is named in order to indicate the general geometry and location of each portion relative to the other of the portions and/or relative to bones and/or ligaments and/or tendons of the joint. Likewise, as used herein, each of the terms the "first wall", the "second wall", and the "side wall" is used to describe a part of the balloon or cushioning implant, and may not be separate parts of the balloon in some embodiments. Rather, in some embodiments, each of the walls is named in order to indicate the general geometry and location of each portion relative to the other of the portions and/or relative to bones and/or ligaments and/or tendons of the joint. In some embodiments, at least two of first wall, the second wall, and the side wall are contiguous. Nevertheless, each of the walls may, in some embodiments, be separate parts of the implant that are joined to form the implant. Likewise, each of the portions may, indeed, in some embodiments, be separate parts of the implant that are joined to form the implant. In some embodiments, one wall may become the second wall with body movement changing the anatomy of the implant as it related to joint motion.

In some embodiments, the first portion is a term used interchangeably with the first wall. In some embodiments, the second portion is a term used interchangeably with the second wall. In some embodiments, the side portion is a term used interchangeably with the side wall. In some embodiments, a wall (whether a first wall, a second wall, and/or a side wall) of the implant may comprise a plurality of layers. The wall may comprise multiple materials to impart physical and/or therapeutic characteristics to the wall. In some embodiments, a side wall may become a first or second wall as the implant changes shape through the application of joint forces.

The distinction between the first wall and the second wall may merely be noted to show relative location, and may be a contiguous wall that has a first side (wall) and a second side (wall) where the first side is adapted to contact the first bone, and the second side is adapted to contact the second bone. The walls may be touching or be made of the same materials, or they may be made of different materials, or they may have additional materials therebetween, such as microstructures, vacuoles, therapeutic agents, padding materials, gels, liquids, solid materials, rigid or semi-rigid materials, meshes, foams, honeycombed materials, capsules, urethanes, human tissues or media, soft tissues, or the like, as described herein. Either of the walls themselves may be made of any of these materials and/or have any of these features. For example, a single sheet of BIONATE (e.g., BIONATE I, BIONATE II, BIONATE 55D, BIONATE 65D, BIONATE 75D, BIONATE 80, BIONATE 80A, BIONATE 90A) may be deemed to have a first wall that contacts the first bone, and second wall that contacts the second bone. In another example, a single sheet of Chronoflex (e.g., ChronoFlexAR®, ChronoFlex AL®, ChronoFlec C®) may be deemed to have a first wall that contacts the first bone, and second wall that contacts the second bone. Nevertheless, the single sheet may be contiguous, having no particular separation between the walls that may be deemed a chamber or balloon. Again, each of the first wall and the second wall may be, in certain embodiments, so designated only to depict relative location—i.e. in relation to the bone each wall is adapted to contact. The first wall may be so designated in order to indicate an intent that the first wall is in a position to contact the first bone, whereas the second wall may be so designated in order to indicate an intent that the second wall is in a position to contact the second bone, but the first wall and the second wall may be part of a contiguous implant, without any chamber or balloon therebetween.

The implant walls (first wall and/or second wall, and/or side wall may comprise a compliant material, and there may not be a separation between any of the walls of the implant which could be deemed a chamber. The material of the wall

itself may be compliant such that the material itself accommodates cartilage irregularity and improved alignment of the joint bodies (ligaments, bones, tissue, etc.).

In some embodiments, the implant comprises a sheet. The sheet may be solid (e.g. comprising polyurethane or another biocompatible material), complex (e.g. comprising Dyneema mesh), or with at least one chamber of any size from a micrometer, to larger chambers as depicted and described elsewhere herein. The implant may comprise Dyneema mesh. The implant may comprise Dyneema fiber. In some instances, the implant comprises Dyneema Purity®. The implant may comprise a fiber. The implant may comprise a polyethylene fiber. The implant may comprise a mesh. The mesh may be a random structure or a repeating structure (such as a honeycomb). The mesh may comprise a polymer structure of interwoven or randomly interlinked fibers or a combination thereof. The mesh may comprise a metal structure of interwoven or randomly interlinked metal fibers or a combination thereof. The mesh may comprise a memory metal (e.g. Nitinol or another memory metal). The mesh may comprise a memory polymer. The mesh may aid in fixing the implant in place. The mesh may be adapted to add cushion to the bones of joint. The mesh may be adapted to add durability to implant upon cyclic loading. The mesh may be adapted to add padding to the bones of joint. The mesh may be filled in its interstices with a softer (in durometer) polymer or other material (softer than the material of the mesh itself). The mesh may be filled in its interstices with a softer (in durometer) polymer or other material (softer than the material of the mesh itself). The interstices of the mesh may comprise a pharmacologic or therapeutic agent (or both) as noted herein. The mesh may be filled with a harder material, or a material that becomes harder, such as methyl methacrylate. The mesh may comprise a biodegradable material. In some instances, the mesh does not comprise a biodegradable material. The mesh may comprise a steel wool. Alternatively, the mesh comprises DNA strands. In some embodiments, the mesh comprises intertwined DNA strands. In some embodiments, the mesh is configured to wrap a joint end.

In some embodiments there is no chamber in the implant. In such an embodiment, the implant may have a single composition throughout the implant, and shaped as noted herein with attachment features as noted herein. In such embodiments, distinction between the first wall and the second wall may be noted to indicate relative location, and may be a contiguous wall that has a first side (wall) and a second side (wall) where the first side is adapted to contact the first bone, and the second side is adapted to contact the second bone. In other embodiments of the implant, the implant comprises no chamber, however it comprises various regions which have different features than other regions—such as comprising a mesh between the first wall and the second wall (as noted above), a cushion between the first wall and the second wall, and/or comprising any aspects of the fill materials noted in the inflation mediums noted elsewhere herein, but not necessarily provided in a chamber which is filled following implantation or at the time of implantation. Rather, these aspects may be built into the implant during implant manufacture, by layering or other manufacturing processes, and not necessarily by filling a chamber. In some embodiments, there are multiple regions having different characteristics—cushioning, some therapeutic agent delivery, defect correction, padding, for non-limiting example, or some combination thereof. In some embodiments, the implant achieves these aspects by varying thickness of one of the walls at a particular region of the implant, for non-limiting example, at load-bearing locations. In some embodiments, the implant is inflatable having large chamber (in the 1-100 cm range), or small chamber (in the 1 micrometer to 1 cm range). In some embodiments, the implant may comprise such a chamber (or chambers) but not involve any inflation. In some embodiments, the implant may not have any inflatable chamber (or chambers) whatsoever. The range of inflation can be consistent with a continuum whereas implant spacing or vacuous interspace can vary at a molecular level as allowing for macromolecular sizes or macrodendritic molecules. The molecules covering the exposed or integral implant makeup may be constructed with coatings or without, that may be suspended in gas, liquid, gel, or solids with vacuoles, bubbles, balloons or bladders of a size producing a foam or trabecular framework or honeycomb that has 'inflation' not visually obvious. When encapsulating the cushioning gas or fluid in small containers, the cushioning effect may become more effective, and for a given amount of cushioning the intercell pressure can be reduced. The implant may comprise a foam between the first wall and the second wall. The implant may comprise a microvoid (i.e. a void in the implant material that is in the 1 micrometer to 1 mm size range). The implant may comprise first wall or second wall that may be prefabricated containing compressible material into which substances may be introduced via needle injection or cannula. The compressible material may be a gas or a foam mixed with a liquid. The implant may comprise first wall or second wall that may be prefabricated containing displaceable material into which substances may be introduced via needle injection or cannula. The displaceable material may be a gas or liquid.

In some embodiments, the implant comprises a selectively inflatable chamber that may pad a uniquely damaged and/or collapsed joint region, thus restoring both protective cushioning and adjacent limb alignment as that otherwise accomplished (for example via proximal tibial or distal femoral osteotomy in the case of a knee implant). A chamber or redundant membrane may, depending on the embodiment, not be inflated at all. In other embodiments, the chamber or redundant membrane may be maximally inflated so as to appear as a diffuse balloon appendage fastened to the otherwise capped and adherent polymer solid joint end wrapping. The singular macroscopic cells or inflated polymer segment make take on any shape conforming to the recipient site defect and/or the inflation depo may have a prefabricated shape planned to accommodate a certain amount of infusion whether as an extension into the knee joint as a flattened bladder mimically meniscal fibrocartilage or topping off a femoral head analogous to the external radius of a bipolar hip hemiarthroplasty. In either or any case the natural polymer pliability and ability to elastically deform may match the normal joint motions physiologically.

The implant may comprise materials without obvious or definable inflation of any sort, producing a cushioning effect usually over one primary joint surface but potentially over multiple, providing a useful cushioning via polymers of variable albeit solid material nature and reasoned compliance. In certain embodiments, the implant material per se and/or inflational enlargement immediately or gradually comes to conform to, accommodate, adjust and fill the indentations or defects on the side of implant in apposition to the defect. A semi-fluid tendency of certain embodiments permits both immediate post insertional and delayed joint surface alignment adjustments that may be increased by injection or cannular infusion, or deceased by aspiration or valvular evacuation.

In some embodiments, the filling material is an inflation medium. The first wall is secured to the end of the first bone by a skirt that extends from the first wall and the second wall engages the end surface of the second bone and may also be secured thereto. In some embodiments, the skirt **18** is called an appendage. The side wall extending between the first and second walls and defines at least in part the implant interior which is filled with filling material (or an inflation medium). The inner surfaces of wall and skirt preferably conform to the particular surface of the head of the patient's first bone. In some embodiments, the inner surfaces of wall and skirt preferably conform to the particular surface of the patient's first bone. The outer surface of the second wall is preferably configured to conform to the end surface of the second bone. In some embodiments, the outer surface of the second wall is preferably configured to conform to a surface of the second bone.

The edge of the implant may have a depending skirt to secure or anchor the implant to the end of bone, but may have one or more depending tabs (or appendages) that may be employed for similar functions as will be discussed in other embodiments. The skirt (and/or tabs, and/or appendages) may tightly fit about the end of the first bone as shown, or the skirt can be secured by adhesive (e.g. methyl methacrylate, bone in-growth) to the supporting bone structure or be mechanically connected by staples, screws and the like. Moreover, the lower portion of the skirt may be secured by a purse string suture or a suitable strand (elastic or tied) that is tightly bound about the outside of the skirt.

In some embodiments the implant comprises an in-growth patch on at least one of the first portion configured to engage the first bone, the second portion configured to engage the second bone, the side portion, and the appendage. The in-growth patch may be configured to encourage and/or promote tissue in-growth, such as bone in-growth, for non-limiting example. The patch may be as large as the portion itself (whether the first portion the second portion, the side portion, or the appendage) or may be smaller than the portion (such as in the shape of a strip or other shaped patch). The in-growth patch may comprise a surface irregularity or roughness. The in-growth patch may be Velcro-like. In some embodiments the implant comprises an in-growth patch on the first portion and/or the second portion, from (and in some embodiments including) a first appendage to a second appendage. In some embodiments, wherein the appendages loosen from attachment from the bone (by design and/or from wear and/or over time), the in-growth patch aids in securing the implant to the bone. In some embodiments, the in-growth patch comprises beads and/or bead-like elements attached to the implant. Such an in-growth patch may be configured to simulate trabecular bone space of a normally cancellous latticework. In some embodiments, the beads are sintered beads of various sizes. In some embodiments, the beads are sintered beads about 400 microns in size. With respect to bead size, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%. In some embodiments, the first bone and/or the second bone is roughened to acquire a bleeding bone to facilitate in-growth. In some embodiments, about 0.5 mm of cortical tissue is removed to facilitate in-growth.

In some embodiments, the appendage of the implant comprises a hook. In some embodiments the hook is angled. The hook may comprise a piece of metal sandwiched between two polymer pieces. The hook may comprise a piece of metal encased in polymer. In some embodiments, the hook may comprise a piece of metal and a portion of the metal piece may be encased in polymer. In some embodiments, the hook may comprise a piece of metal and a portion of the metal piece may be sandwiched between two polymer pieces. The metal of the hook may reinforce the appendage tabs for securing the implant to the bone of the joint. In some embodiments, the metal of the hook is formed of a 1 centimeter by 1 centimeter metal piece. The metal of the hook, or a portion thereof, may protrude from the appendage. The metal may be bent toward the bone to which it is configured to attach. The metal may be bent at about a 270 degree angle (as compared to the non-bent portion of the metal, or as compared to the rest of the appendage, for non-limiting example). The term about when referring to angle of bend of the metal of the hook can mean variations of 1%, 5%, 10%, 20%, and/or 25%, or variations of 1 degree, 5 degrees, 10 degrees, 15 degrees, 20 degrees, 25 degrees, 30 degrees, 40 degrees, 45 degrees, and/or up to 90 degrees. In some embodiments, the bone may be prepared to receive the hook, such as by a hole or slot into which the hook (or a portion thereof) is placed. In some embodiments, the bone is not prepared in advance to receive the hook, and the hook may self-seat into the bone by pressure applied to the hook into the bone. In some embodiments, the implant may comprise multiple appendages, and a plurality of the appendages has hooks. In some embodiment the implant may be screwed on or snapped on or secured with a combination of elements, such as stabilizers and sutures.

In some embodiments, the implant comprises a second appendage coupling the balloon to the first bone of the joint. In some embodiments, the implant comprises a second appendage coupling the balloon to at least one second bone of the joint. In some embodiments, the implant comprises a second appendage configured to couple at least one of the first portion, the second portion, and the side portion to at least one of the first bone and at least one second bone of the joint. In some embodiments, the first appendage and the second appendage are configured to provide ligamentary-like support to the first bone and the at least one second bone of the joint. In some embodiments, the first appendage and the second appendage are configured to provide ligamentary-like support to the joint. In some embodiments, the first appendage and the second appendage are configured to provide tendon-like support to the first bone and the at least one second bone of the joint. In some embodiments, the first appendage and the second appendage are configured to provide tendon-like support to the joint.

In some embodiments, the implant comprises an inflation port in communication with the interior of the balloon for inflation of the interior of the balloon with the first inflation medium. In some embodiments, the balloon is punctured to inflate the interior of the balloon with the first inflation medium. In some embodiments, the balloon is self-sealing. In some embodiments, the balloon is self-sealing upon inflation of the interior of the balloon with the first inflation medium. In some embodiments, the implant comprises a seal capable of closing the interior of the balloon. In some embodiments, a series or collection of balloons as bubble-wrap are adjacent to each other or in a series such that they share or distribute forces across joints or with weight bearing. In some embodiments the contents from one balloon may transfer to another balloon or the size of one balloon may change in relation to adjacent balloons as with shoes that contain air soled subject to roving forces.

The implant interior, if existing depending on the embodiment, between the walls and the wall may be filled with filler material (or an inflation medium) which aids in maintaining the desired implant dynamics within the joint structure. The nature of the filler material such as a fluid and the charac-

teristics of the walls may be selected to maintain a desired spacing between the walls in order to accommodate the pressure applied by the bones of the joint structure to the implant and to allow suitable motion between the first and second walls of the implant which facilitate bone motion which mimics or approximates normal movement for the joint members involved. Alternatively, as mentioned above, the inner chamber may be filled with resilient material to provide the desired spacing, pressure accommodation, while allowing desired physiologic motion between implant layers. The implant is preferably configured to be shaped like the joint space and bone surfaces being replaced or to fill the void produced by injury or disease so that the natural joint spacing and cushioning of the joint interface is restored toward normal physiologic appearance and function. Fluids such as saline, mineral oil and the like may be employed to inflate the implant. In some embodiments, the inflated space can be maintained in the expanded position not by the contents (e.g. gas) but rather by the trabecular framework that props the walls apart, like cancellous bone fills the space between cortices with microscopic cavities that can be filled with various mediums. Such spaces may change with pathology such as bone with osteoporosis or lungs with emphysema. Therapeutic or physiologic filler that may be introduced into the implant, and transferred into the body through varied mechanisms, many of which are described elsewhere herein or would be known to one of skill in the art.

In some embodiments the implant may comprise vacuoles of pharmacologic substances. The vacuoles may be on a bone-engaging portion of the implant. In some embodiments, the implant comprises bubbles comprising an active substance such as a pharmacologic substance or other active substance. The implant may deliver by dissolution of the implant material (i.e. a biodegradable polymer which releases the active substance), and/or by release through pores of the implant (wherein the polymer is permeable to the active substance), and/or by fracture of the vacuole (or bubble, or space) by a catalyst such as ultrasound or pressure or other fracturing catalyst. The implant may deliver the active substance at a time after the actual implanting of the implant into the joint, for example an hour later, less than a day later, a day later, less than a week later, a week later, less than a month later, and/or a month later. In some embodiments, stem cells that are percolating in the bubble (or vacuole, or space) may be delivered to the joint space (or a constituent of the joint) after the implant is inserted into the joint. Active agents may, for non-limiting example, include cells (e.g., stem cells, differentiated cells, pluripotent cells, post-mitotic cells), growth factors, antibodies, biomolecules, biologics, chemical compounds, antibiotics, and/or viscolubricants. In some embodiments, the implant may comprise enzyme absorptive 'microscopic sponges' that could be sucked out or evacuated at or around the time of implant delivery to the joint.

In certain embodiments the implant (or a portion thereof, such as the balloon or balloons) is a weight bearing spacer that allows joint motions to approach normal, whether filling the space left by an entirely collapsed joint bone or the space of ablated cartilage proximate surfaces diffusely as in osteoarthritis or succinctly as in osteonecrotic defects or localized trauma. The walls of the implant may be used as a membrane for holding living cells in proximity of the osteochondral defect long enough for the cells to attach (e.g. 24 hours) or to deeply adhere (up to 28 days) or return to normal (up to one year). Weight bearing may be expected to increase as distal lower extremity joints are treated.

Movement (whether linear or curvilinear) between the first and second walls of the implant (i.e. of the balloon) as a result of movement of the femur and the tibia is illustrated in the comparison between FIGS. **9**B and **10**A, or in the comparison between FIGS. **9**C and **10**B. In some embodiments, the implant may comprise a balloon that is configured to allow a wall of the implant rolling upon another wall (or the same wall) of the implant (e.g. the side wall rolling upon the first wall, the first wall rolling upon the second wall, the second wall rolling upon the first wall, the first wall rolling upon the side wall, the second wall rolling upon the side wall, the side wall rolling upon the second wall, the first wall rolling upon the first wall, the second wall rolling upon the second wall, and/or the side wall rolling upon the side wall). In some embodiments, the implant may comprise a balloon that is configured to allow a portion of the implant rolling upon another portion (or the same portion) of the implant (for non-limiting example, the side wall rolling upon an appendage, the first wall rolling upon an appendage, and/or the second wall rolling upon an appendage). In some embodiments, the implant may comprise a balloon that is configured to allow movement of a portion of the implant rolling upon cartilage. While not shown in the drawings, there may be slippage between a portion of the implant (whether an appendage, a wall, or some other portion of the implant) and a joint component (whether a bone, ligament, tendon or other tissue). This slippage may be in addition to wall movements within the implant per se to provide desired joint movements. While not shown in the drawings, there may be slippage between the second bone (for example, the tibia) and the second wall in addition to wall movements within the implant per se to provide desired joint movements. The appendage (or appendages) is (are) designed to secure the implant to the joint structure so as to avoid dislocation of the implant. Movement of the joint with the implant in place may be a shared function of both the moving opposing walls of the implant but also a function of the movement of the wall which may be less attached to the joint members. There may be slight movement between the appendage, first wall and the first bone. The walls of the balloon may compress and/or stretch to accommodate bone interface movement. Material choices, material dimensions, and implant dimensions, placement and/or coupling may be chosen to allow for the desired amount of compression, stretching relative movement of various joint and/or implant components. For non-limiting example, the walls of the implant may be thicker is some areas to accommodate particular loads and the side wall may be thinner and more elastic to accommodate rolling and stretching thereof.

The interior of implant may be adjustably filled by the physician from an appropriate source thereof after the implant is deployed to ensure that the pathologic joint space becomes a resilient cushion again which aids restoration of worn or damaged cartilage interfaces in the joint by covering cartilage defects with the implant material, cushioning the joint and defects therein and delivering cell regeneration agents. In one embodiment, the arthroplasty implant comprises a bio-compatible inflatable member that is filled with a biocompatible fill material such as a gas, liquid, gel or slurry, or fluid that becomes a resilient solid to provide relative movement between the first and second walls. The filling or inflation media may be inserted through an injection valve site leading to the cannula which delivers the material into the interior of the implant. In an alternative embodiment, the implant may be filled with or have an interior formed of biologically compatible resilient material, e.g. a closed cell sponge filled with suitable fluid that is

inserted into the interior of the implant prior to the implant's deployment or injected into the interior after the implant is deployed at the joint site. The interior of the implant may be provided with lubricious material to facilitate movement between the inner wall surfaces and to minimize contact wear therebetween. The polymeric walls of the implant may be impregnated with or otherwise carry tissue regeneration agents such as stem cells, living chondrocytes, and/or genes to repair joint surfaces.

Motion is believed to be primarily between the spaced walls (or portions) of the implant peripherally secured to joint structures, although some motion may occur between the implant and the joint surfaces. As shown in multiple Figures (including, FIGS. **1**-**7**), the implant may be provided with a slot extending from the periphery of the implant toward the balloon of the implant to accommodate at least one ligament of the joint. Knee implants may have two slots leading to separate passages for receiving the anterior and posterior cruciate ligaments. Implant walls should have sufficient inherent flexibility to mold to the existing deformities imposed by either natural ligament, bone, tendon or remaining cartilage deformities of the internal joint space, and thus filled as a cushion. The wall exteriors may be flat or formed with random or specific patterns for purposes of glide or trends for traction against adjacent surfaces, or as sulci or venues for cell delivery materials.

The exterior of the implant may have a mesh material with a plurality of chords (or appendages) for securing the implant to adjacent bones or to remnant ligaments which are attached to adjacent bones. The exterior of the implant may comprise Dyneema mesh. The exterior of the implant may comprise Dyneema fiber. In some instances, the exterior of the implant comprises Dyneema Purity®. The exterior of the implant may comprise a fiber. The exterior of the implant may comprise a polyethylene fiber.

The dimensions of the various implant walls may vary depending upon the material properties thereof as well as the needs for a particular joint. Additionally, the first and second walls may require a thickness different from the side wall. Generally, the implant may have a wall thicknesses of about 0.125 mm to about 3 mm, preferably about 0.5 mm to about 1.5 mm. The spacing between the first and second wall within the interior can vary from about 0.5 mm to about 5 mm. Thicknesses of the fixation tabs may be at least one of: about 1 mm, about 2 mm, about 3 mm, about 4 mm, about 5 mm, about 6 mm, about 7 mm, about 1 mm to about 6 mm, about 2 mm to about 4 mm, 1 mm to 6 mm, and 2 mm to 4 mm, for non-limiting example. The implant may comprise a reinforcing rim or a reinforced tab, which includes a change in tab material to make it stronger, or include a metal rim to reinforce the attachment location. The reinforcement element may be embedded in the tab or in a wall at the periphery of the implant (for example in instances where the coupler is not located at a tab per se).

In some embodiments, the implant has a first wall, a second wall, and a side wall which define the implant interior (or exterior) which contains filling material. In some embodiments, the filling material is an inflation medium. The first wall is secured to the end of the femur by at least one appendage that extends from the first wall and the second wall engages the end surface of the second bone (which in the case of a femoral-tibial joint implant, would be the tibia) and may also be secured thereto. The side wall extending between the first and second walls defines at least in part the implant interior which is filled with filling material (or an inflation medium). The inner surfaces of wall and appendage may conform to the particular surface femur, for example by being wider in particular locations and/or longer in particular areas. For example a dual compartment implant (described herein) may have a wider section to cover the medial condyle than the lateral condyle (as shown in FIGS. **1**, **2**, **3**, **6**A, **6**B, and **7**). In another example, the length of the implant the along the external edge may be longer than the length of the implant along the trochlear groove edge (as shown in FIGS. **11**A, **11**B and **11**C). In yet another example, the width may vary along a single condyle, such as is shown in FIGS. **12**A-**12**C, wherein the wider edge of the implant is adapted to fit over at least a portion of the anterior condyle, and the narrower portion is adapted to fit over at least a portion of the posterior condyle. In some embodiments, the inner surfaces of the first wall and appendages preferably conform to the particular surface of the patient's femur, and do so by not only dimensions of the implant (lengths, widths, balloon location and shape), but also and/or alternatively due to appendage and/or tab and/or hole and/or coupler location and/or surface contours of the first wall. The outer surface of the second wall may be configured to conform to the end surface of the second bone (which may be a tibia or a patella, for example). In some embodiments, the outer surface of the second wall is configured to conform to a surface of the second bone (which may be a tibia or a patella, for example). The figures provided herein are highly schematic and do not depict details of the joint surface features, since human pathology and variation reflects both the patient's immediate and evolving pathophysiology. Neither do the figures depict other joint features such as cartilage, tendons, ligaments and other soft tissues and fluids of the joint for ease of viewing that which is depicted.

In some embodiments, the implant is configured to resemble the shape of the natural hyaline of a normal knee. For example, the normal hyaline is typically "H" shaped, thus certain embodiments of the implant are generally "H" shaped. The H may be an exaggerated H form, and the notches of the H may be extended on one side, while nearly nonexistent on the other side, such as is shown in certain figures, such the "H" may look more like a "U" or "V" or contain a tab in the notch. For each joint the cartilage surface shapes, implant design, and method of surgery can vary by adapting to normal anatomy in a particular patient, to expected weight bearing, and use intent.

Implant Materials and Material Features

In some embodiments, the implant comprises polymer. Polymers may comprise at least one of: a polyurethane (such as, for example, ChronoFlex AR, ChronoFlex AL®, ChronoFlec C®), a polycarbonate urethane, a thermoplastic polycarbonate urethane (such as BIONATE, e.g., BIONATE I, BIONATE II, BIONATE 55D, BIONATE 65D, BIONATE 75D, BIONATE 80A, BIONATE 90A, BIONATE 55 or BIONATE 80), ethylene-vinyl acetate copolymer, multiblock copolymers of poly(ethylene oxide) (PEO) and poly (butylene terephthalate) (PBT), PEG, PEO, and a polyetheylene. In some embodiments the implant comprises a 125 micron thickness thermoplastic polycarbonate urethane. In some embodiments, the thermoplastic polycarbonate urethane has a low coefficient of friction. In other embodiments, the thickness of walls intends to mimic natural hyaline cartilage a the involved body location and may be one of: about 0.5 mm, about 1 mm, about 2 mm, about 2.5 mm, about 3 mm, about 3.5 mm, about 4 mm, 0.5 mm, 1 mm, 2 mm, 2.5 mm, 3 mm, 3.5 mm, 4 mm, 1 mm-6 mm, 1 mm-4 mm, and 1 mm-3 mm.

The implant may comprise to a plurality of layers of polymer (such as ChronoFlex AR, ChronoFlexAR®, Chro-

noFlex AL®), ChronoFlec C®) in a solvent and evaporating the solvent after applying each layer. In some embodiments, the implant comprises a polyurethane that is sprayed and dried (wherein the spraying and drying is repeated at least once) to a desired thickness.

In some embodiments, the implant is created by dip molding a mandrel having a shape of a bone of the knee joint (the medial condyle, the lateral condyle, the tibia, for non-limiting example) into a polymer solution (for non-limiting example, a urethane polymer such as Chronoflex (e.g., ChronoFlexAR®, ChronoFlex AL®), ChronoFlec C®)). Following each dip, the implant is dried for a specified time, which may be, for example, about 3 seconds, about 4 seconds, about 5 seconds, about 6 seconds, about 7 seconds, about 8 seconds, about 9 seconds, about 10 seconds, about 15 seconds, about 20 seconds, about 25 seconds, about 30 seconds, about 45 seconds, about 1 minute, about 2 minutes, about 5 minutes, about 10 minutes, about 15 minutes, and over about 15 minutes. The term "about" used herein in reference to drying time of the implant can mean variations of at least one of 5%, 10%, 25%, and 50%, In some embodiments, no drying step is used. The dipping may be repeated multiple times. In some embodiments a single dip is sufficient. In some embodiments, the dipping is repeated 2 times. In some embodiments, the dipping is repeated 3 times. In some embodiments, the dipping is repeated 4 times. In some embodiments, the dipping is repeated 5 times. In some embodiments, the dipping is repeated 6 times. In some embodiments, the dipping is repeated 7 times. In some embodiments, the dipping is repeated 8 times. In some embodiments, the dipping is repeated 9 times. In some embodiments, the dipping is repeated 10 times. In some embodiments, the dipping is repeated 11 times. In some embodiments, the dipping is repeated 12 times. In some embodiments, the dipping is repeated 13 times. In some embodiments, the dipping is repeated 14 times. In some embodiments, the dipping is repeated 15 times. In some embodiments, the dipping is repeated 16 times. In some embodiments, the dipping is repeated 17 times. In some embodiments, the dipping is repeated 18 times. In some embodiments, the dipping is repeated 19 times. In some embodiments, the dipping is repeated 20 times. In some embodiments, the dipping is repeated 21 times. In some embodiments, the dipping is repeated 22 times. In some embodiments, the dipping is repeated 23 times. In some embodiments, the dipping is repeated 24 times. In some embodiments, the dipping is repeated 25 times. In some embodiments, the dipping is repeated over 25 times. In some embodiments, the dipping is repeated a sufficient number of times to create an implant that is a prescribed thickness. The thickness may vary depending on the polymer and depending on the embodiment of the implant. The thickness may be at least one of: about 25 microns thick, about 50 microns thick, about 100 microns thick, about 125 microns thick, about 150 microns thick, about 200 microns thick, about 250 microns thick, about 300 microns thick, about 350 microns thick, about 400 microns thick, about 25-50 microns thick, about 50-100 microns thick, about 50-200 microns thick, about 100-150 microns thick, about 150-300 microns thick, about 100-300 microns thick, about 100-500 microns thick, about 200-500 microns thick, and about 200-1000 microns thick. The term "about" used herein in reference to thickness of the implant can mean variations of at least one of 5%, 10%, 25%, and 50%, The thickness may vary at different locations of the implant. In some embodiments, the implant is fabricated in two pieces, one or more of which is molded to form an interior when the two pieces are put together. In some embodiments, the implant is filled by puncturing the implant wall and sealing the puncture hole with a plug, patch or other sealant. The plug, patch, or other sealant may comprise Chronoflex material (e.g., ChronoFlexAR®, ChronoFlex AL®, ChronoFlec C®), for non-limiting example. The plug, patch, or other sealant may comprise the same material from which the implant is constructed, for non-limiting example. In some embodiments, the implant thickness may be many millimeters, for example, where larger defects or malignments are being corrected.

The walls of the implant embodying features of the invention may be composite structures. For example, the innermost layer may be impervious to preclude escape of inflation or other filling media, a central layer may be porous or otherwise contain treatment or cell regeneration agents, and the outer layer may be a thin, but strong layer of a thermoplastic, such as a thermoplastic polyurethane for non-limiting example, which has microporosity sufficient to allow passage or egress of treatment or cell regeneration agents from the central layer (or second layer). The degree of microporosity to enable egress of treatment or cell regeneration agents from the central layer is found in polymer layers such as Chronoflex (e.g., ChronoFlexAR®, ChronoFlex AL®, ChronoFlec C®) or BIONATE (e.g., BIONATE I, BIONATE II, BIONATE 55D, BIONATE 65D, BIONATE 75D, BIONATE 80A, BIONATE 90A, BIONATE 55 or BIONATE 80).

The external wall (and/or the bone engaging surface) of the implant may be coated and/or impregnated with a latticework of polymer that is surface sprayed or layered on the outside (or bone engaging surface) of the implant to promote cartilage tissue regeneration. This most external surface coating may contain living chondrocytes (for example, as is provided in the Carticel procedure by the Genzyme company), and/or may contain stem cells with directed gene mutations to enhance adherence of the coating to the implant. Chondrocytes from companies such as Tygenix or Histogenics may be used for greater aggregation potential. The bone engaging surface may comprise peaks and troughs. The living cells may be imposed in between (and/or provided in the) troughs of the implant surface while the surface areas of prominence (the peaks of the surface) may be used for at least one of: space validation, traction, and cell protection.

The implant may be formed of suitable bioabsorbable materials so that the implant may be absorbed within a particular predetermined time frame. Suitable bioabsorbable materials include polylactic acid, polyglycolic acid, polycaprolactone, copolymers, blends and variants thereof. Suitable bioabsorbable materials may also/alternatively include poly(hydroxyalkanoate)s of the PHB-PHV class, additional poly(ester)s, and natural polymers, particularly, modified poly(saccharide)s, e.g., starch, cellulose, and chitosan. The walls of the implant may be (in whole and/or in part) bioabsorbable. The balloon may be (in whole and/or in part) bioabsorbable. As used herein the terms bioabsorbable, bioerodable, and/or bioabsorbable may be used interchangeably. The walls of the implant may release a pharmaceutical agent or an biological agent (such as stem cells, differentiated cells, pluripotent cells, post-mitotic cells, living chondrocytes, gene therapies, and the like). The release of such agents (whether biological or pharmaceutical, or a combination thereof) may occur over time, as the wall of the implant (or as the balloon) bioabsorbs in some embodiments, or as the joint is used (i.e. through pressure, for non-limiting example). In some embodiments, at least one of

the implant walls is permeable to a pharmaceutical agent and/or a biological agent, such as in an embodiment wherein the inflation medium comprises the pharmaceutical agent and/or biological agent. In some embodiments, at least one of the implant walls has pores through which the pharmaceutical agent and/or the biological agent may fit, such as in an embodiment wherein the inflation medium comprises the pharmaceutical agent and/or biological agent. In some embodiments the contents may contain targeting drugs such as gleevac that turn off tumor molecules as those in GIST. Cell-specific drugs targeting tumors by design may require nano-sized micelles with hydrophilic shells to protect core agents. In some embodiment hydrogels are used and tailored to swell thus releasing trapped molecules or cells through weblike surfaces, controlled by internal or external triggers such as ph, magnetic fields, or temperature. Dendritic macromolecules may be used in implants to deliver agents en masse deploying a controllable size and structure. In some embodiments, individual agent molecules or hubs may be incorporated via covalent bonds.

In some embodiments, the interior comprises a plurality of inflatable chambers. In some embodiments, the interior comprises a plurality of individually inflatable chambers. In some embodiments, a first chamber of the plurality of individually inflatable chambers is adapted to be inflated with the first inflation medium, and a second chamber of the plurality of individually inflatable chambers is adapted to be inflated with a second inflation medium. The implant may be provided with latticework or other reinforcing strands, preferably on the exterior or within the wall thereof to control the maximum expansion of the implant when deployed at the orthopedic site.

In some embodiments, the implant comprises amniotic membrane (and/or a component thereof). In some embodiments, the implant comprises amniotic sac (and/or a component thereof). In some embodiments, the implant comprises amniotic tissue (and/or a component thereof). Amniotic membrane (and/or sac and/or tissue) is unique in that its mechanical properties include that it slippery on one side (lubricious, low modulus of elasticity) and sticky (adherent) on the other. In some embodiments, at least one of the first wall, the second wall and the side wall comprise amniotic membrane or a component thereof. In some embodiments, at least one of the first wall, the second wall and the side wall comprise amniotic sac or a component thereof. In some embodiments, at least one of the first wall, the second wall and the side wall comprise amniotic tissue or a component thereof. The amniotic membrane and/or amniotic sac and/or amniotic tissue may be used in conjunction with other biologic agents, pharmaceutical agents, and/or therapeutic agents. Amniotic tissue is used extensively in pleuripotential cells. It qualifies as HTBP (Human Tissue Based Product) because of the short term time span on the product and origin.

In some embodiments, the balloon is a composite structure. In some embodiments, the balloon comprises layers of porous and/or non-porous materials, or otherwise contain treatment or cell regeneration agents. In some embodiments, a first layer of the balloon is a thin, but strong layer of a thermoplastic, such as a thermoplastic polyurethane, for non-limiting example, which has microporosity sufficient to allow passage or egress of treatment or cell regeneration agents from a second layer. The second layer may be a central layer (which lies between the first layer and a third layer or a fourth layer or more layers). The first layer may comprise a bone engaging surface in some embodiments. The degree of microporosity to enable egress of treatment or cell regeneration agents from the second layer is found in polymer layers such as Chronoflex (e.g., ChronoFlexAR®, ChronoFlex AL®, ChronoFlec C®) or BIONATE (e.g., BIONATE I, BIONATE II, BIONATE 55D, BIONATE 65D, BIONATE 75D, BIONATE 80A, BIONATE 90A, BIONATE 55 or BIONATE 80). The bone engaging surface of the implant may be coated and/or impregnated with a latticework of polymer that is surface sprayed or layered on the bone engaging surface of the implant to promote cartilage tissue regeneration. This bone engaging surface coating may contain living chondrocytes (for example, as is provided in the Carticel procedure by the Genzyme company), and/or may contain stem cells with directed gene mutations to enhance adherence of the coating to the implant. The bone engaging surface may comprise peaks and troughs. The living cells may be provided in troughs while the surface peaks may be used for at least one of: space validation, traction, and cell protection.

In some embodiments, the implant is pre-molded to fit about at least one condyle of the femur. In some embodiments, the implant comprises a memory plastic. In some embodiments, the implant comprises a wire frame. In some embodiments, the wire of the wire frame comprises a memory metal. In some embodiments, the memory metal comprises nitinol. In some embodiments, the wire frame is disposed in the periphery of the implant or a portion thereof. In some embodiments, the wire frame is configured to aid in placement against the posterior of the condyle.

In some embodiments, at least a portion of the implant comprises a slippery surface. In some embodiments the slippery surface is configured to allow for relative movement between the implant (or a portion thereof) that is coupled to the femur and the tibia. In some embodiments the slippery surface is configured to allow for relative movement between the implant (or a portion thereof) that is coupled to the femur and the patella.

In some embodiments, the implant comprises a sheet. The sheet may be solid (e.g. comprising polyurethane or another biocompatible material), complex (e.g. comprising Dyneema mesh), or with at least one chamber of any size from a micrometer, to larger chambers as depicted and described elsewhere herein. The implant may comprise Dyneema mesh. The implant may comprise Dyneema fiber. In some instances, the implant comprises Dyneema Purity®. The implant may comprise a fiber. The implant may comprise a polyethylene fiber. The implant may comprise a mesh. The mesh may be a random structure or a repeating structure (such as a honeycomb). The mesh may comprise a polymer structure of interwoven or randomly interlinked fibers or a combination thereof. The mesh may comprise a metal structure of interwoven or randomly interlinked metal fibers or a combination thereof. The mesh may comprise a memory metal (e.g. Nitinol or another memory metal). The mesh may comprise a memory polymer. The mesh may aid in fixing the implant in place. The mesh may be adapted to add cushion to the bones of joint. The mesh may be adapted to add durability to implant upon cyclic loading. The mesh may be adapted to add padding to the bones of joint. The mesh may be filled in its interstices with a softer (in durometer) polymer or other material (softer than the material of the mesh itself). The mesh may be filled in its interstices with a softer (in durometer) polymer or other material (softer than the material of the mesh itself). The interstices of the mesh may comprise a pharmacologic or therapeutic agent (or both) as noted herein.

To be clear, in some embodiments, there is no chamber in the implant. In such an embodiment, the implant may have

a single composition throughout the implant, and shaped as noted herein with attachment features as noted herein. In other embodiments of the implant, the implant comprises no chamber, however it comprises various regions which have different features than other regions—such as comprising a mesh between the first wall and the second wall (as noted above), a cushion between the first wall and the second wall, and/or comprising any aspects of the fill materials noted in the inflation mediums noted elsewhere herein, but not necessarily provided in a chamber which is filled following implantation or at the time of implantation. Rather, these aspects may be built into the implant during implant manufacture, by layering or other manufacturing processes, and not necessarily by filling a chamber. In some embodiments, there are multiple regions having different characteristics—cushioning, some therapeutic agent delivery, defect correction, padding, for non-limiting example, or some combination thereof. In some embodiments, the implant achieves these aspects by varying thickness of one of the walls at a particular region of the implant, for non-limiting example, at load-bearing locations.

Inflation Medium and Inflation or Filling of the Implant Interior

In some embodiments, the implant comprises an inflation medium that is compressible. In some embodiments, the implant comprises an inflation medium that comprises a viscolubricant. In some embodiments, the implant comprises an inflation medium that comprises a pharmacologic substance. In some embodiments, the implant comprises an inflation medium that comprises an NSAID. In some embodiments, the implant comprises an inflation medium that comprises chondrocytes. In some embodiments, the implant comprises an inflation medium that comprises cells (e.g., stem cells, differentiated cells, pluripotent cells, post-mitotic cells). In some embodiments the implant is configured to anneal the outer most layer of the implant (or a portion thereof) to the peripheral of succinct cartilage defects so as to cover them, allowing for healing. In some embodiments the implant is configured to anneal the outer most layer of the implant (or a portion thereof) to the peripheral of succinct cartilage defects so as to cover them, allowing for healing once new chondrocytes have been installed.

The implant interior (balloon interior) may be inflated with gas. The implant interior (balloon interior) may be inflated with liquid. The implant interior (balloon interior) may be inflated with saline. The implant interior (balloon interior) may be inflated with suspended stem cells. The implant interior (balloon interior) may be inflated with gel. The implant interior (balloon interior) may be inflated with a viscolubricant. The inflation medium in some embodiments stays within the balloon, or a portion thereof (as where there are multiple chambers to the balloon). In some embodiments, balloon contents disburse through microporosities and/or dissolving membranes into the joint. In some embodiments, balloon contents disburse by expulsive or evacuation precipitated through an implant wall after pressure from limb use. In some embodiments, balloon contents disburse by expulsive or evacuation precipitated through an implant wall from planned osmosis. In some embodiments, balloon contents disburse by expulsive or evacuation precipitated through an implant wall from vacuole rupture (whether mechanical rupture, ultrasound, or chemical rupture, for non-limiting example). In some embodiments, balloon contents disburse by expulsive or evacuation precipitated through an implant wall thereby distributing contents of the implant interior to joints as lubricious, analgesic, anti-inflammatory and/or otherwise healing substances. In some embodiments, the implant may comprise solid beads or beads containing gel or liquid for sequential disbursement by compressive force through rupture with varied bead wall thicknesses, or the beads may be time-released (opened) chemically, pharmacologically, or by an outside ultrasound or magnetic force external knee application at appropriate clinical intervals. In some embodiments, the implant may comprise vacuoles containing gel or liquid for sequential disbursement by compressive force through rupture with varied vacuole wall thicknesses, or the vacuoles may be time-released (opened) chemically, pharmacologically, or by an outside ultrasound or magnetic force external knee application at appropriate clinical intervals. The implant material may be foam or complaint material (such as a compliant polymer).

The implant interior (or balloon interior) between the first wall and the second wall is filled with filler material (or an inflation medium) which aids in maintaining the desired implant dynamics within the joint structure. The nature of the filler material such as a fluid and the characteristics of the walls may be selected to maintain a desired spacing between the walls in order to accommodate the pressure applied by the bones of the joint structure to the implant and to allow suitable motion between the first and second walls of the implant which facilitate bone motion which mimics or approximates normal movement for the joint members involved.

Alternatively (and/or additionally), the inner chamber (interior or a portion thereof) may be filled with resilient material to provide the desired spacing, pressure accommodation, while allowing desired physiologic motion between implant layers. The implant may be configured to be shaped like the joint space and bone surfaces being replaced or to fill the void produced by injury or disease so that the natural joint spacing and cushioning of the joint interface is restored toward normal physiologic appearance and function. The interior of implant is adjustably filled by the physician from an appropriate source thereof after the implant is deployed to ensure that the pathologic joint space becomes a resilient cushion again which aids restoration of worn or damaged cartilage interfaces in the joint by covering cartilage defects with the implant material, cushioning the joint and defects therein and delivering cell regeneration agents. In one embodiment, the implant comprises a bio-compatible inflatable member (balloon) that is filled with a biocompatible fill material (inflation medium) such as a gas, liquid, gel or slurry, or fluid that becomes a resilient solid to provide relative movement between the first and second walls.

In some embodiments, the features of the implant change over time. For example, prior to, at, or during implantation, the implant may comprise a powder methyl methacrylate and a liquid that becomes a slurry upon insertion or soon thereafter, and that once implanted hardens (or cures) within the implant. The methyl methacrylate (e.g. as a powder) and a catalyst liquid together become solid and are an example of a cement (or bone cement), however other cements or other materials which cure over time or with heat or with loading or by other methods (chemical or physical) are contemplated as alternatives. In certain embodiments, at least one of the powder methyl methacrylate and the liquid is part of the implant at the time of implantation. In certain embodiments, at least one of the powder methyl methacrylate and the liquid is injected into or loaded into the implant at the time of implantation or soon thereafter. In certain embodiments, both the powder methyl methacrylate and the liquid are injected into or loaded into the implant at the time

of implantation or soon thereafter. In certain embodiments, at least one of the powder methyl methacrylate and the liquid is a fill material. In certain embodiments, the implant does not have a chamber prior to injection of (or loading of) a fill material between the first wall and the second wall. The injection (or loading) of a fill material between the first wall and the second wall creates a chamber. In certain embodiments, the implant comprises interstices which are occupied by the fill material. In some embodiments, the methyl methacrylate powder and liquid catalyst are already inside the implant but only mix after intentional deployment in external or internal manners.

In some embodiments, the first inflation medium imparts rigidity in the implant. In some embodiments, the first inflation medium imparts cushion in the implant. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium aligns the joint. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium aligns the bones of the joint. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium changes the bone alignment. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium improves joint alignment. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium restores, at least in part, joint alignment. In some embodiments, individual chambers of the interior may be selectively inflated with a first inflation medium and/or a second inflation medium. In some embodiments, individual chambers of the interior are selectively inflated with a first inflation medium and/or a second inflation medium in order to reconstruct the joint and/or bones of the joint.

In some embodiments the inflation medium comprises living chondrocytes.

The implant interior (balloon interior) may be inflated with methyl methacrylate as a liquid that becomes a solid or semi-solid (rigid or semi-rigid). In some embodiments, the inflation medium is a methyl methacrylate or other biocompatible hardening substance which can flow when initially put into the chamber, and hardens to become a rigid piece or semi-rigid piece or solid piece. The methyl methacrylate or other biocompatible hardening substance may conform to the shape of the chamber, or may conform to the shape of a space between bones and/or other joint structures. The methyl methacrylate or other biocompatible hardening substance may conform to a form chosen by the surgeon using tools and/or pressure to influence the final shape of the rigid piece formed by the methyl methacrylate or other biocompatible hardening substance upon hardening.

The side wall extends between the first and second walls to form an interior which receives filling material through tube (also called a conduit herein, or may be called an inflation port). In some embodiments, the inflation port is not a tube, but is a valve which may or may not extend from a wall of the implant. The valve may be part of a wall of the implant, or part of the balloon or a portion thereof. The implant would also be appropriate for one condyle of the knee, but other shapes may be desired for other joint configurations whether relatively flat or more inflated toward a ballooning construct. In some embodiments, the inner diameter of the inflation port (or tube) is 5 millimeters maximum. In some embodiments, the inner diameter of the inflation port is about 1 millimeter. In some embodiments, the inner diameter of the inflation port is about 2 millimeters. In some embodiments, a needle (of typical needle sizes) may be used to inflate the implant.

A separate portal or tube (not shown) or the existing conduit (tube or valve), may be used to extract noxious inflammatory enzymes that can be aspirated at appropriate clinical intervals. Inflammatory enzymes in the COX1, COX2 and or 5LOX pathways can be extracted. Viscolubricants can be injected into the interior of the resilient arthroplasty implant through existing conduit or through a long needle to aide in distension, expansion, lubrication (with predetermined microporosity).

In some embodiments, an inflation medium that generates heat (by means of a catalyst reaction or other means) may be used to deliver heat to a joint structure. The heat may aide hyaline cartilage annealing. Thermal effects of the implant materials are calculated accordingly to benefit and protect the joint surface analogous to a dry suit or wet suit for a scuba diver exposed to temperature extremes. Embodiments of the implant generally seek to avoid head from friction via lubricious coatings whether allograph as amniotic membrane or polymer, for non-limiting example.

The implant in some embodiments is inserted arthroscopically through a cannula about 10 mm in diameter with the implant in the deflated construct, and once inside the prepared joint space and secured therein by the appendages or tabs, the implant may be distended or inflated with gas, gel, fluid or fluid that becomes a resilient solid to fill the original natural space of a bone of the joint (whether the tibia, femur or patella). Tensioning may be by the surgeon's sense of proper pressure application aided by a gauged syringe for insertion of viscolubricants such as Synvisc, Hyalgan, Supartz and/or analgesics such as lidocaine gel. The insertion of liquids to the joint per se may be directly, through a cannula to the joint space previously in place for debridement, and or via a cannula or tube that is not part of the original implant assembly. Once the joint is cleaned, the implant is inserted and appropriately fixed to avoid extrusion or dislocation thereof. This may be via attachment of the implant tabs and/or by a combination of tab use plus intended friction created by implant surface coverings (analogous to Velcro) or a draw string at the smaller base of the implant.

In some embodiments, the implant comprises a coil (spring). The coil, or multiple coils, may be secured inside the implant. In some embodiments, the materials of the implant secure the coil or coils within the implant. In some embodiments, the implant coil is positioned perpendicular to the primary flat first wall and/or second wall of the implant. In some embodiments, the coil is positioned parallel to the primary load in the joint. In some embodiments, multiple coils are provided in the implant. In some embodiments, each coil is positioned parallel a direction of load during joint use. In some embodiments, the coil is adapted in material and strength to fix the implant at a desired joint space when not under load by the bones of the joint. In some embodiments, the coil is adapted in material and strength to provide cushion between the unloaded and a loaded state, and/or to provide a minimum joint spacing, for example when the coil is fully compressed. In some embodiments, the coil has an ability to be extended past its unloaded length

(i.e. stretched), but to provide resistance to this extension. The resistance from extension provided by the coil may cooperate with the resistance from extension provided by ligaments of the joint and/or by the attachments of the implant to the first bone and/or the second bone. In the case of a medial compartment arthrosis where the normal 6 degrees valgus degrades to a 'bow legged' varus deformity, the implant may pad the damaged cartilage and cushion the joint,—even inflating selectively as described herein. In one embodiment, a combination of metal and polymer could stack shorter to longer parallel (Nitinol, other metal, or polymer) coils to fit the shape of a normal meniscus so that the longer coils are at the wide peripheral portion of the meniscus (joint edge) providing stability of the joint not available following varus deformity or meniscectomy. Another embodiment implant comprises coils between the inner and outer layers of the hip redundant or primary membranes.

Responsive Implants & Shifting Chambers

In some embodiments, the inflation, compliance, and or materials integrity with mesh, coils, or other fill materials fit the patients limb use needs not only structurally and anatomically at the time of surgical placement, but during normal activities of daily living. The implant may be compressed in certain locations during normal loading cycles, and compressed in other locations also during the same cycle. The implant may be responsive to this and shift the contents of a bladder or chambers (whether small or large). An example of this is shown in FIGS. **10**A and **10**B, where in the normal gait of a person the femur loads against the implant at the back of the joint (back of the knee), and pushes the contents of the chamber (s), toward the patella. It can be seen from this that if the angle of the femur to the tibia and load associated therewith were to shift to about 180 degrees, the contents of the chamber(s) could likewise shift to cushion the joint as the use of the joint required. That is, as the weight and axial load of walking moves the body central forces toward the 'step off' moment of that gait cycle, the chamber has also shifted, enduring oscillating balloon (macro) or vacuolar (micro) space size changes to accommodate and buffer the actions incumbent in natural limb use. As such, in some embodiments, the implant not only restores appendicular limb anatomy of the bone alignments and joint spaces, it also can compress with normal use forces and spring back to aid the best use of lever arms and joint interstacies as bones and joints relate to each other in activities of daily living. This type of implant may be used in multiple joint spaces throughout the body. To the degree the implant obtains and restores the joint spaces and are fixed in place, they may also thus be responsive during use of the joint thereafter.

Smart RADs

In some embodiments, the implant comprises a microminiature recorder and/or transmitter. The recorder (i.e. sensor) may collect joint loading data and comprise electronics that deliver data regarding joint loading. The recorder (i.e. sensor) may collect data regarding chemical or physiologic response at the implant location, such as the presence and composition of various biologic fluids at the sensor site. The sensor may be able to detect inflammatory responses in the joint. The sensor may be able to detect the spacing of the various joint components over time or at a particular time—such as the distance between the tibia and femur during a normal gait. The implant may comprise electronics that deliver data regarding joint loading or the other aspects of the joint sensed as listed herein or otherwise that could be sensed. The transmitters may provide feedback to the patient or to a caregiver. The feedback may be real-time, or may be uploaded periodically, or may be uploaded upon request. The feedback may be provided wirelessly. The transmitters may provide a patient an ongoing feedback and ability to adjust the joint use based to the feedback from the transmitter. For example, the transmitter might signal to the patient that he should adjust his gait to reduce the ligamentary stress in one manner or another. In another example, the transmitter might indicate to a physical therapist that a certain ligament is being stressed during normal use, and that might indicate to the therapist that the patient should strengthen a particular muscle or muscle group to compensate for and balance the stresses in the joint. In another example, the sensor and transmitters transmits information regarding positioning, ligamentary stresses and other information to a graphic display of real-time feedback, enabling a surgeon to visualize and quantify joint loading and balance during implantation. Thus, a surgeon can make an informed choice to modify implant positioning, adjust leg alignment and optimize soft tissue balance through a full range of motion.

In some embodiments, the implant may comprise spacers which can be expanded or reduced following implantation to adjust joint spacing and alignment. This expansion (or reduction) may occur days, weeks, or even years after implantation. The expansion (or reduction) may be done without need to open the joint in a surgery. The expansion (or reduction) may be done remotely. In some embodiments, sensors may be used to detect a need for adjustment of the joint spacing or cushioning. This may be in response to joint changes such as torn ligaments, other wear problems, changes in body weight and thus stress changes in the joint, or other changes, or simply due to the implant fatigue over time which is due to normal use but is not necessarily considered implant failure. In certain embodiments, the implant comprises an insert that may be activated by the patient or health care worker. For example, limb alignment may be achieved by remotely expanding (or reducing) the implant sizing (thickness or other specification) in a particular location in order to correct a varus to valgus alignment. Doing so may have beneficial effects on other parts of the body, such as in the appendicular skeleton (arms and legs) and axial skeleton (spine) given the natural symmetry. For example, a patient or care giver with their external device (such as a computer or Blackberry or iPhone) may expand or reduce, the medial knee compartment by external stimulus so that instead of being a knee with varus deformity and bone on bone (bow legged) the alignment was intentionally changed to normal 6 degree valgus (knock kneed). Nevertheless, if the patient had adjusted to his deformity for years and abruptly "corrected" it to completely normal, his back may act up with aching symptoms of 'out of alignment'. This is because the body attempts to adapt to deformity. Consequently, if a lower extremity fracture healing produces a two centimeter limb shortening, the proper treatment is not to add a 2 cm shoe lift onto the injured side, but rather to start with a one cm shoe lift. Although this may not make the limb lengths equal, it may 'balance the body' as perceived by the patient. In the case of an implant as provided herein that could adjust or be adjusted by doctor or patient, changes can be made to alignment and joint space, and then adjustments dealt with clinically as needed. If not via phone apps, other "black boxes" or tools such as a magnet placed externally adjacent to a medial compartment implant could be used to change the spacing inside the joint with an implant as described herein.

Attachment Elements and Couplers

In some embodiments the attachment elements of the implant comprises holes through which screws or other couplers may be placed to attach the implant to an attachment site (or connection site) in the bone of the knee. In some embodiments the attachment elements are also or alternatively called fixation elements or couplers. In some embodiments, the holes are created arthroscopically. In some embodiments the holes are pre-fabricated in the implant. In some embodiments, the holes may be made prior to implantation based on the patient's particular anatomy. In some embodiments, the holes are reinforced by a reinforcing material of the implant. The reinforcing material may be a polymer of sufficient durometer and/or tear resistance to reinforce the screw hole. The reinforcing material may comprise metal. In some embodiments, there is no pre-formed hole, but rather screws (or another coupler) secure the attachment tabs (which may be a non-balloon portion of the implant) to the joint component (bone, etc) by creating their own hole when implanted. In some embodiments, the implant may comprise tabs that are adapted to receive staples or other couplers described elsewhere herein. In some embodiments, the elasticity of the implant may allow it to stretch over the joint end and hook or snap into place, with the tendency of the material to contract acting to hold it in place (in part or wholly).

The implants described herein may comprise attachment elements (or tabs) which may then by attached or coupled to tissue of a component of the joint (whether to a bone or a ligament or a tendon or other joint component) by a coupling device. Coupling devices (or couplers) may comprise at least one of screws, snaps, washers, pins, sutures, suture anchors (metal and/or biodegradable), rivets, staples (with and/or without teeth), stabilizers, glues, hooks of cylindrical wire or flattened sheet metal into bone holes or slots respectively. The coupling devices may be resorbable or not. Also, the coupling devices may comprise at least one of strings (i.e. drawstrings), reigns, lassos, sutures, and lanyards. The strings, reigns, lassos, sutures, and/or lanyards may join with themselves and/or other coupling devices. The strings, reigns, lassos, sutures and/or lanyards may be directed not only into bone with or without anchors, but also through ligaments, tendons or loose segments of cartilage that the surgeon intends to preserve.

The posterior of the knee can be difficult to access without disturbing joint components (or in order to minimize such disturbance) such as tendons, ligaments, etc. Thus, in some embodiments, the implant comprises strings, reigns, lassos, and/or lanyards that may pass from the posterior of the implant via the intercondylar notch anteriorly to join with themselves and/or other coupling devices. These couplers may be pre-coupled to the implant, and the implant and its couplers may be configured to be pulled (or cinched) from the anterior of the implant once the implant is in its general location relative to the condyle in order to finally position the implant about the condyle—in particular in order to cinch the implant about the posterior of the condyle. Likewise, in some embodiments where the implant is pre-molded, the coupler as described are adapted to move the implant to its final position with conformity to the condyle's posterior with minimal disturbance to the joint structures at the joint's posterior (minimal cutting, minimal moving, and or minimal detachment, for non-limiting example).

In some embodiments, the implant comprises a skirt (or sleeve) that conforms to the contours of the bone (whether a condyle of the femur, a patella, or a tibia) as a coupler.

In some embodiments, a screw through tab having reinforced center holes may be part of the implant. For example, the implant may comprise polymer covered metal washer holes. The screw may go through the holes. Another embodiment may comprise a staple having spikes as shown in FIGS. **13**A-**13**D. FIGS. **13**A-**13**D depict multiple views of a staple adapted to couple an implant to a bone of the joint. FIG. **13**A depicts an embodiment of an implant **20** having a tab **10** *a* that is coupled to bone using a staple **12**. FIGS. **13**B & **13**C depict a staple **12** as described herein having teeth **18**. FIG. **13**C depicts an embodiment of a tab **10** *a* that is coupled to bone using a staple **12** having teeth **18**. Combinations of spikes and screws may be used in some embodiments, or combinations of other couplers. The implant may be configured to allow a surgeon the option of several types and sizes of couplers, as each patient differs with regard to size and depth of lesion, bone stock, regrowth capability, and compliance with advised recovery, and each surgeon has his own strengths and comforts when working with such implants.

The edge of the implant may have a depending skirt to secure or anchor the implant to the end of bone (femur), but may have one or more depending tabs (or appendages) that may be employed for similar functions as are discussed in other embodiments. The skirt (and/or tabs, and/or appendages) may tightly fit about the end of the femur, or the skirt can be secured by adhesive (e.g. HydroMed, Carbopol 934p, Polycarbophil AA1, xanthum gum, hydroxypropyl cellulose). Moreover, the lower portion of the skirt may be secured by a purse string suture or a suitable strand (elastic or tied) that is tightly bound about the outside of the skirt.

FIGS. **12**A, **12**B, and/or **12**C alternatively may be used to describe a patch implant or a unicompartment knee implant described herein, having appendages **4** *a*, **4** *c*, extending from a balloon **6** and including holes **8** *a*, **8** *b*, **8** *c*, and/or tabs **10** *a*, **10** *b*, **10** *c*, **10** *d*, **10** *e*, **10** *f*, which may be used with couplers (not shown) to couple the implant to a bone of the knee joint (which may be the femur, the tibia, or the patella). Features shown in FIG. **12**A, **12**B, and or **12**C are common to both the unicompartment knee implant (also discussed elsewhere herein) and the patch implant (also discussed elsewhere herein), although dimensions may differ as described elsewhere herein.

FIGS. **13**A-**13**D depict multiple views of a staple **12** adapted to couple implant **14** (such as those described herein) to a bone **16** of the joint. FIG. **13**A depicts a staple **12** coupling a tab **10** *a* of an appendage **4** *a* to the bone **16** of the joint (wherein the portion of the staple **12** embedded in the bone **16** is shown as a dashed line). FIG. **13**B depicts a view of a staple **12** having teeth **18** to grasp the tab **10** *a* of the implant **14**. Similarly, FIG. **13**C depicts a view of a staple **12** having teeth **18** to grasp the tab **10** *a* of the implant **14**. FIG. **13**D depicts a staple **12** attaching the tab **10** *a* of an implant to a bone **16**, the dotted lines show the portion of the tab **10** *a* that is compressed by the staple **12** and teeth **18** thereof.

In some embodiments, the implant is configured such that the tabs and/or couplers of the implant couple to the bone where there is no natural cartilage. In some embodiments, the implant may be adapted by the surgeon at the time of surgery such that the tabs are positioned where there is no natural cartilage.

In some embodiments, the implant comprises a tab and a hook that couples to the tab by wrapping around a component of the knee and securing the tab to the hook. In some embodiments, the implant comprises a tab and a hook that couples to the tab by wrapping around a condyle of the knee

and securing the tab to the hook. In some embodiments, the implant is configured to wrap around a condyle of the knee and to secure a first appendage to a second appendage of the implant. In some embodiments the appendages are secured by couplers described herein. In some embodiments, the implant is pre-formed to fit to the condyle in such a wrapping manner.

In some embodiments, the implant comprises a methyl methacrylate what is placed into a balloon chamber that fits into a bone hole. Such an embodiment would generally fix the implant to the bone once the methyl methacrylate cures to a solid.

In some embodiments, the implant can be anchored with generic available sutures and suture anchors fixing and positioning material to bone with proper tensioning.

In some embodiments, fixation may comprise various methods and elements. For example the fixation to a bone (the first, the second or the third bone) may comprise any one of or a combination of a screw, a snap, a pin, a staple, bone in-growth materials, glue, a nanocomposite, and cement. The implant may comprise a snap fit option for fixation. The implant itself may be pre-molded to cup the first bone of the device, or the second bone of the device. The implant may instead have a snap-like device which fixes the device to the bone (the first, second, and/or third bone). In some embodiments, fixation comprises glue. In some embodiments, fixation comprises a nanocomposite. In some embodiments, the nanocomposite comprises a polyurethane hierarchical nanocomposite. Fixation may comprise gluing a nanocomposite to the implant. In other embodiments, fixation comprises bone in-growth materials. For example, bone in-growth may be achieved as described in Vasanji A (2012). In some embodiments the patient's preoperative x-rays, MRI, CT scan, or physical measurements are coordinated with implant custom fit options providing for translation of pathophysiological data into solid works and rapid prototypes. This may provide the forum for anatomic fit of the implant to the patient. Optionally, the implant may be selected from a set of pre-selected sizes of implants and then the device may have inherent malleability which is used to couple the implant to the bone end.

In some embodiments, the implant comprises a rim comprising metal at the edge or a portion of the edge of the implant which may comprise a hole or more than one hole through which a fixation element (snap, screw, staple, other, etc.) or more than one element can be placed to fix the implant to the bone. The rim may comprise Nitinol or another metal (memory metal or deformable).

The implant may be shaped to form a joint cap which is fixed to a first bone or a second bone or a combination thereof with a fixation element such as a screw or staple or cement or another means or combination of these or others as described herein. Cementing the implant in place is an alternative or may be used with other fixation elements (screws, snaps, ties, hooks, staples, etc). In some embodiments the implant is secured in place only by the nature of its location and placement within the joint space. That is, it may naturally be held in place by the surrounding structures (tissue, bone, ligaments) as well as its own geometry in three dimensions. In some embodiments, fixing of the implant to bone is achieved by combining autograph, allograph, xenograph, and/or prosthetic structures.

In some embodiments, the implant comprises a polymer joint cap that may be used similarly to the femoral component of a total knee replacement cement arthroplasty or like a hip resurfacing. In certain cases, cartilage may be sacrificed exposing more bone beneath the implant, and cement could be used as a traditional fixation technique. In certain embodiments, specific portions of cartilage can be removed to allow attachment of the implant undersurface with the bone by localized applications of cement, bone in-growth, tacking devices, countersunk screws, or Velcro like constructs wherein opposing surfaces are set to fix. In an implant embodiment employing a cement for fixation, the anterior cruciate ligament could still be saved maintaining joint stability and proprioception.

A snap fit fixation element ("snap") may alternatively (or additionally) be used. A snap may be a protuberance off the posterior implant surface may be used. The snap may comprise a mushroom shaped peg that may insert into predrilled bone holes. The holes in some embodiments are of corresponding shape to the peg (upside-down mushroom-shaped holes, or similarly shaped holes). The holes in some embodiments are columnar shaped holes. The holes may be at the periphery (edge) of the implant as it opposes bone, or generally located as noted herein where other fixation elements are located (e.g. see FIGS. **1-4**B, **11**, **12** at least). The snap may also fit into more central posterior implant areas. With the natural effects of joint fluid and temperature on hydrophilic polymers, the snap may be designed as to increase stability by swelling beneath the joint cortical surface in the early post operative interval. Implant removal may be facilitated by placing a cooling device over the snap site to shrink or loosen the attachment. In some embodiments the peg of the snap is one of: about 1 mm to about 10 mm in diameter, about 2 mm to about 8 mm in diameter, about 3 mm to about 6 mm in diameter, about 4 mm to about 5 mm in diameter, about 4.5 mm in diameter, 1 mm to 10 mm in diameter, 2 mm to 8 mm in diameter, 3 mm to 6 mm in diameter, 4 mm to 5 mm in diameter, and 4.5 mm in diameter. In some embodiments the mushroom head of the snap is one of: about 1 mm to about 10 mm in diameter, about 2 mm to about 8 mm in diameter, about 3 mm to about 6 mm in diameter, about 4 mm to about 5 mm in diameter, about 4.5 mm in diameter, 1 mm to 10 mm in diameter, 2 mm to 8 mm in diameter, 3 mm to 6 mm in diameter, 4 mm to 5 mm in diameter, and 4.5 mm in diameter The snap or protuberances may have a narrow base that extends perpendicularly from the tabs and/or implant posterior surface. The wider sphere as compared to the diameter of the snap columnar pedestal fits into a predrilled bone hole that matches the location to be fixed. In another embodiment, the snap may be more like anchor which expands into the bone upon insertion, much like a drywall anchor acts. Material compliance allows the distal snap to enter through cortical to cancellous bone. Exposure to joint fluid and bode temperature can expand the snap wherein the snap comprises a hydrophilic polymer to secure implant apposition. In some embodiments, a mushroom shaped protuberance off the posterior of the polymer joint implant is used, with stiff pegs that push connected spheres through a predrilled cortical bone hole. The joint implant may be cap-like holding to the bone by internal elasticity of the implant and further held by the fixation elements which may be snaps or other elements. In some embodiments, a drill into cortical hole cuts a broader cancellous swath to create a location for the ball of the snap. For example the peg hole may be 5 mm, while the mushroom cap head hole section diameter may be 7 mm. Other sizes may be appropriate for the peg hole such as about 1 mm, about 2 mm, about 3 mm, about 4 mm, about 5 mm, about 6 mm, about 7 mm, about 8 mm. Other sizes may be appropriate for the mushroom cap head hole section, such as about 2 mm, about 3 mm, about 4 mm, about 5 mm,

about 6 mm, about 7 mm, about 8 mm, and about 9 mm. A hydrophilic polymer of the snap may then swell and hold the implant into place.

Other variations of fixing an implant to a bone may be known to one of skill in the art, and may include (but is not limited to) cross pins such as those used for ACL graft fixation, whip stitches with newer strong sutures as Ortho-Cord, or combinations of the above or others noted herein.

It should also be recalled that whereas the usual location of implants is over the major surface of a joint, the minor surfaces of joints may be selected optionally or additionally for coverage by an implant depending on the clinical need. In another iteration for fixation, magnets inside pegs or protuberances can allow for size adjustment internally or externally so as to engage a locking mechanism of implant to bone end.

In-Growth Features

In addition to the general in-growth that may occur based on the implant features described herein, the implant undersurface (adjacent the femur) may comprise an in-growth matrix. In some embodiments, at least a portion of the implant adjacent to the femur comprises bone in-growth materials. Such an implant can be attached by a series of tabs with or without holes, using screws, rivets, stabilizers, staples, tacks, washers, pins, snaps, or Sutures and suture anchors, for non-limiting example. The polymer of the implant substitutes for periosteum when the implant comprises living chondrocytes (e.g. Carticel) as the in-growth matrix on a surface of the implant. The polymer of the implant substitutes for periosteum when the implant comprises living chondrocytes (e.g. Carticel) as the in-growth matrix within an implant embodiment configured to reveal and/or release said chondrocytes over time and/or upon implantation.

The bone in-growth undersurface may be used for long term fixation of the tabs or rim. That is, whereas it is important for the surgery to secure the implant to the joint surface in the most desirable corrective location, it is also important in some embodiments to prepare the anatomic undersurface of bone by abrading it, removing about 0.5 mm of cortical bone so as to expose the underlying oxygen, blood, and nutrients of the patient to the undersurface of the implant that can gradually become incorporated into the limb bone. As this healing occurs over the course of weeks and months to one year post operation, the localized tacking sites may become less relevant and potentially inert. Thus, in some embodiments, the implant may comprise a biodegradable (bioresorbable) polymer or other material. The couplers may additionally and/or alternatively be biodegradable or durable (non-bioabsorbable). Once the implant is in place, it may serve to at least one of: pad defects, cushion the joint, and restore the original damage to the joint components. The end goal is to apply minimally morbid treatment that may refurbish arthritic limb regions, leaving only the small skin scar and remote memory of the healed physical mishap.

Undersurface implant materials may involve used of the art and science from Artelon or Gore-Tex research, as each has advantages and limitations. Several implant options per joint damage area may be available to enjoy the primary surgeons manipulation to fit the clinically recovery requirements best.

In some embodiments the implant comprises an in-growth patch on at least one of the first portion configured to engage the femur, the second portion configured to engage the second bone (whether the tibia or the patella), the side portion, and the appendage. In some embodiments, tissue is removed to facilitate in-growth.

The walls of the implant embodying features of the invention may be composite structures. For example, the innermost layer may be impervious to preclude escape of inflation or other filling media, a central layer may be porous or otherwise contain treatment or cell regeneration agents, and the outer layer may be a thin, but strong layer of a thermoplastic, such as a thermoplastic polyurethane for non-limiting example, which has microporosity sufficient to allow passage or egress of treatment or cell regeneration agents from the central layer (or second layer). The degree of microporosity to enable egress of treatment or cell regeneration agents from the central layer is found in polymer layers such as Chronoflex (e.g., ChronoFlexAR®, ChronoFlex AL®, ChronoFlec C®) or BIONATE (e.g., BIONATE I, BIONATE II, BIONATE 55D, BIONATE 65D, BIONATE 75D, BIONATE 80A, BIONATE 90A, BIONATE 55 or BIONATE 80). The external wall (and/or the bone engaging surface) of the implant may be coated and/or impregnated with a latticework of polymer that is surface sprayed or layered on the outside (or bone engaging surface) of the implant to promote cartilage tissue regeneration. This most external surface coating may contain living chondrocytes (for example, as is provided in the Carticel procedure by the Genzyme company), and/or may contain stem cells with or without directed gene mutations to enhance adherence of the coating to the implant. The bone engaging surface may comprise peaks and troughs. The living cells may be imposed in between (and/or provided in the) troughs of the implant surface while the surface areas of prominence (the peaks of the surface) may be used for at least one of: space validation, traction, and cell protection.

The implant embodying features of the invention may be used in a series of treatments wherein the first treatment involves use of autologous or minimally manipulated allograph interpositional tissues or xenograph, the second treatment involves the use of the same type of tissue added to stem cells or chondrocytes and the third treatment involving deployment of the implant if the first two fail or are ineffective.

The implant may comprise materials which allow for bone in-growth following implantation. In-growth may be facilitated by having interstices (or chambers) in the implant or in the fixation elements which are in the range of at least one of: about 10 microns to about 2000 microns, about 50 microns to about 1000 microns, about 100 microns to about 500 microns, about 300 microns to about 500 microns 10 microns to 2000 microns, 50 microns to 1000 microns, 100 microns to 500 microns, and 300 microns to 500 microns. In some embodiments, the chambers are sized to mimic the latticework of trabecular bone. In some embodiments, the chambers are formed by forming the implant using beads of the sizes noted above (e.g. 300 microns to 500 microns) and thereafter dissolving or otherwise breaking the beads such that interstices are left in the implant of the size of the beads. In an alternative, the beads may comprise a pharmacologic or other active agent which is absorbed or used by the body once implanted, and over time the interstices left by the beads (now gone due to absorption or use by the body) promote in-growth. Various methods known to one of skill in the art may be used to prepare the implant surface toward maximally effective union to bone.

Pharmacologics and Therapeutic Agents & Delivery thereof to Various Locations

In some embodiments the implant may comprise vacuoles of pharmacologic substances. The vacuoles may be on a

bone-engaging portion of the implant. In some embodiments, the implant comprises bubbles comprising an active substance such as a pharmacologic substance or other active substance. In some embodiments, the implant comprises spaces filled with an active substance such as a pharmacologic substance (pharmacologic agent) or other active substance (active agent). In some embodiments, the active substance comprises iatrogenically gene mutated cells. In some embodiments, the implant may be inserted into the vacated space following removal of an infected routine total joint replacement. Current treatment of infected prostheses range from IV antibiosis, through arthroscopic washout to single or two stage replantations. With the worst infection the joint is often debrided of the prosthetic components and old cement, and then filled with new bone cement that is impregnated with antibiotics, leaving the hardened materials in place 6-12 months. During this interval 6-12 weeks IV antibiotics are typically used. In this situation if implants as noted herein were inserted with a calculated egress of antibiotics from the polymer container, both increased concentration of local antibiotics and decreased systemic side effects can benefit the patient. Further, since the polymer is both robust and compliant, use of the infected joint being treated is more realistic and comfortable, with a "bag of antibiotics and air" as opposed to a "chunk of cement."

Similar use of implants as noted herein for localized resected bone or soft tissue tumors may allow for drug delivery. Substances that can be delivered via implants noted herein are limitless, though may include (for non-limiting example) antibiotics, anti-fungal and Tb agents, anti-gout, anti-rheumatoid, and anti-tumor. Implants in certain embodiments may specifically elute contents via one or more portals from the primary chamber, and/or from a material liner of the implant. Implants in certain embodiments may specifically elute contents via the multiple chambers (in the 1 micron to 1 mm size) which are filled with the active and/or pharmacologic agent. Alternatively, the implant may have a port to an external source (outside the body or outside the space where the implant has been placed) of therapeutic agent which then may be delivered by elution or other manner from the implant itself. Stem cells such as living chondrocytes can be disbursed immediately and/or over time for regenerative purposes to regrow joint surface cartilage. Polymer layers of the implant material, in certain embodiments, may or may not be biodegradable. Disease fighting orthobiologics, both living and laboratory, can be dispensed via the implants.

Active agent delivery with implants as noted herein may be from their reservoirs wherein the agent is encapsulated in a polymer shell. Optionally matrices with entrapped polymer can elute active agents from the network, and/or the matrix can dissolve as a planned rate.

Still other iterations are contemplated. The implant may comprise micelles can be nano-sized hydrophilic shells that make up an implant layer that protects a core agent. Cell specific targeting drugs design to attach particular molecules may be delivered via implants noted herein as from a vesicle elution or matrix diffusion. For example, Gleevac targeting a GIST tumor molecule may specific address a clinical cancerous problem. Doxorubicine, a hydrophyobic anticancer agent at be emitted via polymer deliver from either a solid or inflated material interface between joint surfaces and/or from a ballooning aspect of that interpositional arthroplasty. Membranes (or walls) of the implants can be of singular or multiple layers with various relationships to each proximate layer so as to absorb or exude drugs using electroactive polymers through controlled transport(dopants) in and out of membranes. Hydrogels can be tailored to swell releasing entrapped molecules/cells through weblike matrices of the implant. Triggers from release of substances from certain embodiments of the implant can be internal or external, involving chemical factors such as pH, electromagnetic factors as magnetic fields, temperature variables as when 37 degrees body temperature induces an additional 30% pliability to the polymer wall, or ultrasonic release of vacuole content. Calculated mechanical vacuole wall thickness in relation to predictable acute, subacute or chronic intra-articular joint forces invoked by movement and limb use can release internal substances abruptly and/or over time.

Dendritic Macromolecules may deliver agent en masse from certain embodiments of the implant. The delivery in such situations may be via controllable size and structure, and may incorporate individual agent molecules or "hubs" via covalent bonds. Any combination of the nanoscopic developments can be created or assembled into the implants described herein and can be distributed, or oozed, or leaked, or expulsed from, or absorbed into as cleansing a noxious environment, or any combination thereof. Combined alternating forces such as materials that suck up or absorb noxious leukokynins or cathepsins while released useful viscolubricants such as Synvisc, Hyalgan or Orthovisc can be constructed to accommodate clinical need consistent with physical joint damage mandates or aligned with and consider of the natural history of disease processes so as to maximize either ones anticipated inevitable chronic deterioration or to thwart the adverse affects delaying degradation from arthritic or pathophysiologic processes.

Patient Symptoms

Symptoms for the patient requiring an implant described herein may include, for non-limiting example, osteoarthritis or rheumatoid or gouty arthritis.

Total Knee Arthroplasty (Dual Compartment):

Provided herein is an implant for placement on both condyles (medial and lateral) of the distal femur. In some embodiments, this is called a dual compartment implant since it covers both condyles of the femur. Such an implant comprises at least one interior (or inflatable chamber), and in some embodiments comprises a plurality of inflatable chambers (or interiors).

In some embodiments, the implant covers the "H" distal femoral cartilage segment (made up of both femoral condyles and the trochlear groove in between). The implant may absorb diffuse force, endure the millions of annual cyclic loads of both knee joints (including the patella-femur joint and the femur-tibia joints), along with rotational and shear forces up to six times body weight, at least.

In some embodiments, the implant comprises attachment tabs or attachment elements over the sides of both condyles medially and laterally. In some embodiments, the implant comprises attachment tabs or attachment elements in the intercondylar notch (or slot). In some embodiments, the implant comprises attachment tabs or attachment elements superiorly at the distal end of the femur anteriorly. In some embodiments, posterior reigns or suture-like lanyards cinch up the implant from inside the posterior intercondylar notch toward another connection site around the femur.

The posterior of the knee can be difficult to access without disturbing joint components (or in order to minimize such disturbance) such as tendons, ligaments, etc. Thus, in some embodiments, the implant comprises strings, reigns, lassos, and/or lanyards that may pass from the posterior of the implant via the intercondylar notch anteriorly to join with themselves and/or other coupling devices. These couplers

may be pre-coupled to the implant, and the implant and its couplers may be configured to be pulled (or cinched) from the anterior of the implant once the implant is in its general location relative to the condyle in order to finally position the implant about the condyle—in particular in order to cinch the implant about the posterior of the condyle. Likewise, in some embodiments where the implant is pre-molded, the coupler as described are adapted to move the implant to its final position with conformity to the condyle's posterior with minimal disturbance to the joint structures at the joint's posterior (minimal cutting, minimal moving, and or minimal detachment, for non-limiting example). In some embodiments at least a portion of the ligamentary structure of the knee is spared.

Although this description focuses on the distal femur as it articulates with the retropatellar and proximal tibial cartilages implants as described generally herein may be also and/or alternatively be used in conjunction with the tibia and/or the patella. Furthermore, separate and/or connected implant components may be inserted to restore natural function to the knee. In some embodiments whereas the implant caps the major joint surface and opposes remnant cartilage, the surgeon may elect to place the implant so that it opposes metal, polymer, or another surface reconstructive material.

Coupling devices to be used as part of the dual compartment implant may include any of those mentioned or described herein, for example. Such coupling devices may comprise at least one of strings (i.e. drawstrings), reigns, lassos, sutures, and lanyards. The strings, reigns, lassos, sutures, and/or lanyards may join with themselves and/or other coupling devices. The strings, reigns, lassos, sutures and/or lanyards may be directed not only into bone with or without anchors, but also through ligaments, tendons or loose segments of cartilage that the surgeon intends to preserve.

FIG. **1** depicts an embodiment of the implant **20** in a 2D view configured for dual condyle (distal femur) coverage. FIG. **1** depicts an embodiment of the knee implant **20** having appendages **4** *a*, **4** *b*, **4** *c*, **4** *d*, including holes **8** *a*, **8** *b*, **8** *c*, **8** *d* and tabs **10** *a*, **10** *b* extending from a balloon **6** and including slots **26** *a*, **26** *b* to accommodate ligaments (not shown) of the knee joint. Couplers as described elsewhere herein may be used to couple the implant **20** to the distal femur. In some embodiments, there may only tabs, only holes, or only appendages, or combinations thereof. In some embodiments, there may be other ways to couple the implant to the distal femur, as described elsewhere herein (sutures, drawstrings, skirts, glue, etc). In some embodiments, the tabs **10** *a*, **10** *b* contain holes. In some embodiments, the couplers create the holes **8** *a*, **8** *b*, **8** *c*, **8** *d*, or other holes (not shown) when the implant is placed against the distal femur **24**. In some embodiments, the holes are pre-formed in the appendage prior to implantation. In some embodiments, the holes are reinforced as described elsewhere herein. In some embodiments, the holes are within the peripheral rim of the knee implant. In some embodiments, the holes are within the region of the intercondylar notch medially and/or laterally. In some embodiments, the holes are through the polymer. In some embodiments, the holes are through a reinforced rim. As shown here, the appendages in some embodiments may be different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage **4** *d* that is intended to wrap over the medial condyle may be longer and/or wider than the appendage **4** *c* intended to wrap over the lateral condyle. Likewise, the slots may be different in shape and/or size and/or position to accommodate the ligaments and/or tendons of the joint or other structures and functions of the joints of the knee, and to allow for placement of the implant with minimal disturbance (cutting, manipulation, for example) of the joint components such as tendons, ligaments, and other soft or hard tissues. For example, slot **26** *a* is shaped and positioned to accommodate the cruciate ligaments of the knee, at least. In some embodiments, the implant as shown in FIG. **1** can have regions **4** *a*, **4** *b*, **4** *c*, **4** *d* where no inflation exists and may be composed of solid or compliant materials. In some embodiments, the implant comprises a Dyneema® mesh. The implant may comprise Dyneema® fiber. In some instances, the implant comprises Dyneema Purity® fiber. In some embodiments, the implant comprises a Dyneema Purity® UG fiber. In some embodiments, the implant comprises a Dyneema Purity® VG fiber. The implant may comprise a fiber. The implant may comprise a polyethylene. The implant may comprise a polyethylene fiber.

FIG. **2** depicts an embodiment of the knee implant **20** having appendages **4** *a*, **4** *b*, **4** *c*, **4** *d*, including holes **8** *a*, **8** *b*, **8** *c*, **8** *d* and tabs **10** *a*, **10** *b* extending from a balloon **6** and including slots **26** *a*, **26** *b* to accommodate ligaments of the knee joint as well as side views of the same knee implant. Couplers as described elsewhere herein may be used to couple the implant **20** to the distal femur. In some embodiments, there may only tabs, only holes, or only appendages, or combinations thereof. In some embodiments, there may be other ways to couple the implant to the distal femur, as described elsewhere herein (sutures, drawstrings, skirts, glue, etc). In some embodiments, the couplers create the holes **8** *a*, **8** *b*, **8** *c*, **8** *d*, or other holes (not shown) when the implant is placed against the distal femur. In some embodiments, the holes are pre-formed in the appendage prior to implantation. In some embodiments, the holes are reinforced as described elsewhere herein. As shown here, the appendages in some embodiments are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage **4** *d* that is intended to wrap over the medial condyle may be longer and/or wider than the appendage **4** *c* intended to wrap over the lateral condyle. Shown in the embodiment depicted in FIG. **2** are the different hole placements from the side view, showing the differences in positioning of the holes to accommodate the differences in anatomic structure and size of the condyles. Likewise, the slots may be different in shape and/or size and/or position to accommodate the ligaments and/or tendons of the joint or other structures and functions of the joints of the knee, and to allow for placement of the implant with minimal disturbance (cutting, manipulation, for example) of the joint components such as tendons, ligaments, and other soft or hard tissues. For example, slot **26** *a* is shaped and positioned to accommodate the cruciate ligaments of the knee, at least. Additionally, as shown in the side views of the embodiment shown in FIG. **2**, the balloon has a first wall **28** adapted to be adjacent the femur that is of a greater thickness than the second wall **30**. In some embodiments, the first wall **28** is configured to have therapeutic benefits (pharmacologic, healing, and/or in-growth properties) as described elsewhere herein. The second wall **30** may additionally and/or alternatively be configured to have a therapeutic effect (pharmacologic, healing, and/or in-growth properties).

Nevertheless, differing thicknesses of the first wall **28** and the second wall **30** are not necessarily required in order to

impart the therapeutic benefits (pharmacologic, healing, and/or in-growth) described elsewhere herein. For example, FIG. **3** depicts an embodiment of the knee implant **20** having appendages **4** *a*, **4** *b*, **4** *c*, **4** *d*, including holes **8** *a*, **8** *b*, **8** *c*, **8** *d* and tabs **10** *a*, **10** *b* extending from a balloon **6** and including slots **26** *a*, **26** *b* to accommodate ligaments of the knee joint as well as side views of the same knee implant. Couplers as described elsewhere herein may be used to couple the implant **20** to the distal femur. In some embodiments, there may only tabs, only holes, or only appendages, or combinations thereof. In some embodiments, there may be other ways to couple the implant to the distal femur, as described elsewhere herein (sutures, drawstrings, skirts, glue, etc). In some embodiments, the couplers create the holes **8** *a*, **8** *b*, **8** *c*, **8** *d*, or other holes (not shown) when the implant is placed against the distal femur. In some embodiments, the holes are pre-formed in the appendage prior to implantation. In some embodiments, the holes are reinforced as described elsewhere herein. As shown here, the appendages in some embodiments are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage **4** *d* that is intended to wrap over the medial condyle may be longer and/or wider than the appendage **4** *c* intended to wrap over the lateral condyle. Shown in the embodiment depicted in FIG. **3** are the different hole placements from the side view, showing the differences in positioning of the holes to accommodate the differences in anatomic structure and size of the condyles. Likewise, the slots may be different in shape and/or size and/or position to accommodate the ligaments and/or tendons of the joint or other structures and functions of the joints of the knee, and to allow for placement of the implant with minimal disturbance (cutting, manipulation, for example) of the joint components such as tendons, ligaments, and other soft or hard tissues. For example, slot **26** *a* is shaped and positioned to accommodate the cruciate ligaments of the knee, at least. Additionally, as shown in the side views of the embodiment shown in FIG. **3**, the balloon has a first wall **28** adapted to be adjacent the femur that is of approximately the same thickness than the second wall **30**. In some embodiments, the first wall **28** is configured to have therapeutic benefits (pharmacologic, healing, and/or in-growth properties) as described elsewhere herein. The second wall **30** may additionally and/or alternatively be configured to have a therapeutic effect (pharmacologic, healing, and/or in-growth properties). The balloon **6** may be singular as depicted, or in certain embodiments, include a plurality of microscopic vesicular structures.

FIG. **4**A depicts an embodiment of the knee implant **20** having appendages **4** *a*-**4** *d* including ten tabs **10** *a*-**10** *j* extending from a balloon **6** and including a slot **26** *a* to accommodate components (such as ligaments or other tissues whether soft tissues, hard tissues, tendons, and/or others) of the knee joint (not shown). The tabs **10** *a*-**10** *j* are not shown with holes in this embodiment, however if screws are used as couplers, such holes may be pre-drilled or formed in situ by the screws. Additionally and/or alternatively, staples, washers, pins, snaps, or sutures may be used (as described elsewhere herein) in order to couple the implant to the bone (femur, for example). Other couplers as described elsewhere herein may also and/or alternatively be used in this coupling process. Furthermore, the number of tabs may be fewer or greater than the ten depicted in order to achieve optimal placement and coupling to the bone. For example, FIG. **4**B depicts an embodiment of the knee implant **20** having appendages **4** *a*-**4** *d* including eight tabs **10** *a*-**10** *h* extending from a balloon **6** and including a slot **26** *a* to accommodate components (such as ligaments or other tissues whether soft tissues, hard tissues, tendons, and/or others) of the knee joint (not shown). In certain embodiments, the implant comprises 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, or 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, and/or 20 tabs. The tabs may be located on either side of the condyles, including the superior, mid, and posterior portions. Any tab may be also and/or alternatively located inside the medial and intercondylar notch.

FIG. **5** depicts an embodiment of the knee implant **32** curved to simulate curvature about the condyles of a femur, the implant having appendages **4** *a*-**4** *d* extending from an uninflated balloon (not shown) and including slots **26** *a*, **26** *b* to accommodate components (such as ligaments or other tissues whether soft tissues, hard tissues, tendons, and/or others) of the knee joint (not shown). This figure also shows an implant comprising a solid compliant material, having no balloon whatsoever. The implant may comprise additional curvatures and/or slots to accommodate other ligaments and/or tissues. In some embodiments, the implant is configured to conform about various hard and/or soft tissues of the joint, such as bone, ligaments, tendons, etc. In some embodiments, the balloon is inflated once the implant is positioned within the joint. In other embodiments, the balloon is partially inflated prior to being positioned within the joint. In other embodiments, the balloon is at least partially inflated prior to being positioned within the joint. In some embodiments, the balloon is fully inflated prior to being positioned within the joint. In some embodiments, the implant is configured to allow an operator to adjust the amount of balloon inflation in situ (whether by adding inflation medium or removing inflation medium, or both, or neither). Couplers as described elsewhere herein may be used to couple the implant **32** to the distal femur.

FIG. **6**A depicts a top-down view of an embodiment of the knee implant **32** curved to simulate curvature about the condyles of a femur, the implant having appendages **4** *a*-**4** *d* extending from two inflated balloons **6**, **34** and including a slot **26** *a* to accommodate components of the knee joint. FIG. **6**B depicts a bottom-up or anterior oblique view of the same embodiment of the knee implant **32** curved to simulate curvature about the condyles of a femur, the implant having appendages **4** *a*-**4** *d* extending from two inflated balloons **6**, **32** and including a slot **26** *a* to accommodate components of the knee joint. Couplers as described elsewhere herein may be used to couple the implant **32** to the distal femur. As shown in FIGS. **6**A and **6**B, the appendages **4** *a*-**4** *d* in some embodiments are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage **4** *d* that is intended to wrap over the medial condyle may be longer and/or wider than the appendage **4** *c* intended to wrap over the lateral condyle. Likewise, the dimensions of the balloon **34** that is adapted for placement over the medial condyle may be a different shape and/or size than the balloon **6** over the lateral condyle (the medial condyle being larger, thus the balloon **34** may be larger for that location) Alternatively and/or additionally, as described elsewhere herein, for various reasons such as injury, realignment needs, injury, etc, there may be a need for more reconstruction of one condyle than needed for the other, thus the inflation medium might be different in one balloon (or a portion thereof) than in the other balloon (or another chamber within the same balloon), or there may be need for a different shaped balloon in one location than in another location. Embodiments provided

herein can accommodate these requirements based on materials of fillers, appendages, balloons, walls, and dimensions and chamber options of the implant and its components.

FIG. **7** depicts a top-down view of an embodiment of the knee implant **32** curved to simulate curvature about the condyles of a femur, the implant having appendages **4** *a*-**4** *d* extending from an inflated balloon **6** and including slots to accommodate components of the knee joint. Couplers as described elsewhere herein may be used to couple the implant **32** to the distal femur. As shown here, the appendages **4** *a*-**4** *d* in some embodiments are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage **4** *d* that is intended to wrap over the medial condyle may be longer and/or wider than the appendage **4** *c* intended to wrap over the lateral condyle. Likewise, the dimensions of the portion of the balloon that is adapted for placement over the medial condyle may be a different shape and/or size than the portion of the balloon over the lateral condyle (the medial condyle being larger, thus the balloon may be larger for that location) Alternatively and/or additionally, as described elsewhere herein, for various reasons such as injury, realignment needs, injury, etc, there may be a need for more reconstruction of one condyle than needed for the other, thus the inflation medium might be different in a portion or chamber of an implant embodiment having a plurality of inflation chambers in a single balloon, or there may be need for a non-symmetric balloon. Embodiments provided herein can accommodate these requirements based on materials of fillers, appendages, balloons, walls, and dimensions and chamber options of the implant and its components.

FIG. **8** depicts a side view of an embodiment of the knee implant **32** curved to simulate curvature about at least one condyle of a femur, the implant having appendages **4** *b*, **4** *d* extending from an uninflated balloon (not shown). This depiction covers the maximum anticipated distal femoral contour; other iterations may be smaller, or shorter covering limited areas of the circumference of the femoral curvatures. This figure also provides a lateral view for a solid implant (without a chamber therein) wherein the material thickness and/or layering provide cushioning.

FIG. **9**A depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4** *b*, **4** *d* extending from an uninflated or minimally inflated balloon **6**. In this view, the knee is positioned essentially in extension (straight), showing the tibia **36**, fibula **38**, and patella **40** of the knee. Note that although there would be other joint structures and knee structures in a true depiction of an implant positioned in the knee, this view of the implant and bones is greatly simplified for ease of understanding of the implant and the joint relative (and approximate) positions and placement. Couplers as described elsewhere herein may be used to couple the implant **20** to the distal femur **24** and/or the condyle **22** thereof (in this image the medial condyle, at least since it is primarily a one-side view of the joint and implant). For the sake of simplicity FIG. **9**A and the implant embodiment depicted show of the femur with opposition to the other surfaces of both knee joints (between femur and tibia, and femur and patella), the areas of contact varying according to activity, forces, and range of motion. Other implant iterations may apply to opposing surfaces.

FIG. **9**B depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4** *b*, **4** *d* extending from an inflated balloon **6**. In this view, the knee is positioned essentially in extension (straight), showing the tibia **36**, fibula **38**, and patella **40** of the knee. Note that although there would be other joint structures and knee structures in a true depiction of an implant positioned in the knee, this view of the implant and bones is greatly simplified for ease of understanding of the implant and the joint relative (and approximate) positions and placement. Couplers as described elsewhere herein may be used to couple the implant **20** to the distal femur **24** and/or the condyle **22** thereof (in this image the medial condyle, at least since it is primarily a one-side view of the joint and implant). In FIG. **9**B wherein the balloon is inflated, as compared to FIG. **9**A wherein the balloon is not inflated or is minimally inflated, the balloon second wall **30** is closer to and/or contacting the tibial plateau **42** (articular surface) when the balloon **6** is inflated. Likewise, FIG. **9**C depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4** *b*, **4** *d* extending from an inflated balloon **6** and having couplers **44** *a*, **44** *b* (which may be, for non-limiting example, staples or screws, pins, or snaps) coupling the appendages **4** *b*, **4** *d* to the femur. In this view, the knee is positioned essentially in extension (straight), showing the tibia **36**, fibula **38**, and patella **40** of the knee. Where the inflated balloon as seen in FIG. **9**B may fill in existing pathologic defects of the joint surface, the medium of inflated and specific balloon location and durometry with the material of the implant may also be constructed so as to force the bones opposed, e.g. the femur and tibia, into a more natural limb alignment such as six (6) degrees valgus. However, if the patient being treated has variations from normal in the affected knee as illustrated by examining and measuring the opposite normal side, then the implant inflation and pressures or balloon location may be adjusted from the population norms thus customizing this implant to the clinical case under consideration. Fixation devices may be appropriately applied at various knee range of motion intervals from full extension (zero degrees) to full flexion (usually 135 degrees) as the knee is adjusted and the implant secured under anesthesia.

FIG. **10**A depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4** *b*, **4** *d* extending from an inflated balloon **6** and showing the inflation medium **46** moved anteriorly toward the patella **40** when the knee joint is slightly flexed. The dynamic nature of the implant material and/or content may be responsive to body forces as a physiological rather than rigid structure. The filling of space inside the joint may add stability to the patient and to the joint. Likewise, FIG. **10**B depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4** *b*, **4** *d* extending from an inflated balloon **6** and having couplers **44** *a*, **44** *b* (which may be, for non-limiting example, staples or screws, pins or snaps) coupling the appendages **4** *b*, **4** *d* to the femur **24** and showing the inflation medium **46** moved anteriorly toward the patella **40** when the knee joint is slightly flexed.

For example, FIG. **14** depicts an embodiment of the knee implant **20** having appendages **4** *a*, **4** *b*, **4** *c*, **4** *d*, including holes **8** *a*, **8** *b*, **8** *c*, **8** *d* and tabs **10** *a*, **10** *b* and including slots **26** *a*, **26** *b* to accommodate ligaments of the knee joint as well as side views of the same knee implant. Couplers as described elsewhere herein may be used to couple the implant **20** to the distal femur. In some embodiments, there may only tabs, only holes, or only appendages, or combinations thereof. In some embodiments, there may be other

ways to couple the implant to the distal femur, as described elsewhere herein (sutures, drawstrings, skirts, glue, etc). In some embodiments, the couplers create the holes **8** *a*, **8** *b*, **8** *c*, **8** *d*, or other holes (not shown) when the implant is placed against the distal femur. In some embodiments, the holes are pre-formed in the appendage prior to implantation. In some embodiments, the holes are reinforced as described elsewhere herein. As shown here, the appendages in some embodiments are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage **4** *d* that is intended to wrap over the medial condyle may be longer and/or wider than the appendage **4** *c* intended to wrap over the lateral condyle. Shown in the embodiment depicted in FIG. **14** are the different hole placements from the side view, showing the differences in positioning of the holes to accommodate the differences in anatomic structure and size of the condyles. Likewise, the slots may be different in shape and/or size and/or position to accommodate the ligaments and/or tendons of the joint or other structures and functions of the joints of the knee, and to allow for placement of the implant with minimal disturbance (cutting, manipulation, for example) of the joint components such as tendons, ligaments, and other soft or hard tissues. For example, slot **26** *a* is shaped and positioned to accommodate the cruciate ligaments of the knee, at least. Additionally, as shown in the side views of the embodiment shown in FIG. **14**, the implant has a first wall **28** adapted to be adjacent the femur that is of approximately the same thickness than the second wall **30**. In some embodiments, the first wall **28** is configured to have therapeutic benefits (pharmacologic, healing, and/or in-growth properties) as described elsewhere herein. The second wall **30** may additionally and/or alternatively be configured to have a therapeutic effect (pharmacologic, healing, and/or in-growth properties). Additionally, the thickness of the implant in certain locations is variable to add cushioning to the implant as well as to provide joint spacing. In certain embodiments, the material is not variable in thickness, but provides the same cushioning and/or joint spacing for the bones of the joint. The central region in the embodiment of FIG. **14** is thicker material to add at least one of: cushioning, buffering, joint space, restore cushioning, and to respond to clinical need.

Any of the balloons described herein with regard to any of the figures may add cushioning, padding, strength, durability, flexibility, or any other aspect noted herein, and need not be a chamber per se, nor be inflatable per se. Rather they are merely distinguishable in certain embodiments from the walls which are on either side of them in composition or function or both. In some embodiments, the balloon and its interior is not materially different in composition or function from one of the walls. In some embodiments, they are not materially different in composition or function from either of the walls.

FIGS. **15**A, **15**B, and **15**C show several views of an embodiment of an implant which has no definable chamber, rather the material of the implant itself provides the cushion to the bones of the joint (at least). The implant in **15**A, **15**B, and **15**C is generally H or V-shaped, having a slot **26** *b* that is significantly smaller than as shown other embodiments (for example FIGS. **3**, **4**, **5**, **6**A, **6**B, **7**, **14**). In certain embodiments, an implant shaped generally like FIGS. **15**A, **15**B, and **15** *c* may comprise a chamber which, if the implant were shown in cross section, may comprise a different material than the wall of the implant itself, or may be the same material but with different geometric or chemical or physical properties, as noted herein. FIGS. **15**A, **15**B, and **15**C depict an embodiment of the knee implant **20** having appendages **4** *a*, **4** *b*, **4** *c*, **4** *d* and tabs **10** *a*, **10** *b*, **10** *c*, **10** *d*, **10** *e*, **10** *f*, **10** *g*, **10** *h* and including slots **26** *a*, **26** *b* to accommodate ligaments of the knee joint. Couplers as described elsewhere herein may be used to couple the implant **20** to the distal femur. In some embodiments, there may only tabs, only holes, or only appendages, or combinations thereof. In some embodiments, there may be other ways to couple the implant to the distal femur, as described elsewhere herein (sutures, drawstrings, skirts, glue, etc). In some embodiments, the couplers create holes (not shown) when the implant is placed against the distal femur. In some embodiments, the holes are pre-formed in the appendage prior to implantation. In some embodiments, the holes are reinforced as described elsewhere herein. As shown here, the appendages in some embodiments are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage **4** *d* that is intended to wrap over the medial condyle may be longer and/or wider than the appendage **4** *c* intended to wrap over the lateral condyle. The slots may be different in shape and/or size and/or position to accommodate the ligaments and/or tendons of the joint or other structures and functions of the joints of the knee, and to allow for placement of the implant with minimal disturbance (cutting, manipulation, for example) of the joint components such as tendons, ligaments, and other soft or hard tissues. For example, slot **26** *a* is shaped and positioned to accommodate the cruciate ligaments of the knee, at least. The thickness of the implant in certain locations is variable to add cushioning to the implant as well as to provide joint spacing. In certain embodiments, the material is not variable in thickness, but provides the same cushioning and/or joint spacing for the bones of the joint.

FIG. **16** depicts a knee implant embodiment that is generally H or V-shaped, having a slot **26** *b* that is significantly smaller than other embodiments, and in this embodiment is effectively replaced with a tab **10** *i* at the same location (e.g. **10** *i*). FIG. **16** depicts an embodiment of the knee implant **20** having appendages **4** *a*, **4** *b*, **4** *c*, **4** *d* and tabs **10** *a*, **10** *b*, **10** *c*, **10** *d*, **10** *e*, **10** *f*, **10** *g*, **10** *h*, **10** *i* and including a slots **26** *a* to accommodate ligament(s) of the knee joint. Couplers as described elsewhere herein may be used to couple the implant **20** to the distal femur. Contour lines **54** *a*, **54** *b*, for example, are also depicted in FIG. **16**, however these are not necessarily significant other than to show contour of parts of the implant **20**, although they may be in the case where a mesh is provided in the implant. In some embodiments, there may only tabs, only holes, or only appendages, or combinations thereof. In some embodiments, there may be other ways to couple the implant to the distal femur, as described elsewhere herein (sutures, drawstrings, skirts, glue, etc). In some embodiments, the couplers create holes (not shown) when the implant is placed against the distal femur. In some embodiments, the holes are pre-formed in the appendage prior to implantation. In some embodiments, the holes are reinforced as described elsewhere herein. As shown here, the appendages in some embodiments are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage **4** *d* that is intended to wrap over the medial condyle may be longer and/or wider than the appendage **4** *c* intended to wrap over the lateral condyle. The slot **26** *a* may be different in shape and/or size and/or position to

accommodate the ligaments and/or tendons of the joint or other structures and functions of the joints of the knee, and to allow for placement of the implant with minimal disturbance (cutting, manipulation, for example) of the joint components such as tendons, ligaments, and other soft or hard tissues. For example, slot **26** *a* is shaped and positioned to accommodate the cruciate ligaments of the knee, at least. The thickness of the implant in certain locations is variable to add cushioning to the implant as well as to provide joint spacing. In certain embodiments, the material is not variable in thickness, but provides the same cushioning and/or joint spacing for the bones of the joint. In certain embodiments, an implant shaped generally like FIG. **16** may or may not comprise a chamber which, if the implant were shown in cross section, may comprise a several materials which may be the same as or different from any wall of the implant itself, or may be the same material but with different geometric or chemical or physical properties, as noted herein.

FIG. **17** depicts a knee implant embodiment similar to FIG. **16** which shows a posterior view including the location(s) **50** *a*-**50** *d* where a fill material such as cement may be placed. The fill material may be added in any one location **50** *a*, **50** *b*, **50** *c*, or **50** *d*, or added in several of locations **50** *a*, **50** *b*, **50** *c*, and **50** *d* or likewise be added anywhere on the first or second wall of the implant which contacts the first, second, and/or third bone. The fill material may be used to both cushion (as do balloons **6** in other figures) and/or secure the device to the bone in the case of a bone cement or a combination of these functions. In the case where the cement is used as the fill material, the cement may be used in an element that may or may not have any, some, or all of tabs **10** *a*-**10** *i*. The cushion, thus can act as a coupler (fixation element) and/or as a cushion and/or spacer for the joint bones. The cushion (whether a fill material such as cement or another material) may also be placed adjacent to a first wall or second wall, and not necessarily between said first wall and second wall.

FIG. **18** is an anterior-posterior view of an embodiment of the implant **20** attached to a knee model. The implant here comprises chambers **52** *a*, **52** *b*, **53** *c*, at least (in this case, nano-inflated air pockets). Although sparsely shown in this embodiment, the frequency, size, etc. could be adapted to smaller chambers, larger chambers, more frequent chambers, more concentrated in particular areas of the implant, less concentrated in particular areas of the implant, or similarly adjusted. The chambers can be diffuse, of any size, containing compressible gas (air), cells, pharmacologics, liquids, beads, metals, or other materials as noted herein.

FIG. **19** depicts an implant **20** which is more squarely cut for interface with a femur, for example, which has been cut square such as is done in certain total knee arthroplasty procedures. The implant in this situation may comprise a polymer alone (of soft or hard durometer) and/or metal. The walls may be contiguous or include a chamber that is optionally filled or Tillable as noted herein. Although tabs are shown in FIG. **19**, these are optional in embodiments where another attachment element (fixation element) is used such as cement or a metal pin or screw or snap through an appendage of the device.

FIGS. **20**A and **20**B depict a knee implant embodiment that is generally V-shaped or Y-shaped, and in this embodiment the slot **26** *b* of other embodiments, or the tab **10** *i* of other embodiments is effectively replaced with an appendage **4** *e* at the same location. FIG. **20**A depicts an embodiment of the knee implant **20** having appendages **4** *c*, **4** *d*, and **4** *e* and holes **8** *a* (not shown, in FIG. **20**B), **8** *b* (not shown, in FIG. **20**B), **8** *c* (not shown, in FIG. **20**B), **8** *d*, **8** *e*, **8** *f*, **8** *g*, **8** *h*, **8** *i*, (not shown, substantially similarly positioned as **8** *e* on the same edge as **8** *a*-**8** *c* of FIG. **20**A), **8** *j* (not shown, substantially similarly positioned as **8** *d* on the same edge as **8** *a*-**8** *c* of FIG. **20**A), and including a slot **26** *a* to accommodate ligament(s) of the knee joint. Couplers as described elsewhere herein may be used to couple the implant **20** to the distal femur through slots **8** *a*-**8** *j*. Contour lines are also depicted in FIGS. **20**A and **20**B, however these are not necessarily significant other than to show contour of parts of the implant **20**, although they may be in the case where a mesh is provided in the implant. In some embodiments, there may only tabs, only holes, or only appendages, or combinations thereof. In some embodiments, there may be other ways to couple the implant to the distal femur, as described elsewhere herein (sutures, drawstrings, skirts, glue, etc). In some embodiments, the tabs comprise holes. In some embodiments, the couplers create holes (not shown) when the implant is placed against the distal femur. In some embodiments, the holes are within the peripheral rim of the knee implant. In some embodiments, the holes are within the region of the intercondylar notch medially and/or laterally. In some embodiments, the holes are through the polymer. In some embodiments, the holes are through a reinforced rim. In some embodiments, the holes are pre-formed in the appendage prior to implantation. In some embodiments, the holes are reinforced as described elsewhere herein. As shown here, the appendages in some embodiments are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage **4** *d* that is intended to wrap over the medial condyle may be longer and/or wider than the appendage **4** *c* intended to wrap over the lateral condyle. The slot **26** *a* may be different in shape and/or size and/or position to accommodate the ligaments and/or tendons of the joint or other structures and functions of the joints of the knee, and to allow for placement of the implant with minimal disturbance (cutting, manipulation, for example) of the joint components such as tendons, ligaments, and other soft or hard tissues. For example, slot **26** *a* is shaped and positioned to accommodate the cruciate ligaments of the knee, at least. The thickness of the implant in certain locations is variable to add cushioning to the implant as well as to provide joint spacing. In certain embodiments, the material is not variable in thickness, but provides the same cushioning and/or joint spacing for the bones of the joint. In certain embodiments, an implant shaped generally like FIG. **20**A or **20**B may or may not comprise a chamber which, if the implant were shown in cross section, may comprise a several materials which may be the same as or different from any wall of the implant itself, or may be the same material but with different geometric or chemical or physical properties, as noted herein. As shown in FIGS. **20**A and **20**B, thickness of between the first wall (part configured to touch the femur condyle) and the second wall (part configured to touch the tibia), is shown for example in the slot **26** *a* (which may be called a notch herein), thus showing a side wall as described elsewhere herein to provide the thickness to the implant at the condyle(s). This thickness may be a result of a thickness of a material of the implant (as in where the implant comprises a compliant polymer), or due to an inflation of a balloon that resides between the first wall and the second wall and the side wall. In some embodiments, the implant comprises a Dyneema® mesh. The implant may comprise Dyneema® fiber. In some instances, the implant comprises Dyneema Purity® fiber. In some embodiments, the implant

comprises a Dyneema Purity® UG fiber. In some embodiments, the implant comprises a Dyneema Purity® VG fiber. The implant may comprise a fiber. The implant may comprise a polyethylene. The implant may comprise a polyethylene fiber.

In all descriptions provided herein of the dual compartment implant, the implant may instead be configured to couple to or emerge from the tibia and/or patella. In all descriptions provided herein of the dual compartment implant, the implant may instead be configured to couple to the tibia. It is the intention and understanding that the implant is suited for this purpose in certain embodiments with adjustments to account for dimensional differences of the tibia. Most descriptions provided herein are directed to embodiments coupling the implant to the femur, however, this is primarily for ease of description and continuity, and does not preclude embodiments wherein the implant is coupled to the tibia. Likewise, as noted elsewhere herein, there are embodiments where the implant may be coupled to two bones (at least), for example to both a tibia and a femur.

Patch

Some embodiments of the implant are configured to repair isolated lesions wherein osteochondral defects as in osteonecrosis create craters in the cartilage that need 'filling in' with a patch. Various size lesions of cartilage defects can be accommodated by the implants provided herein which may have balloons of at least one of: at most about 0.5 cm in diameter, at most about 0.75 cm in diameter, at most about 1 cm in diameter, at most about 1.25 cm in diameter, at most about 1.5 cm in diameter, at most about 1.75 cm in diameter, at most about 2 cm in diameter, at most about 2.25 cm in diameter, at most about 2.5 cm in diameter, at most about 2.75 cm in diameter, at most about 3 cm in diameter, at most about 3.25 cm in diameter, at most about 3.5 cm in diameter, at most about 3.75 cm in diameter, at most about 0.5 cm in length along the longest length of the balloon, at most about 0.75 cm in length along the longest length of the balloon, at most about 1 cm in length along the longest length of the balloon, at most about 1.25 cm in length along the longest length of the balloon, at most about 1.5 cm in length along the longest length of the balloon, at most about 1.75 cm in length along the longest length of the balloon, at most about 2 cm in length along the longest length of the balloon, at most about 2.25 cm in length along the longest length of the balloon, at most about 2.5 cm in length along the longest length of the balloon, at most about 2.75 cm in length along the longest length of the balloon, at most about 3 cm in length along the longest length of the balloon, at most about 3.25 cm in length along the longest length of the balloon, at most about 3.5 cm in length along the longest length of the balloon, at most about 3.75 cm in length along the longest length of the balloon, at most about 4 cm in length along the longest length of the balloon, at most about 4.25 cm in length along the longest length of the balloon, at most about 4.5 cm in length along the longest length of the balloon, at most about 4.75 cm in length along the longest length of the balloon, at most about 5 cm in length along the longest length of the balloon, at most about 5.25 cm in length along the longest length of the balloon, at most about 5.5 cm in length along the longest length of the balloon, at most about 5.75 cm in length along the longest length of the balloon, at most about 6 cm in length along the longest length of the balloon, 6.25 cm in length along the longest length of the balloon, at most about 6.5 cm in length along the longest length of the balloon, at most about 6.75 cm in length along the longest length of the balloon, at most about 7 cm in length along the longest length of the balloon, at most about 7.25 cm in length along the longest length of the balloon, at most about 7.5 cm in length along the longest length of the balloon, at most about 7.75 cm in length along the longest length of the balloon, and at most about 8 cm in length along the longest length of the balloon. As used herein with respect to balloon dimensions whether length or diameter, the term "about" means variations of at least one of 0.1 cm, 0.2 cm, 0.25 cm, 0.5 cm, and 1 cm.

Thus, provided herein is an implant configured to patch osteochondral defects. The defects may occur due to injury, stress, naturally occurring, and/or may created or enhanced by a medical professional during a medical procedure. In some embodiments, the implant may be called a patch having the balloon and an attachment element (or elements—which may be called appendages) described herein and may be sized to fit within a defect in a manhole-cover type manner. In some embodiments, the implant may comprise balloon and attachment elements described elsewhere herein and may be configured to lay over a defect (full defect or partial defect). In some embodiments the implant as described herein as used to patch or repair osteochondral defects may be called a patch or a patch implant.

In some embodiments, the size of the balloon dimensions are prechosen based on the individual patient need, and the balloon size (dimensions, geometry, length, depth, for non-limiting examples) is pre-set. In some embodiments, the balloon comprises multiple chambers which may be inflated (or deflated) selectively to fill the defect in situ or just prior to implantation in order to adjust the implant's balloon size (dimensions, length, width, depth, geometry, for non-limiting example) as needed at the time of implantation. The balloon (or any chamber thereof) of some embodiments can be secondarily inflated or deflated (or both) in situ.

FIGS. **11**A, **11**B, and/or **11**C may be used to describe a patch implant described herein, having appendages **4** *a*, **4** *c*, extending from a balloon **6** (not shown in FIG. **11**A) and including holes **8** *a*-**8** *h*, and/or tabs **10** *a*-**10** *f* which may be used with couplers (not shown) to couple the implant to a bone of the knee joint (which may be the femur, the tibia, or the patella). Features shown in FIGS. **11**A, **11**B, and/or **11**C are common to both the unicompartment knee implant (discussed elsewhere herein) and the patch implant, although dimensions may differ as described herein. Thus, FIGS. **11**A, **11**B, and/or **11**C may be used to describe the unicompartment knee implant and/or the patch implant. FIG. **11**A depicts an embodiment of the patch implant **2** curved to simulate curvature about one condyle of a femur, the implant **2** having appendages **4** *a*, **4** *c*, extending from an uninflated balloon (not shown) and including tabs **10** *a*-**10** *f* and/or holes **8** *a*-**8** *h*, which may be used with couplers (not shown, described elsewhere herein) to couple the implant **2** to the femur of the knee joint. FIG. **11**B depicts an embodiment of

the patch implant **2** curved to simulate curvature about one condyle of a femur, the implant **2** having appendages **4** *a*, **4** *c*, extending from an inflated balloon **6** and including tabs **10** *a*-**10** *f* and/or holes **8** *a*-**8** *h*, which may be used with couplers (not shown, described elsewhere herein) to couple the implant **2** to the femur of the knee joint. FIGS. **11**A and **11**B show the appearance of a compliant solid material for unicompartmental implantation. FIG. **11**C depicts a bottom-up of gliding surface view of an embodiment of the patch implant **2** curved to simulate curvature about one condyle of a femur, the implant **2** having appendages **4** *a*, **4** *c*, extending from an inflated balloon **6** or a padded central area of the implant and including tabs **10** *a*-**10** *f* and/or holes **8** *a*-**8** *h*, which may be used with couplers (not shown, described elsewhere herein) to couple the implant **2** to the femur of the knee joint. In some embodiments, the implant is configured to couple to a tibia. In some embodiments, the implant is configured to couple to a trochlear groove of a femur. In some embodiments, the implant is configured to couple to only a portion of a condyle of a femur.

FIGS. **12**A, **12**B, and/or **12**C may be used to describe a patch implant described herein, having appendages **4** *a*, **4** *c*, extending from a balloon **6** and including holes **8** *a*, **8** *b*, **8** *c* prefabricated into an uninflated area, and/or tabs **10** *a*, **10** *b*, **10** *c*, **10** *d*, **10** *e*, **10** *f* which may be used with couplers (not shown) to couple the implant to a bone of the knee joint (which may be the femur, the tibia, or the patella). Features shown in FIGS. **12**A, **12**B, and/or **12**C are common to both the unicompartment knee implant (discussed elsewhere herein) and the patch implant, although dimensions may differ as described herein. Thus, FIGS. **12**A, **12**B, and/or **12**C may be used to describe the unicompartment knee implant and/or the patch implant. FIG. **12**A depicts a bottom-up view of an embodiment of the implant **2** (unicompartment or patch), the implant having appendages **4** *a*, **4** *c*, extending from a balloon **6** and including holes **8** *a*, **8** *b*, **8** *c*, which may be used with couplers (not shown) to couple the implant **2** to the femur of the knee joint. FIG. **12**B depicts a bottom-up view of an embodiment of the implant **2** (unicompartment or patch), the implant having appendages **4** *a*, **4** *c*, extending from a balloon **6** and including tabs **10** *a*, **10** *b* and hole **8** *a* which may be used with couplers (not shown) to couple the implant to the femur of the knee joint. FIG. **12**C depicts a bottom-up view of an embodiment of the implant **2** (unicompartment or patch), the implant having appendages **4** *a*, **4** *c*, extending from a balloon **6** or padded weight bearing region of the implant and including tabs **10** *c*, **10** *d*, **10** *e*, and **10** *f* and hole **8** *a* which may be used with couplers (not shown) to couple the implant to the femur of the knee joint. In some embodiments, the implant is configured to couple to a tibia. In some embodiments, the implant is configured to couple to a trochlear groove of a femur. In some embodiments, the implant is configured to couple to only a portion of a condyle of a femur. In some embodiments the implant is coupled to the patella. In any embodiment the balloon **6** may extend from one surface of the implant as a focal protuberance to fill a defect, space, or to aide in alignment correct, or the balloon may be full thickness as differences in FIGS. **2** and **3** show respectively. In any embodiment there may be a singular or multiple major balloons, if off a primary surface resembling bubble wrap, and there may be microscopic balloons or vacuoles containing gas, gel, or solid in the material matrix.

In all descriptions provided herein of the patch implant, the implant may instead be configured to couple to the tibia or to the fibula or the patella. It is the intention and understanding that the implant is suited for this purpose in certain embodiments with adjustments to account for dimensional differences of these bones. Most descriptions provided herein are directed to embodiments coupling the implant to the femur, however, this is primarily for ease of description and continuity, and does not preclude embodiments wherein the implant is coupled to the tibia (or other bones). Likewise, as noted elsewhere herein, there are embodiments where the implant may be coupled to two bones (at least), for example to both a tibia and a femur.

Partial Knee Arthroplasty (Unicompartment)

In addition to the total knee-type (dual condyle) and patch implants are implants that serve to cover and adjust alignment for either the medial or lateral condyle of the femur with varus or valgus knees requiring added cushioning to recreate the natural six degrees of knee valgus.

Thus, provided herein is an implant for placement on at least one condyle of the distal femur (a unicompartment implant—named so due to their coverage of a single condyle of the femur). The implant may be configured to be placed over the lateral condyle. The implant may be configured to be placed over the medial condyle. The implant may be configured to be placed over either the medial condyle or the lateral condyle. Two unicompartment implants may be placed in the same knee, one over the medial condyle, one over the lateral condyle.

FIGS. **11**A-**12** C depict example embodiments of unicompartment implants. In some embodiments, the unicompartment implant comprises a balloon that is at least one of: at most about 1.5 cm in diameter, at most about 1.75 cm in diameter, at most about 2 cm in diameter, at most about 2.25 cm in diameter, at most about 2.5 cm in diameter, at most about 2.75 cm in diameter, at most about 3 cm in diameter, at most about 3.25 cm in diameter, at most about 3.5 cm in diameter, at most about 3.75 cm in diameter, at most about 4 cm in diameter, at most about 4.25 cm in diameter, at most about 4.5 cm in diameter, at most about 4.75 cm in diameter, at most about 5 cm in diameter, at most about 5.25 cm in diameter, at most about 5.5 cm in diameter, at most about 5.75 cm in diameter, at most about 6 cm in diameter, at most about 6.25 cm in diameter, at most about 6.5 cm in diameter, at most about 6.75 cm in diameter, at most about 7 cm in diameter, at most about 7.25 cm in diameter, at most about 7.5 cm in diameter, at most about 7.75 cm in diameter, at most about 8 cm in diameter, at most about 3 cm in length along the longest length of the balloon, at most about 3.25 cm in length along the longest length of the balloon, at most about 3.5 cm in length along the longest length of the balloon, at most about 3.75 cm in length along the longest length of the balloon, at most about 4 cm in length along the longest length of the balloon, at most about 4.25 cm in length along the longest length of the balloon, at most about 4.5 cm in length along the longest length of the balloon, at most about 4.75 cm in length along the longest length of the balloon, at most about 5 cm in length along the longest length of the balloon, at most about 5.25 cm in length along the longest length of the balloon, at most about 5.5 cm in length along the longest length of the balloon, at most about 5.75 cm in length along the longest length of the balloon, at most about 6 cm in length along the longest length of the balloon, 6.25 cm in length along the longest length of the balloon, at most about 6.5 cm in length along the longest length of the balloon, at most about 6.75 cm in length along the longest length of the balloon, at most about 7 cm in length along the longest length of the balloon, at most about 7.25 cm in length along the longest length of the balloon, at most about 7.5 cm in length along the longest length of the balloon, at most about 7.75 cm in length along the longest

length of the balloon, and at most about 8 cm in length along the longest length of the balloon. As used herein with respect to balloon dimensions whether length or diameter, the term "about" means variations of at least one of 0.1 cm, 0.2 cm, 0.25 cm, 0.5 cm, and 1 cm.

In some embodiments, the implant comprises attachment tabs or attachment elements over the anterior and/or posterior and/or medial side, and/or lateral side (and/or some combination thereof) of a condyle. In some embodiments, the implant comprises attachment tabs or attachment elements in the intercondylar notch. In some embodiments, the implant comprises attachment tabs or attachment elements superiorly at the distal end of the femur anteriorly.

The posterior of the knee can be difficult to access without disturbing joint components (or in order to minimize such disturbance) such as tendons, ligaments, etc. Thus, in some embodiments, the implant comprises strings, reigns, lassos, and/or lanyards that may pass from the posterior of the implant via the intercondylar notch anteriorly to join with themselves and/or other coupling devices. In some embodiments, posterior reigns or suture-like lanyards cinch up the implant from inside the posterior intercondylar notch toward another connection site around the femur. These couplers may be pre-coupled to the implant, and the implant and its couplers may be configured to be pulled (or cinched) from the anterior of the implant once the implant is in its general location relative to the condyle in order to finally position the implant about the condyle—in particular in order to cinch the implant about the posterior of the condyle. Likewise, in some embodiments where the implant is pre-molded, the coupler as described are adapted to move the implant to its final position with conformity to the condyle's posterior with minimal disturbance to the joint structures at the joint's posterior (minimal cutting, minimal moving, and or minimal detachment, for non-limiting example). In some embodiments at least a portion of the ligamentary structure of the knee is spared.

FIG. **10**A depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4** *b*, **4** *d* extending from an inflated balloon **6** and showing the inflation medium **46** moved anteriorly toward the patella **40** when the knee joint is slightly flexed. Likewise, FIG. **10**B depicts a side view of an embodiment of the knee implant **20** curved about at least one condyle **22** of a femur **24**, the implant **20** having appendages **4** *b*, **4** *d* extending from an inflated balloon **6** and having couplers **44** *a*, **44** *b* (which may be, for non-limiting example, staples or screws, pins or snaps) coupling the appendages **4** *b*, **4** *d* to the femur **24** and showing the inflation medium **46** moved anteriorly toward the patella **40** when the knee joint is slightly flexed.

FIGS. **11**A, **11**B, and/or **11**C may be used to describe a unicompartment implant **2** (or unicompartment knee implant, terms which may be used interchangeably) described herein, having appendages **4** *a*, **4** *c*, extending from a balloon **6** (not shown in FIG. **11**A) and including holes **8** *a*-**8** *h*, and/or tabs **10** *a*-**10** *f* which may be used with couplers (not shown) to couple the implant to a bone of the knee joint (which may be the femur, the tibia, or the patella). Features shown in FIGS. **11**A, **11**B, and/or **11**C are common to both the unicompartment knee implant and the patch implant (discussed elsewhere herein), although dimensions may differ as described herein. Thus, FIGS. **11**A, **11**B, and/or **11**C may be used to describe the unicompartment knee implant and/or the patch implant. FIG. **11**A depicts an embodiment of the unicompartment knee implant **2** curved to simulate curvature about one condyle of a femur, the implant **2** having appendages **4** *a*, **4** *c*, extending from an uninflated balloon (not shown) and including tabs **10** *a*-**10** *f* and/or holes **8** *a*-**8** *h*, which may be used with couplers (not shown, described elsewhere herein) to couple the implant **2** to the femur of the knee joint. FIG. **11**B depicts an embodiment of the unicompartment knee implant **2** curved to simulate curvature about one condyle of a femur, the implant having appendages **4** *a*, **4** *c*, extending from an inflated balloon **6** and including tabs **10** *a*-**10** *f* and/or holes **8** *a*-**8** *h*, which may be used with couplers (not shown, described elsewhere herein) to couple the implant **2** to the femur of the knee joint. FIG. **11**C depicts a bottom-up view of an embodiment of the unicompartment knee implant **2** curved to simulate curvature about one condyle of a femur, the implant **2** having appendages **4** *a*, **4** *c*, extending from an inflated balloon **6** and including tabs **10** *a*-**10** *f* and/or holes **8** *a*-**8** *h*, which may be used with couplers (not shown, described elsewhere herein) to couple the implant **2** to the femur of the knee joint.

In some embodiments, the unicompartment implant including attachment tabs is at least one of: at most about 15 cm in length along the longest length of the implant, at most about 15.25 cm in length along the longest length of the implant, at most about 15.5 cm in length along the longest length of the implant, at most about 15.75 cm in length along the longest length of the implant, at most about 16 cm in length along the longest length of the implant, at most about 16.25 cm in length along the longest length of the implant, at most about 16.5 cm in length along the longest length of the implant, at most about 16.75 cm in length along the longest length of the implant, at most about 17 cm in length along the longest length of the implant, at most about 17.25 cm in length along the longest length of the implant, at most about 17.5 cm in length along the longest length of the implant, at most about 17.75 cm in length along the longest length of the implant, at most about 18 cm in length along the longest length of the implant, 18.25 cm in length along the longest length of the implant, at most about 18.5 cm in length along the longest length of the implant, at most about 18.75 cm in length along the longest length of the implant, at most about 19 cm in length along the longest length of the implant, at most about 19.25 cm in length along the longest length of the implant, at most about 19.5 cm in length along the longest length of the implant, at most about 19.75 cm in length along the longest length of the implant, at most about 20 cm in length along the longest length of the implant, at most about 20.25 cm in length along the longest length of the implant, at most about 20.5 cm in length along the longest length of the implant, at most about 20.75 cm in length along the longest length of the implant, at most about 21 cm in length along the longest length of the implant, at most about 21.25 cm in length along the longest length of the implant, at most about 21.5 cm in length along the longest length of the implant, at most about 21.75 cm in length along the longest length of the implant, at most about 22 cm in length along the longest length of the implant, at most about 22.25 cm in length along the longest length of the implant, at most about 22.5 cm in length along the longest length of the implant, at most about 22.75 cm in length along the longest length of the implant, at most about 23 cm in length along the longest length of the implant, 23.25 cm in length along the longest length of the implant, at most about 23.5 cm in length along the longest length of the implant, at most about 23.75 cm in length along the longest length of the implant, at most about 24 cm in length along the longest length of the implant, at most about 24.25 cm in length along the longest length of the implant, at most about 24.5 cm in length along

the longest length of the implant, at most about 24.75 cm in length along the longest length of the implant, at most about 25 cm in length along the longest length of the implant, at most about 25.25 cm in length along the longest length of the implant, at most about 25.5 cm in length along the longest length of the implant, at most about 25.75 cm in length along the longest length of the implant, and at most about 26 cm in length along the longest length of the implant. As used herein with respect to implant length dimensions, the term "about" means variations of at least one of 0.1 cm, 0.2 cm, 0.25 cm, 0.5 cm, and 1 cm.

In some embodiments, the unicompartment implant is longer than it is wide, and the longer portion of the implant wraps from the anterior of the condyle to the posterior of the condyle. In some embodiments, the length of the implant is longer on the outer edge of the implant than on the inner edge nearest the trochlear groove (whether used on the lateral or medial condyle). In some embodiments, the trochlear groove per se rather than either the medial or lateral compartment is reconstructed with the implant anatomically to oppose the undersurface of the patella.

FIGS. **12**A, **12**B, and/or **12**C may be used to describe a unicompartment knee implant (unicompartment implant) described herein, having appendages **4** *a*, **4** *c*, extending from a balloon **6** and including holes **8** *a*, **8** *b*, **8** *c*, and/or tabs **10** *a*, **10** *b*, **10** *c*, **10** *d*, **10** *e*, **10** *f* which may be used with couplers (not shown) to couple the implant to a bone of the knee joint (which may be the femur, the tibia, or the patella). Features shown in FIGS. **12**A, **12**B, and/or **12**C are common to both the unicompartment knee implant and the patch implant (discussed elsewhere herein), although dimensions may differ as described herein. Thus, FIGS. **12**A, **12**B, and/or **12**C may be used to describe the unicompartment knee implant and/or the patch implant. FIG. **12**A depicts a bottom-up view of an embodiment of the implant **2** (unicompartment or patch), the implant having appendages **4** *a*, **4** *c*, extending from a balloon **6** and including holes **8** *a*, **8** *b*, **8** *c*, which may be used with couplers (not shown) to couple the implant **2** to the femur of the knee joint. FIG. **12**B depicts a bottom-up view of an embodiment of the implant **2** (unicompartment or patch), the implant having appendages **4** *a*, **4** *c*, extending from a balloon **6** and including tabs **10** *a*, **10** *b* and hole **8** *a* which may be used with couplers (not shown) to couple the implant to the femur of the knee joint. FIG. **12**C depicts a bottom-up view of an embodiment of the implant **2** (unicompartment or patch), the implant having appendages **4** *a*, **4** *c*, extending from a balloon **6** and including tabs **10** *c*, **10** *d*, **10** *e*, and **10** *f* and hole **8** *a* which may be used with couplers (not shown) to couple the implant to the femur of the knee joint.

In all descriptions provided herein of the unicompartment implant, the implant may instead be configured to couple to the tibia or to the fibula or the patella. It is the intention and understanding that the implant is suited for this purpose in certain embodiments with adjustments to account for dimensional differences of the particular bones. Most descriptions provided herein are directed to embodiments coupling the implant to the femur, however, this is primarily for ease of description and continuity, and does not preclude embodiments wherein the implant is coupled to the tibia (or other bones). Likewise, as noted elsewhere herein, there are embodiments where the implant may be coupled to two bones (at least), for example to both a tibia and a femur.

Meniscal Replacement or Repair, and Solid, Rigid, or Semi-Rigid Components:

Provided herein is an implant having a balloon having a first and second chamber. The implant may be any of the Dual Compartment, Unicompartment, and Patch implants described herein. The second chamber may be configured to replace and/or partially replace fibrocartilage meniscal loss. The implant may have two lobes of chambers which may be alternatively described as two superimposed balloon radii in apposition to each other. The implant may be configured to provide stability between the femur and tibia by providing a meniscus wedge. In some embodiments the implant comprises a portion configured to replace and/or partially replace fibrocartilage meniscal loss. Such an embodiment may not require a second chamber.

In some embodiments a chamber of the implant is configured to receive a solid piece configured to restore joint and/or bone alignment. In some embodiments, the chamber is configured to receive a plurality of solid pieces, each of which can be used to increase the space between a first bone and a second bone in order to restore and/or improve joint and/or bone alignment. The solid pieces may be wedge-shaped, or be provided in various sizes and/or shapes. The solid pieces may individually or together be used in a chamber or multiple chambers of the implant. The solid piece (or pieces) may be used to ratchet adjacent bones to a desired distraction and/or alignment to restore and/or improve joint and/or bone alignment. The solid piece may be put in a chamber of the implant, which may enclose or partially enclose the piece to hold the piece in place. In some embodiments, a block of biocompatible material (such as PMMA or another bone-like substitute) may be provided and may be formed (by carving or other forming method) by the surgeon to a desired shape. The formed piece may then be put in a chamber of the implant, which may enclose or partially enclose the piece to hold the piece in place.

In some embodiments, the inflation medium is a methyl methacrylate or other biocompatible hardening substance which can flow when initially put into the chamber, and hardens to become a rigid piece (or solid piece). The methyl methacrylate or other biocompatible hardening substance may conform to the shape of the chamber, or may conform to the shape of a space between bones and/or other joint structures. The methyl methacrylate or other biocompatible hardening substance may conform to a form chosen by the surgeon using tools and/or pressure to influence the final shape of the rigid piece formed by the methyl methacrylate or other biocompatible hardening substance upon hardening.

The solid piece (whether formed in situ or by a surgeon or pre-formed) may be cushioned by the implant. The implant may comprise an inflatable chamber between the solid piece and the first bone. In some embodiments, the first bone is a femur. The implant may comprise an inflatable chamber between the solid piece and the tibia. The implant may comprise an inflatable chamber between the solid piece and the patella. The implant may comprise an inflatable chamber between the solid piece and the second bone. The implant may comprise a pad between the solid piece and the first bone as a cushion. In some embodiments, the first bone is a femur. The implant may comprise a pad between the solid piece and the second bone as a cushion. In some embodiments, the second bone is a tibia. In some embodiments, the second bone is a patella.

The solid piece may provide at least one of about 1 degree of joint correction, about 2 degrees of joint correction, about 3 degrees of joint correction, about 4 degrees of joint correction, about 5 degrees of joint correction, about 6 degrees of joint correction, about 7 degrees of joint correction, about 8 degrees of joint correction, about 9 degrees of joint correction, and about 10 degrees of joint correction.

With respect to degrees of joint correction, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%.

The implant can be used in a variety of joints where the implant replaces a bone on bone surface and cushions the interaction between the articular ends of any two bones, such as at the femoral tibial and patella femoral knee interfaces. The implant can be used in a variety of joints where the implant replaces a bone on bone surface and cushions the interaction between the articular ends of any two bones, such as at the femoral-acetabular interspace of a patient's hip, the humerus and glenoid scapular component in the shoulder, the replacement of talus bone in the human ankle between the tibia and calcaneus and the like. Where the implant is substituting or enhancing articular cartilage, the rigidity can be reduced or enhanced to maximize conformation changes that arise during motion as enabled by the two opposing walls and intended inner space, coupled with considerations in any joint surgical reconstruction with accommodation to or amplification of the existing joint ligaments, tendons or dearth thereof. The implant **10** may be deflated and removed by minimally invasive surgery, for example, after the implant has served its purpose of regenerating tissue or if another clinical condition warrants its removal. However, it may not be clinically necessary to remove the implant even if inflation is lost, since the two remaining functions of patching the injured cartilage, and delivering restorative cells may justify implant retention.

In many embodiments the implant (or a portion thereof, such as the balloon or balloon) is a weight bearing spacer that allows joint motions to approach normal, whether filling the space left by an entirely collapsed peripheral joint bone or the space of ablated cartilage proximate surfaces diffusely as in osteoarthritis or succinctly as in osteonecrotic defects or localized trauma. The walls may be used as a membrane for holding living cells in proximity of the osteochondral defect long enough for the cells to attach (e.g. 24 hours) or to deeply adhere (up to 28 days) or return to normal (up to one year). Weight bearing may be expected to increase as distal lower extremity joints are treated.

Additional Locations for Use

Shoulder subacromical bursa may be a target joint for an implant as described herein. Rotator cuff tears may be addressed using an implant as described herein—as adjusted for the particular features, loading profile, and geometries of the joint. In shoulders, 85% of octagenians have massive rotator cuff tears and often less than half normal upper extremity abduction and flexion capabilities. There may not be sufficient remnant supraspinatus and other rotator cuff tissues to pull together. Then the humeral head rides up, in a cephalad direction, rubbing the superior bone surface on a frequently spurred and downward sloping acromion. If a subacromial implant as described herein were implanted beneath the lateral (arthroscopically decompressed and prepared) acromion, the pain of bone on bone could be reduced, and the structural anatomy between the ball and socket (humeral head and glenoid fossa) could be improved. In essence then a shoulder implant could cover the humeral head analogous to the hip redundant membrane wherein that membrane replaces a normal subacromial bursa. Optionally, a singular bladder beneath the acromion per se could pad the ball beneath it. For virtually every joint in the body (arms and legs, at least) there are similar potential implant uses.

The distal femur of the knee, and the distal humerus of the elbow are regions that interface each with two opposite joints. That is, an implant for the knee as designed with polymer capping of the femoral condyles and trochlear groove to provide cushioning of the femorotibial and patellafemoral joints. Analogously, in the humerus the distal coverage enables padding restoration of the humeral-olecranon as well as the radio-capitellar (part of the humerus) joint interfaces. Whereas generally the implant may cover the main or primary joint surface of the surgeon's choice contributing to arthritis, consequently reducing symptoms when treated, another alternative would be that the implant can cover any singular surface entirely or partially. It is generally desired that the implant may cover one surface allowing remnant cartilages in other usually opposing or opposite surfaces to glide against the implant polymer with smooth gliding joint motion. This principle allows for retained joint linings or synovium to produce lubricating substances including enzymes for facile joint movement. It also avoids the wear debris that would accrue from polymer rubbing on polymer, as recently recognized in metal on metal prostheses. In certain embodiments, the implant can cover more than one surface in a joint, such as the radio-capitallar joint wherein the distal humerus and the radial head receive prosthetic capping or interpositional application of polymers.

The surgical techniques may be individualized to fit patient need. The implants may be combined with or comprise autologous or allograph tissues such as fascia lata. Surgeons may implant fascia lata above unreconstructable rotator cuff with consequent symptom relief. Polymers can interface with any human tissue and/or with metals or polyethylenes or polyurethanes. Living tissues that can be combined with implants provided herein for repair or reconstruction may be from the same patient (autograph), and cadaver or other member of the same species (allograph) or from another species (xenograph.) Virtually any combination of polymer interpositioning is feasible with the implant concepts provided herein, as anatomy varies among patients in need, and clinical conditions differ with each person. Therefore, although the general or most common construct is expected to cover just one singular and the primary surface of a joint with an implant, any combination of surfaces can be involved allowing versatile custom applications of this implant and method of surgery.

Additionally, whereas implants as noted herein may be available in specified sizes, the material membrane elastic deformation and resilience may allow for calculated malleability toward goodness of fit. In other iterations the fit of implant over the affected joint surface is customized as paring preoperative findings of MRI or CT or PET imaging pathophysiology with intraoperative reconstructive need. Ultimately best fit implants may serve patient restorative requirement with least morbidity.

Locations wherein implants described herein may be additionally or alternatively applicable include all the limb joints of mammals. In the shoulder mainly the glenohumeral joint, though as discussed above the subacromial space are useful loci for renewed padding when pathophysiologies warrant. In the AC or acromioclavicular joint of the shoulder, a Mumford procedure (resection of the distal clavicle) can be avoided by inserted an implant as described herein. Even the TMJ in the jaw may be amenable to therapy using the implants noted herein. Proceeding distally in the aim, the elbow has two relevant joints mentioned earlier, radiocapitellar and ulnohumeral. Depending on 'where the arthritis forms' (as from fracture or disease) the padding should be restored toward normal. Wrist, thumb and finger joints are many and may respond to vesicular implants with better durometry and vicsolubricant delivery than tradition metal or silicon prostheses. Legs started at the hip joint have been shown via Hip implant prototypes to be amenable to poly-

mer capping. Variations per surgeon's choice could evoke special uses as for coverage of trochanteric bursae.

Additionally, the many functions of the implants noted herein may be coupled with cosmetic aspects in order to restore bulk and soft tissue balance after scarring, injury or atrophy, or for purely cosmetic purposes. Treatment for cosmesis especially when coupled with functional or visual injury deficits can provide a reduction in physiological as well as physical pain and discomfort. Therefore the extent minimally invasive implants restore the injured or diseased patient recipient to become hole, they are being used purposefully and as intended.

The knee joint is an initial focus of the figures wherein application to the largest bone (the distal femur) accommodates padding needs for the opposing patella and tibia. The potential use of implants, however, over the contralateral surfaces is an option that should not be ruled out. In the ankle the supratalar, or tibia talar joint will be a useful location as may the subtalar area, depending on pathology present. Indications for use may depend on the patients symptoms, from the history and physical exam, based on studies such as roentgenograms, MRI or CT imaging, and may depend on test result from localized injections. For example, if a talus fracture pain were alleviated by sinus tarsi injection then implant insertion into the subtalar joint would be preferred. The talonavicular and other foot/toe joints are all amenable to renewed padding via an implant noted herein.

Pets, or other animals, such as cows, dogs, and horses, may be served better by polymer joint capping than hip replacement for congenital dysplasia. The successful treatment and rehabilitation of animals can favorably affect the implant recipient and animal's owner, as pets can provide functions necessary for activities of daily living (as a horse helping to plow a field) or an animal relieved of pain from injury or arthritis can also be a comfort to its owner.

Kits

Provided herein are kits comprising multiple implants described herein. A kit may comprise multiple sizes of a single type of implant. A kit may comprise various implant types, such as the patch, the unicompartment, and/or the dual compartment types of implants described herein. A kit may comprise various couplers, which may be selected by the surgeon depending on his comfort and expertise, and/or based on the particular patient anatomy and/or needs. The kit may further comprise any insertion tools and/or surgery tools that may uniquely assist in implanting the implant in the patient.

In addition to kits involving reparative implants, and insertional tools, there may also be included software for translation of pre-injury data and/or postoperative data collection and analysis, as well as custom implants may be provided.

Implantation Methods

Implantation of implants provided herein may depend on the size of joint surface intended for reconstruction by use of the implant. This may be based upon the nature and extent of injury, and upon the expectations of the patient and surgeon. In some embodiments, an arthroscope can be inserted in one side of the knee joint through a 0.5 cm wound, while the implant is inserted into the opposite joint line wound from 1-10 cm in size. The joint may be first inspected and debrided, performing an arthroscopic synovectomy, chondroplasty, and meniscectomy as needed. Additional distraction under general anesthesia with the knee at variable degrees of flex may allow for implant introduction, systematic peripheral attachment, balancing, and inflation, if warranted.

In some embodiments, the implant may be selectively inflatable depending on the particular needs of the patient. In some embodiments, the filler of the interior of the implant may be rigid, semi-rigid, fluid, air, or combinations thereof, as described herein. In some embodiments, the implant may be used in conjunction with fibrocartilage repair or replacement. In some embodiments, the implant may be used without fibrocartilage repair or replacement. In some embodiments, the implant may be used in conjunction with boney osteotomy. In some embodiments, the implant may be used without boney osteotomy.

The posterior of the knee can be difficult to access without disturbing joint components (or in order to minimize such disturbance) such as tendons, ligaments, etc. Thus, in some embodiments, the method comprises providing an implant comprising strings, reigns, lassos, and/or lanyards that may pass from the posterior of the implant via the intercondylar notch anteriorly to join with themselves and/or other coupling devices. In some embodiments, posterior reigns or suture-like lanyards cinch up the implant from inside the posterior intercondylar notch toward another connection site around the femur. In some embodiments, the methods comprise conforming the implant posterior to the condyle by pulling the strings (or reigns, or lassos, or lanyards or the like) of the implant. Such couplers (strings, reigns, lassos, lanyards, etc) may comprise suture materials and/or wire materials.

These couplers (i.e. strings, reigns, lassos, lanyards, etc) may be pre-coupled to the implant, and the implant and its couplers may be configured to be pulled (or cinched) from the anterior of the implant once the implant is in its general location relative to the condyle in order to finally position the implant about the condyle—in particular in order to cinch the implant about the posterior of the condyle. Likewise, in some embodiments where the implant is pre-molded, the coupler as described are adapted to move the implant to its final position with conformity to the condyle's posterior with minimal disturbance to the joint structures at the joint's posterior (minimal cutting, minimal moving, and or minimal detachment, for non-limiting example). In some embodiments at least a portion of the ligamentary structure of the knee is spared.

In some instances, the implant is inserted arthroscopically through a cannula about 10 mm in diameter with the implant in the deflated construct, and once inside the prepared joint space and secured therein by the skirt or tabs, the implant is distended or inflated with gas, gel, fluid or fluid that becomes a resilient solid to fill the original natural space of about 0.5 cm between the bones of the joint (between at least two bones of the joint). If the implant is not inserted through a cannula, it may be inserted through an open incision from one to forty centimeters in length at the surgeon's discretion. Tensioning may be by the surgeon's sense of proper pressure application aided by a gauged syringe for insertion of viscolubricants such as Synvisc, Hyalgan, Supartz and/or analgesics such as lidocaine gel. The insertion of liquids to the joint per se may be directly, through a cannula to the joint space previously in place for debridement, and or via a cannula or tube that is not part of the original implant assembly. Once the joint is cleaned, the implant is inserted and appropriately fixed to avoid extrusion or dislocation thereof. This may be via attachment of the implant tabs and/or by a combination of tab use plus intended friction

created by implant surface coverings (analogous to Velcro) or a draw string at the smaller base of the implant.

In some embodiments the attachment tabs are positioned on the implant to both secure the implant to the joint components, and to enable a physician to ensure the implant has a minimum amount of slack that could create wrinkles or loose areas to avoid unnecessary friction and/or wear of the implant of the patient's anatomy. Figures depicted herein show examples of properly situated attachment tabs configured for these dual purposes. In some embodiments, fewer tabs are needed to achieve these goals.

In some embodiments, where slack or voids exist, the balloon under compression may fill such areas. The implant in some embodiments is configured to allow hyaline and/or cartilage cells to fill any irregularities or craters in the joint components and grow to refurbish natural joint contour. When the implant implantation is combined with, for example, movement of the treated joint in a constant passive motion machine for 12 hrs a day for 6 weeks after surgery implanting the implant, cell growth may create renewed hyaline cartilage, and/or blood/fibrin and scar to create fibrocartilage filler material.

Each attachment tab insert site may be clinically determined centripitally around the implant during surgery, driving slots or holes sequentially with an osteotome or drill immediately followed by insertion of the triangled tab extension into the bone slots or screw respectively. For example, if the implant were viewed like a clockface the first tab could be tacked/tapped in a 2 o'clock, then 7, 10, 4, 11, 5, 12, 6 (wherein #2, 7, 10, 4 are over the bilateral femurs superior/inferior to collateral ligaments, 11, 12 are superior at the distal anterior femur beneath the upper patella, and 5, 6 are inside the intercondylar notch anterior to cruciates). This can be like putting a saddle on a horse, going around the knee end with a grasper, to tug the polymer toward fit, tapping a slot over the side of the femur with a thin one-half inch osteotome, angling cuts distally, one by one, as if to pull the implant (or saddle) into its angle of repose, seating ideally over the condyles and ridings nicely in the trochlear groove.

In some embodiments, the metal clips could be set angled at about 120 degrees, as greater than 90 can favorably distract/hold the implant to tighter fit analogous to a mylar compliant balloon or stretch sock fitting over a protuberance as opposed to a piece of (non-compliant) paper that results is wrinkles and areas of incongruence between the implant and bone end. Reducing dislodgement tendency and snugging the polymer once stretched to best fit may avoid the failure history as illustrated in the Danish Polymer hip cap solid crescent shaped hip resurfacing implants which lacked inflation, surface stability, accommodation, and fixation.

Inflation may also be specified by clinical need, and modifications in the implant multi-cell (multi-compartment) construction allows for selective inflation with substances ranging from gas to solid, including gels or semi-solids that can as part of material layered integrity either provide calculated hardness (durometer) to overcome and resist limb adjacent bone mal-alignment, and/or to deliver new regenerative tissues for restoration of natural anatomy of time. That is, certain sections of the implant may be electively inflated of left without expansion, to adjust to fit as matching a normal or uninjured contralateral limb for the involved patient.

Indeed, patient interaction and feedback may be sought so as to bring to orthopedic conceived art and science the individual's own needs and concerns. It is said that for patients who have anterior cruciate injuries, one third require reconstruction for knee joint stabilizer, one third do not—living with a reduced activity level, and one third deliberate extensively until a choice between the two continuum options is made.

A goal of embodiments of implants described herein is to maintain remnant living tissue by using minimally invasive technologies, smaller incisions when they serve the patient equally to larger, sacrificing the least normal tissue as possible. Implants described herein assist and improve on current treatment options available by avoiding as much as possible the ablative bone and cartilage resecting, ligament removing total knee arthroplasty and instead to restore the padding lost in injury or disease or surgery.

Examples from within the techniques include electing to repair rather than reconstruct anterior cruciate ligaments in certain situations, proved warranted and effective at a $p<0.3$ statistical level. Whereas Carticel chondrocyte implantation is useful to enable articular surface regrowth with hyaline, rather than scar/fibrocartilage from picking/drilling, the massive morbidity from periosteal harvesting is unnecessary. This is because it takes only 24 hours for the cartilage cloned chondrocytes to attach to the prepared joint surface, and the polymer membrane (patch implant described herein, for example, or use of chondrocytes on surfaces of the dual compartment implant or the unicompartment implant) over the prepared defect (like a manhole cover) can adeptly substitute for periosteum.

With these concepts in mind in is the overall intent to do what is necessary to restore function and nothing more in order to spare the patient removal of injured tissues that may recover or regrow, by implementing a common sense approach to limb repair and reconstruction with the implant and methods of use thereof. In animals as horses and dogs, where recovery instructions are even less likely to be followed than with humans, implanting secure restorative implants for joint surface refurbishment may offer renewed function and save lives that would have otherwise been sacrificed.

Rehabilitation of knee implant treated patients may engage prudent early motion. The amount of weight bearing allowed may be analogous to the procedures written by this primary surgery for Carticel implanted cases, following the principles that excessive amounts and repetitions of stress upon reconstructed areas should be avoided for 6-12 weeks after surgery. However, the knee implant surgeries per se are expected to take less than one hour, involve less than 1 cc blood loss, require wounds less than or equal to 10 cm overall (depending on the embodiment of the implant), and the end result intends to permit early full weight bearing. Zealous sports activities may be restricted until the bone in-growth and cartilage renewal is reasonably expected, between 2 and 12 months after surgery depending upon the amount of joint tissue replaced.

In some situations, the removal of the implant may be needed, and embodiments of the implants described herein are configured for removal arthroscopically, and with the allowance to perform all regular older routine accepted techniques ranging from joint debridement to drilling, partial or total replacement. In some embodiments the implant is configured for removal and replacement with a replacement implant—either immediately (within a week), or after a period of longer time (for example, after about 6 weeks to 1 year in the case of infection once all foreign bodies are removed and depending upon the surgeon's and/or infectious disease consultant's opinion

Specific surgical decisions related to size matching, fixation and or concomitant osteotomy warranted reconstruction are left to the primary surgeon and patient in each case.

The implant is inserted by minimally invasive surgery, in some embodiments; however, in other embodiments, the implant may not be inserted by minimally invasive surgery. In some embodiments, the implant is delivered through an incision that is about 0.5 inches long. In some embodiments, the implant is delivered through an incision that is about 1 centimeter long. In some embodiments, the implant is delivered through an incision that is at most about 1 inch long. In some embodiments, the implant is delivered non-arthroscopically through an incision that is at least 1 centimeter long. In some embodiments, the implant is delivered through an incision that is at most about 0.75 inches long. In some embodiments, the implant is delivered through an incision that is at most about 0.5 inches long. In some embodiments, the implant is delivered through an incision that is about 8 centimeters long. In some embodiments, the implant is delivered through an incision that is about 9 centimeters long. In some embodiments, the implant is delivered through an incision that is about 10 centimeters long. In some embodiments, the implant is delivered through an incision that is about 11 centimeters long. In some embodiments, the implant is delivered through an incision that is about 12 centimeters long. In some embodiments, the implant is delivered through an incision that is over about 10 centimeters long. In some embodiments, the implant is delivered through an incision that is at up to about 40 centimeters long. In some embodiments, the implant is delivered through multiple incisions. In some embodiments, the implant is delivered non-arthroscopically. In other embodiments, the implant is delivered arthroscopically. With respect to incision length, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%.

In some embodiments the implant is configured to be delivered to the joint arthroscopically. In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most about 10 millimeters. In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most about 9 millimeters. In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most about 5 millimeters. With respect to cannula distal end inner diameter, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%.

In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most about 10 millimeters. In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most about 9 millimeters. In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most about 5 millimeters. With respect to cannula distal end inner diameter, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%.

In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most about 10 millimeters. In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most about 9 millimeters. In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most about 5 millimeters. With respect to cannula distal end inner diameter, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%.

In some embodiments the implant may be provided as a deflated balloon for insertion into the joint space. In some embodiments the implant may be provided as folded balloon that may be collapsed like an umbrella for insertion into the joint space. In some embodiments the implant may be provided as collapsed balloon that is of an irregular folded pattern to minimize its folded (or collapsed) size for insertion into the joint space. In some embodiments, the implant is configured to blow up (or expand) to take the form of the expanded, distracted, debrided joint.

In some embodiments, the implant replaces periosteum.

In some embodiments, the implant is implanted to preserve bone as compared to a typical arthroplasty procedure of the joint. In some embodiments, the implant is implanted to preserve cartilage as compared to a typical arthroplasty procedure of the joint. In some embodiments, the implant is implanted with minimal soft tissue dissection as compared to a typical arthroplasty procedure of the joint. In some embodiments, the implant is implanted without joint dislocation. In some embodiments, once implanted, the joint is adaptable to revision surgery. In some embodiments once implanted, the joint retains at least one of: about 90% of normal joint function, about 95% of normal joint function, about 85% of normal joint function, about 80% of normal joint function, about 75% of normal joint function, about 70% of normal joint function, about 65% of normal joint function, about 60% of normal joint function, about 55% of normal joint function, about 50% of normal joint function, at least 95% of normal joint function, at least 90% of normal joint function, at least 85% of normal joint function, at least 80% of normal joint function, at least 75% of normal joint function, at least 70% of normal joint function, at least 65% of normal joint function, at least 60% of normal joint function, at least 55% of normal joint function, at least 50% of normal joint function, about 50%-about 75% of normal joint function, about 50%-about 70% of normal joint function, about 60-about 70% of normal joint function, about 70%-about 80% of normal joint function, about 70%-about 90% of normal joint function, about 80%-about 95% of normal joint function, about 80%-about 90% of normal joint function, and about 90%-about 95% of normal joint function. As used herein with respect to percentage of normal joint function, the term "about" can be ranges of 1%, 5%, 10%, or 25%. For example, a range of 1% with respect to about 90% of normal joint function covers 89% to 90% of normal joint function.

In an example of a hip implant, an upper portion of the implant has a first wall, a second wall and a side wall which define at least in part the interior. A skirt depends from the first wall and secures the first wall to the end of the patient's femur. An upper portion may be configured to engage the corresponding acetabulum of the patient's pelvic bone. The skirt surrounds the head of the patient's femur and secures the implant thereto. In this embodiment, the upper portion of the implant creates overlapping layers, like a redundant membrane, in the side wall between the first and second walls and to accommodate the normal movement of the first or second. This provides greater motion between the femur and the acetabulum and also provides implant stabilization over the head of the femur. This structure also accommodates variation in individual joints that occur from patient to patient.

In an embodiment, the first wall does not extend across the entire end of the patient's femur. However, the implant

may be designed so that first wall may extend over the head of the femur. The second wall and the side wall tend to roll as the femur moves within the acetabulum.

In some embodiments, prior to deploying the implant embodying features of the invention, the cartilage lining the joint is prepared by removing hyaline or fibro cartilage flaps or tears, and areas of chondral advanced fissuring are excised or debrided to create precisely defined defects surrounded by stable normal remnant hyaline cartilage with vertical edges in relation to the damaged surface. It is these defects of the cartilage previously normal surface into which new living cells may be injected or otherwise inserted, and allowed to aggregate by the implant interpositional arthroplasty proximate expanded compressive external wall material. Synovitis invading the joint periphery may be vaporized and extracted conventionally or by the use of steam. Areas of greater cartilage damage are removed for subsequent regeneration and the less afflicted areas having stable cracks are treated to seal or weld the cracks. Areas where the tugor or consistency or minimally damaged cartilage can be preserved are intentionally saved rather than destroyed so as to support the normal spacing and gliding opportunity of the more normal joint interface. Thus, normal cartilage is left behind and abnormal cartilage is removed with the implant making up for the deficiencies. With the present invention, it is preferred in some embodiments to avoid joint dislocation so as to preserve natural innervations and vascularity and thus preserving the blood supply.

Joint preparation is usually performed under a brief general anesthetic of outpatient surgery. A muscle relaxant combined with traction (e.g. 60 pounds force for a hip implant) may be employed to opens the joint wider to permit improved visualization for joint preparation and implant installation, increasing the space between the remnant cartilage from about 3 up to about 12 mm. Increasing the joint space may be necessary and allows the surgeon to wash out noxious enzymes, to remove invasive synovitis, to remove loose bodies, to prepare osteochondral defects ideally and otherwise prepare the joint for the implant. Partial or complete inflation of the implant may precede release of traction in some embodiments. In some embodiments, regeneration agents or cells are inserted with the implant or as a fluid or 3-D template prior to release of traction and wound closure. It is preferred, in some embodiments, to perform joint debridement, implant deployment and application of cell regeneration agent, e.g. stem cell application, under the same anesthetic. As described by several companies in the Stem Cell Summit held in New York, N.Y. on Feb. 17, 2009, it is desirable to obtain an aspiration of the patient's bone marrow from the iliac crest after anesthesia sterilely at the beginning of the operation. The intraoperative technologist may "dial in the cells" to regenerate areas of maximum pathophysiology while the surgeon debrides or otherwise prepares the joint and inserts the implant, placing the cells at the best time. Cell implantation may also occur as a secondary or tertiary reconstructive treatment adjunct. An example resilient implant may be deployed within a patient's hip structure comprising the head of the patient's femur and the acetabulum of the patient's pelvic hip bone. The resilient implant embodying features of the invention is disposed within the space between the femur and the acetabulum. The implant is shaped like a half an orange rind or a hemisphere for a hip joint. The implant has a first wall which is secured to the head of the femur by a plurality of depending tabs (or appendages). The tabs may be attached to the femur by a suitable adhesive or mechanically such as by a screw or pin or snap. The second wall the implant engages the acetabulum, but it also may be provided with tabs and the like for securing the second wall the acetabulum.

The side wall extends between the first and second walls to form an interior which receives filling material through tube (also called a conduit herein, or may be called an inflation port). The implant would also be appropriate for the humeral head in the shoulder or one condyle of the knee or of the humerus, but other shapes may be desired for other joint configurations whether relatively flat as in the thumb base, or more inflated toward a ballooning construct as in the ankle when the talus bone is collapsed.

In many embodiments the implant (or a portion thereof, such as the balloon) is a weight bearing spacer that allows joint motions to approach normal, whether filling the space left by an entirely collapsed peripheral joint bone or the space of ablated cartilage proximate surfaces diffusely as in osteoarthritis or succinctly as in osteonecrotic defects or localized trauma. The walls may be used as a membrane for holding living cells in proximity of the osteochondral defect long enough for the cells to attach (e.g. motion is believed to be primarily between the spaced walls (or portions) of the implant peripherally secured to joint structures, although some motion may occur between the implant and the joint surfaces (as with current bipolar hip hemiarthroplasties)). The implant may be provided with a slot extending from the periphery of the implant to a centrally located passage through the implant to accommodate the ligament of the head of the femur for hip implants. Knee implants may have two slots leading to separate passages for receiving the anterior and posterior cruciate ligaments. Implants for other locations may have similar variable structures to accommodate anatomical features. Implant walls should have sufficient inherent flexibility to mold to the existing deformities imposed by either natural ligament, bone, tendon or remaining cartilage deformities of the internal joint space, and thus filled as a cushion. A separate portal or tube (not shown) or the existing conduit (tube or valve), may be used to extract noxious inflammatory enzymes that can be aspirated at appropriate clinical intervals. Viscolubricants can be injected into the interior of the resilient arthroplasty device through existing conduit or through a long needle to aide in distension, expansion, and/or lubrication (with predetermined microporosity).

The ankle version of the arthroplasty implant of the present invention comprises a square transverse cross-section that must take into account supratalar ankle dorsi/plantar flexion, subtalar eversion/inversion motions, ligament fixation-needs, and the accommodation to existing bony architecture as implant variables accounting for the ipsilateral joint pathophysiology. The implant has a first wall, a second wall and a side wall which extends between the first and second wall. The exterior of the implant may have a mesh material with a plurality of chords (or appendages) for securing the implant to adjacent bones or to remnant ligaments which are attached to adjacent bones.

The implant may be inflated with gas and/or liquid to open wider the space between the tibia above and the calcaneus below to accommodate collapse of the talus bone as in the flattening which succeeds talus fracture with avascular necrosis, or it may be filled with a liquid that becomes a resilient solid. The instant center of the implant's rotation will be constantly changing, with the talus implant mainly stable and with the tibia moving over it. Deformation with weight bearing during the average human's 10,000 daily steps or 2-4 million annual gait cycles required by the stance and walking of normal activities of daily living, must be balanced between sufficient solidarity of the implant to

maintain axial load, avoiding circumferential stress, and shear forces imposed by the tibia distal plafond on the dorsal ankle implant allowing stance and gait of the patient while avoiding implant migration or failure. Further accommodation to lateral forces imposed by the boney medial and lateral malleoli need to be endured through the cyclic load of walking, while collapsing with enough give to absorb shock and to match the shape of surrounding structures of bone and ligament tissue. Whereas the axial load between the distal tibia through the talar implant to the dorsal calcaneus may be loaded during stance and especially while walking on a level plane for supratalar motion, the lateral forces may be loaded particularly with subtalar motion while walking on an uneven plane or with inversion/eversion.

In some embodiments, the first inflation medium imparts rigidity in the implant. In some embodiments, the first inflation medium imparts cushion in the implant. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium aligns the joint. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium aligns the bones of the joint. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium changes the bone alignment. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium improves joint alignment. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium restores, at least in part, joint alignment. In some embodiments, individual chambers of the interior are selectively inflated with a first inflation medium and/or a second inflation medium. In some embodiments, individual chambers of the interior are selectively inflated with a first inflation medium and/or a second inflation medium in order to reconstruct the joint and/or bones of the joint.

In some embodiments, the interior comprises a honeycomb structure. In some embodiments, the interior comprises a mesh structure. In some embodiments, the interior comprises a sponge structure.

The dimensions of the various implant walls may vary depending upon the material properties thereof as well as the needs for a particular joint. The spacing between the first and second wall within the interior can vary from about 0.5 mm to about 5 mm for most joints (except for the implant for an ankle when an entire collapsed bone space is being replaced), preferably about one to five centimeters to fill between the tibia and calcaneus. In the ankle invention version of the implant, the amount of inflation of the implant per se may be directly proportional to the amount of talus bone collapse between the distal tibia and proximal calcaneus—thus as much as 5 cm implant distension or expansion may be required to be maintained between superior and inferior surfaces of the talus, while as much as 10 cm anterior and posterior expansion may be required for the ankle implant between the posterior soft tissues such including the Achilles tendon and the anterior navicular bone as relates to the talus.

The method of insertion for the hip joint invention may be a minimally invasive approach, ideally arthroscopically facilitated, as long as the surgical timing and result quality permit smaller incisions. The hip patient may be placed in the lateral decubitus position (lying non-operative side down on the operating table) with a stabilizing operating table pole and pad apparatus positioned to fix the pelvis. The external stabilizing table and attachments may include a padded metal pole beneath the pubis or pelvic bone from posterior to anterior, along with other external anterior and posterior pelvic stabilizing paddles. The affected leg may be attached beneath the knee with a distracting mechanism that applies about 60 pounds of distal force to open the hip joint about 1 cm once the patient is under general anesthesia. The hip joint is arthroscopically debrided through at least one anterior 0.5 cm incision and one posterior 0.5 cm incision, to remove from the femoral head acetabular (ball and socket) joint arthritic debris such as synovitis, loose bodies and noxious inflammatory enzymes. In certain cases a larger open incision may be needed. A smoothing or electronic/ultrasonic/steam or other chondroplasty method may be performed to make the remaining cartilage smoother to better accommodate the hip implant, and protuberant osteophytes or lateral bone overgrowths may be arthroscopically removed or if needed by open excision. A lateral hip incision may be required between 2 and 10 centimeters in length to deal with deformities and/or to insert the implant. In cases of major deformities appropriate reconstruction may add to the basic procedure.

Once the joint is open and cleared, the hip implant may be inserted laterally and fixed via the skirt or tabs or at least one appendage to the adjacent structures including the peripheral femoral head and/or acetabular rim. Preferably, the implant is inserted arthroscopically through a cannula about 10 mm in diameter with the implant in the deflated construct, and once inside the prepared joint space and secured therein by the skirt or tabs, the implant may be distended or inflated with gas, gel, fluid or fluid that becomes a resilient solid to fill the original natural space of about 0.5 cm between the upper acetabulum and lower femoral head, covering as much of the upper hip joint as required as the implant expands to fit the space.

The method of insertion of the ankle implant generally may be through an anterior surgical ankle approach or tendon separating incision from the distal tibia to the proximal talus (or calcaneus if the talus is absent), removing and reconstructing portions of the superior and inferior ankle extensor retinacula only to the extent required to gain access to the cleared tibiotalar space. Analogous to the hip joint insertional method, the ankle joint may be prepared arthroscopically under general anesthesia, and may benefit from distal distraction as in total ankle joint replacement surgeries with the DePuy Agility technique pinning above and below the ankle joint and then distracting it. The degree of distraction required in all joints to which this invention is applied, including but not limited to those of all appendicular skeletal structures such as the shoulder, elbow, wrist, phalanges, hip, knee, and ankle, may depend both on the nature anatomy and located pathophysiology that must be accommodated on a case by case basis and said distraction may be a combination of body position using gravitational forces and/or superimposed distracting devices. In the ankle, the surgeon may be developing the interval between the extensor hallucis longus and anterior tibial tendons. Injury tissue is removed, and the implant inserted fitting as preplanned. The implant surface may be provided with roughness, e.g. external mesh, to control movement by friction as

described above for the hip joint, and/or attached fixation cords or tabs to connect to proximate ligaments or adjacent boney structures may be used at the surgeon's discretion to balance implant location stability and integrity, with the need for functional joint movements.

Provided herein is a method for restoring a joint comprising: providing an implant configured for deployment between a first bone and at least one second bone of a joint, the implant further comprising a balloon comprising a first portion that is configured to engage the first bone of the joint, a second portion that is configured to engage at least one second bone of the joint, a side portion connecting the first portion and the second portion, in which the side portion facilitates relative motion between the first portion and the second portion, and an interior that is optionally inflatable with a first inflation medium; and coupling a first appendage of the balloon to the first bone of the joint. In the case of a knee device, the first bone may be one of a tibia, a femur and a patella. In the case of a knee device, the second bone may be one of a tibia, a patella and a femur.

In some embodiments, at least two of first portion, the second portion, and the side portion are contiguous. In some embodiments, the first portion comprises a first wall, the second portion comprises a second wall, and the side portion comprises a side wall.

In some embodiments the method comprises providing an in-growth patch on at least one of the first portion configured to engage the first bone (e.g. a femur, a tibia, or a patella, in the case of the knee device), the second portion configured to engage the second bone, the side portion, and the appendage. The in-growth patch may be configured to encourage and/or promote tissue in-growth, such as bone in-growth, for non-limiting example. The patch may be as large as the portion itself (whether the first portion the second portion, the side portion, or the appendage) or may be smaller than the portion (such as in the shape of a strip or other shaped patch). The in-growth patch may comprise a surface irregularity or roughness. The in-growth patch may be Velcro-like. In some embodiments the implant comprises an in-growth patch on the first portion and/or the second portion, from (and in some embodiments including) a first appendage to a second appendage. In some embodiments, wherein the appendages loosen from attachment from the bone (by design and/or from wear and/or over time), the in-growth patch aids in securing the implant to the bone. In some embodiments, the in-growth patch comprises beads and/or bead-like elements attached to the implant. Such an in-growth patch may be configured to simulate trabecular bone space of a normally cancellous latticework. In some embodiments, the beads are sintered beads of various sizes. In some embodiments, the beads are sintered beads about 400 microns in size. With respect to bead size, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%. In some embodiments, the first bone and/or the second bone is roughened to acquire a bleeding bone to facilitate in-growth. In some embodiments, about 0.5 mm of cortical tissue is removed to facilitate in-growth.

In some embodiments, the method comprises coupling a second appendage of the balloon to the first bone of the joint. In some embodiments, the method comprises coupling a second appendage of the balloon to at least one second bone of the joint. In some embodiments, the method comprises coupling a second appendage of at least one of the first portion, the second portion, and the side portion to at least one of the first bone and at least one second bone of the joint. In some embodiments, coupling at least one of the first appendage and the second appendage provides ligamentary-like support to the first bone and at least one second bone of the joint. In some embodiments, coupling at least one of the first appendage and the second appendage provides ligamentary-like support to the joint. In some embodiments, the first appendage and the second appendage are configured to provide tendon-like support to the first bone and the at least one second bone of the joint. In some embodiments, the first appendage and the second appendage are configured to provide tendon-like support to the joint.

In some embodiments, the method comprises providing an inflation port in communication with the interior of the balloon for inflation of the interior of the balloon with the first inflation medium. In some embodiments, the method comprises using an inflation port of the implant that is in communication with the interior of the balloon to inflate the interior of the balloon with the first inflation medium. In some embodiments, the method comprises puncturing the balloon to inflate the interior of the balloon with the first inflation medium. In some embodiments, the method comprises providing a balloon having self-sealing capability. In some embodiments, the method comprises providing a balloon having self-sealing capability upon inflation of the interior of the balloon with the first inflation medium. In some embodiments, the method comprises providing a balloon comprising a seal capable of closing the interior of the balloon.

In some embodiments, the method comprises providing a balloon having an interior comprising a plurality of inflatable chambers. In some embodiments, the interior comprises a plurality of individually inflatable chambers. In some embodiments, the method comprises inflating a first chamber of the plurality of inflatable chambers with a first inflation medium. In some embodiments, the first chamber and the inflation medium is selected based on the particular needs of the patient. For non-limiting example, if the patient has bone loss due to an injury, the chamber may be selected at the location of the missing bone, and may be filled with a rigid inflation medium (or one that becomes rigid once in the chamber) in order to replace the missing and/or damaged bone. Alternatively, or in addition, a chamber may be chosen to restore alignment of the joint, and inflated with an appropriate inflation medium to impart both alignment and cushion to the joint. In some embodiments, the method comprises inflating a second chamber of the plurality of individually inflatable chambers with a second inflation medium.

In some embodiments, the balloon is a composite structure. In some embodiments, the balloon comprises layers of porous and/or non-porous materials, or otherwise contains treatment or cell regeneration agents. In some embodiments, a first layer of the balloon is a thin, but strong layer of a thermoplastic, such as a thermoplastic polyurethane, for non-limiting example, which has microporosity sufficient to allow passage or egress of treatment or cell regeneration agents from a second layer. The second layer may be a central layer (which lies between the first layer and a third layer or a fourth layer or more layers). The first layer may comprise a bone engaging surface in some embodiments. The degree of microporosity to enable egress of treatment or cell regeneration agents from the second layer is found in polymer layers such as Chronoflex (e.g., ChronoFlexAR®, ChronoFlex AL®, ChronoFlec C®) or BIONATE (e.g., BIONATE I, BIONATE II, BIONATE 55D, BIONATE 65D, BIONATE 75D, BIONATE 80A, BIONATE 90A, BIONATE 55 or BIONATE 80). The bone engaging surface of the implant may be coated and/or impregnated with a latticework of polymer that is surface sprayed or layered on the

bone engaging surface of the implant to promote cartilage tissue regeneration. This bone engaging surface coating may contain living chondrocytes (for example, as is provided in the Carticel procedure by the Genzyme company), and/or may contain stem cells with directed gene mutations to enhance adherence of the coating to the implant. The bone engaging surface may comprise peaks and troughs. The living cells may be provided in troughs while the surface peaks may be used for at least one of: space validation, traction, and cell protection.

In some embodiments, the first inflation medium imparts rigidity in the implant. In some embodiments, the first inflation medium imparts cushion in the implant. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium aligns the joint. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium aligns the bones of the joint. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium changes the bone alignment. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium improves joint alignment. In some embodiments, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium restores, at least in part, joint alignment. In some embodiments, individual chambers of the interior are selectively inflated with a first inflation medium and/or a second inflation medium. In some embodiments, individual chambers of the interior are selectively inflated with a first inflation medium and/or a second inflation medium in order to reconstruct the joint and/or in order to reconstruct bones of the joint.

Over time, in-growth of repair tissue aids in fixation and stability externally to the implant, while the soft cushioning implant interior may absorb forces across the joint surfaces and permit proper motion. The turgor or wall tension of the implant as well as the inside distension of the implant per se can be adjusted by adding or removing the inflation substance to the implant's interior space.

Accordingly, the present invention provides a new approach to arthroplasty that involves a resilient implant deployed between bones of the knee joint. In some instances, a joint is comprised of the interface between (a) a first bone and a first cartilage; and (b) a second bone and a second cartilage, wherein the first cartilage is separated from the second cartilage by a space (e.g., joint space) and the cushion expands to fit the joint space. In some instances, where the first cartilage and/or second cartilage is damaged or absent, the cushion expands to fit the joint space between the first bone and second cartilage or the first bone and second bone. In certain joint spaces such as the knee, the cushion expands to fit the spaces of the "knee joint" or "knee joints". For example, the cushion may expand to fit the spaces of the femoral tibial involved on standing or walking on a level plane, and the cushion may expand to fit the spaces of the patella femoral bones of the knee more involved on stair ascent and descent. For example, pressures behind the knee cap or patella when lying are zero, when standing are 0.7 times body weight, and when going up and down the patella femoral pressures are 3-4 times body weight. Thus, in some instances, the implants accommodate some or all of the normal body functional pressures and complex space movements, as described above, and can also be used in other joints such as the elbow, ankle, or hip. When in the hip joint, the normal flexion up to 120 degrees, extension of 20 degrees, abduction of 50 degrees, internal and external rotation of 45 degrees may produce variable axial, shear, and cyclic loads which the implant by design may accommodate and endure as up to 6 times body weight, consistent with a tire on a car that allows for cyclic loads different when driving straight or turning corners. The implant embodying features of the present invention provides more physiologic motion and shock absorption within the joint and has combined characteristics of anatomic design symmetry, balanced rigidity with sufficient attachment connections to adjacent normal structures, and durability that meet the needs of joint reconstruction.

The opposing internal surfaces of the first and second walls of the invention may either move together in synchrony or in opposite directions from one another (e.g. the superior wall moving medially in the hip and the inferior wall moving laterally). Optionally, the implant may be fixed to a concave surface of the joint (e.g., the acetabular hip cup) or to a convex surface of the joint (e.g. the dorsal femoral head surface), to both, or to neither (e.g., having an interference fit within the joint with an expanding balloon or cushion that fills the existing space). The implant may be inserted arthroscopically like a deflated balloon and then inflated through a cannula into the ankle or hip (or other joint structure) to act as a cushion or renewed interface for painless and stable limb motion. When feasible, joint capsular and adjacent ligament tissue as well as bone may be left in place to preserve the natural body, unless interfering with reconstructed limb function.

The application of steam in addition to removing damaged debris, can smooth out and reform the joint surface. The high temperature of the steam tends to weld cracks or fissures which can be present in the cartilage surface of a damaged joint. Smoothing of joint surface cartilage with steam welds or seals existing cracks or flaps in the cartilage, especially superficially as the lamina splendors, which melt together to provide a white shiny gliding joint surface. In cases where bone is exposed, the steam can be used to stabilize the periphery of the defect in the joint surface via capsulorrhaphy or joint tightening. Open mechanical and chemical debridement may also be employed to prepare the surfaces for the implant.

Once the implant is secured to the femur by means of the skirt or tabs or using other couplers, an impregnated transfer medium or cell template may be used, as described by Histogenics and Tygenix chondrocytes delivery systems wherein the position of concentrated cells is mechanically placed about the implant at areas of greatest cartilage damage to promote regrowth, or as in Carticel wherein watery cells are implanted beneath a periosteal membrane (a wall of the implant serving as the membrane), prior to completion of the inflation or expansion of the implant. A syringe or gauged device with measured screw-home pressure is used to inflate the implant.

Once the joint is ready to receive the implant, the deflated implant is advanced through the diaphragm of a delivery cannula (such as the Acufex from Smith & Nephew) or through the open incision site into the joint. It can be inflated by the attached cannula using a common syringe, inserting several cc's of filler material. Inserted contents and locations of cell placements depend on areas of need and joint size. In

some embodiments of the methods several cc's of filler material and a viscolubricant in the interior of the implant allows distension, cushioning, and gliding movements. Cell regeneration agents are placed in the areas of greatest need.

Methods of living cell (e.g., stem cell, differentiated cell, pluripotent cell, post-mitotic cell) or chondrocyte placement depend on the lesions and specific implant construct. Direct infusion into the joint with completion of implant inflation may press the cells into the hyaline surface, whereupon they attach within the first 24 hours. As a result, the patient may be forced to remain sedentary and the joint where the implant is deployed, non-weight bearing for the first day after surgery. Deeper osteochondral defects can be treated by 'hyper-perfusion of cells' via either 3-D cell transfer templates, or microneedle injection as used in treatment of diabetic patients for blood sugar testing and insulin/transdermal drug delivery. In cases of osteochondritis dissecans or localized both cartilage and bone lose, bone graft may be packed into the base of the defect followed by addition of a cell/tissue application. The cannula attached to the implant may be sealed and detached, or left in place for periodic aspiration of noxious enzymes as for the Cox-1, Cox-2, and 5-Lox systems, followed by reinsertion of activated substances including viscolubricants, or even more cells (e.g., stem cells, differentiated cells, pluripotent cells, post-mitotic cells).

Implants embodying features of the invention may be designed for permanent or temporary deployment within a joint structure. Moreover, the implant may be formed of suitable bioabsorbable materials so that the implant may be absorbed within a particular predetermined time frame. Suitable bioabsorbable materials include polylactic acid, polyglycolic acid, polycaprolactone, copolymers, blends and variants thereof. One present method of forming the implant is to apply numerous layers of polymer such as ChronoFlex (e.g., ChronoFlexAR®, ChronoFlex AL®, ChronoFlec C®), ChronoPrene™, ChronoSil®, ChronoThane P™ ChronoThane T™, HydroMed™, HydroThane™, or PolyBlend™ in a solvent and evaporating the solvent after applying each layer.

The coupling aspects (couplers) including but not limited to skirting or fixation tabs of the present implant prevent joint migration during use.

In some embodiments, the implant is adapted to restore natural joint function. In some embodiments, the implant is adapted to preserve viable joint tissue. In some embodiments, the implant is adapted to be placed with minimal surgery as compared to joint replacement therapy currently marketed. In some embodiments, the implant is adapted to permit weight bearing post surgery within at least one of: about 1 week, within about 1 day, within about 2 days, within about 3 days, within about 4 days, within about 5 days, within about 6 days, within about 10 days, within about 2 weeks, within about 3 weeks, within about 4 weeks, within about 5 weeks, within about 6 weeks. In some embodiments, the implant is adapted to permit weight bearing post surgery after about 1 day wherein full weight bearing is allowed in about 6 weeks. As used herein with respect to weight bearing timing, the term "about" can be a range of 1 day, 2 days, or 3 days, in some embodiments. In some embodiments, the implant is adapted to allow for faster recovery and resumption of normal activities as compared to joint replacement therapy currently marketed.

In some embodiments, the balloon (or a portion thereof) is adapted to conform to the patient's anatomy. In some embodiments, the implant (or a portion thereof) is adapted to conform to the patient's anatomy. In some embodiments, the inflation medium is adapted to absorb a force (or forces) exerted on the joint. In some embodiments, the inflation medium is adapted to absorb a force (or forces) exerted on the bones of the joint. In some embodiments, the inflation medium is adapted to absorb a force (or forces) exerted on at least one bone of the joint. In some embodiments, the balloon is adapted to absorb shocks exerted on at least one of a bone, multiple bones, a ligament of the joint, ligaments of the joint, a tendon of the joint, tendons of the joint, and the joint in general. In some embodiments, the implant is adapted to restore natural cartilage cushion with cells (e.g., stem cells, differentiated cells, pluripotent cells, post-mitotic cells). In some embodiments, the implant is adapted to restore natural cartilage cushion with stem cells.

In some embodiments, the balloon (or a portion thereof) is adapted to renew joint space. In some embodiments, the balloon (or a portion thereof) is adapted to reduce pain as compared to the pain felt prior to the implantation of the implant. In some embodiments, the balloon (or a portion thereof) is adapted to restore joint function. In some embodiments, the implant (or a portion thereof) is adapted to renew joint space. In some embodiments, the implant (or a portion thereof) is adapted to reduce pain as compared to the pain felt prior to the implantation of the implant. In some embodiments, the implant (or a portion thereof) is adapted to restore joint function.

In some embodiments, the implant is adapted to reverse arthritis in the joint. In some embodiments, the implant is adapted to prevent, reduce, or ameliorate arthritis in the joint. In some embodiments, the implant is adapted to reduce pain associated with arthritis in the joint.

In some embodiments, the balloon (or a portion thereof) is adapted to be placed into a debrided limb joint arthroscopically. In some embodiments, the balloon is adapted to pad cartilage defects. In some embodiments, the balloon is inflated to cushion the joint. In some embodiments the implant is adapted to deliver stem cells to at least one of the joint and a bone of the joint. In some embodiments the implant is adapted to deliver living chondrocytes to at least one of the joint and a bone of the joint. In some embodiments, the implant is adapted to deliver cells to at least one of the joint and a bone of the joint. In some embodiments, the cells are at least one of stem cells, differentiated cells, pluripotent cells, and post-mitotic cells. In some embodiments, the implant is adapted to provide a new articular surface for the joint. In some embodiments, the implant is adapted to act as a spacer in the joint. In some embodiments, the implant is adapted to space the bones of the joint apart for proper joint articulation. In some embodiments, the implant is adapted to space the bones of the joint apart for reduced bone-on-bone rubbing.

In some embodiments, the implant is configured to at least one of: pad cartilage, cushion the joint, deliver a pharmacologic substance, remove noxious enzymes, debride upon implantation, debride the joint following implantation, deliver a therapeutic substance, deliver a biologic substance, and deliver living stem cells. In some embodiments, the implant is configured to deliver a chemotherapeutic agent to a bone or other surrounding tissues. In some embodiments, the implant is configured to deliver an anti-infectious medication to a bone or other surrounding tissues. In some embodiments, the implant is configured to deliver at least one of an antibiotic, antifungals, and analgesics agent.

In some embodiments, the implant is configured to be selectively inflated to realign limbs.

Provided herein is a method comprising: implanting a knee implant as described herein into a subject, wherein the

implant reverses arthritis in the subject. Provided herein is a method comprising: implanting a knee implant as described herein into a subject, wherein the implant prevents, reduces, or ameliorates arthritis in the subject. Provided herein is a method comprising: implanting a knee implant as described herein into a subject, wherein the implant reduces pain associated with arthritis in the subject.

Provided herein is a method comprising: implanting a knee implant as described herein into a knee joint of a subject and treating a component of the knee joint of the subject with at least one of an allograph tissue, an autograph tissue, and an xenograph tissue. In some embodiments, the tissue comprises a cell. In some embodiments, the tissue comprises a plurality of cells. In some embodiments, the cell is a stem cell, differentiated cell, pluripotent cell, or post-mitotic cell. In some embodiments, the implanting step is at least one of: prior to the treating step, simultaneous with the treating step, and following the treating step.

Provided herein is a method comprising: implanting a knee implant as described herein into a subject, wherein the implant is configured to at least one of: restore joint function and control arthopathies. In some embodiments, the implanting spares existing anatomy.

Provided herein is a method comprising: debriding a femur condyle of a knee joint of a subject, and implanting a knee implant as described herein into the knee joint of the subject, whereby the implant is configured to anneal to the cartilage of the subject. In some embodiments, the debriding is achieved by steam application.

Provided herein is a method comprising implanting a knee implant as described herein into a joint previously treated with a joint replacement. In some embodiments, the method comprises removing the joint replacement prior to implanting the knee implant. In some embodiments, the method comprises clearing infectious matter from the joint and/or surrounding tissues. In some embodiments, the method comprises implanting a second implant of any implant described herein following removing the implant previously implanted in the joint. In some embodiments, the method comprises replacing the joint of the subject following removing the implant previously implanted in the joint. In some embodiments, the method comprises debriding the bone of the joint, and implanting an implant of any implant described herein. In some embodiments, the method comprises repeating the debriding and implanting steps.

The surgical techniques may be individualized to fit patient need. The implants may be combined with or comprise autologous or allograph tissues such as fascia lata. Surgeons may implant fascia lata above unreconstructable rotator cuff with consequent symptom relief Polymers can interface with any human tissue and/or with metals or polyethylenes or polyurethanes. Living tissues that can be combined with implants provided herein for repair or reconstruction may be from the same patient (autograph), and cadaver or other member of the same species (allograph) or from another species (xenograph.) Virtually any combination of polymer interpositioning is feasible with the implant concepts provided herein, as anatomy varies among patients in need, and clinical conditions differ with each person. Therefore, although the general or most common construct is expected to cover just one singular and the primary surface of a joint with an implant, any combination of surfaces can be involved allowing versatile custom applications of this implant and method of surgery.

Additionally, whereas implants may be available in specified sizes, the material membrane elastic deformation and resilience may allow for calculated malleability toward goodness of fit. In other iterations the fit of implant over the affected joint surface can be customized as paring preoperative findings of MRI or CT or PET imaging pathophysiology with intraoperative reconstructive need. Ultimately best fit implants may serve patient restorative requirement with least morbidity.

The implants may be implanted typically during an outpatient surgery, wherein the joint is first arthroscopically debrided and cartilage prepared, similar to the methods used in a Carticel procedure. Cartilage or osteochondral size defects and alignment problems are studied, and measurements taken. Considerations to materials stretch are acknowledged as polyurethanes gain 50% pliability with 100 hours exposure to serum, and 30% additional malleability by heating to 37 degrees C. Thus, implant presentation in the OR may aim for best fit and accommodate patient need.

Intraoperative hyaline cartilage biopsy acquiring e.g. 400 mg of normal hyaline articular tissue from the intercondylar notch (as would be wasted with notchplasty) or from the joint periphery (outside articulating regions) may allow for chondrocytes autologous acquisition. Currently such specimens may be sent to Genzyme Corp. for 2-4 weeks cloning of cells whereupon 2-3 bottles containing e.g. 1 cc of cells, 93% viability, 12 million cells per bottle, are delivered on an exact day to the operating room for placement in the Carticel cartilage regenerative procedure securing the liquid cells beneath a harvested periosteal membrane. In implant surgery contemplated in certain embodiments, the polymer may substitute for the periosteum thus reducing surgical morbidity markedly and changing an otherwise major open procedure into an arthroscopically facilitated outpatient treatment option through a small arthrotomy.

With outpatient surgeries the intraoperative biopsy may be given to the technician in the operating room in early surgery, for insertion into the stem cells generation machine. In 30-40 minutes living autologous chondrocytes may be 'spun down' and separated, then returning the living cells to the primary surgeon. By this time, the implant has been pulled up over the prepared defects and sufficient fixation sites have been locked into place so that the implant is secure in its general location over the distal femoral surface, for example. An unattached portion of the implant is lifted, the newly procured cells inserted potentially on a soft matrix to hold cells inside the prepared defect, and the implantation is completed sealing the living cells for the purpose of articular surface regeneration. After 24 hours the cells are fixed as the aggregate to the surface of the defect into which they were introduced. This begins a one year period of regrowth of the new joint surface. Concurrently the arthritis osteochondral defect so treated is padded by the implant, and the joint cushioned is mechanically restored. Said cushioning is by nano and/or macro inflation and/or by use of polymers with variable compliance. Immediate fixation and the opportunity for a regenerated joint are thus accomplished in the operating room. This may use either the implant matched to size by preoperative planning via X-rays considering the magnification factors, by using one of the other scanning methods available, or by custom generation ultimately of implant partial or entire coverage options in the same surgery.

Once the implant is secured circumferentially and solidly in place with multiple fixation sites verified as patent, one or two forms of orthobiologic activity proceed. Specifically, if chondrocytes were implanted (autologous or potentially allograph) they may mature and in the course of a year the durometry may come to resemble normal hyaline articular cartilage. The other biologic activity promoted during

implantation surgery is the bone in-growth onto the tab undersurface and/or periphery. This fixation at the secondary level in proposed to decrease the probability of loosening of the prosthetic implant, one of the two most common causes of implant failure. With the normal 10,000 steps people take per day during normal gait, or 2-4 million cycles per annum, the compressive and shear forces, and cyclic loads can cause micromotion between the implant and natural underlying tissue. This may lead to implant shift, dislocation, and/or hardware backing out if not appropriately secured to the bones. In the implant technique the immediate fixation is achieved through multiple robust circumferential fixation of implant tabs to bone. Each screw and washer secures the mechanically adequate implant tab to bone at over 300 pounds force to failure. Since, depending on the embodiment, there may be ten (10) tab sites intended the sum of 3000 pounds. In some embodiments, fixation comprises bone in-growth. In some embodiments, the fixation comprises bone in-growth as described in Vasanji A, In vivo bone growth assessment in preclinical studies and clinical trials, Bonezone, 2012, p. 12-17, herein incorporated by reference in its entirety.

The methods of surgery may have certain constants and other variables mandated by materials and fixation management versus altering anatomies and joint forces. In each joint a standardized implant method of surgery may be recommended with variations to be determined by the responsible surgeon.

While particular forms of the invention have been illustrated and described herein, it will be apparent that various modifications and improvements can be made to the invention. One alternative implant construction involves the use of an upper portion of the implant having a net-like construction and filled with balls or ball bearing like elements that are larger than the openings in the netting. The balls or ball bearing like elements provide motion to the implant. The netting and ball bearing like elements may include regeneration agents as previously discussed, and the bearing construction may be directed toward favorable implant movement balanced with content disbursement.

The invention is intended primarily for human use but may be extended to mammalian use. Examples of mammals include, but are not limited to, cats, dogs, sheep, horses, pigs, goats, cows, mice, and rats. To the extent not otherwise disclosed herein, materials and structure may be of conventional design.

Moreover, individual features of embodiments of the invention may be shown in some drawings and not in others, but those skilled in the art will recognize that individual features of one embodiment of the invention can be utilized in another embodiment. Moreover, individual features of one embodiment may be combined with any or all the features of another embodiment. Accordingly, it is not intended that the invention be limited to the specific embodiments illustrated. It is therefore intended that this invention be defined by the scope of the appended claims as broadly as the prior art will permit.

Terms such as "element", "member", "component", "device", "means", "portion", "section", "steps" and words of similar import when used herein shall not be construed as invoking the provisions of 35 U.S.C § 112(6) unless the following claims expressly use the terms "means for" or "step for" followed by a particular function without reference to a specific structure or a specific action. All patents and all patent applications referred to above are hereby incorporated by reference in their entirety.

While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

What is claimed is:

1. A method for restoring a joint comprising: providing an implant configured for deployment between a femur and a tibia of a knee joint, the implant comprising

a first portion that is configured to directly engage a medial condyle and a lateral condyle of the femur of the knee joint,

a second portion that is configured to directly engage the tibia of the knee joint,

a first appendage configured to couple the first portion to a first condyle of the femur of the knee joint, the first appendage having a pre-set curvature configured to simulate curvature of the first condyle and at least one pre-formed hole for securing the first appendage to the first condyle,

a second appendage configured to couple the first portion to a second condyle of the femur of the knee joint, the second appendage having a pre-set curvature configured to simulate curvature of the second condyle and at least one pre-formed hole for securing the second appendage to the second condyle,

a slot between the first appendage and the second appendage, and

a cushioning element within the implant configured to provide a cushion for the femur and tibia, the cushioning element comprising a thermoplastic polyurethane polycarbonate, and

wherein the first portion, the second portion, the first appendage, and the second appendage together comprise a single contiguous polymer sheet, such that the implant results in the restoration of a joint;

deploying the implant between the femur and the tibia of a knee joint; and

securing the implant with at least one coupler wherein the at least one coupler is accommodated by at least one pre-formed hole.

2. The method of claim **1**, wherein the restoration comprises an implant provided with orthobiologics.

3. The method of claim **1**, wherein the restoration comprises an implant provided with a pharmacologic agent.

4. The method of claim **3**, wherein the pharmacologic agent comprises growth factors, antibodies, biomolecules, biologics, chemical compounds, analgesics, antibiotics, anticancer agents, viscolubricants or combinations thereof.

5. The method of claim **3**, wherein the pharmacologic agent comprises Gleevac®, Doxorubicine®, NSAIDs, Synvisc®, Hyalgan®, Supartz® or lidocaine.

6. The method of claim **1**, wherein the restoration comprises tissue regeneration, reduction of arthritis, amelioration of arthritis or the reduction of pain.

7. The method of claim **6**, wherein the tissue regeneration comprises an implant provided with joint tissue regeneration agents.

8. The method of claim 7, wherein the tissue regeneration agents comprise stem cells, living chondrocytes, genes or combinations thereof.

9. A method for restoring a joint comprising: providing an implant configured for deployment between a femur and a patella of a knee joint, the implant comprising

a first portion that is configured to directly engage at a trochlear groove of the femur of the knee joint,

a second portion that is configured to directly engage the patella of the knee joint,

a first appendage configured to couple the first portion to a first condyle of the femur of the knee joint, the first appendage having a pre-set curvature configured to simulate curvature of the first condyle and at least one pre-formed hole for securing the first appendage to the first condyle,

a second appendage configured to couple the first portion to a second condyle of the femur of the knee joint, the second appendage having a pre-set curvature configured to simulate curvature of the second condyle and at least one pre-formed hole for securing the second appendage to the second condyle, and

a slot between the first appendage and the second appendage, and

a cushioning element within the implant configured to cushion the femur and patella, the cushioning element comprising a thermoplastic polyurethane polycarbonate, and wherein the first portion, the second portion, the first appendage, and the second appendage together comprise a single contiguous polymer sheet, such that the implant results in the restoration of a joint; and

deploying the implant between the femur and the patella of a knee joint; and

securing the implant with at least one coupler wherein the at least one coupler is accommodated by at least one pre-formed hole.

10. The method of claim 9, wherein the restoration comprises an implant provided with orthobiologics.

11. The method of claim 9, wherein the restoration comprises an implant provided with a pharmacologic agent.

12. The method of claim 9, wherein the restoration comprises tissue regeneration, reduction of arthritis, amelioration of arthritis or the reduction of pain.

13. The method of claim 12, wherein the tissue regeneration comprises an implant provided with joint tissue regeneration agents.

14. The method of claim 13, wherein the tissue regeneration agents comprise stem cells, living chondrocytes, genes or combinations thereof.

15. A method for restoring a joint comprising: providing an implant configured for deployment between a tibia and a patella of a knee joint, the implant comprising

a first portion that is configured to directly engage at the tibia of the knee joint,

a second portion that is configured to directly engage the patella of the knee joint,

a first appendage configured to couple the first portion to a first condyle of the tibia of the knee joint, the first appendage having a pre-set curvature configured to simulate curvature of the first condyle and at least one pre-formed hole for securing the first appendage to the second condyle,

a second appendage configured to couple the first portion to a second condyle of the tibia of the knee joint, the second appendage having a pre-set curvature configured to simulate curvature of the second condyle and at least one pre-formed hole for securing the first appendage to the second condyle, and

a slot between the first appendage and the second appendage, and

a cushioning element within the implant configured to cushion the tibia and patella, the cushioning element comprising a mesh sheet or inflatable chamber, and

wherein the first portion, the second portion, the first appendage, and the second appendage together comprise a single contiguous polymer sheet, such that the implant results in the restoration of a joint; and

deploying the implant between the tibia and the patella of a knee joint; and

securing the implant with at least one coupler wherein the at least one coupler is accommodated by at least one pre-formed hole.

16. The method of claim 15, wherein the restoration comprises an implant provided with orthobiologics.

17. The method of claim 15, wherein the restoration comprises an implant provided with a pharmacologic agent.

18. The method of claim 15, wherein the restoration comprises tissue regeneration, reduction of arthritis, amelioration of arthritis or the reduction of pain.

19. The method of claim 18, wherein the tissue regeneration comprises an implant provided with joint tissue regeneration agents.

20. The method of claim 19, wherein the tissue regeneration agents comprise stem cells, living chondrocytes, genes or combinations thereof.

* * * * *

US010085846B2

(12) **United States Patent**
Grotz

(10) **Patent No.: US 10,085,846 B2**
(45) **Date of Patent: *Oct. 2, 2018**

(54) **UNIVERSALLY EXPANDING CAGE**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

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A61F 2/46 (2006.01)
A61F 2/30 (2006.01)

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CPC ***A61F 2/4425*** (2013.01); ***A61F 2/446*** (2013.01); ***A61F 2/447*** (2013.01); ***A61F 2/4611*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61F 2/446; A61F 2/447; A61F 2/4611; A61F 2/4425; A61F 2/4637;
(Continued)

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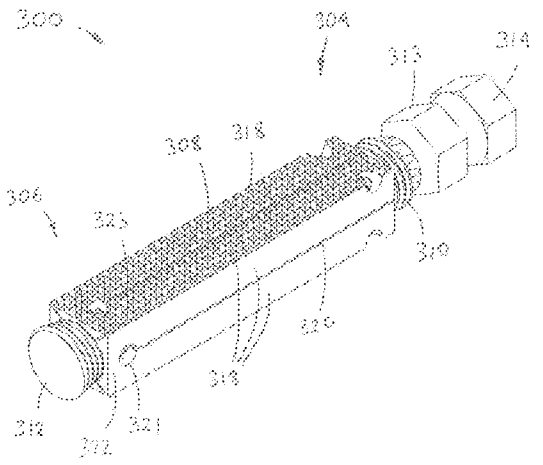
(74) *Attorney, Agent, or Firm* — Michel Graffeo

(57) **ABSTRACT**

An expandable medical implant is provided with an implantable cage body. Methods for stabilizing and correcting the alignment of a spine with an expandable medical implant are provided. The proximal and distal ends of the cage body may each be provided with a plug for causing expansion of the ends of the implant and therefore the bone engaging surfaces of the implant. The proximal plug member may be configured to move longitudinally such that the proximal end of the cage body resiliently expands. The distal plug member may be configured to move longitudinally such that the distal end of the cage body resiliently expands. The proximal and distal plug members are moved longitudinally independently from one another to allow for independent expansion and contraction of each of the proximal and distal ends of the cage body itself.

17 Claims, 28 Drawing Sheets



Related U.S. Application Data

No. 15/668,650, filed on Aug. 3, 2017, now Pat. No. 9,861,494, which is a continuation of application No. 15/485,131, filed on Apr. 11, 2017, now Pat. No. 9,872,778, which is a continuation of application No. 14/939,905, filed on Nov. 12, 2015, now Pat. No. 9,622,878.

(60) Provisional application No. 62/078,850, filed on Nov. 12, 2014.

(52) **U.S. Cl.**
CPC .. ***A61F 2/4637*** (2013.01); *A61F 2002/30408* (2013.01); *A61F 2002/30411* (2013.01); *A61F 2002/30507* (2013.01); *A61F 2002/30538* (2013.01); *A61F 2002/30545* (2013.01); *A61F 2002/30556* (2013.01); *A61F 2002/30579* (2013.01); *A61F 2002/30841* (2013.01); *A61F 2002/448* (2013.01); *A61F 2002/4642* (2013.01)

(58) **Field of Classification Search**
CPC .. A61F 2002/30408; A61F 2002/30411; A61F 2002/30507; A61F 2002/30545; A61F 2002/30538; A61F 2002/30556; A61F 2002/30515; A61F 2002/30579; A61F 2002/30841; A61F 2002/448; A61F 2002/4642
USPC 606/246–249, 313, 90; 623/17.11, 17.13, 623/17.15, 17.16
See application file for complete search history.

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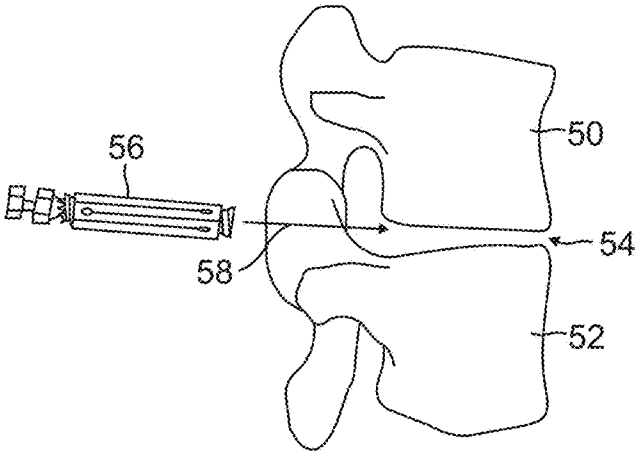

FIG. 1

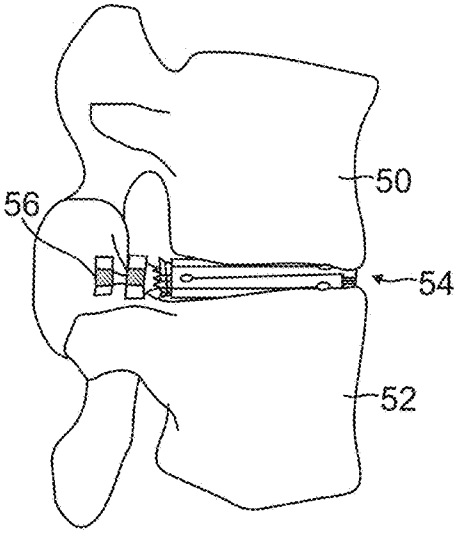

FIG. 2

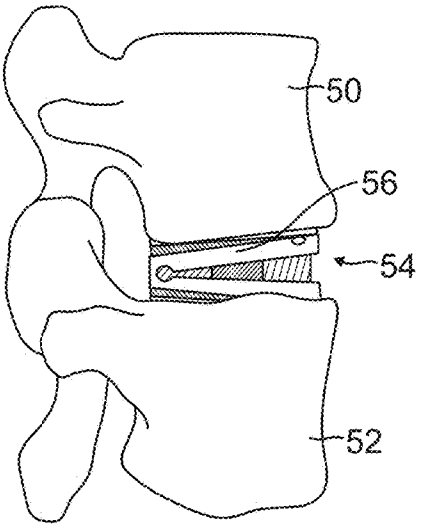

FIG. 3

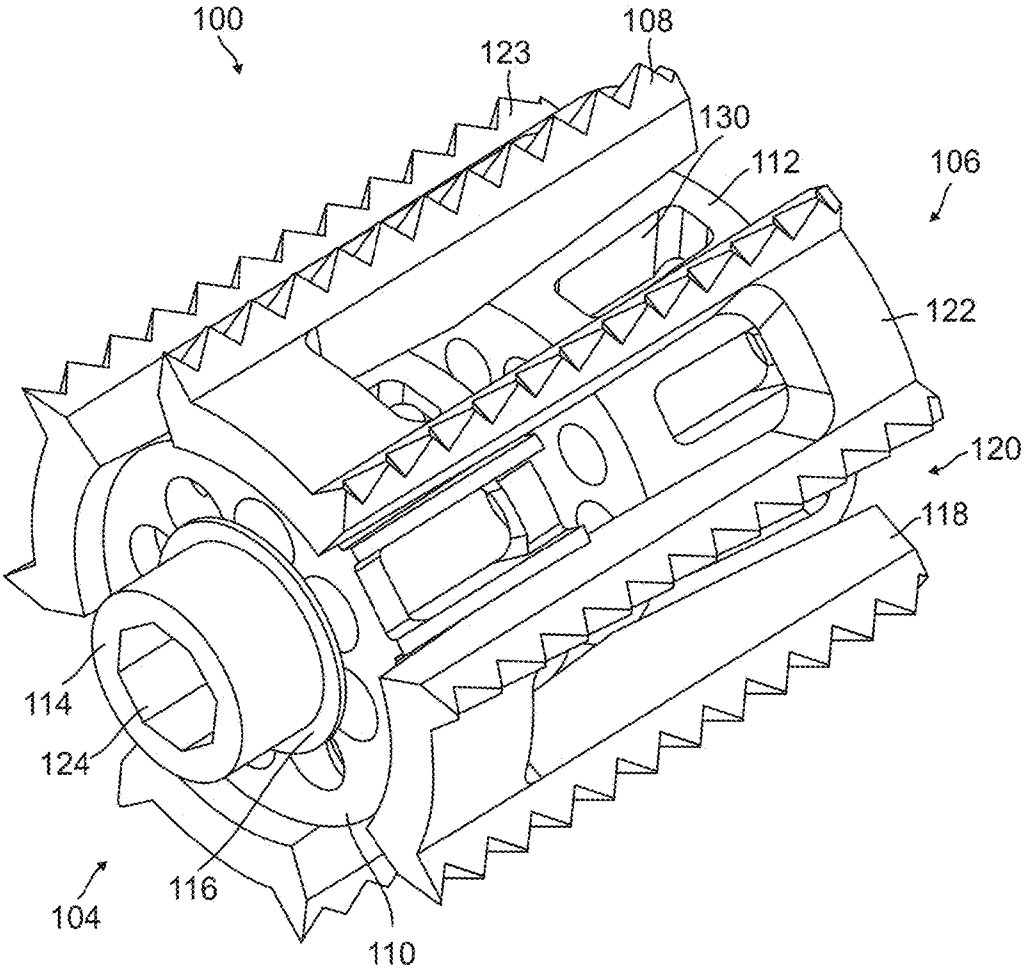

FIG. 4

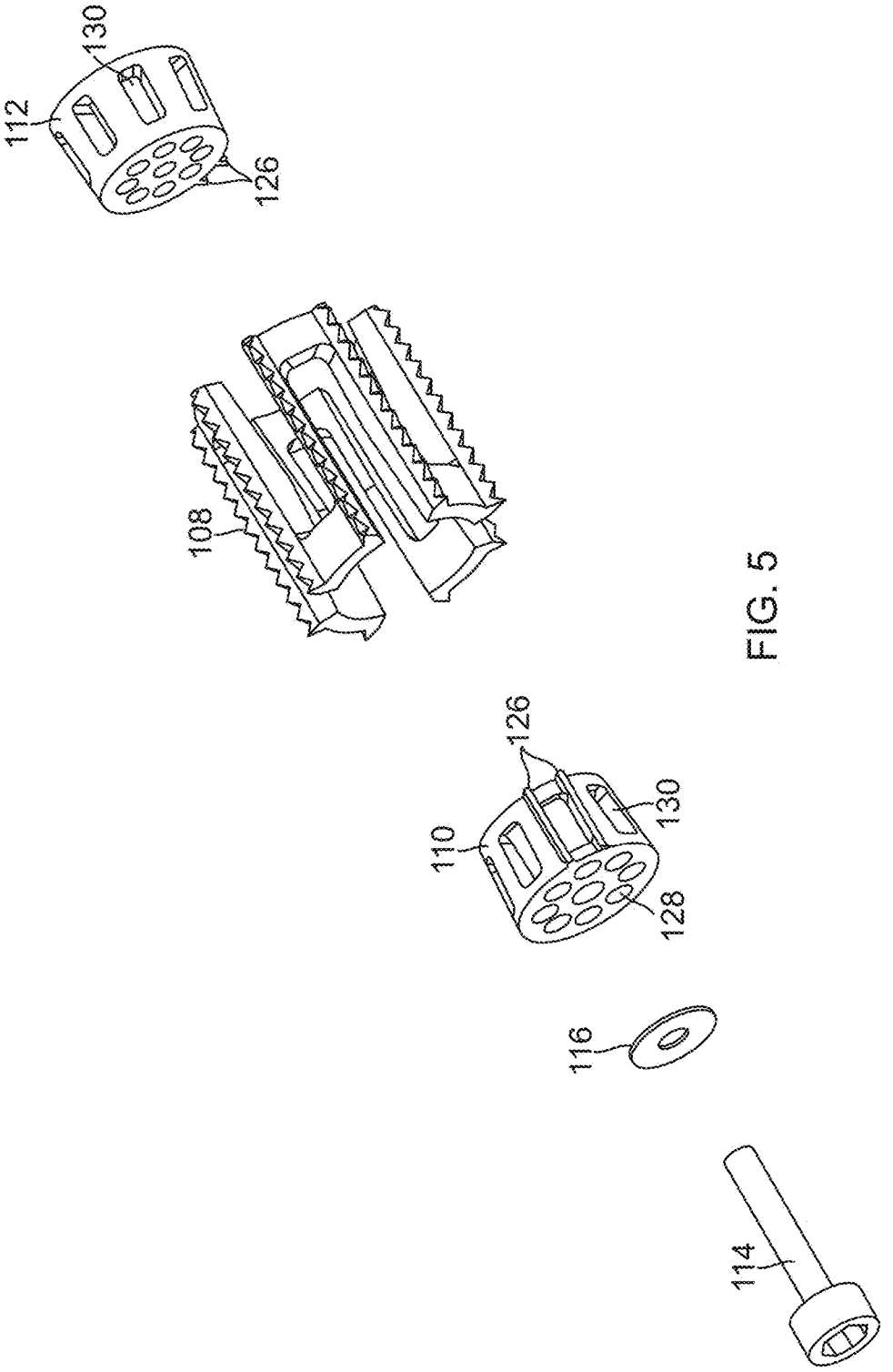

FIG. 5

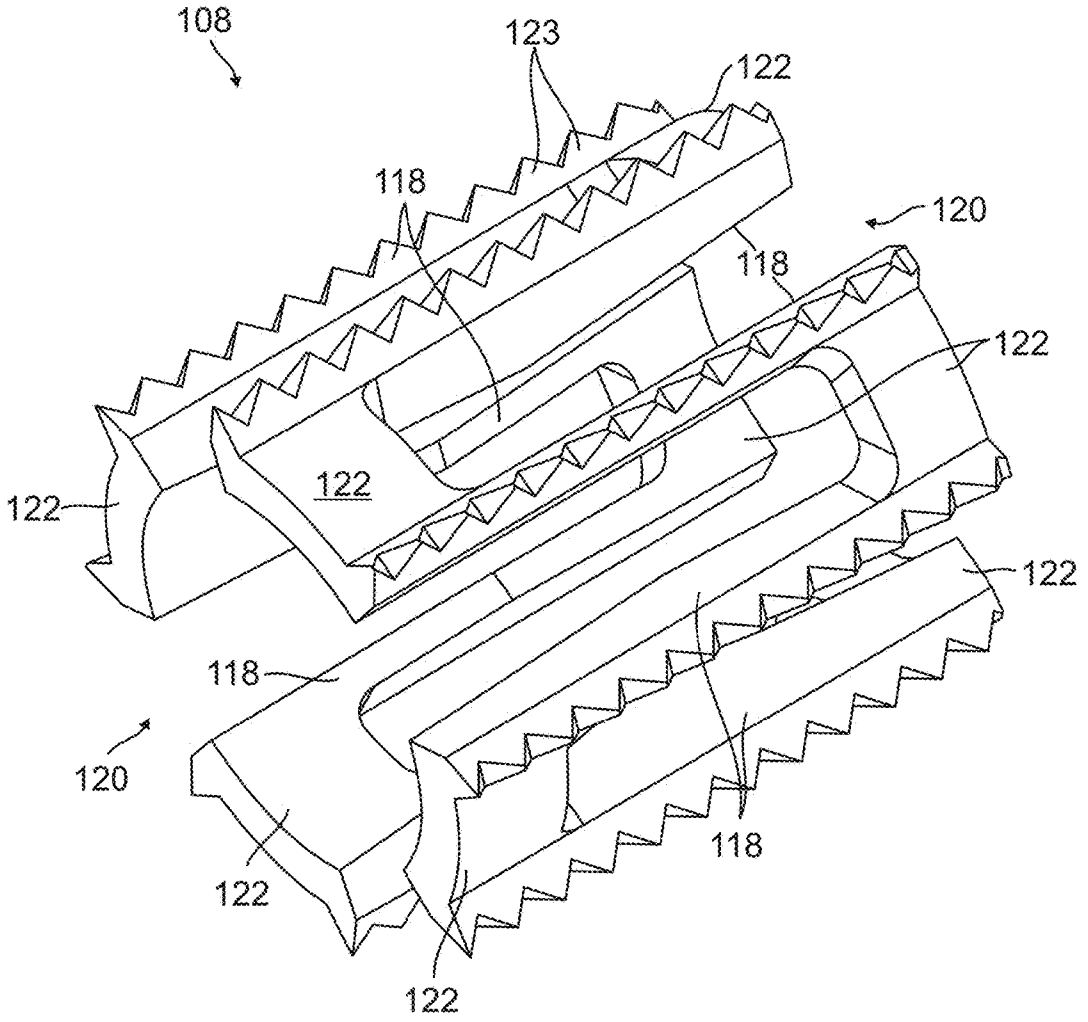

FIG. 6

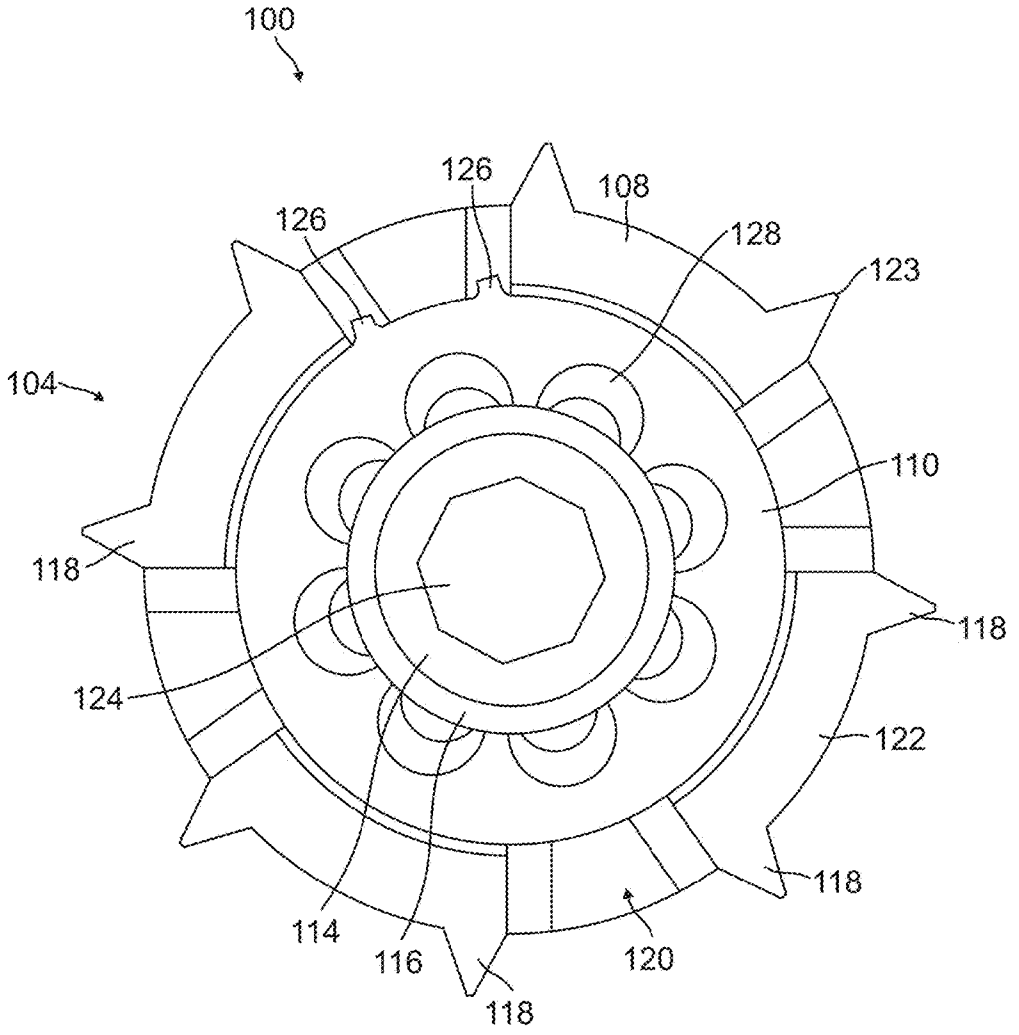
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FIG. 7

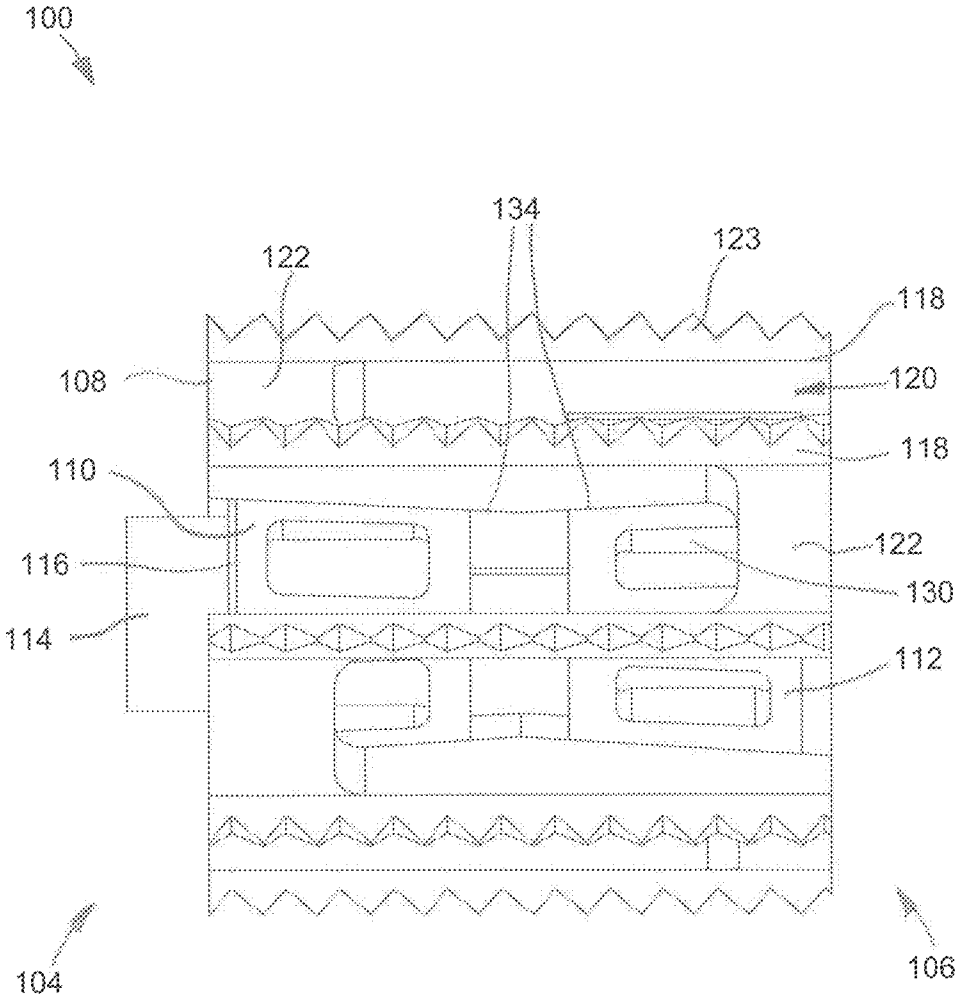

FIG. 8

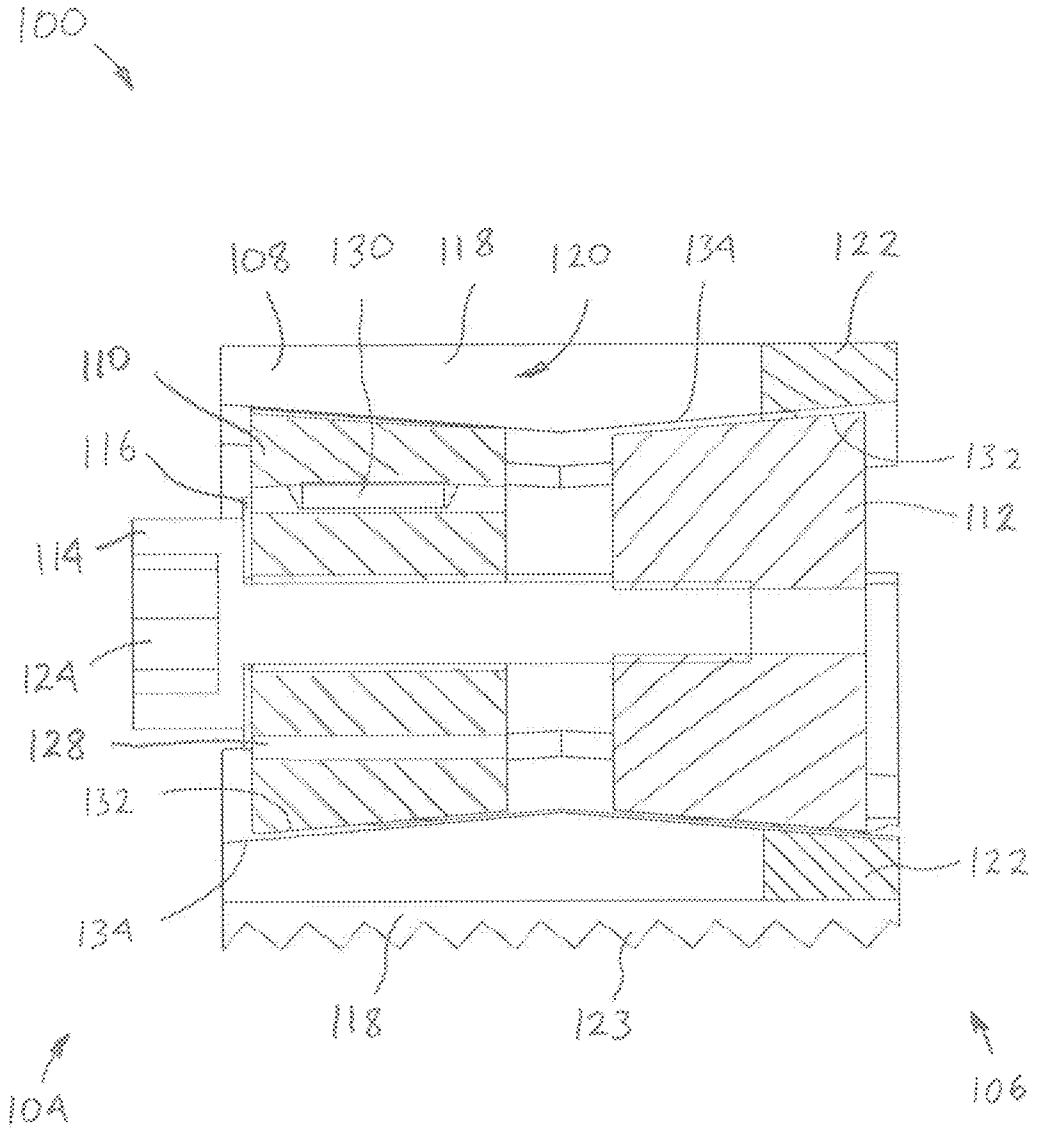
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FIG. 9

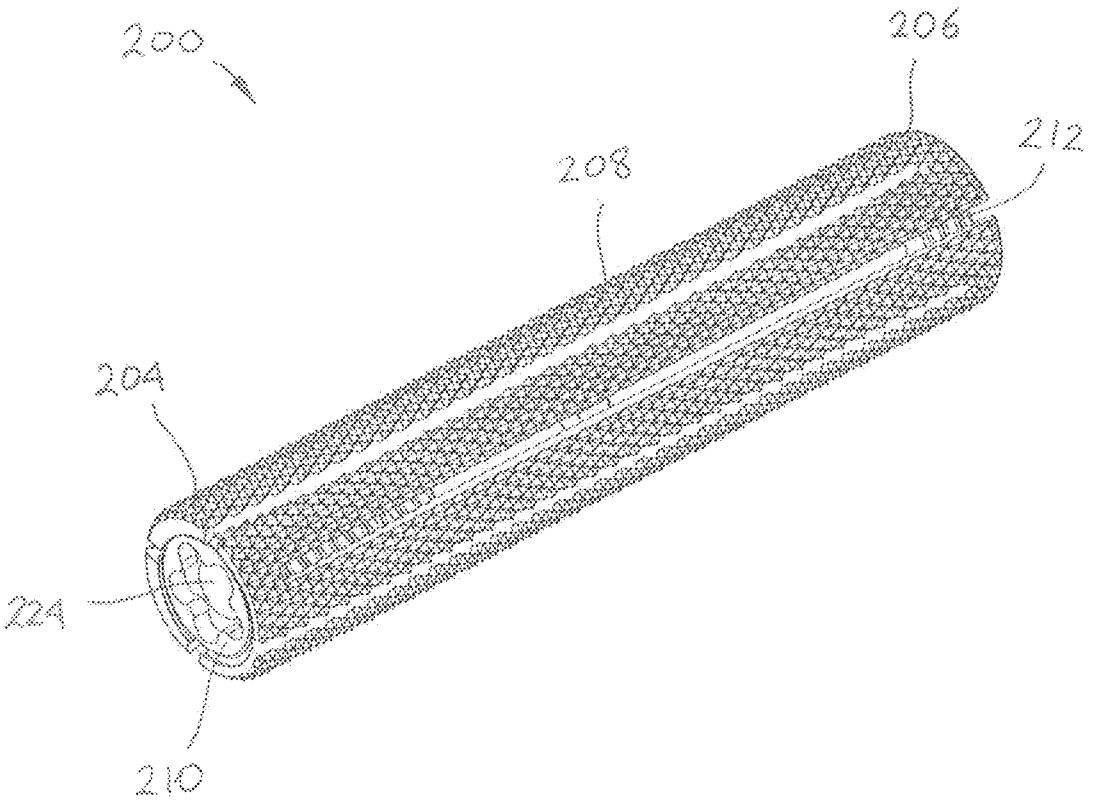

FIG. 10

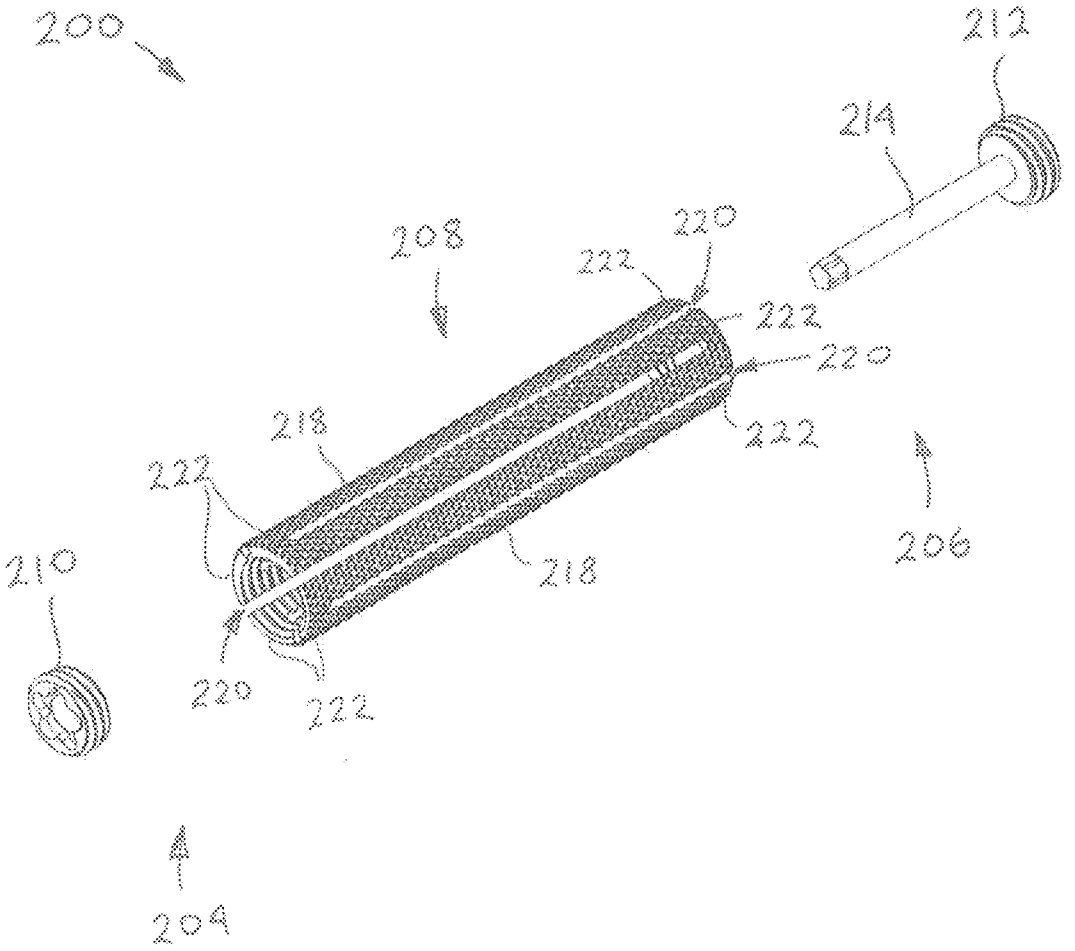
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FIG. 11

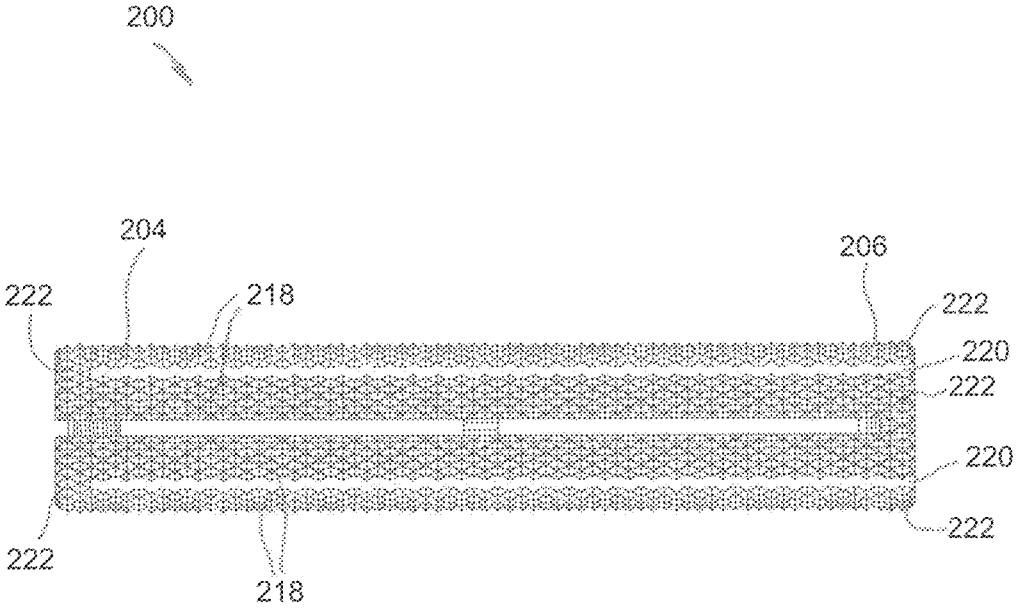

FIG. 12

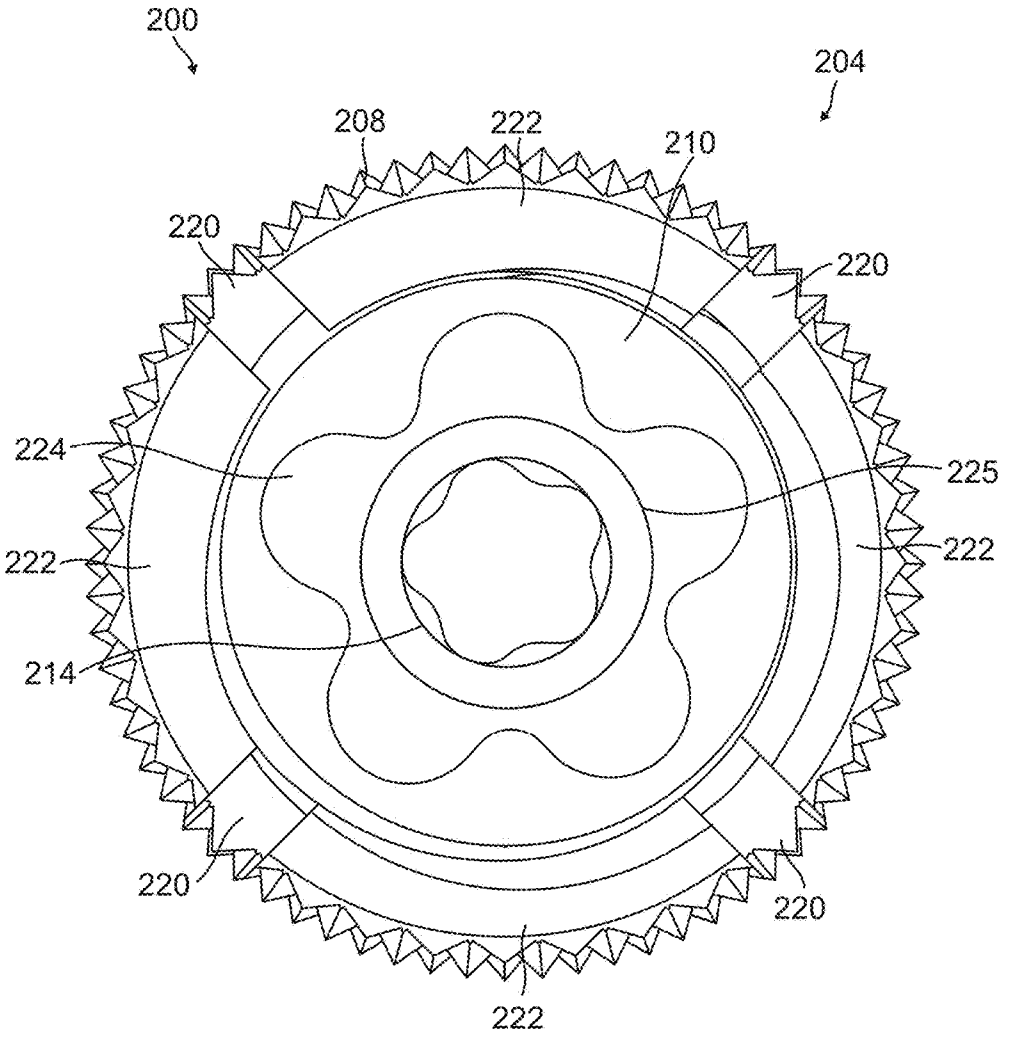

FIG. 13

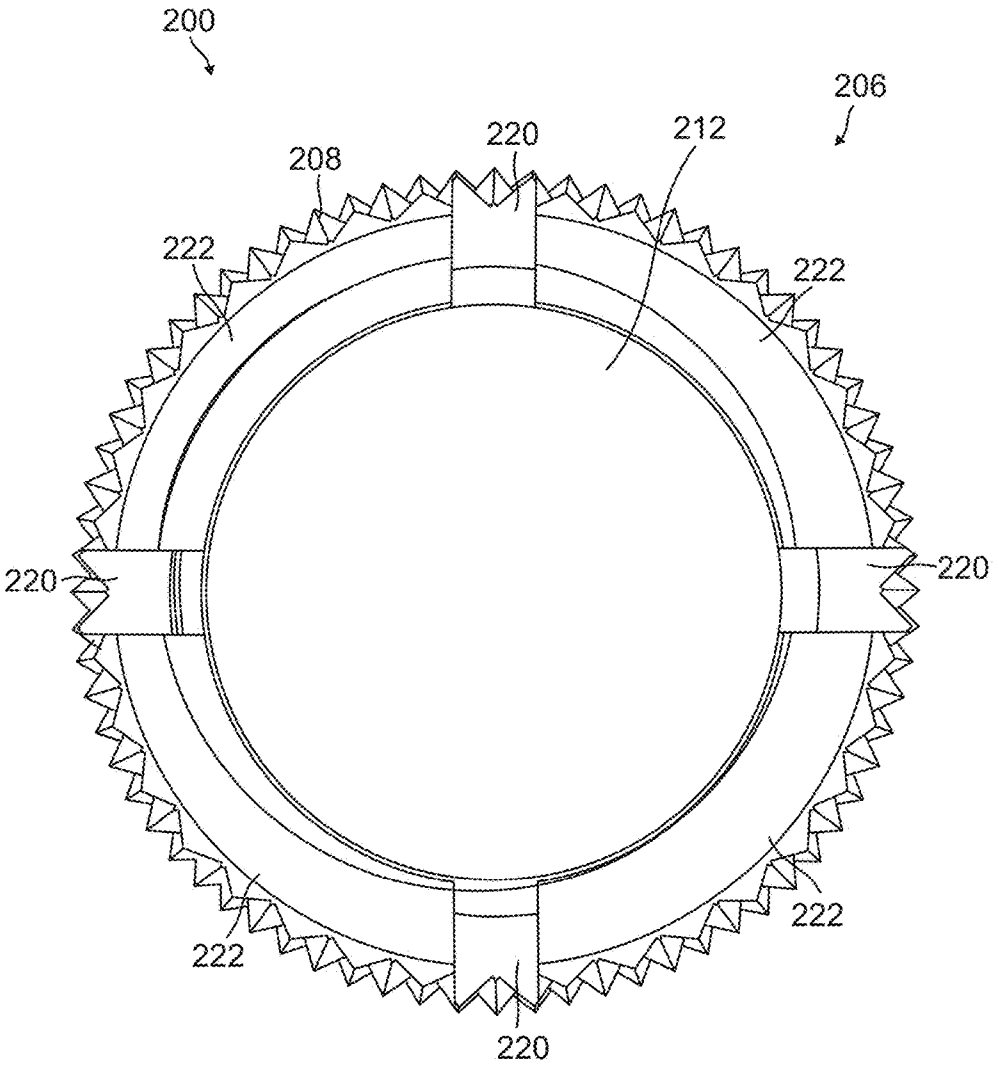

FIG. 14

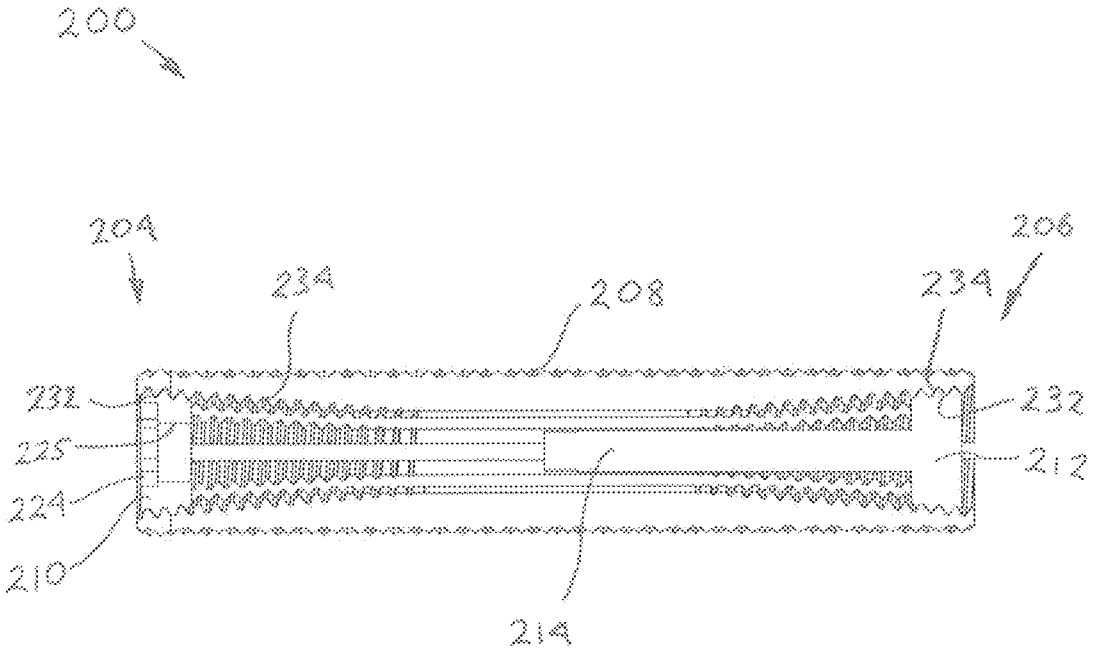

FIG. 15

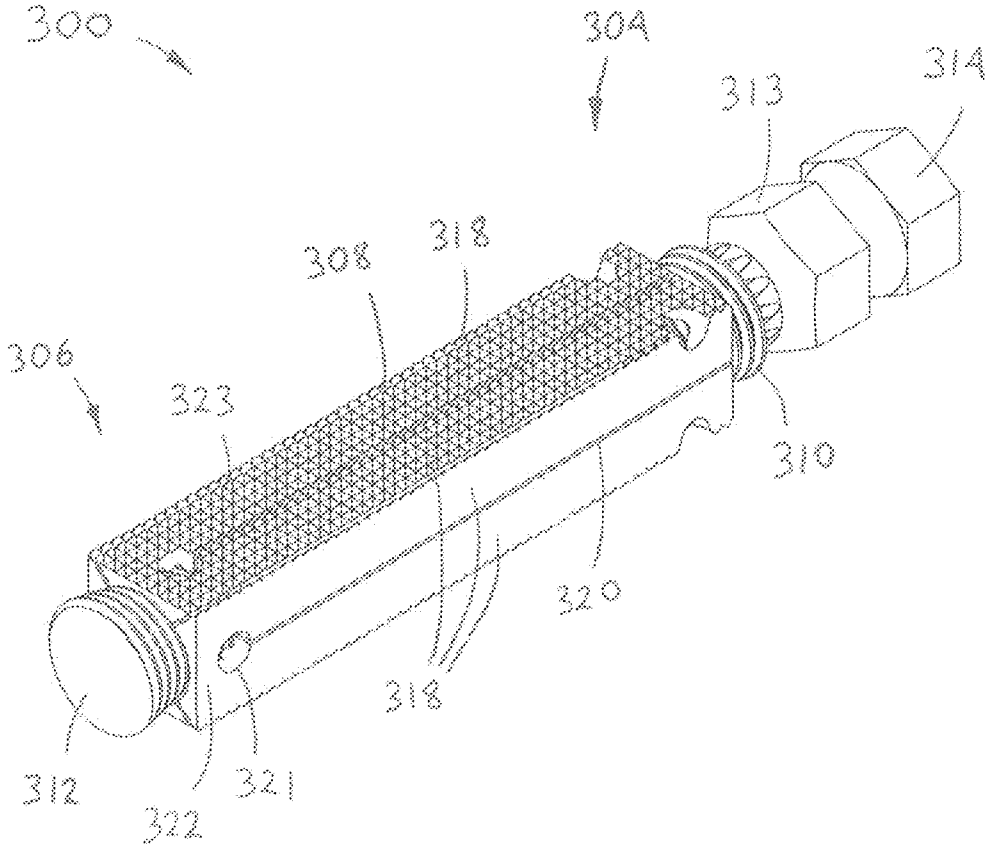

FIG. 16

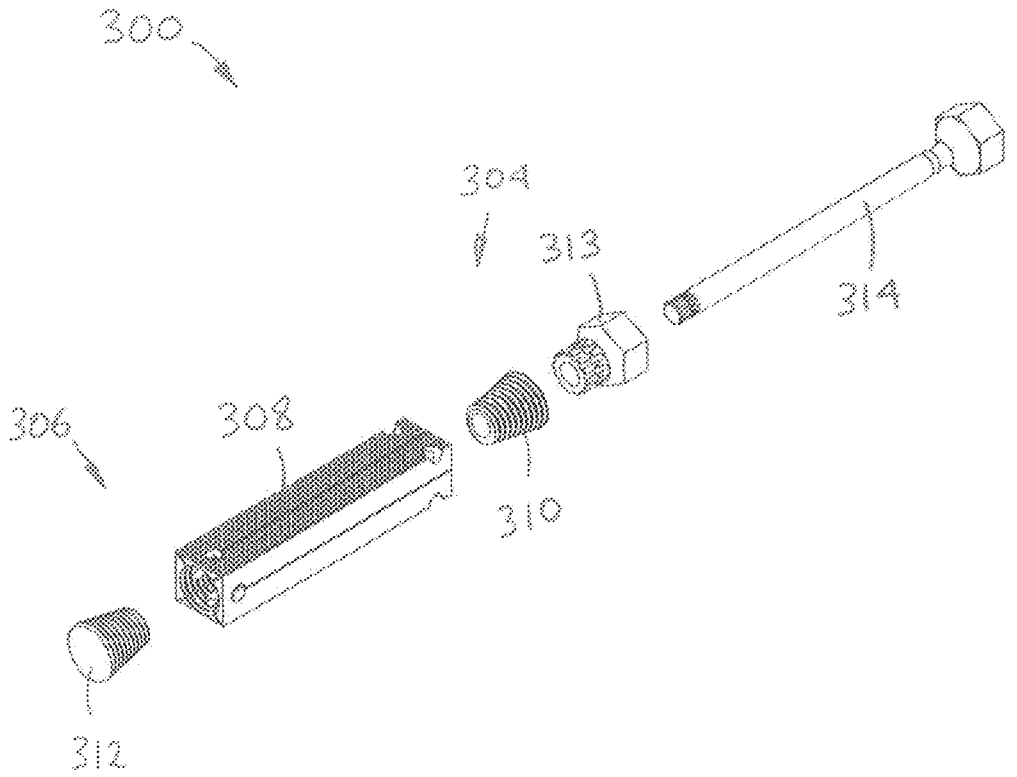

FIG. 17

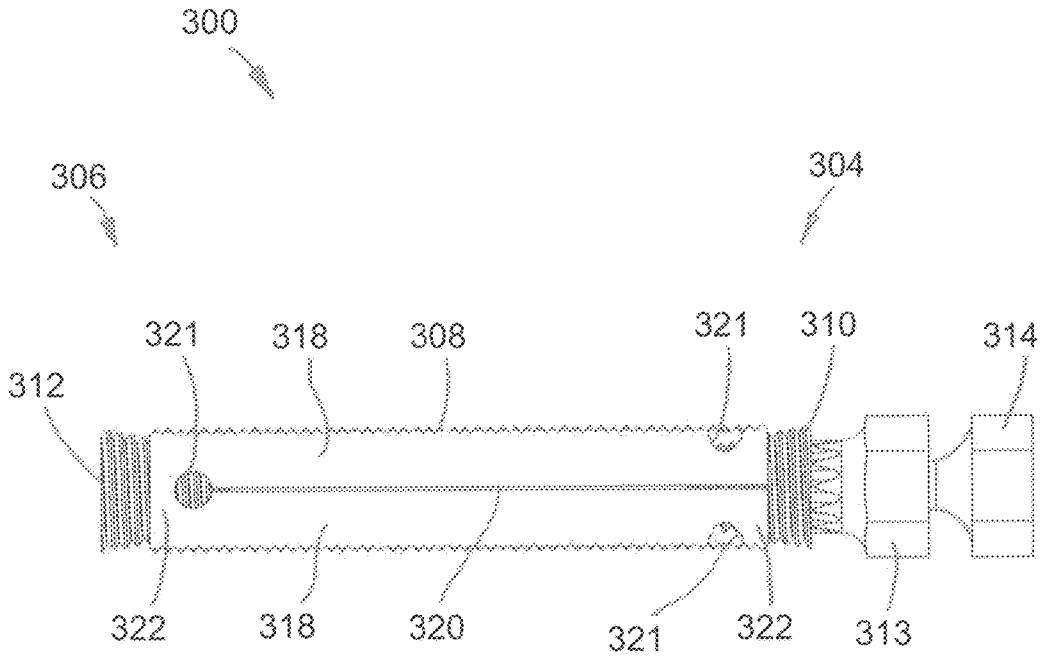

FIG. 18

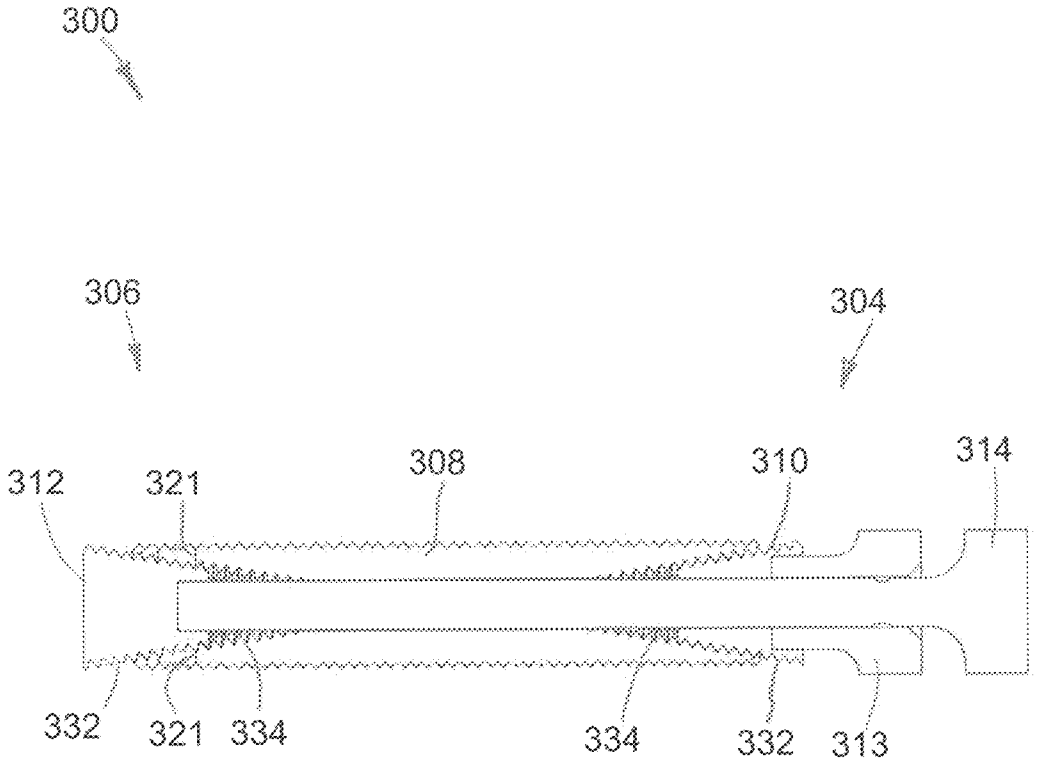

FIG. 19A

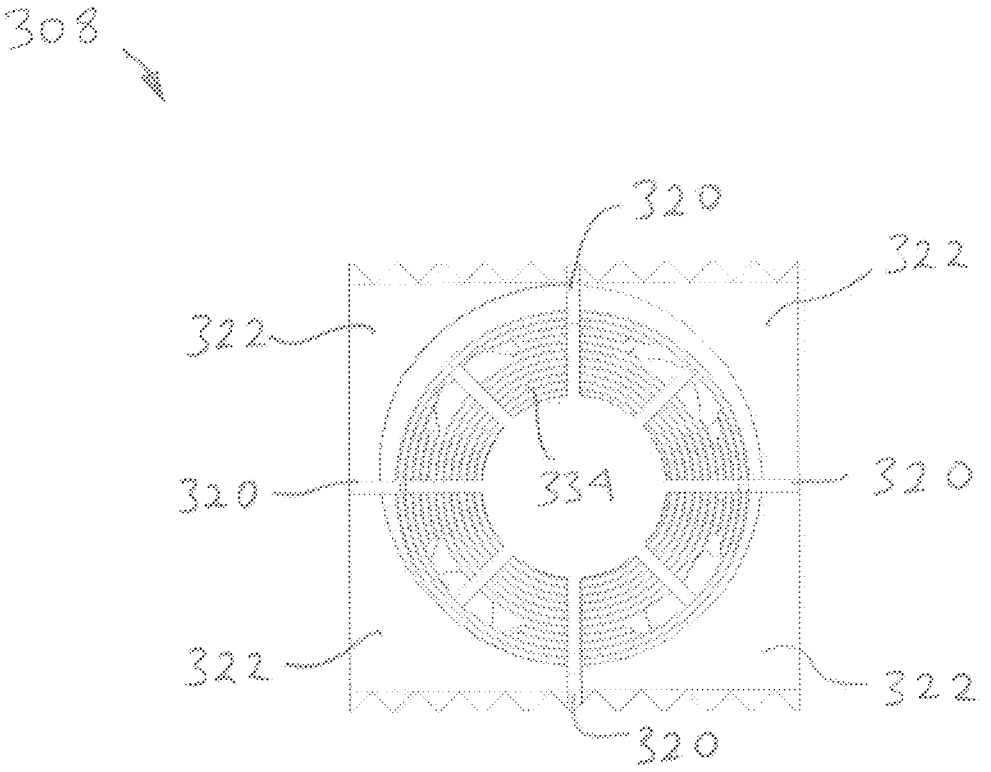

FIG. 19B

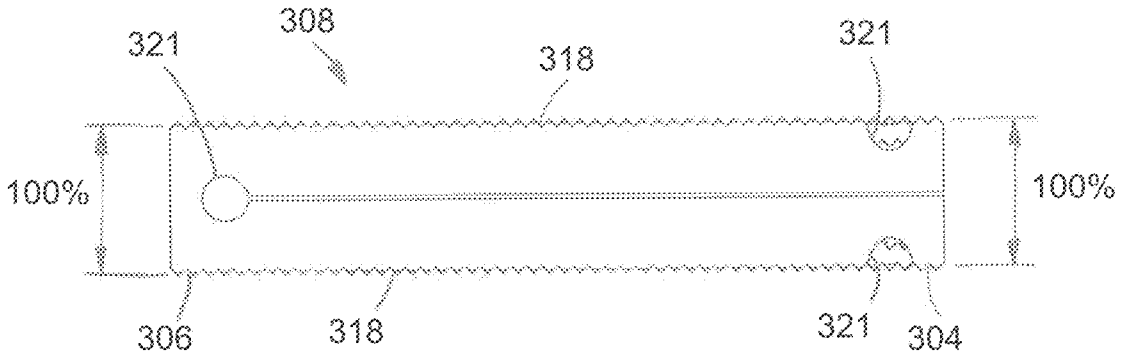

FIG. 20A

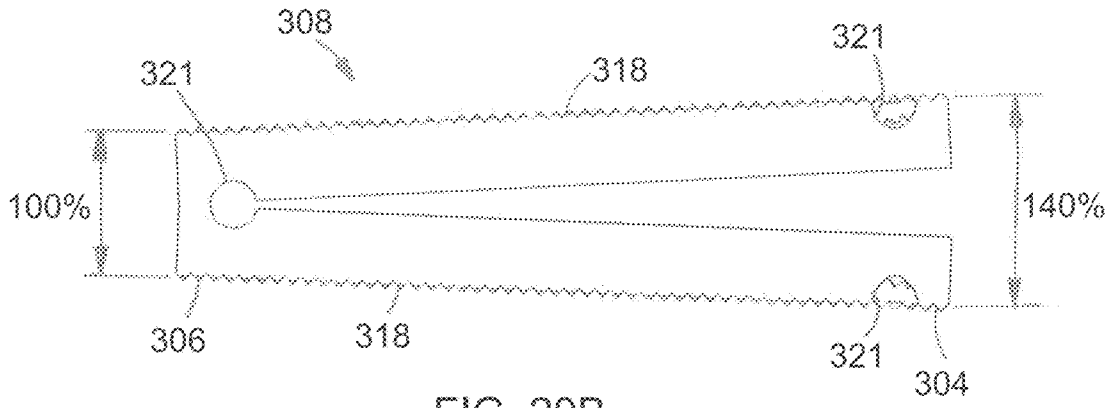

FIG. 20B

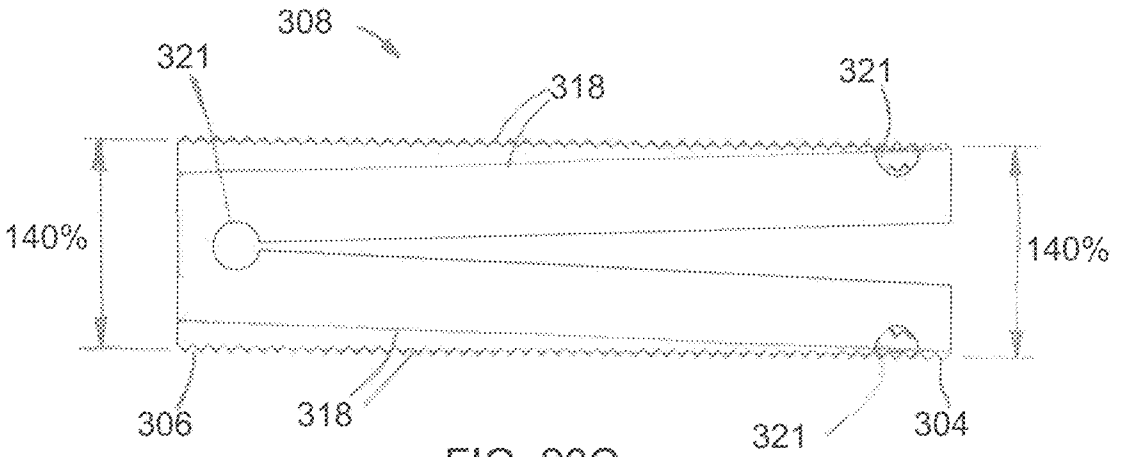

FIG. 20C

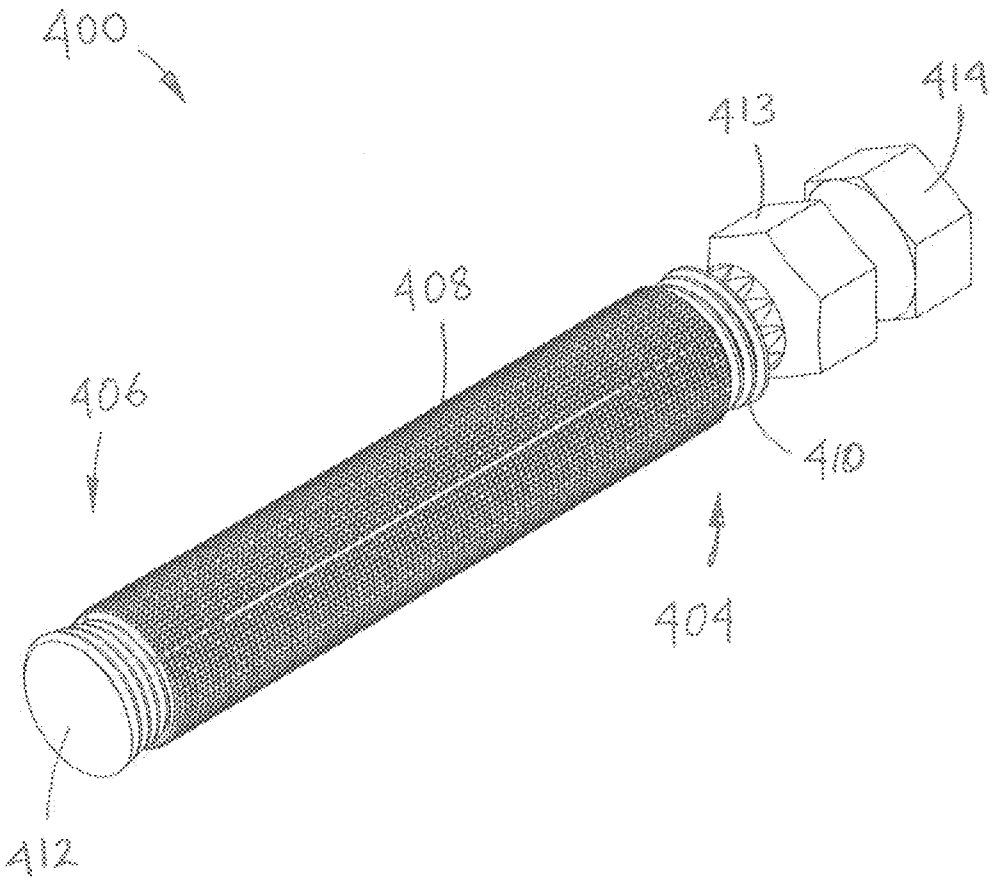

FIG 21

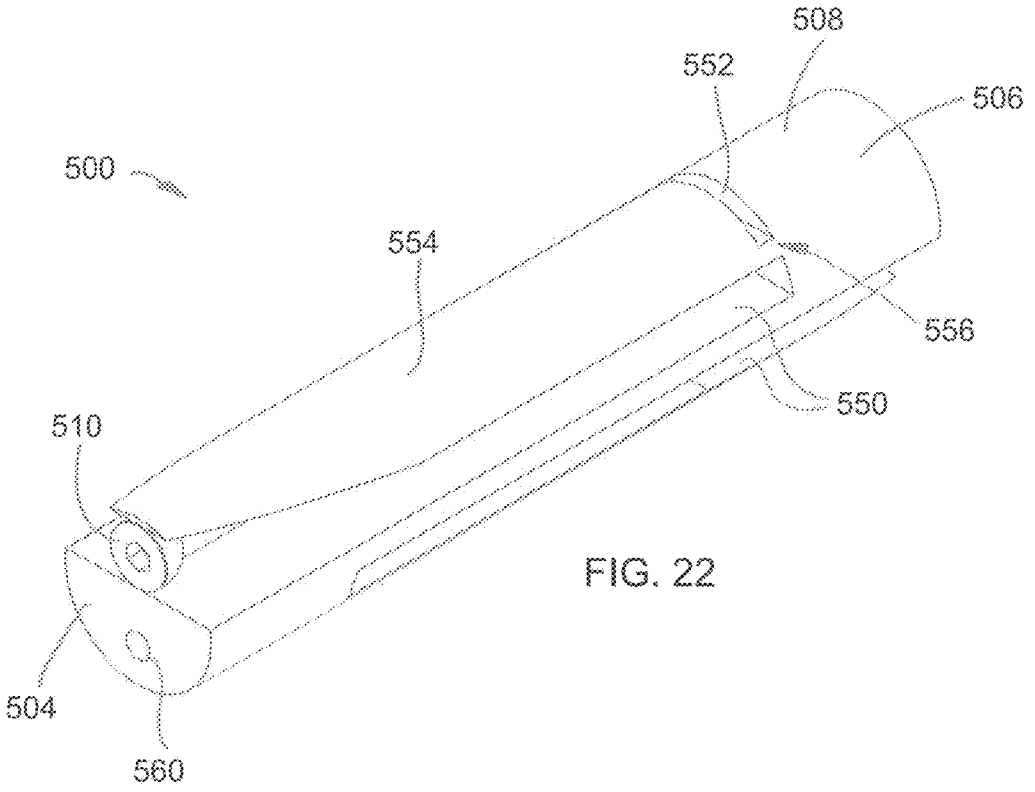
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FIG. 22

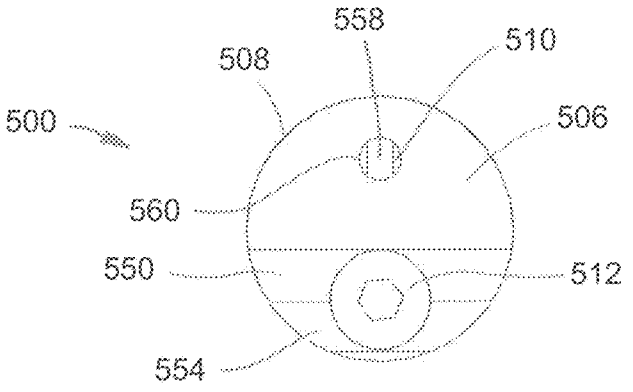
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FIG. 23

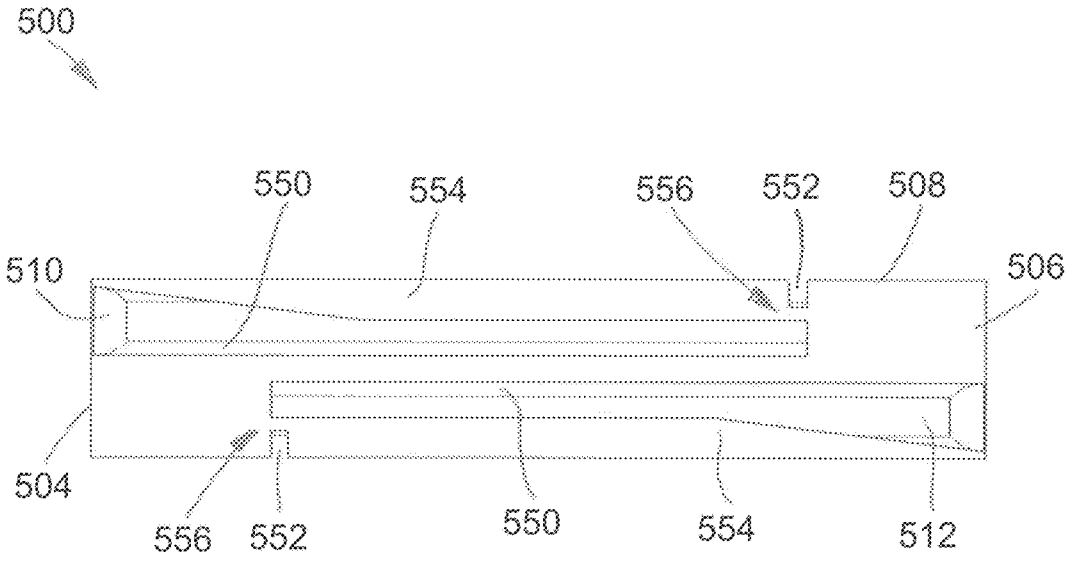
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FIG. 24

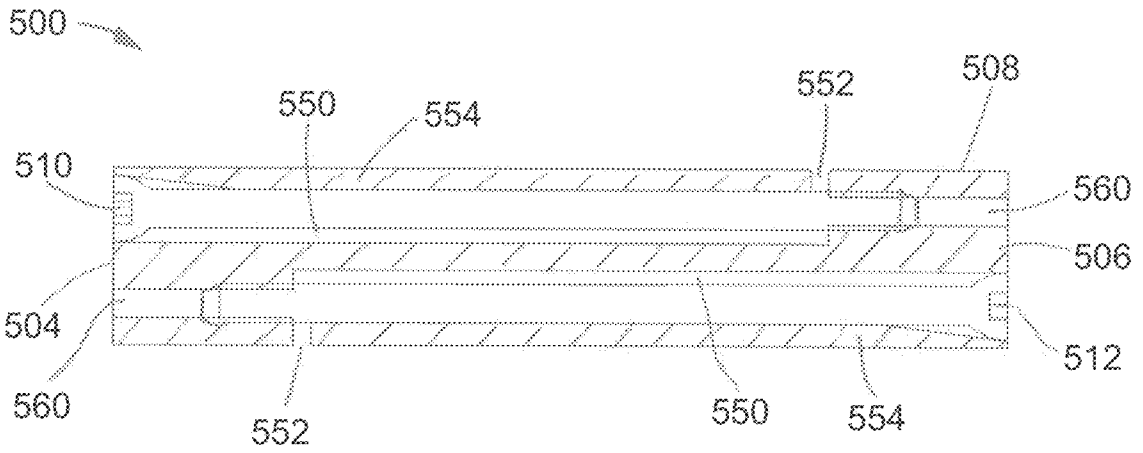
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FIG. 25

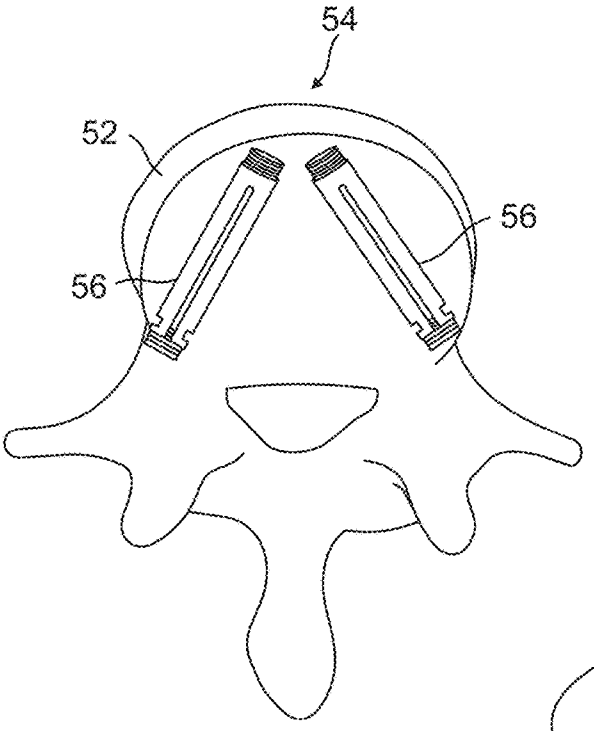

FIG. 26

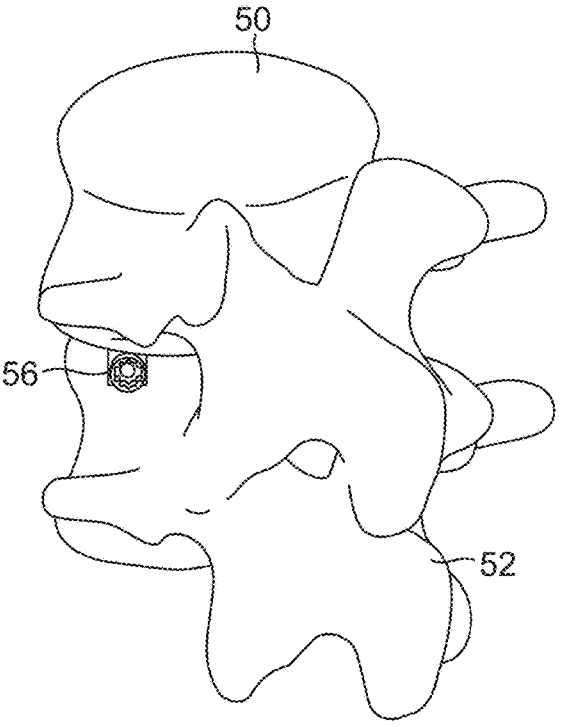

FIG. 27

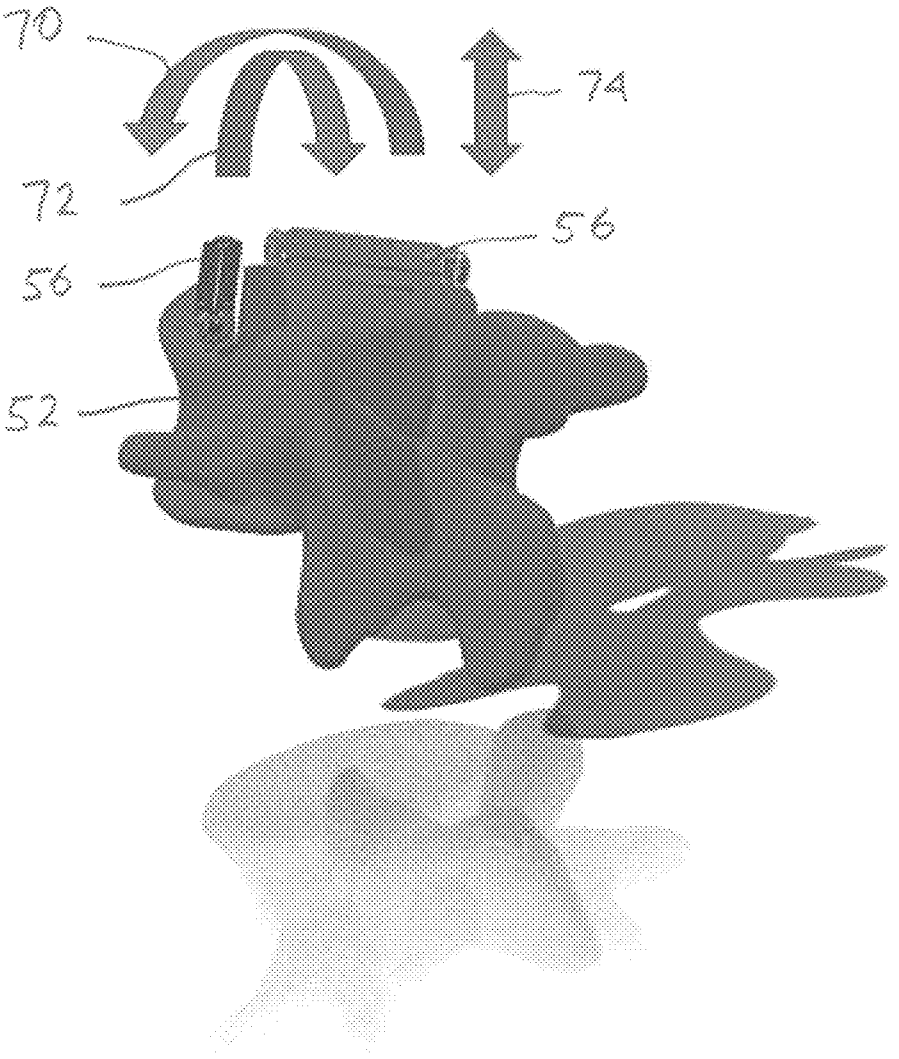

FIG. 28

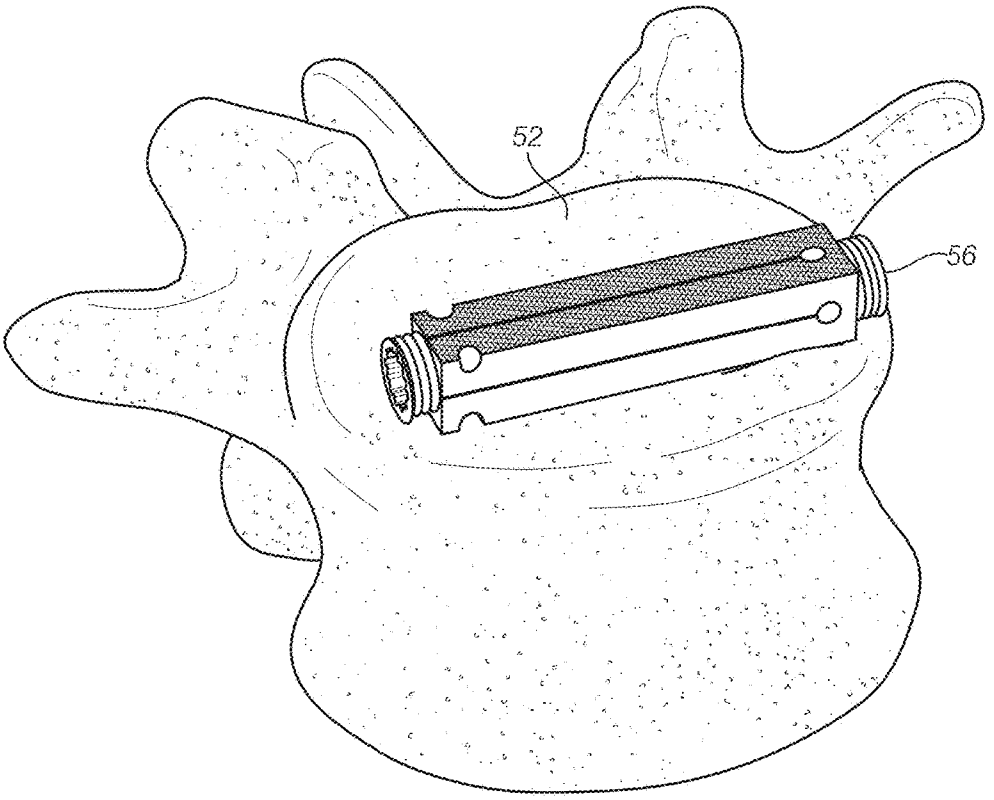

FIG. 29

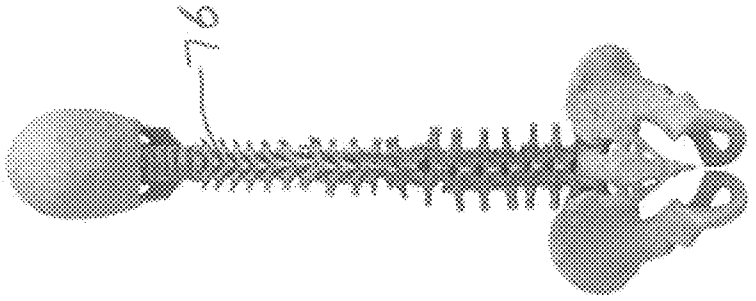

FIG. 31

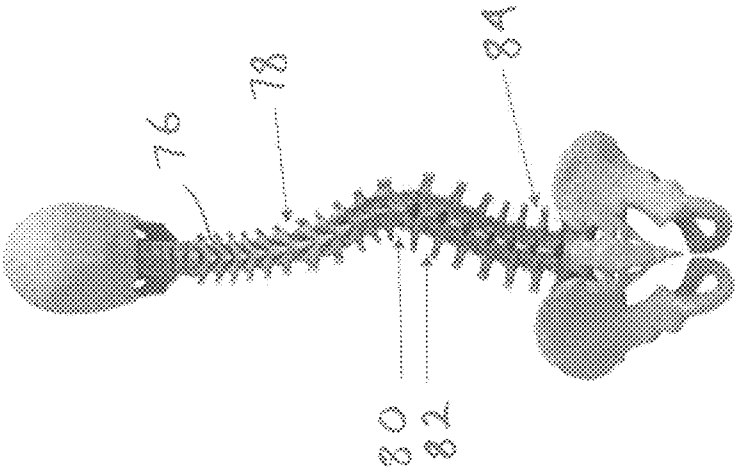

FIG. 30

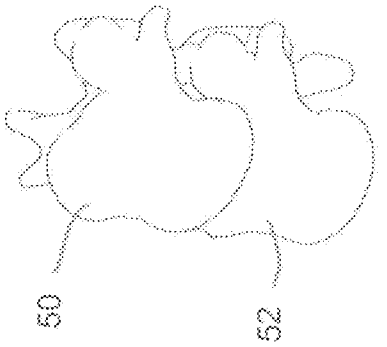

FIG. 32C

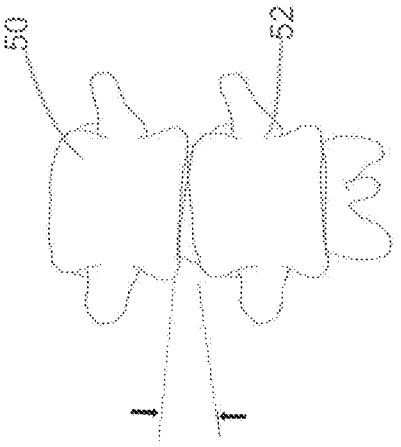

FIG. 32A

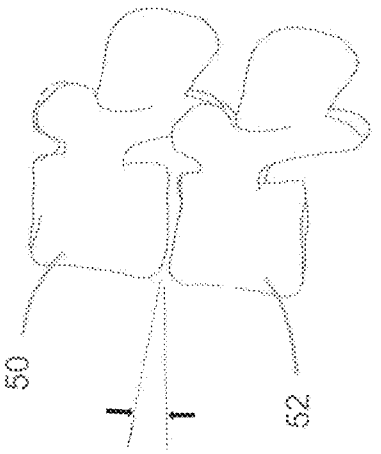

FIG. 32B

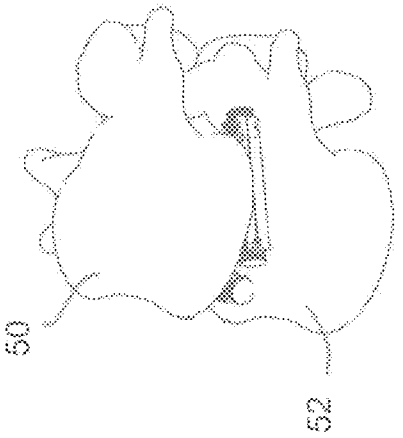

FIG. 33C

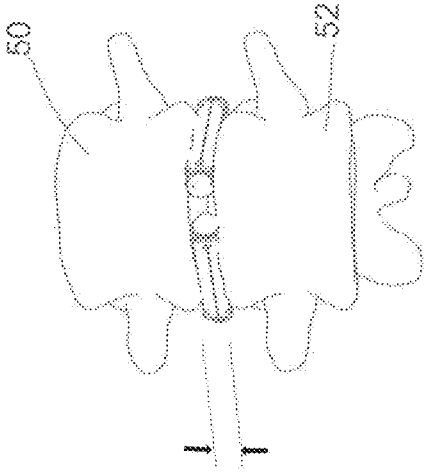

FIG. 33A

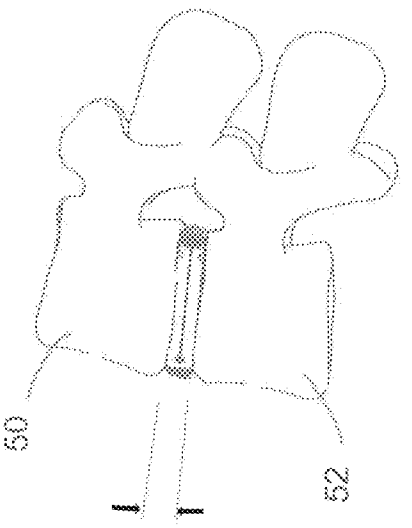

FIG. 33B

UNIVERSALLY EXPANDING CAGE

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims benefit of U.S. Non-provisional patent application Ser. No. 15/831,192 filed Dec. 4, 2017, which claims the benefit of U.S. Non-provisional patent application Ser. No. 15/668,650 filed Aug. 3, 2017, now U.S. Pat. No. 9,861,494 which claims the benefit of U.S. Non-provisional patent application Ser. No. 15/485,131 filed Apr. 11, 2017, now U.S. Pat. No. 9,872,778 which claims the benefit of U.S. non-provisional patent application Ser. No. 14/939,905 filed Nov. 12, 2015, now U.S. Pat. No. 9,622,878 which claims the benefit of U.S. Provisional Application No. 62/078,850 filed Nov. 12, 2014, all of which are incorporated herein by reference in their entirety.

INCORPORATION BY REFERENCE

All publications and patent applications mentioned in this specification are herein incorporated by reference in their entirety to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

FIELD

The present disclosure generally relates to medical devices for stabilizing the vertebral motion segment or other bone segments. More particularly, the field of the disclosure relates to a universally expanding cage (UEC) and method of use for providing controlled spinal correction or other bond segment spacing and/or alignment.

BACKGROUND

Conventional spine cages or implants are typically characterized by a kidney bean-shaped body comprising a hydroxyapatite-coated surface provided on the exterior surface for contact with adjacent vertebral segments or endplates which are shown in FIG. **1**. A conventional spine cage with flat endplates is typically inserted posterolaterally proximate to the neuroforamen of the distracted spine after a trial implant creates a pathway. Optionally two parallel externally threaded conduits are inserted anteriorly to achieve lumbar arthrodesis. The implants are often of constant diameter whereas the L5-S1 disc space is trapezoidal, thus a 'flat back' syndrome may be iatrogenically created. Generally spine intradiscal implants are for lumbar fusion or cervical motion preservation, while a separate system of rods and screws corrects alignment.

With the novel UECs disclosed herein, additional options include fusion throughout the spinal column, and deformity angular correction.

Existing devices for interbody stabilization have important and significant limitations. Among the limitations are an inability to expand and distract the endplates. Consequently, if a cage that is "to small" is inserted it can 'rattle around and never heal'. If the static cage is too big, it can injure adjacent nerves or destabilize the spine via end plate resection or subsidence.

Current devices for interbody stabilization include static spacers composed of titanium, PEEK, and high performance thermoplastic polymer produced by VICTREX, (Victrex USA Inc, 3A Caledon Court, Greenville, S.C. 29615), carbon fiber, or resorbable polymers. Current interbody spacers

may not maintain interbody lordosis and can contribute to the formation of a straight or even kyphotic segments and the clinical problem of "flatback syndrome." Separation of the endplates increases space available for the neural elements, specifically the neural foramen. Existing static cages do not reliably improve space for the neural elements. Therefore, what is needed is an expanding cage that will increase space for the neural elements posteriorly between the vertebral bodies, or at least maintain the natural bone contours to avoid neuropraxia (nerve stretch) or encroachment.

U.S. Pat. No. 7,985,256, filed Sep. 26, 2006 and titled "Selectively Expanding Spine Cage, Hydraulically Controllable in Three Dimensions for Enhanced Spinal Fusion", and U.S. Pat. No. 7,819,921, filed Oct. 31, 2007 and titled "Linearly expanding spine cage for enhanced spinal fusion", both provide detailed background on expanding spine cages.

The cages disclosed in U.S. Pat. No. 7,985,256 above are restricted to use with hydraulics, and lumbar fusion. The cage disclosed in U.S. Pat. No. 7,819,921 allows for trapezoidal linear expanding, not uniform expansion, thus a trapezoidal L5 cage as disclosed therein will preserve natural lumbar lordosis. The disclosed cage was never developed. It is intended for use as two (2) parallel linearly expanding split conduits inserted anteriorly for lumbar fusion.

In contrast, the UEC cages disclosed herein expands either uniformly, or at either end proximally or distally. Given the adjustment option the surgeon can correct angulation deformity with the novel UEC.

Another problem with conventional devices of interbody stabilization includes poor interface between bone and biomaterial. Conventional static interbody spacers form a weak interface between bone and biomaterial. Although the surface of such implants is typically provided with a series of ridges or coated with hydroxyapetite, the ridges may be in parallel with applied horizontal vectors or side-to-side motion. That is, the ridges or coatings offer little resistance to movement applied to either side of the endplates. Thus, nonunion is common in allograft, titanium and polymer spacers, due to motion between the implant and host bone. Conventional devices typically do not expand between adjacent vertebrae. Since the UEC expands under surgeon control, the visible, palpable 'goodness of fit' setting can ideal lock opposing vertebral endplates at the time of surgery. As healing accrues, the implants become inert. Since no motion equates with no pain, clinical results are improved with UECs.

Therefore, what is needed is a way to expand an implant to develop immediate fixation forces that can exceed the ultimate strength at healing, with improved abilities to enable disc space fixation solidarity while correcting spine angular deformity. Such an expandable implant ideally will maximize stability of the interface and enhance stable fixation. The immediate fixation of such an expandable interbody implant advantageously will provide stability that is similar to that achieved at the time of healing. Such an implant will have valuable implications enhancing early post-operative rehabilitation for the patient.

Another problem of conventional interbody spacers is their large diameter requiring wide exposure. Existing devices used for interbody spacers include structural allograft, threaded cages, cylindrical cages, and boomerang-shaped cages. Conventional devices have significant limitation with regard to safety and efficacy. Regarding safety of the interbody spacers, injury to neural and aortic elements may occur with placement from an anterior or posterior

approach. A conventional spine cage lacks the ability to expand, diminishing its fixation capabilities. Prior attempts to preserve lumbar motion have failed by extrusion of the implant after implantation. The risks to neural elements are primarily due to the disparity between the large size of the cage required to adequately support the interbody space, and the small space available for insertion of the device, especially when placed from a posterior or transforaminal approach. Existing boomerang cages are shaped like a partially flattened kidney bean. Their implantation requires a wide exposure and potential compromise of vascular and neural structures, both because of their inability to enter small and become larger, and due to the fact that their insertion requires mechanical manipulation during insertion and expanding of the implant. Once current boomerang implants are prepared for insertion via a trial spacer to make a pathway toward the anterior spinal column, the existing static cage is shoved toward the end point with the hope that it will reach a desired anatomic destination. Given the proximity of nerve roots and vascular structures to the insertion site, and the solid, relatively large size of conventional devices, such constraints predispose a patient to foraminal (nerve passage site) encroachment, and possible neural and vascular injury.

Therefore, what is needed is a minimally invasive expanding spine cage that is capable of insertion with minimal invasion into a smaller aperture. Such a minimally invasive spine cage advantageously could be expanded with completely positional control or adjustment in three dimensions. What is also needed is a smaller expanding spine cage that is easier to operatively insert into a patient with minimal surgical trauma in contrast to conventional, relatively large devices that create the needless trauma to nerve roots in the confined space of the vertebral region. Existing interbody implants have limited space available for bone graft. Adequate bone graft or bone graft substitute is critical for a solid interbody arthrodesis. It would be desirable to provide an expandable interbody cage that will permit a large volume of bone graft material to be placed within the cage and around it, to fill the intervertebral space. Additionally, conventional interbody implants lack the ability to stabilize endplates completely and prevent them from moving. Therefore, what is also needed is an expanding spine cage wherein the vertebral end plates are subject to forces that both distract them apart, and hold them from moving. Such an interbody cage would be capable of stabilization of the motion segment, thereby reducing micromotion, and discouraging pseudoarthrosis (incomplete fusion) and pain.

Ideally, what is needed is a spine cage or implant that is capable of increasing its expansion in height and angle, spreading to a calculated degree. Furthermore, what is needed is a spine cage that can adjust the amount of not only overall anterior posterior expansion, but also medial and lateral variable expansion so that both the normal lordotic curve is maintained, and adjustments can be made for scoliosis or bone defects. Such a spine cage or implant would permit restoration of normal spinal alignment after surgery and hold the spine segments together rigidly, mechanically, until healing occurs.

What is also needed is an expanding cage or implant that is capable of holding the vertebral or joint sections with increased pullout strength to minimize the chance of implant fixation loss during the period when the implant is becoming incorporated into the arthrodesis bone block.

SUMMARY OF THE DISCLOSURE

According to some aspects of the disclosure, an expandable medical implant is provided with an implantable cage body having a proximal end and a distal end.

An expandable medical implant comprising: a cage body comprising a distal end and a proximal end; a central channel or a central bore; and an actuator comprising: a distal end configured to mate with a distal expansion means; and a proximal end configured to mate with a first adjustment tool; wherein the actuator is positioned through the central channel and when rotated in a first direction causes an expansion in the distal end of the cage body and when rotated in a second direction causes a contraction in the distal end of the cage body.

In some embodiments, the cage body has a central bore or channel. In a preferred embodiment, the actuator is accommodated by the central channel of the cage body and coaxial therewith. In a preferred embodiment, the actuator is also accommodated by a proximal expansion means. In one embodiment, the proximal expansion means is a plug. In another embodiment, the actuator is coaxially accommodated by a central opening in the proximal expansion means. In another embodiment, the actuator is coaxially accommodated by a central opening in the proximal expansion means through which central opening the actuator passes to meet with and engage with a distal expansion means. In one embodiment, the distal expansion means is a plug. In one embodiment, a second adjustment tool is configured to engage with the proximal expansion means. In another embodiment, the proximal expansion means comprises a central bore which is configured to engage with a second adjustment tool. In another preferred embodiment, the second adjustment tool is configured to actuate the proximal expansion means. In some aspects, the proximal expansion means causes expansion or contraction of the proximal bone engaging surfaces of the cage body.

In another aspect, the invention provides an expandable medical implant comprising a proximal expansion means. In one embodiment, the proximal expansion means is configured to cause expansion or contraction of the bone engaging surfaces of the proximal part of the cage body. In another aspect, the invention provides an expandable medical implant comprising a distal expansion means. The distal expansion means causes expansion or contraction of the distal bone engaging surfaces of the cage body.

In some embodiments, the expandable medical implant has a first and second adjustment tool. In some embodiments, the first and/or second adjustment tools are manipulated by a surgeon. In some embodiments, the first and/or second adjustment tools are manipulated by another tool used by the surgeon. In a preferred embodiment, the adjustment tools are configured to engage directly or indirectly the expansion means.

The expandable medical implant of claim **1**, wherein the actuator is threaded.

In some embodiments, the proximal and distal ends of the cage body are each provided with a tapered or cam portion. The cage body further has a longitudinal axis extending between the proximal end and the distal end of the cage body. The implant may further comprise at least one proximal flexure at least partially located adjacent to the proximal end of the cage body and configured to allow a circumference of the distal end of the cage body to resiliently expand. The implant may further comprise at least one distal flexure at least partially located adjacent to the distal end of the cage body and configured to allow a circumference of the proximal end of the cage body to resiliently expand. The implant may further comprise a proximal plug member having a tapered portion configured to mate with the tapered portion of the proximal end of the cage body. The proximal plug member may be configured to move longitudinally relative

to the cage body from a first position to a second position such that the at least one distal flexure moves and the circumference of the proximal end of the cage body resiliently expands. The proximal plug member may also be configured to move from the second position to the first position such that the circumference of the proximal end resiliently contracts. The implant may further comprise a distal plug member having a tapered portion configured to mate with the tapered portion of the distal end of the cage body. The distal plug member may be configured to move longitudinally relative to the cage body from a third position to a fourth position such that the at least one proximal flexure moves and the circumference of the distal end of the cage body resiliently expands. The distal plug member may also be configured to move from the fourth position to the third position such that the circumference of the distal end resiliently contracts.

In some embodiments, the cage body further comprises a first tapered bore at the proximal end configured to slidably receive the proximal plug member, and a second tapered bore at the distal end configured to slidably receive the distal plug member. The first tapered bore may threadably engage the proximal plug member such that when the proximal plug member is rotated relative to the cage body, the proximal plug member advances in a longitudinal direction relative to the cage body. The second tapered bore may threadably engage the distal plug member such that when the distal plug member is rotated relative to the cage body, the distal plug member advances in a longitudinal direction relative to the cage body.

In some embodiments, the at least one proximal flexure comprises a generally circular and open ended aperture and a pair of generally flexible beam portions extending longitudinally from the aperture. The at least one proximal flexure may include a pair of longitudinally extending beam portions separated by a longitudinally extending gap, wherein the at least one proximal flexure further comprises a connector portion interconnecting proximal ends of the beam portions. The at least one proximal flexure may include a plurality of circumferentially spaced proximal flexures, and the at least one distal flexure may include a plurality of circumferentially spaced distal flexures. The plurality of proximal flexures may be rotationally staggered from the plurality of distal flexures.

In some embodiments, each of the proximal flexures includes a pair of longitudinally extending beam portions separated by a longitudinally extending gap and bridged together by a connector portion interconnecting only proximal ends of the beam portions. Each of the distal flexures may include a pair of longitudinally extending beam portions separated by a longitudinally extending gap and bridged together by a connector portion interconnecting only distal ends of the beam portions. Each of the proximal flexures can share a beam portion with two of the distal flexures that are adjacent to each proximal flexure, thereby forming a continuous serpentine pattern along the cage body.

In some embodiments, the implant includes a first adjustment member coupled to at least the proximal plug member such that when the first adjustment member is rotated, the proximal plug member is caused to move longitudinally. The implant may further include a second adjustment member coupled to the distal plug member such that when the second adjustment member is rotated, the distal plug member is caused to move longitudinally, thereby allowing the proximal and the distal ends of the cage body to be expanded and contracted independent from one another. The first and the second adjustment members may be coaxially nested one within the other and independently rotatable. In some embodiments, the first and the second adjustment members each have knobs axially spaced but adjacent to one another such that the knobs may alternately be rotated in unison or individually. At least one of the first and the second adjustment members may have a keyed end configured to slidably mate and rotationally couple with its associated plug member such that the at least one adjustment member can be removed from the expandable medical implant.

In some embodiments, the cage body has a square or circular cross-section transverse to the longitudinal axis.

In some embodiments, an expandable medical implant includes an implantable cage, a plurality of proximal flexures, a plurality of distal flexures, a proximal plug member, a distal plug member, and first and second adjustment members. In these embodiments, the implantable cage body has a proximal end and a distal end each provided with a threaded and tapered bore. The cage body has a longitudinal axis extending between the proximal end and the distal end of the cage body. The plurality of proximal flexures are circumferentially spaced and each is at least partially located adjacent to the proximal end of the cage body and configured to allow a circumference of the distal end of the cage body to resiliently expand. Each of the proximal flexures comprises a pair of longitudinally extending beam portions separated by a longitudinally extending gap and bridged together by a connector portion interconnecting only proximal ends of the beam portions. The plurality of distal flexures are circumferentially spaced and each is at least partially located adjacent to the distal end of the cage body and configured to allow a circumference of the proximal end of the cage body to resiliently expand. Each of the distal flexures comprises a pair of longitudinally extending beam portions separated by a longitudinally extending gap and bridged together by a connector portion interconnecting only distal ends of the beam portions. Each of the proximal flexures shares a beam portion with two of the distal flexures that are adjacent to each proximal flexure, thereby forming a continuous serpentine pattern along the cage body. The proximal plug member has a threaded and tapered circumference configured to mate with the threaded and tapered bore of the proximal end of the cage body. The proximal plug member is configured to move along the longitudinal axis relative to the cage body from a first position to a second position such that the plurality of distal flexures move and the circumference of the proximal end of the cage body resiliently expands. The proximal plug member is also configured to move from the second position to the first position such that the circumference of the proximal end resiliently contracts. The distal plug member has a threaded and tapered circumference configured to mate with the threaded and tapered bore of the distal end of the cage body. The distal plug member is configured to move along the longitudinal axis relative to the cage body from a third position to a fourth position such that the plurality of proximal flexures move and the circumference of the distal end of the cage body resiliently expands. The distal plug member is also configured to move from the fourth position to the third position such that the circumference of the distal end resiliently contracts. The first adjustment member is rotationally coupled to the proximal plug member such that when the first adjustment member is rotated, the proximal plug member is caused to move along the longitudinal axis. The second adjustment member rotationally coupled to the distal plug member such that when the second adjustment member is rotated, the distal plug member is caused to move longitudinally, thereby allowing the proximal and the distal

ends of the cage body to be expanded and contracted independent from one another. The first and the second adjustment members are coaxially nested one within the other and independently rotatable. The first and the second adjustment members each have knobs axially spaced but adjacent to one another such that the knobs may alternately be rotated in unison or individually. At least one of the first and the second adjustment members may have a keyed end configured to slidably mate and rotationally couple with its associated plug member such that the at least one adjustment member can be removed from the expandable medical implant.

According to some aspects of the disclosure, a method of distracting adjacent bone segments having opposing surfaces is provided. The method comprises the steps of inserting an expandable medical implant as described above between the opposing surfaces of the bone segments, and moving the proximal and the distal plug members longitudinally and independently from one another such that the proximal and the distal ends of the cage body expand independently to alter the distance and the angle between the opposing surfaces of the bone segments. In some embodiments, the method further includes the step of removing at least one adjustment member from the medical implant after the adjustment member has been used to move at least one of the proximal and distal plug members. In some embodiments, the bone segments are adjacent vertebrae, and the opposing surfaces are end plates of the adjacent vertebrae.

In some embodiments, the implant includes a proximal end, a distal end, a first adjustment tool and a second adjustment tool wherein the first adjustment tool adjusts one of the proximal end or the distal end of the implant and the second adjustment tool adjusts the other of the proximal end of the implant or the distal end of the implant wherein the first adjustment tool and the second adjustment tool are located at the proximal end of the implant and the first adjustment tool and the second adjustment tool are coaxially nested one within the other and independently rotatable.

In other embodiments, the first adjustment tool adjusts for expansion or contraction of the proximal end of the implant. In some embodiments, the second adjustment tool adjusts for expansion or contraction of the distal end of the implant. In other embodiments, the implant further comprises a cage body, at least one proximal flexure and at least one distal flexure such that the proximal flexure shares a beam portion of the cage body with a distal flexure to form a continuous serpentine pattern along the cage body.

In some aspects, the implant includes a proximal end which is capable of independent resilient expansion by means of a distal flexure, a distal end which is capable of independent resilient expansion by means of a proximal flexure, an expansion means that is functionally associated with the proximal end, an expansion means that is functionally associated with the distal end, an adjustment tool interface that is located at the proximal end, wherein the proximal and distal ends are physically associated by beam portions.

In some other aspects, a first adjustment tool and a second adjustment tool wherein the first adjustment tool adjusts one of the proximal end or the distal end of the implant and the second adjustment tool adjusts the other of the proximal end of the implant or the distal end of the implant.

In other aspects, the first adjustment tool and the second adjustment tool are located at the proximal end of the implant and the first adjustment tool and the second adjustment tool are coaxially nested one within the other and independently rotatable. In some aspects, the first adjustment tool adjusts for expansion or contraction of the proximal end of the implant. In some other aspects, the first adjustment tool adjusts for expansion or contraction of the distal end of the implant. In some other aspects, the second adjustment tool adjusts for expansion or contraction of the proximal end of the implant. In other aspects, the second adjustment tool adjusts for expansion or contraction of the distal end of the implant.

In some aspects, the implant further comprises a cage body, at least one proximal flexure and at least one distal flexure such that the proximal flexure shares a beam portion of the cage body with a distal flexure to form a continuous serpentine pattern along the cage body.

BRIEF DESCRIPTION OF THE DRAWINGS

For the purpose of illustrating concepts of the disclosure, the drawings show aspects of one or more embodiments. However, it should be understood that the present disclosure is not limited to the precise arrangements and instrumentalities shown in the drawings, wherein:

FIGS. **1-3** are a series of lateral representations of two vertebral bodies, wherein FIG. **1** depicts the insertion of an exemplary Universally Expanding Cage (UEC) in its unexpanded state, FIG. **2** depicts the UEC in place between the vertebral bodies and still in its unexpanded state, and FIG. **3** depicts the inserted UEC in its expanded state.

FIG. **4** is a perspective view of a first embodiment of a UEC in an unexpanded state according to aspects of the disclosure.

FIG. **5** is an exploded perspective view showing the UEC of FIG. **4**.

FIG. **6** is a perspective view showing the cage body of the UEC of FIG. **4**.

FIG. **7** is a proximal end view of the UEC of FIG. **4**.

FIG. **8** is a side view of the UEC of FIG. **4**.

FIG. **9** is a side cross-sectional view of the UEC of FIG. **4**.

FIG. **10** is a perspective view of a second embodiment of a UEC in an unexpanded state according to aspects of the disclosure.

FIG. **11** is an exploded perspective view showing the UEC of FIG. **10**.

FIG. **12** is a side view showing the UEC of FIG. **10**.

FIG. **13** is a proximal end view showing the UEC of FIG. **10**.

FIG. **14** is a distal end view showing the UEC of FIG. **10**.

FIG. **15** is a side cross-sectional view showing the UEC of FIG. **10**.

FIG. **16** is a perspective view of a third embodiment of a UEC in an unexpanded state according to aspects of the disclosure.

FIG. **17** is an exploded perspective view showing the UEC of FIG. **16**.

FIG. **18** is a side view showing the UEC of FIG. **16**.

FIG. **19**A is a side cross-sectional view showing the UEC of FIG. **16**.

FIG. **19**B is an end cross-sectional view showing the UEC of FIG. **16**.

FIGS. **20**A-**20**C are a series of side views showing the progressive expansion of the UEC of FIG. **16**, wherein FIG. **20**A shows both ends of the UEC in the unexpanded state, FIG. **20**B shows only one end expanded, and FIG. **20**C shows both ends expanded.

FIG. **21** is a perspective view of a fourth embodiment of a UEC in an unexpanded state according to aspects of the disclosure.

FIG. **22** is a perspective view of a fifth embodiment of a UEC in an unexpanded state according to aspects of the disclosure.

FIG. **23** is a distal end view showing the UEC of FIG. **22**.

FIG. **24** is a side view showing the UEC of FIG. **22**.

FIG. **25** is a side cross-sectional view showing the UEC of FIG. **22**.

FIG. **26** is a cranial to caudal view showing the insertion sites of dual UECs on a vertebral body in one example implementation.

FIG. **27** is an oblique posterolateral view showing one of the insertion sites of the implementation of FIG. **26**.

FIG. **28** is an oblique posterolateral view showing the axes of adjustment provided by the implementation of FIG. **26**.

FIG. **29** is an oblique anterior view showing an anterior column implant.

FIG. **30** is a posterior view showing a human spine exhibiting scoliosis.

FIG. **31** is a posterior view showing the spine of FIG. **29** after being corrected according to aspects of the disclosure.

FIGS. **32**A-**32**C are anterior, lateral and oblique views, respectively, showing adjacent vertebral bodies having misalignments/uneven spacing.

FIGS. **33**A-**33**C are anterior, lateral and oblique views, respectively, showing the vertebral bodies of FIGS. **32**A-**32**C with the misalignments/uneven spacing corrected according to aspects of the disclosure.

DETAILED DESCRIPTION

Referring to FIG. **1-3**, a series of lateral views of vertebral segments **50** and **52** are shown, depicting the insertion and expansion of one embodiment of UEC (Universally Expanding Cage). The depicted vertebral bodies **50** and **52** have an average 8 mm gap between vertebral end plates, representing an average intervertebral space **54**. In a typical implementation, a complete discectomy is performed prior to the insertion of the UEC **56**. The intervertebral disc occupying space **54** is removed using standard techniques including rongeur, curettage, and endplate preparation to bleeding subcondral bone. The posterior longitudinal ligament is divided to permit expansion of the intervertebral space.

The intervertebral space **54** may be distracted to about 10 mm using a rotating spatula (not shown). This is a well-known device that looks like a wide screw driver that can be placed into the disc space horizontally and turned 90 degrees to separate the endplates. A novel feature of the UEC is that after intervertebral disc space expansion and preparation (by curetting or ideally arthroscopically facilitated disc material removal), the UEC implant per se can be inserted through any orifice or angle that does not cause injury to nerves or other structures, positioned at the immediate implant location and consequent expansion platform to yield both the best fusion and angular correction results.

In the example implementation depicted in FIGS. **1-3**, UEC **56** is inserted posteriorly (in the direction of arrow **58**) between vertebral bodies **50** and **52**, as shown in FIG. **1**. The vertebral space **54** depicted is meant to represent any vertebral space in which it is desired to insert the UEC (sacral, lumbar, thoracic and/or cervical), and from any direction permitted by the surrounding anatomy. In accordance with an aspect of the disclosure, the UEC is reduced to a small size in its unexpanded state to enable it to be inserted through into the intervertebral space **54** as shown in FIG. **1**. FIG. **2** shows UEC **56** inserted between vertebral bodies **50** and **52**, with UEC **56** still in its unexpanded state. In one exemplary embodiment, dimensions of an unexpanded UEC are: 10-12 mm wide, 10 mm high and 28 mm long to facilitate insertion and thereby minimize trauma to the patient and risk of injury to nerve roots. These dimensions may accommodate the flat external surfaces. Once in place, the exemplary UEC **56** may be expanded to 140 percent of its unexpanded size (as shown in FIG. **3**), enabling 20 degrees or more of spinal correction depending on the 3D clinical pre-operation anatomic analysis.

It should be noted that while the exemplary UEC **56** depicted in FIGS. **1-3** is an implant intended to ideally fill the warranted space, other shapes of implants such as those shown in later figures and/or described herein may be used. In various embodiments, the implants may have a transverse cross-section that is circular, oval, elliptical, square, rectangular, trapezoidal, or other shape suited to fill the implant site and transmit the required loads. The implants may straight, curved, bean-shaped, and/or include other shapes and aspect ratios. Additionally, the external surfaces may be smooth, spiked, threaded, coated and/or further adapted as subsequently described in more detail. The UEC can be used at any spinal level the surgeon deems in need of fusion, and may be placed at any position and angle relative to the vertebral endplates as may be needed. One, two, or more UECs may be placed at any particular level to achieve the desired height and angles between vertebral bodies. As will be later described, multiple UECs may be used to adjust the overall cranio-caudal height, the anterior-posterior angle, and the medio-lateral angle between adjacent vertebral bodies. UECs may be implanted at multiple levels to obtain or restore the desired three dimensional curvature and positioning of the spine.

Referring to FIGS. **4-9**, a first embodiment of an exemplary UEC **100** according to aspects of the disclosure is shown. FIG. **4** is an enlarged perspective view which shows details of UEC **100**. For ease of understanding, a proximal end **104** and a distal end **106** of UEC **100** can be defined as shown in FIG. **4**. It should be noted that while the distal end **106** of UEC **100** is typically inserted first into a patient and proximal end **104** is typically closest to the surgeon, other orientations of this exemplary device and other devices described herein may be adopted in certain procedures despite the distal and proximal nomenclature being used.

Referring to FIG. **5**, an exploded perspective view shows the individual components of UEC **100**. In this first embodiment, UEC **100** includes a cylindrically-shaped cage body **108**, a proximal plug **110**, a distal plug **112**, a threaded actuator **114**, and a washer **116**. The terms "plug" and "plug member" are used interchangeably herein. Actuator **114** has a shank sized to slidably pass through a central bore within proximal plug **110** when UEC **100** is assembled. Actuator **114** also has threads on its distal end for engaging with a threaded central bore within distal plug **112**. Proximal plug **110** and distal plug **112** each have outer surfaces that are inwardly tapered to match inwardly tapered surfaces within cage body **108** (as best seen in FIG. **9**) With this arrangement, actuator **114** may be rotated in a first direction to draw distal plug **112** toward proximal plug **110** to outwardly expand cage body **108**, as will be subsequently described in more detail.

Referring to FIG. **6**, this perspective view shows details of cage body **108** of the first exemplary embodiment of UEC **100**. In this embodiment, cage body **108** includes eight longitudinally extending beam portions **118**, each separated from an adjacent beam portion **118** by a longitudinally extending gap **120**. In other embodiments (not shown), the cage body may include fewer or more than eight beam

portions, and/or beam portions having a different or varying cross-section or shape. Cage body **108** of the current embodiment also includes eight circumferentially extending connector portions **122**. The connector portions **122** interconnect the ends of the beam portions **118**. Four of the connector portions **122** are located at the proximal end **104** of cage body **108**, and the other four connector portions **122** are located at the distal end **106**. The connector portions **122** located at the proximal end **104** are staggered in relation to the connector portions **122** located at the distal end **106** such that each pair of adjacent beam portions **118** are connected at only one end by a connector portion **122**. With this arrangement the beam portions **118** and connector portions **122** form a continuous serpentine or repeating S-shaped pattern. The beam portions **118** and or the connector portions **122** are configured to resiliently flex to allow the cage body **108** to increase in diameter when urged radially outward by plugs **110** and **112** (shown in FIG. **4**). When plugs **110** and **112** are not urging cage body **108** radially outward, the resiliency of beam portions **118** and or connector portions **122** allows cage body **108** to return to its original reduced diameter. It can be appreciated that as beam portions **118** and or connector portions **122** flex outwardly, gaps **120** become wider at their open ends opposite connector portions **122**. The outwardly facing surfaces of beam portions **118** may each be provided with one or more points or spikes **123** as shown, to permit cage body **108** to grip the end plates of the vertebral bodies.

Referring to FIG. **7**, an end view of the proximal end **104** of UEC **100** is shown. The enlarged head at the proximal end of actuator **114** may be provided with a recessed socket **124** as shown for removably receiving a tool for turning actuator **114**. Proximal plug **110** (and distal plug **112**, not shown) may be provided with radially outwardly extending protuberances **126** that reside in one or more gaps **120** and abut against the side of beam portions **118**. This arrangement prevents plugs **110** and **112** from rotating when actuator **114** is turned, thereby constraining plugs **110** and **112** to only move axially toward or away from each other. Proximal plug **110** (and distal plug **112**) may be provided with through holes and or recesses **128** to allow for bony ingrowth from the vertebral bodies for more solidly healing/fusing UEC **100** in place. Longitudinally extending slots **130** (shown in FIG. **4**) may also be provided for this purpose, and or for packing plugs **110** and **112** with autograft, allograft, and/or other materials for promoting healing/fusion.

Referring to FIGS. **8** and **9**, a side view and side cross-sectional view, respectively, are shown. In operation, UEC **100** is expanded by inserting a tool such as a hex key wrench or driver (not shown) into the recessed socket **124** at the proximal end of actuator **114** and turning it clockwise. As best seen in FIG. **9**, the distal end of actuator **114** is threaded into the central bore of distal plug **112**. Turning actuator **114** clockwise causes the distal end of actuator **114** to pull distal plug **112** towards the center of cage body **108** while the enlarged head at the proximal and of actuator **114** pushes proximal plug **110** towards the center. This movement in turn causes the ramped surfaces **132** of plugs **110** and **112** to slide inwardly along the ramped surfaces **134** located along the inside of beam portions **118** and connector portions **122** to cause these elements to flex and expand radially outward as previously described. This process may be reversed by turning actuator **114** counterclockwise. The resilient inward forces from the beam portions **118** and or connector portions **122** (and or the compressive forces from adjacent vertebral bodies) against plugs **110** and **112** causes the two plugs to separate axially, thereby allowing UEC **100** to return to its non-expanded state.

Referring to FIGS. **10-15**, a second embodiment of an exemplary UEC **200** according to aspects of the disclosure is shown. FIG. **10** is a perspective view which shows details of UEC **200**. UEC **200** includes a proximal end **204** and a distal end **206**, and shares many of the same features of previously described UEC **100**, which are identified with similar reference numerals.

Referring to FIG. **11**, an exploded perspective view shows the individual components of UEC **200**. In this second embodiment, UEC **200** includes an elongated cylindrical cage body **208**, a proximal plug **210**, and a distal plug **212**. Distal plug **212** includes an integrally formed actuator rod **214** that extends along the internal central axis of cage body **208** towards proximal plug **210** when UEC **200** is assembled. Proximal plug **210** and distal plug **212** each have outer surfaces that are threaded and inwardly tapered to match threaded and inwardly tapered surfaces within cage body **208** (as best seen in FIG. **15**). With this arrangement, each plug **210** and **212** may be independently rotated to move the particular plug axially toward the middle of cage body **208** to outwardly expand that particular end **204** or **206** of cage body **208**, as will be subsequently described in more detail.

As shown in FIGS. **11** and **12**, cage body **208** includes eight longitudinally extending beam portions **218**, each separated from an adjacent beam portion **218** by a longitudinally extending gap **220**. In other embodiments (not shown), the cage body may include fewer or more than eight beam portions, and/or beam portions having a different or varying cross-section or shape. Cage body **208** of the current embodiment also includes eight circumferentially extending connector portions **222**. The connector portions **222** interconnect the ends of the beam portions **218**. Four of the connector portions **222** are located at the proximal end **204** of cage body **208**, and the other four connector portions **222** are located at the distal end **206**. The connector portions **222** located at the proximal end **204** are staggered in relation to the connector portions **222** located at the distal end **206** such that each pair of adjacent beam portions **218** are connected at only one end by a connector portion **222**. With this arrangement the beam portions **218** and connector portions **222** form a continuous serpentine or repeating S-shaped pattern. The beam portions **218** and or the connector portions **222** are configured to resiliently flex to allow the cage body **208** to increase in diameter when urged radially outward by plugs **210** and **212**. When plugs **210** and **212** are not urging cage body **208** radially outward, the resiliency of beam portions **218** and or connector portions **222** allows cage body **208** to return to its original reduced diameter. It can be appreciated that as beam portions **218** and or connector portions **222** flex outwardly, gaps **220** become wider at their open ends opposite connector portions **222**. The outwardly facing surfaces of beam portions **218** may each be provided with one or more points or spikes **223** as shown, to permit cage body **208** to grip the end plates of the vertebral bodies.

Referring to FIG. **13**, an end view of the proximal end **204** of UEC **200** is shown. The proximal plug **210** may be provided with a recessed socket **224** as shown for removably receiving a tool for turning proximal plug **210** in either direction, such as a five-lobed driver (not shown). Alternatively, other suitable types of recessed sockets, slots, protruding and/or keyed features may be utilized with a mating driver. The proximal end of actuator shaft **214** (which

extends proximally from distal plug **212** inside cage body **208**) may be accessed through a central bore **225** in proximal plug **210**. The proximal end of actuator shaft **214** may be shaped as shown to be received within a mating driver socket (such as a five-lobed socket, not shown), which can be removably extended into the center of cage body **208** through central bore **225**. With this arrangement, both the proximal plug **210** and the distal plug **212** can be independently accessed and rotated from the proximal end of UEC **200** so that the proximal end **204** and the distal end **206** of UEC **200** can be expanded or contracted independently.

Referring to FIG. **14**, an end view of the distal end **206** of UEC **200** is shown. By comparing FIGS. **13** and **14**, it can be appreciated that connector portions **222** at the proximal end **204** of UEC **200** are staggered (i.e. rotated 45°) in relation to the connector portions **222** at the distal end **206** of UEC **200**.

Referring to FIG. **15**, a side cross-sectional view of UEC **200** is shown. In operation, the proximal end **204** of UEC **200** may be independently expanded by inserting a tool such as a five-lobed driver (not shown) into the recessed socket **224** of proximal plug **210** and turning it clockwise. Turning proximal plug **210** clockwise causes the threaded ramped surfaces **232** of plug **210** to translate inwardly (to the right in FIG. **15**) along the threaded ramped surfaces **234** located along the inside of beam portions **218** and connector portions **222** to cause these elements to flex and expand radially outward as previously described. This process may be reversed by turning proximal plug **210** counterclockwise, thereby allowing the proximal end **204** of UEC **200** to return to its non-expanded state. Similarly, the distal end **206** of UEC **200** may be independently expanded by inserting a tool such as a five-lobed socket (not shown) through the central bore **225** in proximal plug **210** until it engages with the proximal end of actuator **214**, which is attached to distal plug **212**. Turning distal plug **212** counterclockwise (from the perspective of the proximal end) causes the threaded ramped surfaces **232** of plug **212** to translate inwardly (to the left in FIG. **15**) along the threaded ramped surfaces **234** located along the inside of beam portions **218** and connector portions **222** to cause these elements to flex and expand radially outward as previously described. This process may be reversed by turning distal plug **212** clockwise, thereby allowing the distal end **206** of UEC **200** to return to its non-expanded state.

The adjustment tools described above (not shown) for turning proximal plug **210** and distal plug **212** may be inserted one at a time into UEC **200**. Alternatively, the two tools may be nested together, with the tool for turning the distal plug **212** passing through a central bore in the tool for turning the proximal plug, as will be subsequently shown and described in relation to other embodiments. With this arrangement, both tools may be turned simultaneously or individually. In some embodiments, both proximal plug **210** and distal plug **212** are provided with right-handed threads, so that when both tools are simultaneously turned in the same direction, one end of UEC **200** expands while the other end contracts, thereby changing the outer surface angle of UEC **200** without substantially changing its overall diameter (i.e. without substantially changing the diameter or height of the midpoint of UEC **200**.) For example, by turning the two tools in the same direction, the lordotic angle between two vertebral bodies can be changed by UEC **200** without substantially changing the height between the two vertebral bodies.

In other embodiments, one of the plugs **210** or **212** may be provides with a right-handed thread and the other plug provided with a left-handed thread. In these embodiments, when both adjustment tools are simultaneously turned in the same direction, both ends **204** and **206** of UEC **200** expand or contact together without substantially changing the outer surface angle of UEC **200**. For example, by turning the two tools in the same direction, the height between the two vertebral bodies can be changed by UEC **200** without substantially changing the lordotic angle between two vertebral bodies.

In some embodiments, plugs **210** and **212** may each be provided with threads having a different pitch from the other. Such an arrangement allows both the height and the angle between adjacent vertebral bodies to be adjusted simultaneously in a predetermined relationship when both adjustment tools are turned together in unison. For example, proximal plug **210** may be provided with right-handed threads of a particular pitch while distal plug **212** may be provided with finer, left-handed threads having half the pitch of the proximal plug threads. In this embodiment, when both adjustment tools are turned together in a clockwise direction, both ends of UEC **200** expand at the same time but the proximal end **204** expands at twice the rate of the distal end **206**. This allows the surgeon to increase the height between adjacent vertebral bodies and at the same time angle the bodies away from him or her. One or both of the tools may then be turned individually to more finely adjust the height and angle between the vertebral bodies.

In some embodiments the above-described adjustment tools may be removed from UEC **200** before the surgical procedure is completed. In some embodiments the above adjustment tools may remain in place after the procedure is completed.

In some embodiments. UEC **200** is 50 mm long, has an unexpanded diameter of 10 mm, and an expanded diameter of 14 mm. In other embodiments, the UEC may be configured to expand to about 11, 12, or 13 mm, or more than 14 mm. In still other embodiments, the UEC may be configured with dimensions larger or smaller than these to conform to a particular anatomy or procedure.

Referring to FIGS. **16-20**, a third embodiment of an exemplary UEC **300** according to aspects of the disclosure is shown. FIG. **16** is a perspective view which shows details of UEC **300**. UEC **300** includes a proximal end **304** and a distal end **306**, and shares many of the same features of previously described UECs **100** and **200**, which are identified with similar reference numerals.

Referring to FIG. **17**, an exploded perspective view shows the individual components of UEC **300**. In this third embodiment, UEC **300** includes a rectangular cage body **308**, a proximal plug **310**, a distal plug **312**, a proximal plug adjustment tool **313**, and a distal plug adjustment tool **314**. As in the previously described UEC **200**, both plugs **310** and **312** are threaded and tapered, and each end of cage body **308** is provided with an inwardly tapered and threaded bore configured to receive one of the plugs **310** or **312**. Adjustment tools **313** and **314** are similar in construction and operation to the adjustment tools previously described (but not shown) in reference to UEC **200**. Proximal plug **310** includes a mating recess on its proximal end (not shown) configured to removably receive the splined distal end of proximal plug adjustment tool **313** for rotating proximal plug **310**. Distal plug **312** includes a smaller mating recess on its proximal end (not shown) configured to removably receive the smaller splined distal end of distal plug adjustment tool **314** for rotating distal plug **312**. Both proximal plug adjustment tool **313** and proximal plug **312** are provided with central bores that permit the distal end of distal

plug adjustment tool **314** to pass therethrough, through the center of cage body **308**, and partially into distal plug **312**. In this exemplary embodiment, the proximal ends of adjustment tools **313** and **314** each have a hexagonally-shaped head that permits them to be turned together in unison or individually (as previously described in relation to UEC **200**), using wrench(es), socket(s) (not shown) and/or by hand.

As shown in FIGS. **16** and **17**, cage body **308** includes eight longitudinally extending beam portions **318**, each separated from an adjacent beam portion **318** by a longitudinally extending gap **320**. In other embodiments (not shown), the cage body may include fewer or more than eight beam portions, and/or beam portions having a different or varying cross-section or shape. It can be seen that in this embodiment, four of the gaps **320** are formed through the middle of the four faces of cage body **308**, and the other four gaps **320** are formed along the corner edges of cage body **308**. Cage body **308** also includes eight circumferentially extending connector portions **322**. The connector portions **322** interconnect the ends of the beam portions **318**. Circular apertures **321** may be provided as shown between the ends of gaps **320** and the connector portions **322** to relieve stress concentrations at those locations as connector portions **322** flex. Four of the connector portions/flexures **322** are located at the proximal end **304** of cage body **308** (across the corner edges of cage body **308**), and the other four connector portions/flexures **322** are located at the distal end **306** (across the distal end of the faces of cage body **308**.) The connector portions **322** located at the proximal end **304** are staggered in relation to the connector portions **322** located at the distal end **306** such that each pair of adjacent beam portions **318** are connected at only one end by a connector portion **322**. As with previously described embodiments, the beam portions **318** and connector portions **322** form a continuous serpentine or repeating S-shaped pattern. The beam portions **318** and or the connector portions **322** are configured to resiliently flex to allow the cage body **308** to increase in circumference when urged radially outward by plugs **310** and **312**. When plugs **310** and **312** are not urging cage body **308** radially outward, the resiliency of beam portions **318** and or connector portions **322** allows cage body **308** to return to its original reduced circumference. It can be appreciated that as beam portions **318** and or connector portions **322** flex outwardly, gaps **320** become wider at their open ends opposite connector portions **322**. The outwardly facing surfaces of beam portions **318** may each be provided with one or more points or spikes **323** as shown, to permit cage body **308** to grip the end plates of the vertebral bodies. In this exemplary embodiment, spiked or knurled surfaces are provided along the top and bottom of UEC **300** while the side surfaces are left smooth.

Referring to FIGS. **18** and **19**, a side view and a side cross-sectional view, respectively, of UEC **300** are shown. In operation, the proximal end **304** of UEC **300** may be independently expanded by inserting proximal plug adjustment tool **313** into the mating recessed socket of proximal plug **310** (as shown in FIG. **19**) and turning it clockwise. Turning proximal plug **310** clockwise causes the threaded ramped surfaces **332** of plug **310** to translate inwardly (to the left in FIGS. **18** and **19**) along the threaded ramped surfaces **334** located along the inside of beam portions **318** and connector portions **322** to cause these elements to flex and expand radially outward as previously described. This process may be reversed by turning proximal plug **310** counterclockwise, thereby allowing the proximal end **304** of UEC **300** to return to its non-expanded state. Similarly, the distal end **306** of UEC **300** may be independently expanded by inserting a tool such as a five-lobed socket (not shown) through the central bore **325** in proximal plug **310** until it engages with the proximal end of actuator **314**, which is attached to distal plug **312**. Turning distal plug **312** counterclockwise (from the perspective of the proximal end) causes the threaded ramped surfaces **332** of plug **312** to translate inwardly (to the right in FIGS. **18** and **19**) along the threaded ramped surfaces **334** located along the inside of beam portions **318** and connector portions **322** to cause these elements to flex and expand radially outward as previously described. This process may be reversed by turning distal plug **312** clockwise, thereby allowing the distal end **306** of UEC **300** to return to its non-expanded state.

Referring to FIGS. **20**A-**20**C, a series of sides views depicts the progression from a fully retracted and a fully expanded UEC **300**. In FIG. **20**A, cage body **308** is shown in a fully retracted position. In this figure, the height of each end of cage body **308** is labeled as 100% of retracted cage height. In FIG. **20**B, the proximal end **304** of cage body **308** has been fully expanded while the distal end **306** remains fully retracted. In this exemplary embodiment, each end is capable of being expanded to a height (and therefore also a width) that is 140% of the fully retracted height, as shown. In FIG. **20**C, the distal end **306** has also been expanded by 40%.

In some embodiments, UEC **300** has a cage length of 50 mm, an unexpanded cage height of 10 mm, and an expanded cage height of 14 mm. The overall length of UEC **300** with adjustment tools **313** and **314** in place and in the unexpanded state may be 75 mm. In other embodiments, the UEC may be configured to expand to about 11, 12, or 13 mm, or more than 14 mm. In still other embodiments, the UEC may be configured with dimensions larger or smaller than these to conform to a particular anatomy or procedure. In some embodiments, the UEC can form an included angle between its top and bottom surfaces of at least 20 degrees.

Referring to FIG. **21**, a fourth embodiment of an exemplary UEC **400** according to aspects of the disclosure is shown. FIG. **21** is a perspective view which shows details of UEC **400**. UEC **400** includes a proximal end **404**, a distal end **406**, cage body **408**, proximal plug **410**, distal plug **412**, proximal plug adjusting tool **413**, and distal plug adjusting tool **414**. Other than cage body **408** having a circular cross-section rather than a square cross-section, UEC **400** is essentially identical in construction and operation to previously described UEC **300**. In other embodiments (not shown), the UEC may have a cross-section transverse to the central longitudinal axis that is rectangular, trapezoidal, oval, elliptical or other shape.

Referring to FIGS. **22-25**, a fifth embodiment of an exemplary UEC **500** according to aspects of the disclosure is shown. FIG. **16** is a perspective view which shows details of UEC **500**. UEC **500** includes a proximal end **504** and a distal end **506**, and shares many of the same features of previously described UECs **100-400**, which are identified with similar reference numerals.

UEC **500** includes three components: a generally cylindrical, unitary cage body **508**; a proximal actuator screw **510**; and a distal actuator screw **512**. The heads of actuator screws **510** and **512** may be referred to as plug members. Cage body **508** includes two longitudinal, off-center slots **550** which each extend about three-quarters of the length of cage body **508**, and emanate from opposite ends and opposite sides of cage body **508**. Cage body **508** is also provided with two transverse slots **552**, each located adjacent to the closed end of one of the longitudinal slots **550**. Each

transverse slot **552** extends from the outer circumference of cage body **508** and approaches the base of a longitudinal slot **550**. Each of the two pairings of a longitudinal slot **550** with a transverse slot **552** defines a cantilevered arm **554** that is connected with the remainder of the cage body **508** by a living hinge **556** near the closed ends of the two slots **550** and **552**. Each living hinge **556** allows its associated arm **554** to flex outwardly against a vertebral body.

The open ends of longitudinal slots **550** are outwardly tapered to receive the enlarged, tapered heads of an actuator screw **510** or **512**, as best seen in FIG. **24**. The opposite ends of actuator screws **510** and **512** extend through longitudinal slots **550** and thread into the opposite ends of cage body **508**. With this arrangement, each actuator screw **510** and **512** may be turned independently of the other, causing the screw to move axially relative to bone cage **508**. This axial movement causes the head of the screw to urge the tapered tip of the associated arm **554** outward, or allowing it to flex back inward when the screw is turned in the opposite direction. If both actuator screws **510** and **512** are turned in the same direction the same amount, UEC **500** expands uniformly and increases the height between adjacent vertebral bodies. If one of the two actuator screws **510** or **512** is turned more than the other, the surgeon is able to change the angle between the vertebral bodies.

As best seen in FIG. **23**, a slot **558** or other suitable feature may be provided in the end of each actuator screw **510** and **512** at the opposite end from the screw head. A hole **560** may also be provided through each end of cage body **508** to allow access to each of the two slots **558**. This arrangement allows both of the actuator screws **510** and **512** to be turned from either end **504** and/or **506** of cage body **508**.

Referring to FIGS. **26-28**, an example implementation utilizing two UECs **56** in tandem is shown. Each UEC **56** may be inserted as previously described in relation to FIGS. **1-3**. In this implementation, UECs **56** are placed non-parallel to one another. As best seen in FIG. **28**, this arrangement allows the surgeon to adjust the angle between the vertebrae about two different axes, and also translate the vertebrae with respect to one another about another axis.

FIG. **29** is an oblique anterior view showing placement of an anterior column implant **56** on a vertebral body **52**. In this implementation, implant **56** is placed laterally across the vertebral body **52**, forward of the lateral midline. After adjustment of implant **56**, its plugs are flush with or recessed within the outer perimeter of the endplate of vertebral body **52** so as not to impinge upon adjacent tissue.

Referring to FIG. **30**, a human spine **76** is shown that exhibits scoliosis. According to aspects of the disclosure, dual UECs may be placed at various levels of the spine to treat the condition. For example, a single UEC or pairs of UECs may be implanted at the levels depicted by reference numerals **78**, **80**, **82** and **84** shown in FIG. **30**. By using the adjustments described above relative to FIG. **28**, the curvature of the spine may be adjusted in three dimensions at these four levels to a correct alignment, as shown in FIG. **31**.

FIGS. **32A-32C** are anterior, lateral and oblique views, respectively, showing adjacent vertebral bodies **50** and **52** having misalignments/uneven spacing.

FIGS. **33A-33C** are anterior, lateral and oblique views, respectively, showing the vertebral bodies **50** and **52** of FIGS. **32A-32C** with the misalignments/uneven spacing corrected according to aspects of the disclosure.

The implants can be made of, for example, such materials as titanium, 64 titanium, or an alloy thereof, 316 or 321 stainless steel, biodegradable and biologically active materials, e.g. stem cells, and polymers, such as semi-crystalline, high purity polymers comprised of repeating monomers of two ether groups and a ketone group, e.g. polyaryetheretherketone (PEEK)™, or Teflon™.

To prevent movement of proximal and distal plugs or actuators after implantation, in some implementations a biocompatible adhesive or thread locking compound may be applied to one or more of the moving parts. In some embodiments (not shown) a pin may be inserted radially or axially between the plug/actuator and the cage body to lock the parts in place post operatively. In some embodiments, a ratchet, spring loaded detent, or other locking mechanism may be provided for this purpose.

In general, as disclosed in the above embodiments, the cage body is cut with openings at every other end of each slot, like a sine wave, allowing expansion when the center of the cage becomes occupied with a cone or mandrill shaped unit. The cage body's series of alternating slots allows the expansion to take place while keeping the outside of the UEC one single piece. The slots plus the teeth on the surface allow for a solid grip on the bone surfaces and plenty of opportunities for good bone ingrowth. Also, by allowing the surgeon to make one end of the UEC thicker than the other, the effects of the cone (mandrill) introduction vary from uniform to selective conduit expansion. The UEC expansion mechanism is adaptable to both fixed fusion and mobile 'motion preservation' implants, with exteriors of the expanding implant per surgeon's choice (round, flat, custom, etc.) As such, in some implementations, relative motion may be preserved between the vertebral bodies adjacent the implanted UEC(s). In other implementations, it may be desirable to fuse the adjacent vertebral bodies around the implanted UEC(s).

To provide motion preservation between adjacent vertebrae, robust compressible materials may be used between the UEC and one or both of the vertebral endplates, and/or one or more components of the UEC may comprise such materials. These materials may replicate the load distributing and shock absorbing functions of the annulus and nucleus of a natural disk. For example, in some embodiments the UEC may be provided with tapered plugs made of a resilient polymer to allow the UEC to compress and expand to accommodate relative motion of the adjacent vertebrae. Examples of biocompatible materials suitable for some UEC embodiments include Bionate®, a thermoplastic polycarbonate-urethane (PCU) provided by DSM Biomedical in Exton, Pa., and ChronoFlex®, a PCU provided by AdvanSource Biomaterials in Wilmington, Mass.

The UEC provides advantages over currently existing technology that include correction of coronal plane deformity; introduction of interbody lordosis and early stabilization of the interbody space with rigidity that is greater than present spacer devices. This early stability may improve post-operative pain, preclude the need for posterior implants including pedicle screws, and improve the rate of successful arthrodesis. Importantly, the UEC provides improvement of space available for the neural elements while improving lordosis. Traditional implants are limited to spacer effects, as passive fillers of the intervertebral disc locations awaiting eventual fusion if and when bone graft in and around the implant fuses. By expanding and morphing into the calculated shape which physiologically corrects spine angulation, the UEC immediately fixes the spine in its proper, painless, functional position. As infused osteoinductive/osteoconductive bone graft materials heal, the patient becomes well and the implant becomes inert and quiescent, embedded in bone, and no longer needed.

In some embodiments, the external surface of the UEC may be 3D printed to not only fit into the intervertebral space per se, but to match the surface topography at each insertion location. In other words, a 3D printed endplate may be utilized, computer calculated to fit and expand the disc space of the individual patient, resulting in both best 'goodness of fit' for fusion, and improved axial skeletal alignment.

By creating to 'maps' that fit e.g. as a precisely congruent superior and inferior surface to fit into a particular patients disc space, and placing these UEC end plates on either side the novel UEC expansion mechanism, a patient's disc space AND overall spine alignment will be ideally treated toward best fusion (or motion preservation) and alignment.

"Method of Surgery" instructions may recommend the surgeon and/or robotic unit deploy expansion as programmed to insert the UEC into a particular disc level of pathology, to achieve best results. For example, preoperative patient scans/films can predict ideal UEC surgeon use, such as "turn Knob A a certain number of rotations clockwise," to maximize visible, palpable, and roentgenographic 'Goodness of Fit'. With this approach, post activation, the UEC implant fits the location, entering at the predetermined best angle (in **3** axes) using the proprietary Method of Surgery and UEC insertion tools provided.

In some embodiments, the UEC may be coated with hydroxyapatite. In some embodiments, toothed or 400 μm beaded surfaces may be utilized to promote bony ingrowth. Inflatable chambers may be provided within the endplate that can expand after being implanted. This approach addresses the 3-D congruence to proximate disc pathology. It can also allow for intervertebral arthrodesis or arthroplasty treatment and overall improved spinal alignment, integrating the internal proprietary expansion with the variable external endplate shapes and their contents. UEC inflatable endplates of polymer may be employed, such as tiny vacuoles, "bubblewrap", and multiple or singular bladder constructs. If a portion of the disk space were collapsed, that region could be aptly elevated or expanded by the UEC endplate variation in material and/or inflation. The inflatable chambers may contain compressible gas (such as air), granules as pharmacologics, and/or stem cells that are delivered via liquids. In cases where the UEC is compressible or force absorbing, the material and/or chamber could be used as a cushion or to 'selectively direct and protect chondrocytes' toward improvement of existing pathophysiology via best drug use or regeneration.

The 'preparation' of the UEC insertion site will vary per surgeon. In some implementations, an arthroscopic burr may be advisable for removing 0.5 mm of cortical bone along with all aberrant disc contents under digital arthroscopic camera control. In other implementations, the surgeon may just carefully curette the intervertebral space to 'clean it out' in preparation for the UEC implant insertion.

The UEC may be inserted directly into the insertion site, or may be inserted through proprietary or commercially available insertion tube. The insertion tube typically will have a blunt distal tip so that it can be inserted through an incision without causing tissue damage. The tube can be used with or without additional tissue retractors. The UEC may be preloaded into the insertion tube, or placed into the tube after the tube has been introduced into the insertion site. A pusher rod or other device may be utilized to deploy the UEC from the insertion tube into the insertion site. In some procedures, the placement of the UEC may be arthroscopically assisted.

Note that regardless of the endplate preparation, in the deformed, aging, pathologic spine there will be pathology to correct. According to various aspects of the present disclosure, the UECs provided herein may accomplish this in several ways as pertains to the external implant composition. For example, the UEC can expand as an externally threaded conduit, either uniformly end to end resulting in same diameters at each end post-operatively (such as 40% overall expansion), or precisely at either end, thus creating an overall conical albeit expanded UEC. Also, the UEC can be flat superiorly and inferiorly as shown in the above drawings, thus more likely matching the rather flat vertebral body end plates. However, according to further aspects of the present disclosure, special care should be taken to consider both the peripheral end plate bony rim as thicker more prominent cortical bone at the vertebral end plates with a sunken or concave thinner interior (thus subject to potential subsidence). The UEC MOS (Method of Surgery) contemplated herein considers the preoperative findings (e.g. MRI, 3D CT scan, X-rays) to integrate information on bone density, specific disc space and longitudinal spine anatomy, topography and alignment.

The various expanding cages disclosed herein and variations thereof are not limited to use in the spinal column but may be used between other bone segments throughout the human or animal body. For example, a UEC can be used during arthrodesis of a metatarsal joint. The UEC can aid in setting the orientation of the toe to a desired angle before fusion of the apposing bone segments occurs. Similarly, a UEC may be utilized in the knee, elbow or other body joints, or between two or more bone segments that have been fractured by trauma.

According to various aspects of the disclosure:

1) the UEC corrects spine surgical pathology both locally via horizontal (disc) and longitudinal vertical axial (scoliotic/kyphotic) spine deformity improvements.

2) the UEC is applicable cervical through lumbar for
A) arthrodesis (fusion) or
B) arthroplasty (motion preservation) or
C) drug/cell therapy delivery

3) the UEC can expand uniformly throughout implant length, and/or expand only proximally (toward the surgical incision) or distally, thus enabling clinical adjustments favorable to spine diseased or injured patients for local and overall spondylopathies.

4) the UEC can be surgically inserted via outpatient MIS (Minimally Invasive-outpatient Surgery) as safe, efficacious implants "doing no harm" applying advantages from
A) materials thicknesses for height differentials or
B) expansion adjustments surgically controlled (before/during or after implantation) or via prefabricated portals or injections-programming implant 'mapped' corrections using
C) polymers durometrically calculated with variable compressions, permanent or biodegradable activations at will.
D) inflation of the implant as via UEC surface chambers or bladder(s).
E) adding endplate biologics, foam, or other adaptables for best results.
F) UEC expansion can adapt to expand variable external surface parameters including flat, round, or customized external maximally congruent surfaces to interface as with proximate endplates.

5) Delivery either via UEC materials per se (eluding substances-cells or pharmacologics) or through extrusion from a UEC container or delivery vesicle/depot/chamber/portal will enable not only immediate surgically correction but

long term enhanced bone in growth and local/general therapeutic and/or regenerative clinical benefits.

While the disclosure has been described in connection with example embodiments, it is to be understood that the disclosure is not limited to the disclosed embodiments and alternatives as set forth above, but on the contrary is intended to cover various modifications and equivalent arrangements included within the claim scope.

The invention claimed is:

1. An expandable medical implant comprising:
- a cage body comprising a distal end and a proximal end and at least a first beam portion and a second beam portion;
- a central channel; and
- an actuator comprising:
  - a distal end configured to engage with a distal expansion means; and
  - a proximal end configured to mate with a first adjustment tool;
- wherein the actuator is positioned through the central channel and when rotated in a first direction causes an expansion in the distal end of the cage body thereby causing a separation between the first beam portion and the second beam portion at the distal end of the cage body that is greater than any resulting separation between the first beam portion and the second beam portion at the proximal end, and when rotated in a second direction causes a contraction in the distal end of the cage body.

2. The expandable medical implant of claim **1**, comprising a proximal expansion means.

3. The expandable medical implant of claim **2**, wherein the proximal expansion means has a central bore.

4. The expandable medical implant of claim **3**, wherein the actuator is received through the central bore of the proximal expansion means.

5. The expandable medical implant of claim **2**, wherein the proximal expansion means is configured to engage with a second adjustment tool.

6. The expandable medical implant of claim **5**, wherein the second adjustment tool has a central bore.

7. The expandable medical implant of claim **6**, wherein the actuator is coaxially accommodated by the central bore of the second adjustment tool.

8. The expandable medical implant of claim **1**, wherein the actuator is threaded.

9. An expandable medical implant comprising:
- a cage body comprising a distal end and a proximal end;
- a central channel;
- a proximal expansion means;
- a distal expansion means which is distinct from the proximal expansion means; and
- an actuator comprising:
  - a distal end configured to engage with the distal expansion means; and
  - a proximal end configured to be coaxially accommodated through a central bore in the proximal expansion means.

10. The expandable medical implant of claim **9**, wherein the actuator is adjusted by a first adjustment tool.

11. The expandable medical implant of claim **10**, wherein the proximal expansion means is actuated by a second adjustment tool.

12. An expandable medical implant comprising:
- a cage body comprising a distal end and a proximal end;
- a proximal expansion means wherein the proximal expansion means is configured to engage with a second adjustment tool;
- a central channel; and
- an actuator comprising:
  - a distal end configured to engage with a distal expansion means; and
  - a proximal end configured to mate with a first adjustment tool;
- wherein the actuator is positioned through the central channel and when rotated in a first direction causes an expansion in the distal end of the cage body and when rotated in a second direction causes a contraction in the distal end of the cage body.

13. The expandable medical implant of claim **12**, wherein the actuator is threaded.

14. The expandable medical implant of claim **12**, wherein the proximal expansion means has a central bore.

15. The expandable medical implant of claim **14**, wherein the actuator is received through the central bore of the proximal expansion means.

16. The expandable medical implant of claim **12**, wherein the second adjustment tool has a central bore.

17. The expandable medical implant of claim **16**, wherein the actuator is coaxially accommodated by the central bore of the second adjustment tool.

* * * * *

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Grotz

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(54) **METHOD OF TREATING A PATIENT'S JOINT USING A RESILIENT ARTHROPLASTY DEVICE**

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(58) **Field of Classification Search**
CPC A61F 2/30756; A61F 2002/30757; A61F 2/38; A61F 2/40
See application file for complete search history.

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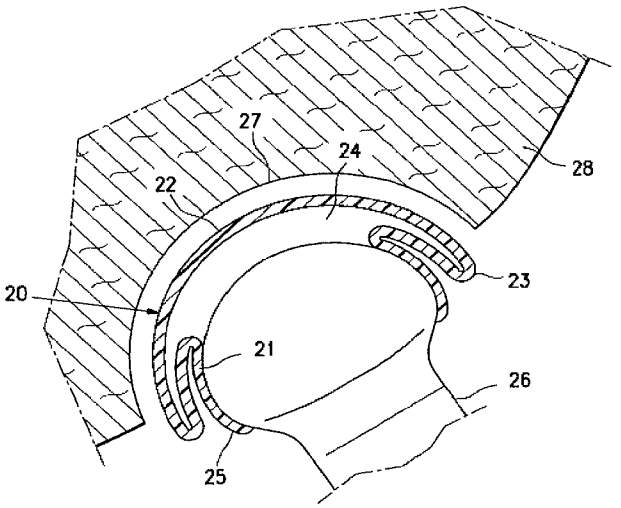
(57) **ABSTRACT**

The disclosure is directed to a resilient implant for implantation into human or animal joints to act as a cushion allowing for renewed joint motion. The implant endures variable joint forces and cyclic loads while reducing pain and improving function after injury or disease to repair, reconstruct, and regenerate joint integrity. The implant is deployed in a prepared debrided joint space, secured to at least one of the joint bones and expanded in the space, molding to surrounding structures with sufficient stability to avoid extrusion or dislocation. The implant has opposing walls that move in varied directions, and an inner space filled with suitable filler to accommodate motions which mimic or approximate normal joint motion. The implant pads the damaged joint surfaces, restores cushioning immediately and may be employed to restore cartilage to normal by delivering regenerative cells.

10 Claims, 9 Drawing Sheets



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A61B 17/84	(2006.01)

(52) **U.S. Cl.**

CPC ***A61F 2/3603*** (2013.01); ***A61F 2/38*** (2013.01); ***A61F 2/389*** (2013.01); ***A61F 2/3872*** (2013.01); ***A61F 2/40*** (2013.01); ***A61F 2/4202*** (2013.01); *A61B 17/562* (2013.01); *A61B 17/842* (2013.01); *A61F 2002/30019* (2013.01); *A61F 2002/30563* (2013.01); *A61F 2002/30576* (2013.01); *A61F 2002/30581* (2013.01); *A61F 2002/30589* (2013.01); *A61F 2002/30594* (2013.01); *A61F 2002/30688* (2013.01); *A61F 2002/30754* (2013.01); *A61F 2002/30757* (2013.01); *A61F 2002/4212* (2013.01); *A61F 2250/0048* (2013.01)

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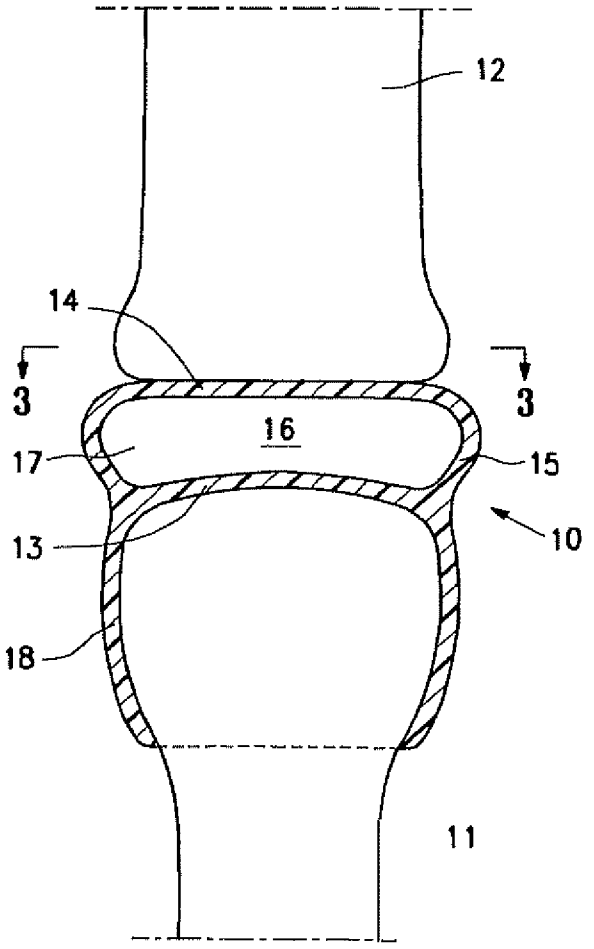

FIG. 1

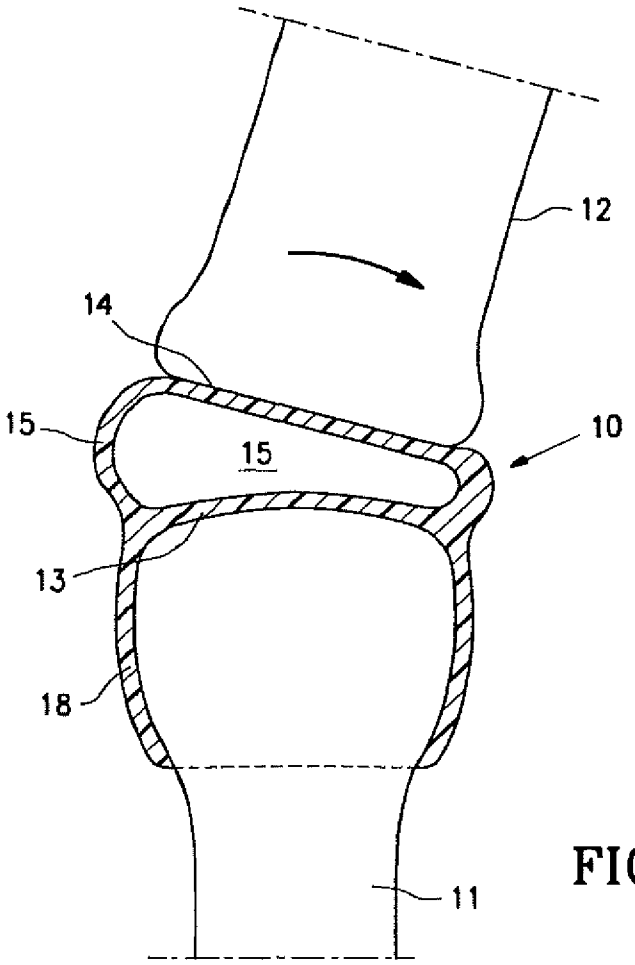

FIG. 2

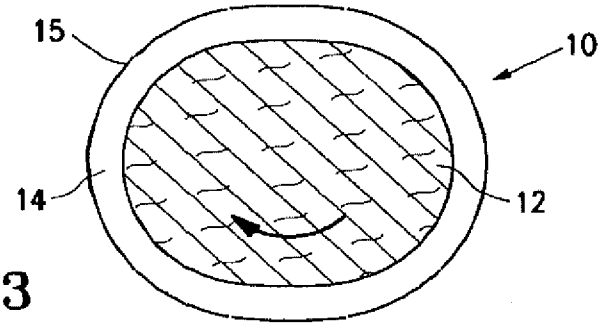

FIG. 3

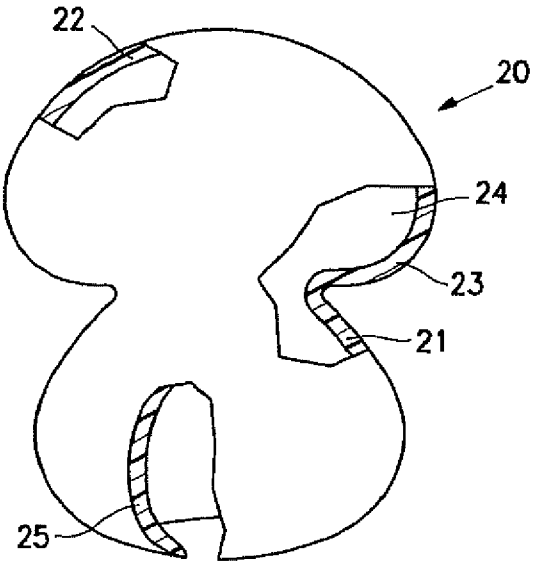

FIG. 4

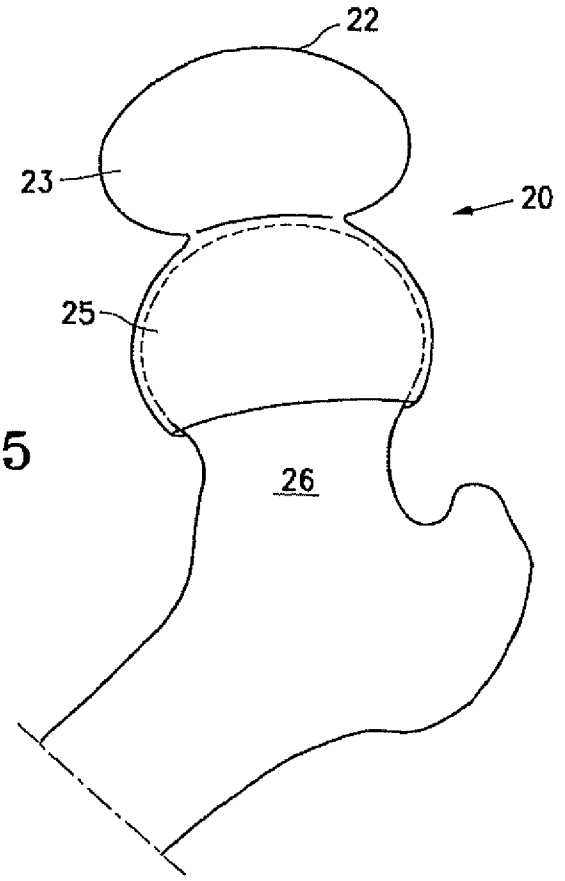

FIG. 5

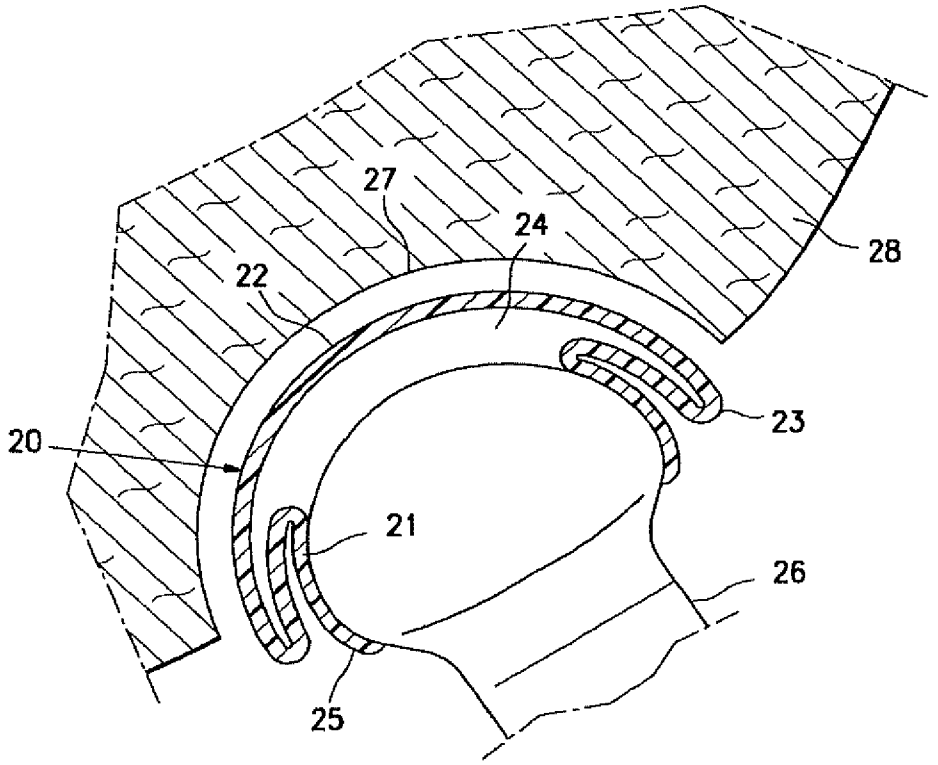

FIG. 6

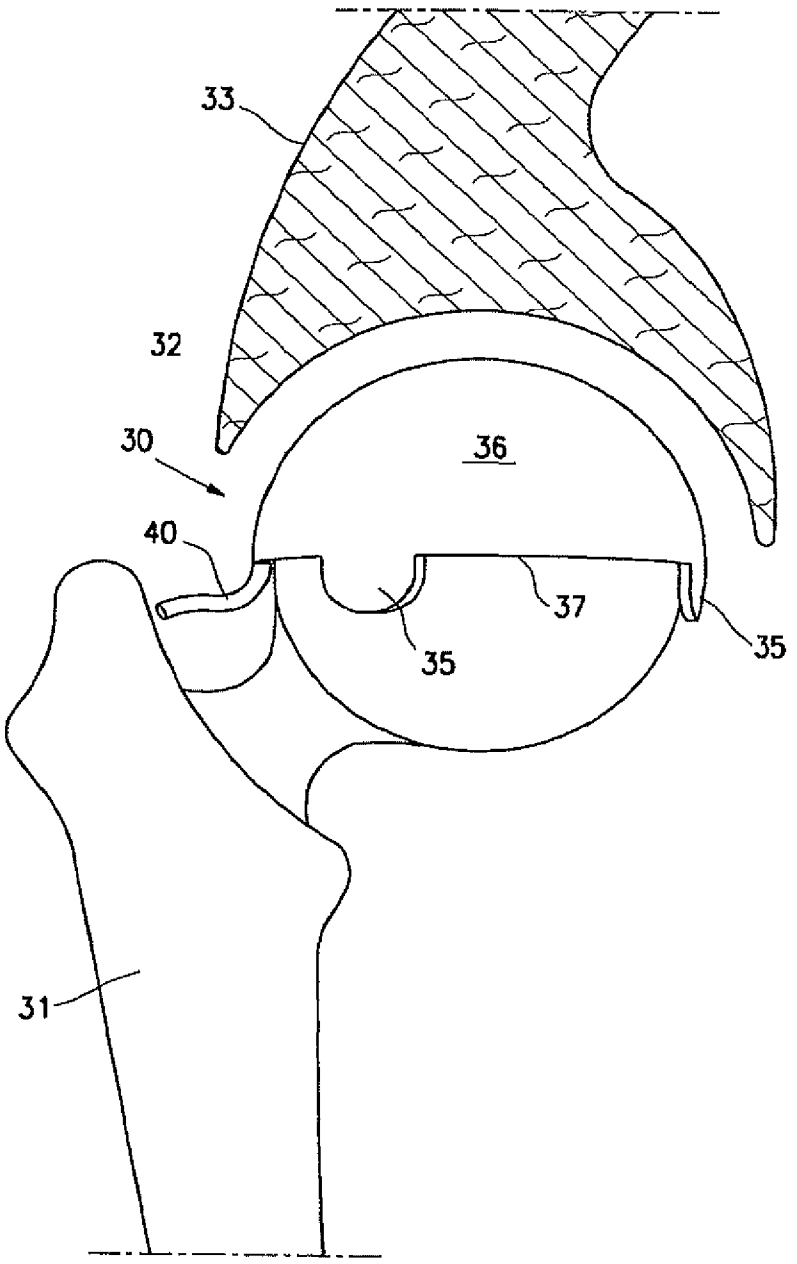

FIG. 7

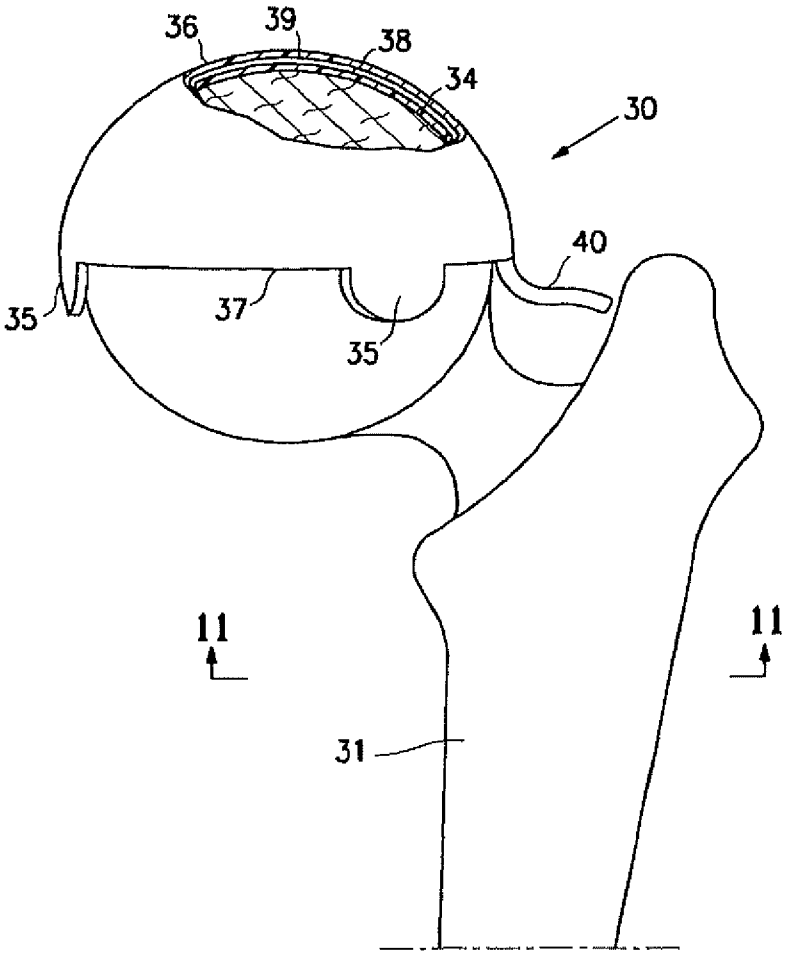

FIG. 8

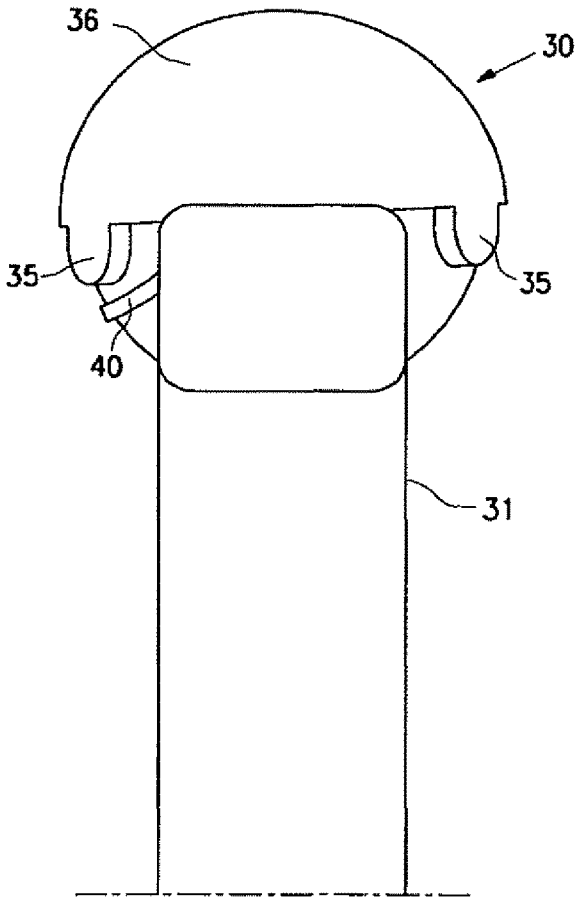

FIG. 9

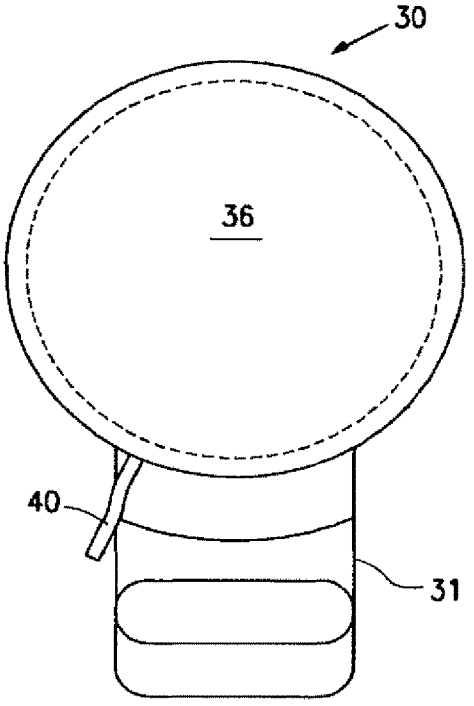

FIG. 10

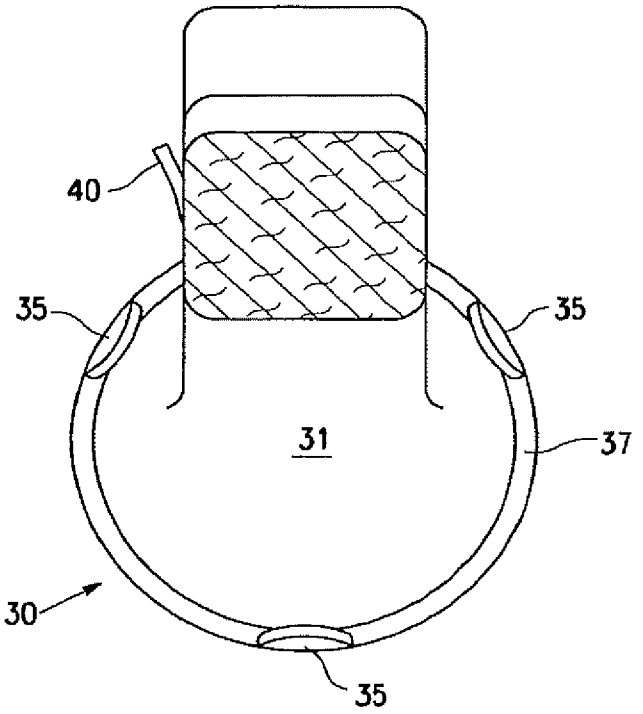

FIG. 11

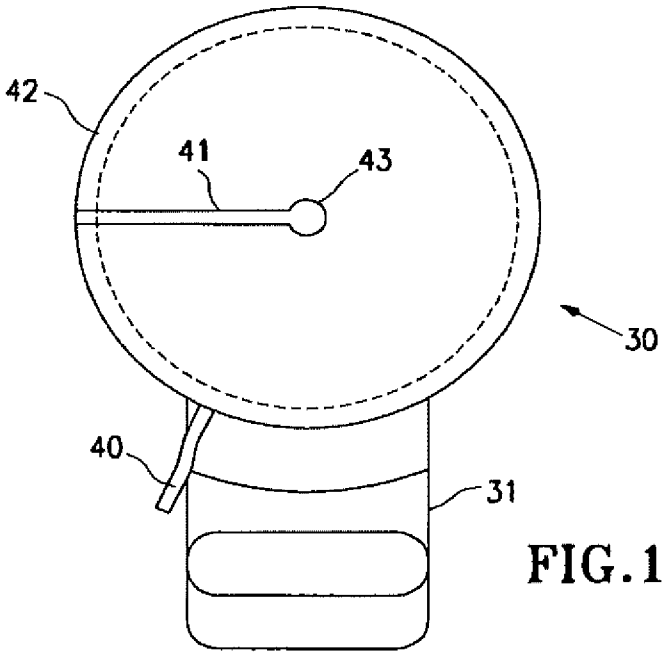

FIG. 12

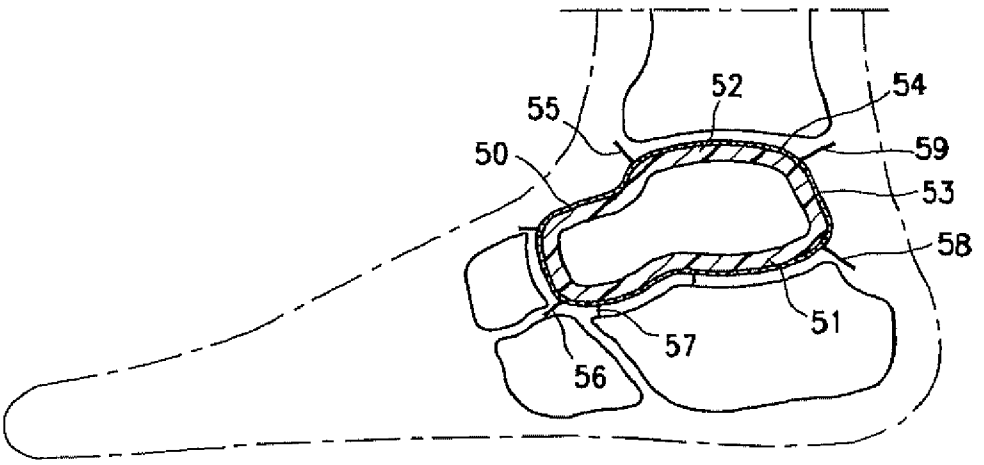

FIG. 13

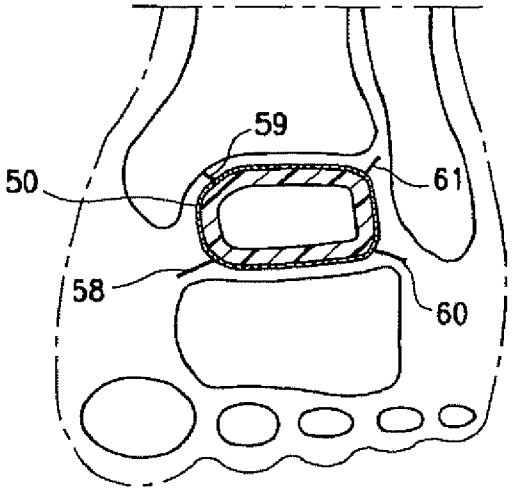

FIG. 14

METHOD OF TREATING A PATIENT'S JOINT USING A RESILIENT ARTHROPLASTY DEVICE

RELATED APPLICATIONS

This application claims the benefit of U.S. Non-provisional 12/460703 filed on Jul. 23, 2009, now U.S. Pat. No. 9,808,345, issued Nov. 7, 2017 which claims the benefit of U.S. Provisional Application No. 61/135820 filed on Jul. 24, 2008, all of which are incorporated herein by reference in their entirety.

BACKGROUND OF THE INVENTION

This invention relates to arthroplasty, and more particularly, to an implant for use in arthroplasty. When hyaline articular cartilage is damaged, it breaks down and joint space is lost. Inflammatory enzymes such as from the Cox-1, Cox-2 and/or 5-Lox systems, are released and loose bodies form adding to the degradation of joint function. Such joint damage is conventionally treated by physical therapy, analgesics, pain medication and injections. When these treatments fail, the traditionally accepted treatment option is arthroplasty implantation or replacing the joint with an artificial joint construct. Current arthroplasty techniques typically use "plastic and metal" implants that are rigid and which ultimately fail due to loosening or infection. Conventional materials for the artificial joint components include chrome-cobalt-molybdenum alloy (metal) and high molecular weight polyethylene (plastic). Each is often fixed by a cement-like mixture of methyl methacrylate to the ends of the bones that define the joint that is the subject of the arthroplasty, or coated with a surface that enables bone ingrowth. Current hip joint replacements typically last about 10-15 years and knee replacements typically last about 5-10 years. Ankle joint replacements, on the other hand, are not very successful, and often fail in the first several years after surgery.

Conditions requiring arthroplasty include traumatic arthritis, osteoarthritis, rheumatoid arthritis, osteonecrosis, and failed surgical procedures.

SUMMARY OF THE INVENTION

The present invention is directed to an orthopedic implant configured for deployment between opposing members of a joint structure that addresses many of the shortcomings of prior artificial joints. The arthroplasty implants embodying features of the invention are configured to preserve joint motions while removing the pain and dysfunction following the development of arthritis or joint injury. The arthroplasty implant in accordance with the present invention achieves improved physiologic motion and shock absorption during gait and acts as a resilient spacer between moving bones during limb movement. The combined characteristics of the implant include anatomic design symmetry, balanced rigidity with variable attachment connections to at least one of adjacent normal structures, and durability which addresses and meets the needs for repair or reconstruction thus far missed in the prior art. The implant should be secured to at least one of the bones of the joint structure.

More specifically, the resilient implant embodying features of the invention has a first wall configured to be secured to a first bone of the joint structure by one or more appendages such as a skirt or one or more tabs and a second wall configured to engage a second and usually opposing

bone of the joint structure. A side wall extends between the first and second walls of the implant and together with the first and second walls preferably defines at least in part an inner chamber or space between the first and second walls. The implant is configured to provide linear or curvilinear and/or rotational motion between the first and second bones which mimics or approximates the natural motion between these bones. The inner chamber or space is configured to maintain a filler material therein such as an inflation fluid or a resilient material and preferably to maintain spacing and provide support between the interior of the first and second walls to avoid significant contact therebetween. The walls of the implant are preferably sealed about the periphery thereof to maintain the interior chamber in a sealed condition to avoid loss of inflation fluid or filling media. The side wall or walls may be formed from the edges or periphery of the first and second walls. The properties of the implant walls and the interior are controlled to provide the particular resiliency desired for the joint in which the implant is to be placed as well as any desired motion between the first and second walls. A conduit may extend from a source of inflation fluid or other filling medium to the interior of the implant to facilitate expansion of the implant after deployment within the joint. The inflation fluid may be a gas, a liquid, a gel or a slurry, or a fluid that becomes a suitable resilient solid such as a curable polymer. Selection of the inflation or interior filling medium may depend upon the nature of the joint structure in which the implant is to be deployed, its anatomy, pathophysiology, and the properties of the implant material.

There may be several alternative embodiments depending upon the site in which the implant is to be deployed. For example, the polymer forming the side wall may be semi-compliant or elastic and the inflation fluid may be incompressible (e.g., a liquid). Alternatively, the polymer forming the side wall may be non-compliant (non-elastic) and the inflation fluid or filling medium may be compressible, e.g., a gas or a resilient polymeric foam or sponge-like solid that may have a closed cell structure. The first and second walls of the implant need not have the same properties as the side wall. For example, parts of the implant such as the side wall portion may be compliant and the first and second wall portions in contact with the bone or other joint structure may be non-compliant. Additionally, the various walls or portions thereof may also be reinforced with non-compliant or semi-compliant polymer strands, beads or gel coating such as biologic or polymer latticework. The thicknesses of the first, second and side walls may be varied to accommodate for the needs of the joint structure from the standpoint of strength, elasticity and wear resistance. Moreover, the walls of the implant may be provided with joint tissue regeneration agents that rebuild the joint structure in which the implant is deployed. The regeneration agent may be incorporated into the wall of the implant prior to delivery or placed between the surface of the implant and the joint structure which it contacts after delivery. All or part of the walls of the implant may also be made of a biodegradable polymer, by minimally manipulated autograph, allograph or xenograph tissues, or a combination thereof. The method of surgery may incorporate a progressive application of the implant embodiments depending upon clinical needs.

The implant is preferably formed of suitable biocompatible polymeric materials, such as Chronoflex, which is a family of thermoplastic polyurethanes based on a polycarbonate structure (Al, the aliphatic version, Ar, the aromatic version and C, the casting version) available from AdvanSource Biomaterials, Corp. Other polymers include Bionate 80, 90A, 55 or 56, which are also thermoplastic polyure-

thane polycarbonate copolymers, available from PTG Medical LLC., an affiliate of the Polymer Technology Group located in Berkeley, Calif. Other commercially available polymers include Purisil 20 80A which is a thermoplastic silicone polyether urethane, Carbosil 20 90A which is a thermoplastic silicone polycarbonate urethane and Biospan which is a segmented polyurethane. These polymers are available as tubing, molded or dipped components, solution, pellets, as a casting and as a cast film for the side and first and second walls. The implant may be formed by casting, blow molding or by joining sheets of polymeric material by adhesives, laser welding and the like. Other methods of forming the implant may also be suitable. The walls may also be provided with reinforcing strands which are located on the surface of the walls or incorporated within the walls. The implant material should be biocompatible, non-toxic, and non-carcinogenic and should be resistant to particulation.

The present invention provides an improved joint implant which is designed to endure variable joint forces and cyclic loads enabling reduced pain and improved function. Depending upon the particular joint involved there may be linear or curvilinear motion between the first and second walls, rotational motion between the first and second walls or both linear and curvilinear motion and rotation motion between the first and second walls. Preferably, a space is maintained between the inner surfaces of the first and second walls to avoid erosion and wear therebetween,

The resilient arthroplasty implant embodying features of the invention is preferably deployed as a minimally invasive procedure to deliver the implant into a prepared space in a preselected joint structure, where upon it is inflated to create a cushion, to cover damaged or arthritic cartilage and to be employed to deliver stem cells or living chondrocytes or other tissue regeneration agents. The goal of such deployment is to reduce pain and improve function, to reverse arthritis, to fill in osteochondral defects succinctly, thereby avoiding living with both dysfunctional and ablative metal/plastic prostheses or the pathophysiologic state necessitating the procedure. The operative plan is simple, systematic, and productive of new joint space with regrowth potential involving joint debridement by routine arthroscopic methods or steam application, followed by implantation of the implant. The implant provides three things, namely a covering or patch for the damaged or worn joint surface, an inflated cushion to pad gait as in normal walking in the lower extremity, and delivery of regenerative cells on the cartilage remnant surface. The stern cells may be injected as the implant is being expanded and/or directed into the adjacent hyaline cartilage via an implant coating or perfused cell template. Viscolubricants such as Synvisc or Hyalgan, analgesics such as Lidoderm, anti-inflammatory and/or antibiotic coatings as well as those stimulating cell growth may accompany the composite external implant. The implant is left in place as long as feasible, at least until regenerative cells can attach to the adjacent natural joint surface (usually in about 24 hours), or until wound healing (which may take up to 28 days or more depending on the joint structure). Preferably, the implant is designed stay within the joint structure for years, providing inert padding, cushioning and a new cell source. The implant may be used in weight bearing and non-weight bearing interfaces. Animal usage of the implant, such as in horses and dogs, will benefit following hip and knee injuries. The implant is intended primarily for mammalian use.

These and other advantages of the invention will become more apparent from the following detailed description and the attached exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic cross-sectional view of an idealized joint structure having first and second bones with an implant having features of the invention disposed within the space between the opposing bones of the joint structures.

FIG. **2** is similar to FIG. **1** illustrating curvilinear movement between the two opposing bones.

FIG. **3** is a transverse cross sectional view taken along the lines **3-3** in FIG. **1** illustrating rotational movement between the two opposing bones.

FIG. **4** is a perspective view, partially in section, of an implant embodying features of the invention with an enlarged upper portion prior to implantation.

FIG. **5** is an elevational view of the implant shown in FIG. **4** mounted on the head of a patient's femur.

FIG. **6** is a cross-sectional view of the implant shown in FIGS. **4** and **5** deployed between the head of a patient's femur and acetabulum after release of traction to allow for the bones to settle into their natural albeit pathologic angles of repose.

FIG. **7** is an elevational view of a resilient arthroplasty implant with a smaller upper portion than that shown in FIGS. **4-6** that has been deployed between the head of patient's femur and the acetabulum of the pubic bone.

FIG. **8** is an elevational anterior view of a left proximal femur with an implant placed over the femoral head portion of the hip joint as shown in FIG. **7**, in partial cross section, to illustrate details thereof.

FIG. **9** is a lateral elevational view of a femur with the implant shown in FIG. **6**, as viewed from the "side of the body" or lateral hip aspect.

FIG. **10** is a superior view of a femur with the implant shown in FIG. **7**.

FIG. **11** is an inferior view of the hip joint invention iteration or implant in FIG. **10**.

FIG. **12** is a superior or cephalad view of a patient's hip with a resilient implant having features of the invention, viewed from the head of the patient or from a cephalad to caudad direction.

FIG. **13** is a lateral view of the patient's ankle having a resilient arthroplasty device implant which embodies features of the invention between opposing joint structures.

FIG. **14** is a mortise (30 degree oblique AP) view of the patient's left ankle with implant shown in FIG. **13**.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

The present invention is directed to arthroplasty implants and procedures for a wide variety of joints such as, for example, hips, knees, shoulders, ankles, elbows, wrists, fingers, toes, temporomandibular joints and the like, but for clarity, as well as brevity, the discussion herein will focus on an implant for a hip joint and an implant for replacing the talus bone of a patient's ankle.

FIG. **1** is a highly schematic idealized view of an implant **10** embodying features of the invention that is deployed within a joint structure having a first bone **11** and a second bone **12**. The implant **10** has a first wall **13**, a second wall **14**, and a side wall **15** which define the implant interior **16** which contains filling material **17**. The first wall **13** is secured to the end of the first bone **11** by the skirt **18** that

extends from the first wall **13** and the second wall **14** engages the end surface of the second bone **12** and may also be secured thereto. The side wall **15** extending between the first and second walls **13** and **14** defines at least in part the implant interior **16** which is filled with filling material **17**. The inner surfaces of wall **13** and skirt **18** preferably conform to the particular surface of the head of the patient's first bone **11**. The outer surface of the second wall **14** is preferably configured to conform to the end surface of the second bone **12**. The drawings are highly schematic and do not depict details of the joint surface features such as of the end of the first bone **11** or the end of the second bone **12**, since human pathology and variation reflects both the patient's immediate and evolving pathophysiology.

The edge of the implant **10** shown in FIG. **1** has a depending skirt **18** to secure or anchor the implant to the end of bone **11**, but may have one or more depending tabs that may be employed for similar functions as will be discussed in other embodiments. The skirt **18** (and/or tabs) may tightly fit about the end of the first bone **11** as shown, or the skirt can be secured by adhesive (e.g. methyl methacrylate, bone ingrowth) to the supporting bone structure or be mechanically connected by staples, screws and the like. Moreover, the lower portion of the skirt **18** may be secured by a purse string suture or a suitable strand (elastic or tied) that is tightly bound about the outside of the skirt.

As shown in FIG. **1**, the implant interior **16** between the wall **13** and the wall **14** is filled with filler material which aids in maintaining the desired implant dynamics within the joint structure. The nature of the filler material such as a fluid and the characteristics of the walls **13**, **14** and **15** may be selected to maintain a desired spacing between the walls in order to accommodate the pressure applied by the bones of the joint structure to the implant **10** and to allow suitable motion between the first and second walls **13** and **14** of the implant **10** which facilitate bone motion which mimics or approximates normal movement for the joint members involved such as shown in FIGS. **2** and **3**. Alternatively, as mentioned above, the inner chamber may be filled with resilient material to provide the desired spacing, pressure accommodation, while allowing desired physiologic motion between implant layers. The implant **10** is preferably configured to be shaped like the joint space and bone surfaces being replaced or to fill the void produced by injury or disease so that the natural joint spacing and cushioning of the joint interface is restored toward normal physiologic appearance and function. Fluids such as saline, mineral oil and the like may be employed to inflate the implant.

Linear or curvilinear movement between the first and second walls **13** and **14** as a result of movement of the first and second bones **11** and **12** is illustrated by the arrow shown in FIG. **2**. Rotational movement about the bone axis between the first and second walls **13** and **14** as a result of axial rotation between the first and second bones **11** and **12** is illustrated by the arrow shown in FIG. **3**. While not shown in the drawings, there may be slippage between the second bone and the second wall in addition to wall movements within the implant per se to provide desired joint movements. The skirt **18** is designed to secure the general implant to the joint structure so as to avoid dislocation of the implant. Movement of the joint with the implant **10** in place will be a shared function of both the moving opposing walls **13** and **14** of the implant but also a function of the movement of the wall **14** which may be less attached to the joint members. There may be slight movement between the skirt **18**, wall **13** and the first bone **11**. As shown in FIG. **2** one side of the side wall **15** is in compression and the other is stretched to accommodate bone interface movement. The walls **13** and **14** may be thicker is some areas to accommodate particular loads and the side wall **15** may be thinner and more elastic to accommodate rolling and stretching thereof.

The interior **16** of implant **10** is adjustably filled by the physician from an appropriate source thereof after the implant is deployed to ensure that the pathologic joint space becomes a resilient cushion again which aids restoration of worn or damaged cartilage interfaces in the joint by covering cartilage defects with the implant material, cushioning the joint and defects therein and delivering cell regeneration agents. In one embodiment, the arthroplasty implant comprises a bio-compatible inflatable member that is filled with a biocompatible fill material such as a gas, liquid, gel or slurry, or fluid that becomes a resilient solid to provide relative movement between the first and second walls **13** and **14**. The filling or inflation media may be inserted through an injection valve site leading to the cannula which delivers the material into the interior of the implant. In an alternative embodiment, the implant may be filled with or have an interior formed of biologically compatible resilient material, e.g. a closed cell sponge filled with suitable fluid that is inserted into the interior of the implant prior to the implant's deployment or injected into the interior after the implant is deployed at the joint site. The interior of the implant may be provided with lubricious material to facilitate movement between the inner wall surfaces and to minimize contact wear therebetween. The polymeric walls of the implant may be impregnated with or otherwise carry tissue regeneration agents such as stem cells, living chondrocytes, and/or genes to repair joint surfaces.

The implant can be used in a variety of joints where the implant replaces a bone on bone surface and cushions the interaction between the articular ends of any two bones, such as at the femoral-acetabular interspace of a patient's hip, the humerus and glenoid scapular component in the shoulder, the femoral tibial and patella femoral knee interfaces, the replacement of talus bone in the human ankle between the tibia and calcaneus and the like. Where the implant is substituting or enhancing articular cartilage, the rigidity can be reduced or enhanced to maximize conformation changes that arise during motion as enabled by the two opposing walls and intended inner space, coupled with considerations in any joint surgical reconstruction with accommodation to or amplification of the existing joint ligaments, tendons or dearth thereof. The implant **10** may be deflated and removed by minimally invasive surgery, for example after the implant has served its purpose of regenerating tissue or if another clinical condition warrants its removal. However, it may not be clinically necessary to remove the implant even if inflation is lost, since the two remaining functions of patching the injured cartilage, and delivering restorative cells may justify implant retention.

FIG. **4** is a perspective view, partially in section, illustrating a hip implant **20**, similar to that shown in FIG. **1**, but with a much larger upper portion. The large upper portion of the implant **20** has a first wall **21**, a second wall **22** and a side wall **23** which define at least in part the interior **24**. Skirt **25** depends from the first wall **21** and secures the first wall **21** to the end of the patient's femur **26** as best shown in FIGS. **5** and **6**. FIG. **6** illustrates the implant mounted on the head of the femur **26** with the second wall **22** of the filled upper portion configured to engage the corresponding acetabulum **27** of the patient's pelvic bone **28**. The skirt **25** surrounds the head of the patient's femur **26** and secures the implant **20** thereto. In this embodiment, the enlarged upper portion of the implant creates overlapping layers, like a redundant

membrane, in the side wall **23** between the first and second walls **21** and **22** to accommodate the normal movement of the first or second. This provides greater motion between the femur and the acetabulum and also provides implant stabilization over the head of the femur **26**. This structure also accommodates variation in individual joints that occur from patient to patient.

In the embodiment shown in FIGS. **4-6** the first wall **21** does not extend across the entire end of the patient's femur as in the embodiment shown in FIGS. **1-3**. However, the implant **20** may be designed so that first wall **21** may extend over the head of the femur as shown in FIGS. **1-3** (and FIGS. **7-12** discussed hereinafter). The second wall **22** and the side wall **23** tend to roll as the femur **26** moves within the acetabulum **27**.

Prior to deploying the implant embodying features of the invention, the cartilage lining the joint is prepared by removing hyaline or fibro cartilage flaps or tears, and areas of chondral advanced fissuring are excised or debrided to create precisely defined defects surrounded by stable normal remnant hyaline cartilage with vertical edges in relation to the damaged surface. It is these defects of the cartilage previously normal surface into which new living cells may be injected or otherwise inserted, and allowed to aggregate by the implant interpositional arthroplasty proximate expanded compressive external wall material. Synovitis invading the joint periphery may be vaporized and extracted conventionally or by the use of steam. Areas of greater cartilage damage are removed for subsequent regeneration and the less afflicted areas having stable cracks are treated to seal or weld the cracks. Areas where the tugor or consistency or minimally damaged cartilage can be preserved are intentionally saved rather than destroyed so as to support the normal spacing and gliding opportunity of the more normal joint interface. Thus, normal cartilage is left behind and abnormal cartilage is removed with the implant making up for the deficiencies. With the present invention, it is preferred to avoid joint dislocation so as to preserve natural innervations and vascularity and thus preserving the blood supply afforded by the medial and lateral circumflex arteries for the hip joint to the femoral head.

Joint preparation is usually performed under a brief general anesthetic of outpatient surgery. A muscle relaxant combined with traction (e.g. 60 pounds force for a hip implant) opens the joint wider to permit improved visualization for joint preparation and implant installation, increasing the space between the remnant cartilage from about 3 up to about 12 mm. Increasing the space allows the surgeon to wash out noxious enzymes, to remove invasive synovitis, to remove loose bodies, to prepare osteochondral defects ideally and otherwise prepare the joint for the implant. Partial or complete inflation of the implant will usually precede release of traction. Regeneration agents or cells are inserted with the implant or as a fluid or 3-D template prior to release of traction and wound closure. It is preferred to perform joint debridement, implant deployment and application of cell regeneration agent, e.g. stem cell application, under the same anesthetic. As described by several companies in the Stem Cell Summit held in New York, N.Y. on Feb. 17, 2009, it is desirable to obtain an aspiration of the patient's bone marrow from the iliac crest after anesthesial sterilely at the beginning of the operation. The intraoperative technologist will "dial in the cells" to regenerate areas of maximum pathophysiology while the surgeon debrides or otherwise prepares the joint and inserts the implant, placing the cells at the best time. Cell implantation may also occur as a secondary or tertiary reconstructive treatment adjunct.

FIG. **7** is an elevational view, partially in section, of an alternative resilient implant **30** deployed within a patient's hip structure comprising the head of the patient's femur **31** and the acetabulum **32** of the patient's pelvic hip bone **33**. The upper portion of the implant **30** is smaller than that shown in FIGS. **4-6**. Details of the interior of the joint are not provided such as cartilage, ligaments and the like for the purpose of clarity. The resilient implant **30** embodying features of the invention is disposed within the space between the femur **31** and the acetabulum **32**. FIGS. **7-11** illustrates the implant **30** mounted on the head of femur **31** without the pressure from the acetabulum **32** for purposes of clarity.

The implant **30** shown in FIGS. **7-12** is shaped like a half an orange rind or a hemisphere for a hip joint. The implant **30** has a first wall **34** seen in FIG. **8** which is secured to the head of the femur **31** by a plurality of depending tabs **35**. The tabs **35** may be attached to the femur **31** by a suitable adhesive or mechanically such as by a screw or pin. The second wall **36** of the implant engages the acetabulum **32**, but it also may be provided with tabs and the like for securing the second wall the acetabulum **32**.

The side wall **37** extends between the first and second walls **34** and **36** to form an interior **38** which receives filling material **39** through tube **40**. The implant **30** would also be appropriate for the humeral head in the shoulder or one condyle of the knee or of the humerus, but other shapes may be desired for other joint configurations whether relatively flat as in the thumb base, or more inflated toward a ballooning construct as in the ankle when the talus bone is collapsed. In many embodiments the implant **30** is a weight bearing spacer that will allow joint motions to approach normal, whether filling the space left by an entirely collapsed peripheral joint bone or the space of ablated cartilage proximate surfaces diffusely as in osteoarthritis or succinctly as in osteonecrotic defects or localized trauma. The walls **34** and **36** may be used as a membrane for holding living cells in proximity of the osteochondral defect long enough for the cells to attach (e.g. 24 hours) or to deeply adhere (up to 28 days) or return to normal (up to one year). Weight bearing will be expected to increase as distal lower extremity joints are treated.

Motion is believed to be primarily between the spaced walls of the implant peripherally secured to joint structures, although some motion may occur between the implant and the joint surfaces (as with current bipolar hip hemiarthroplasties). As shown in FIG. **12**, the implant **30** may be provided with a slot **41** extending from the periphery **42** of the implant to a centrally located passage **43** through the implant to accommodate the ligament of the head of the femur for hip implants. Knee implants (not shown) may have two slots leading to separate passages for receiving the anterior and posterior cruciate ligaments. Implants for other locations may have similar variable structures to accommodate anatomical features. Implant walls **34** and **36** should have sufficient inherent flexibility to mold to the existing deformities imposed by either natural ligament, bone, tendon and remaining cartilage deformities of the internal joint space filled as a cushion. The wall exteriors may be flat or formed with random or specific patterns for purposes of glide or trends for traction against adjacent surfaces, or as sulci or venues for cell delivery materials.

A separate portal or tube (not shown) or the existing conduit **40**, may be used to extract noxious inflammatory

enzymes that can be aspirated at appropriate clinical intervals. Inflammatory enzymes in the COX1, COX2 and or 5LOX pathways can be extracted. Viscolubricants can be injected into the interior of the resilient arthroplasty device through existing conduit **40** or through a long needle to aide in distension, expansion, lubrication (with predetermined microporosity).

The ankle version of the arthroplasty implant **50** of the present invention shown in FIGS. **13** and **14** has basically a square transverse cross-section that must take into account supratalar ankle dorsi/plantar flexion, subtalar eversion/inversion motions, ligament fixation-needs, and the accommodation to existing bony architecture as implant variables accounting for the ipsilateral joint pathophysiology. The implant **50** has a first wall **51**, a second wall **52** and a side wall **53** which extends between the first and second wall. The exterior of the implant **50** may have a mesh material **54** with a plurality of chords **55-61** for securing the implant **50** to adjacent bones or to remnant ligaments which are attached to adjacent bones.

The implant **50** may be inflated with gas and/or liquid to open wider the space between the tibia above and the calcaneus below to accommodate collapse of the talus bone as in the flattening which succeeds talus fracture with avascular necrosis, or it may be filled with a liquid that becomes a resilient solid. The instant center of the implant's rotation will be constantly changing, with the talus implant mainly stable and with the tibia moving over it. Deformation with weight bearing during the average human's 10,000 daily steps or 2-4 million annual gait cycles required by the stance and walking of normal activities of daily living, must be balanced between sufficient solidarity of the implant to maintain axial load, avoiding circumferential stress, and shear forces imposed by the tibia distal plafond on the dorsal ankle implant allowing stance and gait of the patient while avoiding implant migration or failure. Further accommodation to lateral forces imposed by the boney medial and lateral malleoli, need to be endured through the cyclic load of walking, while collapsing with enough give to absorb shock and to match the shape of surrounding structures of bone and ligament tissue. Whereas the axial load between the distal tibia through the talar implant to the dorsal calcaneus will be loaded during stance and especially while walking on a level plane for supratalar motion, the lateral forces will be loaded particularly with subtalar motion while walking on an uneven plane or with inversion/eversion.

The dimensions of the various implant walls will vary depending upon the material properties thereof as well as the needs for a particular joint. Additionally, the first and second walls may require a thickness different from the side wall. Generally, the implant may have a wall thicknesses of about 0.125 mm to about 3 mm, preferably about 0.5 mm to about 1.5 mm. The spacing between the first and second wall within the interior can vary from about 0.5 mm to about 5 mm for most joints (except for the implant for an ankle when an entire collapsed bone space is being replaced), preferably about one to five centimeters to fill between the tibia and calcaneus. In the ankle invention version of the implant, the amount of inflation of the implant per se will be directly proportional to the amount of talus bone collapse between the distal tibia and proximal calcaneus—thus as much as 5 cm implant distension or expansion may be required to be maintained between superior and inferior surfaces in FIG. **13** of the talus, while as much as 10 cm anterior and posterior expansion may be required for the ankle implant between the posterior soft tissues such including the Achilles tendon and the anterior navicular bone as relates to the talus as seen in FIG. **13**.

The method of insertion for the hip joint invention will be a minimally invasive approach, ideally arthroscopically facilitated, as long as the surgical timing and result quality permit smaller incisions. The hip patient will be placed in the lateral decubitus position (lying non-operative side down on the operating table) with a stabilizing operating table pole and pad apparatus positioned to fix the pelvis. The external stabilizing table and attachments will include a padded metal pole beneath the pubis or pelvic bone from posterior to anterior, along with other external anterior and posterior pelvic stabilizing paddles. The affected leg will be attached beneath the knee with a distracting mechanism that applies about 60 pounds of distal force to open the hip joint about 1 cm once the patient is under general anesthesia. The hip joint is arthroscopically debrided through at least one anterior 0.5 cm incision and one posterior 0.5 cm incision, to remove from the femoral head acetabular (ball and socket) joint arthritic debris such as synovitis, loose bodies and noxious inflammatory enzymes. In certain cases a larger open incision may be needed. A smoothing or electronic/ultrasonic/steam or other chondroplasty method may be performed to make the remaining cartilage smoother to better accommodate the hip implant, and protuberant osteophytes or lateral bone overgrowths may be arthroscopically removed or if needed by open excision. A lateral hip incision may be required between 2 and 10 centimeters in length to deal with deformities and/or to insert the implant. In cases of major deformities appropriate reconstruction will add to the basic procedure.

Once the joint is open and cleared, the hip implant will be inserted laterally and fixed via the skirt or tabs to the adjacent structures including the peripheral femoral head and/or acetabular rim. Preferably, the implant is inserted arthroscopically through a cannula about 10 mm in diameter with the implant in the deflated construct, and once inside the prepared joint space and secured therein by the skirt or tabs, the implant will be distended or inflated with gas, gel, fluid or fluid that becomes a resilient solid to fill the original natural space of about 0.5 cm between the upper acetabulum and lower femoral head, covering as much of the upper hip joint as required as the implant expands to fit the space. Tensioning will be by the surgeon's sense of proper pressure application aided by a gauged syringe for insertion of viscolubricants such as Synvisc, Hyalgan, Supartz and/or analgesics such as lidocaine gel. The insertion of liquids to the joint per se may be directly, through a cannula to the joint space previously in place for debridement, and or via a cannula or tube that is not part of the original implant assembly. Once the joint is cleaned, the implant is inserted and appropriately fixed to avoid extrusion or dislocation thereof. This may be via attachment of the implant tabs and/or by a combination of tab use plus intended friction created by implant surface coverings (analogous to Velcro) or a draw string at the smaller base of the implant.

The walls of the implant embodying features of the invention may be composite structures. For example, the innermost layer may be impervious to preclude escape of inflation or other filling media, a central layer may be porous or otherwise contain treatment or cell regeneration agents, and the outer layer may be a thin, but strong layer of a thermoplastic such as a thermoplastic polyurethane which has microporosity sufficient to allow passage or egress of treatment or cell regeneration agents from the central layer. The degree of microporosity to enable egress of treatment or

cell regeneration agents from the central layer is found in polymer layers such as Chronoflex or Bionate 55. The external wall of the implant may be coated and/or impregnated with a latticework of polymer surface sprayed or layered on the outside of the implant to promote cartilage tissue regeneration. This most external surface coating may contain living chondrocytes as in the Carticel procedure by the Genzyme company, and/or may contain stem cells with directed gene mutations to enhance adherence of the coating to the implant. The living cells may be imposed in between troughs while the surface areas of prominence may be used for space validation, traction, and cell protection.

The implant embodying features of the invention may be used in a series of treatments wherein the first treatment involves use of autologous or minimally manipulated allograph interpositional tissues or xenograph, the second treatment involves the use of the same type of tissue added to stem cells or chondrocytes and the third treatment involving deployment of the implant if the first two fail or are ineffective.

The implant may be provided with latticework or other reinforcing strands, preferably on the exterior or within the wall thereof to control the maximum expansion of the implant when deployed at the orthopedic site.

The method of insertion of the ankle implant generally will be through an anterior surgical ankle approach or tendon separating incision from the distal tibia to the proximal talus (or calcaneus if the talus is absent), removing and reconstructing portions of the superior and inferior ankle extensor retinacula only to the extent required to gain access to the cleared tibiotalar space. Analogous to the hip joint insertional method, the ankle joint will be prepared arthroscopically under general anesthesia, and may benefit from distal distraction as in total ankle joint replacement surgeries with the DePuy Agility technique pinning above and below the ankle joint and then distracting it. The degree of distraction required in all joints to which this invention is applied, including but not limited to those of all appendicular skeletal structures such as the shoulder, elbow, wrist, phalanges, hip, knee, and ankle, will depend both on the nature anatomy and located pathophysiology that must be accommodated on a case by case basis and said distraction may be a combination of body position using gravitational forces and/or superimposed distracting devices. In the ankle, the surgeon will be developing the interval between the extensor hallucis longus and anterior tibial tendons. Injury tissue is removed, and the implant inserted fitting as preplanned. The implant surface may be provided with roughness, e.g. external mesh, to control movement by friction as described above for the hip joint, and/or attached fixation cords or tabs to connect to proximate ligaments or adjacent boney structures may be used at the surgeon's discretion to balance implant location stability and integrity, with the need for functional joint movements.

Over time, ingrowth of repair tissue aids in fixation and stability externally to the implant, while the soft cushioning implant interior will absorb forces across the joint surfaces and permit proper motion. The tugor or wall tension of the implant as well as the inside distension of the implant per se can be adjusted by adding or removing the inflation substance to the implant's interior space.

Accordingly, the present invention provides a new approach to arthroplasty that involves a resilient implant device deployed between bones of the joint. Whereas a joint is comprised of the interface between bone cartilage space cartilage bone, in certain joint spaces such as the knee, the invention cushion may expand to fit the spaces between both "knee joints"—the femoral tibial involved on standing or walking on a level plane, and the patella femoral bones of the knee more involved on stair ascent and decent. For example, pressures behind the knee cap or patella when lying are zero, when standing are 0.7 times body weight, and when going up and down the patella femoral pressures are 3-4 times body weight. Thus, the implants will need to accommodate all the normal body functional pressures and complex space movements, as described above also in the ankle. When in the hip joint, the normal flexion up to 120 degrees, extension of 20 degrees, abduction of 50 degrees, internal and external rotation of 45 degrees will produce variable axial, shear, and cyclic loads which the implant by design will accommodate and endure as up to 6 times body weight, consistent with a tire on a car that allows for cyclic loads different when driving straight or turning corners. The implant embodying features of the present invention provides more physiologic motion and shock absorption within the joint and has combined characteristics of anatomic design symmetry, balanced rigidity with sufficient attachment connections to adjacent normal structures, and durability that meet the needs of joint reconstruction.

The opposing internal surfaces of the first and second walls of the invention may either move together in synchrony or in opposite directions from one another (e.g. the superior wall moving medially in the hip and the inferior wall moving laterally). Optionally, the implant may be fixed to a concave surface of the joint (e.g., the acetabular hip cup) or to a convex surface of the joint (e.g. the dorsal femoral head surface), to both, or to neither (e.g., having an interference fit within the joint with an expanding balloon or cushion that fills the existing space). The implant may be inserted arthroscopically like a deflated balloon and then inflated through a cannula into the ankle or hip (or other joint structure) to act as a cushion or renewed interface for painless and stable limb motion. When feasible joint capsular and adjacent ligament tissue as well as bone will be left in place to preserve the natural body, unless interfering with reconstructed limb function.

The application of steam in addition to removing damaged debris, can smooth out and reform the joint surface. The high temperature of the steam tends to weld cracks or fissures which can be present in the cartilage surface of a damaged joint. Smoothing of joint surface cartilage with steam welds or seals existing cracks or flaps in the cartilage, especially superficially as the lamina splendors, which melt together to provide a white shiny gliding joint surface. In cases where bone is exposed, the steam can be used to stabilize the periphery of the defect in the joint surface via capsulorrhaphy or joint tightening. Open mechanical and chemical debridement may also be employed to prepare the surfaces for the implant.

Once the implant is secured to the femoral head by means of the skirt or tabs, an impregnated transfer medium or cell template may be used, as described by Histogenics and Tygenix chondrocytes delivery systems wherein the position of concentrated cells is mechanically placed about the implant at areas of greatest cartilage damage to promote regrowth, or as in Carticel wherein watery cells are implanted beneath a periosteal membrane (a wall of the implant serving as the membrane), prior to completion of the inflation or expansion of the implant. At syringe or gauged device with measured screw-home pressure is used to inflate the implant.

Once the joint is ready to receive the implant, the deflated implant is advanced through the diaphragm of a delivery cannula (such as the Acufex from Smith & Nephew) and into

the joint. It can be inflated by the attached cannula using a common syringe, inserting several cc's of filler material. Inserted contents and locations of cell placements depend on areas of need and joint size. In the hip implant several cc's of filler material and a viscolubricant in the interior of the implant will allow distension, cushioning, and gliding movements. Cell regeneration agents are placed in the areas of greatest need.

Methods of living stem cell or chondrocyte placement depend on the lesions and specific implant construct. Direct infusion into the joint with completion of implant inflation will press the cells into the hyaline surface, whereupon they attach within the first 24 hours. As a result, the patient should remain sedentary and the joint where the implant is deployed, non-weight bearing for the first day after surgery. Deeper osteochondral defects can be treated by 'hyper-perfusion of cells' via either 3-D cell transfer templates, or microneedle injection as used in treatment of diabetic patients for blood sugar testing and insulin/transdermal drug delivery. The cannula attached to the implant may be sealed and detached, or left in place for periodic aspiration of noxious enzymes as for the Cox-1, Cox-2, and 5-Lox systems, followed by reinsertion of activated substances including viscolubricants, or even more cells.

Implants embodying features of the invention may be designed for permanent or temporary deployment within a joint structure. Moreover, the implant may be formed of suitable bioabsorbable materials so that the implant may be absorbed within a particular predetermined time frame. Suitable bioabsorbable materials include polylactic acid, polyglycolic acid, polycaprolactone, copolymers, blends and variants thereof. One present method of forming the implant is to apply numerous layers of polymer such as ChronoFlex AR in a solvent and evaporating the solvent after applying each layer.

The skirting or fixation tabs of the present implant prevent joint migration during use. This is in contradistinction with prior solid polymer implants that tended toward dislocation and poor post operative function.

While particular forms of the invention have been illustrated and described herein, it will be apparent that various modifications and improvements can be made to the invention. One alternative implant construction involves the use of an upper portion of the implant having a net-like construction and filled with balls or ball bearing like elements that are larger than the openings in the netting. The balls or ball bearing like elements provide motion to the implant. The netting and ball bearing like elements may include regeneration agents as previously discussed, and the bearing construction may be directed toward favorable implant movement balanced with content disbursement.

The invention is intended primarily for human use but may be extended to mammalian use. To the extent not otherwise disclosed herein, materials and structure may be of conventional design.

Moreover, individual features of embodiments of the invention may be shown in some drawings and not in others, but those skilled in the art will recognize that individual features of one embodiment of the invention can be utilized in another embodiment. Moreover, individual features of one embodiment may be combined with any or all the features of another embodiment. Accordingly, it is not intended that the invention be limited to the specific embodiments illustrated. It is therefore intended that this invention be defined by the scope of the appended claims as broadly as the prior art will permit.

Terms such as "element", "member", "component", "device", "means", "portion", "section", "steps" and words of similar import when used herein shall not be construed as invoking the provisions of 35 U.S.C § 112(6) unless the following claims expressly use the terms "means for" or "step for" followed by a particular function without reference to a specific structure or a specific action. All patents and all patent applications referred to above are hereby incorporated by reference in their entirety.

I claim:

1. A method of treating a patient's joint comprising:

a. providing a resilient orthopedic single continuous sheet implant with a first wall, a second wall and a side wall wherein the first wall is configured to engage a first bone, the second wall is configured to surround a portion of a second bone sufficiently enough to secure the implant to the second bone, the side wall is configured to extend between the first wall and the second wall with sufficient compliancy for creating a first fold in the implant between the second wall and the side wall and a second fold in the implant comprising the side wall such that some length of an exterior surface of the side wall has a concave shape at the second fold to allow for dynamic overlapping on itself and accommodation of normal movement between the first bone and the second bone;

b. deploying the implant, within the joint to be treated, between the first bone and the second bone such that the implant further comprises an interior portion configured to be directly enclosed by only the first wall, the side wall, and a portion of the second bone; and

c. securing the second wall to the second bone of the joint;

wherein the deployed implant treats the joint in the patient.

2. The method of claim **1**, wherein the first bone is an articulating end of an acetabulum of a pelvic bone and the second bone is a femoral head.

3. The method of claim **1**, wherein the second bone is a humeral head in a shoulder.

4. The method of claim **1**, further comprising deploying a tissue generating agent on or incorporated within at least one of the walls of the implant.

5. The method of claim **1**, in which the first wall or the side wall is punctured to deliver one or more active agents to the interior portion.

6. The method of claim **5**, wherein the active agents comprise restorative, analgesic or pharmaceutical agents.

7. The method of claim **6**, wherein the restorative agents are regeneration agents, stem cells, living chondrocytes, growth factors, hyaline cartilage regenerating agents or genes.

8. The method of claim **6**, wherein the analgesic agents include viscolubricants, lidocaine, anti-inflammatory agents or anti-arthritic agents.

9. The method of claim **6**, wherein the pharmaceutical agents include antibiotics, antifungals, chemotherapeutics or enzymes.

10. The method of claim **1**, wherein the sheet is multi-layered.

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(12) **United States Design Patent** (10) **Patent No.: US D833,613 S**
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(54) **RESILIENT KNEE IMPLANT**

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See application file for complete search history.

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(Continued)

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(74) *Attorney, Agent, or Firm* — Michel Graffeo

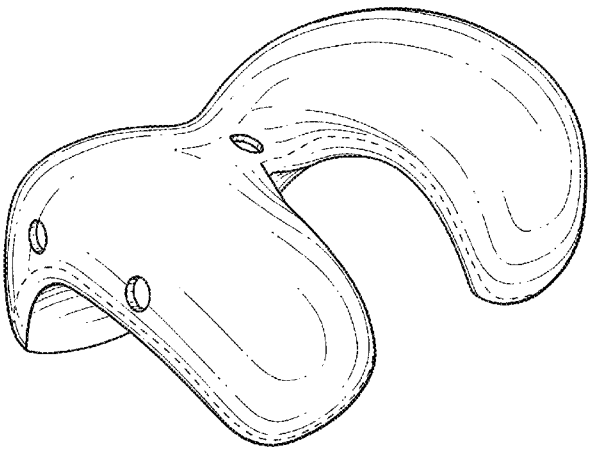
(57) **CLAIM**

The ornamental design for the resilient knee implant, as shown and described.

DESCRIPTION

FIG. **1** is a side perspective view of the resilient knee implant comprising the new design;
FIG. **2** is a side perspective view of the new design of FIG. **1**;
FIG. **3** is a top perspective view of the new design of FIG. **1**;
FIG. **4** is a front elevation view of the new design of FIG. **1**; and,
FIG. **5** is a side elevation view of the new design of FIG. **1**.
The broken lines in the figures are for illustrative purposes only and form no part of the claimed invention.

1 Claim, 5 Drawing Sheets



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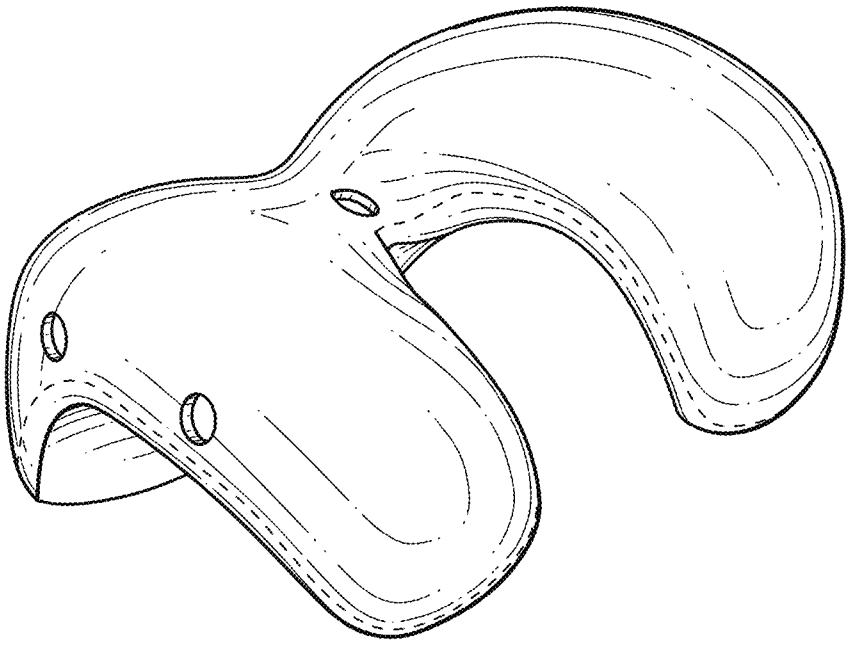

FIG. 1

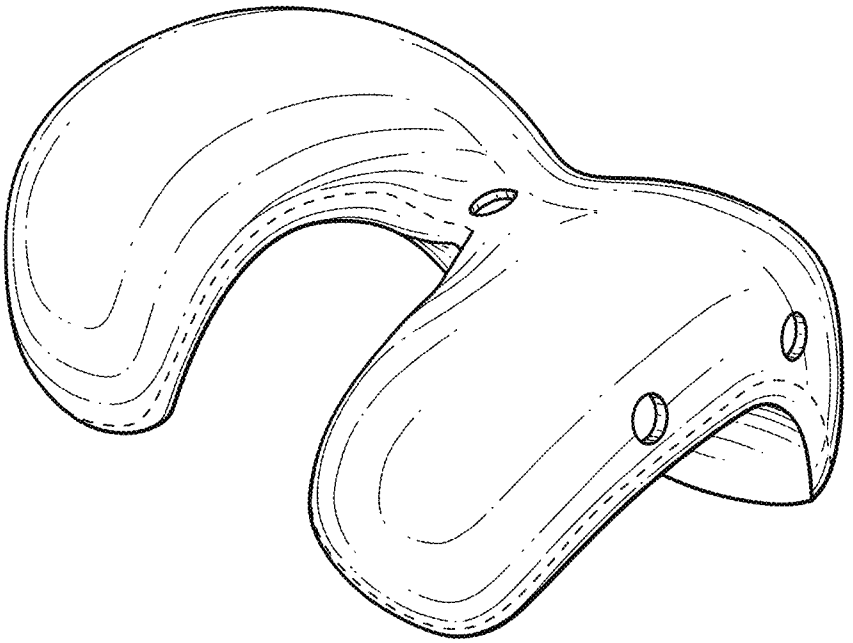

FIG. 2

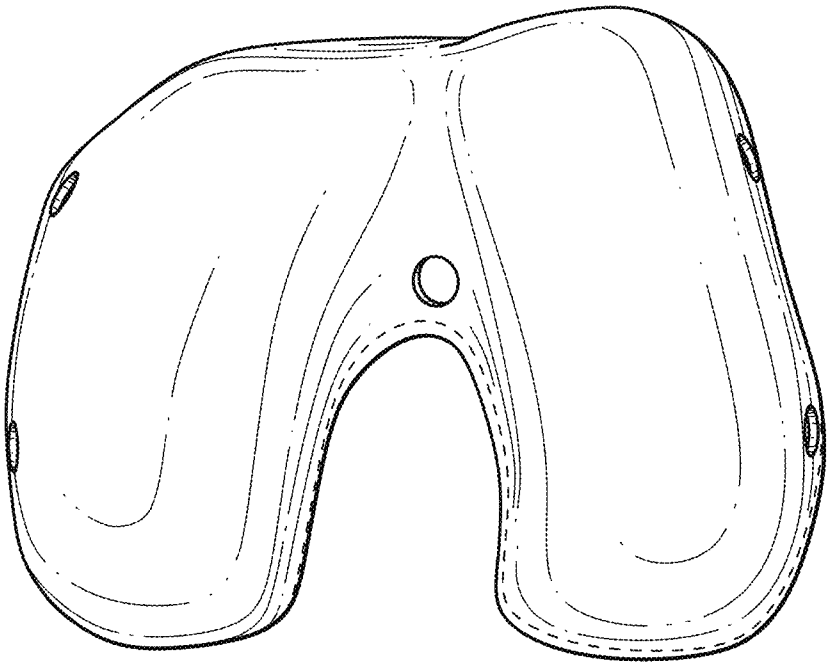

FIG. 3

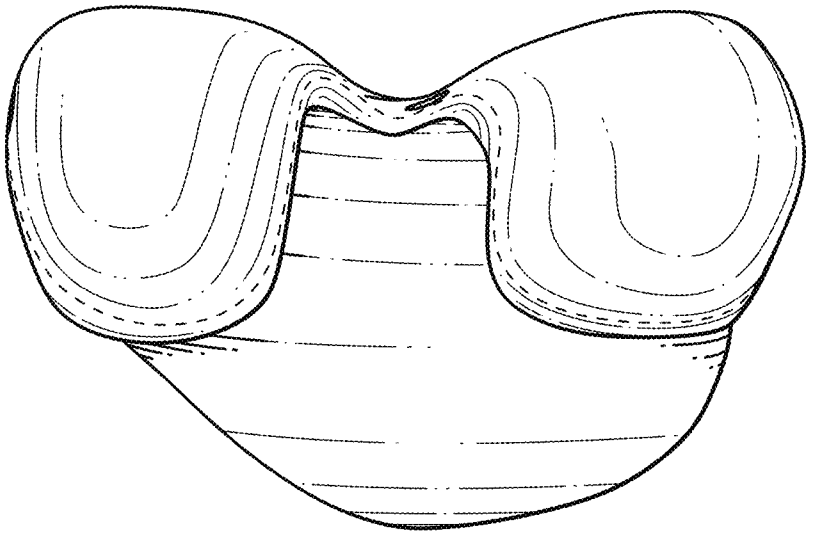

FIG. 4

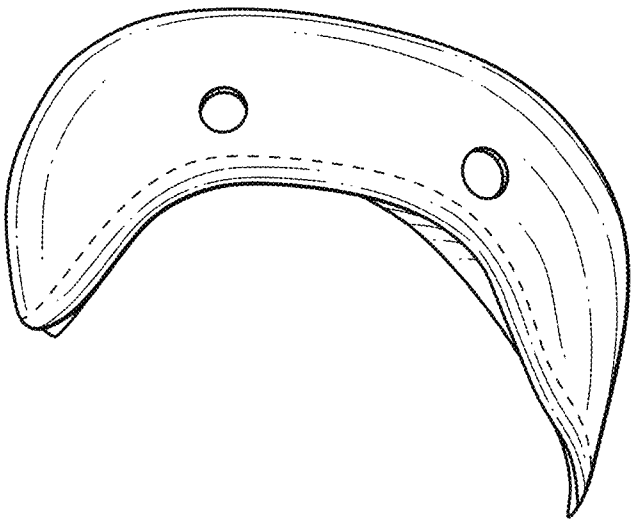

FIG. 5

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A61L 27/38(2006.01)

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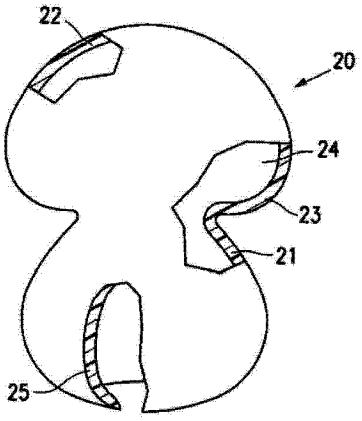
权利要求书4页 说明书26页 附图4页

(54)发明名称

弹性间置式髋关节成型术装置

(57)摘要

本公开涉及弹性间置式关节成型术植入物，其用于施用到关节内以填补软骨缺损、缓冲关节以及取代或恢复关节面，这样可以保持关节完整性，减轻疼痛和改善功能。该植入物可承受可变的关节压缩力和剪切力以及循环负荷。该植入物可修复、重建和再生关节解剖结构，从而改进了关节置换术备选方案。本发明的壁可以俘获、分配和保留活细胞直至发生聚集和透明软骨再生长，而不是在关节表面再建中使用骨膜收获以实现细胞包封。该植入物可部署到已清创的关节空间内，成型并且符合周围结构，具有足够的稳定性以避免挤出或脱位。该植入物的附件可修复或重建肌腱或韧带，并且植入物的可膨胀的内部可适应模拟或近似于正常关节活动的运动。



CN 102821715 B

1. 一种配置用于部署在髋关节的股骨头与髋臼之间的髋植入物，该植入物包括：

球囊，包括：

第一部分，其配置用于接合髋关节的股骨头，

第二部分，其配置用于接合髋关节的髋臼，

连接所述第一部分和所述第二部分的侧面部分，其中该侧面部分促进所述第一部分与所述第二部分之间的相对运动，以及

可选地可用第一膨胀介质膨胀的内部；以及

第一附件，其配置用于将所述球囊联接至关节的股骨头，

其中所述内部包含多个可膨胀的腔室。

2. 根据权利要求 1 所述的髋植入物，其中所述第一部分、所述第二部分和所述侧面部分中的至少两个是毗邻的。

3. 根据权利要求 1 所述的髋植入物，其中所述第一部分包括第一壁，所述第二部分包括第二壁，并且所述侧面部分包括侧壁。

4. 根据权利要求 1 所述的髋植入物，还包括膨胀端口，该膨胀端口与所述球囊的所述内部连通，用于用所述第一膨胀介质来膨胀所述球囊的所述内部。

5. 根据权利要求 1 所述的髋植入物，其中可以刺穿所述球囊以利用所述第一膨胀介质来膨胀所述球囊的内部。

6. 根据权利要求 5 所述的髋植入物，其中所述球囊是自密封的。

7. 根据权利要求 5 所述的髋植入物，其中当用所述第一膨胀介质使所述球囊的内部膨胀后，所述球囊是自密封的。

8. 根据权利要求 5 所述的髋植入物，其中所述植入物包含能够封闭所述球囊的内部的密封件。

9. 根据权利要求 1 所述的髋植入物，其中所述内部包含多个可单独膨胀的腔室。

10. 根据权利要求 9 所述的髋植入物，其中所述多个可单独膨胀的腔室中的第一腔室适合用所述第一膨胀介质来膨胀，并且所述多个可单独膨胀的腔室中的第二腔室适合用第二膨胀介质来膨胀。

11. 根据权利要求 10 所述的髋植入物，其中所述第一膨胀介质赋予所述植入物内的刚度。

12. 根据权利要求 10 所述的髋植入物，其中所述第一膨胀介质赋予所述植入物中的缓冲。

13. 根据权利要求 1 所述的髋植入物，其中所述内部包含蜂窝状结构。

14. 根据权利要求 1 所述的髋植入物，其中所述内部包含网状结构。

15. 根据权利要求 1 所述的髋植入物，其中所述内部包含海绵状结构。

16. 根据权利要求 1 所述的髋植入物，包含将所述球囊联接至所述关节的股骨头的第二附件。

17. 根据权利要求 1 所述的髋植入物，包含将所述球囊联接至所述关节的髋臼的第二附件。

18. 根据权利要求 1 所述的髋植入物，包含配置用于将所述第一部分、所述第二部分和所述侧面部分中的至少一个联接至所述髋关节的股骨头和髋臼中的至少一个上的第二附

件。

19. 根据权利要求 16 所述的髋植入物，其中所述第一附件和所述第二附件配置用于为所述髋关节的股骨头和髋臼提供韧带样支撑。

20. 根据权利要求 17 所述的髋植入物，其中所述第一附件和所述第二附件配置用于为所述髋关节的股骨头和髋臼提供韧带样支撑。

21. 根据权利要求 18 所述的髋植入物，其中所述第一附件和所述第二附件配置用于为所述髋关节的股骨头和髋臼提供韧带样支撑。

22. 根据权利要求 16 所述的髋植入物，其中所述第一附件和所述第二附件配置用于为所述髋关节提供韧带样支撑。

23. 根据权利要求 17 所述的髋植入物，其中所述第一附件和所述第二附件配置用于为所述髋关节提供韧带样支撑。

24. 根据权利要求 18 所述的髋植入物，其中所述第一附件和所述第二附件配置用于为所述髋关节提供韧带样支撑。

25. 根据权利要求 1 所述的髋植入物，其中所述植入物配置用于适配到具有最多为 10 毫米的远端内径的套管内。

26. 根据权利要求 1 所述的髋植入物，其中所述植入物配置用于适配到具有最多为 9 毫米的远端内径的套管内。

27. 根据权利要求 1 所述的髋植入物，其中所述植入物配置用于适配到具有最多为 5 毫米的远端内径的套管内。

28. 根据权利要求 1 所述的髋植入物，其中所述植入物配置用于折叠从而适配到具有最多为 10 毫米的远端内径的套管内。

29. 根据权利要求 1 所述的髋植入物，其中所述植入物配置用于折叠从而适配到具有最多为 9 毫米的远端内径的套管内。

30. 根据权利要求 1 所述的髋植入物，其中所述植入物配置用于折叠从而适配到具有最多为 5 毫米的远端内径的套管内。

31. 根据权利要求 1 所述的髋植入物，其中所述植入物配置用于通过具有最多为 10 毫米的远端内径的套管递送到关节。

32. 根据权利要求 1 所述的髋植入物，其中所述植入物配置用于通过具有最多为 9 毫米的远端内径的套管递送到关节。

33. 根据权利要求 1 所述的髋植入物，其中所述植入物配置用于通过具有最多为 5 毫米的远端内径的套管递送到关节。

34. 根据权利要求 1 所述的髋植入物，其中所述植入物置换骨膜。

35. 根据权利要求 1-34 中任一项所述的髋植入物，其中该植入物配置用于以下至少一项：填补软骨、缓冲关节、递送药理性物质、清除有毒的酶、植入时清创、植入后给关节清创、递送治疗性物质、递送生物物质以及递送活的干细胞。

36. 根据权利要求 1-34 中任一项所述的髋植入物，其中所述植入物配置用于向骨或其他周围组织递送化疗剂。

37. 根据权利要求 35 所述的髋植入物，其中所述植入物配置用于向骨或其他周围组织递送化疗剂。

38. 根据权利要求 1-34 中任一项所述的髓植入物，其中所述植入物配置用于向骨或其他周围组织递送抗感染药物。

39. 根据权利要求 35 所述的髓植入物，其中所述植入物配置用于向骨或其他周围组织递送抗感染药物。

40. 根据权利要求 36 所述的髓植入物，其中所述植入物配置用于向骨或其他周围组织递送抗感染药物。

41. 根据权利要求 37 所述的髓植入物，其中所述植入物配置用于向骨或其他周围组织递送抗感染药物。

42. 根据权利要求 1-34 中任一项所述的髓植入物，其中所述植入物配置用于递送抗生素、抗真菌剂和镇痛剂之中的至少一种。

43. 根据权利要求 35 所述的髓植入物，其中所述植入物配置用于递送抗生素、抗真菌剂和镇痛剂之中的至少一种。

44. 根据权利要求 36 所述的髓植入物，其中所述植入物配置用于递送抗生素、抗真菌剂和镇痛剂之中的至少一种。

45. 根据权利要求 37 所述的髓植入物，其中所述植入物配置用于递送抗生素、抗真菌剂和镇痛剂之中的至少一种。

46. 根据权利要求 1-34 中任一项所述的髓植入物，其中所述植入物配置用于选择性地膨胀以重新对齐肢体。

47. 根据权利要求 35 所述的髓植入物，其中所述植入物配置用于选择性地膨胀以重新对齐肢体。

48. 根据权利要求 36 所述的髓植入物，其中所述植入物配置用于选择性地膨胀以重新对齐肢体。

49. 根据权利要求 37 所述的髓植入物，其中所述植入物配置用于选择性地膨胀以重新对齐肢体。

50. 根据权利要求 38 所述的髓植入物，其中所述植入物配置用于选择性地膨胀以重新对齐肢体。

51. 根据权利要求 39 所述的髓植入物，其中所述植入物配置用于选择性地膨胀以重新对齐肢体。

52. 根据权利要求 40 所述的髓植入物，其中所述植入物配置用于选择性地膨胀以重新对齐肢体。

53. 根据权利要求 41 所述的髓植入物，其中所述植入物配置用于选择性地膨胀以重新对齐肢体。

54. 根据权利要求 42 所述的髓植入物，其中所述植入物配置用于选择性地膨胀以重新对齐肢体。

55. 根据权利要求 43 所述的髓植入物，其中所述植入物配置用于选择性地膨胀以重新对齐肢体。

56. 根据权利要求 44 所述的髓植入物，其中所述植入物配置用于选择性地膨胀以重新对齐肢体。

57. 根据权利要求 45 所述的髓植入物，其中所述植入物配置用于选择性地膨胀以重新

对齐肽体。

弹性间置式髋关节成型术装置

[0001] 交叉引用

[0002] 本申请要求于 2010 年 1 月 22 号提交的美国临时申请号 61/297,697 的权益，该申请通过引用整体并入本文。

背景技术

[0003] 本发明涉及关节成形术，更具体地，涉及当透明关节软骨受损、其损坏以及关节空间丧失时在关节成形术中使用的植入物。诸如来自 Cox-1、Cox-2 和 / 或 5-Lox 系统的炎性酶被释放出来，并且松散体形式加重了关节功能的退化。常规上通过物理疗法、镇痛药、止痛药和注射剂来治疗此类关节损伤。当这些治疗失败时，传统上认可的治疗选择是关节成形术植入或用人工关节建构物来置换关节。目前的关节成形术技术通常使用刚性的“塑料和金属”植入物，并且其最终由于松动或感染而失效。用于人工关节组件的常规材料包括铬 - 钴 - 钼合金（金属）和高分子量聚乙烯（塑料）。每种材料通常通过甲基丙烯酸甲酯的水泥状混合物固定到限定作为关节成形术对象的关节的骨的末端，或者涂覆有支持骨长入的表面。目前的髋关节置换物通常维持约 10-15 年。

[0004] 需要关节成形术的状况包括创伤性关节炎、骨关节炎、类风湿性关节炎、骨坏死和失败的外科手术。

发明内容

[0005] 本发明涉及配置用于部署在关节结构的相对的构件之间的矫形外科植入物，其解决了现有人工关节的许多不足之处。体现本发明特征的关节成形术植入物配置用于在消除与关节炎或关节损伤的发展相伴的疼痛和功能障碍的同时保留关节活动。根据本发明的关节成形术植入物实现了在步行中改善的生理运动和减震，并且在肢体运动中充当移动的骨之间的弹性垫片。植入物的组合特性包括迄今为止现有技术所缺失的解剖设计对称性、具有与至少一个相邻正常结构的可变附着连接的平衡刚性、以及解决和满足修复或重建需求的耐久性。植入物应当紧固到关节结构的至少一块骨上。

[0006] 髋部患者可能需要治疗股骨头和 / 或髋臼杯软骨和 / 或唇纤维软骨。间置式关节成形术（比如在此提供的植入物和方法）旨在恢复关节空间，并且根据临床需要考虑提供无痛滑动。

[0007] 本文提供了用于植入到髋部球窝内充当缓冲垫以允许恢复髋关节运动的弹性植入物。

[0008] 本文提供了一种配置用于部署在髋关节的股骨头和髋臼之间的髋植入物，该植入物包括球囊和配置用于将球囊联接至关节的股骨头的第一附件，所述球囊包括 ：第一部分，其配置用于接合髋关节的股骨头 ；第二部分，其配置用于接合髋关节的髋臼 ；连接第一部分和第二部分的侧面部分，其中该侧面部分促进第一部分与第二部分之间的相对运动 ；以及可选地可用第一膨胀介质来膨胀的内部。

[0009] 在一些实施方式中，第一部分、第二部分和侧面部分中的至少两个是毗邻的。在一

些实施方式中，第一部分包括第一壁，第二部分包括第二壁，并且侧面部分包括侧壁。

[0010] 在一些实施方式中，植入物包括与球囊的内部相连通的膨胀端口，用于以第一膨胀介质来使该球囊内部膨胀。在一些实施方式中，可以刺穿所述球囊以利用第一膨胀介质来膨胀球囊的内部。在一些实施方式中，球囊是自密封的。在一些实施方式中，当用第一膨胀介质使球囊的内部膨胀后，球囊是自密封的。在一些实施方式中，植入物包含能够封闭球囊的内部的密封件。

[0011] 在一些实施方式中，内部包含多个可膨胀的腔室。在一些实施方式中，内部包含多个可单独膨胀的腔室。在一些实施方式中，多个可单独膨胀的腔室中的第一腔室适合用第一膨胀介质来膨胀，并且多个可单独膨胀的腔室中的第二腔室适合用第二膨胀介质来膨胀。在一些实施方式中，第一膨胀介质赋予了植入物内的刚度。在一些实施方式中，第一膨胀介质赋予了植入物内的缓冲。

[0012] 在一些实施方式中，该内部包括蜂窝状结构。在一些实施方式中，该内部包括网状结构。在一些实施方式中，该内部包括海绵状结构。

[0013] 在一些实施方式中，植入物包括将球囊联接至关节的股骨头的第二附件。在一些实施方式中，植入物包括将球囊联接至关节的髋臼的第二附件。在一些实施方式中，植入物包括配置用于将第一部分、第二部分和侧面部分中的至少一个联接至髋关节的股骨头和髋臼中的至少一个上的第二附件。在一些实施方式中，第一附件和第二附件配置用于给髋关节的股骨头和髋臼提供韧带样支撑。在一些实施方式中，第一附件和第二附件配置用于给髋关节提供韧带样支撑。

[0014] 在一些实施方式中，植入物配置为适配到具有最多为 10 毫米的远端内径的套管内。在一些实施方式中，植入物配置为适配到具有最多为 9 毫米的远端内径的套管内。在一些实施方式中，植入物配置为适配到具有最多为 5 毫米的远端内径的套管内。在一些实施方式中，植入物配置为折叠从而适配到具有最多为 10 毫米的远端内径的套管内。在一些实施方式中，植入物配置为折叠从而适配到具有最多为 9 毫米的远端内径的套管内。在一些实施方式中，植入物配置为折叠从而适配到具有最多为 5 毫米的远端内径的套管内。在一些实施方式中，植入物配置为通过具有最多为 10 毫米的远端内径的套管递送到关节。在一些实施方式中，植入物配置为通过具有最多为 9 毫米的远端内径的套管递送到关节。在一些实施方式中，植入物配置为通过具有最多为 5 毫米的远端内径的套管递送到关节。

[0015] 在一些实施方式中，植入物置换骨膜。

[0016] 在一些实施方式中，植入物配置用于以下至少一项：填补软骨、缓冲关节、递送药理性物质、清除有毒的酶、植入时清创、植入后给关节清创、递送治疗性物质、递送生物物质以及递送活干细胞。在一些实施方式中，植入物配置用于向骨或其他周围组织递送化疗剂。在一些实施方式中，植入物配置用于向骨或其他周围组织递送抗感染药物。在一些实施方式中，植入物配置用于递送抗生素、抗真菌剂和镇痛剂中的至少一种。

[0017] 在一个实施方式中，植入物配置成选择性地膨胀以重新对齐肢体。

[0018] 本文提供一种方法，包括：将本文所述的髋植入物植入个体内，其中该植入物逆转个体内的关节炎。

[0019] 本文提供一种方法，包括：将本文所述的髋植入物植入个体的髋关节并且使用同种异体移植组织、自体移植组织和异种移植组织中的至少一种来治疗个体髋关节的组件。

在一些实施方式中，植入步骤为以下情况中的至少一种：在治疗步骤之前，与治疗步骤同时，以及在治疗步骤之后。

[0020] 本文提供一种方法，包括：将本文所述的髋植入物植入个体内，其中该植入物起到以下作用中的至少一个：恢复关节功能和控制关节病。在一些实施方式中，该植入保存现有解剖结构。

[0021] 本文提供一种方法，包括：给个体髋关节的股骨头清创，以及将本文所述的髋植入物植入到个体髋关节内，从而使植入物配置成与个体的软骨炼合。在一些实施方式中，清创是通过蒸汽施用来完成的。

[0022] 本文提供一种方法，包括将本文所述的髋植入物植入先前用全关节置换物治疗过的关节内。在一些实施方式中，该方法包括在植入髋植入物之前移除全关节置换物。在一些实施方式中，该方法包括从关节和 / 或周围组织清除感染性物质。在一些实施方式中，该方法包括在移除先前植入关节中的植入物之后植入本文所述的任何植入物的第二植入物。在一些实施方式中，该方法包括在移除先前植入关节中的植入物之后置换个体的关节。在一些实施方式中，该方法包括对关节的骨进行清创，以及植入本文所述的任何植入物的植入物。在一些实施方式中，该方法包括重复清创和植入步骤。

[0023] 通过以下详细描述和示范性附图，本发明的这些优点以及其他优点将变得更加明显。

[0024] 援引并入

[0025] 本说明书中所述的所有出版物、专利和专利申请均通过引用而以相同程度并入本文，犹如每个单独的出版物、专利或专利申请特别地和单独地被指出为通过引用而并入。

附图说明

[0026] 本发明的新颖特征在随附的权利要求中具体阐述。通过参考以下对在其中利用到本发明原理的示例说明性实施方式加以阐述的详细描述和附图，可以获得对本发明的特征和优点更好的理解，在附图中：

[0027] 图 1 是体现本发明特征的植入物在植入前的部分切割的透视图，具有扩展的上部。

[0028] 图 2 是安放在患者股骨头上的图 1 所示植入物的立视图。

[0029] 图 3 是部署在患者股骨头和髋臼之间的图 1 和图 2 所示植入物在牵引释放后的剖视图，以允许骨适应虽然为病理性但自然的休止角。

[0030] 图 4 是已部署于患者股骨头和髋骨的髋臼之间的弹性关节成形术植入物的立视图，它具有比图 1- 图 3 所示植入物更小的上部。

[0031] 图 5 是如图 4 所示植入物放置于髋关节的股骨头部分之上的左近端股骨的前立视图，其中部分横切，以说明它的细节。

[0032] 图 6 是从“身体一侧”或髋侧面观察的，具有图 4 所示的植入物的股骨的侧立视图。

[0033] 图 7 是具有图 4 所示植入物的股骨的俯视图。

[0034] 图 8 是图 7 中的髋关节发明迭代或植入物的仰视图。

[0035] 图 9 是从患者头部或从头向尾方向观察的，带有具有本发明特征的弹性植入物的患者髋部的俯视图或头向视图。

[0036] 图 10A 描绘了安放到股骨头上并且植入到股骨头和髋骨髋臼之间间隙中的、具有裙筒和球囊形式的附件的植入物的实施方式。

[0037] 图 10B 描绘了安放到股骨头上并且植入到股骨头和髋骨髋臼之间的间隙中的、具有附件（翼片类型）和球囊的植入物的实施方式。

[0038] 图 11A 描绘了安放到股骨头上的具有附件（翼片类型）和球囊的植入物的实施方式，其中该球囊最低限度地膨胀（或未膨胀）。图 11B 描绘了安放到股骨头上的具有附件（翼片类型）和球囊的植入物的实施方式，其中该球囊最低限度地膨胀（或未膨胀），并且显示了可用于膨胀植入物球囊或抽取炎性酶的管。图 11C 描绘了安放到股骨头上的具有附件（翼片类型）和球囊的植入物的实施方式，其中该球囊膨胀，并且显示了膨胀管。

[0039] 图 12 描绘了安放到股骨头上并且被植入到股骨头和髋骨髋臼之间间隙中的、具有附件（翼片类型）和已膨胀球囊的植入物的实施方式。

具体实施方式

[0040] 本发明涉及用于髋部的关节成形术植入物和方法。

[0041] 植入物的一些实施方式包括球囊或囊状物，一旦软骨受损，其作为人和动物关节的间置式关节成形术以重建软骨。植入物在膨胀后可符合内部关节组件，例如适应关节相对面的小间隙。

[0042] 髋要比一些其他的关节（比如膝关节）更简单，因为髋仅具有一个软骨 / 间隙 / 软骨 - 骨界面（其等同于关节）。

[0043] 髋部疼痛是人最常见的关节病之一，并且其在腹股沟中表现为疼痛、磨擦音、不能移动和搏动不适。每个人都有其自己的疼痛忍受度和处理这种情况的方式。一些人能简单地通过“让疼痛过去”而忍受疼痛，然而其他人则由于疼痛而在精神上和身体上失能。本文所述的装置的实施方式填充股骨头（球）和髋臼（杯）之间的间隙，通过恢复关节中的缓冲和功能以减轻髋部疼痛和不适。

[0044] 对髋部状况的诊断涉及患者报告常常进展性的但偶尔突发性的进而持续性的腹股沟疼痛发作（生殖器和髋部最外侧之间的一半处）的病史，其中疼痛、磨擦音（＝捻发音）、打软腿（如果存在唇撕裂）、搏动性地从睡觉中惊醒或极少数急性发作（如由像梅毒的感染或像痛风或缺血性坏死的代谢问题所引起）会导致关节面间隔打破。通常股骨头和髋臼软骨为约 2-3mm 厚，包括组织结构上独特的、白色有光泽的平滑滑动的光滑低模量相对表面的透明层。然而，在病理上，表面会遭到破坏。患者主诉腹股沟疼痛。如果疼痛位于外侧，即在夜间侧卧时，其髋部接触床而感到由触压髋部外侧所引起的疼痛，则诊断结果更可能是粘液囊炎，而与关节无关。在这种情况下，“髋部”疼痛来自背部，其从髋部外侧周围斜向前进穿过腹股沟到达大腿中部，其可能是 L2 神经根（脊椎）撞击。

[0045] X 射线可显示松散体或直径大约一厘米的射线不透处，就像沉积在关节囊区域的小雪球状的聚集的骨状软骨碎片。通常 X 射线下的关节空间为约 8mm，但是由于类风湿性或骨关节炎发生广泛变窄，关节空间变窄，特别是在立位胶片上，此时与对侧（假如正常）髋相比可看出差异。核磁共振扫描能显示缺血性坏死（骨坏死）的 Ficat I-IV 或 Glimshire I-VI 期，所述缺血性坏死通常是先天性的，但有时在流行病学上与酒精或类固醇使用有关，或者戴水肺的潜水员可能发展 Caison 病。无论如何，体征和症状通常出现在髋前部中心位

置。

[0046] 体检通常允许髋弯曲 120 度、伸展 20 度、外展、向外及向内旋转 45 度以及内收 20 度。如具有髋部疾病或损伤，活动范围经常缩小，并且在前部有压痛。可见跛行步态。

[0047] 治疗包括时间痊愈、运动调整、物理疗法、药物（针对 Cox-1、Cox-2 和 / 或 5-Lox 酶系统的局部、口服非甾体抗炎药）、镇痛药、肌肉松弛剂、注射剂（类固醇，因为它们能使降解软骨或引发感染，所以不鼓励使用）或粘润滑剂如欣维可 (Synvisc) 或海尔根 (Hyalgan)，然后进行关节镜检查（由极少数有经验的外科医生操作，在全身麻醉和 60 磅的特殊牵引力下进入髋关节），直到全关节置换关节成形术。作为遏止严重的腹股沟疼痛和日常生活活动功能缺失的最后手段，髋关节置换能减轻或消除疼痛，从而可步行 10-20 年，如果从事每一项体力活，该植入物最终总是失败。髋关节成形术由于松动或由于感染而失败。修正手术伴随着更多的骨切除，并且当感染时要使用静脉注射抗生素超过 6 周至 6 个月的时间，含有抗生素的水泥样植入物保留在髋关节中（阻止了运动）。每个在 THR（全髋关节置换术）中有理想结果的患者仍然处于伴随髋部弯曲和内旋转（例如在系鞋带时）而脱位的危险中。在这种情况下，产生严重的疼痛，患者不能行走并且必需将其送往急症室 / 手术室以通常进行全身麻醉和植入部件的复位 / 重对齐。一旦发生脱位，由于关节囊扩张，更可能重复发作。

[0048] 全髋关节置换术通常需要开放式外科手术，打开 4-12 英寸的切口，并且手术持续时间约为 2-4 小时。此外，在手术期间存在较少的骨和软骨保护，大量的软组织切开和髋部脱位，因此关节的正常解剖结构没有得到保留。这种脱位能导致破坏中心韧带和其他韧带、稳定性囊以及通过前和后旋动脉进入股骨颈的通往股骨头的血液供应。一旦发生脱位（不管是外伤性的还是为了“治疗”），股骨头骨坏死（例如，缺血性坏死）的可能性增大。对于患者的全髋关节置换术选择不太适合修正手术，并且常常导致对关节功能的限制，患者的自然步幅通常无法保留。在全置换手术过程中，返回工作的时间约为 6 周，总康复时间大约为一年。植入物通常是金属，会导致金属检测问题。手术后住院可持续 3-6 天，并且患者一生中的治疗费用约为 25 万美元。

[0049] 作为备选方案，加帽治疗或表面再建治疗是目前可用的疗法，包括将金属置于已磨损的软骨表面上的治疗，其中金属与剩余的杯状软骨本身通过关节连接。在一些这类手术中，金属股骨头相对地覆盖金属杯状植入物。无论如何，非常类似于全关节置换术，髋部仍然需要脱位，其后果与以上关于全髋关节置换术选择所述的后果相似。在这些手术中，外科手术是开放式手术，其通常持续约 2-4 小时并且需要 4-12 英寸的切口。有大量的软组织被切开。存在一些对关节功能的限制，然而自然步幅通常无法保留。返回工作的时间可能约为 6 周，需要约 6-10 个月后才能完全康复。手术后通常需住院 2-4 天，并且患者一生中的手术治疗费用可能超过约 10 万美元。

[0050] 不同于髋需要脱位的其他髋关节治疗，并且可能地，本文提供的植入物的实施方式不需要脱位来正确地放置植入物。本文所述的植入物的一些实施方式可利用最多各为半英寸的切口插入。在一些实施方式中，手术持续时间为约 1 小时，并且只有非功能性组织（骨和 / 或软骨）被移除—从而保留了功能性组织（或大部分）。在一些实施方式中，仅需要最低限度地切开软组织，并且植入物非常适合修正手术。在一些实施方式中，会导致对关节功能的最低限度的限制，并且患者的正常步幅可以得到保留。在一些实施方式中，返回工

作的时间可为几天，并且恢复时间可少于几个月。同样，一些实施方式仅需要一个门诊手术，因此患者一生中的该装置的实施方式的费用可少于目前可用的其他选择。

[0051] 一些实施方式将与关节镜清创术一起使用。髋部的关节镜清创术是专业疗法，通常需要引入的牵引系统，所述牵引系统将拐杖样弯曲填柄放置于骨盆中间区域（如阴囊下），然后其腿部附接到牵引或拉伸装置，所述装置可在全身麻醉的情况下拉伸髋关节，使其从正常的 5-6mm 拉伸至射线照相或图像增强器在前后位投影中所显示的 10-12mm，以便关节镜套管能进入髋关节，通过光纤使其显现在手术室的电视屏幕上，以及给关节清创。在一些实施方式中，这种设置和清创可能是放置植入物的前期工作，可能需要使用 3-M 泵及 0.25 英寸 (5-6mm) 和 0.5 英寸 (10-12mm) 的关节周围伤口（切口）（以避免对第三髋关节镜切口的需求）。在髋关节镜中，进行以下四个过程 :1) 除去松散体，2) 机械地和电子地消除滑膜炎，3) 对剩余的透明软骨股骨头和髋臼界面进行观察、评估，潜在地准备稳定的缺损边缘，以及 4) 修整唇纤维软骨（半月板样）撕裂。

[0052] 一旦完成了关节镜检查，如果外科医生止于此处，预期疼痛减轻和功能改善可能会持续 3-6 个月，特别是在加入粘润滑剂的情况下。然而，已逐渐不鼓励给关节炎患者的髋部提供关节镜检查的操作作为常规疗法，因为在 VA 研究中，症状的减轻是相当短暂的，并且不是治愈性的努力。

[0053] 在所需的治疗中跳至全关节置换术或关节面置换术是重要的。在目前的此类手术中，需要侧面和 / 或前面的直到髋关节的 10-20 英寸长度的切口。股骨头将被舍弃，韧带将被移除，有时要重新接上（尽管通常会导致典型的跛行或特伦德伦堡步态 (Trendelenburg gait)）。铰除股骨头软骨。螺钉将布置于杯内或用甲基丙烯酸甲酯将其粘接至腹股沟内。髋干或者或者卡入股骨以希望最终发生骨长入，或者粘合（其通常最终会松动）。除了钉牢外，金属干然后通过（莫尔斯或 C) 锥度附接至金属球，所以它通常“粘接到干上”。一旦金属杯位于骨盆内，坚硬的、几乎具有类似于金属的硬度的白色塑料高分子量聚乙烯被插入金属髋臼杯内。然后将干和球重新定位到骨盆的新的人造杯内，开始韧带和囊修复。此后患者仍处于脱位或感染的危险中

[0054] 总之，现有技术和科学停留在关节镜检查并且治疗缺口延伸至关节的完全切除。缺乏的工具是本文所述的植入物的实施方式所提供的间置式关节成形术。髋植入物的适应症是当疼痛和功能障碍需要进一步的外科处理时，针对或通过关节镜清创术对患者的保守性治疗失败。较年轻的患者想要享受正常的生理活动，不希望进行关节切除，不希望接受舍弃他们正常的软骨、骨、韧带和囊的手术，不希望大失血，不希望永久性感染或脱位的风险，并且不希望有排除后期重建的‘不可逆的情况’或‘关节炎逆转’，应该把关节囊作为暂时性或永久性恢复正常软骨界面的机会。在一些实施方式中，植入物使用的禁忌症包括同侧关节的活动性感染，对植入物组成的聚合物的变态反应，以及具有不稳定性的晚期关节变形，它们将另外需要截骨术或复杂的重建努力，从而导致在正常情况下不会脱位的假体植入物，比如半髋关节成形术。

[0055] 在一些实施方式中，植入物可根据患者的特殊需求进行选择性膨胀。在一些实施方式中，如本文所述，植入物内部的填充物可以是刚性的、半刚性的、流体、气体或它们的组合。在一些实施方式中，植入物可与纤维软骨修复或置换一起使用。在一些实施方式中，可以使用植入物而不采用纤维软骨修复或置换。在一些实施方式中，植入物可连同骨截骨术

一起使用。在一些实施方式中，可以使用植入物而不采用骨截骨术。

[0056] 准备、麻醉、关节牵拉、预防作用于与牵引装置有关的软组织结构上的感染和有害压力、以及普通的关节镜髋部清创对于植入物放置来说都是相同的（即，不管“球囊”是否插入）。当关节已准备好时，需要特别注意第三和第四级软骨缺损，它们可受益于软骨细胞插入，以使不规则边缘变得更稳固，达到植入物倾向于需要或无需辅助性药理性生长诱导 / 抗炎药 / 抗感染药 / 粘润滑剂 / 膨胀（缓冲 / 填补）剂来递送软骨的软骨细胞或干细胞的程度，从而恢复关节面和界面至正常。

[0057] 植入物的某些实施方式可以通过具有密闭装置（作为非限制性实例，Smith and Nephew, Inc.，带有的 4 mm 套管密闭管的 Acufex10 mm X 756 mm Clear-Trac 螺纹套管）的套管而插入。然而，一些植入物的插入可能需要更大的切口，如通过可达 10 厘米或更长的创口，向股骨头应用球囊或聚合物盖。在可以使用关节镜辅助的程度上，植入物将在非膨胀状态下插入，将搭在股骨头上，带有或不带空隙（或沟槽）以适应黄韧带，将通过缝合线或缝合锚、U 形钉、螺钉、稳定器和 / 或本文所述的其它联接器固定，考虑自然解剖结构和植入物顺应性，受益于预期的设计并发的非顺应性半球形特征，以产生类似于半球形的覆盖（类似于半个橘子皮）以覆盖在股骨头的上部承重表面上。一些实施方式将植入物应用到股骨杯或髋臼的较大的相邻半径和 / 或相对的表面。

[0058] 一些实施方式直接覆盖股骨头，有半径或表面连接至残余的球，用填料和 / 或修复细胞填充透明表面的缺陷，固定到球（或可选地，杯）上，植入物的另一半径将可以自由移动。一些实施方式含有大量冗余膜，其自身随正常的髋关节活动而滚动。在一些实施方式中，冗余膜不仅可用来增强可变层之间的自然运动，而且也用来修复由围绕髋臼的透明软骨外周的纤维软骨边缘自然提供的稳定性。例如，这样的冗余膜至少在图 1-3 中示出。在一些实施方式中，植入物是紧缩的而没有冗余，以便有较小的半径固定在球上，而较大的半径抵靠着窝移动和滑动。在本文所述的方法和植入物的实施方式中，有保留所有正常组织的趋势。

[0059] 在植入后髋关节体征和症状预期会报道减少疼痛和改善功能。由于韧带得到保留，切口微小，预期可能不会发生脱位。失血可以忽略不计。手术时间短。并发症通常可以通过门诊手术处理。在由于二次创伤引起的感染或植入物损坏的情况下，可以完全取出，而仍然保留现有的保守疗法和 / 或关节成形术选择的可能。某些实施方式的皱缩的植入物，其形状类似于股骨头的上半部，且可以通过可能的最小创口插入，固定以避免脱位，用最小量的空气 / 胶体 / 液体膨胀以适应滑动和适当的固定，并且患者将会享受修复的关节面。

[0060] 理想情况下植入物将无限期地保留在适当的位置上，而不会失效，也不会有即时的或后期的毒性作用，如过去的硅滑膜炎。然而，选择包括应用球囊或植入物作为暂时性的球囊，以递送包括药物和干细胞在内的药理性物质少至 23 小时，以便细胞能在该时期内附着，这在现有的 FDA 已批准的 Genzyme Carticel 软骨细胞中已实现。在植入物使用的一些实施方式中，大量破坏性的骨膜切开和通过至多 4 英尺长的切口的骨膜收集将不再需要，因为该植入物聚合物在细胞附着的前 23 小时将是“人孔盖”或容器，之后植入物盖可被移去。使用聚合物进行填补、缓冲和生理恢复性治疗 27 天直至伤口愈合是更好的。

[0061] 在一些实施方式中，植入物是可生物降解的（部分地或全部地）。

[0062] 在一些实施方式中，将插入包含可膨胀球囊的植入物。在一些实施方式中，植入物

配置用于缓冲关节，以承受 6-8 倍于体重的压力和剪切力，数以百万计的循环负荷，以及能够使治疗的患者获得最好的可行的生活质量的其他要求。

[0063] 该植入物的一些实施方式用于将填料添加到清创的髋关节以清除疼痛，并通过稳定的可膨胀的间置式关节成形置换术改善功能，从而缓冲关节连接结构，并恢复新软骨生长以便康复。

[0064] 本文提供了用于植入髋关节中充当缓冲垫从而允许复原的关节运动的弹性植入物。该植入物可在减轻伤后或病后疼痛和改善功能从而修复、重建和再生关节完整性的同时，承受可变的关节外力和循环负荷。植入物可部署在准备好的已清创的关节空间内，紧固到至少一个关节骨并且在该间隙中扩张，以足够的稳定性成型至周围结构以避免挤出或脱位。植入物可具有在变化的方向上移动的相对的壁，以及用合适的填料填充的内部空间，以便适应模拟或近似于正常关节运动的运动。植入物可填补损坏的关节面，立即恢复缓冲并且可用于通过递送再生细胞而将软骨恢复正常。

[0065] 本文提供了弹性间置式关节成形术植入物，用于施用到髋关节内以便修补软骨缺损、缓冲关节以及取代或恢复关节面从而保持关节完整性、减轻疼痛和改善功能。在损伤或疾病需要干预之后，该植入物可承受可变的关节压缩力和剪切力以及数百万次循环负荷。植入物可利用改进了现有的刚性塑料和金属关节置换备选方案的生理解决方案，以最低病态的方式来修复、重建和再生关节解剖结构。在细胞已用于需要大量骨膜收获以供包封的关节面再建的情况中，植入物的一些实施方式的聚合物壁可俘获、分配和保留活细胞直到发生聚集和透明软骨再生长。植入物可部署在准备好的已清创的关节空间内，以足够的稳定性成型至周围结构并与之相符，以避免挤出或脱位。植入物的附件可用于修复或重建肌腱或韧带。植入物也可具有在变化的方向上移动的相对的壁，以及填充有合适的气体、液体和 / 或作为力吸收移动成分的复合聚合物层的单个的或分开的内部空间，从而使强健有效和可靠的关节运动得到支持。

[0066] 本文提供了髋植入物，其配置成部署在髋关节的股骨头与髋臼之间，该植入物包括球囊和配置用于将该球囊联接至关节的股骨头的第一附件，所述球囊包括 ：第一部分，其配置用于接合关节的股骨头 ；第二部分，其配置用于接合关节的髋臼 ；连接第一部分和第二部分的侧面部分，其中该侧面部分促进第一部分与第二部分之间的相对运动 ；以及可选地可用第一膨胀介质加以膨胀的内部。在本公开全文各处中可互换使用术语“球囊”和“囊状物”来描述具有在此所述特征的植入物。

[0067] 在一些实施方式中，第一部分、第二部分和侧面部分中的至少两个是毗邻的。在一些实施方式中，第一部分包括第一壁，第二部分包括第二壁，并且侧面部分包括侧壁。在此所使用的术语“第一部分”、“第二部分”和“侧面部分”中的每个术语用于描述球囊的一部分，并且在一些实施方式中可能不是单独的部分。相反，在一些实施方式中，每个术语被命名用以指出每个部分相对于其他部分以及 / 或者相对于关节的骨和 / 或韧带和 / 或肌腱的总体几何及位置。同样地，在此所使用的术语“第一壁”、“第二壁”和“侧壁”用于描述球囊的一部分，并且在一些实施方式中可以不是单独的球囊部件。相反，在一些实施方式中，每个壁被命名用以指出每个部分相对于其他部分以及 / 或者相对于关节的骨和 / 或韧带和 / 或肌腱的总体几何及位置。在一些实施方式中，第一壁、第二壁和侧壁中的至少两个是毗邻的。然而在一些实施方式中，每个壁可以是单独的植入物部件，它们结合在一起形成植入

物。同样地，在一些实施方式中，每个部分的确可以是结合在一起形成植入物的、单独的植入物部件。

[0068] 在一些实施方式中，第一部分是可与第一壁互换使用的术语。在一些实施方式中，第二部分是可与第二壁互换使用的术语。在一些实施方式中，侧面部分是可与侧壁互换使用的术语。在一些实施方式中，植入物的壁（无论第一壁、第二壁和/或侧壁）可包括多个层。壁可以包含多种材料以便给予壁物理特性和/或治疗特性。

[0069] 植入物的一些实施方式可包括第一壁、第二壁和侧壁，它们限定了包含填充材料的植入物内部（或内部）。在一些实施方式中，填充材料是膨胀介质。第一壁通过从第一壁延伸的裙筒而紧固到股骨头末端，并且第二壁接合髋臼的端面并且也可紧固于此。在一些实施方式中，裙筒被称为附件。在第一壁与第二壁之间延伸的的侧壁至少部分地限定了填充有填充材料（或膨胀介质）的植入物内部。壁和裙筒的内表面优选地符合股骨头的特定表面。在一些实施方式中，壁和裙筒的内表面优选地符合患者股骨头的特定表面。第二壁的外表面优选地配置成符合髋臼的端面。在一些实施方式中，第二壁的外表面优选地配置成符合髋臼的表面。

[0070] 在一些实施方式中，植入物的附接元件（另外和/或备选地称为联接元件和/或翼片和/或附接元件）包括孔洞，经该孔洞可以放置螺钉或其他联接器，以便将植入物附接到股骨（和/或髋臼）中的附接位点（或连接位点或联连位点）。在一些实施方式中，孔洞可在关节镜下制出。在一些实施方式中，孔洞预制在植入物中。在一些实施方式中，孔洞可基于患者的特定解剖结构而在植入前制成。在一些实施方式中，通过植入物的增强材料来加固孔洞。增强材料可以是用于加固螺孔的，具有足够硬度和/或抗撕裂性的聚合物。增强材料可包括金属。在一些实施方式中，不存在预先形成的孔洞，而是在植入时通过创造附接翼片自己的孔洞而用螺钉（或另一联接器）将附接翼片（它可以是植入物的非球囊部分）紧固到关节组件（骨，等）。在一些实施方式中，植入物可包括适合接纳本文其他各处所述的U形钉或其他联接器的翼片。

[0071] 在此所述的植入物可包括附接元件（或翼片），附接元件可继而通过联接器件附接或联接到关节的组件（无论是到骨或韧带或肌腱或其他关节组件）。联接器件（或联接器）可包括相应地进入骨孔或狭槽的螺钉、衬垫、缝合线、缝合锚（金属的和/或可生物降解的）、铆钉、U形钉（有齿或没有齿）、稳定器、胶合剂、圆柱线挂勾或平整的金属片中的至少一种。联接器件可以是可重新吸收的或是不可重新吸收的。并且，连接器件可包括线绳（即，细绳）、勒绳、套索和系索中的至少一种。线绳、勒绳、套索和/或系索可以与其自身和/或其他联接器件相连接。此处提供的联接器可包括配置用于拉住围绕股骨颈的植入物的外围的细绳。

[0072] 在一些实施方式中，穿过具有经加固中心孔的翼片的螺钉可以是植入物的一部分。例如，植入物可包括聚合物覆盖的金属衬垫孔。螺钉可穿过所述孔。另一实施方式可包括具有销钉的U形钉。在一些实施方式中，可使用销钉和螺钉的组合，或者其他联接器的组合。植入物可配置成允许外科医生选择若干种类型和尺寸的联接器，这是因为关于损伤的大小和深度、骨量、再生长能力和与所建议的恢复的相符性而言每个患者是不同的，并且在使用这样的植入物时，每个外科医生都有他自己的优势和舒适。

[0073] 在一些实施方式中，将植入物配置成使得植入物的翼片和/或联接器联接到骨上

没有天然软骨之处。在一些实施方式中，该植入物可由外科医生在外科手术时进行适配，从而使翼片被放置在没有天然软骨之处。

[0074] 植入物的边缘可具有依附的裙筒，用于将植入物紧固或锚固到骨的末端，但亦可具有如将在其他实施方式中讨论的可用于相似功能的一个或多个依附的翼片（或附件）。该裙筒（和/或翼片，和/或附件）可如所示地紧密贴合在股骨头末端周围，或者该裙筒可通过粘合剂（例如，甲基丙烯酸甲酯，骨长入）而紧固到支撑性骨结构，或者通过U形钉、螺钉等机械地连接。此外，该裙筒的下部可通过荷包缝合或者牢固绑定在裙筒外部周围的合适的丝线（有弹性的或系紧的）来紧固。

[0075] 在一些实施方式中，植入物包括放置在适合于进入骨孔的球囊腔室中的甲基丙烯酸甲酯。一旦甲基丙烯酸甲酯固化成固体，这个实施方式一般会将植入物固定到骨上。

[0076] 在一些实施方式中，可以用一般可用的缝合线和缝合锚固定及定位材料，以适当的张拉将植入物锚固到骨上。

[0077] 除了可基于在此所述的植入物特征而发生的一般长入之外，植入物底面（邻近股骨头）可包括长入基质。在一些实施方式中，邻近股骨的植入物的至少一部分包括骨长入材料。作为非限制性实例，可以使用螺钉、铆钉、稳定器、U形钉、大头钉或者缝合线和缝合锚，通过一系列有孔洞或无孔洞的翼片来附接此类植入物。当植入物包含活软骨细胞（例如，Carticel）时，植入物的聚合物替代骨膜，作为植入物表面上的长入基质。当植入物包含活软骨细胞（例如，Carticel）时，植入物的聚合物替代骨膜，作为在植入物实施方式中的长入基质，该长入基质配置用于随着时间的推移和/或在植入后露出和/或释放所述软骨细胞。

[0078] 骨长入底面可用于翼片或周缘的长期固定。亦即，虽然对于外科手术而言将植入物以最期望的矫正位置紧固到关节表面是很重要的，但在一些实施方式中准备骨解剖底面也是很重要的——通过对其进行磨削而清除约0.5mm皮质骨，以便将患者潜在的氧气、血液和营养物暴露给可逐渐合并到肢骨之中的植入物的底面。由于这种康复发生在术后数周和数个月到一年的过程中，因而局部紧钉位点可能变得不那么相关并且可能潜在地不起作用。因此，在一些实施方式中，植入物可包括可生物降解（可生物吸收）聚合物或其他材料。附加地和/或另外地，联接器可以是可生物降解的。一旦植入物处于合适的位置，它将发挥以下至少一个作用：填补缺损、缓冲关节和恢复对关节组件的原始损伤。最终目标是施用最小病态治疗，该治疗将会整修患关节炎的肢体区域，仅留下很小的皮肤疤痕和对治愈的身体事故的遥远记忆。

[0079] 植入物底面材料可涉及来自Artelon或Gore-Tex研究的技术和科学的使用，这是因为各自都有优势和局限性。对于关节损伤区可能有若干种植入物选项可用，以便利用主要外科医生操作，从而最佳地适合临床恢复要求。

[0080] 在一些实施方式中，植入物包括位于配置用于接合股骨头的第一部分、配置用于接合髋臼的第二部分、侧面部分和附件之中的至少一个上的长入补片。作为非限制性实例，长入骨片可配置用于助长和/或促进组织长入，比如骨长入。补片可以和所述部分本身一样大（无论是第一部分、第二部分、侧面部分，还是附件），或者可以小于所述部分（诸如形为条状或其他形状的补片）。长入补片可包括表现不规则性或粗糙性。长入补片可以像维可牢那样。在一些实施方式中，植入物从（并且在某些实施方式中，包括）第一附件到第二

附件包括位于第一部分和/或第二部分之上的长入补片。在一些实施方式中——其中附件（通过设计和/或由于磨损和/或随着时间的推移）从与骨的附接中松开——长入补片帮助将植入物紧固到骨上。在一些实施方式中，长入补片包括附接到植入物的小珠和/或珠状元件。这样的长入补片可配置用于模拟正常松质骨网格的小梁骨空间。在一些实施方式中，小珠是各种形状的烧结小珠。在一些实施方式中，小珠是约 400 微米大小的烧结小珠。关于小珠大小而言，术语“约”可指 1%、5%、10%、25%或 50%的范围。在一些实施方式中，使股骨头和/或髋臼变粗糙以获得出血的骨从而促进长入。在一些实施方式中，清除大约 0.5mm 的皮层组织以促进长入。

[0081] 在一些实施方式中，植入物的附件包括钩。在一些实施方式中，钩是成角度的。该钩可包括夹在两个聚合物片之间的一片金属。该钩可包括包裹在聚合物中的一片金属。在一些实施方式中，该钩可包括一片金属并且该金属片的一部分可以包裹在聚合物中。在一些实施方式中，该钩可以包括一片金属并且该金属片的一部分可以夹在两个聚合物片之间。该钩的金属可以加强附件翼片以将植入物固定到关节骨上。在一些实施方式中，该钩的金属由 1 厘米 ×1 厘米的金属片形成。该钩的金属或其一部分可从附件伸出。该金属可弯向其配置用于连接到的骨上。该金属可以约 270 度角（作为非限制性实例，与金属的非弯曲部分对比，或与附件的其余部分对比）弯曲。当涉及到该钩的金属的弯曲角度时，术语“约”可意指 1%、5%、10%、20%和/或 25%的变化，或 1 度、5 度、10 度、15 度、20 度、25 度、30 度、40 度、45 度和/或高达 90 度的变化。在一些实施方式中，可准备好骨以接受钩，例如通过使钩（或其一部分）放置于其内的孔或狭槽。在一些实施方式中，未事先准备好骨来接受钩，该钩可通过施加到钩上以进入骨的压力而自行就位于骨内。在一些实施方式中，该植入物可包括多个附件，并且多个附件具有钩。

[0082] 在一些实施方式中，植入物包括将球囊联接至关节的股骨头的第二附件。在一些实施方式中，植入物包括将球囊联接至关节的至少一个髋臼的第二附件。在一些实施方式中，植入物包括第二附件配置用于将第一部分、第二部分和侧面部分中的至少一个联接到关节的股骨头和至少一个髋臼中的至少一个上的第二附件。在一些实施方式中，第一附件和第二附件配置用于为关节的股骨头和至少一个髋臼提供韧带样支撑。在一些实施方式中，第一附件和第二附件配置用于为关节提供韧带样支撑。在一些实施方式中，第一附件和第二附件配置用于为关节的股骨头和至少一个髋臼提供肌腱样支撑。在一些实施方式中，第一附件和第二附件配置用于为关节提供肌腱样支撑。

[0083] 在一些实施方式中，植入物包括与球囊的内部相连通的膨胀端口，用于以第一膨胀介质来使该球囊内部膨胀。在一些实施方式中，可以刺穿所述球囊以利用第一膨胀介质来膨胀球囊的内部。在一些实施方式中，球囊是自密封的。在一些实施方式中，当用第一膨胀介质使球囊的内部膨胀后，球囊是自密封的。在一些实施方式中，植入物包含能够封闭球囊的内部的密封件。

[0084] 植入物内部填充有填充材料（或膨胀介质），该填充材料帮助在关节结构内维持期望的植入物动力学。可对诸如流体等填充材料的性质和壁的特征加以选择，从而维持壁间的期望间距，以便适应关节结构的骨施加给植入物的压力以及允许在植入物的第一壁与第二壁之间的适当运动，所述壁促进了模拟或接近所涉关节构件的正常活动的骨运动。此外，如上所述，内室可填充有弹性材料，以便在允许植入物层之间期望的生理运动的同时，

提供期望的间距和压力适应。植入物优选地可配置成为形似被取代的关节空间和骨表面，或者配置用于填充由损伤或疾病所产生的空隙，以便使自然关节间隙和关节界面的缓冲朝正常生理外观和功能恢复。可利用诸如盐水、矿物油等流体来膨胀植入物。

[0085] 植入物内部（球囊内部）可用气体来膨胀。植入物内部（球囊内部）可用液体来膨胀。植入物内部（球囊内部）可用盐水来膨胀。植入物内部（球囊内部）可用悬浮干细胞来膨胀。植入物内部（球囊内部）可用凝胶来膨胀。植入物内部（球囊内部）可用粘润滑剂来膨胀。在一些实施方式中，膨胀介质留在球囊内或其一部分内（当球囊有多个腔室时）。在一些实施方式中，球囊内容物通过微孔和/或溶解性膜分配到关节内。在一些实施方式中，在来自肢体使用的压力后，球囊内容物通过排出或撤出加速穿过植入物壁来分配。在一些实施方式中，由于预设的渗透，球囊内容物通过排出或撤出加速穿过植入物壁来分配。在一些实施方式中，由于液泡状物破裂（作为非限制性实例，不管是机械破裂、超声波或化学破裂），球囊内容物通过排出或撤出加速穿过植入物壁来分配。在一些实施方式中，球囊内容物通过排出或撤出加速穿过植入物壁来分配，从而将植入物内部的内容物分配到关节作为润滑物质、止痛物质、抗炎物质和/或其他治疗物质。

[0086] 在一些实施方式中，植入物包括可压缩的膨胀介质。在一些实施方式中，植入物包括包含粘润滑剂的膨胀介质。在一些实施方式中，植入物包括包含药理性物质的膨胀介质。在一些实施方式中，植入物包括包含NSAID的膨胀介质。在一些实施方式中，植入物包括包含软骨细胞的膨胀介质。在一些实施方式中，植入物配置用于使植入物（或其一部分）的最外层与紧贴的软骨缺损的外围炼合以便覆盖它们，从而允许愈合。在一些实施方式中，植入物配置用于一旦已安设新的软骨细胞，则使植入物（或其一部分）的最外层的与紧贴的软骨缺损的外围炼合以便覆盖它们，从而允许愈合。

[0087] 在一些实施方式中，植入物可包括药理性物质的液泡状物。液泡状物可位于植入物的骨接合部分上。在一些实施方式中，植入物包括圆泡状物，所述圆泡状物包含活性物质，诸如药理性物质或其他活性物质。在一些实施方式中，植入物包括以诸如药理性物质或其他活性物质等活性物质填充的空间。植入物可通过植入物材料（即，释放活性物质的可生物降解聚合物）的溶解，和/或通过经植入物的孔洞释放（其中聚合物对活性物质是可渗透的），和/或通过由诸如超声波或压力或其他破裂促进因素之类的促进因素所引起的液泡状物（或圆泡状物，或空间）破裂，来进行递送。植入物可在植入物实际植入关节后的某个时间，比如在一小时后、不到一天后、一天后、不到一周后、一周后、不到一个月后和/或一个月后递送活性物质。在一些实施方式中，在圆泡状物（或液泡状物，或空间）中渗透的干细胞可在植入物插入到关节之后被递送到关节空间（或关节的组成部分）。作为非限制性实例，活性剂可包括干细胞、生长因子、抗生素和/或粘润滑剂。在一些实施方式中，植入物可以包括酶吸收性‘微小海绵’，所述酶吸收性‘微小海绵’可在向关节的植入物递送时或在此时间左右被吸出或排除。

[0088] 第一壁和第二壁之间的线性或曲线运动可能是由股骨头相对于髋臼的运动造成的。第一壁和第二壁之间围绕骨轴的旋转运动可能是由股骨头和髋臼之间的轴向旋转造成的。除了植入物本身内部的壁运动外，髋臼和第二壁之间可存在滑动以提供期望的关节运动。裙筒被设计用于将普通的植入物紧固到关节结构以便避免植入物脱位。植入物已在适当位置上的关节的运动将是植入物的两个移动的对立面的共有功能，并且也是可能较少附

接到关节成员上的壁的运动功能。裙筒、壁和股骨头之间可能存在轻微的运动。在一些实施方式中，侧壁的一侧处于压缩状态，而另一侧则被拉伸以适应骨界面运动。在一些区域，壁可能要厚一点以适应特定载荷，并且侧壁可以更薄并且更有弹性以适应它的滚动和拉伸。

[0089] 在部署植入物之后，植入物的内部可由医生从其适当的源可调节地填充，以确保病态关节空间再次变成弹性缓冲垫，所述弹性垫通过用植入物材料覆盖软骨缺损、缓冲其中的关节和缺损以及递送细胞再生剂，而帮助关节中磨损的或损伤的软骨界面的恢复。在一个实施方式中，关节成形术植入物包括生物相容性可膨胀构件（球囊），其填充有生物相容性填充材料（膨胀介质），诸如气体、液体、凝胶或浆体、或者变为弹性固体的流体，以便提供第一壁与第二壁之间的相对移动。填充或膨胀介质可经过通向套管的注射阀位点插入，该套管将材料递送到植入物的内部之中。在备选实施方式中，植入物可以填充生物相容性弹性材料或者具有由生物相容性弹性材料形成的内部，例如，填充以合适流体的闭孔海绵，该闭孔海绵在植入物部署之前插入到植入物的内部或者在植入物部署在关节部位之后注入该内部。植入物的内部可具有润滑材料以促进内壁表面之间的移动以及使它们之间的接触磨损最小化。植入物的聚合物壁可用诸如干细胞、活软骨细胞和/或基因之类组织再生剂浸渍或者除此之外携带此类组织再生剂以修复关节面。

[0090] 植入物的壁可以（全部地和/或部分地）是可生物吸收的。球囊可以（全部地和/或部分地）是可生物吸收的。在此所用的术语“可生物吸收”、“可生物侵蚀”和/或“可生物吸收”可以互换使用。植入物的壁可释放药剂或生物剂（诸如干细胞、活软骨细胞、基因治疗，等等）。在一些实施方式中，此类药剂（不管是生物性的还是药物性的，或者它们的组合）的释放可随着植入物的壁（或者随着球囊）的生物吸收或者随着关节被使用（即，作为非限制性实例，通过压力），而随着时间的推移发生。在一些实施方式中，诸如在其中膨胀介质包含药剂和/或生物剂的实施方式中，至少一个植入物壁对于药剂和/或生物剂是可渗透的。在一些实施方式中，诸如在其中膨胀介质包含药剂和/或生物剂的实施方式中，至少一个植入物壁具有可让药剂和/或生物剂适合穿过的孔。

[0091] 在一些实施方式中，植入物包括羊膜（和/或其组成部分）。在一些实施方式中，植入物包括羊膜囊（和/或其组成部分）。在一些实施方式中，植入物包括羊膜组织（和/或其组成部分）。羊膜（和/或囊和/或组织）在其机械性能方面是独特的，包括它一面是滑的（光滑的、低弹性模量），而另一面是粘的（粘附的）。在一些实施方式中，第一壁、第二壁和侧壁中的至少一个包括羊膜或其组成部分。在一些实施方式中，第一壁、第二壁和侧壁中的至少一个包括羊膜囊或其组成部分。在一些实施方式中，第一壁、第二壁和侧壁中的至少一个包括羊膜组织或其组成部分。羊膜和/或羊膜囊和/或羊膜组织可结合其他生物剂、药剂和/或治疗剂一起使用。羊膜组织广泛用于多能细胞。由于产品和来源的短期时间跨度，它算得上是 HTBP（基于人体组织的产品）。

[0092] 在一些实施方式中，该内部包括多个可膨胀的腔室。在一些实施方式中，内部包括多个可单独膨胀的腔室。在一些实施方式中，多个可单独膨胀腔室中的第一腔室适合用第一膨胀介质来膨胀，并且多个可单独膨胀腔室中的第二腔室适合用第二膨胀介质来膨胀。

[0093] 在一些实施方式中，第一膨胀介质赋予植入物中的刚度。在一些实施方式中，第一膨胀介质给赋予植入物中的缓冲。在一些实施方式中，为第一膨胀介质选择的膨胀介质和/或用这样的第一膨胀介质填充的腔室的特定选择（在具有多个腔室的实施方式中）使关

节对齐。在一些实施方式中，为第一膨胀介质选择的膨胀介质和 / 或用这样的第一膨胀介质填充的腔室的特定选择（在具有多个腔室的实施方式中）使关节的骨对齐。在一些实施方式中，为第一膨胀介质选择的膨胀介质和 / 或用这样的第一膨胀介质填充的腔室的特定选择（在具有多个腔室的实施方式中）改变了骨对齐。在一些实施方式中，为第一膨胀介质选择的膨胀介质和 / 或用这样的第一膨胀介质填充的腔室的特定选择（在具有多个腔室的实施方式中）改善了关节对齐。在一些实施方式中，为第一膨胀介质选择的膨胀介质和 / 或用这样的第一膨胀介质填充的腔室的特定选择（在具有多个腔室的实施方式中）至少部分地恢复关节对齐。在一些实施方式中，可以选择性地用第一膨胀介质和 / 或第二膨胀介质来膨胀内部的个别腔室。在一些实施方式中，用第一膨胀介质和 / 或第二膨胀介质选择性地膨胀内部的个别腔室，以便重建关节和 / 或关节的骨。

[0094] 在一些实施方式中，膨胀介质包含活软骨细胞。

[0095] 在一些实施方式中，内部包括蜂窝状结构。在一些实施方式中，内部包括网状结构。在一些实施方式中，内部包括海绵状结构。

[0096] 在一些实施方式中，植入物的腔室被配置用于接纳固体片，该固体片配置用于恢复关节和 / 或骨对齐。在一些实施方式中，植入物的腔室被配置用于接纳配置用来恢复关节和 / 或骨对齐的刚性片。在一些实施方式中，植入物的腔室被配置为接纳配置用来恢复关节和 / 或骨对齐的半刚性片。在一些实施方式中，腔室配置用于接纳多个固体片，其中每个固体片都可以用来增加股骨头与髋臼之间的空间，以便恢复和 / 或改善关节和 / 或骨对齐。固体片可以是楔形的，或者可以提供为各种大小和 / 或形状。固体片可以单独或一起用在植入物的一个腔室或多个腔室中。固体片（或者多个片）可用于将相邻的骨棘推至期望的牵张和 / 或对齐，以便恢复和 / 或改善关节和 / 或骨对齐。固体片可以放置在植入物的腔室中，该腔室可以封闭或部分地封闭所述片以将该片保持在适当位置。在一些实施方式中，可以提供一块生物相容性材料（诸如 PMMA 或其它骨样替代物），并且其可由外科医生（通过雕刻或其他成形方法）形成为期望的形状。形成的固体片继而可以置于植入物的腔室中，该腔室可以封闭或部分地封闭所述片以将该片保持在适当位置。固体（或刚性或半刚性片，取决于需要）片可以用来填充关节结构的损伤处。

[0097] 植入物内部（球囊内部）可以用作为液体的甲基丙烯酸甲酯膨胀，该液体会变为固体或半固体（刚性或半刚性）。在一些实施方式中，膨胀介质是甲基丙烯酸甲酯或其它生物相容性硬化物质，其在最初放入腔室时可以流动，并且硬化成刚性片（或固体片）。甲基丙烯酸甲酯或其它生物相容性硬化物质可能与腔室的形状相符，或者可能与骨和 / 或其他关节结构之间的空间的形状相符。甲基丙烯酸甲酯或其它生物相容性硬化物质可通过由外科医生使用工具和 / 或压力来影响由甲基丙烯酸甲酯或其它生物相容性硬化物质在硬化后形成的刚性片的最终形状而符合于外科医生所选的形式。

[0098] 固体片（或刚性片或半刚性片 -- 无论是原位形成的，还是由外科医生形成的或者预成形的）可由植入物缓冲。植入物可在固体片与股骨头之间包含可膨胀腔室。植入物可在固体片与髋臼之间包含可膨胀腔室。植入物可在固体片与股骨头之间包含垫片作为缓冲垫。植入物可在固体片与髋臼之间包含垫片作为缓冲垫。

[0099] 固体片可提供以下至少一项：约 1 度的关节矫正，约 2 度的关节矫正，约 3 度的关节矫正，约 4 度的关节矫正，约 5 度的关节矫正，约 6 度的关节矫正，约 7 度的关节矫正，约

8 度的关节矫正，约 9 度的关节矫正，以及约 10 度的关节矫正。关于关节矫正的角度，术语“约”可以指 1%、5%、10%、25%或 50%的范围。

[0100] 植入物可用在多种关节中，其中植入物置换骨表面上的骨并且缓冲任何两块骨的关节末端之间的相互作用，如在患者髋部的股骨 - 髋臼间隙处。在植入物替代或加强关节软骨的情况下，可以降低或增强刚性以便最大化如通过两个相对的壁和预计的内部空间并连同考虑适应或扩增现有关节韧带、肌腱或现有关节韧带、肌腱的缺乏的任何关节外科手术重建而实现的在运动中产生的构形变化。在植入物例如已发挥其使组织再生的用途之后，或者如果另一临床状况需要将该植入物移除，则植入物可通过微创手术被收缩和移除。然而，即使已经丧失膨胀，在临床上可能也并不一定要将植入物移除，这是因为修补受损软骨和递送恢复性细胞这两个剩余功能可使植入物的保留成为合理的。

[0101] 在一些实施方式中，植入物通过微创手术插入，然而，在另一些实施方式中，植入物也可能不通过微创手术插入。在一些实施方式中，植入物通过约 0.5 英寸长的切口来投送。在一些实施方式中，植入物通过约 1 厘米长的切口来投送。在一些实施方式中，植入物通过至多约 1 英寸长的切口来投送。在一些实施方式中，植入物在不用关节镜的情况下通过至少 1 厘米长的切口来投送。在一些实施方式中，植入物通过至多约 0.75 英寸长的切口来投送。在一些实施方式中，植入物通过至多约 0.5 英寸长的切口来投送。在一些实施方式中，植入物通过约 8 厘米长的切口来投送。在一些实施方式中，植入物通过约 9 厘米长的切口来投送。在一些实施方式中，植入物通过约 10 厘米长的切口来投送。在一些实施方式中，植入物通过约 11 厘米长的切口来投送。在一些实施方式中，植入物通过约 12 厘米长的切口来投送。在一些实施方式中，植入物通过长于约 10 厘米长的切口来投送。在一些实施方式中，植入物通过长达约 40 厘米长的切口来投送。在一些实施方式中，植入物通过多个切口来投送。关于切口长度而言，术语“约”可以指 1%、5%、10%、25%或 50%的范围。

[0102] 在一些实施方式中，植入物被配置成在关节镜下投送至关节。在一些实施方式中，植入物被配置成适合装入具有至多 10 毫米的远端内径的套管内。在一些实施方式中，植入物被配置成适合装入具有至多 9 毫米的远端内径的套管内。在一些实施方式中，植入物被配置成适合装入具有至多为 5 毫米的远端内径的套管内。

[0103] 在一些实施方式中，植入物被配置成折叠的，以便适合装入具有至多 10 毫米的远端内径的套管内。在一些实施方式中，植入物被配置成折叠的，以便适合装入具有至多 9 毫米的远端内径的套管内。在一些实施方式中，植入物被配置成折叠的，以便适合装入具有至多 5 毫米的远端内径的套管内。

[0104] 在一些实施方式中，植入物被配置成通过具有至多 10 毫米远端内径的套管而投送到关节。在一些实施方式中，植入物被配置成通过具有至多 9 毫米远端内径的套管而投送到关节。在一些实施方式中，植入物被配置成通过具有至多 5 毫米远端内径的套管而投送到关节。

[0105] 在一些实施方式中，植入物被配置成在关节镜下投送至关节。在一些实施方式中，植入物被配置成适合装入具有至多约 10 毫米远端内径的套管内。在一些实施方式中，植入物被配置成适合装入具有至多约 9 毫米远端内径的套管内。在一些实施方式中，植入物被配置成适合装入具有至多约 5 毫米远端内径的套管内。关于套管的末端内径而言，术语“约”可以指 1%、5%、10%、25%或 50%的范围。

[0106] 在一些实施方式中，植入物被设置成折叠的，以便适合装入具有至多约 10 毫米远端内径的套管内。在一些实施方式中，植入物被设置成折叠的，以便适合装入具有至多约 9 毫米远端内径的套管内。在一些实施方式中，植入物被设置成折叠的，以便适合装入具有至多约 5 毫米远端内径的套管内。关于套管的末端内径而言，术语“约”可以指 1%、5%、10%、25%、或 50%的范围。

[0107] 在一些实施方式中，植入物被配置成通过具有至多约 10 毫米远端内径的套管而投送到关节。在一些实施方式中，植入物被配置成通过具有至多约 9 毫米远端内径的套管而投送到关节。在一些实施方式中，植入物被配置成通过具有至多约 5 毫米远端内径的套管而投送到关节。关于套管的末端内径而言，术语“约”可以指 1%、5%、10%、25%或 50%的范围。

[0108] 在一些实施方式中，可将植入物提供成收缩的球囊，以便插入关节空间。在一些实施方式中，可将植入物提供成可像伞那样溃缩的折叠的球囊，以便插入关节空间。在一些实施方式中，可将植入物提供成具有用以使其折叠（或溃缩）尺寸最小化的不规则折叠图案的溃缩球囊，以便插入关节空间。在一些实施方式中，植入物被配置成胀大（或扩张）的，以便采取扩张的、牵张的、经清创的关节的形式。

[0109] 在一些实施例中，植入物置换骨膜。

[0110] 在一些实施方式中，相比于典型的关节成形手术，植入物被植入以保留骨骼。在一些实施方式中，相比于典型的关节成形手术，植入物被植入以保留软骨。在一些实施方式中，相比于典型的关节成形手术，植入物伴随最少的软组织剖开而被植入。在一些实施方式中，植入物不伴随关节脱位而被植入。在一些实施方式中，一旦进行了植入，关节就可适合于修正手术。在一些实施方式中，一旦进行了植入，关节就保持以下至少一项：约 90%的正常关节功能，约 95%的正常关节功能，约 85%的正常关节功能，约 80%的正常关节功能，约 75%的正常关节功能，约 70%的正常关节功能，约 65%的正常关节功能，约 60%的正常关节功能，约 55%的正常关节功能，约 50%的正常关节功能，至少 95%的正常关节功能，至少 90%的正常关节功能，至少 85%的正常关节功能，至少 80%的正常关节功能，至少 75%的正常关节功能，至少 70%的正常关节功能，至少 65%的正常关节功能，至少 60%的正常关节功能，至少 55%的正常关节功能，至少 50%的正常关节功能，约 50% - 约 75%的正常关节功能，约 50% - 约 70%的正常关节功能，约 60% - 约 70%的正常关节功能，约 70% - 约 80%的正常关节功能，约 70% - 约 90%的正常关节功能，约 80% - 约 95%的正常关节功能，约 80% - 约 90%的正常关节功能，约 90% - 约 95%的正常关节功能。在此关于正常关节功能的百分比所使用的术语“约”可以是 1%、5%、10%或 25%的范围。例如，关于约 90%的正常关节功能而言的 1%的范围覆盖了 89%至 90%的正常关节功能。

[0111] 图 1 是部分切开的透视图，示出了髋植入物 20。植入物 20 的上部具有第一壁 21、第二壁 22 和侧壁 23，它们至少部分地界定了内部 24。裙筒 25 依附于第一壁 21，且将第一壁 21 紧固至患者的股骨 26 的末端，如图 2 和图 3 最佳示出的。图 2 是安装在患者股骨头的图 1 所示植入物的立视图。图 3 显示了安装在股骨 26 的头部的植入物，填充的上部的第二壁 22 配置为接合患者的髋骨 28 的相应的髋臼 27。图 3 是部署于患者的股骨头部和髋臼之间的图 1 和图 2 所示植入物在牵引释放后的剖视图，以允许骨适应虽然为病理性但自然的休止角。裙筒 25 围绕在患者的股骨 26 的头部，并将植入物 20 紧固于此。在该实施方式

中，植入物的放大的上部在第一和第二壁 21 和 22 之间的侧壁 23 中产生重叠层，如冗余膜，以适应第一或第二壁的正常运动。这提供了更大的股骨和髋臼之间的运动，也提供了覆盖股骨 26 的头部的植入物稳定性。这种结构也适应患者与患者之间的个体关节的差异。

[0112] 在图 1-3 所示的实施方式中，第一壁 21 并不延伸穿过患者的股骨的整个末端。然而，植入物 20 可被设计使得第一壁 21 可以在股骨头上延伸（以及下文所述的图 4-9）。第二壁 22 和侧壁 23 倾向于随股骨 26 在髋臼 27 内移动而滚动。

[0113] 在一些实施方式中，在部署体现本发明特征的植入物之前，通过清除透明软骨或纤维软骨皮瓣或撕痕来准备好内衬于关节的软骨，并且对软骨的晚期裂隙区域进行切除或清创，以便创造精确限定的缺损，所述缺损被关于受损表面具有垂直边缘的稳定的正常残余透明软骨所围绕。先前是正常表面的软骨的这些缺损之中可以注入或者除此之外插入新的活细胞，并且所述新的活细胞被允许通过经植入物间置式关节成形术近端扩张的压缩性外壁材料而得以聚集。侵入关节外围的滑膜炎可以常规地或者通过使用蒸汽而得到汽化和抽出。为了后续的再生而将更大的软骨损伤区域移除，并对具有稳定裂缝的受害较少的区域进行处理以密封或融合所述裂缝。可以保留膨胀或一致性或最小受损软骨的区域得到保存而不是被破坏，以便支持更多正常关节界面的正常间隔和滑动的机会。因此，留下正常软骨并且移除异常软骨，用植入物来弥补缺失。就本发明而言，在一些实施方式中更优选地要避免关节脱位，以便保留自然的神经分布和血管分布，从而保持由髋关节的中间和侧面旋动脉对股骨头提供的血液供应。

[0114] 关节准备通常是在门诊手术的短暂全身麻醉下进行。肌肉松弛药与牵引（例如对髋植入物的 60 磅力）相结合更宽地打开关节，以允许改善对关节准备和植入物安装的可视化，将剩余软骨之间的空间从约 3mm 增大到可达约 12mm。增大空间允许外科医生洗掉有毒的酶，以便清除侵入性滑膜炎，清除游离体，理想地准备骨软骨缺损和以其他方式另外为植入物准备关节。植入物的部分膨胀或完全膨胀通常将在释放牵引之前。在一些实施方式中，在释放牵引和闭合创口之前，再生剂或细胞随植入物而插入，或者作为流体或 3-D 模板而被插入。在一些实施方式中，优选地在相同的麻醉剂作用下进行关节清创、植入物部署和细胞再生剂施用，例如干细胞施用。正如在纽约举行的干细胞峰会 (Stem Cell Summit，2009 年 2 月 17 日于纽约举行）上的数家公司所描述，在手术开始时，诱导麻醉后获得从髂嵴中对患者骨髓的抽吸是期望的。术中技师将会“拨入细胞 (dial in the cells)”以便再生最大的病理生理面积，而外科医生会清创或以其他方式准备关节和插入植入物，从而在最佳时机置入细胞。细胞移植还可以作为二次或三次重建性辅助治疗而进行。

[0115] 图 4 是部署在患者髋结构内的备选弹性植入物 30 的部分切开的立视图，该髋结构包括患者股骨 31 的头部和患者髋骨 33 的髋臼 32。植入物 30 的上部小于图 1-3 中显示的。为了清晰起见，没有提供关节内部的细节如软骨、韧带等。体现本发明特征的弹性植入物 30 被置于股骨 31 和髋臼 32 之间的空间内。为了清楚起见，图 4-8 显示了安装在股骨 31 的头部上、没有来自髋臼 32 的压力的植入物 30。图 5 是如图 4 所示的左侧近端股骨的前立视图，植入物放置在髋关节的股骨头部，部分横切，以显示其细节。图 6 是从“身体一侧”或髋侧面观察，如图 4 所示的具有植入物的股骨的侧立视图。图 7 是如图 4 所示的具有植入物的股骨的俯视图。图 8 是图 7 中的髋关节发明迭代或植入物的仰视图。

[0116] 图 4-9 所示的植入物 30 形似一半橘子皮或相对于髋关节的半球。植入物 30 具有

图 5 中可见的第一壁 34，第一壁 34 通过多个依附的翼片 35（或附件）被紧固在股骨 31 的头部。翼片 35 可通过合适的胶粘剂或机械地如通过螺钉或销钉附接在股骨 31 上。植入物的第二壁 36 接合髋臼 32，但它也可以具有翼片及类似物以将第二壁固定在髋臼 32 上。

[0117] 在一些实施方式中，植入物含有阀门。阀门可以是植入物壁的部件，或球囊或其部分的部件，或者它可以将管或导管连接到球囊，或者它也可以定位在皮下以通过注射和 / 或吸引周期性使用。

[0118] 侧壁 37 在第一和第二壁 34 和 36 之间延伸以形成内部 38，内部 38 通过管 40（此处也称为导管，或者也称为膨胀端口）接收填充材料 39。在一些实施方式中，膨胀端口不是管而是可从植入物的壁延伸或者不从其延伸的阀门。阀门可以是植入物壁的部件，或球囊或其部分的部件。在一些实施方式中，膨胀端口（或管）的内径最大为 5 毫米。在一些实施方式中，膨胀端口的内径约为 1 毫米。在一些实施方式中，膨胀端口的内径约为 2 毫米。在一些实施方式中，可以用针（或典型的针的大小）来膨胀植入物。

[0119] 在许多实施方式中，植入物 30（或其一部分，诸如球囊或球囊）是将会允许关节运动趋于正常的承重垫片，无论是填充如在骨关节炎中那样广泛地还是如在骨坏死缺损或局部创伤中那样局限地由完全坍塌的关节骨所留下的空间或是切除的软骨邻面空间，情况都是这样。壁 34 和 36 也可用作膜，用于将活细胞在骨软骨缺陷处附近保留足够长的时间，该时间足以使细胞附着（例如，24 小时）或深度粘附（可达 28 天）或恢复正常（可达一年）。当治疗下肢远端关节时，预计承重将会增大。

[0120] 运动据信主要介于外围紧固到关节结构上的植入物的隔开的壁（或部分）之间，尽管一些运动可发生在植入物与关节面之间（正如现在的双极髋半关节置换术）。如图 9 所示，植入物 30 可配备有从植入物的外周 42 通过植入物向位于中心的通道 43 延伸的狭槽 41，用以使髋植入物适应股骨头的韧带。图 9 是从患者头部或从头向尾方向观察的，带有具有本发明特征的弹性植入物的患者髋部的俯视图或头向视图。植入物的壁 34 和 36 应当具有足够的固有柔性，以便吻合现有的由自然的韧带、骨、肌腱所施加的形变和已被填充作为缓冲垫的内部关节空间的残留软骨形变。壁的外部可以是平坦的，或者形成为具有用于滑行用途的随机或特定的图案或者用于抵靠相邻表面的牵引的纹线，或者形成为用于细胞递送材料的沟槽或地点。

[0121] 图 10A 描绘了安放到股骨头 11 上并且植入到股骨头 11 和髋骨 28 的髋臼 27 之间间隙中的、具有裙筒 25 和球囊 62 形式的附件的植入物的实施方式。图 10B 描绘了安放到股骨头 11 上并且植入到股骨头 11 和髋骨 28 的髋臼 27 之间的间隙中的、具有附件 35（翼片类型）和球囊 62 的植入物的实施方式。

[0122] 图 11A 描绘了安放到股骨头 11 上的具有附件 35（翼片类型）和球囊 62 的植入物的实施方式，其中该球囊最低限度地膨胀（或未膨胀）。

[0123] 可以使用单独的端口或管（未示出）或存在的导管 40（管或阀门）抽取出有毒的炎性酶，该酶可以按照合适的临床间隔抽吸。可以抽取 COX1、COX2 和 / 或 5LOX 途径中的炎性酶。图 11B 描绘了安放到股骨头 11 上的具有附件 35（翼片类型）和球囊 62 的植入物的实施方式，其中该球囊最低限度地膨胀（或未膨胀），并且示出了在一些实施方式中可用于膨胀植入物的球囊 62 或可用于抽取例如炎性酶的管 40。

[0124] 在一些实施方式中，可以使用（通过催化剂反应或其他方式）产生热量的膨胀介

质来向关节结构传递热量。热量可以辅助透明软骨炼合。植入物材料的热效应经过了相应计算，以有益于和保护关节面，类似用于暴露在极端温度下的戴水肺潜水员的干式潜水服和湿式潜水服。作为非限制性实例，植入物的实施方式一般力图通过同种异体移植作为羊膜或作为聚合物的润滑涂层来避免由摩擦产生的热。

[0125] 可以通过已有的导管 40 或通过长针将粘润滑剂注入弹性关节成形术装置的内部，以助于扩张、膨胀、润滑（具有预定的微孔率）。图 11C 描绘了安放到股骨头 11 上的具有附件 35（翼片类型）和球囊 62 的植入物的实施方式，其中球囊 62 膨胀，并且显示了膨胀管 40。

[0126] 在一些实施方式中，第一膨胀介质赋予植入物中的刚度。在一些实施方式中，第一膨胀介质赋予植入物中的缓冲。在一些实施方式中，为第一膨胀介质选择的膨胀介质和 / 或用这样的第一膨胀介质填充的腔室的特定选择（在具有多个腔室的实施方式中）使关节对齐。在一些实施方式中，为第一膨胀介质选择的膨胀介质和 / 或用这样的第一膨胀介质填充的腔室的特定选择（在具有多个腔室的实施方式中）使关节的骨对齐。在一些实施方式中，为第一膨胀介质选择的膨胀介质和 / 或用这样的第一膨胀介质填充的腔室的特定选择（在具有多个腔室的实施方式中）改变了骨对齐。在一些实施方式中，为第一膨胀介质选择的膨胀介质和 / 或用这样的第一膨胀介质填充的腔室的特定选择（在具有多个腔室的实施方式中）改善了关节对齐。在一些实施方式中，为第一膨胀介质选择的膨胀介质和 / 或用这样的第一膨胀介质填充的腔室的特定选择（在具有多个腔室的实施方式中）至少部分地恢复关节对齐。在一些实施方式中，可以选择性地用第一膨胀介质和 / 或第二膨胀介质来膨胀内部的个别腔室。在一些实施方式中，用第一膨胀介质和 / 或第二膨胀介质选择性地膨胀内部的个别腔室，以便重建关节和 / 或关节的骨。

[0127] 在一些实施方式中，内部包括蜂窝状结构。在一些实施方式中，内部包括网状结构。在一些实施方式中，内部包括海绵状结构。

[0128] 各植入物壁的尺寸将依据其材料性质以及针对特殊关节的需求而改变。此外，第一壁和第二壁可能需要不同于侧壁的厚度。通常，植入物可具有约 0.125mm 至约 3mm，优选地约 0.5mm 至约 1.5mm 的壁厚度。对于大部分关节，内部中第一壁与第二壁之间的间距可在约 0.5mm 至约 5mm 之间变化。

[0129] 本髋关节发明的插入方法将是一种微创方法，理想地是关节镜辅助的，只要是在手术时机和结果质量允许较小的切口的情况下。髋部患者取侧卧位（非手术侧向下躺在手术台上），放置稳定手术台杆和衬垫设备来固定骨盆。外部稳定台和附件将包括在耻骨或髋骨下、沿着其他外部前及后骨盆稳定桨从后向前的具有垫料的金属杆。患腿在膝盖下方束缚，一旦患者处于全身麻醉状态，即用撑开牵引机构施加约 60 磅的远端力来打开髋关节约 1cm。通过至少一个前 0.5cm 切口和一个后 0.5cm 切口对髋关节进行关节镜清创，以从股骨头髋臼（球和窝）移除关节炎碎片如滑膜炎、松散体和有害的炎性酶。在某些情况下，可能需要较大的开放切口。可以进行平滑处理或电子 / 超声 / 蒸汽或其他软骨成形方法来使得残余的软骨更平滑以更好地适应髋植入物，并且可以通过关节镜移除或者如果需要通过开放切除移除突起的骨刺或侧向骨质增生。侧向髋关节切口可能需要 2 到 10 厘米长以处理变形和 / 或插入植入物。在主要变形的情况中，适当的重建会加到基本操作中。

[0130] 一旦打开并且清理了关节，髋植入物将会在侧面插入，并通过裙筒或翼片或至少

一个附件固定在相邻的结构上，包括外周股骨头和 / 或髋臼缘。优选地，在植入物处于收缩结构的情况下，在关节镜下通过约 10mm 直径的套管插入植入物，并且一旦植入物位于已准备好的关节空间中并通过裙筒或翼片紧固于其中，则用气体、凝胶、流体或者变成弹性固体的流体来扩张或膨胀植入物，以便填充在上方髋臼和下方股骨头之间约 0.5cm 的的原始自然空间，从而按照植入物扩张以适配该间隙的需要覆盖尽可能多的上部髋关节。将通过外科医生对适当压力施用的感觉并辅以用于注射诸如欣维可 (Synvisc)、海尔根 (Hyalgan) 和透明质酸钠注射剂 (Supartz) 等粘润滑剂和 / 或诸如利多卡因凝胶等镇痛药的经校准注射器来进行张力调整。通过先前为了清创而存在的通往关节空间的套管，或者经由不是原始植入物组装件一部分的套管或管，可以直接地将液体插入关节本身。一旦关节得到清理，则植入物将被插入并适当地固定以避免在此挤出或脱位。这可通过植入物翼片的附接和 / 或对翼片加上由植入物表面覆盖物（类似于维可牢）或位于植入物较小底部的细绳所引起的预期摩擦的组合使用来实现。

[0131] 在一些实施方式中，附接翼片定位在植入物上，以便既把植入物紧固到关节组件，又使医生能够确保植入物具有最小量的可能产生褶皱或松散区域的松弛，以避免植入物或患者解剖结构的不必要的摩擦和 / 或磨损。本文所示的图中显示了为了此双重目的而配置的附接翼片的例子。在一些实施方式中，只需要较少的翼片来实现这些目的。图 12 描绘了安放到股骨头 11 上并且被植入到股骨头 11 和髋骨 28 的髋臼 27 之间间隙中的、具有附件 35（翼片类型）和已膨胀球囊 62 的植入物的实施方式。在一些实施方式中，需要更多的翼片来实现这些目的。在其中存在松弛或空隙的一些实施方式中，受到压缩的球囊可以填充此类区域。在一些实施方式中，植入物配置成允许透明质和 / 或软骨细胞填充关节组件中的任何不规则性或盆坑 (crater) 并且生长以整修天然的关节轮廓。

[0132] 膨胀可根据临床需要而指定，并且在植入物多单元（多隔区）构造中的改动允许用可作为材料分层完整性的一部分的、包括名叫或半固体在内的、范围从气体到固体的材料来进行选择性膨胀，以便提供计算的硬度（硬度计）以克服和抵制肢体相邻的骨的不正常对齐，和 / 或提供新的再生组织用于随时间恢复天然解剖结构。也就是说，可以选择性地膨胀植入物的某些部分或者保持其不扩张，以便调整去适应所涉患者的相匹配的正常或未受伤的对侧肢体。

[0133] 在一些情况下，可能需要将植入物移除，并且文中所述的植入物的实施方式被配置成在关节镜下移除，并且允许执行所有更旧的被例行认可的技术，范围从关节清创术到钻孔、局部或全部置换术。在一些实施方式中，植入物被设置成一旦所有的外来体被移除后则被移除并用另一个代替植入物替换——或者是立即（一周以内）的，或者在更长一段时间之后（例如，在感染的情况下，在约 6 周到 1 年后）进行，这取决于外科医生和 / 或传染病顾问的意见。

[0134] 在一些实施方式中，植入物包含聚合物。聚合物可包括以下至少一种 :聚氨酯（举例而言，诸如 ChronoFlex AR)、聚碳酸酯氨基甲酸乙酯、热塑性聚碳酸酯氨基甲酸乙酯（诸如 Bionate 55)、乙烯 - 醋酸乙烯酯共聚物、聚（环氧乙烷）(PEO) 和聚（对苯二甲酸丁二酯）(PBT) 的多嵌段共聚物、PEG、PEO 和聚乙烯。植入物可包含在溶剂中的多层聚合物（诸如 ChronoFlex AR) 并且在施用每一层之后蒸发溶剂。植入物可含有聚合物如（但不限于）Bionate、ChronoFlex 或 ChrnoPrene。在一些实施方式中，植入物包括喷涂和干燥（其中喷

涂和干燥重复至少一次）至期望厚度的聚氨酯。

[0135] 可以采用辅助治疗如粘润滑剂和细胞。

[0136] 在一些实施方式中，通过将具有髋关节骨（股骨头和/或髋臼）形状的芯轴到聚合物溶液（作为非限制性实例，氨基甲酸乙酯聚合物，诸如Chronoflex）中浸渍成型来生成植入物。每次浸渍之后，将植入物干燥一段特定时间，所述特定时间例如可以是约3秒、约4秒、约5秒、约6秒、约7秒、约8秒、约9秒、约10秒、约15秒、约20秒、约25秒、约30秒、约45秒、约1分钟、约2分钟、约5分钟、约10分钟、约15分钟和超过约15分钟。在此关于植入物干燥时间所使用的术语“约”可以指5％、10％、25％和50％中的至少一个的变化。在一些实施方式中，不使用干燥步骤。浸渍可重复多次。在一些实施方式中，单次浸渍就已足够。在一些实施方式中，浸渍重复2次。在一些实施方式中，浸渍重复3次。在一些实施方式中，浸渍重复4次。在一些实施方式中，浸渍重复5次。在一些实施方式中，浸渍重复6次。在一些实施方式中，浸渍重复7次。在一些实施方式中，浸渍重复8次。在一些实施方式中，浸渍重复9次。在一些实施方式中，浸渍重复10次。在一些实施方式中，浸渍重复11次。在一些实施方式中，浸渍重复12次。在一些实施方式中，浸渍重复13次。在一些实施方式中，浸渍重复14次。在一些实施方式中，浸渍重复15次。在一些实施方式中，浸渍重复16次。在一些实施方式中，浸渍重复17次。在一些实施方式中，浸渍重复18次。在一些实施方式中，浸渍重复19次。在一些实施方式中，浸渍重复20次。在一些实施方式中，浸渍重复21次。在一些实施方式中，浸渍重复22次。在一些实施方式中，浸渍重复23次。在一些实施方式中，浸渍重复24次。在一些实施方式中，浸渍重复25次。在一些实施方式中，浸渍重复超过25次。在一些实施方式中，浸渍重复足够的次数以生成规定厚度的植入物。厚度可根据聚合物和根据植入物的实施方式而改变。厚度可以是以下至少一项：约25微米厚、约50微米厚、约100微米厚、约125微米厚、约150微米厚、约200微米厚、约250微米厚、约300微米厚、约350微米厚、约400微米厚、约25-50微米厚、约50-100微米厚、约50-200微米厚、约100-150微米厚、约150-300微米厚、约100-300微米厚、约100-500微米厚、约200-500微米厚、以及约200-1000微米厚。在此关于植入物厚度所使用的术语“约”可以指5％、10％、25％和50％中的至少一个的变化。厚度可在植入物的不同位置处变化。在一些实施方式中，植入物以两个零件制成，当将这两个零件放在一起时，其中一个或多个零件成型以形成内部。在一些实施方式中，通过刺穿植入物壁以及用塞子、补片或其他密封剂密封穿孔来填充植入物。作为非限制性实例，塞子、补片或其他密封剂可包括Chronoflex材料。作为非限制性实例，塞子、补片或其他密封剂可包括与该植入物的构造材料相同的材料。

[0137] 体现本发明特征的植入物的壁可以是复合结构。例如，最内层可以是不可渗透的，以阻止膨胀介质或其他填充介质的逸出；中心层可以是多孔的或者除此之外包含治疗剂或细胞再生剂；并且外层可以是薄而坚固的热塑性塑料（作为非限制性实例，诸如热塑性聚氨酯）层，其具有足以允许来自中心层（或第二层）的治疗剂或细胞再生剂通过或排出的微孔率。在诸如Chronoflex或Bionate 55等聚合物层中发现使来自中心层的治疗剂或细胞再生剂能够排出的微孔率程度。植入物的外壁（和/或骨接合表面）可涂覆有和/或浸渍聚合物网格，该聚合物网格喷涂在或分层堆积在植入物的外面（或骨接合表面）上以促进软骨组织再生。该最外层表面涂层可包含活软骨细胞（例如，在Carticel手术中由

Genzyme 公司提供的软骨细胞），并且 / 或者可包含具有定向基因突变的干细胞以促进涂层到植入物的粘附。骨接合表面可包括峰和槽。活细胞可施用于植入物表面的槽之间（和 / 或提供在槽内），而突出物（表面的峰）的表面积可用于以下至少一项：空间验证、牵引和细胞保护。

[0138] 体现本发明特征的植入物可在一系列治疗中使用，其中，第一治疗涉及自体移植或最低程度操作的同种异体移植的间置组织或异种移植的使用，第二治疗涉及添加到干细胞或软骨细胞中的同种类型的组织的使用，而第三治疗涉及当第一、第二治疗失败或无效时植入物的部署。

[0139] 植入物可配备有网格或其他加强线，优选位于它的外面或壁内，以便当植入物部署在矫形部位时控制其最大扩张。

[0140] 髋关节中所要求的撑开牵引程度将取决于自然解剖结构和定位的病理生理学，其必须逐个病例地加以调节，且所述撑开牵引可以是使用重力和 / 或叠加的牵引装置的体位的组合。

[0141] 本文提供了一种用于恢复髋关节的方法，包括：提供配置用于部署在关节的股骨头与髋臼之间的植入物，所述植入物包括球囊，该球囊包括配置用于接合关节的股骨头的第一部分，配置用于接合关节的髋臼的第二部分，连接第一部分与第二部分的侧面部分，以及可选地可用第一膨胀介质膨胀的内部，其中所述侧面部分促进第一部分与第二部分之间的相对运动；以及将球囊的第一附件联接至关节的股骨头。

[0142] 在一些实施方式中，第一部分、第二部分和侧面部分中的至少两个是毗连的。在一些实施方式中，第一部分包含第一壁，第二部分包含第二壁，侧面部分包含侧壁。

[0143] 在一些实施方式中，该方法包括在配置用于接合股骨头的第一部分、配置用于接合髋臼的第二部分、侧面部分以及附件之中的至少一个上提供长入补片。作为非限制性实例，长入补片可配置用于助长和 / 或促进组织长入，诸如骨长入。该补片可以和所述部分本身（无论是第一部分、第二部分、侧面部分还是附件）一样大，或者可以小于该部分（诸如形如条状的或其他形状的补片）。长入补片可包括表面不规则性或粗糙性。长入补片可以像维可牢那样。在一些实施方式中，植入物从（并且在某些实施方式中，包括）第一附件到第二附件包括位于第一部分和 / 或第二部分之上的长入补片。在一些实施方式中——其中附件（通过设计和 / 或由于磨损和 / 或随着时间的推移）从与骨的附接中松开——长入补片帮助将植入物紧固到骨上。在一些实施方式中，长入补片包括附接到植入物的小珠和 / 或珠状元件。这样的长入补片可配置用于模拟正常松质骨网格的小梁骨空间。在一些实施方式中，小珠是各种形状的烧结小珠。在一些实施方式中，小珠是约 400 微米大小的烧结小珠。关于小珠大小而言，术语“约”可指 1％、5％、10％、25％或 50％的范围。在一些实施方式中，使股骨头和 / 或髋臼变粗糙以获得出血的骨从而促进长入。在一些实施方式中，清除约 0.5mm 的皮质组织以便促进长入。

[0144] 在一些实施方式中，该方法包括将球囊的第二附件联接至关节的股骨头。在一些实施方式中，该方法包括将球囊的第二附件联接至关节的髋臼。在一些实施方式中，该方法包括将第一部分、第二部分和侧面部分中的至少一个的第二附件联接到关节的股骨头和髋臼中的至少一个。在一些实施方式中，联接第一附件和第二附件中的至少一个向关节的股骨头和髋臼提供了韧带样支撑。在一些实施方式中，联接第一附件和第二附件中的至少一

个向关节提供了韧带样支撑。在一些实施方式中，第一附件和第二附件配置用于向关节的股骨头和髋臼提供肌腱样支撑。在一些实施方式中，第一附件和第二附件配置用于向关节提供肌腱样支撑。

[0145] 在一些实施方式中，所述方法包括：提供与球囊的内部相连通的膨胀端口，用于以第一膨胀介质来膨胀球囊的内部。在一些实施方式中，该方法包括使用与球囊的内部相连通的植入物的膨胀端口来用第一膨胀介质膨胀球囊的内部。在一些实施方式中，该方法包括刺穿球囊以便用第一膨胀介质来膨胀球囊的内部。在一些实施方式中，该方法包括提供具有自密封能力的球囊。在一些实施方式中，该方法包括提供在用第一膨胀介质膨胀球囊的内部之后具有自密封能力的球囊。在一些实施方式中，该方法包括提供包含能够封闭球囊内部的密封件的球囊。

[0146] 在一些实施方式中，该方法包括提供包括多个可膨胀腔室的内部的球囊。在一些实施方式中，所述内部包括多个可单独膨胀的腔室。在一些实施方式中，该方法包括用第一膨胀介质来膨胀多个可膨胀腔室之中的第一腔室。在一些实施方式中，第一腔室和膨胀介质基于病人的特定需求来选择。作为非限制性实例，如果病人有由于损伤而带来的骨缺失，则腔室可以选择在缺失的骨的位置上，并且可以用刚性的（或者一旦在腔室中即会变成刚性的）膨胀介质填充，以便置换缺失和/或损伤的骨。备选地，或者附加地，可以选择腔室用于恢复关节的对齐，并用合适的膨胀介质对该腔室加以填充，以便同时向关节给予对齐和缓冲。在一些实施方式中，该方法包括用第二膨胀介质来膨胀多个可单独膨胀的腔室之中的第二腔室。

[0147] 在一些实施方式中，球囊是复合结构。在一些实施方式中，球囊包括多孔材料层和/或非多孔材料层，或者除此之外包含治疗剂或细胞再生剂。在一些实施方式中，球囊的第一层是薄而坚固的热塑性塑料层，作为非限制性实例，诸如热塑性聚氨酯，其具有足以允许来自第二层的治疗剂或细胞再生剂通过或排出的微孔率。第二层可以是中心层（其位于第一层与第三层或第四层或者更多的层之间）。在一些实施方式中，第一层可包括骨接合表面。在诸如 Chronoflex 或 Bionate 55 等聚合物层中发现使来自第二层的治疗剂或细胞再生剂能够排出的微孔率程度。植入物的骨接合表面可涂覆和/或浸渍聚合物网格，该聚合物网格表面喷涂在或分层堆积在植入物的骨接合表面上以促进软骨组织再生。这种骨接合表面涂层可包含活软骨细胞（例如，在 Carticel 手术中由 Genzyme 公司提供的软骨细胞），并且/或者可包含具有定向基因突变的干细胞，以增强涂层到植入物的粘附。骨接合表面可包括峰和槽。活细胞可提供于槽中，而表面峰可用于以下至少一项：空间验证、牵引和细胞保护。

[0148] 在一些实施方式中，第一膨胀介质赋予植入物中的刚度。在一些实施方式中，第一膨胀介质赋予植入物中的缓冲。在一些实施方式中，为第一膨胀介质选择的膨胀介质和/或用这样的第一膨胀介质填充的腔室的特定选择（在具有多个腔室的实施方式中）使关节对齐。在一些实施方式中，为第一膨胀介质选择的膨胀介质和/或用这样的第一膨胀介质填充的腔室的特定选择（在具有多个腔室的实施方式中）使关节的骨对齐。在一些实施方式中，为第一膨胀介质选择的膨胀介质和/或用这样的第一膨胀介质填充的腔室的特定选择（在具有多个腔室的实施方式中）改变了骨对齐。在一些实施方式中，为第一膨胀介质选择的膨胀介质和/或用这样的第一膨胀介质填充的腔室的特定选择（在具有多个腔室的

实施方式中）改善了关节对齐。在一些实施方式中，为第一膨胀介质选择的膨胀介质和/或用这样的第一膨胀介质填充的腔室的特定选择（在具有多个腔室的实施方式中）至少部分地恢复关节对齐。在一些实施方式中，可以选择性地用第一膨胀介质和/或第二膨胀介质来膨胀内部的个别腔室。在一些实施方式中，用第一膨胀介质和/或第二膨胀介质选择性地膨胀内部的个别腔室，以便重建关节和/或重建关节的骨。

[0149] 随着时间的推移，修复组织的长入有助于植入物外部的固定和稳定性，而软的缓冲性植入物内部将会吸收跨关节表面的力，并允许适当的运动。植入物的膨胀或壁张力以及植入物本身的内部膨大可以通过向植入物的内部空间添加膨胀物质或移除膨胀物质来加以调整。

[0150] 因此，本发明提供了针对关节成形术的一种新方法，其涉及部署在关节的骨之间的弹性植入物装置。在某些实施方式中，植入物将需要适应所有正常的身体功能压力和复杂的空间移动。当在髋关节中时，可达120度的正常弯曲、20度的伸展、50度的外展、45度的向内和向外旋转将产生可变的轴向、剪切和循环负荷，设计的植入物将适应和承受高达6倍体重，就像汽车上的轮胎一样，当直线行驶或转弯时它要允许不同的循环负荷。体现本发明特征的植入物提供了更多的生理运动和关节内的减震，并且具有以下的组合特性：解剖结构设计对称性，伴随与相邻正常结构的充分附接连接的平衡的刚性，以及满足关节重建需求的耐久性。

[0151] 本发明的第一壁和第二壁的相对的内部表面可以同步地或在彼此相反的方向上一起移动（例如，上壁在髋部中内侧地移动，而下壁则外侧地移动）。可选地，所述植入物可以固定到关节的凹面（例如髋臼杯）或固定到关节的凸面（例如背侧股骨头表面），或者固定到全部两者，或者不固定到任何一个（例如，在关节内具有过盈配合，伴随填充了现有空间的扩张的球囊或缓冲垫）。植入物可像收缩的球囊那样在关节镜下通过套管插入踝或髋（或其他关节结构）并继而膨胀，以便充当用于无痛和稳定的肢体运动的缓冲垫或复原的界面。在可行的情况下，关节囊和相邻的韧带组织以及骨将留在原处以保持自然的身体组织，除非与重建的肢体的功能相干扰。

[0152] 蒸汽的应用除了移除受损的碎片之外，还能平滑和重新形成关节表面。蒸汽的高温易于融合可能存在于受损关节的软骨表面之中的裂缝或裂隙。用蒸汽对关节表面软骨的平滑融合或密封了软骨中的现有裂缝或皮瓣，特别是在薄层表面上，它们汇集在一起提供了一个白色有光泽的滑动关节面。在暴露出骨的情况下，可以使用蒸汽来经由囊缝合术或关节紧缩术而稳定关节表面中缺损的外周。机械还可以利用开放式机械和化学清创来准备针对植入物的表面。一些方法可包括手术前扫描定位，或者关节镜检查可能有助于组织、聚合物和其他内容物的部署。

[0153] 一旦植入物通过裙筒或翼片紧固到股骨头，则可以在植入物的膨胀或扩张完成之前采用浸渍的转移介质或细胞模板——如Histogenics和Tygenix软骨细胞运载系统所描述，其中浓缩的细胞的位置被机械地放置在植入物周围的最大软骨损伤区域处以便促进再生长；或者如在Carticel中所描述，其中含水的细胞被移植在骨膜薄膜下方（植入物的壁充当薄膜的）。使用具有经测量的旋拧-原位压强的注射器或者经校准的装置来膨胀植入物。

[0154] 一旦关节准备好接纳植入物，则使收缩的植入物前进穿过递送套管的隔膜（诸如

来自 Smith&Nephew 的 Acufex）或者穿过开放的切口部位而进入关节。它可以通过附接的套管，使用插入若干毫升填充材料的常用注射器而得以膨胀。注入的内容物和细胞放置的位置取决于所需的面积和关节的大小。在髋植入物中，在植入物的内部中的若干毫升的填充材料和粘润滑剂将允许膨大、缓冲和滑动移动。细胞再生剂被置于最需要的区域。

[0155] 活体干细胞或软骨细胞放置的方法取决于病变和具体的植入物结构。通过完成植入物的膨胀而直接注入到关节会将细胞压入透明质表面，它们在最初的 24 小时内附接于其上。因此，病人应该在术后第一天保持久坐不动，并保持部署了植入物的关节不负重。更深层的骨软骨缺损可以经由 3-D 细胞转移模板，或者经由如在针对血糖检测和胰岛素 / 经皮给药而对糖尿病人进行的治疗中所使用的微针注射，而通过“细胞超灌注”来加以治疗。对剥脱性骨软骨炎或局部的软骨和骨损失的情况，骨移植物可能被塞入缺损的基底，接着增加细胞和组织应用。附接到植入物的套管可以密封和卸下，或者留在原处用于定期吸引如 Cox-1、Cox-2 和 5-Lox 系统的有害酶，然后重新插入活性物质，包括粘润滑剂，甚至更多的细胞。

[0156] 体现本发明特征的植入物可设计用于永久地或临时地部署在关节结构内。此外，可以用合适的可生物吸收材料来形成该植入物，从而使植入物可在特定的预定时间范围内被吸收。合适的可生物吸收材料包括聚乳酸、聚羟基乙酸、聚己内酯，及其共聚物、共混物和变体。形成植入物的一种现有方法是涂敷诸如溶剂中的 ChronoFlex AR 之类的多个聚合物层，以及在涂敷每个层之后将溶剂蒸发。

[0157] 本植入物的裙筒或固定翼片在使用中防止关节移位。这与现有的易脱位和术后功能较差的固体聚合物植入物有截然不同。

[0158] 在一些实施方式中，植入物适于恢复天然关节功能。在一些实施方式中，植入物适于保持活体关节组织。在一些实施方式中，植入物适于通过与目前市场上的关节置换疗法相比最小的手术来放置。在一些实施方式中，植入物适于允许在手术后的以下天数中的至少一项内负重：约 1 周、约 1 天内、约 2 天内、约 3 天内、约 4 天内、约 5 天内、约 6 天内、约 10 天内、约 2 周内、约 3 周内、约 4 周内、约 5 周内、约 6 周内。在一些实施方式中，植入物适于在手术后约 1 天之后允许负重，其中在大约 6 周后允许完全负重。在一些实施方式中，此处关于负重时机所使用的术语“约”可以是 1 天、2 天或 3 天的范围。在一些实施方式中，植入物适于允许与目前市场上的关节置换疗法相比更快地恢复和重新开始正常活动。

[0159] 在一些实施方式中，球囊（或其一部分）适于符合患者的解剖结构。在一些实施方式中，植入物（或其一部分）适于符合患者的解剖结构。在一些实施方式中，膨胀介质适于吸收施加在关节上的力（或多个力）。在一些实施方式中，膨胀介质适于吸收施加在关节的骨上的力（或多个力）。在一些实施方式中，膨胀介质适于吸收施加在关节的至少一个骨上的力（或多个力）。在一些实施方式中，球囊适于吸收施加在骨、多个骨、关节韧带、多个关节韧带、关节肌腱，多个关节肌腱和总体关节中的至少一个上的冲击。在一些实施方式中，植入物适于用干细胞来恢复天然软骨缓冲。

[0160] 在一些实施方式中，球囊（或其一部分）适于复原关节空间。在一些实施方式中，球囊（或其一部分）适于与植入物植入前感受到的疼痛相比减轻疼痛。在一些实施方式中，球囊（或其一部分）适于恢复关节功能。在一些实施方式中，植入物（或其一部分）适于复原关节空间。在一些实施方式中，植入物（或其一部分）适于与植入物植入前感受到的

疼痛相比减轻疼痛。在一些实施方式中，植入物（或其一部分）适于恢复关节功能。

[0161] 在一些实施方式中，植入物适于在关节中逆转关节炎。

[0162] 在一些实施方式中，球囊（或其一部分）适于在关节镜下放置到经清创的肢体关节中。在一些实施方式中，球囊适于填补软骨缺损。在一些实施方式中，球囊被膨胀以缓冲关节。在一些实施方式中，植入物适于向关节和关节的骨之中的至少一个递送干细胞。在一些实施方式中，植入物适于向关节和关节的骨之中的至少一个递送活软骨细胞。在一些实施方式中，植入物适合于为关节提供新的关节面。在一些实施方式中，植入物适合于充当关节的垫片。在一些实施方式中，植入物适合于为了适当的关节接合而分隔开关节的骨。在一些实施方式中，植入物适合于为减少骨与骨间的摩擦而分隔开关节的骨。

[0163] 本文已经阐释和描述了本发明的具体形式，但是应当明白可以对本发明作出各种修改和改进。一种备选的植入物构造涉及使用植入物的上部，其具有网状结构并且填充有大于网格开口的球或球轴承样元件。球或球轴承样元件给植入物提供移动。网格和球轴承样元件可含有如前面所讨论的再生剂，且轴承结构可定向于有利的与内容物分配平衡的植入物运动。

[0164] 在一些实施方式中，植入物配置用于向骨或其他周围组织提供化疗剂。

[0165] 在一些实施方式中，植入物配置用于植入先前用常规全关节置换物（已移除）治疗的关节中。在一些实施方式中，植入物配置用于提供抗感染药物（作为非限制性实例，抗生素、抗真菌剂和/或镇痛剂），其在治疗受感染的关节的同时允许关节运动，然后进行修正手术植入如本文所述的植入物，或在感染被清除后修正全关节置换物。在一些实施方式中，该方法可以包括对关节的骨清创，植入本文所述的植入物，并且在一些实施方式中，重复清创和使用额外的植入物的植入步骤。在完成最终的癌症或感染治疗前，可以保证连续的系列清创和植入物的植入。

[0166] 本发明预期主要供人使用，但可能会扩展到供哺乳动物使用。在本文没有另外公开的情况下，材料和结构可以是常规设计。

[0167] 此外，本发明的实施方式的个别特征可能在一些附图中显示，而在其他附图中没有显示，但本领域技术人员应当认识到，本发明的一个实施方式的个别特征可以在另一实施方式中应用。此外，一个实施方式的个别特征可与另一实施方式的任何或所有的特征相结合。因此，并非旨在将本发明限于示出的具体实施方式。因此，如现有技术广泛允许的，本发明旨在由所附的权利要求的范围所限定。

[0168] 诸如“元件”、“构件”、“组件”、“器件”、“装置”、“部分”、“片段”、“步骤”等术语以及类似含义的词语，用在这里时不应援引 35U.S.C§112(6) 的条款来解释，除非接下来的权利要求明确地使用了术语“用于…的装置 (means for)”或“用于…的步骤 (step for)”，且后接特定功能但没有提及特定的结构或特定的行动。上文提到的所有专利和所有专利申请的全部内容通过引用并入本文。

[0169] 虽然本文已经展示和描述了本发明的优选实施方式，但对本领域中技术人员而言显然的是，这样的实施方式仅仅是以实例的方式提供的。本领域中技术人员现将在不背离本发明的情况下想到多种变化、改变和替换。应当理解，本文所述的本发明的实施方式的各种替代方案在发明的实践中也可得到采用。下面的权利要求旨在限定本发明的范围，这些权利要求的范围内的方法和结构以及它们的等同物从而也被覆盖。

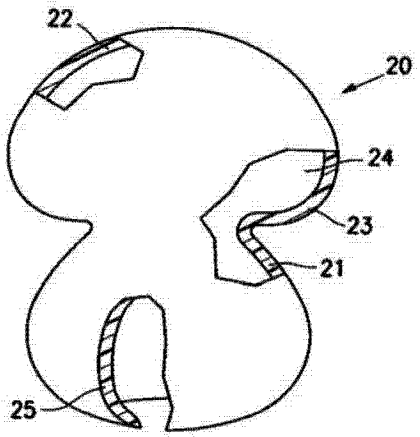

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图 1

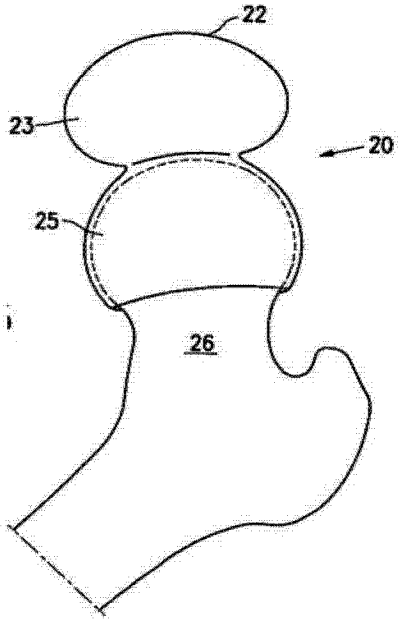
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图 2

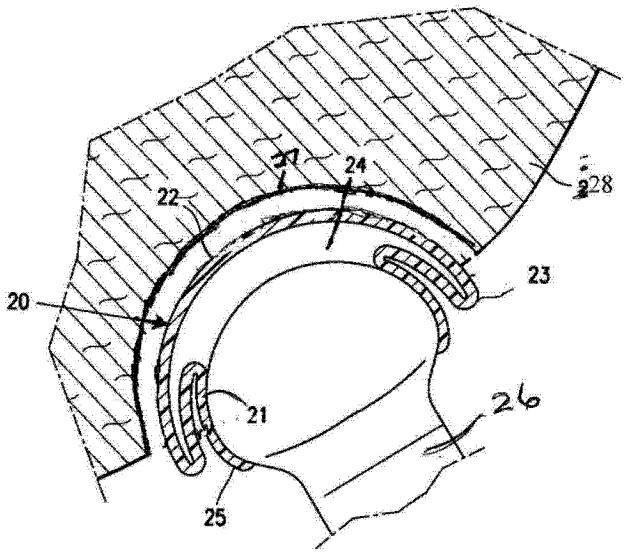
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图 3

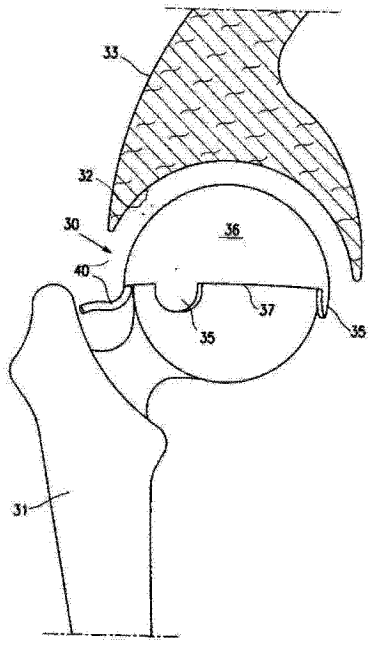
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图 4

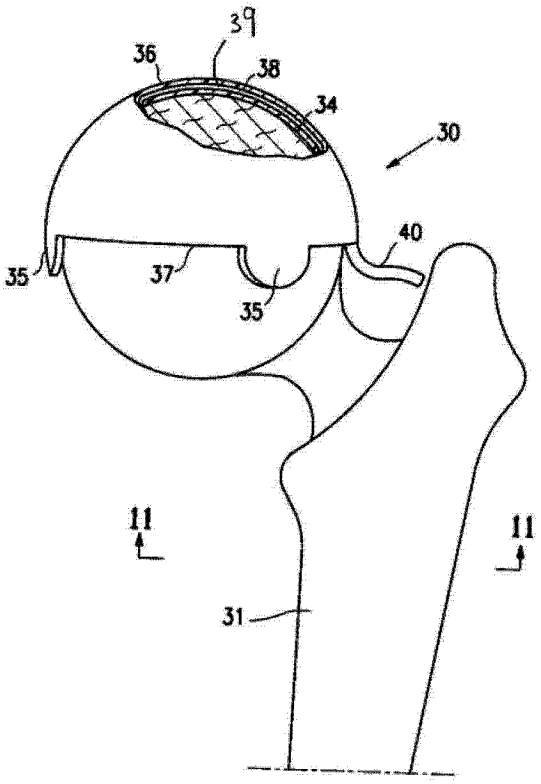
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图 5

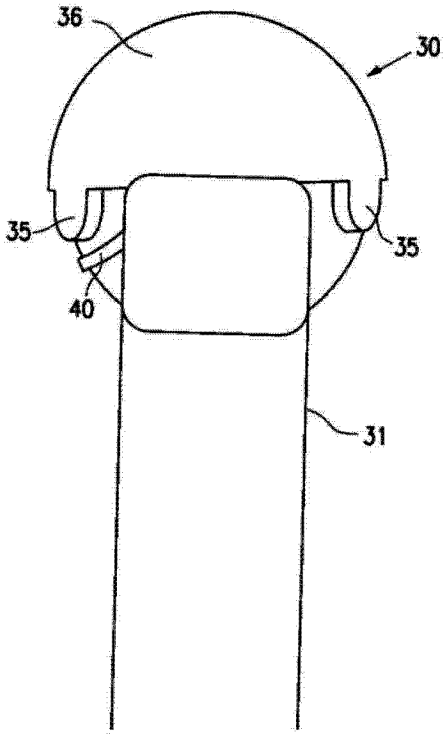
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图 6

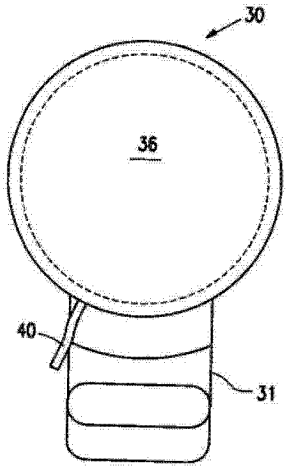
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图 7

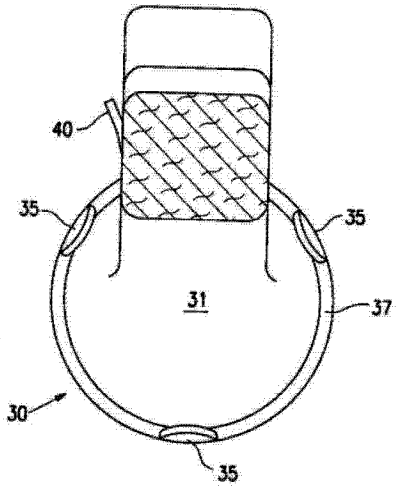
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图 8

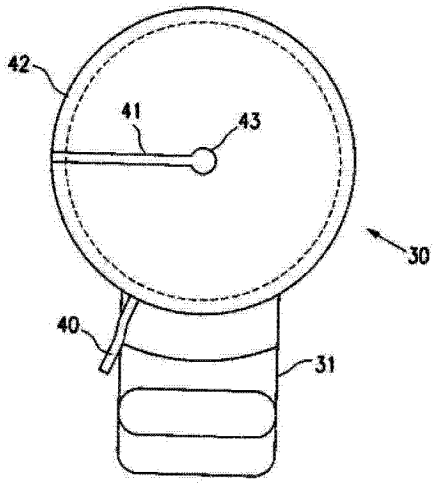
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图 9

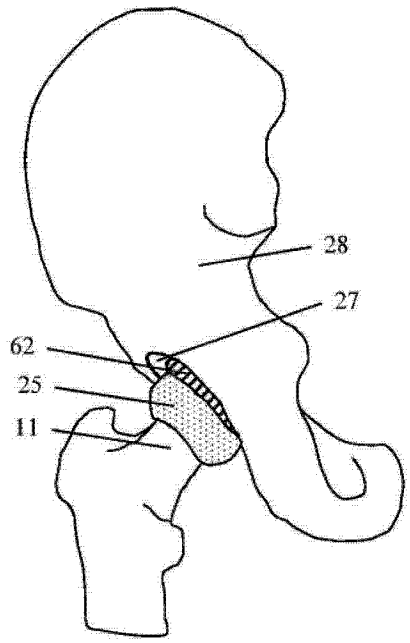

图 10A

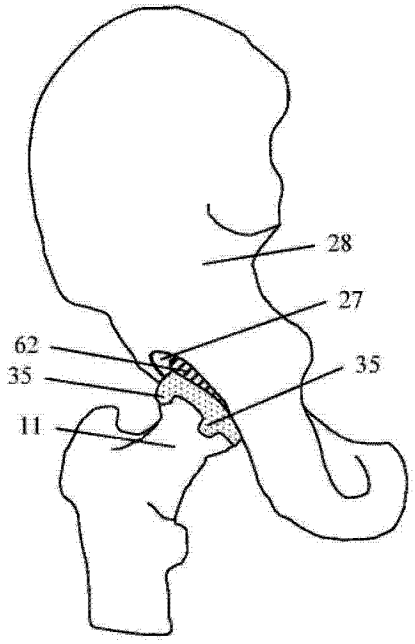

图 10B

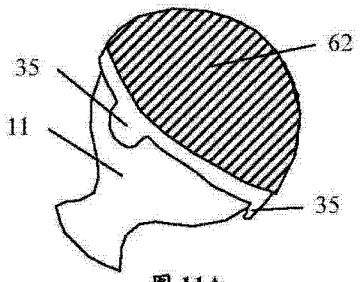

图 11A

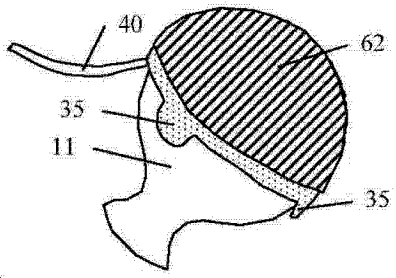

图 11B

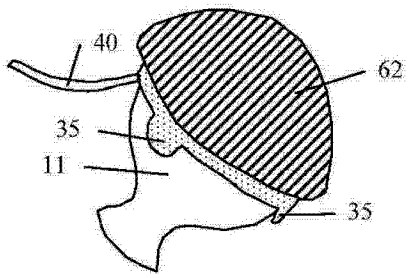

图 11C

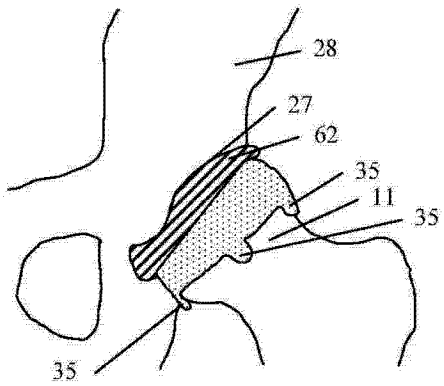

图 12

(19)中华人民共和国国家知识产权局

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(56)对比文件
US 2009/0076605 A1,2009.03.19,说明书第4-7段、38-42段及图1.
US 2009/0076605 A1,2009.03.19,说明书第4-7段、38-42段及图1.
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CN 101500512 A,2009.08.05,说明书第5页第13行至第9页第17行、第22页第21行至第24页第5行、第24页第8-18行.
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审查员 纪徐源

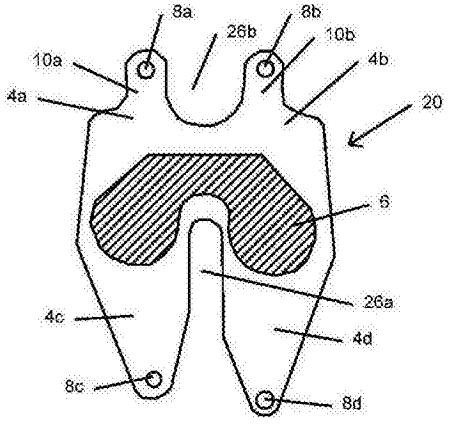
权利要求书6页 说明书40页 附图6页

(54)发明名称

弹性膝盖植入物及方法

(57)摘要

本公开涉及弹性间置式关节成形术植入物，其用于施用到膝关节内以填补软骨缺损、缓冲关节以及取代或恢复关节面，这样可以保持关节完整性，减轻疼痛和改善功能。该植入物可承受可变的关节压缩力和剪切力以及循环负荷。该植入物可修复、重建和再生关节解剖结构，并且从而改进了关节置换术备选方案。本发明的壁可以俘获、分配和保留活细胞直至发生聚集和透明软骨再生长，而不是在关节面再建中使用骨膜收获以实现细胞包封。该植入物可部署到已清创的关节间隙内，成型并且符合周围结构，具有足够的稳定性以避免挤出或脱位。该植入物的附件可修复或重建肌腱或韧带，并且植入物的可膨胀的内部可适应模拟或近似于正常关节活动的运动。



CN 102834073 B

1. 一种配置用于部署在膝关节的股骨与胫骨之间的植入物，该植入物包括：

球囊，包括：

第一部分，其配置用于接合膝关节的股骨的内侧髁和外侧髁，

第二部分，其配置用于接合膝关节的胫骨，

连接所述第一部分和所述第二部分的侧面部分，其中该侧面部分促进所述第一部分与所述第二部分之间的相对运动，以及

包括多个可膨胀的腔室的内部，所述多个可膨胀的腔室配置为可以选择性地膨胀和可以选择性地收缩；以及

第一附件，其配置用于将所述球囊联接至膝关节的股骨。

2. 根据权利要求 1 所述的植入物，包括至少一个位于髁间窝内的附接元件。

3. 根据权利要求 1 所述的植入物，包括至少一个位于股骨末端前部之上的附接元件。

4. 根据权利要求 1 所述的植入物，包括至少一根后部勒绳，配置用于将所述植入物从后髁间窝的内侧向股骨附近的连接位点捆紧。

5. 根据权利要求 1 所述的植入物，包括至少一根缝合线状系索，配置用于将所述植入物从后髁间窝的内侧向股骨附近的连接位点捆紧。

6. 根据权利要求 1 所述的植入物，其中所述第一部分包括第一壁，所述第二部分包括第二壁，并且所述侧面部分包括侧壁。

7. 根据权利要求 1 所述的植入物，还包括膨胀端口，该膨胀端口与所述球囊的所述内部连通，用于用第一膨胀介质来膨胀所述球囊的所述内部。

8. 根据权利要求 1 所述的植入物，其中所述多个可单独膨胀的腔室中的第一腔室适合用第一膨胀介质来膨胀，并且所述多个可单独 膨胀的腔室中的第二腔室适合用第二膨胀介质来膨胀。

9. 根据权利要求 8 所述的植入物，其中所述第一膨胀介质赋予了所述植入物内的刚度和所述植入物内的缓冲之中的至少一个。

10. 根据权利要求 1 的所述植入物，包括第二附件，该第二附件将所述球囊联接至关节的股骨和关节的胫骨之中的至少一个。

11. 根据权利要求 7 所述的植入物，其中所述第一膨胀介质是可压缩的。

12. 根据权利要求 7 所述的植入物，其中所述第一膨胀介质包含粘润滑剂。

13. 根据权利要求 7 所述的植入物，其中所述第一膨胀介质包含 NSAID。

14. 根据权利要求 7 所述的植入物，其中所述第一膨胀介质包含软骨细胞。

15. 根据权利要求 8 所述的植入物，其中所述第一和第二膨胀介质是可压缩的。

16. 根据权利要求 8 所述的植入物，其中所述第一和第二膨胀介质包含粘润滑剂。

17. 根据权利要求 8 所述的植入物，其中所述第一和第二膨胀介质包含 NSAID。

18. 根据权利要求 8 所述的植入物，其中所述第一和第二膨胀介质包含软骨细胞。

19. 一种配置用于部署在膝关节的股骨与胫骨之间的植入物，该植入物包括：

球囊，包括：

第一部分，其配置用于接合膝关节的股骨的至少一个髁，

第二部分，其配置用于接合膝关节的胫骨，

连接所述第一部分和所述第二部分的侧面部分，其中该侧面部分促进所述第一部分与

所述第二部分之间的相对运动，以及

包括多个腔室的内部，所述多个腔室配置为可以选择性地 膨胀和可以选择性地收缩；以及

第一附件，其配置用于将所述球囊联接至膝关节的股骨。

20. 根据权利要求 19 所述的植入物，其中所述至少一个髁是内侧髁。

21. 根据权利要求 19 所述的植入物，其中所述至少一个髁是外侧髁。

22. 根据权利要求 19 所述的植入物，其中所述球囊是以下至少一项：直径至多 1.5cm，直径至多 1.75cm，直径至多 2cm，直径至多 2.25cm，至今至多 2.5cm，直径至多 2.75cm，直径至多 3cm，直径至多 3.25cm，直径至多 3.5cm，直径至多 3.75cm，直径至多 4cm，直径至多 4.25cm，直径至多 4.5cm，直径至多 4.75cm，直径至多 5cm，直径至多 5.25cm，直径至多 5.5cm，直径至多 5.75cm，直径至多 6cm，直径至多 6.25cm，直径至多 6.5cm，直径至多 6.75cm，直径至多 7cm，直径至多 7.25cm，直径至多 7.5cm，直径至多 7.75cm，直径至多 8cm，沿所述球囊最长长度至多 3cm 长度，沿所述球囊最长长度至多 3.25cm 长度，沿所述球囊最长长度至多 3.5cm 长度，沿所述球囊最长长度至多 3.75cm 长度，沿所述球囊最长长度至多 4cm 长度，沿所述球囊最长长度至多 4.25cm 长度，沿所述球囊最长长度至多 4.5cm 长度，沿所述球囊最长长度至多 4.75cm 长度，沿所述球囊最长长度至多 5cm 长度，沿所述球囊最长长度至多 5.25cm 长度，沿所述球囊最长长度至多 5.5cm 长度，沿所述球囊最长长度至多 5.75cm 长度，沿所述球囊最长长度至多 6cm 长度，沿所述球囊最长长度至多 6.25cm 长度，沿所述球囊最长长度至多 6.5cm 长度，沿所述球囊最长长度至多 6.75cm 长度，沿所述球囊最长长度至多 7cm 长度，沿所述球囊最长长度至多 7.25cm 长度，沿所述球囊最长长度至多 7.5cm 长度，沿所述球囊最长长度至多 7.75cm 长度以及沿所述球囊最长长度至多 8cm 长度。

23. 根据权利要求 19 所述的植入物，其中所述第一部分包括第一壁，所述第二部分包括第二壁，并且所述侧面部分包括侧壁。

24. 根据权利要求 19 所述的植入物，还包括膨胀端口，该膨胀端口与所述球囊的所述内部连通，用于用第一膨胀介质来膨胀所述球囊的所述内部。

25. 根据权利要求 19 所述的植入物，其中所述多个可单独膨胀的腔室中的第一腔室适合用第一膨胀介质来膨胀，并且所述多个可单独膨胀的腔室中的第二腔室适合用第二膨胀介质来膨胀。

26. 根据权利要求 25 所述的植入物，其中所述第一膨胀介质赋予了所述植入物内的刚度和所述植入物内的缓冲之中的至少一个。

27. 根据权利要求 19 所述的植入物，包括第二附件，该第二附件将所述球囊联接至关节的股骨和关节的胫骨之中的至少一个。

28. 根据权利要求 19 所述的植入物，包括至少一个位于髁间窝内的附接元件。

29. 根据权利要求 19 所述的植入物，包括至少一个位于股骨末端前部之上的附接元件。

30. 根据权利要求 19 所述的植入物，包括至少一根后部勒绳，配置用于将所述植入物从后髁间窝的内侧向股骨附近的连接位点捆紧。

31. 根据权利要求 19 所述的植入物，包括至少一根缝合线状系索，配置用于将所述植入物从后髁间窝的内侧向股骨附近的连接位点捆紧。

32. 根据权利要求 24 所述的植入物，其中所述第一膨胀介质是可压缩的。

33. 根据权利要求 24 所述的植入物，其中所述第一膨胀介质包含粘润滑剂。

34. 根据权利要求 24 所述的植入物，其中所述第一膨胀介质包含 NSAID。

35. 根据权利要求 24 所述的植入物，其中所述第一膨胀介质包含软骨细胞。

36. 根据权利要求 25 所述的植入物，其中所述第一和第二膨胀介质是可压缩的。

37. 根据权利要求 25 所述的植入物，其中所述第一和第二膨胀介质包含粘润滑剂。

38. 根据权利要求 25 所述的植入物，其中所述第一和第二膨胀介质包含 NSAID。

39. 根据权利要求 25 所述的植入物，其中所述第一和第二膨胀介质包含软骨细胞。

40. 一种配置用于部署在膝关节的股骨与髌骨之间的植入物，该植入物包括 ：

球囊，包括 ：

第一部分，其配置用于接合膝关节的股骨的滑车沟，

第二部分，其配置用于接合膝关节的髌骨，

连接所述第一部分和所述第二部分的侧面部分，其中该侧面部分促进所述第一部分与所述第二部分之间的相对运动，以及

包括多个腔室的内部，所述多个腔室配置为可以选择性地膨胀和可以选择性地收缩 ；以及

第一附件，其配置用于将所述球囊联接至膝关节的股骨。

41. 根据权利要 1、19 和 40 中任一项所述的植入物，包括将所述附件与股骨相联接的联接器。

42. 根据权利要求 41 所述的植入物，其中所述联接器是可生物吸收的。

43. 根据权利要求 41 所述的植入物，其中所述联接器是以下至少一种 ：螺钉、衬垫、缝合锚、铆钉、U 形钉、胶合剂、挂勾、线绳、销钉以及它们的组合。

44. 根据权利要求 43 所述的植入物，其中所述 U 形钉是带齿的 U 形钉。

45. 根据权利要求 43 所述的植入物，其中所述线绳是缆线、套索或系索。

46. 一种配置用于部署在膝关节胫骨与髌骨之间的植入物，该植入物包括

球囊，包括 ：

第一部分，其配置用于接合在膝关节的胫骨，

第二部分，其配置用于接合膝关节的髌骨，

连接所述第一部分和所述第二部分的侧面部分，其中该侧面部分促进所述第一部分与所述第二部分之间的相对运动，以及

包括多个腔室的内部，所述多个腔室配置为可以选择性地膨胀和可以选择性地收缩 ；以及

第一附件，其配置用于将所述球囊联接至膝关节的胫骨。

47. 根据权利要求 1、19、40 和 46 中任一项所述的植入物，包括位于邻近股骨的所述植入物的至少一部分上的长入基质。

48. 根据权利要求 47 所述的植入物，其中所述长入基质包括活软骨细胞。

49. 根据权利要求 48 所述的植入物，其中所述植入物配置用于随着时间的推移而释放所述软骨细胞。

50. 根据权利要求 48 所述的植入物，其中所述植入物包括可生物吸收聚合物，所述可

生物吸收聚合物配置用于随着时间的推移而释放所述软骨细胞。

51. 根据权利要求 48 所述的植入物，其中所述植入物包括聚合物，所述聚合物配置用于随着时间的推移而释放所述软骨细胞，其中所述聚合物是不可生物吸收的。

52. 根据权利要求 47 所述的植入物，其中所述长入基质包括自体细胞、同种异体移植细胞和异种移植细胞之中的至少一种，用以恢复股骨的关节面。

53. 根据权利要求 47 所述的植入物，其中所述长入基质包括自体细胞、同种异体移植细胞和异种移植细胞之中的至少一种，用以修复股骨的关节面。

54. 根据权利要求 46 所述的植入物，包括将所述附件与胫骨相联接的联接器。

55. 根据权利要求 54 所述的植入物，其中所述联接器是可生物吸 收的。

56. 根据权利要求 54 所述的植入物，其中所述联接器是以下至少一种 ：螺钉、衬垫、缝合锚、铆钉、U 形钉、胶合剂、挂勾、线绳、销钉以及它们的组合。

57. 根据权利要求 56 所述的植入物，其中所述 U 形钉是带齿的 U 形钉。

58. 根据权利要求 56 所述的植入物，其中所述线绳是缆线、套索或系索。

59. 根据权利要求 1、19、40 和 46 中任一项所述的植入物，其包含药剂。

60. 根据权利要求 59 所述的植入物，其中所述药剂位于邻近股骨的所述植入物的表面上。

61. 根据权利要求 59 所述的植入物，其中所述药剂随着时间的推移而从所述植入物释放。

62. 根据权利要求 59 所述的植入物，其中所述药剂随着时间的推移而从所述植入物内释放。

63. 根据权利要求 59 所述的植入物，其中所述药剂随着时间的推移而从所述球囊内释放。

64. 根据权利要求 1、19、40 和 46 中任一项所述的植入物，其中所述植入物的至少一部分配置成与软骨缺损的外围炼合。

65. 根据权利要求 1、19、40 和 46 中任一项所述的植入物，其中液泡状物位于所述植入物的骨接合部分上，该液泡状物含有药理性物质或活性剂。

66. 根据权利要求 1、19、40 和 46 中任一项所述的植入物，其中所述植入物包括圆泡状物，所述圆泡状物包含活性物质。

67. 根据权利要求 66 所述的植入物，其中所述活性物质是药理性物质。

68. 根据权利要求 65 所述的植入物，其中所述活性剂包括以下至少一种 ：干细胞、生长因子、抗生素和粘润滑剂。

69. 根据权利要求 65 所述的植入物，其中所述活性剂包括医源性基因突变细胞。

70. 根据权利要求 1、19、40 和 46 中任一项所述的植入物，其中所述植入物包括酶吸收性微小海绵，所述海绵可在植入物被递送至关节时或在此时间左右被吸出或排除。

71. 根据权利要求 1、19、40 和 46 中任一项所述的植入物，其中所述植入物包括用活性物质填充的空间。

72. 根据权利要求 71 所述的植入物，其中所述活性物质是药理性物质。

73. 根据权利要求 1、19、40 和 46 中任一项所述的植入物，其中所述植入物配置成通过植入物材料的溶解来递送。

74. 根据权利要求 1、19、40 和 46 中任一项所述的植入物，其中所述植入物配置成通过经所述植入物的孔隙的释放来递送。

75. 根据权利要求 1、19、40 和 46 中任一项所述的植入物，其中所述植入物配置成通过由破裂性促进因素所导致的液泡状物破裂来递送。

76. 根据权利要求 75 所述的植入物，其中所述破裂性促进因素是超声波或压力。

77. 根据权利要求 1、19、40 和 46 中任一项所述的植入物，其中该植入物配置用于以下至少一项：填补软骨、缓冲关节、递送药理性物质、植入后清创、递送治疗性物质以及递送生物物质。

78. 根据权利要求 77 所述的植入物，其中所述植入后清创包括清除有毒的酶和植入后给关节清创。

79. 根据权利要求 77 所述的植入物，其中所述递送生物物质包括递送活的干细胞。

80. 根据权利要求 1、19、40 和 46 中任一项所述的植入物，其中所述植入物配置用于向骨或其他周围组织递送化疗剂。

81. 根据权利要求 1、19、40 和 46 中任一项所述的植入物，其中所述植入物配置用于向骨或其他周围组织递送抗感染药物。

82. 根据权利要求 1、19、40 和 46 中任一项所述的植入物，其中所述植入物配置用于递送抗生素、抗真菌剂和镇痛剂之中的至少一种。

83. 根据权利要求 1、19、40 和 46 中任一项所述的植入物，其中所述植入物配置用于选择性地膨胀以重新对齐肢体。

84. 一种配置用于部署在膝关节的股骨与胫骨之间的植入物，该植入物包括：

球囊，包括：

第一部分，其配置用于接合膝关节的股骨的至少一个髁，

第二部分，其配置用于接合膝关节的胫骨，

连接所述第一部分和所述第二部分的侧面部分，其中该侧面部分促进所述第一部分与所述第二部分之间的相对运动，以及

包括多个可膨胀的腔室的内部，所述多个腔室配置为可选择性地膨胀和可选择性地收缩；以及

第一附件，其配置用于将所述球囊联接至膝关节的股骨；

其中所述球囊具有内部，并且其中该内部包括蜂窝状结构。

85. 根据权利要求 84 所述的植入物，其中液泡状物位于所述植入物的骨接合部分上，该液泡状物含有药理性物质或活性剂。

86. 根据权利要求 85 所述的植入物，其中所述活性剂包括以下至少一种：干细胞、生长因子、抗生素和粘润滑剂。

87. 一种配置用于部署在膝关节的股骨与胫骨之间的植入物，该植入物包括：

球囊，包括：

第一部分，其配置用于接合膝关节的股骨的至少一个髁，

第二部分，其配置用于接合膝关节的胫骨，

连接所述第一部分和所述第二部分的侧面部分，其中该侧面部分促进所述第一部分与所述第二部分之间的相对运动，以及

包括多个可膨胀的腔室的内部，所述多个腔室配置为可选择性地膨胀和可选择性地收缩；以及

第一附件，其配置用于将所述球囊联接至膝关节的股骨；

其中所述植入物包括聚合物。

88. 根据权利要求 87 所述的植入物，其中所述聚合物是聚碳酸酯氨基甲酸乙酯。

弹性膝盖植入物及方法

[0001] 交叉引用

[0002] 本申请要求于 2010 年 1 月 22 号提交的美国临时申请号 61/297,698 的权益，该申请通过引用整体并入本文。

背景技术

[0003] 本发明涉及关节成形术，更具体地，涉及当透明关节软骨受损、其损坏以及关节间隙丧失时在关节成形术中使用的植入物。诸如来自 Cox-1、Cox-2 和 / 或 5-Lox 系统的炎性酶被释放出来，并且松散体形式加重了关节功能的退化。常规上通过物理疗法、镇痛药、止痛药和注射剂来治疗此类关节损伤。当这些治疗失败时，传统上认可的治疗选择是关节成形术植入或用人工关节结构来置换关节。目前的关节成形术技术通常使用刚性的“塑料和金属”植入物，并且其最终由于松动和感染而失效。用于人工关节组件的常规材料包括铬 - 钴 - 钼合金(金属)和高分子量聚乙烯(塑料)。每种材料通常通过甲基丙烯酸甲酯的水泥状混合物固定到限定作为关节成形术对象的关节的骨的末端，或者涂覆有支持骨长入的表面。众所周知，置换手术会在数年内失效。

[0004] 需要关节成形术的状况包括创伤性关节炎、骨关节炎、类风湿性关节炎、骨坏死和失败的外科手术。

发明内容

[0005] 本发明涉及配置用于部署在关节结构的相对的构件之间的矫形外科植入物，其解决了现有人工关节的许多不足之处。体现本发明特征的关节成形术植入物配置用于在消除与关节炎或关节损伤的发展相伴的疼痛和功能障碍的同时保留关节活动。根据本发明的关节成形术植入物实现了在步行中改善的生理运动和减震，并且在肢体运动中充当移动的骨之间的弹性垫片。植入物的组合特性包括迄今为止现有技术所缺失的解剖设计对称性、具有与至少一个相邻正常结构的可变附着连接的平衡的刚性、以及解决和满足修复或重建需求的耐久性。植入物应当紧固到关节结构的至少一块骨上。

[0006] 在此提供了一种配置用于部署在膝关节的股骨和胫骨之间的植入物，该植入物包括球囊和配置用于将球囊联接至膝关节股骨的第一附件，所述球囊包括 ：第一部分，其配置用于接合膝关节股骨的内侧髁和外侧髁 ；第二部分，其配置用于接合膝关节的胫骨 ；连接第一部分和第二部分的侧面部分，其中该侧面部分促进第一部分与第二部分之间的相对运动 ；以及可选地可用第一膨胀介质来膨胀的内部。

[0007] 在一些实施方式中，该植入物包括至少一个处于髁间窝中的附接元件。在一些实施方式中，该植入物包括至少一个处于股骨远端前上部的附接元件。在一些实施方式中，该植入物包括至少一根后部勒绳，配置用于将植入物从后踝间窝的内部向股骨周围的连接部位捆紧。在一些实施方式中，该植入物包括至少一根缝线状系索，配置用于将植入物从后踝间窝的内部向股骨周围的连接部位捆紧。

[0008] 在一些实施方式中，第一部分包括第一壁，第二部分包括第二壁，并且侧面部分包

括侧壁。

[0009] 在一些实施方式中，植入物包括与球囊的内部相连通的膨胀端口，用于以第一膨胀介质来使该球囊内部膨胀。在一些实施方式中，该内部包括多个可膨胀腔室。在一些实施方式中，多个单独的可膨胀腔室中的第一腔室适合用第一膨胀介质来膨胀，并且多个单独的可膨胀腔室中的第二腔室适合用第二膨胀介质来膨胀。在一些实施方式中，第一膨胀介质赋予了植入物内的刚度和植入物内的缓冲之中的至少一项。

[0010] 在一些实施方式中，该植入物包括第二附件，该第二附件将球囊联接至关节股骨和关节胫骨中的至少一个。

[0011] 在此提供了一种配置用于部署在膝关节的股骨和胫骨之间的植入物，该植入物包括球囊和配置用于将球囊联接至膝关节股骨的第一附件，所述球囊包括：第一部分，其配置用于接合膝关节股骨的至少一个髁；第二部分，其配置用于接合膝关节的胫骨；连接第一部分和第二部分的侧面部分，其中该侧面部分促进了第一部分与第二部分之间的相对运动；以及可选地可用第一膨胀介质来膨胀的内部。

[0012] 在一些实施方式中，所述至少一个髁是内侧髁。在一些实施方式中，所述至少一个髁是外侧髁。

[0013] 在一些实施方式中，球囊是以下至少一项：直径至多约 1.5cm，直径至多约 1.75cm，直径至多约 2cm，直径至多约 2.25cm，直径至多约 2.5cm，直径至多约 2.75cm，直径至多约 3cm，直径至多约 3.25cm，直径至多约 3.5cm，直径至多约 3.75cm，直径至多约 4cm，直径至多约 4.25cm，直径至多约 4.5cm，直径至多约 4.75cm，直径至多约 5cm，直径至多约 5.25cm，直径至多约 5.5cm，直径至多约 5.75cm，直径至多约 6cm，直径至多约 6.25cm，直径至多约 6.5cm，直径至多约 6.75cm，直径至多约 7cm，直径至多约 7.25cm，直径至多约 7.5cm，直径至多约 7.75cm，直径至多约 8cm，沿球囊最长长度至多约 3cm 长度，沿球囊最长长度至多约 3.25cm 长度，沿球囊最长长度至多约 3.5cm 长度，沿球囊最长长度至多约 3.75cm 长度，沿球囊最长长度至多约 4cm 长度，沿球囊最长长度至多约 4.25cm 长度，沿球囊最长长度至多约 4.5cm 长度，沿球囊最长长度至多约 4.75cm 长度，沿球囊最长长度至多约 5cm 长度，沿球囊最长长度至多约 5.25cm 长度，沿球囊最长长度至多约 5.5cm 长度，沿球囊最长长度至多约 5.75cm 长度，沿球囊最长长度至多约 6cm 长度，沿球囊最长长度至多约 6.25cm 长度，沿球囊最长长度至多约 6.5cm 长度，沿球囊最长长度至多约 6.75cm 长度，沿球囊最长长度至多约 7cm 长度，沿球囊最长长度至多约 7.25cm 长度，沿球囊最长长度至多约 7.5cm 长度，沿球囊最长长度至多约 7.75cm 长度，以及沿球囊最长长度至多约 8cm 长度。

[0014] 在一些实施方式中，第一部分包括第一壁，第二部分包括第二壁，并且侧面部分包括侧壁。

[0015] 在一些实施方式中，植入物包括与球囊的内部相连通的膨胀端口，用于以第一膨胀介质来使球囊内部膨胀。在一些实施方式中，该内部包括多个可膨胀的腔室。在一些实施方式中，多个可单独膨胀的腔室中的第一腔室适合用第一膨胀介质来膨胀，并且多个可单独膨胀的腔室中的第二腔室适合用第二膨胀介质来膨胀。在一些实施方式中，第一膨胀介质赋予了植入物内的刚度和植入物内的缓冲之中的至少一项。

[0016] 在一些实施方式中，植入物包括第二附件，该第二附件将球囊联接至关节的股骨和关节的胫骨中的至少一个。在一些实施方式中，植入物包括至少一个位于髁间窝内的附

接元件。在一些实施方式中，该植入物包括至少一个附接元件，该附接元件处于股骨远端前部之上。在一些实施方式中，植入物包括至少一根后部勒绳，配置用于将植入物从后髁间窝的内部向股骨附近的连接部位捆紧。在一些实施方式中，植入物包括至少一根缝线状系索，配置用于将植入物从后髁间窝的内部向股骨附近的连接部位捆紧。

[0017] 在此提供了一种配置用于修补膝关节骨缺损的植入物，该植入物包括球囊和配置用于将球囊联接至膝关节骨的第一附件，该球囊配置用于接合膝关节骨的缺损并且包括可选地可用第一膨胀介质来膨胀的内部。

[0018] 在一些实施方式中，附件和球囊中的至少一个被配置用于置换软骨。

[0019] 在一些实施方式中，球囊是以下至少一项：直径至多约 0.5cm，直径至多约 0.75cm，直径至多约 1cm，直径至多约 1.25cm，直径至多约 1.5cm，直径至多约 1.75cm，直径至多约 2cm，直径至多约 2.25cm，直径至多约 2.5cm，直径至多约 2.75cm，直径至多约 3cm，直径至多约 3.25cm，直径至多约 3.5cm，直径至多约 3.75cm，沿球囊最长长度至多约 0.5cm 长度，沿球囊最长长度至多约 0.75cm 长度，沿球囊最长长度至多约 1cm 长度，沿球囊最长长度至多约 1.25cm 长度，沿球囊最长长度至多约 1.5cm 长度，沿球囊最长长度至多约 1.75cm 长度，沿球囊最长长度至多约 2cm 长度，沿球囊最长长度至多约 2.25cm 长度，沿球囊最长长度至多约 2.5cm 长度，沿球囊最长长度至多约 2.75cm 长度，沿球囊最长长度至多约 3cm 长度，沿球囊最长长度至多约 3.25cm 长度，沿球囊最长长度至多约 3.5cm 长度，沿球囊最长长度至多约 3.75cm 长度，以及沿球囊最长长度至多约 4cm 长度。

[0020] 在一些实施方式中，球囊尺寸的大小是预设的。在一些实施方式中，球囊包括可以选择性地膨胀的多个腔室。在一些实施方式中，球囊包括可以选择性地收缩的多个腔室。在一些实施方式中，球囊包括可以选择性地原位膨胀以填充缺损的多个腔室。在一些实施方式中，球囊包括可以在即将植入之前选择性地膨胀的多个腔室。

[0021] 在一些实施方式中，球囊或其腔室可原位进行二次膨胀、收缩或它们的组合。

[0022] 在一些实施方式中，植入物包括位于邻近股骨的植入物的至少一部分之上的长入基质。在一些实施方式中，该长入基质包含活软骨细胞。在一些实施方式中，植入物配置成随着时间的推移而释放软骨细胞。在一些实施方式中，植入物包括配置成随着时间的推移而释放软骨细胞的可生物吸收聚合物。在一些实施方式，植入物包括配置成随着时间的推移而释放软骨细胞的聚合物，其中该聚合物是不可生物吸收的。在一些实施方式中，该长入基质包括自体细胞、同种异体移植细胞和异种移植细胞中的至少一种，用以恢复股骨的关节面。在一些实施方式中，该长入基质包括自体细胞、同种异体移植细胞和异种移植细胞中的至少一种，用以修复股骨的关节面。

[0023] 在一些实施方式中，植入物包括将附件联接至股骨的联接器。在一些实施方式中，该联接器是可生物吸收的。在一些实施方式中，该联接器是以下至少一种：螺钉、衬垫、缝合线、缝合锚、铆钉、U 形钉、带齿的 U 形钉、稳定器、胶合剂、挂勾、缆线、线绳、套索、系索、销钉以及它们的组合。植入物还可以和 / 或备选地经由骨长入而附接。

[0024] 在一些实施方式中，植入物包括药剂。在一些实施方式中，该药剂位于邻近股骨的植入物的表面上。在一些实施方式中，该药剂随着时间的推移而从植入物释放。在一些实施方式中，该药剂随着时间的推移而从植入物内释放。在一些实施方式中，该药剂随着时间的推移而从球囊内释放。

[0025] 在一些实施方式中，膨胀介质是可压缩的。在一些实施方式中，膨胀介质包含粘润滑剂。在一些实施方式中，膨胀介质包含 NSAID。在一些实施方式中，膨胀介质包含软骨细胞。

[0026] 在一些实施方式中，植入物的至少一部分配置成与软骨缺损的外围炼合。

[0027] 在一些实施方式中，植入物包括药理性物质的液泡状物。在一些实施方式中，液泡状物可位于植入物的骨接合部分之上。在一些实施方式中，植入物包括含有诸如药理性物质或其他活性剂等活性物质的圆泡状物。在一些实施方式中，活性剂包括以下至少一种：干细胞、生长因子、抗生素和粘润滑剂。在一些实施方式中，活性剂包括医源性基因突变细胞。

[0028] 在一些实施方式中，植入物包括酶吸收性微小海绵，所述微小海绵可在植入物被递送至关节时或在此时间左右被吸出或排除。

[0029] 在一些实施方式中，植入物包括填充有诸如药理性物质或其他活性物质等活性物质的空间。在一些实施方式中，植入物配置成通过植入物材料的溶解来递送。在一些实施方式中，植入物配置成通过经植入物孔隙的释放来递送。在一些实施方式中，植入物配置成通过由诸如超声波或压力等促进因素或者其他破裂性促进因素导致的液泡状物破裂来递送。

[0030] 在一些实施方式中，植入物配置用于以下至少一项：填补软骨、缓冲关节、递送药理性物质、清除有毒的酶、植入后清创、植入后给关节清创、递送治疗性物质、递送生物物质以及递送活干细胞。在一些实施方式中，植入物配置用于向骨或其他周围组织递送化疗剂。在一些实施方式中，植入物配置用于向骨或其他周围组织递送抗感染药物。在一些实施方式中，植入物配置用于递送抗生素、抗真菌剂和镇痛剂中的至少一种。

[0031] 在一个实施方式中，植入物配置成选择性地膨胀以重新对齐肢体。

[0032] 在此提供一种方法，包括：将在此所述的膝盖植入物植入个体内，其中该植入物逆转个体内的关节炎。

[0033] 在此提供一种方法，包括：将在此所述的膝盖植入物植入个体的膝关节并且使用同种异体移植组织、自体移植组织和异种移植组织中的至少一种来治疗个体膝关节的组件。在一些实施方式中，植入步骤为以下所列之中的至少一项：在治疗步骤之前，与治疗步骤同时，以及在治疗步骤之后。

[0034] 在此提供一种方法，包括：将在此所述的膝盖植入物植入个体内，其中该植入物起到以下作用中的至少一个：恢复关节功能和控制关节病。在一些实施方式中，该植入保存现有解剖结构。

[0035] 在此提供一种方法，包括：给个体膝关节的股骨髁清创，以及将在此所述的膝盖植入物植入到个体膝关节内，从而使植入物配置成与个体的软骨炼合。在一些实施方式中，清创是通过蒸汽施用来完成的。

[0036] 在此提供一种方法，包括将在此所述的膝盖植入物植入先前用关节置换物治疗过的关节内。在一些实施方式中，该方法包括在植入膝盖植入物之前移除关节置换物。在一些实施方式中，该方法包括从关节和 / 或周围组织清除感染性物质。在一些实施方式中，该方法包括在移除先前植入关节中的植入物之后植入在此所述的任何植入物的第二植入物。在一些实施方式中，该方法包括在移除先前植入关节中的植入物之后置换个体的关节。在一些实施方式中，该方法包括对关节的骨进行清创，以及植入在此所述的任何植入物的植入物。在一些实施方式中，该方法包括重复清创和植入步骤。

[0037] 通过以下详细描述和示范性附图，本发明的这些优点以及其他优点将变得更加明显。

[0038] 援引并入

[0039] 本说明书中所述的所有出版物、专利和专利申请均通过引用而以相同程度并入本文，犹如每个单独的出版物、专利或专利申请特别地和单独地被指出为通过引用而并入。

附图说明

[0040] 本发明的新颖特征在随附的权利要求中具体阐述。通过参考以下对在其中利用到本发明原理的示例说明性实施方式加以阐述的详细描述和附图，可以获得对本发明的特征和优点更好的理解，在附图中：

[0041] 图 1 描绘了膝盖植入物的实施方式，其具有从球囊延伸的包括孔洞和翼片的附件，并且包括用以适应膝关节韧带的狭槽。

[0042] 图 2 描绘了膝盖植入物的实施方式以及同一膝盖植入物的侧视图，该膝盖植入物具有从球囊延伸的包括孔洞和翼片的附件，并且包括用以适应膝关节韧带的狭槽。

[0043] 图 3 描绘了膝盖植入物的实施方式以及同一膝盖植入物的侧视图，该膝盖植入物具有从球囊延伸的包括孔洞和翼片的附件，并且包括用以适应膝关节韧带的狭槽。

[0044] 图 4A 描绘了膝盖植入物的实施方式，其具有从球囊延伸的包括十个翼片的附件，并且包括用以适应膝关节韧带的狭槽。

[0045] 图 4B 描述了膝盖植入物的实施方式，其具有从球囊延伸的包括八个翼片的附件，并且包括用以适应膝关节韧带的狭槽。

[0046] 图 5 描绘了弯曲成模拟股骨髁周围曲率的膝盖植入物的实施方式，该植入物具有从未膨胀的球囊（未示出）延伸的附件并且包括用以适应膝关节韧带的狭槽。

[0047] 图 6A 描绘了弯曲成模拟股骨髁周围曲率的膝盖植入物的实施方式的俯视图，该植入物具有从两个已膨胀球囊延伸的附件并且包括用以适应膝关节组件的狭槽。

[0048] 图 6B 描绘了弯曲成模拟股骨髁周围曲率的膝盖植入物的实施方式的仰视图，该植入物具有从两个已膨胀球囊延伸的附件并且包括用以适应膝关节组件的狭槽。

[0049] 图 7 描绘了弯曲成模拟股骨髁周围曲率的膝盖植入物的实施方式的俯视图，该植入物具有从已膨胀球囊延伸的附件并且包括用以适应膝关节组件的狭槽。

[0050] 图 8 描绘了弯曲成模拟至少一个股骨髁周围曲率的膝盖植入物的实施方式的侧视图，该植入物具有从未膨胀球囊（未示出）延伸的附件。

[0051] 图 9A 描绘了围绕至少一个股骨髁弯曲的膝盖植入物的实施方式的侧视图，该植入物具有从未膨胀或最低限度膨胀的球囊延伸的附件。

[0052] 图 9B 描绘了围绕至少一个股骨髁弯曲的膝盖植入物的实施方式的侧视图，该植入物具有从已膨胀球囊延伸的附件。

[0053] 图 9C 描绘了围绕至少一个股骨髁弯曲的膝盖植入物的实施方式的侧视图，该植入物具有从已膨胀球囊延伸的附件并且具有将附件联接至股骨的 U 形钉或螺钉。

[0054] 图 10A 描绘了围绕至少一个股骨髁弯曲的膝盖植入物的实施方式的侧视图，并且示出了当膝关节屈曲时膨胀介质向前朝髌骨移动，该植入物具有从已膨胀球囊延伸的附件。图 10B 描述了围绕至少一个股骨髁弯曲的膝盖植入物的实施方式的侧视图，并且示出

了当膝关节屈曲时膨胀介质向前朝髌骨移动，该植入物具有从已膨胀球囊延伸的附件并且具有将附件联接至股骨的 U 形钉和螺钉。

[0055] 图 11A 描绘了弯曲成模拟股骨的一个髁周围曲率的单隔室膝盖植入物的实施方式，该植入物具有从未膨胀球囊（未示出）延伸并且包括翼片和孔洞的附件，所述翼片和孔洞可与联接器一起使用以将该植入物联接至膝关节的股骨。

[0056] 图 11B 描绘了弯曲成模拟股骨的一个髁周围曲率的单隔室膝盖植入物的实施方式，该植入物具有从已膨胀球囊延伸并且包括翼片和孔洞的附件，所述翼片和孔洞可与联接器一起使用以将该植入物联接至膝关节的股骨。

[0057] 图 11C 描绘了弯曲成模拟股骨的一个髁周围曲率的单隔室膝盖植入物的实施方式的仰视图，该植入物具有从已膨胀球囊延伸并且包括翼片和孔洞的附件，所述翼片和孔洞可与联接器一起使用以将该植入物联接至膝关节的股骨。

[0058] 图 12A 描绘了单隔室膝盖植入物或补片植入物的实施方式的仰视图，该植入物具有从球囊延伸并且包括孔洞的附件，所述孔洞可与联接器（未示出）一起使用以将该植入物联接至膝关节的股骨。

[0059] 图 12B 描绘了单隔室膝盖植入物或补片植入物的实施方式的仰视图，该植入物具有从球囊延伸并且包括翼片和孔洞的附件，所述翼片和孔洞可与联接器（未示出）一起使用以将该植入物联接至膝关节的股骨。

[0060] 图 12C 描绘了单隔室膝盖植入物或补片植入物的实施方式的仰视图，该植入物具有从球囊延伸并且包括翼片和孔洞的附件，所述翼片和孔洞可与联接器（未示出）一起使用以将该植入物联接至膝关节的股骨。

[0061] 图 13A- 图 13D 描绘了适合将植入物联接至关节骨的 U 形钉的多个视图。

具体实施方式

[0062] 本发明涉及用于膝盖的关节成形术植入物和操作。

[0063] 膝盖间置式膝关节成形术可以取代现有的全关节金属 / 塑料技术。其旨在于在关节镜清创术无法提供治愈的情况下填充间隙（在该植入物的一些实施方式中确实如此），这是因为到目前为止人们仅可以‘磨光关节炎’和‘清理关节’。医学上可膨胀的聚合物植入物可以在生理上恢复关节功能。在软骨损坏之处进行填补，从而在股骨 - 胫骨关节和髌骨 - 股骨关节变窄或为病态时对它们给予缓冲。在一些实施方式中，植入物适合递送恢复关节面的自体细胞（来自患者）、同种异体移植细胞（来自同一物种的另一成员）或异体移植细胞（来自不同物种）。由于软骨是免疫特免组织，因此抗原被埋在软骨基质内，并且抗体不排斥翻新的表面覆层。

[0064] 由植入物的一个或多个球囊所填充的间隙（或多个间隙）将会在相对的关节面（一个或多个股骨髁与胫骨平台）之间提供相符性。股骨可具有通常约 5mm 厚的、髌后圆面“V”形透明质的一些部分（并不是全部），或当插入植入物时其也可不具有此类透明质。胫骨平台可具有半月板纤维软骨的一些部分，包括所有的所述纤维软骨、没有任何所述纤维软骨、或者它们的一些部分。当膝盖伸展（平直）时，植入物缓冲股骨 - 胫骨关节。当膝盖屈曲时，植入物球囊并置更多地处在前股骨远端的滑车沟部分（“膝盖前侧”的髁之间的沟）与髌骨之间。

[0065] 膝盖解剖结构相对其他关节解剖结构是独特的，因此具有一系列由在此所述的植入物实施方式所解决的独特的挑战。例如，膝盖不是像髋部那样的球窝关节；它是股骨－胫骨关节和髌骨－股骨关节这两个关节的组合。膝盖的骨具有小面和不规则性，这必须由针对特定骨形的相符植入物在不阻碍关节功能和移动以及／或者最小地阻碍此类关节功能和移动的情况下加以适应。膝盖的关节不仅一起工作以便允许膝盖的伸展和屈曲，而且膝盖还被设计成允许以像螺旋一样的方式进行旋转移动。亦即，当胫骨相对于股骨扭转时，关节被独特地设计成允许这种扭转，但还限制该扭转。此外，膝关节能够承受根据个体的特定运动而不仅在力的强度上改变而且还在力的方向上改变的力。因此，在此所述的植入物独特地设计成顾及这些因素，并导致膝关节与典型的关节成形术操作（诸如局部膝盖置换或者全膝盖置换）相比具有保留下来的自然组织和保留下来的功能和移动。

[0066] 如在此所述，植入物的实施方式符合患者自己的关节特征，不仅在于其可以预成型和／或适配用于联接至患者的骨（髁，等等）的轮廓，而且还在于其具有拥有膨胀介质的球囊，该球囊可符合关节解剖结构并且在尽可能保留关节和骨自然组织的同时允许非常像自然关节的关节运动自由度。凭借用不同材料填充球囊的各个腔室以及向植入物添加刚性和／或半刚性零件的能力，该植入物可以额外地具有校平能力和校准能力。

[0067] 诊断：

[0068] 患者可能主诉疼痛和以僵硬、咔哒声或者打软腿为征兆的膝关节功能障碍。膝盖可能肿胀、错位或者显出捻发音（运动时明显的摩擦音）。不管是前／后交叉韧带还是中间／侧面侧副韧带，其不稳定性都可由通过允许愈合（比如对于侧副韧带）或通过交叉修复或重建而单独针对这些实体的技术来加以治疗。

[0069] 在此提供的植入物的使用适应症可以是那些确认高于或等于 2 平方厘米的 3-4+/4 创伤性关节炎（亦称 Carticel）的患者。在此类病例中，软骨缺损通常是精确地在局部有症状，伴有点压痛，如果存在松脱的软骨瓣则发出咔哒声，并且在 MRI 和／或关节镜检查中和／或通过触诊可见。当诸如‘捡拾’、K 线钻和／或同种异体移植物等现有技术无效时，在此所用的植入物可能附加地和／或替代地是合适的。

[0070] 膝盖有问题的患者通常主诉疼痛和功能障碍。半月板撕裂的示病性症状包括由于膝盖的磨损和扭转而引起的僵硬、咔哒声、打软腿。疼痛可能广泛地由关节炎或滑膜炎所引起；膝前疼痛一般是髌骨－股骨性的，随着爬楼梯，由于身体重力加大而增大。诊断应当准确，以区别于由 L4 神经根刺激而引起的穿过膝盖而实际出现在背部的疼痛。病态膝盖的体检结果包括观察到的肿胀、发红或变形。触诊通常帮助将注意力关注于累及哪些隔室。髌骨抑制试验位置暗示髌后病状，并且经常追踪需要软组织和骨矫正的问题。改善的肢体对齐将增加益处，并且可部分地来自于在此提供的植入物实施方式的选择性膨胀。膝盖的 X 射线从负重视图得到最好的评估，并且应当结合包括 MRI 或 CT 等其他数据。相对的隔室缩窄提示软骨退化。一旦在此所述的植入物的实施方式已成功植入并且膝盖得到充分恢复，则具有此植入物的关节的外观应当类似于正常关节的 X 射线。膝盖扩张由盐水和／或空气喷注引起。膝盖植入患者将受益于定制的康复计划、谨慎的负重、早期活动和持续的被动式运动机械方案的潜在使用。

[0071] 一般特征

[0072] 植入物方面

[0073] 在此提供了用于植入膝关节中充当缓冲垫从而允许复原的关节运动的弹性植入物。该植入物可在减轻伤后或病后疼痛和改善功能从而修复、重建和再生关节完整性的同时，承受可变的膝关节外力和循环荷载。植入物可部署在准备好的已清创的膝关节间隙内，紧固到至少一个膝关节骨并且在该间隙中扩张，以足够的稳定性成型至周围结构以避免挤出或脱位。植入物可具有在变化的方向上移动的相对的壁，以及用合适的填料填充的内部空间，以便适应模拟或近似于正常膝关节运动的运动。植入物可填补损坏的关节面，立即恢复缓冲并且可用于通过递送再生细胞而将软骨恢复正常。

[0074] 在此提供了弹性间置式关节成形术植入物，用于施用到膝关节内以便修补软骨缺损、缓冲关节以及取代或恢复关节面从而保持关节完整性、减轻疼痛和改善功能。在损伤或疾病需要干预之后，该植入物可承受可变的膝关节压缩力和剪切力以及数百万次循环负荷。植入物可利用改进了现有的刚性塑料和金属关节置换备选方案的生理解决方案，以最低病态的方式来修复、重建和再生膝关节解剖结构。在细胞已用于需要大量骨膜收获以供包封的关节面再建的情况中，植入物的一些实施方式的聚合物壁可俘获、分配和保留活细胞直到发生聚集和透明软骨再生长。植入物可部署在准备好的已清创的膝关节间隙内，以足够的稳定性成型至周围结构并与之相符，以避免挤出或脱位。植入物的附件（或翼片）可用于修复或重建肌腱或韧带。植入物也可具有在变化的方向上移动的相对的壁，以及填充有合适的气体、液体和 / 或作为力吸收移动成分的复合聚合物层的单个的或分开的内部空间，从而使强健有效和可靠的关节运动得到支持。

[0075] 在此提供了弹性矫形植入物，其配置成部署在股骨与关节的至少一个第二骨之间。第二骨可以是胫骨。第二骨可以是髌骨。该植入物还包括球囊和配置用于将该球囊联接至股骨的第一附件，所述球囊包括：第一部分，其配置用于接合股骨；第二部分，其配置用于接合关节的第二骨；连接第一部分和第二部分的侧面部分，其中该侧面部分促进第一部分与第二部分之间的相对运动；以及可选地可用第一膨胀介质加以膨胀的内部。在本公开全文各处中可互换使用术语“球囊”和“囊状物”来描述具有在此所述特征的植入物。

[0076] 在一些实施方式中，第一部分、第二部分和侧面部分中的至少两个是毗邻的。在一些实施方式中，第一部分包括第一壁，第二部分包括第二壁，并且侧面部分包括侧壁。在此所使用的术语“第一部分”、“第二部分”和“侧面部分”中的每个术语用于描述球囊的一部分，并且在一些实施方式中可能不是单独的部件。相反，在一些实施方式中，每个术语被命名用以指出每个部分相对于其他部分以及 / 或者相对于关节的骨和 / 或韧带和 / 或肌腱的总体几何及位置。同样地，在此所使用的术语“第一壁”、“第二壁”和“侧壁”用于描述球囊的一部分，并且在一些实施方式中可以不是单独的球囊部件。相反，在一些实施方式中，每个壁被命名用以指出每个部分相对于其他部分以及 / 或者相对于关节的骨和 / 或韧带和 / 或肌腱的总体几何及位置。在一些实施方式中，第一壁、第二壁和侧壁中的至少两个是毗邻的。然而在一些实施方式中，每个壁可以是单独的植入物部件，它们结合在一起形成植入物。同样地，在一些实施方式中，每个部分的确可以是结合在一起形成植入物的、单独的植入物部件。

[0077] 在一些实施方式中，第一部分是可与第一壁互换使用的术语。在一些实施方式中，第二部分是可与第二壁互换使用的术语。在一些实施方式中，侧面部分是可与侧壁互换使用的术语。在一些实施方式中，植入物的壁（无论第一壁、第二壁和 / 或侧壁）可包括多个

层。壁可以包含多种材料以便向壁给予物理特性和 / 或治疗特性。

[0078] 在一些实施方式中，植入物包括第二附件，该第二附件将球囊联接至关节的第一骨。在一些实施方式中，该植入物包括第二附件，该第二附件将球囊联接到关节的至少一个第二骨。在一些实施方式中，植入物包括第二附件，该第二附件配置用于将第一部分、第二部分和侧面部分中的至少一个联接到关节的第一骨和至少一个第二骨中的至少一个。在一些实施方式中，第一附件和第二附件配置用于向关节的第一骨和至少一个第二骨提供韧带样支撑。在一些实施方式中，第一附件和第二附件配置用于向关节提供韧带样支撑。在一些实施方式中，第一附件和第二附件配置用于向关节的第一骨和至少一个第二骨提供肌腱样支撑。在一些实施方式中，第一附件和第二附件配置用于向关节提供肌腱样支撑。

[0079] 在一些实施方式中，植入物包括与球囊的内部相连通的膨胀端口，该膨胀端口用于以第一膨胀介质来膨胀球囊的内部。在一些实施方式中，刺穿该球囊，以便使用第一膨胀介质来膨胀球囊的内部。在一些实施方式中，球囊是自密封的。在一些实施方式中，球囊在使用第一膨胀介质使球囊的内部膨胀后是自密封的。在一些实施方式中，植入物包括能够封闭球囊内部的密封件。

[0080] 在一些实施方式中，该内部包括多个可膨胀的腔室。在一些实施方式中，内部包括多个可单独膨胀的腔室。在一些实施方式中，多个可单独膨胀腔室中的第一腔室适合用第一膨胀介质来膨胀，并且多个可单独膨胀腔室中的第二腔室适合用第二膨胀介质来膨胀。

[0081] 在一些实施方式中，内部包括蜂窝状结构。在一些实施方式中，内部包括网状结构。在一些实施方式中，内部包括海绵状结构。

[0082] 在许多实施方式中，植入物（或者其一部分，诸如一个或多个球囊）是将会允许关节运动趋于正常的承重垫片，无论是填充如在骨关节炎中那样广泛地还是如在骨坏死缺损或局部创伤中那样局限地由完全坍塌的关节骨所留下的空间或是切除的软骨邻面空间，情况都是这样。植入物的壁可用作膜，用于将活细胞在骨软骨缺陷处附近保留足够长的时间，该时间足以使细胞附着（例如，24 小时）或深度粘附（长达 28 天）或恢复正常（可达一年）。当治疗下肢远端关节时，预计承重将会增大。

[0083] 在图 9B 和图 10A 的对比中，或在图 9C 和图 10B 的对比中图示了由股骨和胫骨的移动而引起的植入物（例如，球囊的）第一壁与第二壁之间的移动（不管是直线的还是曲线的）。在一些实施方式中，植入物可包括如下的球囊：该球囊配置成允许植入物的一个壁在该植入物的另一个壁（或同一个壁）上滚动（例如，侧壁在第一壁上滚动，第一壁在第二壁上滚动，第二壁在第一壁上滚动，第一壁在侧壁上滚动，第二壁在侧壁上滚动，侧壁在第二壁上滚动，第一壁在第一壁上滚动，第二壁在第二壁上滚动以及 / 或者侧壁在侧壁上滚动）。在一些实施方式中，植入物可包括如下球囊：该球囊配置成允许植入物的一个部分在该植入物的另一部分（或同一部分）上滚动（作为非限制性实例，侧壁在附件上滚动，第一壁在附件上滚动以及 / 或者第二壁在附件上滚动）。在一些实施方式中，植入物可包括配置成允许植入物的一部分在软骨上滚动的运动的球囊。虽然未在图中示出，但是在植入物的一部分（无论是附件、壁或室插入物的一些其他部分）与关节组件（无论是骨、韧带、肌腱或是其他组织）之间可存在滑动。这样的滑动除植入物本身内的壁运动之外可以用于提供期望的关节运动。虽然未在图中示出，但是在第二骨（例如，胫骨）与第二壁之间可能存在滑动，除了在植入物本身内的壁运动之外，用于提供期望的关节运动。附件（或多个附件）设计用于将

植入物紧固到膝关节结构以便避免植入物脱位。在植入物已就位的情况下的关节的移动将是植入物的移动的相对壁的共享功能，而且也是可较少地联接至关节构件的壁的运动的功能。在附件、第一壁和股骨之间可能有轻微的移动。球囊壁可以压缩和 / 或伸展以适应骨界面移动。可以对材料选择、材料尺寸以及植入物的尺寸、放置和 / 或联接加以选择，以便允许多个关节和 / 或植入物组件的相对运动的期望的压缩、拉伸量。作为非限制性实例，在一些区域植入物的壁可以更厚以适应特定负荷，并且侧壁可以更薄和更有弹性以适合其滚动和拉伸。

[0084] 移动据信主要介于外围紧固到关节结构上的植入物的隔开的壁（或部分）之间，尽管一些运动可发生在植入物与关节面之间。如多幅图（包括图 1- 图 7）中所示，植入物可配备有从植入物的外围向植入物的球囊延伸的狭槽，用以适应关节的至少一条韧带。膝盖植入物可具有两个狭槽，它们通向用于接纳前交叉韧带和后交叉韧带的单独通路。植入物的壁应当具有足够的固有柔性，以便吻合现有的由自然的韧带、骨、肌腱所施加的形变和已被填充作为缓冲垫的内部关节间隙的残留软骨形变。壁的外部可以是平坦的，或者形成为具有用于滑行用途的随机或特定的图案或者用于抵靠相邻表面的牵引的纹线，或者形成为用于细胞递送材料的沟槽或地点。

[0085] 植入物的外部可具有带多个弦（或附件）的网状材料，所述弦用于将植入物紧固到相邻的骨或者紧固到附着至相邻的骨的残余韧带。

[0086] 各植入物壁的尺寸将依据其材料性质以及针对特殊关节的需求而改变。此外，第一壁和第二壁可能需要不同于侧壁的厚度。通常，植入物可具有约 0.125mm 至约 3mm，优选地约 0.5mm 至约 1.5mm 的壁厚度。内部中第一壁与第二壁之间的间距可在约 0.5mm 至约 5mm 之间变化。

[0087] 在一些实施方式中，植入物具有第一壁、第二壁和侧壁，它们限定了包含填充材料的植入物内部（或内部）。在一些实施方式中，填充材料是膨胀介质。第一壁通过至少一个从第一壁延伸的附件而紧固到股骨末端，并且第二壁接合第二骨（在股骨 - 胫骨关节植入物的情况中，将会是胫骨）的端面并且也可紧固于此。在第一壁与第二壁之间延伸的的侧壁至少部分地限定了填充有填充材料（或膨胀介质）的植入物内部。壁和附件的内表面可例如通过在特定位置上更宽和 / 或在特定区域中更长而符合股骨的特定表面。例如，相对于覆盖外侧髁的截面而言，双隔室植入物（在此所述）可具有更宽的截面来覆盖内侧髁（如图 1、图 2、图 3、图 6A、图 6B 和图 7 中所示）。在另一示例中，沿外部边缘的植入物长度可长于沿滑车沟边缘的植入物长度（如图 11A、图 11B 和图 11C 中所示）。在又一示例中，宽度可沿单个髁改变，如图 12A- 图 12C 中所示，其中更宽的植入物边缘适合于安装在前髁的至少一部分之上，而较窄的部分则适合于安装在后髁的至少一部分之上。在一些实施方式中，第一壁和附件的内表面优选地符合患者股骨的特定表面，而这样不仅是因为植入物的尺寸（长度、宽度、球囊位置和形状），而且还以及 / 或者备选地是由于附件和 / 或翼片和 / 或孔洞和 / 或联接器位置和 / 或第一壁的表面轮廓。第二壁的外表面可配置成符合第二骨（例如，其可以是胫骨或髌骨）的端面。在一些实施方式中，第二壁的外表面配置成符合第二骨（例如，其可以是胫骨或髌骨）的表面。在此提供的图是高度示意性的，而并没有描绘关节表面特征的细节，因为人体病理学和变化反映了患者的即时病理生理学和不断发展的病理生理学。为了易于查看所描绘的视图，图中也没有描绘其他关节特征，诸如软骨、肌腱、韧带以及关节

的其他软组织和流体。

[0088] 在一些实施方式中，植入物配置成类似于正常膝盖的天然透明质的形状。例如，正常透明质通常是“H”型，因此植入物的某些实施方式大体上为“H”型。

[0089] 植入物材料和材料特征

[0090] 在一些实施方式中，植入物包括聚合物。聚合物可包括以下至少一种：聚氨酯(举例而言，诸如 ChronoFlex AR)、聚碳酸酯氨基甲酸乙酯、热塑性聚碳酸酯氨基甲酸乙酯(诸如 Bionate 55)、乙烯 - 醋酸乙烯酯共聚物、聚(环氧乙烷)(PEO) 和聚(对苯二甲酸丁二酯)(PBT) 的多嵌段共聚物、PEG、PEO 和聚乙烯。在一些实施方式中，植入物包括 125 微米厚度的热塑性聚碳酸酯氨基甲酸乙酯。

[0091] 植入物可包括在溶剂中的多层聚合物(诸如 ChronoFlex AR)并且在施用每一层之后蒸发溶剂。在一些实施方式中，植入物包括喷涂和干燥(其中喷涂和干燥重复至少一次)至期望厚度的聚氨酯。

[0092] 在一些实施方式中，通过将具有膝关节骨(作为非限制性实例，内侧髁、外侧髁、胫骨)形状的芯轴到聚合物溶液(作为非限制性实例，氨基甲酸乙酯聚合物，诸如 Chronoflex)中浸渍成型来生成植入物。每次浸渍之后，将植入物干燥一段特定时间，所述特定时间例如可以是约 3 秒、约 4 秒、约 5 秒、约 6 秒、约 7 秒、约 8 秒、约 9 秒、约 10 秒、约 15 秒、约 20 秒、约 25 秒、约 30 秒、约 45 秒、约 1 分钟、约 2 分钟、约 5 分钟、约 10 分钟、约 15 分钟和超过约 15 分钟。在此关于植入物干燥时间所使用的术语“约”可以指 5%、10%、25% 和 50% 中的至少一个的变化。在一些实施方式中，不使用干燥步骤。浸渍可重复多次。在一些实施方式中，单次浸渍就已足够。在一些实施方式中，浸渍重复 2 次。在一些实施方式中，浸渍重复 3 次。在一些实施方式中，浸渍重复 4 次。在一些实施方式中，浸渍重复 5 次。在一些实施方式中，浸渍重复 6 次。在一些实施方式中，浸渍重复 7 次。在一些实施方式中，浸渍重复 8 次。在一些实施方式中，浸渍重复 9 次。在一些实施方式中，浸渍重复 10 次。在一些实施方式中，浸渍重复 11 次。在一些实施方式中，浸渍重复 12 次。在一些实施方式中，浸渍重复 13 次。在一些实施方式中，浸渍重复 14 次。在一些实施方式中，浸渍重复 15 次。在一些实施方式中，浸渍重复 16 次。在一些实施方式中，浸渍重复 17 次。在一些实施方式中，浸渍重复 18 次。在一些实施方式中，浸渍重复 19 次。在一些实施方式中，浸渍重复 20 次。在一些实施方式中，浸渍重复 21 次。在一些实施方式中，浸渍重复 22 次。在一些实施方式中，浸渍重复 23 次。在一些实施方式中，浸渍重复 24 次。在一些实施方式中，浸渍重复 25 次。在一些实施方式中，浸渍重复超过 25 次。在一些实施方式中，浸渍重复足够的次数以生成规定厚度的植入物。厚度可根据聚合物和根据植入物的实施方式而改变。厚度可以是以下至少一项：约 25 微米厚、约 50 微米厚、约 100 微米厚、约 125 微米厚、约 150 微米厚、约 200 微米厚、约 250 微米厚、约 300 微米厚、约 350 微米厚、约 400 微米厚、约 25-50 微米厚、约 50-100 微米厚、约 50-200 微米厚、约 100-150 微米厚、约 150-300 微米厚、约 100-300 微米厚、约 100-500 微米厚、约 200-500 微米厚、以及约 200-1000 微米厚。在此关于植入物厚度所使用的术语“约”可以指 5%、10%、25% 和 50% 中的至少一个的变化。厚度可在植入物的不同位置处变化。在一些实施方式中，植入物以两个零件制成，当将这两个零件放在一起时，其中一个或多个零件成型以形成内部。在一些实施方式中，通过刺穿植入物壁以及用塞子、补片或其他密封剂密封穿孔来填充植入物。作为非限制性实例，塞子、补片或其他密封

剂可包括 Chronoflex 材料。作为非限制性实例，塞子、补片或其他密封剂可包括与该植入物的构造材料相同的材料。

[0093] 体现本发明特征的植入物的壁可以是复合结构。例如，最内层可以是不可渗透的，以阻止膨胀介质或其他填充介质的逸出；中心层可以是多孔的或者除此之外包含治疗剂或细胞再生剂；并且外层可以是薄而坚固的热塑性塑料（作为非限制性实例，诸如热塑性聚氨酯）层，其具有足以允许来自中心层（或第二层）的治疗剂或细胞再生剂通过或排出的微孔率。在诸如 Chronoflex 或 Bionate 55 等聚合物层中发现使来自中心层的治疗剂或细胞再生剂能够排出的微孔率程度。

[0094] 植入物的外壁（和 / 或骨接合表面）可涂覆有和 / 或浸渍聚合物网格，该聚合物网格喷涂在或分层堆积在植入物的外面（或骨接合表面）上以促进软骨组织再生。该最外层表面涂层可包含活软骨细胞（例如，在 Carticel 手术中由 Genzyme 公司提供的软骨细胞），并且 / 或者可包含具有定向基因突变的干细胞以促进涂层到植入物的粘附。骨接合表面可包括峰和槽。活细胞可施用于植入物表面的槽之间（和 / 或提供在槽内），而突出物（表面的峰）的表面积可用于以下至少一项：空间验证、牵引和细胞保护。

[0095] 植入物可由合适的可生物吸收材料形成，以便使植入物可在特定的预定时间范围内被吸收。合适的可生物吸收材料包括聚乳酸、聚乙醇酸、聚乙酸内酯、共聚物以及它们的混合物和变异体。合适的可生物吸收材料还可以 / 备选地包括 PHB-PHV 类的聚（羟基链烷酸酯）、额外的聚（酯）以及天然聚合物，特别是经过修饰的聚（糖），例如，淀粉、纤维素和和壳聚糖。植入物的壁可以（全部地和 / 或部分地）是可生物吸收的。球囊可以（全部地和 / 或部分地）是可生物吸收的。在此所用的术语“可生物吸收”、“可生物侵蚀”和 / 或“可生物吸收”可以互换使用。植入物的壁可释放药剂或生物剂（诸如干细胞、活软骨细胞、基因治疗，等等）。在一些实施方式中，此类药剂（不管是生物性的还是药物性的，或者它们的组合）的释放可随着植入物的壁（或者随着球囊）的生物吸收或者随着关节被使用（即，作为非限制性实例，通过压力），而随着时间的推移发生。在一些实施方式中，诸如在其中膨胀介质包含药剂和 / 或生物剂的实施方式中，至少一个植入物壁对于药剂和 / 或生物剂是可渗透的。在一些实施方式中，诸如在其中膨胀介质包含药剂和 / 或生物剂的实施方式中，至少一个植入物壁具有可让药剂和 / 或生物剂适合穿过的孔。

[0096] 植入物可配备有网格或其他加强线，优选位于它的外面或壁内，以便当植入物部署在矫形部位时控制其最大扩张。

[0097] 在一些实施方式中，植入物包括羊膜（和 / 或其组成部分）。在一些实施方式中，植入物包括羊膜囊（和 / 或其组成部分）。在一些实施方式中，植入物包括羊膜组织（和 / 或其组成部分）。羊膜（和 / 或囊和 / 或组织）在其机械性能方面是独特的，包括它一面是滑的（光滑的、低弹性模量），而另一面是粘的（粘附的）。在一些实施方式中，第一壁、第二壁和侧壁中的至少一个包括羊膜或其组成部分。在一些实施方式中，第一壁、第二壁和侧壁中的至少一个包括羊膜囊或其组成部分。在一些实施方式中，第一壁、第二壁和侧壁中的至少一个包括羊膜组织或其组成部分。羊膜和 / 或羊膜囊和 / 或羊膜组织可结合其他生物剂、药剂和 / 或治疗剂一起使用。羊膜组织广泛用于多能细胞。由于产品和来源的短期时间跨度，它算得上是 HTBP（基于人体组织的产品）。

[0098] 在一些实施方式中，球囊是复合结构。在一些实施方式中，球囊包括多孔材料层

和/或非多孔材料层，或者除此之外包含治疗剂或细胞再生剂。在一些实施方式中，球囊的第一层是薄而坚固的热塑性塑料层，作为非限制性实例，诸如热塑性聚氨酯，其具有足以允许来自第二层的治疗剂或细胞再生剂通过或排出的微孔率。第二层可以是中心层(其位于第一层与第三层或第四层或者更多的层之间)。在一些实施方式中，第一层可包括骨接合表面。在诸如 Chronoflex 或 Bionate55 等聚合物层中发现使来自第二层的治疗剂或细胞再生剂能够排出的微孔率程度。植入物的骨接合表面可涂覆和/或浸渍聚合物网格，该聚合物网格喷涂在或分层堆积在植入物的骨接合表面上以促进软骨组织再生。该骨接合表面涂层可包含活软骨细胞(例如，在 Carticel 手术中由 Genzyme 公司提供的软骨细胞)，并且/或者可包含具有定向基因突变的干细胞，以增强涂层到植入物的粘附。骨接合表面可包括峰和槽。活细胞可提供于槽中，而表面峰可用于以下至少一项：空间验证、牵引和细胞保护。

[0099] 在一些实施方式中，植入物经过预成型以适配在股骨的至少一个髁周围。在一些实施方式中，植入物包括记忆塑料。在一些实施方式中，植入物包括线框。在一些实施方式中，线框的线包括记忆金属。在一些实施方式中，记忆金属包括镍钛诺。在一些实施方式中，线框安设在植入物或其一部分的外围中。在一些实施方式中，线框配置用于辅助抵靠髁后部的放置。

[0100] 在一些实施方式中，植入物的至少一部分包括光滑面。在一些实施方式中，该光滑面配置用于允许联接至股骨的植入物(或其一部分)与胫骨之间的相对移动。在一些实施方式中，该光滑面配置用于允许联接至股骨的植入物(或其一部分)与髌骨之间的相对移动。

[0101] 膨胀介质与植入物内部的膨胀或填充

[0102] 在一些实施方式中，植入物包括可压缩的膨胀介质。在一些实施方式中，植入物包括包含粘润滑剂的膨胀介质。在一些实施方式中，植入物包括包含药理性物质的膨胀介质。在一些实施方式中，植入物包括包含 NSAID 的膨胀介质。在一些实施方式中，植入物包括包含软骨细胞的膨胀介质。在一些实施方式中，植入物配置用于使植入物(或其一部分)的最外层与紧贴的软骨缺损的外围炼合以便覆盖它们，从而允许愈合。在一些实施方式中，植入物配置用于一旦已安设新的软骨细胞，则使植入物(或其一部分)的最外层的与紧贴的软骨缺损的外围炼合以便覆盖它们，从而允许愈合。

[0103] 植入物内部(球囊内部)可用气体来膨胀。植入物内部(球囊内部)可用液体来膨胀。植入物内部(球囊内部)可用盐水来膨胀。植入物内部(球囊内部)可用悬浮干细胞来膨胀。植入物内部(球囊内部)可用凝胶来膨胀。植入物内部(球囊内部)可用粘润滑剂来膨胀。在一些实施方式中，膨胀介质留在球囊内或其一部分内(当球囊有多个腔室时)。在一些实施方式中，球囊内容物通过微孔和/或溶解性膜分配到关节内。在一些实施方式中，在来自肢体使用的压力后，球囊内容物通过排出或撤出加速穿过植入物壁来分配。在一些实施方式中，由于预设的渗透，球囊内容物通过排出或撤出加速穿过植入物壁来分配。在一些实施方式中，由于液泡状物破裂(作为非限制性实例，不管是机械破裂、超声波或化学破裂)，球囊内容物通过排出或撤出加速穿过植入物壁来分配。在一些实施方式中，球囊内容物通过排出或撤出加速穿过植入物壁来分配，从而将植入物内部的内容物分配到关节作为润滑物质、止痛物质、抗炎物质和/或其他治疗物质。在一些实施方式中，植入物可包括固体珠或包含凝胶或液体的珠，用于通过经改变珠壁厚度造成的破裂而产生的压缩力而进行连续分配，或者珠可以化学地、药学地或通过膝外施用的外部超声波或磁力而以适当的临

床间隔定时释放(打开)。在一些实施方式中,植入物可包括包含凝胶或液体的液泡状物,其用于通过经改变液泡状物壁厚度造成的破裂而产生的压缩力而进行连续分配,或者液泡状物可以化学地、药学地或通过膝外施用的外部超声波或磁力而以适当的临床间隔定时释放(打开)。

[0104] 在第一壁与第二壁之间的植入物内部(或球囊内部)填充有填充材料(或膨胀介质),该填充材料帮助在关节结构内维持期望的植入物动力学。可对诸如流体等填充材料的性质和壁的特征加以选择,从而维持壁间的期望间距,以便适应关节结构的骨施加给植入物的压力以及允许在植入物的第一壁与第二壁之间的适当运动,所述壁促进了模拟或接近所涉关节构件的正常活动的骨运动。

[0105] 备选地(和/或附加地),腔室(其内部或其一部分)可填充有弹性材料,以便在允许植入物层之间期望的生理运动的同时,提供期望的间距和压力适应。植入物可配置成为形似被取代的关节间隙和骨表面,或者配置用于填充由损伤或疾病所产生的空隙,以便使自然关节间隙和关节界面的缓冲朝正常生理外观和功能恢复。可利用诸如盐水、矿物油等流体来膨胀植入物。

[0106] 在部署植入物之后,植入物的内部可由医生从其适当的源可调节地填充,以确保病态关节间隙再次变成弹性缓冲垫,所述弹性垫通过用植入物材料覆盖软骨缺损、缓冲其中的关节和缺损以及递送细胞再生剂,而帮助关节中磨损的或损伤的软骨界面的恢复。在一个实施方式中,植入物包括生物相容性可膨胀构件(球囊),其填充有生物相容性填充材料(膨胀介质),诸如气体、液体、凝胶或浆体、或者变为弹性固体的流体,以便提供第一壁与第二壁之间的相对移动。填充或膨胀介质可经过通向套管的注射阀位点插入,该套管将材料递送到植入物的内部之中。在备选实施方式中,植入物可以填充生物相容性弹性材料或者具有由生物相容性弹性材料形成的内部,例如,填充以合适流体的闭孔海绵,该闭孔海绵在植入物部署之前插入到植入物的内部或者在植入物部署在关节部位之后注入该内部。植入物的内部可配备润滑材料,以促进内壁表面之间的移动以及使其间的接触磨损最小化。植入物的聚合物壁可用诸如干细胞、活软骨细胞和/或基因之类组织再生剂浸渍或者除此之外携带此类组织再生剂以修复关节表面。

[0107] 在一些实施方式中,第一膨胀介质给予了植入物中的刚度。在一些实施方式中,第一膨胀介质给予了植入物中的缓冲。在一些实施方式中,为第一膨胀介质选择的膨胀介质和/或用这样的第一膨胀介质填充的腔室的特定选择(在具有多个腔室的实施方式中)使关节对齐。在一些实施方式中,为第一膨胀介质选择的膨胀介质和/或用这样的第一膨胀介质填充的腔室的特定选择(在具有多个腔室的实施方式中)使关节的骨对齐。在一些实施方式中,为第一膨胀介质选择的膨胀介质和/或用这样的第一膨胀介质填充的腔室的特定选择(在具有多个腔室的实施方式中)改变了骨对齐。在一些实施方式中,为第一膨胀介质选择的膨胀介质和/或用这样的第一膨胀介质填充的腔室的特定选择(在具有多个腔室的实施方式中)改善了关节对齐。在一些实施方式中,为第一膨胀介质选择的膨胀介质和/或用这样的第一膨胀介质填充的腔室的特定选择(在具有多个腔室的实施方式中)至少部分地恢复关节对齐。在一些实施方式中,可以选择性地用第一膨胀介质和/或第二膨胀介质来膨胀内部的个别腔室。在一些实施方式中,用第一膨胀介质和/或第二膨胀介质选择性地膨胀内部的个别腔室,以便重建关节和/或关节的骨。

[0108] 在一些实施方式中，膨胀介质包含活软骨细胞。

[0109] 可以用作为液体的甲基丙烯酸甲酯来膨胀植入物内部(球囊内部)，该液体会变成固体或半固体(刚性或半刚性)。在一些实施方式中，膨胀介质是甲基丙烯酸甲酯或其他生物相容性硬化物质，它们在最初放入腔室时可以流动，并且硬化变成刚性块或半刚性块或固体块。甲基丙烯酸甲酯或其他生物相容性硬化物质可符合腔室的形状，或者可符合骨和/或其他关节结构之间的空间的形状。甲基丙烯酸甲酯或其他生物相容性硬化物质可符合由外科医生使用工具和/或压力来影响由甲基丙烯酸甲酯或其他生物相容性硬化物质在硬化后形成的刚性块的最终形状从而选定的形式。

[0110] 侧壁在第一壁与第二壁之间延伸以形成通过管(在此也称为导管，或称为膨胀端口)接受填充材料的内部。在一些实施方式中，膨胀端口不是管，而是可以从植入物的壁延伸或者可以不从其延伸的阀。所述阀可以是植入物的壁的一部分，或者是球囊或其部分的一部分。植入物也将适合于膝盖的一个髁，但其他形状对于相对平坦的或者更加向鼓胀结构膨胀的其他关节配置而言是期望的。在一些实施方式中，膨胀端口(或管)的内径最大为5mm。在一些实施方式中，膨胀端口(或管)的内径为约1mm。在一些实施方式中，膨胀端口(或管)的内径为约2mm。在一些实施方式中，可以使用(典型针尺寸的)针来使植入物膨胀。

[0111] 可以使用单独的出孔或管(未示出)或现有的导管(管或阀)，以适当的临床间隔来提取可被抽出的有毒炎性酶。可以提取在COX1、COX2和/或5LOX途径中的炎性酶。粘润滑剂可通过现有的导管或通过长针注入弹性关节成形术植入物的内部，以辅助膨胀、扩张、润滑(用预定的微孔)。

[0112] 在一些实施方式中，可以使用(通过催化剂反应或其他方式)产生热量的膨胀介质来向关节结构传递热量。热量可以辅助透明软骨炼合。植入物材料的热效应经过了相应计算，以有益于和保护关节表面，类似用于暴露在极端温度下的戴水肺潜水员的干式潜水服和湿式潜水服。作为非限制性实例，植入物的实施方式一般力图通过同种异体移植作为羊膜或作为聚合物的润滑涂层来避免由摩擦产生的热量。

[0113] 在一些实施方式中，在植入物处于收缩结构中的情况下，在关节镜下通过约10mm直径的套管插入植入物，并且一旦植入物位于已准备好的关节间隙并在其中由附件或翼片所固定，则将会用气体、凝胶、流体或者变成弹性固体的流体来扩张或膨胀植入物，以便填充关节的骨(不论是胫骨、股骨还是髌骨)的原始自然空间。将通过外科医生对适当压力施用的感觉并辅以用于注射诸如欣维可(Synvisc)、海尔根(Hyalgan)和透明质酸钠注射剂(Supartz)等粘润滑剂和/或诸如利多卡因凝胶等镇痛药的经校准注射器来进行张力调整。通过先前为了清创而存在的通往关节间隙的套管，或者经由不是原始植入物组装件一部分的套管或管，可以直接地将液体插入关节本身。一旦关节得到清理，则植入物将被插入并适当地固定以避免在此挤出或脱位。这可通过植入物翼片的附接和/或对翼片加上由植入物表面覆盖物(类似于维可牢)或位于植入物较小底部的细绳所引起的预期摩擦的组合使用来实现。

[0114] 附接元件和联接器

[0115] 在一些实施方式中，植入物的附接元件包括孔洞，经该孔洞可以放置螺钉或其他联接器，以便将植入物附接到膝盖骨中的附接位点(或连接位点)。在一些实施方式中，孔洞可在关节镜下制出。在一些实施方式中，孔洞预制在植入物中。在一些实施方式中，孔洞可

基于患者的特定解剖结构而在植入前制成。在一些实施方式中，通过植入物的增强材料来加固孔洞。增强材料可以是用于加固螺孔的，具有足够硬度和 / 或抗撕裂性的聚合物。增强材料可包括金属。在一些实施方式中，不存在预先形成的孔洞，而是在植入时通过创造附接翼片自己的孔洞而用螺钉（或另一联接器）将附接翼片（它可以是植入物的非球囊部分）紧固到关节组件（骨，等）。在一些实施方式中，植入物可包括适合接纳本文其他各处所述的 U 形钉或其他联接器的翼片。

[0116] 在此所述的植入物可包括附接元件（或翼片），附接元件可继而通过联接器件附接或联接到关节的组件（无论是到骨或韧带或肌腱或其他关节组件）。联接器件（或联接器）可包括相应地进入骨孔或狭槽的螺钉、衬垫、缝合线、缝合锚（金属的和 / 或可生物降解的）、铆钉、U 形钉（有齿或没有齿）、稳定器、胶合剂、圆柱线挂勾或平整的金属片中的至少一种。联接器件可以是可重新吸收的或是不可重新吸收的。并且，连接器件可包括线绳（即，细绳）、勒绳、套索、缝合线和系索中的至少一种。线绳、勒绳、套索、缝合线和 / 或系索可以与其自身和 / 或其他联接器件相连接。线绳、勒绳、套索、缝合线和 / 或系索不仅可以用锚或者不用锚而引入骨中，而且也可以穿过外科医生想要保留的韧带、肌腱或软骨的松脱片段。

[0117] 在不干扰诸如肌腱、韧带等关节组件（或者为了使此类干扰最小化）的情况下，可能难以接近膝盖后部。因此，在一些实施方式中，植入物包括线绳、勒绳、套索和 / 或系索，它们可从植入物后部向前穿过髁间窝以与它们自己和 / 或其他联接器件连接。为了最终将植入物定位在髁附近——尤其是为了在髁后部附近捆紧该植入物，这些联接器可预先联接到植入物，并且该植入物及其联接器可配置成一旦该植入物位于其相对于髁的大体位置，则所述植入物及其联接器将从植入物前部被拉出（或捆紧）。同样地，在其中植入物被预成型的一些实施方式中，所述联接器适合于将植入物移动至其最终位置，该位置以对关节后部的关节结构的最低限度干扰（作为非限制性实例，最小切割、最小移动和 / 或最小分离）而符合髁后部。

[0118] 在一些实施方式中，植入物包括符合骨轮廓（无论是股骨、髌骨还是胫骨的髁）的裙筒（或套筒）作为联接器。

[0119] 在一些实施方式中，穿过具有经加固中心孔的翼片的螺钉可以是植入物的一部分。例如，植入物可包括聚合物覆盖的金属衬垫孔。螺钉可穿过所述孔。如图 13A- 图 13D 中所示，另一实施方式可包括具有销钉的 U 形钉。图 13A- 图 13D 描绘了适合于将植入物联接至关节骨的 U 形钉的多个视图。图 13A 描绘了植入物 20 的实施方式，该植入物 20 具有翼片 10a，该翼片 10a 使用 U 形钉 12 联接至骨。图 13B 和图 13C 描绘了在此所述具有齿 18 的 U 形钉。图 13C 描绘了使用具有齿 18 的 U 形钉 12 联接至骨的翼片 10a 的实施方式。在一些实施方式中，可使用销钉和螺钉的组合，或者其他联接器的组合。植入物可配置成允许外科医生选择若干种类型和尺寸的联接器，这是因为关于损伤的大小和深度、骨量、再生长能力和与所建议的恢复的相符性而言每个患者是不同的，并且在使用这样的植入物时，每个外科医生都有他自己的优势和舒适。

[0120] 植入物的边缘可具有依附的裙筒，用于将植入物紧固或锚固到骨（股骨）末端，但亦可具有如将在其他实施方式中讨论的可用于相似功能的一个或多个依附的翼片（或附件）。该裙筒（和 / 或翼片，和 / 或附件）可紧密贴合在股骨末端周围，或者该裙筒可通过粘合剂（例如，甲基丙烯酸甲酯，骨长入）而紧固到支撑性骨结构，或者通过 U 形钉、螺钉等机械

地连接。此外，该裙筒的下部可通过荷包缝合或者牢固绑定在裙筒外部周围的合适的丝线(有弹性的或系紧的)来紧固。

[0121] 或者，图 12A、图 12B 和 / 或图 12C 可用于描述在此所述补片植入物或单隔室膝盖植入物，其具有从球囊 6 延伸并且包括孔洞 8a、8b、8c 和 / 或翼片 10a、10b、10c、10d、10e、10f 的附件 4a、4e，孔洞和翼片可与联接器(未示出)一起使用，以便将植入物联接至膝关节的骨(可以是股骨、胫骨或髌骨)。图 12A、图 12B 和 / 或图 12C 中所示的特征是单隔室膝盖植入物(本文其他各处也有论述)和补片植入物(本文其他各处也有论述)所共有的，虽然如本文其他各处所述尺寸可能不同。

[0122] 图 13A- 图 13D 描绘了适合于将植入物 14 (诸如文中所述的那些植入物)联接至关节的骨 16 的 U 形钉 12 的多个视图。图 13A 描绘了将附件 4a 的翼片 10a 与关节的骨 16 相联接的 U 形钉 12 (其中嵌入在骨 16 中的 U 形钉 12 的部分以虚线示出)。图 13B 描绘了具有齿 18 的 U 形钉 12 的视图，所述齿 18 用于抓住植入物 14 的翼片 10a。类似地，图 13C 描绘了具有齿 18 的 U 形钉 12 的视图，所述齿 18 用于抓住植入物 14 的翼片 10a。图 13D 描绘了将植入物翼片 10a 附接到骨 16 的 U 形钉 12，虚线示出了由 U 形钉 12 和它的齿 18 压紧的翼片 10a 的部分。

[0123] 在一些实施方式中，将植入物配置成使得植入物的翼片和 / 或联接器联接到骨上没有天然软骨之处。在一些实施方式中，该植入物可由外科医生在外科手术时进行适配，从而使翼片被放置在没有天然软骨之处。

[0124] 在一些实施方式中，植入物包括翼片和挂勾，该挂勾通过在膝盖组件周围缠绕而联接到翼片，并且将翼片紧固到挂勾。在一些实施方式中，植入物包括翼片和挂勾，该挂勾通过在膝盖的髁周围缠绕而联接到翼片，并且将翼片紧固到挂勾。在一些实施方式中，植入物配置成环绕膝盖的髁，并且配置用于将植入物的第一附件紧固到植入物的第二附件。在一些实施方式中，附件由在此所述的联接器来紧固。在一些实施方式中，植入物预先形成，以便通过这样的缠绕方式而适合于髁。

[0125] 在一些实施方式中，植入物包括放置在适合于进入骨孔的球囊腔室中的甲基丙烯酸甲酯。一旦甲基丙烯酸甲酯固化成固体，这个实施方式一般会将植入物固定到骨上。

[0126] 在一些实施方式中，可以用一般可用的缝合线和缝合锚固定及定位材料，以适当的张拉将植入物锚固到骨上。

[0127] 长入特征

[0128] 除了可基于在此所述的植入物特征而发生的一般长入之外，植入物底面(邻近股骨)可包括长入基质。在一些实施方式中，邻近股骨的植入物的至少一部分包括骨长入材料。作为非限制性实例，可以使用螺钉、铆钉、稳定器、U 形钉、大头钉或者缝合线和缝合锚，通过一系列有孔洞或无孔洞的翼片来附接此类植入物。当植入物包含活软骨细胞(例如，Carticel)时，植入物的聚合物替代骨膜，作为在植入物表面上的长入基质。当植入物包含活软骨细胞(例如，Carticel)时，植入物的聚合物替代骨膜，作为在植入物实施方式中的长入基质，该长入基质配置用于随着时间的推移和 / 或在植入后露出和 / 或释放所述软骨细胞。

[0129] 骨长入底面可用于翼片或周缘的长期固定。亦即，虽然对于外科手术而言将植入物以最期望的矫正位置紧固到关节表面是很重要的，但在一些实施方式中准备骨解剖底面

也是很重要的——通过对其进行磨削而清除约0.5mm皮质骨，以便将患者潜在的氧气、血液和营养物暴露给可逐渐合并到肢骨之中的植入物的底面。由于这种康复发生在术后数周和数个月到一年的过程中，因而局部紧钉位点可能变得不那么相关并且可能潜在地不起作用。因此，在一些实施方式中，植入物可包括可生物降解（可生物吸收）聚合物或其他材料。附加地和/或另外地，联接器可以是可生物降解的。一旦植入物处于合适的位置，它将发挥以下至少一个作用：填补缺损、缓冲关节和恢复对关节组件的原始损伤。最终目标是施用最小病态治疗，该治疗将会整修患关节炎的肢体区域，仅留下很小的皮肤疤痕和对治愈的身体事故的遥远记忆。

[0130] 植入物底面材料可涉及来自Artelon或Gore-Tex研究的技术和科学的使用，这是因为各自都有优势和局限性。对于关节损伤区可能有若干种植入物选项可用，以便利用主要外科医生操作，从而最佳地适合临床恢复要求。

[0131] 在一些实施方式中，植入物包括位于配置用于接合股骨的第一部分、配置用于接合第二骨（无论是胫骨还是髌骨）、侧面部分和附件之中的至少一个上的长入补片。作为非限制性实例，长入骨片可配置用于助长和/或促进组织长入，比如骨长入。补片可以和所述部分本身一样大（无论是第一部分、第二部分、侧面部分，还是附件），或者可以小于所述部分（诸如形为条状或其他形状的补片）。长入补片可包括表现不规则性或粗糙性。长入补片可以像维可牢那样。在一些实施方式中，植入物从（并且在某些实施方式中，包括）第一附件到第二附件包括位于第一部分和/或第二部分之上的长入补片。在一些实施方式中——其中附件（通过设计和/或由于磨损和/或随着时间的推移）从与骨的附接中松开——长入补片帮助将植入物紧固到骨上。在一些实施方式中，长入补片包括附接到植入物的小珠和/或珠状元件。这样的长入补片可配置用于模拟正常松质骨网格的小梁骨空间。在一些实施方式中，小珠是各种形状的烧结小珠。在一些实施方式中，小珠是约400微米大小的烧结小珠。关于小珠大小而言，术语“约”可指1%、5%、10%、25%或50%的范围。在一些实施方式中，使第一骨和/或第二骨变粗糙以获得出血的骨从而促进长入。在一些实施方式中，对组织加以清除以促进长入。

[0132] 体现本发明特征的植入物壁可以是复合结构。例如，最内层可以是不可渗透的以阻止膨胀介质或其他填充介质的逸出，中心层可以是多孔的或者另外包含治疗剂或细胞再生剂，并且最外层可以是薄而坚固的热塑性塑料层——作为非限制性实例，诸如热塑性聚氨酯层，它具有足以允许来自中心层（或第二层）的治疗剂或细胞再生剂通过或排出的微孔率。在诸如Chronoflex或Bionate 55等聚合物层中发现能使来自中心层的治疗剂或细胞再生剂排出的微孔率程度。植入物的外壁（和/或骨接合表面）可涂覆有和/或浸渍聚合物网格，该聚合物表面喷涂在或者分层堆积在植入物的外表面（和/或骨接合表面）上以促进软骨组织再生。最外层表面涂层可包含活软骨细胞（例如，由Genzyme公司在Carticel手术中提供的软骨细胞），并且/或者可以包含具有或不具有定向基因突变的干细胞，以便增强涂层向植入物的粘附。骨接合表面可包括峰和槽。活细胞可施用于植入物表面的槽之间（和/或提供在槽内），而突出物（表面的峰）的表面区域可用于以下至少一项：空间验证、牵引和细胞保护。

[0133] 体现本发明特征的植入物可在一系列治疗中使用，其中，第一治疗涉及自体移植或最低程度操作的同种异体移植的间置组织或异种移植的使用，第二治疗涉及添加到干细

胞或软骨细胞中的同种类型的组织的使用，而第三治疗涉及当第一、第二治疗失败或无效时植入物的部署。

[0134] 药剂和治疗剂

[0135] 在一些实施方式中，植入物可包括药理性物质液泡状物。液泡状物可位于植入物的骨接合部分上。在一些实施方式中，植入物包括圆泡状物，所述圆泡状物包含活性物质，诸如药理性物质或其他活性物质。在一些实施方式中，植入物包括以诸如药理性物质（药剂）或其他活性物质（活性剂）等活性物质填充的空间。植入物可通过植入物材料（即，释放活性物质的可生物降解聚合物）的溶解，和/或通过经植入物的孔洞释放（其中聚合物对活性物质是可渗透的），和/或通过由诸如超声波或压力或其他破裂促进因素之类的促进因素所引起的液泡状物（或圆泡状物，或空间）破裂，来进行递送。植入物可在植入物实际植入关节后的某个时间，比如在一小时后、不到一天后、一天后、不到一周后、一周后、不到一个月后和/或一个月后递送活性物质。在一些实施方式中，在圆泡状物（或液泡状物，或空间）中渗透的干细胞可在植入物插入到关节之后被递送到关节间隙（或关节的组成部分）。作为非限制性实例，活性剂可包括干细胞、生长因子、抗生素和/或粘润滑剂。在一些实施方式中，植入物可以包括酶吸收性‘微小海绵’，所述酶吸收性‘微小海绵’可在向关节的植入物递送时或在此时间左右被吸出或排除。在一些实施方式中，活性物质包括医源性基因突变细胞。

[0136] 患者症状

[0137] 作为非限制性实例，需要在此所述植入物的患者的症状可包括骨关节炎或者风湿病或者痛风性关节炎。

[0138] 全膝关节成形术（双隔室）：

[0139] 在此提供了一种用于放置在股骨远端的双髁（内侧髁或外侧髁）上的植入物。在一些实施方式中，这被称为双隔室植入物，因为它覆盖了股骨的双髁。这样的植入物包括至少一个内部（或可膨胀腔室），并且在一些实施方式中，包括多个可膨胀的腔室（或内部）。

[0140] 在一些实施方式中，植入物将覆盖“H”型股骨远端软骨段（由两个股骨髁和介于其间的滑车沟组成）。植入物可吸收分散力，承受两个膝关节（包括髌骨-股骨关节和股骨-胫骨关节）的每年数百万次的循环负荷连同高达至少六倍于体重的旋转力和剪切力。

[0141] 在一些实施方式中，植入物包括位于两个髁的内侧和外侧之上的附接翼片或附接元件。在一些实施方式中，植入物包括位于髁间窝（或狭槽）内的附接翼片或附接元件。在一些实施方式中，植入物包括位于股骨远端前方之上的附接翼片或附接元件。在一些实施方式中，后部勒绳或缝合线状系索将植入物从后髁间窝的内侧朝股骨周围的另一个连接位点捆紧。

[0142] 在不干扰诸如肌腱、韧带等关节组件（或者为了使此类干扰最小化）的情况下，可能难以接近膝盖后部。因此，在一些实施方式中，植入物包括线绳、勒绳、套索和/或系索，它们可从植入物后部向前穿过髁间窝以与它们自己和/或其他联接器件连接。为了最终将植入物定位在髁附近——尤其是为了在髁后部附近捆紧该植入物，这些联接器可预先联接到植入物，并且该植入物及其联接器可配置成一旦该植入物位于其相对于髁的大体位置，则所述植入物及其联接器将从植入物前部被牵拉（或捆紧）。同样地，在其中植入物被预成型的一些实施方式中，所述联接器适合于将植入物移动至其最终位置，该位置以对关节后部的关节结构的最低限度干扰（作为非限制性实例，最小切割、最小移动和/或最小分离）而

符合髁后部。在一些实施方式中，膝盖的韧带结构的至少一部分得到保存。

[0143] 尽管本施用集中在股骨远端，但因为它通过关节与髌后及胫骨近端软骨连接，因此在此总体描述的植入物可以还以及 / 或者备选地协同胫骨和 / 或髌骨使用。此外，可以插入单独的和 / 或相连的植入物组件以恢复膝盖的天然功能。

[0144] 例如，用作双隔室植入物一部分的联接器件可包括任何在此提到或描述的连接器件。此类联接器件可包括线绳（即，细绳）、勒绳、套索、缝合线和系索中的至少一种。线绳、勒绳、套索、缝合线和 / 或系索可以与其自身和 / 或其他联接器件相连接。线绳、勒绳、套索、缝合线和 / 或系索不仅可以用锚或者不用锚而引入骨中，而且也可以穿过外科医生想要保留的韧带、肌腱或软骨的松脱片段。

[0145] 图 1 以 2D 视图描绘了配置用于双髁（股骨远端）覆盖的植入物 20 的实施方式。图 1 描绘了具有附件 4a、4b、4c、4d 的膝盖植入物 20 的实施方式，所述附件包括孔洞 8a、8b、8c、8d 以及从球囊 6 延伸的翼片 10a、10b，并且包括用以适应膝关节韧带（未示出）的狭槽 26a、26b。本文其他各处所述的联接器可用于将植入物 20 联接至股骨远端。在一些实施方式中，可只存在翼片，只存在孔洞，或只存在附件，或者存在它们的组合。在一些实施方式中，可存在将植入物联接至股骨远端的其他方式，如本文其他各处所述（缝合线、细绳、裙筒、胶合剂等）。在一些实施方式中，当将植入物紧靠股骨远端 24 放置时，联接器创造出孔洞 8a、8b、8c、8d 或其他孔洞（未示出）。在一些实施方式中，孔洞在植入之前预先形成在附件中。在一些实施方式中，孔洞如本文其他各处所述那样得到加强。如此处所示，在一些实施方式中，附件的形状和 / 或大小是不同的，以便适应髁的大小和 / 或形状的差别。例如，内侧髁往往大于外侧髁，因此预计要缠绕在内侧髁上的附件 4d 可能长于和 / 或宽于预计要缠绕在外侧髁上的附件 4c。同样地，狭槽的形状和 / 或大小和 / 或位置可能不同，以便适应关节或其他结构的韧带和 / 或肌腱以及膝关节功能，以及允许以对诸如肌腱、韧带和其他软组织或硬组织等关节组件的最低限度干扰（例如，切伤、操纵）来放置植入物。例如，狭槽 26a 经过塑形和放置以便至少适应膝盖的交叉韧带。

[0146] 图 2 描绘了具有附件 4a、4b、4c、4d 的膝盖植入物 20 的实施方式以及同一膝盖植入物的侧视图，所述附件包括孔洞 8a、8b、8c、8d 和从球囊 6 延伸的翼片 10a、10b，并且包括狭槽 26a、26b 用以适应膝关节的韧带。本文其他各处所述的联接器可用于将植入物 20 联接至股骨远端。在一些实施方式中，可只存在翼片，只存在孔洞，或只存在附件，或者存在它们的组合。在一些实施方式中，可存在将植入物联接至股骨远端的其他方式，如本文其他各处所述（缝合线、细绳、裙筒、胶合剂等）。在一些实施方式中，当将植入物紧靠股骨远端放置时，联接器创造出孔洞 8a、8b、8c、8d 或其他孔洞（未示出）。在一些实施方式中，孔洞在植入之前预先形成在附件中。在一些实施方式中，孔洞如本文其他各处所述那样得到加强。如此处所示，在一些实施方式中，附件的形状和 / 或大小是不同的，以便适应髁的大小和 / 或形状的差别。例如，内侧髁往往大于外侧髁，因此预计要缠绕在内侧髁上的附件 4d 可能长于和 / 或宽于预计要缠绕在外侧髁上的附件 4c。在图 2 中所描绘的实施方式中示出的是从侧视图看的不同的孔洞放置，其示出了用以适应髁的解剖结构和大小的差异的、在孔洞定位中的差异。同样地，狭槽的形状和 / 或大小和 / 或位置可能不同，以便适应关节或其他结构的韧带和 / 或肌腱以及膝关节功能，以及允许以对诸如肌腱、韧带和其他软组织或硬组织等关节组件的最低限度干扰（例如，切割、操纵）来放置植入物。例如，狭槽 26a 经过塑

形和放置以便至少适应膝盖的交叉韧带。此外，如图 2 中所示的实施方式的侧视图中所示，球囊具有适合于邻近股骨的第一壁 28，该第一壁 28 的厚度大于第二壁 30。在一些实施方式中，第一壁 28 配置成具有如本文其他各处所述的疗效（药理性能、康复性能和 / 或长入性能）。附加地和 / 或备选地，第二壁 30 可配置成具有疗效（药理性能、康复性能和 / 或长入性能）。

[0147] 然而，并不一定要为了给予本文其他各处所述的疗效（药理性能、康复性能和 / 或长入性能）而要求第一壁 28 和第二壁 30 的厚度不同。例如，图 3 描绘了具有附件 4a、4b、4c、4d 的膝盖植入物 20 的实施方式以及同一膝盖植入物的侧视图，所述附件包括孔洞 8a、8b、8c、8d 和从球囊 6 延伸的翼片 10a、10b，并且包括用以适应膝关节韧带（未示出）的狭槽 26a、26b。本文其他各处所述的联接器可用于将植入物 20 联接至股骨远端。在一些实施方式中，可只存在翼片，只存在孔洞，或只存在附件，或者存在它们的组合。在一些实施方式中，可存在将植入物联接至股骨远端的其他方式，如本文其他各处所述（缝合线、细绳、裙筒、胶合剂等）。在一些实施方式中，当将植入物紧靠股骨远端放置时，联接器创造出孔洞 8a、8b、8c、8d 或其他孔洞（未示出）。在一些实施方式中，孔洞在植入之前预先形成在附件中。在一些实施方式中，孔洞如本文其他各处所述那样得到加强。如此处所示，在一些实施方式中，附件的形状和 / 或大小是不同的，以便适应髁的大小和 / 或形状的差别。例如，内侧髁往往大于外侧髁，因此预计要缠绕在内侧髁上的附件 4d 可能长于和 / 或宽于预计要缠绕在外侧髁上的附件 4c。在图 3 中所描绘的实施方式中示出的是从侧视图看的不同的孔洞放置，其示出了用以适应髁的解剖结构和大小的差异的、在孔洞定位中的差异。同样地，狭槽的形状和 / 或大小和 / 或位置可能不同，以便适应关节或其他结构的韧带和 / 或肌腱以及膝关节功能，以及允许以对诸如肌腱、韧带和其他软组织或硬组织等关节组件的最低限度干扰（例如，切割、操纵）来放置植入物。例如，狭槽 26a 经过塑形和放置以便至少适应膝盖的交叉韧带。此外，如图 3 中所示的实施方式的侧视图中所示，球囊具有适合于邻近股骨的第一壁 28，该第一壁 28 的厚度大致与第二壁 30 相同。在一些实施方式中，第一壁 28 配置成具有如本文其他各处所述的疗效（药理性能、康复性能和 / 或长入性能）。附加地和 / 或备选地，第二壁 30 可配置成具有疗效（药理性能、康复性能和 / 或长入性能）。

[0148] 图 4A 描绘了具有附件 4a-4d 的膝盖植入物 20 的实施方式，所述附件包括从球囊 6 延伸的十个翼片 10a-10j 并且包括用以适应膝关节（未示出）的组件（诸如韧带或其他组织，无论是软组织、硬组织、肌腱和 / 或其他组织）的狭槽 26a。在本实施方式中，翼片 10a-10j 未被示出为具有孔洞，然而，如果使用螺钉作为联接器，则可通过螺钉在原位预钻出或形成此类孔洞。附加地和 / 或备选地，为了将植入物联接至骨（例如，股骨），可使用 U 形钉或缝合线（如本文其他各处所述）。在这种联接过程中，还可以和 / 或备选地可以使用本文其他各处所述的其他联接器。此外，为了实现与骨的最佳放置和联接，翼片的数目可以少于或多于所描绘的十个。例如，图 4B 描绘了具有附件 4a-4d 的膝盖植入物 20 的实施方式，所述附件包括从球囊 6 延伸的八个翼片 10a-10h 并且包括用以适应膝关节（未示出）的组件（诸如韧带或其他组织，无论是软组织、硬组织、肌腱和 / 或其他组织）的狭槽 26a。

[0149] 图 5 描绘了被弯曲以便模拟股骨髁周围曲率的膝盖植入物 32 的实施方式，该植入物具有从未膨胀的球囊（未示出）延伸的附件 4a-4d 并且包括用以适应膝关节（未示出）的组件（诸如韧带或其他组织，无论是软组织、硬组织、肌腱和 / 或其他组织）的狭槽 26a、26b。

该植入物可包括额外的弯曲和/或狭槽以适应其他的韧带和/或组织。在一些实施方式中，该植入物配置成符合关节的各种硬组织和/或软组织，比如骨、韧带、肌腱等。在一些实施方式中，一旦将该植入物定位在关节内，就会使球囊膨胀。在其他实施方式中，球囊在定位于关节内之前已部分膨胀。在其他实施方式中，球囊在定位于关节内之前至少部分地膨胀。在一些实施方式中，球囊在定位于关节内之前完全膨胀。在一些实施方式中，植入物配置成允许操作者原位调整球囊膨胀量(无论是通过添加膨胀介质还是移除膨胀介质，或两者都可，或两者皆不)。如本文其他各处所述的联接器可用于将植入物 32 联接至股骨远端。

[0150] 图 6A 描绘了弯曲成模拟股骨髁周围曲率的膝盖植入物 32 的实施方式的俯视图，该植入物具有从两个已膨胀的球囊 6、34 延伸的附件 4a-4d 并且包括用以适应膝关节组件的狭槽 26a。图 6B 描绘了弯曲成模拟股骨髁周围曲率的膝盖植入物 32 的同一实施方式的自底向上或前向斜视图，该植入物具有从两个已膨胀的球囊 6、32 延伸的附件 4a-4d 并且包括用以适应膝关节组件的狭槽 26a。如本文其他各处所述的联接器可用于将植入物 32 联接至股骨远端。如图 6A 和图 6B 中所示，在一些实施方式中，附件 4a-4d 的形状和/或大小是不同的以适应髁的大小和/或形状的差别。例如，内侧髁往往大于外侧髁，因此预计要缠绕在内侧髁周围的附件 4d 可能长于和/或宽于预计要缠绕在外侧髁周围的附件 4c。同样地，适合放置在内侧髁之上的球囊 34 的尺寸可以是不同于外侧髁上的球囊 6 的大小和形状(内侧髁更大，因此球囊 34 在那个位置上可以更大)。备选地和/或附加地，如本文其他各处所述，由于诸如损伤、重新对准需要、损伤等各种原因，相对于另一个髁所需的重建，可能需要对一个髁进行更多重建，因此一个球囊(或其一部分)中的膨胀介质可不同于另一球囊(或同一个球囊内的另一腔室)中的膨胀介质，或者可能在一个位置需要与另一位置处形状不同的球囊。在此提供的实施方式可以基于填充物、附件、球囊、壁的材料以及植入物及其组件的尺寸和腔室的选择而适应这些需求。

[0151] 图 7 描绘了弯曲成模拟股骨髁周围曲率的膝盖植入物 32 的实施方式的俯视图，该植入物具有从已膨胀的球囊 6 延伸的附件 4a-4d 并且包括用以适应膝关节组件的狭槽。本文其他各处所述的联接器可用于将植入物 32 联接至股骨远端。如此处所示，在一些实施方式中，附件 4a-4d 的形状和/或大小是不同的以适应髁的大小和/或形状的差别。例如，内侧髁往往大于外侧髁，因此预计要缠绕在内侧髁周围的附件 4d 可能长于和/或宽于预计要缠绕在外侧髁周围的附件 4c。同样地，适合放置在内侧髁之上的球囊部分的尺寸可以是不同于外侧髁上的球囊部分的大小和形状(内侧髁更大，因此球囊在那个位置上可以更大)。备选地和/或附加地，如本文其他各处所述，由于诸如损伤、重新对准需要、损伤等各种原因，相对于另一个髁所需的重建，可能需要对一个髁进行更多重建，因此在具有单个球囊中的多个膨胀腔室的植入物实施方式的部分或腔室中，膨胀介质可能是不同的，或者可能需要非对称式球囊。在此提供的实施方式可以基于填充物、附件、球囊、壁的材料以及植入物及其组件的尺寸和腔室的选择而适应这些需求。

[0152] 图 8 描绘了弯曲成模拟至少一个股骨髁周围曲率的膝盖植入物 32 的实施方式的侧视图，该植入物具有从未膨胀的球囊(未示出)延伸的附件 4b、4d。这种描绘覆盖了最大预期的股骨末端轮廓；其他复述可以更小，或者更短地覆盖股骨弯曲的周界的有限区域。

[0153] 图 9A 描绘了在股骨 24 的至少一个髁 22 周围弯曲的膝盖植入物 20 的实施方式的侧视图，该植入物 20 具有从未膨胀的或最低限度膨胀的球囊 6 延伸的附件 4b、4d。在此视

图中，膝盖基本上伸展(笔直)地定位，从而示出膝盖的胫骨 36、腓骨 38 和髌骨 40。注意，虽然在位于膝盖中的植入物的真实描绘中将会存在其他关节结构和膝盖结构，但是为了易于理解植入物和关节的相对(和大致)位置和放置，植入物和骨的此视图已大大简化。如本文其他各处所述的联接器可用于将植入物 20 联接至股骨远端 24 和 / 或它的髁 22(在本图像中是内侧髁，至少是因为它主要是关节和植入物的单侧视图)。为简单起见，图 9A 和所描绘的植入物实施方式示出了相对两个膝盖关节(股骨和胫骨之间，以及股骨和髌骨之间)的其他表面的股骨，接触面积根据活动、力和运动范围而改变。其他植入物的复述可应用于相反表面。

[0154] 图 9B 描绘了在股骨 24 的至少一个髁 22 周围弯曲的膝盖植入物 20 的实施方式的侧视图，植入物 20 具有从已膨胀球囊 6 延伸的附件 4b、4d。在此视图中，膝盖基本上以伸展状态(笔直)放置，从而示出了膝盖的胫骨 36、腓骨 38 和髌骨 40。注意，虽然在位于膝盖中的植入物的真实描绘中将会存在其他关节结构和膝盖结构，但是为了易于理解植入物和关节的相对(和大致)位置和放置，植入物和骨的此视图已大大简化。如本文其他各处所述的联接器可用于将植入物 20 联接至股骨远端 24 和 / 或它的髁 22 (在本图像中是内侧髁，至少是因为它主要是关节和植入物的单侧视图)。与在其中球囊未膨胀或最低限度膨胀的图 9A 相比，在其中球囊得到膨胀的图 9B 中，当球囊 6 膨胀时，球囊第二壁 30 更靠近和 / 或接触胫骨平台 42 (关节表面)。同样地，图 9C 描绘了在股骨 24 的至少一个髁 22 周围弯曲的膝盖植入物 20 的实施方式的侧视图，植入物 20 具有从已膨胀球囊 6 延伸的附件 4b、4d 并且具有将附件 4b、4d 联接至股骨的联接器 44a、44b(作为非限制性实例，其可以是 U 形钉或螺钉)。在此视图中，膝盖基本上以伸展状态(笔直)放置，从而示出了膝盖的胫骨 36、腓骨 38 和髌骨 40。在如图 9B 中所示的已膨胀球囊可填充关节表面的现有病理缺损的情况下，还可以构建已扩张的和特定的球囊位置的介质以及植入物材料的硬度，以便促使相对的骨(例如，股骨和胫骨)进入更自然的肢体对齐，比如六(6)度外翻。然而，如通过检查和测量正常相对侧所示，假如正接受治疗的患者在受影响膝盖处有不同于正常的变化，则可根据群体指标来调整植入物的膨胀和压力或者球囊位置，从而根据所考虑的临床病例来定制该植入物。固定器件可以适当地施用于膝盖从完全伸展(0 度)到完全屈曲(通常是 135 度)的各种运动间隔范围。

[0155] 图 10A 描绘了在股骨 24 的至少一个髁 22 周围弯曲的膝盖植入物 20 的实施方式的侧视图并且示出了当膝关节稍微屈曲时朝髌骨 40 前向移动的膨胀介质 46，植入物 20 具有从已膨胀球囊 6 延伸的附件 4b、4d。同样地，图 10B 描绘了在股骨 24 的至少一个髁 22 周围弯曲的膝盖植入物 20 的实施方式的侧视图，并且示出了当膝关节稍微屈曲时朝髌骨 40 前向移动的膨胀介质 46，植入物 20 具有从已膨胀球囊 6 延伸的附件 4b、4d 并且具有将附件 4b、4d 联接至股骨 24 的联接器 44a、44b (作为非限制性实例，其可以是 U 形钉或螺钉)。

[0156] 在本文提供的对双隔室植入物的所有描述中，可以替代地将植入物配置成联接至胫骨和 / 或髌骨或从胫骨和 / 或髌骨露出。在本文提供的对双隔室植入物的所有描述中，可以替代地将植入物配置成联接至胫骨。意图和理解是，在某些实施方式中通过调整而使植入物适合这一目的，以便顾及胫骨的尺寸差异。在此提供的大多数描述是针对将植入物联接至股骨的实施方式，然而，这主要是为了便于描述和连贯，并且不排除其中植入物联接至胫骨的实施方式。同样地，如本文其他各处所述，存在可将植入物联接到(至少)两个骨，

例如联接至胫骨和股骨二者的实施方式。

[0157] 补片

[0158] 植入物的一些实施方式配置用于修复孤立性损伤，其中如在骨坏死中的骨软骨缺损在需要用补片“填充”的软骨中形成盆坑。在此提供的植入物可适应于软骨缺损的各种大小的损伤，所述植入物可具有是以下至少一种的球囊：直径至多约 0.5cm，直径至多约 0.75cm，直径至多约 1cm，直径至多约 1.25cm，直径至多约 1.5cm，直径至多约 1.75cm，直径至多约 2cm，直径至多约 2.25cm，直径至多约 2.5cm，直径至多约 2.75cm，直径至多约 3cm，直径至多约 3.25cm，直径至多约 3.5cm，直径至多约 3.75cm，沿球囊最长长度至多约 0.5cm 长度，沿球囊最长长度至多约 0.75cm 长度，沿球囊最长长度至多约 1cm 长度，沿球囊最长长度至多约 1.25cm 长度，沿球囊最长长度至多约 1.5cm 长度，沿球囊最长长度至多约 1.75cm 长度，沿球囊最长长度至多约 2cm 长度，沿球囊最长长度至多约 2.25cm 长度，沿球囊最长长度至多约 2.5cm 长度，沿球囊最长长度至多约 2.75cm 长度，沿球囊最长长度至多约 3cm 长度，沿球囊最长长度至多约 3.25cm 长度，沿球囊最长长度至多约 3.5cm 长度，沿球囊最长长度至多约 3.75cm 长度，沿球囊最长长度至多约 4cm 长度，直径至多约 4.25cm，直径至多约 4.5cm，直径至多约 4.75cm，直径至多约 5cm，直径至多约 5.25cm，直径至多约 5.5cm，直径至多约 5.75cm，直径至多约 6cm，直径至多约 6.25cm，直径至多约 6.5cm，直径至多约 6.75cm，直径至多约 7cm，直径至多约 7.25cm，直径至多约 7.5cm，直径至多约 7.75cm，直径至多约 8cm，沿球囊最长长度至多约 3cm 长度，沿球囊最长长度至多约 3.25cm 长度，沿球囊最长长度至多约 3.5cm 长度，沿球囊最长长度至多约 3.75cm 长度，沿球囊最长长度至多约 4cm 长度，沿球囊最长长度至多约 4.25cm 长度，沿球囊最长长度至多约 4.5cm 长度，沿球囊最长长度至多约 4.75cm 长度，沿球囊最长长度至多约 5cm 长度，沿球囊最长长度至多约 5.25cm 长度，沿球囊最长长度至多约 5.5cm 长度，沿球囊最长长度至多约 5.75cm 长度，沿球囊最长长度至多约 6cm 长度，沿球囊最长长度至多约 6.25cm 长度，沿球囊最长长度至多约 6.5cm 长度，沿球囊最长长度至多约 6.75cm 长度，沿球囊最长长度至多约 7cm 长度，沿球囊最长长度至多约 7.25cm 长度，沿球囊最长长度至多约 7.5cm 长度，沿球囊最长长度至多约 7.75cm 长度以及沿球囊最长长度至多约 8cm 长度。在此关于球囊尺寸——无论是长度还是直径——所使用的术语“约”意指 0.1cm、0.2cm、0.25cm、0.5cm 和 1cm 中的至少一种变化。

[0159] 因此，在此提供了配置用于修补骨软骨缺损的植入物。缺损可能是由于损伤、应力、自然发生而产生的，以及 / 或者可能是在医疗过程中由专业医师所造成的或增大的。在一些实施方式中，该植入物可称为补片，该补片具有在此所述的球囊和附接元件（或多个元件——其可称为附件），并且大小可设为适于以口盖方式装入缺损内。在一些实施方式中，植入物可包括本文其他各处所述的球囊和附接元件，并且可配置用于敷设在缺损（全缺损或部分缺损）之上。在一些实施方式中，在此所述用于修补或修复骨软骨缺损的植入物可称为补片或补片植入物。

[0160] 在一些实施方式中，可基于个别患者需求而预先选择球囊尺寸的大小，并且球囊大小（作为非限制性实例，尺寸、几何结构、长度、深度）是预设的。在一些实施方式中，球囊可包括多个腔室，所述腔室可以得到选择性的膨胀（或收缩）来原位填充缺损或者在即将植入之前得到选择性的膨胀，以便根据植入时的需要来调整植入物的球囊大小（作为非限制性实例，尺寸、长度、宽度、深度、几何结构）。一些实施方式的球囊（或其任何腔室）可原位进

行二次膨胀或收缩(或两者皆可)。

[0161] 图 11A、图 11B 和 / 或图 11C 可用于描绘在此所述的补片植入物,其具有从球囊 6(图 11A 中未示出)延伸的附件 4a、4c,并且包括可与联接器(未示出)一同用于将植入物联接至膝关节骨(其可以是股骨、胫骨或髌骨)的孔洞 8a-8h 和 / 或翼片 10a-10f。图 11A、图 11B 和 / 或图 11C 中所示的特征为(本文其他各处所讨论的)单隔室膝盖植入物和 / 或补片植入物所共有,尽管尺寸如本文所述可能有所不同。因此,图 11A、图 11B 和 / 或图 11C 可用于描述单隔室膝盖植入物和 / 或补片植入物。图 11A 描绘了弯曲成模拟股骨的一个髁周围曲率的补片植入物 2 的实施方式,该植入物 2 具有从未膨胀的球囊(未示出)延伸的附件 4a、4c,并且包括翼片 10a-10f 和 / 或孔洞 8a-8h,所述翼片和 / 或孔洞可与联接器(未示出,在本文其他各处有述)一同用于将植入物 2 联接至膝关节的股骨。图 11B 描绘了弯曲成模拟股骨的一个髁周围曲率的补片植入物 2 的实施方式,该植入物 2 具有从已膨胀球囊 6 延伸的附件 4a、4c,并且包括翼片 10a-10f 和 / 或孔洞 8a-8h,所述翼片和 / 或孔洞可与联接器(未示出,在本文其他各处有述)一同用于将植入物 2 联接至膝关节的股骨。图 11C 描绘了弯曲成模拟股骨的一个髁周围曲率的补片植入物 2 的实施方式的滑移面的底视图,该植入物 2 具有从已膨胀球囊 6 延伸的附件 4a、4c,并且包括翼片 10a-10f 和 / 或孔洞 8a-8h,所述翼片和 / 或孔洞可与联接器(未示出,在本文其他各处有述)一同用于将植入物 2 联接至膝关节的股骨。在一些实施方式中,植入物配置成联接至胫骨。在一些实施方式中,植入物配置成联接至股骨的滑车沟。在一些实施方式中,植入物配置成联接至股骨的髁的仅一部分。

[0162] 图 12A、图 12B 和 / 或图 12C 可用于描绘在此所述的补片植入物,其具有从球囊 6 延伸的附件 4a、4c,并且包括可与联接器(未示出)一同用于将植入物联接至膝关节骨(其可以是股骨、胫骨或髌骨)的孔洞 8a、8b、8c 和 / 或翼片 10a、10b、10c、10d、10e、10f。图 12A、图 12B 和 / 或图 12C 中所示的特征为(本文其他各处所讨论的)单隔室膝盖植入物和 / 或补片植入物所共有,尽管尺寸如本文所述可能有所不同。因此,图 12A、图 12B 和 / 或图 12C 可用于描述单隔室膝盖植入物和 / 或补片植入物。图 12A 描绘了(单隔室或补片)植入物 2 的实施方式的底视图,该植入物具有从球囊 6 延伸的附件 4a、4c,并且包括孔洞 8a、8b、8c,所述孔洞可与联接器(未示出)一同用于将植入物 2 联接至膝关节的股骨。图 12B 描绘了(单隔室或补片)植入物 2 的实施方式的底视图,该植入物具有从球囊 6 延伸的附件 4a、4c,并且包括翼片 10a、10b 和孔洞 8a,所述翼片和孔洞可与联接器(未示出)一同用于将植入物联接至膝关节的股骨。图 12C 描绘了(单隔室或补片)植入物 2 的实施方式的底视图,该植入物具有从球囊 6 延伸的附件 4a、4c,并且包括翼片 10c、10d、10e 和 10f 以及孔洞 8a,所述翼片和孔洞可与联接器(未示出)一同用于将植入物联接至膝关节的股骨。在一些实施方式中,植入物配置成联接至胫骨。在一些实施方式中,植入物配置成联接至股骨的滑车沟。在一些实施方式中,植入物配置成联接至股骨的髁的仅一部分。在一些实施方式中,植入物配置成联接至髌骨。在任何实施方式中,球囊 6 可从植入物的一个表面延伸作为病灶隆起物,用以填充缺损、空间,或者用以辅助对齐矫正,或者球囊可以如图 2 和图 3 分别示出的差异那样是全厚度的。在任何实施方式中,可存在单个或多个主要球囊——如果其脱离类似圆泡状物包装膜的主表面,并且可存在包含材料基质中的气体、凝胶或固体的微小球囊或液泡状物。

[0163] 在本文提供的对补片植入物的所有描述中，可以替代地将植入物配置成联接至胫骨或股骨或或髌骨。意图和理解是，在某些实施方式中通过调整而使植入物适合这一目的，以便顾及这些骨的尺寸差异。在此提供的大多数描述是针对将植入物联接至股骨的实施方式，然而，这主要是为了便于描述和连贯，并且不排除其中植入物联接至胫骨（或其他骨）的实施方式。同样地，如本文其他各处所述，存在可将植入物联接到（至少）两个骨，例如联接至胫骨和股骨二者的实施方式。

[0164] 局部膝盖关节成形术（单隔室）

[0165] 除了全膝型（双隔室）和补片植入物以外，还有这样的植入物：其用来对需要附加缓冲的内翻或外翻膝盖的内侧或外侧股骨髁进行覆盖和调整对齐，以便再造自然的六度膝外翻。

[0166] 因此，本文提供了用于放置在至少股骨远端的至少一个髁上的植入物（单隔室植入物——因其覆盖股骨的单个髁而如此命名）。该植入物可配置成放置在外侧髁上。该植入物可配置成放置在内侧髁上。该植入物可配置成放置在内侧髁或外侧髁中的任一个上。可在同一膝盖中放置两个单隔室植入物，一个在内侧髁上，一个在外侧髁上。

[0167] 图 11A- 图 12C 描绘了单隔室植入物的实施方式。在一些实施方式中，单隔室植入物包括是以下至少一种的球囊：直径至多约 1.5cm，直径至多约 1.75cm，直径至多约 2cm，直径至多约 2.25cm，直径至多约 2.5cm，直径至多约 2.75cm，直径至多约 3cm，直径至多约 3.25cm，直径至多约 3.5cm，直径至多约 3.75cm，直径至多约 4cm，直径至多约 4.25cm，直径至多约 4.5cm，直径至多约 4.75cm，直径至多约 5cm，直径至多约 5.25cm，直径至多约 5.5cm，直径至多约 5.75cm，直径至多约 6cm，直径至多约 6.25cm，直径至多约 6.5cm，直径至多约 6.75cm，直径至多约 7cm，直径至多约 7.25cm，直径至多约 7.5cm，直径至多约 7.75cm，直径至多约 8cm，沿球囊最长长度至多约 3cm 长度，沿球囊最长长度至多约 3.25cm 长度，沿球囊最长长度至多约 3.5cm 长度，沿球囊最长长度至多约 3.75cm 长度，沿球囊最长长度至多约 4cm 长度，沿球囊最长长度至多约 4.25cm 长度，沿球囊最长长度至多约 4.5cm 长度，沿球囊最长长度至多约 4.75cm 长度，沿球囊最长长度至多约 5cm 长度，沿球囊最长长度至多约 5.25cm 长度，沿球囊最长长度至多约 5.5cm 长度，沿球囊最长长度至多约 5.75cm 长度，沿球囊最长长度至多约 6cm 长度，沿球囊最长长度至多约 6.25cm 长度，沿球囊最长长度至多约 6.5cm 长度，沿球囊最长长度至多约 6.75cm 长度，沿球囊最长长度至多约 7cm 长度，沿球囊最长长度至多约 7.25cm 长度，沿球囊最长长度至多约 7.5cm 长度，沿球囊最长长度至多约 7.75cm 长度，以及沿球囊最长长度至多约 8cm 长度。在此关于球囊尺寸——无论是长度还是直径——所使用的术语“约”意指 0.1cm、0.2cm、0.25cm、0.5cm 和 1cm 中的至少一种变化。

[0168] 在一些实施方式中，植入物包括位于髁的前部和 / 或后部以及 / 或者内侧和 / 或外侧（和 / 或它们的一些组合）之上的附接翼片或附接元件。在一些实施方式中，植入物包括处在髁间窝中的附接翼片或附接元件。在一些实施方式中，植入物包括处在股骨远端前部之上的附接翼片或附接元件。

[0169] 在不干扰诸如肌腱、韧带等关节组件（或者为了使此类干扰最小化）的情况下，可能难以接近膝盖后部。因此，在一些实施方式中，植入物包括线绳、勒绳、套索和 / 或系索，它们可从植入物后部向前穿过髁间窝以与它们自己和 / 或其他联接器件连接。在一些实施

方式中，后部勒绳或缝合线状系索将植入物从后髁间窝内部朝向股骨周围的另一连接位点捆紧。为了最终将植入物定位在髁附近——尤其是为了在髁后部附近捆紧该植入物，这些联接器可预先联接到植入物，并且该植入物及其联接器可配置成一旦该植入物位于其相对于髁的大体位置，则所述植入物及其联接器将从植入物前部被牵拉(或捆紧)。同样地，在其中植入物被预成型的一些实施方式中，所述联接器适合于将植入物移动至其最终位置，该位置以对关节后部的关节结构的最低限度干扰(作为非限制性实例，最小切割、最小移动和/或最小分离)而符合髁后部。在一些实施方式中，膝盖的韧带结构的至少一部分得到保存。

[0170] 图 10A 描绘了在股骨 24 的至少一个髁 22 周围弯曲的膝盖植入物 20 的实施方式的侧视图并且示出了当膝关节稍微屈曲时朝髌骨 40 前向移动的膨胀介质 46，植入物 20 具有从已膨胀球囊 6 延伸的附件 4b、4d。同样地，图 10B 描绘了在股骨 24 的至少一个髁 22 周围弯曲的膝盖植入物 20 的实施方式的侧视图，并且示出了当膝关节稍微屈曲时朝髌骨 40 前向移动的膨胀介质 46，植入物 20 具有从已膨胀球囊 6 延伸的附件 4b、4d 并且具有将附件 4b、4d 联接至股骨 24 的联接器 44a、44b (作为非限制性实例，其可以是 U 形钉或螺钉)。

[0171] 图 11A、图 11B 和/或图 11C 可用于描绘在此所述的单隔室植入物(或者可互换使用的术语单隔室膝盖植入物)，其具有从球囊 6 (图 11A 中未示出) 延伸的附件 4a、4c，并且包括可与联接器(未示出) 一同用于将植入物联接至膝关节骨(其可以是股骨、胫骨或髌骨)的孔洞 8a-8h 和/或翼片 10a-10f。图 11A、图 11B 和/或图 11C 中所示的特征为(本文其他各处所讨论的)单隔室膝盖植入物和/或补片植入物所共有，尽管尺寸如本文所述可能有所不同。因此，图 11A、图 11B 和/或图 11C 可用于描述单隔室膝盖植入物和/或补片植入物。图 11A 描绘了弯曲成模拟股骨的一个髁周围曲率的单隔室膝盖植入物 2 的实施方式，该植入物 2 具有从未膨胀的球囊(未示出) 延伸的附件 4a、4c，并且包括翼片 10a-10f 和/或孔洞 8a-8h，所述翼片和/或孔洞可与联接器(未示出，在本文其他各处有述)一同用于将植入物 2 联接至膝关节的股骨。图 11B 描绘了弯曲成模拟股骨的一个髁周围曲率的单隔室膝盖植入物 2 的实施方式，该植入物具有从已膨胀球囊 6 延伸的附件 4a、4c，并且包括翼片 10a-10f 和/或孔洞 8a-8h，所述翼片和/或孔洞可与联接器(未示出，在本文其他各处有述)一同用于将植入物 2 联接至膝关节的股骨。图 11C 描绘了弯曲成模拟股骨的一个髁周围曲率的单隔室膝盖植入物 2 的实施方式的底视图，该植入物 2 具有从已膨胀球囊 6 延伸的附件 4a、4c，并且包括翼片 10a-10f 和/或孔洞 8a-8h，所述翼片和/或孔洞可与联接器(未示出，在本文其他各处有述)一同用于将植入物 2 联接至膝关节的股骨。

[0172] 在一些实施方式中，单隔室植入物包括是以下至少一种的附接翼片：沿植入物最长长度至多约 15cm 长度，沿植入物最长长度至多约 15.25cm 长度，沿植入物最长长度至多约 15.5cm 长度，沿植入物最长长度至多约 15.75cm 长度，沿植入物最长长度至多约 16cm 长度，沿植入物最长长度至多约 16.25cm 长度，沿植入物最长长度至多约 16.5cm 长度，沿植入物最长长度至多约 16.75cm 长度，沿植入物最长长度至多约 17cm 长度，沿植入物最长长度至多约 17.25cm 长度，沿植入物最长长度至多约 17.5cm 长度，沿植入物最长长度至多约 17.75cm 长度，沿植入物最长长度至多约 18cm 长度，沿植入物最长长度至多约 18.25cm 长度，沿植入物最长长度至多约 18.5cm 长度，沿植入物最长长度至多约 18.75cm 长度，沿植入物最长长度至多约 19cm 长度，沿植入物最长长度至多约 19.25cm 长度，沿植入物最长长度至多约 19.5cm 长度，沿植入物最长长度至多约 19.75cm 长度，沿植入物最长长度至多约

20cm长度，沿植入物最长长度至多约20.25cm长度，沿植入物最长长度至多约20.5cm长度，沿植入物最长长度至多约20.75cm长度，沿植入物最长长度至多约21cm长度，沿植入物最长长度至多约21.25cm长度，沿植入物最长长度至多约21.5cm长度，沿植入物最长长度至多约21.75cm长度，沿植入物最长长度至多约22cm长度，沿植入物最长长度至多约22.25cm长度，沿植入物最长长度至多约22.5cm长度，沿植入物最长长度至多约22.75cm长度，沿植入物最长长度至多约23cm长度，沿植入物最长长度至多约23.25cm长度，沿植入物最长长度至多约23.5cm长度，沿植入物最长长度至多约23.75cm长度，沿植入物最长长度至多约24cm长度，沿植入物最长长度至多约24.25cm长度，沿植入物最长长度至多约24.5cm长度，沿植入物最长长度至多约24.75cm长度，沿植入物最长长度至多约25cm长度，沿植入物最长长度至多约25.25cm长度，沿植入物最长长度至多约25.5cm长度，沿植入物最长长度至多约25.75cm长度，以及沿植入物最长长度至多约26cm长度。在此关于植入物长度尺寸所使用的术语“约”意指0.1cm、0.2cm、0.25cm、0.5cm和1cm中的至少一种变化。

[0173] 在一些实施方式中，单隔室植入物的长度大于其宽度，且植入物的较长部分从髁的前方向髁的后方缠绕。在一些实施方式中，所述植入物在其外边缘上的长度要长于在最接近滑车沟的内边缘上的长度(不论是使用在外侧髁还是内侧髁上)。

[0174] 图12A、图12B和/或图12C可用于描绘在此所述的单隔室膝盖植入物(单隔室植入物)，其具有从球囊6延伸的附件4a、4c，并且包括可与联接器(未示出)一同用于将植入物联接至膝关节骨(其可以是股骨、胫骨或髌骨)的孔洞8a、8b、8c和/或翼片10a、10b、10c、10d、10e、10f。图12A、图12B和/或图12C中所示的特征为(本文其他各处所讨论的)单隔室膝盖植入物和/或补片植入物所共有，尽管尺寸如本文所述可能有所不同。因此，图12A、图12B和/或图12C可用于描述单隔室膝盖植入物和/或补片植入物。图12A描绘了(单隔室或补片)植入物2的实施方式的底视图，该植入物具有从球囊6延伸的附件4a、4c，并且包括孔洞8a、8b、8c，所述孔洞可与联接器(未示出)一同用于将植入物2联接至膝关节的股骨。图12B描绘了(单隔室或补片)植入物2的实施方式的底视图，该植入物具有从球囊6延伸的附件4a、4c，并且包括翼片10a、10b和孔洞8a，所述翼片和孔洞可与联接器(未示出)一同用于将植入物联接至膝关节的股骨。图12C描绘了(单隔室或补片)植入物2的实施方式的底视图，该植入物具有从球囊6延伸的附件4a、4c，并且包括翼片10c、10d、10e和10f以及孔洞8a，所述翼片和孔洞可与联接器(未示出)一同用于将植入物联接至膝关节的股骨。

[0175] 在本文提供的对单隔室植入物的所有描述中，可以替代地将植入物配置成联接至胫骨或股骨或或髌骨。意图和理解是，在某些实施方式中通过调整而使植入物适合这一目的，以便顾及特定骨的尺寸差异。在此提供的大多数描述是针对将植入物联接至股骨的实施方式，然而，这主要是为了便于描述和连贯，并且不排除其中植入物联接至胫骨(或其他骨)的实施方式。同样地，如本文其他各处所述，存在可将植入物联接到(至少)两个骨，例如联接至胫骨和股骨二者的实施方式。

[0176] 半月板置换或修复，以及固体、刚性或准刚性组件：

[0177] 此处提供了一种植入物，其包括球囊，该球囊具有第一腔室和第二腔室。该植入物可以是本文中描述的双隔室、单隔室和补片植入物中的任何一种。第二腔室可配置用于置换和/或部分地置换纤维软骨半月板损失。植入物可具有两个腔叶，所述腔叶可替代地描

述为半径彼此并置的两个重叠球囊。植入物可配置成通过提供半月板楔而在股骨与胫骨之间提供稳定性。在一些实施方式中，植入物具有设置用于置换和 / 或部分地置换纤维软骨半月板损失的部分。这种实施方式可能不需要第二腔室。

[0178] 在一些实施方式中，植入物的腔室被配置用于接纳固体片，该固体片配置用于恢复关节和 / 或骨对齐。在一些实施方式中，腔室配置用于接纳多个固体片，其中每个固体片都可以用来增加第一骨与第二骨之间的空间，以便恢复和 / 或改善关节和 / 或骨对齐。固体片可以是楔形的，或者可以提供为各种大小和 / 或形状。固体片可以单独或一起用在植入物的一个腔室或多个腔室中。固体片(或者多个片)可用于将相邻的骨棘推至期望的牵张和 / 或对齐，以便恢复和 / 或改善关节和 / 或骨对齐。固体片可以放置在植入物的腔室中，该腔室可以封闭或部分地封闭所述片以将该片保持在适当位置。在一些实施方式中，可以提供一块生物相容性材料(诸如 PMMA 或其它类骨替代物)，并且其可由外科医生(通过雕刻或其他成形方法)形成为期望的形状。形成的固体片继而可以置于植入物的腔室中，该腔室可以封闭或部分地封闭所述片以将该片保持在适当位置。

[0179] 在一些实施方式中，膨胀介质是甲基丙烯酸甲酯或其它生物相容性硬化物质，其在最初放入腔室时可以流动，并且硬化成刚性片(或固体片)。甲基丙烯酸甲酯或其它生物相容性硬化物质可能与腔室的形状相符，或者可能与骨和 / 或其他关节结构之间的空间的形状相符。甲基丙烯酸甲酯或其它生物相容性硬化物质可通过由外科医生使用工具和 / 或压力来影响由甲基丙烯酸甲酯或其它生物相容性硬化物质在硬化后形成的刚性片的最终形状而符合于外科医生所选的形式。

[0180] 固体片(无论是原位形成的，还是由外科医生形成的或者预成形的)可由植入物缓冲。植入物可在固体片与股骨之间包含可膨胀腔室。植入物可在固体片与胫骨之间包含可膨胀腔室。植入物可在固体片与髌骨之间包含可膨胀腔室。植入物可在固体片与第二骨之间包含可膨胀腔室。植入物可在固体片与股骨之间包含垫片作为缓冲垫。植入物可在固体片与胫骨之包含垫片作为缓冲垫。植入物可在固体片与髌骨之间包含垫片作为缓冲垫。

[0181] 固体片可提供以下至少一项：约 1 度的关节矫正，约 2 度的关节矫正，约 3 度的关节矫正，约 4 度的关节矫正，约 5 度的关节矫正，约 6 度的关节矫正，约 7 度的关节矫正，约 8 度的关节矫正，约 9 度的关节矫正，以及约 10 度的关节矫正。关于关节矫正的角度，术语“约”可以指 1%、5%、10%、25% 或 50% 的范围。

[0182] 植入物可用在多种关节中，其中植入物置换骨表面上的骨并且缓冲任何两块骨的关节末端之间的相互作用，如在股骨胫骨和股骨髌骨界面处的相互作用。在植入物替代或加强关节软骨的情况下，可以降低或增强刚性以便最大化如通过两个相对的壁和预计的内部空间并连同考虑适应或扩增现有关节韧带、肌腱或现有关节韧带、肌腱的缺乏的任何关节外科手术重建而实现的在运动中产生的构形变化。在植入物 10 例如已发挥其使组织再生的用途之后，或者如果另一临床状况需要将该植入物移除，则植入物 10 可通过微创手术被收缩和移除。然而，即使已经丧失膨胀，在临床上可能也并不一定要将植入物移除，这是因为修补受损软骨和递送恢复性细胞这两个剩余功能可使植入物的保留成为合理的。

[0183] 在许多实施方式中，植入物(或者其一部分，诸如一个或多个球囊)是将会允许关节运动趋于正常的承重垫片，无论是如在骨关节炎中那样广泛地还是如在骨坏死缺损或局部创伤中那样局限地填充由完全坍塌的外周关节骨所留下的空间或是切除的软骨近端表

面的空间，情况都是这样。壁可以用作膜，用于将活细胞在骨软骨缺损处附近保留足够长的时间，从而使细胞附着（例如，24 小时）或深度粘附（长达 28 天）或恢复正常（长达一年）。当治疗下肢远端关节时，预计承重将会增大。

[0184] 套件

[0185] 在此提供了包含文中所述多种植入物的套件。套件可包含多种尺寸的单一类型植入物。套件可包含各种植入物类型，诸如文中所述的补片型植入物、单隔室型植入物和 / 或双隔室型植入物。套件可包含多种联接器，所述联接器可由外科医生按照他的舒适和专业技能来选择，和 / 或基于特定病人解剖结构和 / 或需要来选择。套件还可以包含可独特地协助将植入物植入患者体内的任何插入工具和 / 或手术工具。

[0186] 植入方法

[0187] 本文中所提供的植入物的植入方法将取决于预计要通过使用植入物而重建的关节表面的大小。在一些实施方式中，可将关节内窥镜通过 0.5cm 的创口插入膝关节的一侧，而植入物则插入到大小为 1-10cm 的相对的关节线创口中。可以首先对关节进行检查和清创，根据需要进行关节镜下滑膜切除术，软骨成形术和半月板切除术。在全身麻醉下伴随不同程度的膝盖屈曲的附加牵张可以允许植入物的引入、系统性外周附接、平衡和膨胀。

[0188] 在一些实施方式中，可以根据患者的特定需要而选择性地使植入物膨胀。在一些实施方式中，如本文所述，植入物的内部的填充物可能是刚性的、半刚性的、流体、空气或者它们的组合。在一些实施方式中，植入物可连同纤维软骨修复或置换一起使用。在一些实施方式中，植入物可不随纤维软骨修复或置换一起使用。在一些实施方式中，植入物可连同截骨术一起使用。在一些实施方式中，植入物可不随截骨术一起使用。

[0189] 在不干扰诸如肌腱、韧带等关节组件（或者为了使此类干扰最小化）的情况下，可能难以接近膝盖后部。因此，在一些实施方式中，该方法包括提供包含线绳、勒绳、套索和 / 或系索的植入物，所述线绳、勒绳、套索和 / 或系索可从植入物后部向前穿过髁间窝以与它们自己和 / 或其他联接器件连接。在一些实施方式中，后部勒绳或缝合线状系索将植入物从后髁间窝内部朝向股骨周围的另一连接位点捆紧。在一些实施方式中，该方法包括通过牵拉植入物的线绳（或者勒绳，或者套索，或者系索等）而使植入物符合于髁的后部。此类连接器（线绳、勒绳、套索、系索等）可包含缝合材料和 / 或缆线材料。

[0190] 为了最终将植入物定位在髁附近——尤其是为了在髁后部附近捆紧该植入物，这些联接器（即，线绳、勒绳、套索、系索等）可预先联接到植入物，并且该植入物及其联接器可配置成一旦该植入物位于其相对于髁的大体位置，则所述植入物及其联接器将从植入物前部被牵拉（或捆紧）。同样地，在其中植入物被预成型的一些实施方式中，所述联接器适合于将植入物移动至其最终位置，该位置以对关节后部的关节结构的最低限度干扰（作为非限制性实例，最小切割、最小移动和 / 或最小分离）而符合髁后部。在一些实施方式中，膝盖的韧带结构的至少一部分得到保存。

[0191] 在植入物处于收缩结构中的情况下，在关节镜下通过约 10mm 直径的套管插入植入物，并且一旦植入物位于已准备好的关节空间并在其中由裙筒或翼片所紧固，则将会用气体、凝胶、流体或者变成弹性固体的流体来扩张或膨胀植入物，以便填充关节的骨之间（关节的至少两根骨之间）大约 0.5cm 的原始自然空间。如果植入物不通过套管插入，则其可以通过由外科医生酌情决定的长度从 1 厘米至四十厘米的开放切口而插入。将通过外科

医生对适当压力施用的感觉并辅以用于注射诸如欣慰可(Synvisc)、膝乐根(Hyalgan)、透明质酸钠(Supartz)等粘润滑剂和/或诸如利多卡因凝胶等镇痛药的经校准注射器来进行张力调整。通过通往先前为了清创而存在的关节空间的套管,及/或经由不是原始植入物组装件一部分的套管或管,可以直接地将液体插入关节本身。一旦关节得到清理,则将植入物插入并适当地固定以避免在此挤出或脱位。这可通过植入物翼片的附接和/或对翼片加上由植入物表面覆盖物(类似于维可牢)或位于植入物较小底部的细绳所引起的预期摩擦的组合使用来实现。

[0192] 在一些实施方式中,附接翼片定位在植入物上,以便既把植入物紧固到关节组件,又使医生能够确保植入物具有最小量的可能产生褶皱或松散区域的松弛,以避免患者解剖结构的植入物的不必要的摩擦和/或磨损。图中描绘了针对这双重目的而配置的适当放置的附接翼片的实例。在一些实施方式中,需要较少的翼片来实现这些目标。

[0193] 在其中存在松弛或空隙的一些实施方式中,受到压缩的球囊可以填充此类区域。在一些实施方式中,植入物配置成允许透明质和/或软骨细胞填充关节组件中的任何不规则性或盆坑并且生长以整修天然的关节轮廓。举例而言,当植入物的植入与经治疗的关节在手术植入植入物后的6周中每天12小时处于恒定被动运动机器上的移动相结合时,细胞生长将会产生再生的透明软骨和/或血液/纤维蛋白和瘢痕,以便产生纤维软骨填充材料。

[0194] 临床上,每个附接翼片插入位点可在手术期间向心地围绕植入物确定,依次用骨刀或钻头钻出狭槽或者孔洞,紧接着分别向骨狭槽或螺钉中插入三角形翼片延伸物。例如,如果像钟面那样观看植入物,则可将第一翼片钉/敲入2点钟位置,然后是7点钟、10点钟、4点钟、11点钟、5点钟、12点钟、6点钟(其中:# 2、7、10、4处在副韧带上方/下方的双侧股骨之上,11、12处于髌骨上部下方的股骨远端前部之上,并且5、6处于交叉部前方的髁间窝内侧。)这可能就像在马上放置马鞍那样,用抓钳围绕膝盖进行,从而拖曳聚合物朝向配合,用半英寸的薄骨刀在股骨侧上敲出狭槽,一个接一个地沿远侧变向切入,就像是将植入物(或鞍)拉入其休止角,理想地坐落在髁上并且恰好地骑跨在滑车沟中。

[0195] 在一些实施方式中,金属夹可以设置成约120度角,这是因为大于90度将有利地牵张/保持植入物以便更紧密地贴合,类似于固定在隆起物上的柔顺的聚脂薄膜球囊或延展的袜子,而不像是一张(不柔顺的)纸——这会导致植入物与骨端之间的褶皱和不一致区域。一旦延伸到最合适的位置,就减少脱位趋势和收紧聚合物,这样可避免如在丹麦聚合物髋关节帽月牙状固体髋关节表面重塑植入物所展现的失败的历史——其缺乏膨胀性、表面稳定性、适应性和固定性。

[0196] 膨胀可根据临床需要而指定,并且在植入物多单元(多隔室)构造中的改动允许用可作为材料分层完整性的一部分的、包括名叫或半固体在内的、范围从气体到固体的材料来进行选择性膨胀,以便提供计算的硬度(硬度计)以克服和抵制肢体相邻的骨的不正常对齐,和/或提供新的再生组织用于随时间恢复天然解剖结构。也就是说,可以选择性地膨胀植入物的某些部分或者保持其不扩张,以便调整去适应所涉患者的相匹配的正常或未受伤的对侧肢体。

[0197] 事实上,可征求病人的互动和反馈,以便将个人自己的需要和考虑带给骨科构思的技术和科学。据说,对于患有前交叉韧带损伤的患者而言,三分之一的人要求重建膝关节稳定器,三分之一的人没有——生活在降低的活动水平上,还有三分之一的人仔细考虑直

到在这两个连续的选项之间做出选择。

[0198] 本文所述植入物的实施方式的目标是通过使用微创技术来维持残余的活组织，所述微创技术在与更大的切口等效地用于患者时切口更小，从而尽可能地牺牲最少的正常组织。本文所述的植入物通过尽可能地避免切除性骨即软骨切除术、韧带清除性全膝置换术并且相反地恢复损伤或疾病或外科手术中的填充缺失，而帮助和改善目前可行的治疗选项。

[0199] 来自这些技术中的实例包括在某些情况下选择修复而不是重建前交叉韧带，被证明是有保证的并且有效性在P<0.3的统计水平。虽然Carticel软骨移植法对于实现用透明质而非来自采摘/钻孔的瘢痕/纤维软骨来进行关节表面重新生长是有用的，但是源于骨膜收获的大量病态是不必要的。这是因为仅需24小时即可将软骨克隆的软骨细胞附着到准备好的关节面，并且在准备好的缺损(像口盖一样)之上的聚合物膜(例如，文中所述补片植入物，或者软骨细胞在双隔室植入物或单隔室植入物的表面上的使用)巧妙地代替骨膜。

[0200] 带着这些概念，整体上来考虑哪些是必须做的，通过实施植入物及其使用方法来进行肢体修复和重建的一个常识性的方法来恢复功能且仅此而已，以便省去对可以恢复或重新生长的患者受损组织的移除。在诸如马和狗等动物中，它们甚至比人类更不会遵守恢复指令，植入安全的恢复性植入物用于关节表面整修可以提供复原的功能和挽救否则将会被牺牲掉的生命。

[0201] 接受膝盖植入物的康复治疗的患者将参与谨慎的早期活动。所允许的负重量将会类似于这种针对Carticel软骨移植病例的主要手术而写的手术过程，遵循以下的原则：在术后6-12周内应避免在重建区域上的过量和反复的盈利。然而，膝关节植入手术本身预期耗时不到一小时，涉及小于1cc的失血，需要整体小于或等于10厘米的创口(取决于植入物的实施方式)，而最终的结果拟允许早期完全负重。激烈的体育活动可能受到限制，直到在术后2个月和12个月之间骨长入和软骨复原达到合理预期——这取决于关节组织的置换量。

[0202] 在一些情况下，可能需要将植入物移除，并且文中所述的植入物的实施方式被配置成在关节镜下移除，并且允许执行所有更旧的被例行认可的技术，范围从关节清创术到钻孔、局部或全部置换术。在一些实施方式中，植入物被设置成一旦所有的外来体被移除后则被移除并用另一个代替植入物替换，要么是立即(一个星期以内)的，或者在更长一段时间之后(例如，在感染的情况下，在约6周到1年后)进行，这取决于外科医生和/或传染病顾问的意见。

[0203] 关于尺寸匹配、固定和/或相伴的需要重建的截骨术的具体手术决定，在每个病例中留给主治医生和患者。

[0204] 在一些实施方式中，植入物通过微创手术插入，然而，在另一些实施方式中，植入物也可能不通过微创手术插入。在一些实施方式中，植入物通过约0.5英寸长的切口来投送。在一些实施方式中，植入物通过约1厘米长的切口来投送。在一些实施方式中，植入物通过至多约1英寸长的切口来投送。在一些实施方式中，植入物在不用关节镜的情况下通过至少1厘米长的切口来投送。在一些实施方式中，植入物通过至多约0.75英寸长的切口来投送。在一些实施方式中，植入物通过至多约0.5英寸长的切口来投送。在一些实施方式中，植入物通过约8厘米长的切口来投送。在一些实施方式中，植入物通过约9厘米长的

切口来投送。在一些实施方式中，植入物通过约 10 厘米长的切口来投送。在一些实施方式中，植入物通过约 11 厘米长的切口来投送。在一些实施方式中，植入物通过约 12 厘米长的切口来投送。在一些实施方式中，植入物通过长于约 10 厘米长的切口来投送。在一些实施方式中，植入物通过长达约 40 厘米长的切口来投送。在一些实施方式中，植入物通过多个切口来投送。关于切口长度而言，术语“约”可以指 1%、5%、10%、25% 或 50% 的范围。

[0205] 在一些实施方式中，植入物被配置成在关节镜下投送至关节。在一些实施方式中，植入物被配置成适合装入具有至多 10 毫米的远端内径的套管内。在一些实施方式中，植入物被配置成适合装入具有至多 9 毫米的远端内径的套管内。在一些实施方式中，植入物被配置成适合装入具有至多为 5 毫米的远端内径的套管内。

[0206] 在一些实施方式中，植入物被配置成折叠的，以便适合装入具有至多 10 毫米的远端内径的套管内。在一些实施方式中，植入物被配置成折叠的，以便适合装入具有至多 9 毫米的远端内径的套管内。在一些实施方式中，植入物被配置成折叠的，以便适合装入具有至多 5 毫米的远端内径的套管内。

[0207] 在一些实施方式中，植入物被配置成通过具有至多 10 毫米远端内径的套管而投送到关节。在一些实施方式中，植入物被配置成通过具有至多 9 毫米远端内径的套管而投送到关节。在一些实施方式中，植入物被配置成通过具有至多 5 毫米远端内径的套管而投送到关节。

[0208] 在一些实施方式中，植入物被配置成在关节镜下投送至关节。在一些实施方式中，植入物被配置成适合装入具有至多约 10 毫米远端内径的套管内。在一些实施方式中，植入物被配置成适合装入具有至多约 9 毫米远端内径的套管内。在一些实施方式中，植入物被配置成适合装入具有至多约 5 毫米远端内径的套管内。关于套管的末端内径而言，术语“约”可以指 1%、5%、10%、25% 或 50% 的范围。

[0209] 在一些实施方式中，植入物被设置成折叠的，以便适合装入具有至多约 10 毫米远端内径的套管内。在一些实施方式中，植入物被设置成折叠的，以便适合装入具有至多约 9 毫米远端内径的套管内。在一些实施方式中，植入物被设置成折叠的，以便适合装入具有至多约 5 毫米远端内径的套管内。关于套管的末端内径而言，术语“约”可以指 1%、5%、10%、25%、或 50% 的范围。

[0210] 在一些实施方式中，植入物被配置成通过具有至多约 10 毫米远端内径的套管而投送到关节。在一些实施方式中，植入物被配置成通过具有至多约 9 毫米远端内径的套管而投送到关节。在一些实施方式中，植入物被配置成通过具有至多约 5 毫米远端内径的套管而投送到关节。关于套管的末端内径而言，术语“约”可以指 1%、5%、10%、25% 或 50% 的范围。

[0211] 在一些实施方式中，可将植入物提供成收缩的球囊，以便插入关节空间。在一些实施方式中，可将植入物提供成可像伞那样溃缩的折叠的球囊，以便插入关节空间。在一些实施方式中，可将植入物提供成具有用以使其折叠（或溃缩）尺寸最小化的不规则折叠图案的溃缩球囊，以便插入关节间隙。在一些实施方式中，植入物被配置成胀大（或扩张）的，以便采取扩张的、牵张的、经清创的关节的形式。

[0212] 在一些实施例中，植入物置换骨膜。

[0213] 在一些实施方式中，相比于典型的关节成形手术，植入物被植入以保留骨骼。在一

些实施方式中，相比于典型的关节成形手术，植入物被植入以保留软骨。在一些实施方式中，相比于典型的关节成形手术，植入物伴随最少的软组织剖开而被植入。在一些实施方式中，植入物不伴随关节脱位而被植入。在一些实施方式中，一旦进行了植入，关节就可适合于修正手术。在一些实施方式中，一旦进行了植入，关节就保持以下至少一项：约 90% 的正常关节功能，约 95% 的正常关节功能，约 85% 的正常关节功能，约 80% 的正常关节功能，约 75% 的正常关节功能，约 70% 的正常关节功能，约 65% 的正常关节功能，约 60% 的正常关节功能，约 55% 的正常关节功能，约 50% 的正常关节功能，至少 95% 的正常关节功能，至少 90% 的正常关节功能，至少 85% 的正常关节功能，至少 80% 的正常关节功能，至少 75% 的正常关节功能，至少 70% 的正常关节功能，至少 65% 的正常关节功能，至少 60% 的正常关节功能，至少 55% 的正常关节功能，至少 50% 的正常关节功能，约 50%- 约 75% 的正常关节功能，约 50%- 约 70% 的正常关节功能，约 60%- 约 70% 的正常关节功能，约 70%- 约 80% 的正常关节功能，约 70%- 约 90% 的正常关节功能，约 80%- 约 95% 的正常关节功能，约 80%- 约 90% 的正常关节功能，约 90%- 约 95% 的正常关节功能。在此关于正常关节功能的百分比所使用的术语“约”可以是 1%、5%、10% 或 25% 的范围。例如，关于约 90% 的正常关节功能而言的 1% 的范围覆盖了 89% 至 90% 的正常关节功能。

[0214] 在一些实施方式中，在部署体现本发明特征的植入物之前，通过清除透明软骨或纤维软骨皮瓣或撕痕来准备好内衬于关节的软骨，并且对软骨的晚期裂隙区域进行切除或清创，以便创造精确限定的缺损，所述缺损被关于受损表面具有垂直边缘的稳定的正常残余透明软骨所围绕。先前是正常表面的软骨的这些缺损之中可以注入或者除此之外插入新的活细胞，并且所述新的活细胞被允许通过经植入物间置式关节成形术近端扩张的压缩性外壁材料而得以聚集。侵入关节外围的滑膜炎可以常规地或者通过使用蒸汽而得到汽化和抽出。为了后续的再生而将更大的软骨损伤区域移除，并对具有稳定裂缝的受害较少的区域进行处理以密封或融合所述裂缝。可以保留膨胀或一致性或最小受损软骨的区域得到保存而不是被破坏，以便支持更多正常关节界面的正常间隔和滑动的机会。因此，留下正常软骨并且移除异常软骨，用植入物来弥补缺失。就本发明而言，在一些实施方式中更优选地要避免关节脱位，以便保留自然的神经分布和血管分布，从而保持血液供应。

[0215] 关节准备通常是在门诊手术的短暂全身麻醉下进行。增大关节空间可能是必要的，并且允许了外科医生洗掉有毒的酶，以便清除侵入性滑膜炎，清除游离体，理想地准备骨软骨缺损和以其他方式另外为植入物准备关节。在一些实施方式中，植入物的部分膨胀或完全膨胀可能会在释放牵引之前。在一些实施方式中，在释放牵引和闭合创口之前，再生剂或细胞随植入物而插入，或者作为流体或 3-D 模板而被插入。在一些实施方式中，优选地在相同的麻醉剂作用下进行关节清创、植入物部署和细胞再生剂施用，例如干细胞施用。正如在纽约举行的干细胞峰会（Stem Cell Summit，2009 年 2 月 17 日于纽约举行）上的数家公司所描述，在手术开始时，麻醉除菌后获得从髂嵴中对患者骨髓的抽吸是期望的。术中技师将会“拨入细胞（dial in the cells）”以便再生最大的病理生理面积，而外科医生会清创或以其他方式准备关节和插入植入物，从而在最佳时机置入细胞。细胞移植还可以作为二次或三次重建性辅助治疗而进行。

[0216] 本文提供了一种用于恢复关节的方法，包括：提供配置用于部署在关节的股骨与至少一个第二骨之间的植入物，所述植入物包括球囊，该球囊包括配置用于接合关节的股

骨的第一部分，配置用于接合关节的至少一个第二骨的第二部分，连接第一部分与第二部分的侧面部分，以及可选地可用第一膨胀介质膨胀的内部，其中所述侧面部分促进第一部分与第二部分之间的相对运动；以及将球囊的第一附件联接至关节的股骨。本文提供了一种用于恢复关节的方法，包括：提供配置用于部署在关节的胫骨与至少一个第二骨之间的植入物，所述植入物包括球囊，该球囊包括配置用于接合关节的胫骨的第一部分，配置用于接合关节的至少一个第二骨的第二部分，连接第一部分和第二部分的侧面部分，以及可选地可用第一膨胀介质膨胀的内部，其中所述侧面部分促进第一部分与第二部分之间的相对运动；以及将球囊的第一附件联接至关节的胫骨。

[0217] 在一些实施方式中，第一部分、第二部分和侧面部分中的至少两个是毗连的。在一些实施方式中，第一部分包含第一壁，第二部分包含第二壁，侧面部分包含侧壁。

[0218] 在一些实施方式中，该方法包括在配置用于接合股骨的第一部分、配置用于接合第二骨的第二部分、侧面部分以及附件之中的至少一个上提供长入补片。在一些实施方式中，该方法包括在配置用于接合胫骨的第一部分、配置用于接合第二骨的第二部分、侧面部分以及附件之中的至少一个上提供长入补片。作为非限制性实例，长入补片可配置用于助长和/或促进组织长入，诸如骨长入。该补片可以和所述部分本身(无论是第一部分、第二部分、侧面部分还是附件)一样大，或者可以小于该部分(诸如形如条状的或其他形状的补片)。长入补片可包括表面不规则性或粗糙性。长入补片可以像维可牢那样。在一些实施方式中，植入物从(并且在某些实施方式中，包括)第一附件到第二附件包括位于第一部分和/或第二部分之上的长入补片。在一些实施方式中——其中附件(通过设计和/或由于磨损和/或随着时间的推移)从与骨的附接中松开——长入补片帮助将植入物紧固到骨上。在一些实施方式中，长入补片包括附接到植入物的小珠和/或珠状元件。这样的长入补片可配置用于模拟正常松质骨网格的小梁骨空间。在一些实施方式中，小珠是各种形状的烧结小珠。在一些实施方式中，小珠是约 400 微米大小的烧结小珠。关于小珠大小而言，术语“约”可指 1%、5%、10%、25% 或 50% 的范围。在一些实施方式中，使第一骨和/或第二骨变粗糙以获得出血的骨从而促进长入。在一些实施方式中，清除约 0.5mm 的皮质骨以便促进长入。

[0219] 在一些实施方式中，该方法包括将球囊的第二附件联接至关节的股骨。在一些实施方式中，该方法包括将球囊的第二附件联接至关节的胫骨。在一些实施方式中，该方法包括将球囊的第二附件联接至关节的至少一个第二骨。在一些实施方式中，该方法包括将第一部分、第二部分和侧面部分中的至少一个的第二附件联接到关节的股骨和至少一个第二骨中的至少一个。在一些实施方式中，该方法包括将第一部分、第二部分和侧面部分中的至少一个的第二附件联接到关节的胫骨和至少一个第二骨中的至少一个。在一些实施方式中，联接第一附件和第二附件中的至少一个向关节的股骨和至少一个第二骨提供了韧带样支撑。在一些实施方式中，联接第一附件和第二附件中的至少一个向关节的胫骨和至少一个第二骨提供了韧带样支撑。在一些实施方式中，联接第一附件和第二附件中的至少一个向关节提供了韧带样支撑。在一些实施方式中，第一附件和第二附件配置用于向关节的股骨和至少一个第二骨提供肌腱样支撑。在一些实施方式中，第一附件和第二附件配置用于向关节的胫骨和至少一个第二骨提供肌腱样支撑。在一些实施方式中，第一附件和第二附件配置用于向关节提供肌腱样支撑。

[0220] 在一些实施方式中，所述方法包括：提供与球囊的内部相连通的膨胀端口，用于以第一膨胀介质来膨胀球囊的内部。在一些实施方式中，该方法包括使用与球囊的内部相连通的植入物的膨胀端口来用第一膨胀介质膨胀球囊的内部。在一些实施方式中，该方法包括刺穿球囊以便用第一膨胀介质来膨胀球囊的内部。在一些实施方式中，该方法包括提供具有自密封能力的球囊。在一些实施方式中，该方法包括提供在用第一膨胀介质膨胀球囊的内部之后具有自密封能力的球囊。在一些实施方式中，该方法包括提供包含能够封闭球囊内部的密封件的球囊。

[0221] 在一些实施方式中，该方法包括提供包括多个可膨胀腔室的内部的球囊。在一些实施方式中，所述内部包括多个可单独膨胀的腔室。在一些实施方式中，该方法包括用第一膨胀介质来膨胀多个可膨胀腔室之中的第一腔室。在一些实施方式中，第一腔室和膨胀介质基于病人的特定需求来选择。作为非限制性实例，如果病人有由于损伤而带来的骨缺失，则腔室可以选择在缺失的骨的位置上，并且可以用刚性的(或者一旦在腔室中即会变成刚性的)膨胀介质填充，以便置换缺失和/或损伤的骨。备选地，或者附加地，可以选择腔室用于恢复关节的对齐，并用合适的膨胀介质对该腔室加以填充，以便同时向关节给予对齐和缓冲。在一些实施方式中，该方法包括用第二膨胀介质来多个可单独膨胀的腔室之中的第二腔室。

[0222] 在一些实施方式中，球囊是复合结构。在一些实施方式中，球囊包括多孔材料层和/或非多孔材料层，或者除此之外包含治疗剂或细胞再生剂。在一些实施方式中，球囊的第一层是薄而坚固的热塑性塑料层，作为非限制性实例，诸如热塑性聚氨酯，其具有足以允许来自第二层的治疗剂或细胞再生剂通过或排出的微孔率。第二层可以是中心层(其位于第一层与第三层或第四层或者更多的层之间)。在一些实施方式中，第一层可包括骨接合表面。在诸如 Chronoflex 或 Bionate 55 等聚合物层中发现使来自第二层的治疗剂或细胞再生剂能够排出的微孔率程度。植入物的骨接合表面可涂覆和/或浸渍聚合物网格，该聚合物网格表面喷涂在或分层堆积在植入物的骨接合表面上以促进软骨组织再生。这种骨接合表面涂层可包含活软骨细胞(例如，在 Carticel 手术中由 Genzyme 公司提供的软骨细胞)，并且/或者可包含具有定向基因突变的干细胞，以增强涂层到植入物的粘附。骨接合表面可包括峰和槽。活细胞可提供于槽中，而表面峰可用于以下至少一项：空间验证、牵引和细胞保护。

[0223] 在一些实施方式中，第一膨胀介质给予了植入物中的刚度。在一些实施方式中，第一膨胀介质给予了植入物中的缓冲。在一些实施方式中，为第一膨胀介质选择的膨胀介质和/或用这样的第一膨胀介质填充的腔室的特定选择(在具有多个腔室的实施方式中)使关节对齐。在一些实施方式中，为第一膨胀介质选择的膨胀介质和/或用这样的第一膨胀介质填充的腔室的特定选择(在具有多个腔室的实施方式中)使关节的骨对齐。在一些实施方式中，为第一膨胀介质选择的膨胀介质和/或用这样的第一膨胀介质填充的腔室的特定选择(在具有多个腔室的实施方式中)改变了骨对齐。在一些实施方式中，为第一膨胀介质选择的膨胀介质和/或用这样的第一膨胀介质填充的腔室的特定选择(在具有多个腔室的实施方式中)改善了关节对齐。在一些实施方式中，为第一膨胀介质选择的膨胀介质和/或用这样的第一膨胀介质填充的腔室的特定选择(在具有多个腔室的实施方式中)至少部分地恢复关节对齐。在一些实施方式中，可以选择性地用第一膨胀介质和/或第二膨胀介质来

膨胀内部的个别腔室。在一些实施方式中，用第一膨胀介质和 / 或第二膨胀介质选择性地膨胀内部的个别腔室，以便重建关节和 / 或重建关节的骨。

[0224] 随着时间的推移，修复组织的长入有助于植入物外部的固定和稳定性，而软的缓冲性植入物内部将会吸收跨关节表面的力，并允许适当的运动。植入物的膨胀或壁张力以及植入物本身的内部膨大可以通过向植入物的内部空间添加膨胀物质或移除膨胀物质来加以调整。

[0225] 因此，本发明提供了针对关节成形术的一种新方法，涉及部署在膝关节的骨之间的弹性植入物。虽然一个关节由骨 - 软骨 - 空间 - 软骨 - 骨之间的界面组成，但是在诸如膝盖之类的某些关节空间中，本发明的缓冲垫可扩展以适应在两个“膝关节”之间的空间——这两个“膝关节”是涉及站立或平面行走的股骨胫骨，以及更多地涉及上、下楼梯的膝盖的髌骨 - 股骨。例如，膝盖或髌骨后的压力在平躺时为零，在站立时是体重的 0.7 倍，而当向上走和向下走时，髌骨 - 股骨的压力是 3-4 倍体重。因此，植入物将需要适应所有正常的身体功能压力和复杂的空间移动。体现本发明特征的植入物提供了更多的生理运动和关节内的减震，并且具有以下的组合特性 :解剖结构设计对称性，伴随与相邻正常结构的充分附接连接的平衡的刚性，以及满足关节重建需求的耐久性。

[0226] 本发明的第一壁和第二壁的相对的内部表面可以同步地或在彼此相反的方向上一起移动(例如，上壁在髁部中内侧地移动，而下壁则外侧地移动)。可选地，所述植入物可以固定到关节的凹面或固定到关节的凸面，或者固定到全部两者，或者不固定到任何一个(例如，在关节内具有过盈配合，伴随填充了现有空间的扩张的球囊或缓冲垫)。植入物可像收缩的球囊那样在关节镜下通过套管插入关节结构并继而膨胀，以便充当用于无痛和稳定的肢体运动的缓冲垫或复原的界面。在可行的情况下，关节囊和相邻的韧带组织以及骨将留在原处以保持自然的身体组织，除非与重建的肢体的功能相干扰。

[0227] 蒸汽的应用除了移除受损的碎片之外，还能平滑和重新形成关节表面。蒸汽的高温易于融合可能存在于受损关节的软骨表面之中的裂缝或裂隙。用蒸汽对关节表面软骨的平滑融合或密封了软骨中的现有裂缝或皮瓣，特别是在薄层表面上，它们汇集在一起提供了一个白色有光泽的滑动关节面。在暴露出骨的情况下，可以使用蒸汽来经由囊缝合术或关节紧缩术而稳定关节表面中缺损的外周。机械还可以利用开放式机械和化学清创来准备针对植入物的表面。

[0228] 一旦植入物通过裙筒或翼片或者使用其他联接器紧固到股骨，则可以在植入物的膨胀或扩张完成之前采用浸渍的转移介质或细胞模板——如 Histogenics 和 Tygenix 软骨细胞运载系统所描述，其中浓缩的细胞的位置被机械地放置在植入物周围的最大软骨损伤区域处以便促进再生长 ;或者如在 Carticel 中所描述，其中含水的细胞被移植在骨膜薄膜下方(植入物的壁充当薄膜的)。使用具有经测量的旋拧 - 原位压强的注射器或者经校准的装置来膨胀植入物。

[0229] 一旦关节准备好接纳植入物，则使收缩的植入物前进穿过递送套管的隔膜(诸如来自 Smith&Nephew 的 Acufex)或者穿过开放的切口部位而进入关节。它可以通过附接的套管，使用插入若干毫升填充材料的常用注射器而得以膨胀。注入的内容物和细胞放置的位置取决于所需的面积和关节的大小。在该方法的一些实施方式中，在植入物的内部中的若干毫升的填充材料和粘润滑剂将允许膨大、缓冲和滑动移动。细胞再生剂被置于最需要

的区域。

[0230] 活体干细胞或软骨细胞放置的方法取决于病变和具体的植入物结构。通过完成植入物的膨胀而直接注入到关节会将细胞压入透明质表面，它们在最初的 24 小时内附接于其上。因此，病人可能会被迫在术后第一天保持久坐不动，并保持部署了植入物的关节不负重。更深层的骨软骨缺损可以经由 3-D 细胞转移模板，或者经由如在针对血糖检测和胰岛素 / 经皮给药而对糖尿病人进行的治疗中所使用的微针注射，而通过“细胞超灌注”来加以治疗。对剥脱性骨软骨炎或局部的软骨和骨损失的情况，骨移植物可能被塞入缺损的基底，接着增加细胞和组织应用。附接到植入物的套管可以密封和卸下，或者留在原处用于定期吸引如 Cox-1、Cox-2 和 5-Lox 系统的有害酶，然后重新插入活性物质，包括粘润滑剂，甚至更多的细胞。

[0231] 体现本发明特征的植入物可设计用于永久地或临时地部署在关节结构内。此外，可以用合适的可生物吸收材料来形成该植入物，从而使植入物可在特定的预定时间范围内被吸收。合适的可生物吸收材料包括聚乳酸、聚羟基乙酸、聚己内酯，及其共聚物、共混物和变体。形成植入物的一种现有方法是涂敷诸如溶剂中的 ChronoFlexAR 之类的多个聚合物层，以及在涂敷每个层之后将溶剂蒸发。

[0232] 联接器方面（联接器）包括但不限于在使用中防止关节移位的本植入物的裙筒或固定翼片。

[0233] 在一些实施方式中，植入物适于恢复天然关节功能。在一些实施方式中，植入物适于保持活体关节组织。在一些实施方式中，植入物适于通过与目前市场上的关节置换疗法相比最小的手术来放置。在一些实施方式中，植入物适于允许在手术后的以下天数中的至少一项内负重：约 1 周、约 1 天内、约 2 天内、约 3 天内、约 4 天内、约 5 天内、约 6 天内、约 10 天内、约 2 周内、约 3 周内、约 4 周内、约 5 周内、约 6 周内。在一些实施方式中，植入物适于在手术后约 1 天之后允许负重，其中在大约 6 周后允许完全负重。在一些实施方式中，此处关于负重时机所使用的术语“约”可以是 1 天、2 天或 3 天的范围。在一些实施方式中，植入物适于允许与目前市场上的关节置换疗法相比更快地恢复和重新开始正常活动。

[0234] 在一些实施方式中，球囊（或其一部分）适于符合患者的解剖结构。在一些实施方式中，植入物（或其一部分）适于符合患者的解剖结构。在一些实施方式中，膨胀介质适于吸收施加在关节上的力（或多个力）。在一些实施方式中，膨胀介质适于吸收施加在关节的骨上的力（或多个力）。在一些实施方式中，膨胀介质适于吸收施加在关节的至少一个骨上的力（或多个力）。在一些实施方式中，球囊适于吸收施加在骨、多个骨、关节韧带、多个关节韧带、关节肌腱，多个关节肌腱和总体关节中的至少一个上的冲击。在一些实施方式中，植入物适于用干细胞来恢复天然软骨缓冲。

[0235] 在一些实施方式中，球囊（或其一部分）适于复原关节空间。在一些实施方式中，球囊（或其一部分）适于与植入物植入前感受到的疼痛相比减轻疼痛。在一些实施方式中，球囊（或其一部分）适于恢复关节功能。在一些实施方式中，植入物（或其一部分）适于复原关节空间。在一些实施方式中，植入物（或其一部分）适于与植入物植入前感受到的疼痛相比减轻疼痛。在一些实施方式中，植入物（或其一部分）适于恢复关节功能。

[0236] 在一些实施方式中，植入物适于在关节中逆转关节炎。

[0237] 在一些实施方式中，球囊（或其一部分）适于在关节镜下放置到经清创的肢体关节

中。在一些实施方式中，球囊适于填补软骨缺损。在一些实施方式中，球囊被膨胀以缓冲关节。在一些实施方式中，植入物适于向关节和关节的骨之中的至少一个递送干细胞。在一些实施方式中，植入物适于向关节和关节的骨之中的至少一个递送活软骨细胞。在一些实施方式中，植入物适合于为关节提供新的关节面。在一些实施方式中，植入物适合于充当关节的垫片。在一些实施方式中，植入物适合于为了适当的关节接合而分隔开关节的骨。在一些实施方式中，植入物适合于为减少骨与骨间的摩擦而分隔开关节的骨。

[0238] 在一些实施方式中，植入物配置用于以下至少一项：填补软骨、缓冲关节、递送药理性物质、清除有毒的酶、植入后清创、植入后给关节清创、递送治疗性物质、递送生物物质以及递送活的干细胞。在一些实施方式中，植入物配置用于向骨或其他周围组织递送化疗剂。在一些实施方式中，植入物配置用于向骨或其他周围组织递送抗感染药物。在一些实施方式中，植入物配置用于递送抗生素、抗真菌剂和镇痛剂之中的至少一种。

[0239] 在一些实施方式中，植入物配置用于选择性地膨胀以重新对齐肢体。

[0240] 本文提供了一种方法，包括：将如本文所述的膝盖植入物植入到个体内，其中该植入物逆转个体内的关节炎。

[0241] 本文提供了一种方法，包括：将如本文所述的膝盖植入物植入到个体的膝关节中，并且用同种异体移植组织、自体移植组织和异种移植组织中的至少一个来治疗个体的膝关节的组件。在一些实施方式中，植入步骤为以下至少一项：在治疗步骤之前、与治疗步骤同时、以及在治疗步骤之后。

[0242] 本文提供了一种方法，包括：将如本文所述的膝盖植入物植入到个体内，其中所述植入物发挥以下至少一项功能：恢复关节功能和控制关节病。在一些实施方式中，植入保存现有解剖结构。

[0243] 本文提供了一种方法，包括：给个体的膝关节的股骨髁清创，以及将如本文所述的膝盖植入物植入到个体的膝关节内，从而使所述植入物被配置用于与个体的软骨炼合。在一些实施方式中，清创是通过蒸汽施用来实现的。

[0244] 本文提供了一种方法，包括：将如本文所述的膝盖植入物植入到先前已用关节置换物治疗过的关节中。在一些实施方式中，该方法包括在植入膝盖植入物之前移除关节置换物。在一些实施方式中，该方法包括从关节和/或周围组织清除感染性物质。在一些实施方式中，该方法包括在移除先前植入在关节中的植入物之后，植入本文所述的任何植入物的第二植入物。在一些实施方式中，该方法包括在移除先前植入在关节中的植入物之后，置换个体的关节。在一些实施方式中，该方法包括给关节的骨清创，以及植入如本文所述的任何植入物的植入物。在一些实施方式中，该方法包括重复清创和植入步骤。

[0245] 本文已经阐释和描述了本发明的具体形式，但是应当明白可以对本发明作出各种修改和改进。一种备选的植入物构造涉及使用植入物的上部，其具有网状结构并且填充有大于网格开口的球或球轴承样元件。球或球轴承样元件给植入物提供移动。网格和球轴承样元件可含有如前面所讨论的再生剂，且轴承结构可定向于有利的与内容物分配平衡的植入物运动。

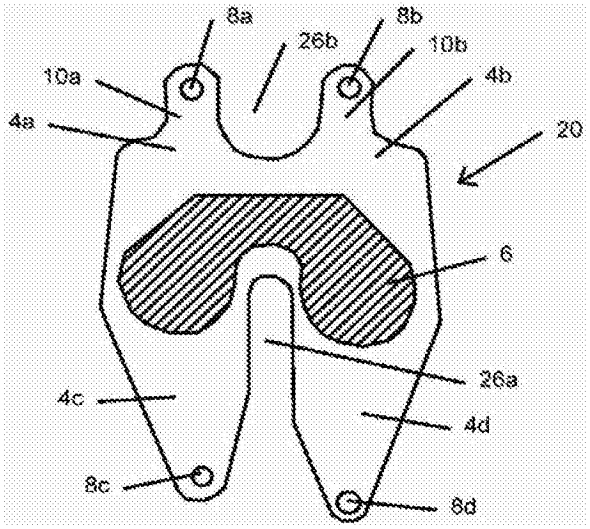
[0246] 本发明预期主要供人使用，但可能会扩展到供哺乳动物使用。在本文没有另外公开的情况下，材料和结构可以是常规设计。

[0247] 此外，本发明的实施方式的个别特征可能在一些附图中显示，而在其他附图中没

有显示，但本领域技术人员应当认识到，本发明的一个实施方式的个别特征可以在另一实施方式中应用。此外，一个实施方式的个别特征可与另一实施方式的任何或所有的特征相结合。因此，并非旨在将本发明限于示出的具体实施方式。因此，如现有技术广泛允许的，本发明旨在由所附的权利要求的范围所限定。

[0248] 诸如“元件”、“构件”、“组件”、“器件”、“装置”、“部分”、“片段”、“步骤”等术语以及类似含义的词语，用在这里时不应援引 35U.S.C§112(6) 的条款来解释，除非接下来的权利要求明确地使用了术语“用于…的装置(means for)”或“用于…的步骤(step for)”，且后接特定功能但没有提及特定的结构或特定的行动。上文提到的所有专利和所有专利申请的全部内容通过引用并入本文。

[0249] 虽然本文已经展示和描述了本发明的优选实施方式，但对本领域中技术人员而言显然的是，这样的实施方式仅仅是以示例的方式提供的。本领域中技术人员现将在不背离本发明的情况下想到多种变化、改变和替换。应当理解，本文所述的本发明的实施方式的各种替代方案在发明的实践中也可得到采用。下面的权利要求旨在限定本发明的范围，这些权利要求的范围内的方法和结构以及它们的等同物从而也被覆盖。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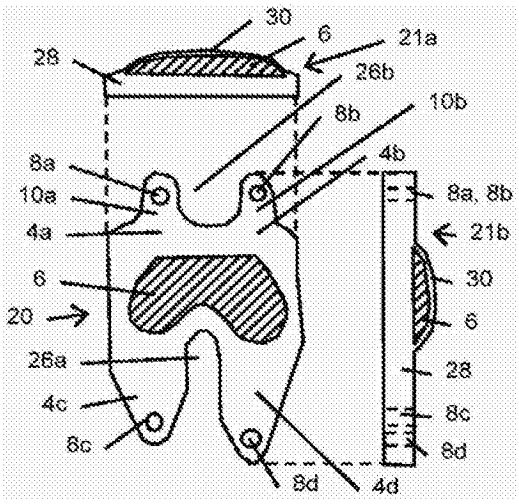
26b
8b
10b
10a
4b
4a
20
6
26a
4c
4d
8c
8d

图 1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28
26b
10b
8b
4b
8a
10a
8a, 8b
4a
21b
6
30
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6
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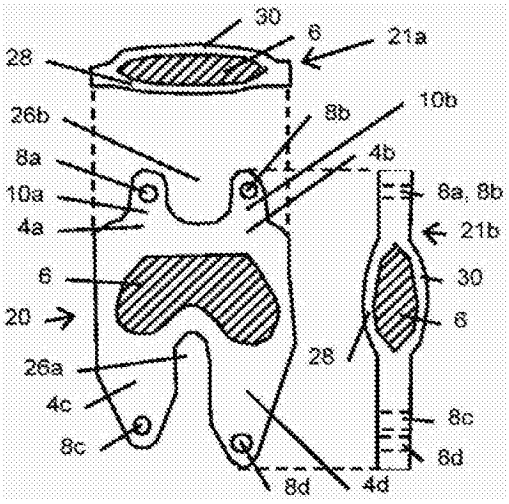
28
4c
8c
8c
8d
8d
4d

图 2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6
21a
28
26b
8b
10b
8a
4b
10a
8a, 8b
4a
21b
6
30
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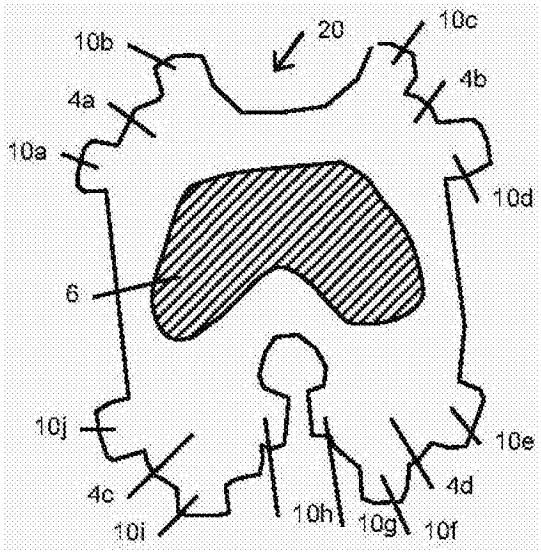
6
28
26a
4c
8c
8c
8d
8d
4d

图 3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10c
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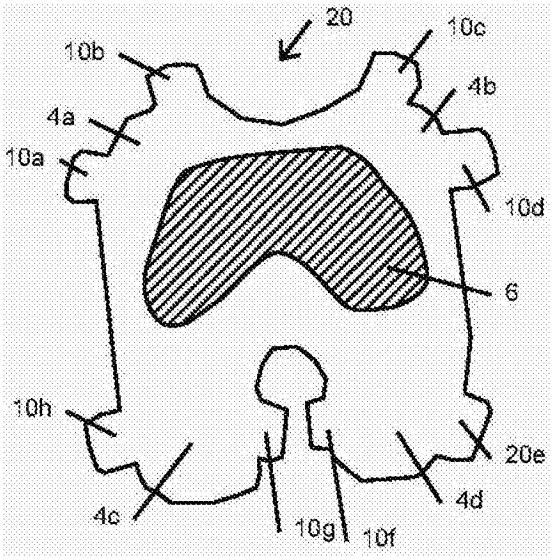
4a
10a
10d
6
10j
10e
4c
4d
10i
10h
10g
10f

图 4A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10c
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6
10h
20e
4c
10g
10f
4d

图 4B

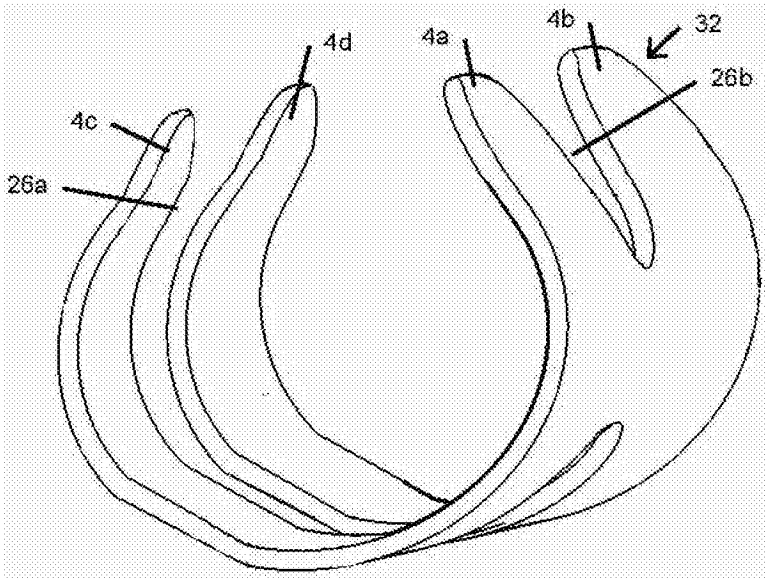
4d
4a
4b
32
26b
4c
26a

图 5

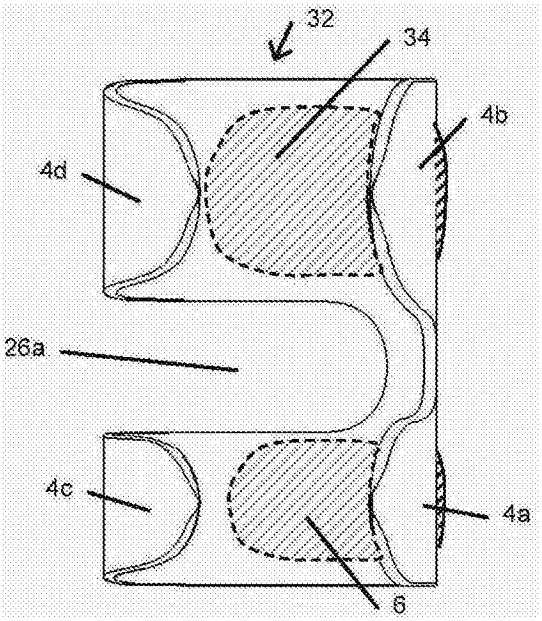

图 6A

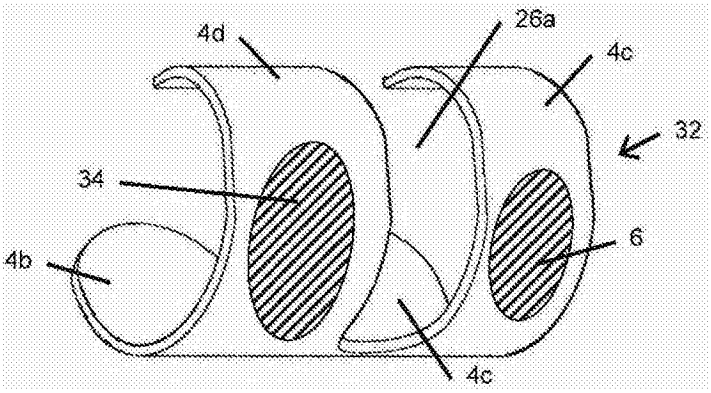

图 6B

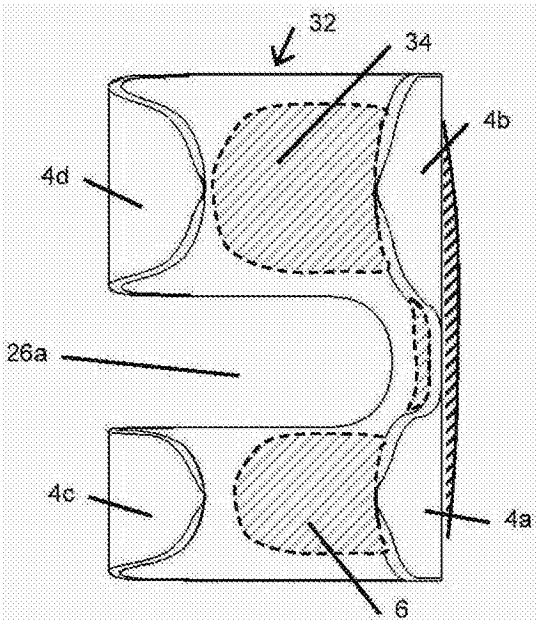

图 7

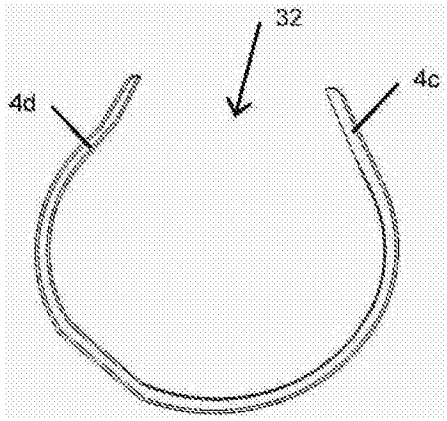

图 8

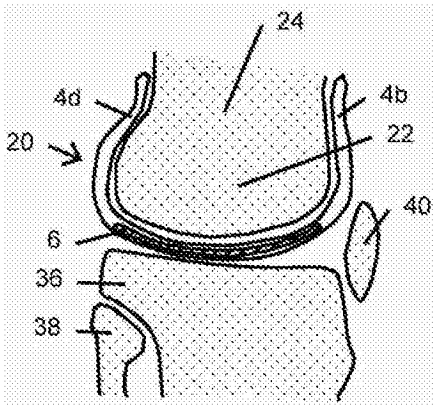

图 9A

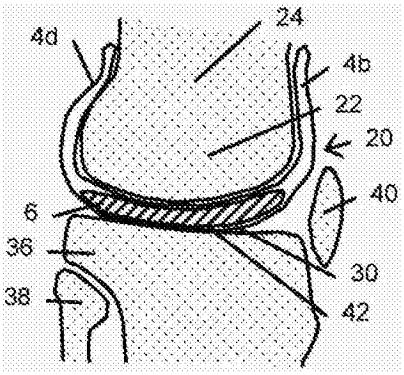

图 9B

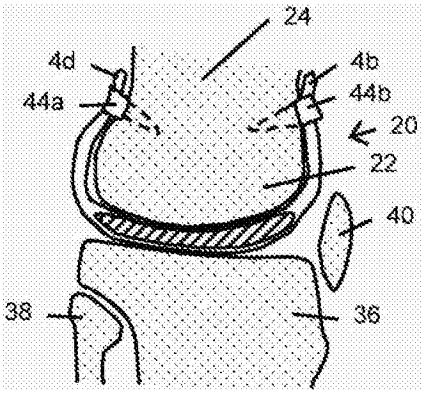

图 9C

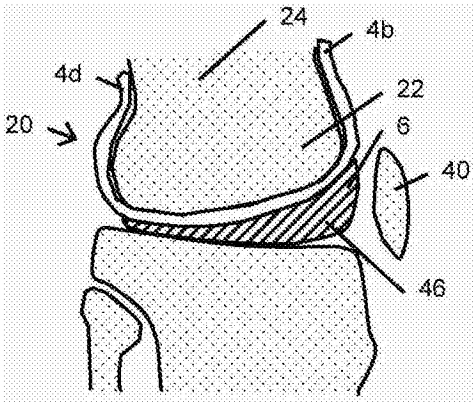

图 10A

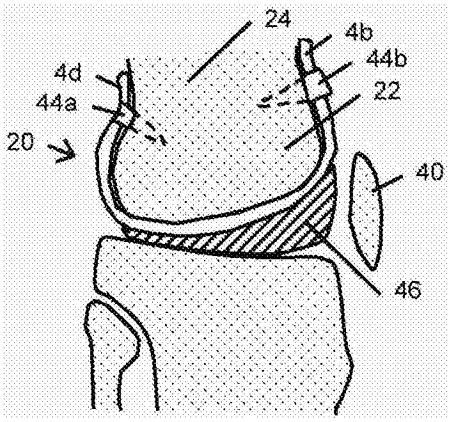

图 10B

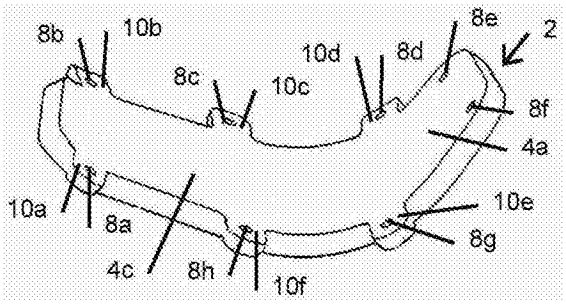

图 11A

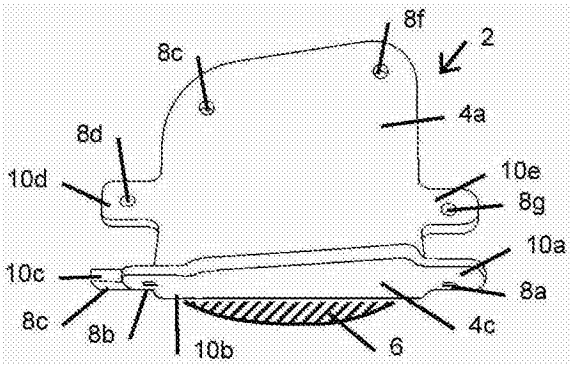

图 11B

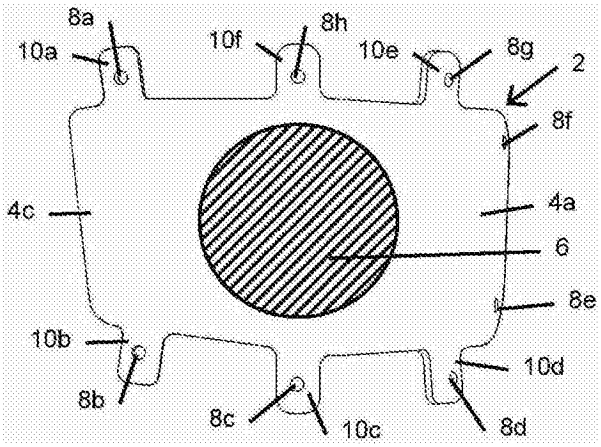

图 11C

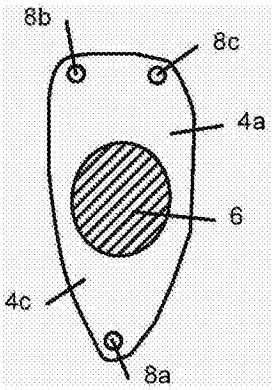

图 12A

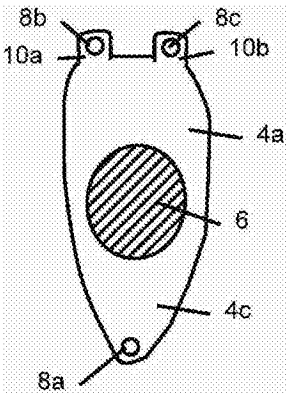

图 12B

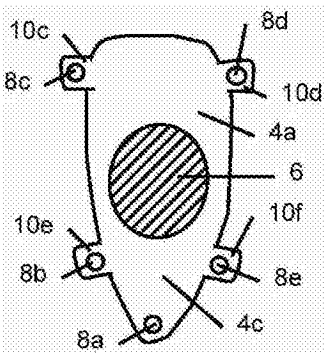

图 12C

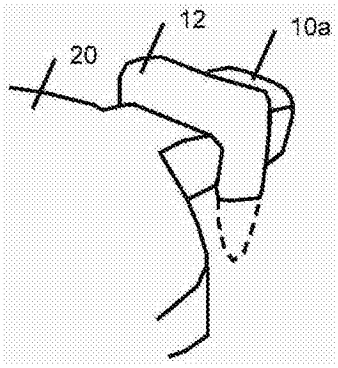

图 13A

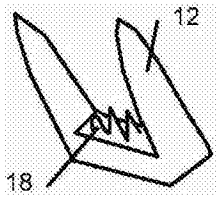

图 13B

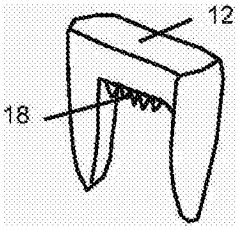

图 13C

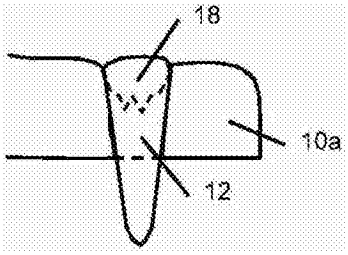

图 13D

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Office européen des brevets

(11) EP 2 344 083 B1

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(51) Int Cl.:
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A61F 2/38 *(2006.01)* ***A61F 2/40*** *(2006.01)*
A61F 2/42 *(2006.01)*

(86) International application number:
PCT/US2009/004305

(87) International publication number:
WO 2010/011338 (28.01.2010 Gazette 2010/04)

(54) **RESILIENT ARTHROPLASTY DEVICE**

NACHGIEBIGE ARTHROPLASTIK-PROTHESE

DISPOSITIF D'ARTHROPLASTIE RÉSILIENTE

(84) Designated Contracting States:
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO SE SI SK SM TR

(30) Priority: **24.07.2008 US 135820 P**
23.07.2009 US 460703

(43) Date of publication of application:
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Novato, CA 94947 (US)

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FR-A- 2 803 190
US-A1- 2004 267 375

EP 2 344 083 B1

Description

BACKGROUND OF THE INVENTION

[0001] This invention relates to arthroplasty, and more particularly, to an implant for use in arthroplasty. When hyaline articular cartilage is damaged, it breaks down and joint space is lost. Inflammatory enzymes such as from the Cox-1, Cox-2 and/or 5-Lox systems, are released and loose bodies form adding to the degradation of joint function. Such joint damage is conventionally treated by physical therapy, analgesics, pain medication and injections. When these treatments fail, the traditionally accepted treatment option is arthroplasty implantation or replacing the joint with an artificial joint construct. Current arthroplasty techniques typically use "plastic and metal" implants that are rigid and which ultimately fail due to loosening or infection. Conventional materials for the artificial joint components include chrome-cobalt-molybdenum alloy (metal) and high molecular weight polyethylene (plastic). Each is often fixed by a cement-like mixture of methyl methacrylate to the ends of the bones that define the joint that is the subject of the arthroplasty, or coated with a surface that enables bone ingrowth. Current hip joint replacements typically last about 10-15 years and knee replacements typically last about 5 -10 years. Ankle joint replacements, on the other hand, are not very successful, and often fail in the first several years after surgery.

[0002] The features of the preamble of claim 1 are known from DE 2501080 A1.

[0003] Conditions requiring arthroplasty include traumatic arthritis, osteoarthritis, rheumatoid arthritis, osteonecrosis, and failed surgical procedures.

SUMMARY OF THE INVENTION

[0004] The present invention is directed to an orthopedic implant as defined by claim 1. Said implant is configured for deployment between opposing members of a joint structure that addresses many of the shortcomings of prior artificial joints. The arthroplasty implants embodying features of the invention are configured to preserve joint motions while removing the pain and dysfunction following the development of arthritis or joint injury. The arthroplasty implant in accordance with the present invention achieves improved physiologic motion and shock absorption during gait and acts as a resilient spacer between moving bones during limb movement. The combined characteristics of the implant include anatomic design symmetry, balanced rigidity with variable attachment connections to at least one of adjacent normal structures, and durability which addresses and meets the needs for repair or reconstruction thus far missed in the prior art. The implant should be secured to at least one of the bones of the joint structure.

[0005] More specifically, the resilient implant embodying features of the invention has a first wall configured to be secured to a first bone of the joint structure by one or more appendages such as a skirt or one or more tabs and a second wall configured to engage a second and usually opposing bone of the joint structure. A side wall extends between the first and second walls of the implant and together with the first and second walls preferably defines at least in part an inner chamber or space between the first and second walls. The implant is configured to provide linear or curvilinear and/or rotational motion between the first and second bones which mimics or approximates the natural motion between these bones. The inner chamber or space is configured to maintain a filler material therein such as an inflation fluid or a resilient material and preferably to maintain spacing and provide support between the interior of the first and second walls to avoid significant contact therebetween. The walls of the implant are preferably sealed about the periphery thereof to maintain the interior chamber in a sealed condition to avoid loss of inflation fluid or filling media. The side wall or walls may be formed from the edges or periphery of the first and second walls. The properties of the implant walls and the interior are controlled to provide the particular resiliency desired for the joint in which the implant is to be placed as well as any desired motion between the first and second walls. A conduit may extend from a source of inflation fluid or other filling medium to the interior of the implant to facilitate expansion of the implant after deployment within the joint. The inflation fluid may be a gas, a liquid, a gel or a slurry, or a fluid that becomes a suitable resilient solid such as a curable polymer. Selection of the inflation or interior filling medium may depend upon the nature of the joint structure in which the implant is to be deployed, its anatomy, pathophysiology, and the properties of the implant material.

[0006] There may be several alternative embodiments depending upon the site in which the implant is to be deployed. For example, the polymer forming the side wall may be semi-compliant or elastic and the inflation fluid may be incompressible (e.g., a liquid). Alternatively, the polymer forming the side wall may be non-compliant (non-elastic) and the inflation fluid or filling medium may be compressible, e.g., a gas or a resilient polymeric foam or sponge-like solid that may have a closed cell structure. The first and second walls of the implant need not have the same properties as the side wall. For example, parts of the implant such as the side wall portion may be compliant and the first and second wall portions in contact with the bone or other joint structure may be non-compliant. Additionally, the various walls or portions thereof may also be reinforced with non-compliant or semi-compliant polymer strands, beads or gel coating such as biologic or polymer latticework. The thicknesses of the first, second and side walls may be varied to accommodate for the needs of the joint structure from the standpoint of strength, elasticity and wear resistance. Moreover, the walls of the implant may be provided with joint tissue regeneration agents that rebuild the joint structure in

which the implant is deployed. The regeneration agent may be incorporated into the wall of the implant prior to delivery or placed between the surface of the implant and the joint structure which it contacts after delivery. All or part of the walls of the implant may also be made of a biodegradable polymer, by minimally manipulated autograph, allograph or xenograph tissues, or a combination thereof. The method of surgery may incorporate a progressive application of the implant embodiments depending upon clinical needs.

[0007] The implant is preferably formed of suitable biocompatible polymeric materials, such as Chronoflex, which is a family of thermoplastic polyurethanes based on a polycarbonate structure (AI, the aliphatic version, Ar, the aromatic version and C, the casting version) available from AdvanSource Biomaterials, Corp. Other polymers include Bionate 80, 90A, 55 or 56, which are also thermoplastic polyurethane polycarbonate copolymers, available from PTG Medical LLC., an affiliate of the Polymer Technology Group located in Berkeley, CA. Other commercially available polymers include Purisil 20 80A which is a thermoplastic silicone polyether urethane, Carbosil 20 90A which is a thermoplastic silicone polycarbonate urethane and Biospan which is a segmented polyurethane. These polymers are available as tubing, molded or dipped components, solution, pellets, as a casting and as a cast film for the side and first and second walls. The implant may be formed by casting, blow molding or by joining sheets of polymeric material by adhesives, laser welding and the like. Other methods of forming the implant may also be suitable. The walls may also be provided with reinforcing strands which are located on the surface of the walls or incorporated within the walls. The implant material should be biocompatible, non-toxic, and non-carcinogenic and should be resistant to particulation.

[0008] The present invention provides an improved joint implant which is designed to endure variable joint forces and cyclic loads enabling reduced pain and improved function. Depending upon the particular joint involved there may be linear or curvilinear motion between the first and second walls, rotational motion between the first and second walls or both linear and curvilinear motion and rotation motion between the first and second walls. Preferably, a space is maintained between the inner surfaces of the first and second walls to avoid erosion and wear therebetween.

[0009] The resilient arthroplasty implant embodying features of the invention is preferably deployed as a minimally invasive procedure to deliver the implant into a prepared space in a preselected joint structure, where upon it is inflated to create a cushion, to cover damaged or arthritic cartilage and to be employed to deliver stem cells or living chondrocytes or other tissue regeneration agents. The goal of such deployment is to reduce pain and improve function, to reverse arthritis, to fill in osteochondral defects succinctly, thereby avoiding living with both dysfunctional and ablative metal/plastic prostheses or the pathophysiologic state necessitating the procedure. The operative plan is simple, systematic, and productive of new joint space with regrowth potential involving joint debridement by routine arthroscopic methods or steam application, followed by implantation of the implant. The implant provides three things, namely a covering or patch for the damaged or worn joint surface, an inflated cushion to pad gait as in normal walking in the lower extremity, and delivery of regenerative cells on the cartilage remnant surface. The stem cells may be injected as the implant is being expanded and/or directed into the adjacent hyaline cartilage via an implant coating or perfused cell template. Viscolubricants such as Synvisc or Hyalgan, analgesics such as Lidoderm, anti-inflammatory and/or antibiotic coatings as well as those stimulating cell growth may accompany the composite external implant. The implant is left in place as long as feasible, at least until regenerative cells can attach to the adjacent natural joint surface (usually in about 24 hours), or until wound healing (which may take up to 28 days or more depending on the joint structure). Preferably, the implant is designed to stay within the joint structure for years, providing inert padding, cushioning and a new cell source. The implant may be used in weight bearing and non-weight bearing interfaces. Animal usage of the implant, such as in horses and dogs, will benefit following hip and knee injuries. The implant is intended primarily for mammalian use.

[0010] These and other advantages of the invention will become more apparent from the following detailed description and the attached exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011]

Figure 1 is a schematic cross-sectional view of an idealized joint structure having first and second bones with an implant having features of the invention disposed within the space between the opposing bones of the joint structures.

Figure 2 is similar to Figure 1 illustrating curvilinear movement between the two opposing bones.

Figure 3 is a transverse cross sectional view taken along the lines 3-3 in Figure 1 illustrating rotational movement between the two opposing bones.

Figure 4 is a perspective view, partially in section, of an implant embodying features of the invention with an enlarged upper portion prior to implantation.

Figure 5 is an elevational view of the implant shown in Figure 4 mounted on the head of a patient's femur.

Figure 6 is a cross-sectional view of the implant shown in Figures 4 and 5 deployed between the head

of a patient's femur and acetabulum after release of traction to allow for the bones to settle into their natural albeit pathologic angles of repose.

Figure 7 is an elevational view of a resilient arthroplasty implant with a smaller upper portion than that shown in Figures 4-6 that has been deployed between the head of patient's femur and the acetabulum of the pubic bone.

Figure 8 is an elevational anterior view of a left proximal femur with an implant placed over the femoral head portion of the hip joint as shown in Figure 7, in partial cross section, to illustrate details thereof.

Figure 9 is a lateral elevational view of a femur with the implant shown in Figure 6, as viewed from the "side of the body" or lateral hip aspect.

Figure 10 is a superior view of a femur with the implant shown in Figure 7.

Figure 11 is an inferior view of the hip joint invention iteration or implant in Figure 10.

Figure 12 is a superior or cephalad view of a patient's hip with a resilient implant having features of the invention, viewed from the head of the patient or from a cephalad to caudad direction.

Figure 13 is a lateral view of the patient's ankle having a resilient arthroplasty device implant which embodies features of the invention between opposing joint structures.

Figure 14 is a mortise (30 degree oblique AP) view of the patient's left ankle with implant shown in Figure 13.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

[0012] The present invention is directed to arthroplasty implants and procedures for a wide variety of joints such as, for example, hips, knees, shoulders, ankles, elbows, wrists, fingers, toes, temporomandibular joints and the like, but for clarity, as well as brevity, the discussion herein will focus on an implant for a hip joint and an implant for replacing the talus bone of a patient's ankle.

[0013] Figure 1 is a highly schematic idealized view of an implant 10 embodying features of the invention that is deployed within a joint structure having a first bone 11 and a second bone 12. The implant 10 has a first wall 13, a second wall 14, and a side wall 15 which define the implant interior 16 which contains filling material 17. The first wall 13 is secured to the end of the first bone 11 by the skirt 18 that extends from the first wall 13 and the second wall 14 engages the end surface of the second bone 12 and may also be secured thereto. The side wall 15 extending between the first and second walls 13 and 14 defines at least in part the implant interior 16 which is filled with filling material 17. The inner surfaces of wall 13 and skirt 18 preferably conform to the particular surface of the head of the patient's first bone 11. The outer surface of the second wall 14 is preferably configured to conform to the end surface of the second bone 12. The drawings are highly schematic and do not depict details of the joint surface features such as of the end of the first bone 11 or the end of the second bone 12, since human pathology and variation reflects both the patient's immediate and evolving pathophysiology.

[0014] The edge of the implant 10 shown in Figure 1 has a depending skirt 18 to secure or anchor the implant to the end of bone 11, but may have one or more depending tabs that may be employed for similar functions as will be discussed in other embodiments. The skirt 18 (and/or tabs) may tightly fit about the end of the first bone 11 as shown, or the skirt can be secured by adhesive (e.g. methyl methacrylate, bone ingrowth) to the supporting bone structure or be mechanically connected by staples, screws and the like. Moreover, the lower portion of the skirt 18 may be secured by a purse string suture or a suitable strand (elastic or tied) that is tightly bound about the outside of the skirt.

[0015] As shown in Figure 1, the implant interior 16 between the wall 13 and the wall 14 is filled with filler material which aids in maintaining the desired implant dynamics within the joint structure. The nature of the filler material such as a fluid and the characteristics of the walls 13, 14 and 15 may be selected to maintain a desired spacing between the walls in order to accommodate the pressure applied by the bones of the joint structure to the implant 10 and to allow suitable motion between the first and second walls 13 and 14 of the implant 10 which facilitate bone motion which mimics or approximates normal movement for the joint members involved such as shown in Figures 2 and 3. Alternatively, as mentioned above, the inner chamber may be filled with resilient material to provide the desired spacing, pressure accommodation, while allowing desired physiologic motion between implant layers. The implant 10 is preferably configured to be shaped like the joint space and bone surfaces being replaced or to fill the void produced by injury or disease so that the natural joint spacing and cushioning of the joint interface is restored toward normal physiologic appearance and function. Fluids such as saline, mineral oil and the like may be employed to inflate the implant.

[0016] Linear or curvilinear movement between the first and second walls 13 and 14 as a result of movement of the first and second bones 11 and 12 is illustrated by the arrow shown in Figure 2. Rotational movement about the bone axis between the first and second walls 13 and 14 as a result of axial rotation between the first and second bones 11 and 12 is illustrated by the arrow shown in Figure 3. While not shown in the drawings, there may be

slippage between the second bone and the second wall in addition to wall movements within the implant per se to provide desired joint movements. The skirt 18 is designed to secure the general implant to the joint structure so as to avoid dislocation of the implant. Movement of the joint with the implant 10 in place will be a shared function of both the moving opposing walls 13 and 14 of the implant but also a function of the movement of the wall 14 which may be less attached to the joint members. There may be slight movement between the skirt 18, wall 13 and the first bone 11. As shown in Figure 2 one side of the side wall 15 is in compression and the other is stretched to accommodate bone interface movement. The walls 13 and 14 may be thicker is some areas to accommodate particular loads and the side wall 15 may be thinner and more elastic to accommodate rolling and stretching thereof.

[0017] The interior 16 of implant 10 is adjustably filled by the physician from an appropriate source thereof after the implant is deployed to ensure that the pathologic joint space becomes a resilient cushion again which aids restoration of worn or damaged cartilage interfaces in the joint by covering cartilage defects with the implant material, cushioning the joint and defects therein and delivering cell regeneration agents. In one embodiment, the arthroplasty implant comprises a biocompatible inflatable member that is filled with a biocompatible fill material such as a gas, liquid, gel or slurry, or fluid that becomes a resilient solid to provide relative movement between the first and second walls 13 and 14. The filling or inflation media may be inserted through an injection valve site leading to the cannula which delivers the material into the interior of the implant. In an alternative embodiment, the implant may be filled with or have an interior formed of biologically compatible resilient material, e.g. a closed cell sponge filled with suitable fluid that is inserted into the interior of the implant prior to the implant's deployment or injected into the interior after the implant is deployed at the joint site. The interior of the implant may be provided with lubricious material to facilitate movement between the inner wall surfaces and to minimize contact wear therebetween. The polymeric walls of the implant may be impregnated with or otherwise carry tissue regeneration agents such as stem cells, living chondrocytes, and/or genes to repair joint surfaces.

[0018] The implant can be used in a variety of joints where the implant replaces a bone on bone surface and cushions the interaction between the articular ends of any two bones, such as at the femoral-acetabular interspace of a patient's hip, the humerus and glenoid scapular component in the shoulder, the femoral tibial and patella femoral knee interfaces, the replacement of talus bone in the human ankle between the tibia and calcaneus and the like. Where the implant is substituting or enhancing articular cartilage, the rigidity can be reduced or enhanced to maximize conformation changes that arise during motion as enabled by the two opposing walls and intended inner space, coupled with considerations in any joint surgical reconstruction with accommodation to or amplification of the existing joint ligaments, tendons or dearth thereof. The implant 10 may be deflated and removed by minimally invasive surgery, for example after the implant has served its purpose of regenerating tissue or if another clinical condition warrants its removal. However, it may not be clinically necessary to remove the implant even if inflation is lost, since the two remaining functions of patching the injured cartilage, and delivering restorative cells may justify implant retention.

[0019] Figure 4 is a perspective view, partially in section, illustrating a hip implant 20, similar to that shown in Figure 1, but with a much larger upper portion. The large upper portion of the implant 20 has a first wall 21, a second wall 22 and a side wall 23 which define at least in part the interior 24. Skirt 25 depends from the first wall 21 and secures the first wall 21 to the end of the patient's femur 26 as best shown in Figures 5 and 6. Figure 6 illustrates the implant mounted on the head of the femur 26 with the second wall 22 of the filled upper portion configured to engage the corresponding acetabulum 27 of the patient's pelvic bone 28. The skirt 25 surrounds the head of the patient's femur 26 and secures the implant 20 thereto. In this embodiment, the enlarged upper portion of the implant creates overlapping layers, like a redundant membrane, in the side wall 23 between the first and second walls 21 and 22 to accommodate the normal movement of the first or second. This provides greater motion between the femur and the acetabulum and also provides implant stabilization over the head of the femur 26. This structure also accommodates variation in individual joints that occur from patient to patient.

[0020] In the embodiment shown in Figures 4-6 the first wall 21 does not extend across the entire end of the patient's femur as in the embodiment shown in Figures 1-3. However, the implant 20 may be designed so that first wall 21 may extend over the head of the femur as shown in Figures 1-3 (and Figures 7-12 discussed hereinafter). The second wall 22 and the side wall 23 tend to roll as the femur 26 moves within the acetabulum 27.

[0021] Prior to deploying the implant embodying features of the invention, the cartilage lining the joint is prepared by removing hyaline or fibro cartilage flaps or tears, and areas of chondral advanced fissuring are excised or debrided to create precisely defined defects surrounded by stable normal remnant hyaline cartilage with vertical edges in relation to the damaged surface. It is these defects of the cartilage previously normal surface into which new living cells may be injected or otherwise inserted, and allowed to aggregate by the implant interpositional arthroplasty proximate expanded compressive external wall material. Synovitis invading the joint periphery may be vaporized and extracted conventionally or by the use of steam. Areas of greater cartilage damage are removed for subsequent regeneration and the less afflicted areas having stable cracks are treated to seal or weld the cracks. Areas where the tugor or consistency or minimally damaged cartilage can be preserved are intentionally

saved rather than destroyed so as to support the normal spacing and gliding opportunity of the more normal joint interface. Thus, normal cartilage is left behind and abnormal cartilage is removed with the implant making up for the deficiencies. With the present invention, it is preferred to avoid joint dislocation so as to preserve natural innervations and vascularity and thus preserving the blood supply afforded by the medial and lateral circumflex arteries for the hip joint to the femoral head.

[0022] Joint preparation is usually performed under a brief general anesthetic of outpatient surgery. A muscle relaxant combined with traction (e.g. 60 pounds (about 267 N) force for a hip implant) opens the joint wider to permit improved visualization for joint preparation and implant installation, increasing the space between the remnant cartilage from about 3 up to about 12 mm. Increasing the space allows the surgeon to wash out noxious enzymes, to remove invasive synovitis, to remove loose bodies, to prepare osteochondral defects ideally and otherwise prepare the joint for the implant. Partial or complete inflation of the implant will usually precede release of traction. Regeneration agents or cells are inserted with the implant or as a fluid or 3-D template prior to release of traction and wound closure. It is preferred to perform joint debridement, implant deployment and application of cell regeneration agent, e.g. stem cell application, under the same anesthetic. As described by several companies in the Stem Cell Summit held in New York, New York on February 17, 2009, it is desirable to obtain an aspiration of the patient's bone marrow from the iliac crest after anesthesial sterilely at the beginning of the operation. The intraoperative technologist will "dial in the cells" to regenerate areas of maximum pathophysiology while the surgeon debrides or otherwise prepares the joint and inserts the implant, placing the cells at the best time. Cell implantation may also occur as a secondary or tertiary reconstructive treatment adjunct.

[0023] Figure 7 is an elevational view, partially in section, of an alternative resilient implant 30 deployed within a patient's hip structure comprising the head of the patient's femur 31 and the acetabulum 32 of the patient's pelvic hip bone 33. The upper portion of the implant 30 is smaller than that shown in Figures 4-6. Details of the interior of the joint are not provided such as cartilage, ligaments and the like for the purpose of clarity. The resilient implant 30 embodying features of the invention is disposed within the space between the femur 31 and the acetabulum 32. Figures 7-11 illustrates the implant 30 mounted on the head of femur 31 without the pressure from the acetabulum 32 for purposes of clarity.

[0024] The implant 30 shown in Figures 7-12 is shaped like a half an orange rind or a hemisphere for a hip joint. The implant 30 has a first wall 34 seen in Figure 8 which is secured to the head of the femur 31 by a plurality of depending tabs 35. The tabs 35 may be attached to the femur 31 by a suitable adhesive or mechanically such as by a screw or pin. The second wall 36 of the implant engages the acetabulum 32, but it also may be provided with tabs and the like for securing the second wall the acetabulum 32.

[0025] The side wall 37 extends between the first and second walls 34 and 36 to form an interior 38 which receives filling material 39 through tube 40. The implant 30 would also be appropriate for the humeral head in the shoulder or one condyle of the knee or of the humerus, but other shapes may be desired for other joint configurations whether relatively flat as in the thumb base, or more inflated toward a ballooning construct as in the ankle when the talus bone is collapsed. In many embodiments the implant 30 is a weight bearing spacer that will allow joint motions to approach normal, whether filling the space left by an entirely collapsed peripheral joint bone or the space of ablated cartilage proximate surfaces diffusely as in osteoarthritis or succinctly as in osteonecrotic defects or localized trauma. The walls 34 and 36 may be used as a membrane for holding living cells in proximity of the osteochondral defect long enough for the cells to attach (e.g. 24 hours) or to deeply adhere (up to 28 days) or return to normal (up to one year). Weight bearing will be expected to increase as distal lower extremity joints are treated.

[0026] Motion is believed to be primarily between the spaced walls of the implant peripherally secured to joint structures, although some motion may occur between the implant and the joint surfaces (as with current bipolar hip hemiarthroplasties). As shown in Figure 12, the implant 30 may be provided with a slot 41 extending from the periphery 42 of the implant to a centrally located passage 43 through the implant to accommodate the ligament of the head of the femur for hip implants. Knee implants (not shown) may have two slots leading to separate passages for receiving the anterior and posterior cruciate ligaments. Implants for other locations may have similar variable structures to accommodate anatomical features. Implant walls 34 and 36 should have sufficient inherent flexibility to mold to the existing deformities imposed by either natural ligament, bone, tendon and remaining cartilage deformities of the internal joint space filled as a cushion. The wall exteriors may be flat or formed with random or specific patterns for purposes of glide or trends for traction against adjacent surfaces, or as sulci or venues for cell delivery materials.

[0027] A separate portal or tube (*not shown*) or the existing conduit 40, may be used to extract noxious inflammatory enzymes that can be aspirated at appropriate clinical intervals. Inflammatory enzymes in the COX1, COX2 and or 5LOX pathways can be extracted. Viscolubricants can be injected into the interior of the resilient arthroplasty device through existing conduit 40 or through a long needle to aide in distension, expansion, lubrication (with predetermined microporosity).

[0028] The ankle version of the arthroplasty implant 50 of the present invention shown in Figures 13 and 14 has basically a square transverse cross-section that must take into account supratalar ankle dorsi/plantar flexion, subtalar eversion/inversion motions, ligament fixation-

needs, and the accommodation to existing bony architecture as implant variables accounting for the ipsilateral joint pathophysiology. The implant 50 has a first wall 51, a second wall 52 and a side wall 53 which extends between the first and second wall. The exterior of the implant 50 may have a mesh material 54 with a plurality of chords 55-61 for securing the implant 50 to adjacent bones or to remnant ligaments which are attached to adjacent bones.

[0029] The implant 50 may be inflated with gas and/or liquid to open wider the space between the tibia above and the calcaneus below to accommodate collapse of the talus bone as in the flattening which succeeds talus fracture with avascular necrosis, or it may be filled with a liquid that becomes a resilient solid. The instant center of the implant's rotation will be constantly changing, with the talus implant mainly stable and with the tibia moving over it. Deformation with weight bearing during the average human's 10,000 daily steps or 2 - 4 million annual gait cycles required by the stance and walking of normal activities of daily living, must be balanced between sufficient solidarity of the implant to maintain axial load, avoiding circumferential stress, and shear forces imposed by the tibia distal plafond on the dorsal ankle implant allowing stance and gait of the patient while avoiding implant migration or failure. Further accommodation to lateral forces imposed by the boney medial and lateral malleoli, need to be endured through the cyclic load of walking, while collapsing with enough give to absorb shock and to match the shape of surrounding structures of bone and ligament tissue. Whereas the axial load between the distal tibia through the talar implant to the dorsal calcaneus will be loaded during stance and especially while walking on a level plane for supratalar motion, the lateral forces will be loaded particularly with subtalar motion while walking on an uneven plane or with inversion/eversion.

[0030] The dimensions of the various implant walls will vary depending upon the material properties thereof as well as the needs for a particular joint. Additionally, the first and second walls may require a thickness different from the side wall. Generally, the implant may have a wall thicknesses of about 0.125 mm to about 3 mm, preferably about 0.5 mm to about 1.5 mm. The spacing between the first and second wall within the interior can vary from about 0.5 mm to about 5 mm for most joints (except for the implant for an ankle when an entire collapsed bone space is being replaced), preferably about one to five centimeters to fill between the tibia and calcaneus. In the ankle invention version of the implant, the amount of inflation of the implant per se will be directly proportional to the amount of talus bone collapse between the distal tibia and proximal calcaneus - thus as much as 5 cm implant distension or expansion may be required to be maintained between superior and inferior surfaces in Figure 13 of the talus, while as much as 10 cm anterior and posterior expansion may be required for the ankle implant between the posterior soft tissues such including the Achilles tendon and the anterior navicular bone as relates to the talus as seen in Figure 13.

[0031] The method of insertion for the hip joint invention will be a minimally invasive approach, ideally arthroscopically facilitated, as long as the surgical timing and result quality permit smaller incisions. The hip patient will be placed in the lateral decubitus position (lying non-operative side down on the operating table) with a stabilizing operating table pole and pad apparatus positioned to fix the pelvis. The external stabilizing table and attachments will include a padded metal pole beneath the pubis or pelvic bone from posterior to anterior, along with other external anterior and posterior pelvic stabilizing paddles. The affected leg will be attached beneath the knee with a distracting mechanism that applies about 60 pounds (about 267 N) of distal force to open the hip joint about 1 cm once the patient is under general anesthesia. The hip joint is arthroscopically debrided through at least one anterior 0.5 cm incision and one posterior 0.5 cm incision, to remove from the femoral head acetabular (ball and socket) joint arthritic debris such as synovitis, loose bodies and noxious inflammatory enzymes. In certain cases a larger open incision may be needed. A smoothing or electronic/ultrasonic/steam or other chondroplasty method may be performed to make the remaining cartilage smoother to better accommodate the hip implant, and protuberant osteophytes or lateral bone overgrowths may be arthroscopically removed or if needed by open excision. A lateral hip incision may be required between 2 and 10 centimeters in length to deal with deformities and/or to insert the implant. In cases of major deformities appropriate reconstruction will add to the basic procedure.

[0032] Once the joint is open and cleared, the hip implant will be inserted laterally and fixed via the skirt or tabs to the adjacent structures including the peripheral femoral head and/or acetabular rim. Preferably, the implant is inserted arthroscopically through a cannula about 10 mm in diameter with the implant in the deflated construct, and once inside the prepared joint space and secured therein by the skirt or tabs, the implant will be distended or inflated with gas, gel, fluid or fluid that becomes a resilient solid to fill the original natural space of about 0.5 cm between the upper acetabulum and lower femoral head, covering as much of the upper hip joint as required as the implant expands to fit the space. Tensioning will be by the surgeon's sense of proper pressure application aided by a gauged syringe for insertion of viscolubricants such as Synvisc, Hyalgan, Supartz and/or analgesics such as lidocaine gel. The insertion of liquids to the joint per se may be directly, through a cannula to the joint space previously in place for debridement, and or via a cannula or tube that is not part of the original implant assembly. Once the joint is cleaned, the implant is inserted and appropriately fixed to avoid extrusion or dislocation thereof. This may be via attachment of the implant tabs and/or by a combination of tab use plus intended friction created by implant surface coverings (analogous

to Velcro) or a draw string at the smaller base of the implant.

[0033] The walls of the implant embodying features of the invention may be composite structures. For example, the innermost layer may be impervious to preclude escape of inflation or other filling media, a central layer may be porous or otherwise contain treatment or cell regeneration agents, and the outer layer may be a thin, but strong layer of a thermoplastic such as a thermoplastic polyurethane which has microporosity sufficient to allow passage or egress of treatment or cell regeneration agents from the central layer. The degree of microporosity to enable egress of treatment or cell regeneration agents from the central layer is found in polymer layers such as Chronoflex or Bionate 55. The external wall of the implant may be coated and/or impregnated with a latticework of polymer surface sprayed or layered on the outside of the implant to promote cartilage tissue regeneration. This most external surface coating may contain living chondrocytes as in the Carticel procedure by the Genzyme company, and/or may contain stem cells with directed gene mutations to enhance adherence of the coating to the implant. The living cells may be imposed in between troughs while the surface areas of prominence may be used for space validation, traction, and cell protection.

[0034] The implant embodying features of the invention may be used in a series of treatments wherein the first treatment involves use of autologous or minimally manipulated allograph interpositional tissues or xenograph, the second treatment involves the use of the same type of tissue added to stem cells or chondrocytes and the third treatment involving deployment of the implant if the first two fail or are ineffective.

[0035] The implant may be provided with latticework or other reinforcing strands, preferably on the exterior or within the wall thereof to control the maximum expansion of the implant when deployed at the orthopedic site.

[0036] The method of insertion of the ankle implant generally will be through an anterior surgical ankle approach or tendon separating incision from the distal tibia to the proximal talus (or calcaneus if the talus is absent), removing and reconstructing portions of the superior and inferior ankle extensor retinacula only to the extent required to gain access to the cleared tibiotalar space. Analogous to the hip joint insertional method, the ankle joint will be prepared arthroscopically under general anesthesia, and may benefit from distal distraction as in total ankle joint replacement surgeries with the DePuy Agility technique pinning above and below the ankle joint and then distracting it. The degree of distraction required in all joints to which this invention is applied, including but not limited to those of all appendicular skeletal structures such as the shoulder, elbow, wrist, phalanges, hip, knee, and ankle, will depend both on the nature anatomy and located pathophysiology that must be accommodated on a case by case basis and said distraction may be a combination of body position using gravitational forces and/or superimposed distracting devices. In the ankle, the surgeon will be developing the interval between the extensor hallucis longus and anterior tibial tendons. Injury tissue is removed, and the implant inserted fitting as preplanned. The implant surface may be provided with roughness, e.g. external mesh, to control movement by friction as described above for the hip joint, and/or attached fixation cords or tabs to connect to proximate ligaments or adjacent boney structures may be used at the surgeon's discretion to balance implant location stability and integrity, with the need for functional joint movements.

[0037] Over time, ingrowth of repair tissue aids in fixation and stability externally to the implant, while the soft cushioning implant interior will absorb forces across the joint surfaces and permit proper motion. The tugor or wall tension of the implant as well as the inside distension of the implant per se can be adjusted by adding or removing the inflation substance to the implant's interior space.

[0038] Accordingly, the present invention provides a new approach to arthroplasty that involves a resilient implant device deployed between bones of the joint. Whereas a joint is comprised of the interface between bone cartilage space cartilage bone, in certain joint spaces such as the knee, the invention cushion may expand to fit the spaces between both "knee joints" - the femoral tibial involved on standing or walking on a level plane, and the patella femoral bones of the knee more involved on stair ascent and decent. For example, pressures behind the knee cap or patella when lying are zero, when standing are 0.7 times body weight, and when going up and down the patella femoral pressures are 3 - 4 times body weight. Thus, the implants will need to accommodate all the normal body functional pressures and complex space movements, as described above also in the ankle. When in the hip joint, the normal flexion up to 120 degrees, extension of 20 degrees, abduction of 50 degrees, internal and external rotation of 45 degrees will produce variable axial, shear, and cyclic loads which the implant by design will accommodate and endure as up to 6 times body weight, consistent with a tire on a car that allows for cyclic loads different when driving straight or turning corners. The implant embodying features of the present invention provides more physiologic motion and shock absorption within the joint and has combined characteristics of anatomic design symmetry, balanced rigidity with sufficient attachment connections to adjacent normal structures, and durability that meet the needs of joint reconstruction.

[0039] The opposing internal surfaces of the first and second walls of the invention may either move together in synchrony or in opposite directions from one another (e.g. the superior wall moving medially in the hip and the inferior wall moving laterally). Optionally, the implant may be fixed to a concave surface of the joint (e.g., the acetabular hip cup) or to a convex surface of the joint (e.g. the dorsal femoral head surface), to both, or to neither (e.g., having an interference fit within the joint with an expand-

ing balloon or cushion that fills the existing space). The implant may be inserted arthroscopically like a deflated balloon and then inflated through a cannula into the ankle or hip (or other joint structure) to act as a cushion or renewed interface for painless and stable limb motion. When feasible joint capsular and adjacent ligament tissue as well as bone will be left in place to preserve the natural body, unless interfering with reconstructed limb function.

[0040] The application of steam in addition to removing damaged debris, can smooth out and reform the joint surface. The high temperature of the steam tends to weld cracks or fissures which can be present in the cartilage surface of a damaged joint. Smoothing of joint surface cartilage with steam welds or seals existing cracks or flaps in the cartilage, especially superficially as the lamina splendors, which melt together to provide a white shiny gliding joint surface. In cases where bone is exposed, the steam can be used to stabilize the periphery of the defect in the joint surface via capsulorrhaphy or joint tightening. Open mechanical and chemical debridement may also be employed to prepare the surfaces for the implant.

[0041] Once the implant is secured to the femoral head by means of the skirt or tabs, an impregnated transfer medium or cell template may be used, as described by Histogenics and Tygenix chondrocytes delivery systems wherein the position of concentrated cells is mechanically placed about the implant at areas of greatest cartilage damage to promote regrowth, or as in Carticel wherein watery cells are implanted beneath a periosteal membrane (a wall of the implant serving as the membrane), prior to completion of the inflation or expansion of the implant. At syringe or gauged device with measured screw-home pressure is used to inflate the implant.

[0042] Once the joint is ready to receive the implant, the deflated implant is advanced through the diaphragm of a delivery cannula (such as the Acufex from Smith & Nephew) and into the joint. It can be inflated by the attached cannula using a common syringe, inserting several cc's of filler material. Inserted contents and locations of cell placements depend on areas of need and joint size. In the hip implant several cc's of filler material and a viscolubricant in the interior of the implant will allow distension, cushioning, and gliding movements. Cell regeneration agents are placed in the areas of greatest need.

[0043] Methods of living stem cell or chondrocyte placement depend on the lesions and specific implant construct. Direct infusion into the joint with completion of implant inflation will press the cells into the hyaline surface, whereupon they attach within the first 24 hours. As a result, the patient should remain sedentary and the joint where the implant is deployed, non-weight bearing for the first day after surgery. Deeper osteochondral defects can be treated by 'hyper-perfusion of cells' via either 3-D cell transfer templates, or microneedle injection as used in treatment of diabetic patients for blood sugar testing and insulin/transdermal drug delivery. The cannula attached to the implant may be sealed and detached, or left in place for periodic aspiration of noxious enzymes as for the Cox-1, Cox-2, and 5-Lox systems, followed by reinsertion of activated substances including viscolubricants, or even more cells.

[0044] Implants embodying features of the invention may be designed for permanent or temporary deployment within a joint structure. In accordance with the present invention, the implant is formed of suitable bioabsorbable materials so that the implant may be absorbed within a particular predetermined time frame. Suitable bioabsorbable materials include polylactic acid, polyglycolic acid, polycaprolactone, copolymers, blends and variants thereof. One present method of forming the implant is to apply numerous layers of polymer such as ChronoFlex AR in a solvent and evaporating the solvent after applying each layer.

[0045] The skirting or fixation tabs of the present implant prevent joint migration during use. This is in contradistinction with prior solid polymer implants that tended toward dislocation and poor post operative function.

[0046] While particular forms of the invention have been illustrated and described herein, it will be apparent that various modifications and improvements can be made to the invention. One alternative implant construction involves the use of an upper portion of the implant having a net-like construction and filled with balls or ball bearing like elements that are larger than the openings in the netting. The balls or ball bearing like elements provide motion to the implant. The netting and ball bearing like elements may include regeneration agents as previously discussed, and the bearing construction may be directed toward favorable implant movement balanced with content disbursement.

[0047] The invention is intended primarily for human use but may be extended to mammalian use. To the extent not otherwise disclosed herein, materials and structure may be of conventional design.

[0048] Moreover, individual features of embodiments of the invention may be shown in some drawings and not in others, but those skilled in the art will recognize that individual features of one embodiment of the invention can be utilized in another embodiment. Moreover, individual features of one embodiment may be combined with any or all the features of another embodiment. Accordingly, it is not intended that the invention be limited to the specific embodiments illustrated. It is therefore intended that this invention be defined by the scope of the appended claims.

Claims

1. A resilient orthopedic implant (10) configured for deployment between opposing first (11) and second (12) bones of a joint structure, comprising:

a. a first wall (13) having one or more appendages configured to secure directly or indirectly the first wall (13) to the first bone (11) of a joint structure;
b. a second wall (14) configured to engage the second bone (12) of the joint structure;
c. a side wall (15) extending between the first wall (13) and second wall (14) and configured to facilitate relative motion between the first (13) and second (14) walls; and
d. an interior (16) defined by the first (13), second (14), and side (15) walls;

wherein the implant (10) comprises a resilient material, **characterised in that** the resilient material is bioabsorbable.

2. The implant (10) of claim 1 wherein the one or more appendages is a skirt (18).

3. The implant (10) of claim 1 wherein the one or more appendages are tabs (35).

4. The implant (10) of claim 1 wherein the one or more appendages are chords.

5. The implant (10) of claim 1 wherein the relative motion between the first (13) and second (14) walls is rotational motion.

6. The implant (10) of claim 1 wherein the relative motion between the first (13) and second (14) walls is linear or curvilinear motion.

7. The implant (10) of claim 1 wherein the second wall (14) of the joint structure is a force applying bone (12).

8. The implant (10) of claim 1 wherein the second wall (14) has a skirt (18) or one or more tabs (35) which extend from the second wall (14) to secure the second wall (14) of the implant to the second bone (12).

9. The implant (10) of claim 1 wherein the resilient material is a biodurable thermoplastic polyurethane.

10. The implant (10) of claim 1 wherein one or more of the walls (13, 14, 15) comprise a plurality of layers.

11. The implant (10) of claim 10 wherein at least one of the layers are porous.

12. The implant (10) of claim 1 wherein the side wall (15) of the implant has reinforcing strands to control expansion upon compression of the implant (10).

13. The implant (10) of claim 1 wherein the interior (16) is filled with inflation medium.

14. The implant (10) of claim 12 wherein the inflation medium is a resilient material.

15. The implant (10) of claim 1 wherein a lubricious material is maintained between the first (13) and second (14) walls to facilitate relative motion between the first (13) and second (14) walls.

16. The implant (10) of claim 2 or 3, further comprising at least one of an adhesive and a mechanical connector, wherein the skirt (18) or the tab (35) of the appendage is configured to be secured to a supporting bone structure using the adhesive or mechanical connector in order to secure the first wall (13) to the first bone (11) of the joint structure.

Patentansprüche

1. Elastisches orthopädisches Implantat (10), konfiguriert zum Einsetzen zwischen einem ersten (11) und einem diesem gegenüberliegenden zweiten (12) Knochen einer Gelenkanordnung, Folgendes umfassend:

a. eine erste Wand (13) mit einem oder mehreren Anhängen, konfiguriert zum direkten oder indirekten Sichern der ersten Wand (13) an dem ersten Knochen (11) einer Gelenkanordnung;
b. eine zweite Wand (14), konfiguriert zum Ineingriffnehmen des zweiten Knochens (12) der Gelenkanordnung;
c. eine Seitenwand (15), die sich zwischen der ersten Wand (13) und der zweiten Wand (14) erstreckt und konfiguriert ist, eine Bewegung der ersten (13) mit Bezug auf die zweite (14) Wand zu ermöglichen; und
d. einen Innenraum (16), definiert durch die erste (13), die zweite (14) und Seitenwände (15);

wobei das Implantat (10) ein elastisches Material umfasst, **dadurch gekennzeichnet, dass** das elastische Material bioresorbierbar ist.

2. Implantat (10) nach Anspruch 1, wobei der eine oder die mehreren Anhänge eine Schürze (18) sind.

3. Implantat (10) nach Anspruch 1, wobei der eine oder die mehreren Anhänge Laschen (35) sind.

4. Implantat (10) nach Anspruch 1, wobei der eine oder die mehreren Anhänge Sehnen sind.

5. Implantat (10) nach Anspruch 1, wobei die Bewegung der ersten (13) mit Bezug auf die zweite (14) Wand eine Drehbewegung ist.

6. Implantat (10) nach Anspruch 1, wobei die Bewe-

gung der ersten (13) mit Bezug auf die zweite (14) Wand eine lineare oder eine bogenförmige Bewegung ist.

7. Implantat (10) nach Anspruch 1, wobei die zweite Wand (14) der Gelenkanordnung ein eine Kraft aufbringender Knochen (12) ist.

8. Implantat (10) nach Anspruch 1, wobei die zweite Wand (14) eine Schürze (18) oder eine oder mehrere Laschen (35) aufweist, die sich von der zweiten Wand (14) aus erstrecken, um die zweite Wand (14) des Implantats an dem zweiten Knochen (12) zu sichern.

9. Implantat (10) nach Anspruch 1, wobei das elastische Material ein biobeständiges thermoplastisches Polyurethan ist.

10. Implantat (10) nach Anspruch 1, wobei eine oder mehrere der Wände (13, 14, 15) mehrere Schichten umfassen.

11. Implantat (10) nach Anspruch 10, wobei wenigstens eine der Schichten porös ist.

12. Implantat (10) nach Anspruch 1, wobei die Seitenwand (15) des Implantats Verstärkungsstränge aufweist, um eine Verlängerung beim Komprimieren des Implantats (10) zu regeln.

13. Implantat (10) nach Anspruch 1, wobei der Innenraum (16) mit einem Aufblasmedium gefüllt ist.

14. Implantat (10) nach Anspruch 12, wobei das Aufblasmedium ein elastisches Material ist.

15. Implantat (10) nach Anspruch 1, wobei ein schlüpfriges Material zwischen der ersten (13) und der zweiten (14) Wand gehalten wird, um eine Bewegung der ersten (13) mit Bezug auf die zweite (14) Wand zu ermöglichen.

16. Implantat (10) nach Anspruch 2 oder 3, ferner umfassend einen Klebstoff und/oder einen mechanischen Verbinder, wobei die Schürze (18) oder die Lasche (35) des Anhangs konfiguriert ist, unter Einsatz des Klebstoffs oder des mechanischen Verbinders an einer stützenden Knochenanordnung gesichert zu werden, um die erste Wand (13) an dem ersten Knochen (11) der Gelenkanordnung zu sichern.

Revendications

1. Implant orthopédique élastique (10) configuré pour le déploiement entre un premier os (11) et un deuxième os (12) opposés d'une structure d'articulation, comprenant :

   a. une première paroi (13) ayant un ou plusieurs appendices configurés pour fixer directement ou indirectement la première paroi (13) au premier os (11) d'une structure d'articulation ;
   b. une deuxième paroi (14) configurée pour venir en prise avec le deuxième os (12) de la structure d'articulation ;
   c. une paroi latérale (15) qui s'étend entre la première paroi (13) et la deuxième paroi (14) et configurée pour faciliter le mouvement relatif entre la première paroi (13) et la deuxième paroi (14) ; et
   d. un intérieur (16) défini par la première paroi (13), la deuxième paroi (14), et la paroi latérale (15) ;

   l'implant (10) comprenant un matériau élastique, **caractérisé en ce que** le matériau élastique est bioabsorbable.

2. Implant (10) selon la revendication 1 dans lequel le ou les appendices sont une jupe (18).

3. Implant (10) selon la revendication 1 dans lequel le ou les appendices sont des languettes (35).

4. Implant (10) selon la revendication 1 dans lequel le ou les appendices sont des cordes.

5. Implant (10) selon la revendication 1 dans lequel le mouvement relatif entre la première paroi (13) et la deuxième paroi (14) est un mouvement de rotation.

6. Implant (10) selon la revendication 1 dans lequel le mouvement relatif entre la première paroi (13) et la deuxième paroi (14) est un mouvement linéaire ou curviligne.

7. Implant (10) selon la revendication 1 dans lequel la deuxième paroi (14) de la structure d'articulation est un os appliquant une force (12).

8. Implant (10) selon la revendication 1 dans lequel la deuxième paroi (14) présente une jupe (18) ou une ou plusieurs languettes (35) qui s'étendent à partir de la deuxième paroi (14) pour fixer la deuxième paroi (14) de l'implant au deuxième os (12).

9. Implant (10) selon la revendication 1 dans lequel le matériau élastique est un polyuréthane thermoplastique biodurable.

10. Implant (10) selon la revendication 1 dans lequel une ou plusieurs des parois (13, 14, 15) comprennent une pluralité de couches.

11. Implant (10) selon la revendication 10 dans lequel au moins une des couches est poreuse.

12. Implant (10) selon la revendication 1 dans lequel la paroi latérale (15) de l'implant présente des fils de renfort pour contrôler l'expansion lors de la compression de l'implant (10).

13. Implant (10) selon la revendication 1 dans lequel l'intérieur (16) est rempli d'un milieu de gonflage.

14. Implant (10) selon la revendication 12 dans lequel le milieu de gonflage est un matériau élastique.

15. Implant (10) selon la revendication 1 dans lequel un matériau lubrifiant est maintenu entre la première paroi (13) et la deuxième paroi (14) pour faciliter le mouvement relatif entre la première paroi (13) et la deuxième paroi (14).

16. Implant (10) selon la revendication 2 ou 3, comprenant en outre au moins un adhésif et un raccord mécanique, dans lequel la jupe (18) ou la languette (35) de l'appendice est configurée pour être fixée à une structure osseuse de soutien en utilisant le raccord adhésif ou mécanique afin de fixer la première paroi (13) au premier os (11) de la structure d'articulation.

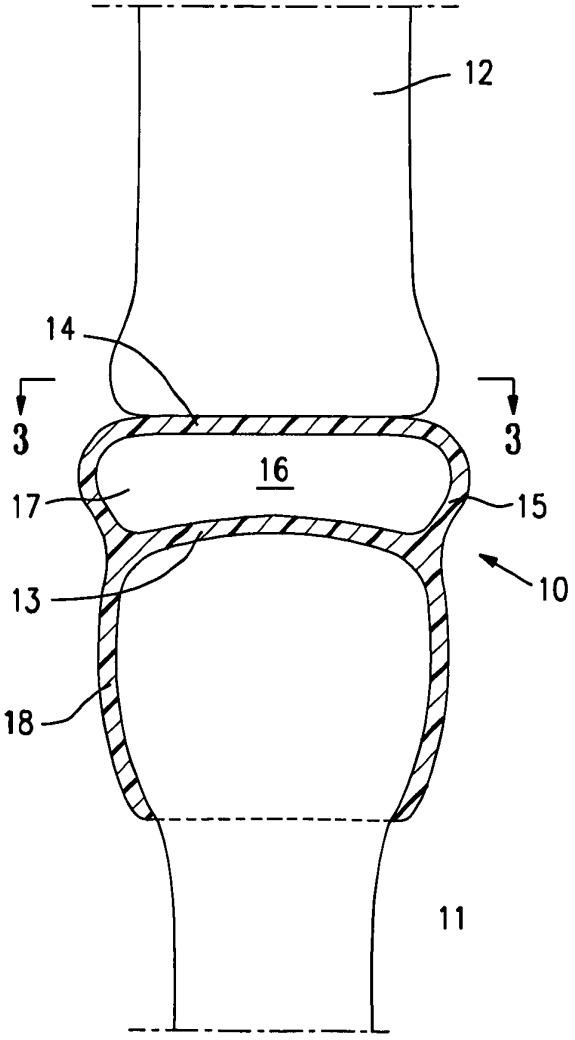

FIG. 1

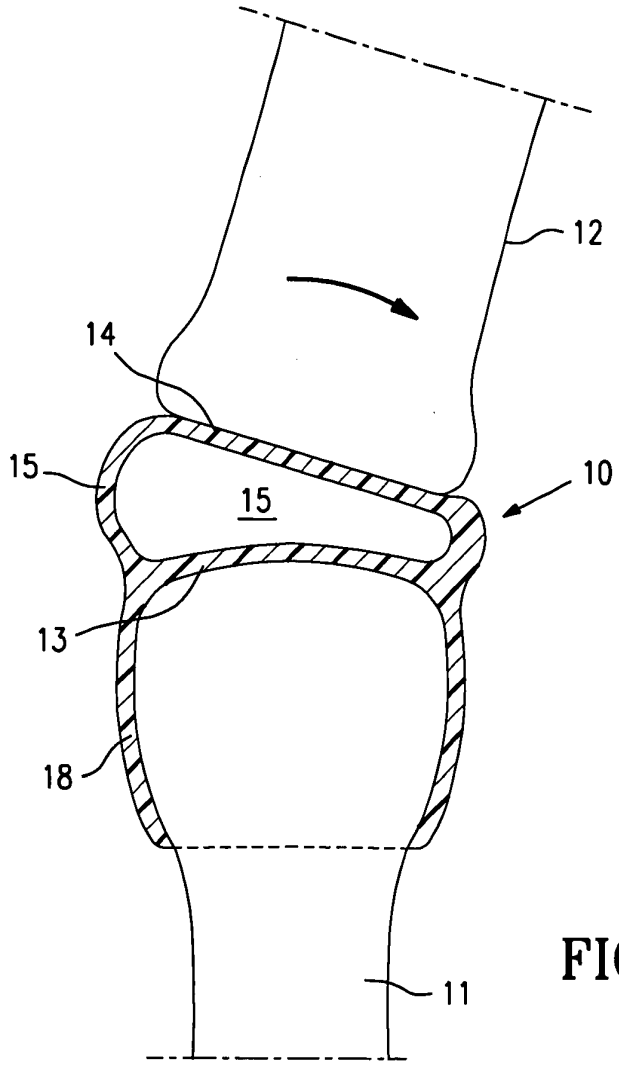

FIG. 2

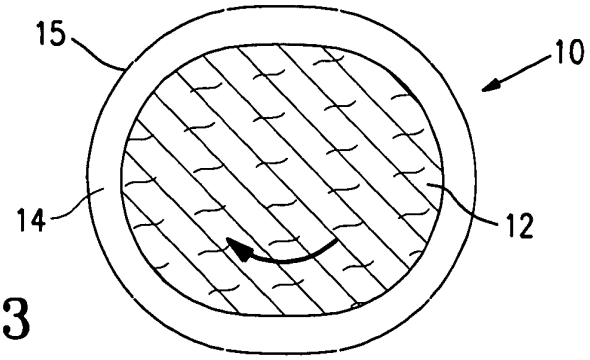

FIG. 3

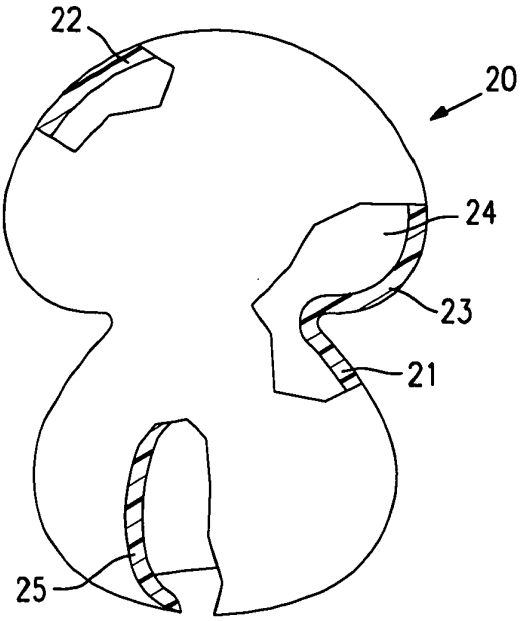

FIG. 4

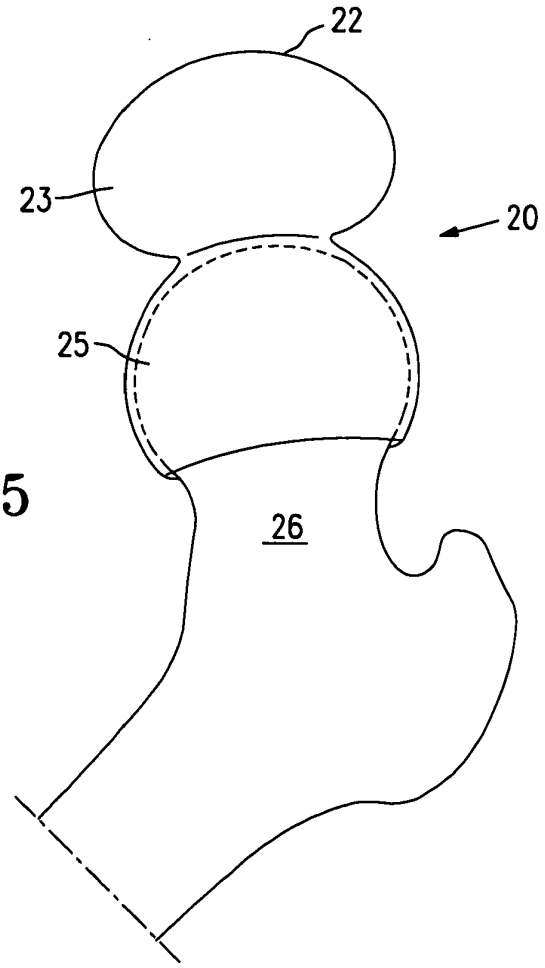

FIG. 5

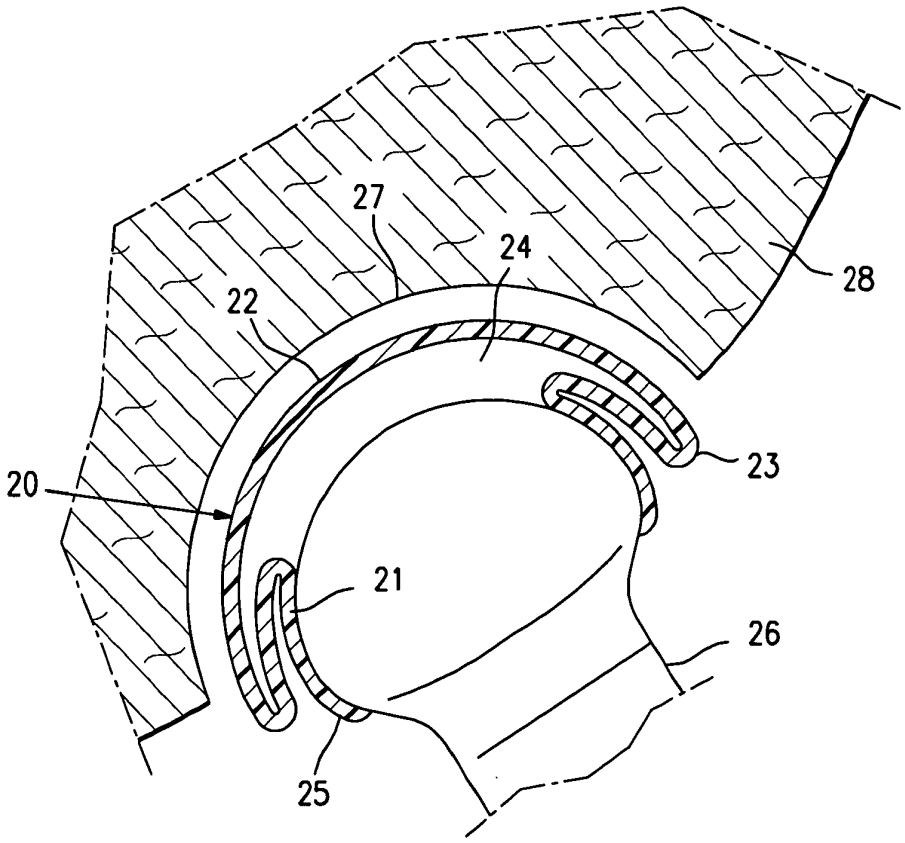

FIG. 6

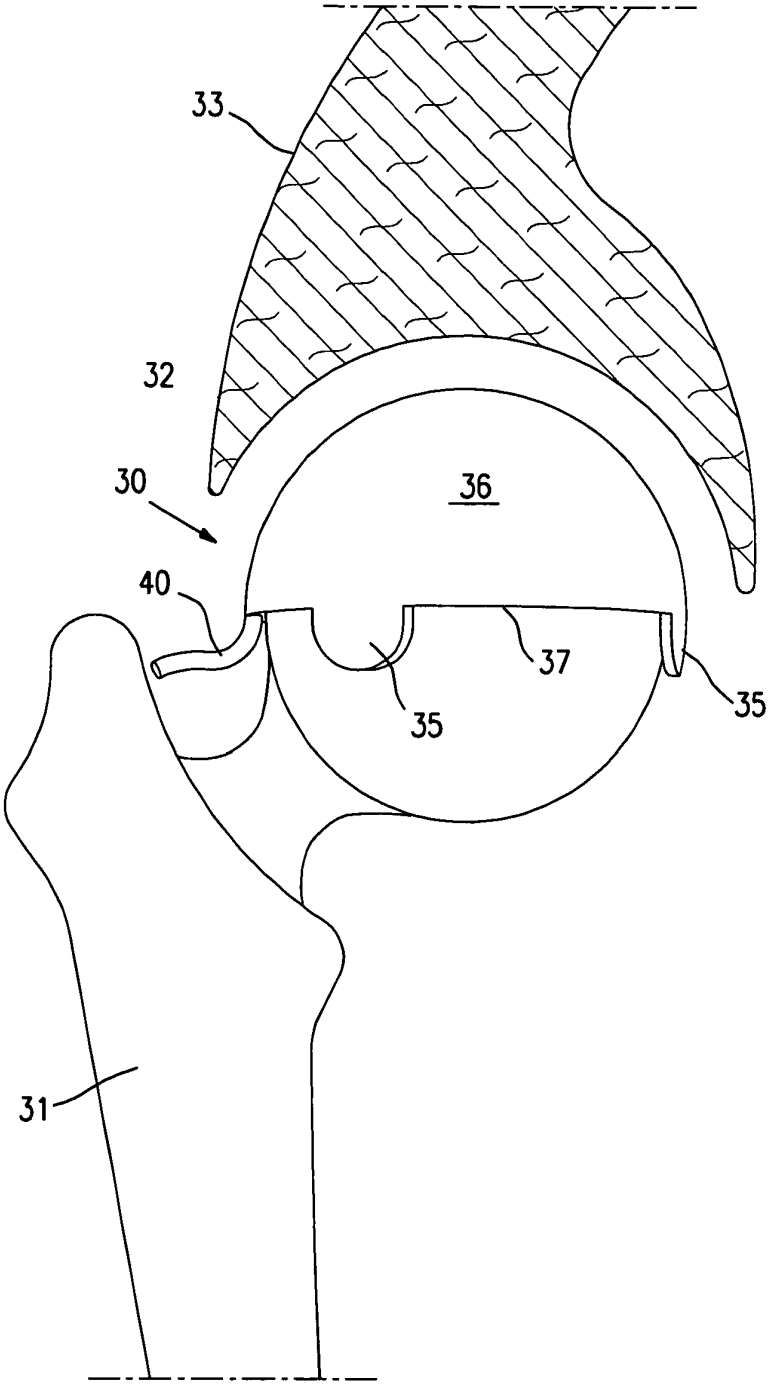

FIG. 7

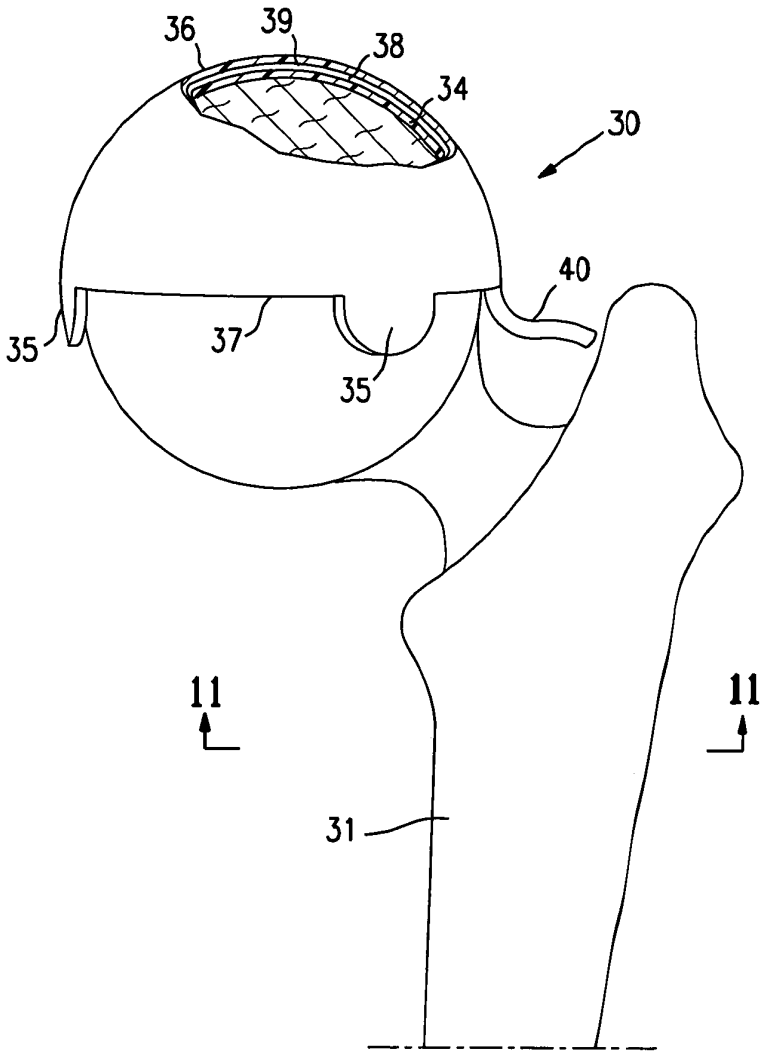

FIG. 8

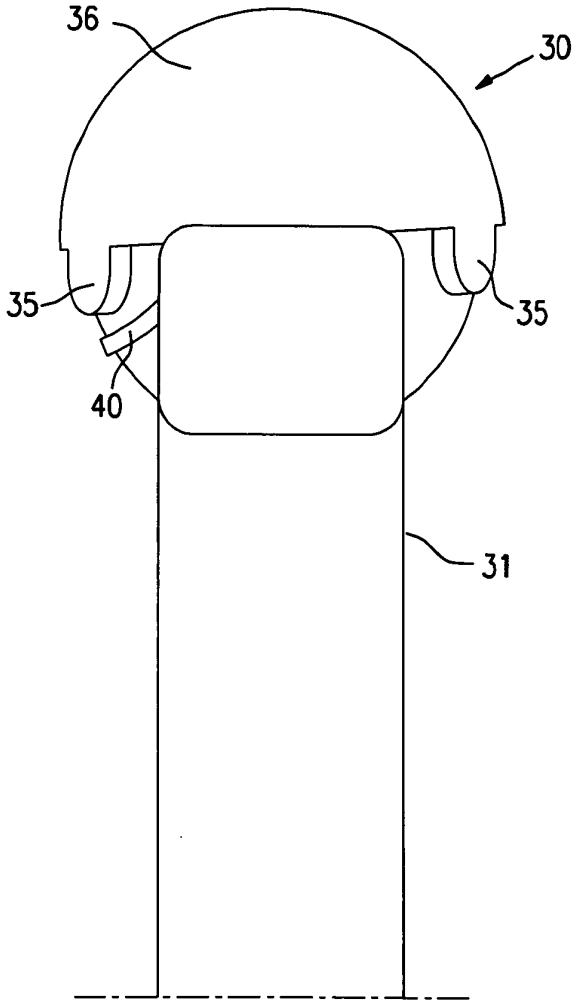

FIG. 9

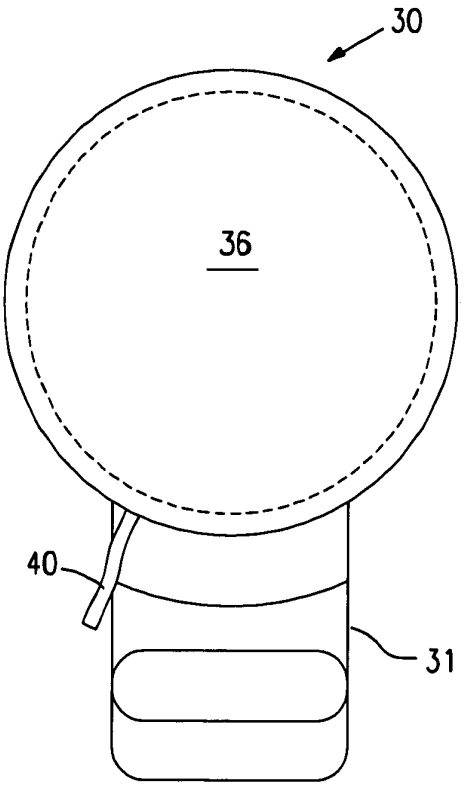

FIG.10

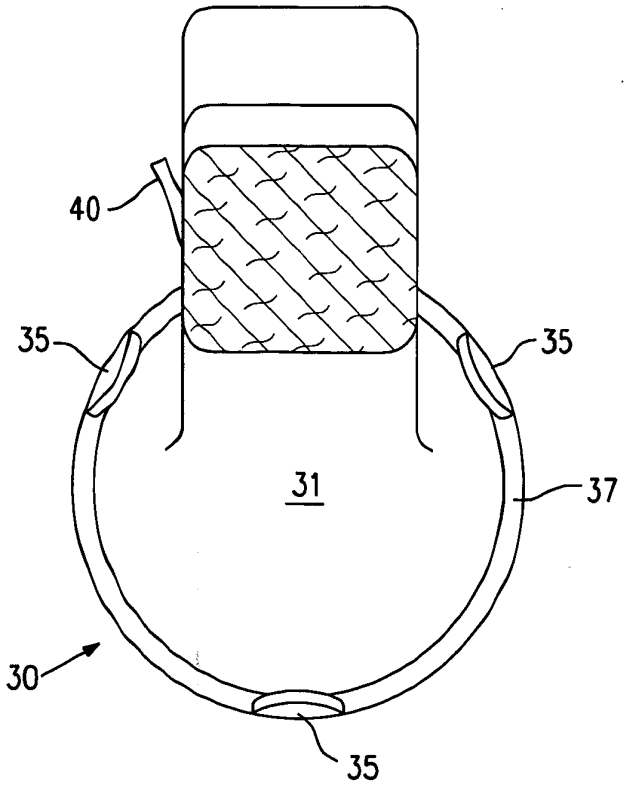

FIG.11

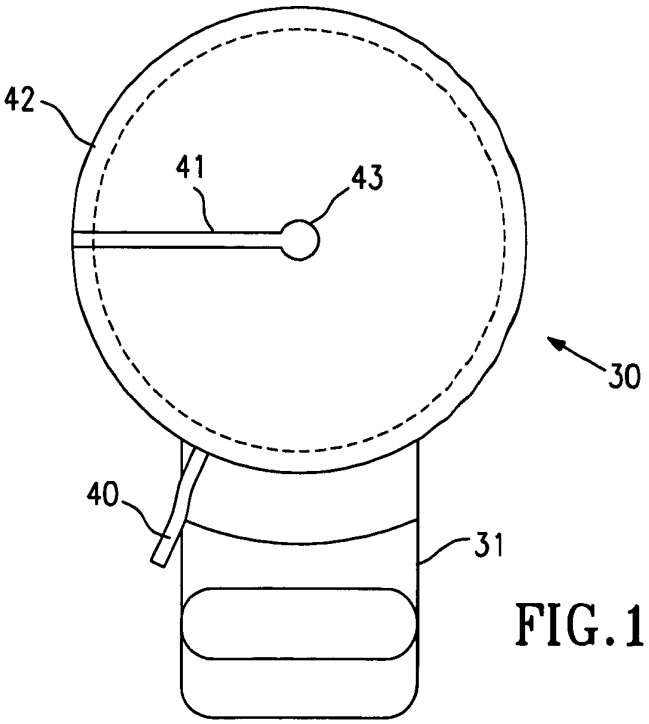

FIG.12

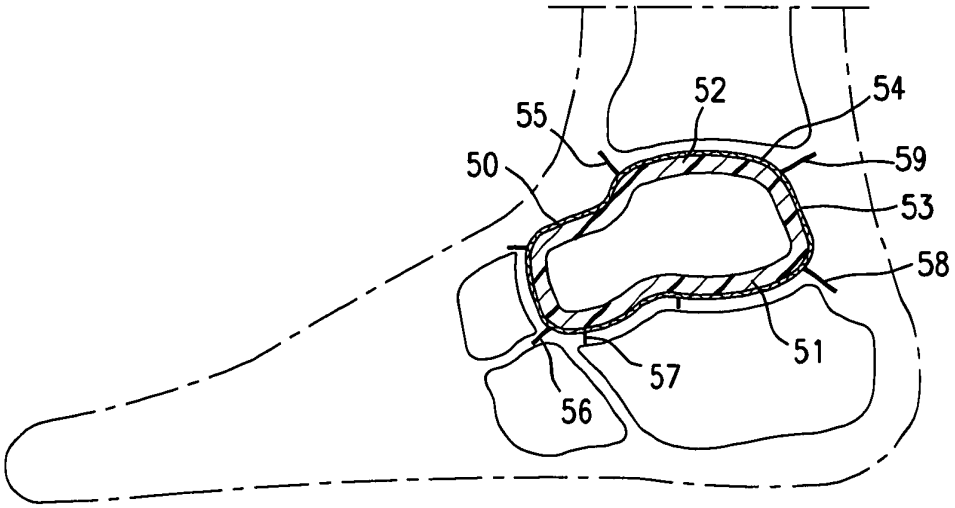

FIG. 13

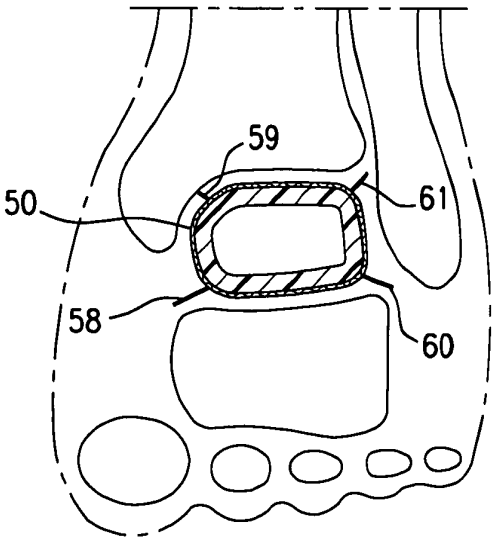

FIG. 14

REFERENCES CITED IN THE DESCRIPTION

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Office européen des brevets

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A61L 27/34 *(2006.01)* ***A61L 27/56*** *(2006.01)*
A61L 27/54 *(2006.01)* ***A61F 2/20*** *(2006.01)*
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(54) **RESILIENT INTERPOSITIONAL ARTHROPLASTY DEVICE**

ELASTISCHE ZWISCHENPOSITIONIERUNGSVORRICHTUNG FÜR DIE ARTHROPLASTIK

DISPOSITIF D'ARTHROPLASTIE AVEC INTERPOSITION ÉLASTIQUE

(84) Designated Contracting States:
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EP 2 750 629 B1

Description

BACKGROUND OF THE INVENTION

[0001] This invention relates to arthroplasty, and more particularly, to an implant for use in arthroplasty when hyaline articular cartilage is damaged, it breaks down and joint space is lost. Inflammatory enzymes such as from the Cox-1, Cox-2 and/or 5-Lox systems are released and loose bodies form adding to the degradation of joint function. Such joint damage is conventionally treated by physical therapy, analgesics, pain medication and injections. When these treatments fail, the traditionally accepted treatment option is arthroplasty implantation or replacing the joint with an artificial joint construct. Current arthroplasty techniques typically use "plastic and metal" implants that are rigid and which ultimately fail due to loosening or infection or debris from wear. Conventional materials for the artificial joint components include chrome-cobalt-molybdenum alloy (metal) and high molecular weight polyethylene (plastic). Each is often fixed by a cement-like mixture of methyl methacrylate to the ends of the bones that define the joint that is the subject of the arthroplasty, or coated with a surface that enables bone in-growth. Current hip joint replacements typically last about 10-15 years and knee replacements typically last about 5 -10 years. Ankle joint replacements, on the other hand, are not very successful, and often fail in the first several years after surgery.

[0002] Conditions requiring arthroplasty include traumatic arthritis, osteoarthritis, rheumatoid arthritis, osteonecrosis, and failed surgical procedures.

[0003] WO 2011/091005 (Grotz) relates to a resilient knee implant including a balloon with an inflatable interior and having a first appendage for coupling the balloon to the femur of the knee joint.

SUMMARY OF THE INVENTION

[0004] The invention is defined in the appended claims. The present invention is directed to an orthopedic implant configured for deployment between opposing members of a joint structure that addresses many of the shortcomings of prior artificial joints. The arthroplasty implants embodying features of the invention are configured to preserve joint motions while removing the pain and dysfunction following the development of arthritis or joint injury. The arthroplasty implant in accordance with the present invention achieves improved physiologic motion and shock absorption during gait and acts as a resilient spacer between moving bones during limb movement. The combined characteristics of the implant include anatomic design symmetry, balanced rigidity with variable attachment connections to at least one of adjacent normal structures, and durability which addresses and
meets the needs for repair or reconstruction thus far missed in the prior art. The implant should be secured to at least one of the bones of the joint structure.

[0005] Provided herein is a resilient implant for implantation into human or animal joints to act as a cushion allowing for renewed joint motion. The implant may endure variable joint forces and cyclic loads while reducing pain and improving function after injury or disease to repair, reconstruct, and regenerate joint integrity. The implant may be deployed in a prepared debrided joint space, secured to at least one of the joint bones and expanded in the space, molding to surrounding structures with sufficient stability to avoid extrusion or dislocation. The implant may pad the damaged joint surfaces, may restore cushioning immediately and may be employed to restore cartilage to normal by delivering regenerative cells.

[0006] Provided herein is a resilient interpositional arthroplasty implant for application into human or animal joints to pad cartilage defects, cushion joints, and replace or restore the articular surface, preserving joint integrity, reducing pain and improving function. The implant may endure variable joint compressive and shear forces, and millions of cyclic loads, after injury or disease requires intervention. The implant may repair, reconstruct, and regenerate joint anatomy in a minimally morbid fashion, with physiologic solutions that improve upon the rigid existing joint replacement alternatives of plastic and metal. In cases where cells have been used for joint resurfacing requiring massive periosteal harvesting for containment, the polymer walls of some embodiments of the implant can capture, distribute and hold living cells until aggregation and hyaline cartilage regrowth occurs. The implant may be deployed into a prepared debrided joint space, molding and conforming to surrounding structures with sufficient stability to avoid extrusion or dislocation. Appendages of the implant may serve to repair or reconstruct tendons or ligaments. Appendages of the implant may serve to repair or reconstruct fibrocartilage as in menisci, or the labrum tissues of hips or shoulders.

[0007] In some embodiments, the implant comprises at least one attachment element in the intercondylar notch. In some embodiments, the implant comprises at least one attachment element in the medial region of the intercondylar notch. In some embodiments, the implant comprises at least one attachment element in the lateral region of the intercondylar notch. In some embodiments, the implant comprises at least one attachment element superiorly at the distal end of the femur anteriorly. In some embodiments, the implant comprises at least one posterior reign configured to cinch up the implant from inside a posterior intercondylar notch toward a connection site around the femur. In some embodiments, the implant comprises at least one suture-like lanyard configured to cinch up the implant from inside a posterior intercondylar notch toward a connection site around the femur.

[0008] In some embodiments, at least two of first portion, the second portion, and the side portion are contiguous. In some embodiments, the first portion comprises a first wall, the second portion comprises a second wall, and the side portion comprises a side wall.

[0009] In some embodiments, the at least one condyle is the medial condyle. In some embodiments, the at least one condyle is the lateral condyle. In some embodiments, the retropatellar surface could be the anatomic region padded. In some embodiments, the tibia-medial or lateral or both is capped. In certain knee implant embodiments, the implant articulates against cartilage of the first bone, second bone, and/or the third bone

[0010] In some embodiments, the implant is fabricated to resemble a certain anatomic region over which the implant is stretched or pulled into place. The implant then may settle into its angle of repose via inherent elasticity. In some embodiments the ambient environment of the joint via exposure to serum or temperature or acidity has a specified effect on the implant materials such as increasing the implant malleability that affects implant performance.

[0011] In some embodiments, the implant comprises an in-growth matrix on at least a portion of the implant adjacent the femur. In some embodiments, the in-growth matrix comprises living chondrocytes. In some embodiments, the implant is configured to release the chondrocytes over time. In some embodiments, the implant comprises a bioabsorbable polymer configured to release the chondrocytes over time. In some embodiments, the implant comprises a polymer configured to release the chondrocytes over time, wherein the polymer is not bioabsorbable. In some embodiments, the in-growth matrix comprises cells. In some embodiments, the in-growth matrix comprises at least one of: stem cells, differentiated cells, pluripotent cells, post-mitotic cells. In some embodiments, the cells restore an articular surface of the femur. In other embodiments, the cells repair an articular surface of the femur. In some embodiments, the implant comprises a bioabsorbable polymer configured to release the cells over time. In some embodiments, the implant comprises a polymer configured to release the cells over time, wherein the polymer is not bioabsorbable. In some embodiments, the in-growth matrix comprises at least one of: autologous cells, allograph cells, and xenograph cells to restore an articular surface of the femur. In some embodiments, the in-growth matrix comprises at least one of: autologous cells, allograph cells, and xenograph cells to repair an articular surface of the femur. In some embodiments, the in-growth matrix comprises a pharmacologic substance. In some embodiments, the patch implant comprises a matrix that is coated with a hydrophilic or a hydrophobic polymer. In some embodiments the patch is vessicular with or without matrices in the wall components. In certain embodiments, the patch is a solid compliant material. In some embodiments, the walls or material construct is responsive or performs in a dynamic fashion to exogenous joint forces. For non-limiting example, in bone under normal physiologic stress of bearing weight, calcification yields sufficient bone density so as to deter fracture. However, in circumstances wherein prolonged dearth of weight bearing stress is produced by immobilization the bone becomes osteoporotic and pathologic. The implant herein may have smart features to adjust to stimulate healing and tissue regeneration. In some embodiments such materials can be composed of macromolecules or dendritic connections that regulate permeability and transfer of adjacent media.

[0012] In some embodiments, the implant comprises couplers that couple the appendage to the femur. In some embodiments, the coupler is bioabsorbable. In some embodiments, the coupler is at least one of: a screw, a snap, a washer, a suture, a suture anchor, a rivet, a staple, a staple having teeth, a magnet, an electromagnet, a microminiature transmitter that regulates implant fixation or performance responsive to patient need as perceived by the patient or a care giver, a stabilizer, a glue, a hook, a wire, a string, a lasso, a lanyard, a spike, and combinations thereof. The implant may also and/or alternatively be attached via bone in-growth. In some embodiments, the implant is attached via bone in-growth as described in Vasanji A, In vivo bone growth assessment in preclinical studies and clinical trials, Bonezone, 2012, p. 12-17.

[0013] In some embodiments, the implant comprises a pharmacologic agent. In some embodiments, the pharmacologic agent is on a surface of the implant adjacent the femur. In some embodiments, the pharmacologic agent is released from the implant over time. In some embodiments, the pharmacologic agent is released from within the implant over time. In some embodiments, the pharmacologic agent is released from within the balloon over time. In some embodiments, the agent is released as a combination of vessicular and matrix origins using internal or external stimuli from normal or exogenous sources.

[0014] In some embodiments, at least a portion of the implant is configured to anneal to a periphery of a cartilage defect.

[0015] In some embodiments, the implant comprises vacuoles of pharmacologic substances. In some embodiments, the vacuoles may be on a bone-engaging portion of the implant. In some embodiments, the implant comprises bubbles comprising an active substance such as a pharmacologic substance or other active agent. In some embodiments, the active agent comprises at least one of: stem cells, growth factors, antibiotics, antifungals, antituberculous, antitumor, antigout agents and viscolubricants. In some embodiments, the active agent comprises iatrigenically gene mutated cells.

[0016] In some embodiments, the implant comprises enzyme absorptive microscopic sponges that could be sucked out or evacuated at or around the time of implant delivery to the joint.

[0017] In some embodiments, the interior comprises a honeycomb structure. In some embodiments, the interior comprises a mesh structure. In some embodiments, the interior comprises a sponge structure. In some embodiments the implant comprises a sponge structure. In some embodiments the implant comprises a compliant membrane.

[0018] In some embodiments, the implant comprises

spaces filled with an active substance such as a pharmacologic substance or other active substance. In some embodiments, the implant comprises spaces for deliverables (e.g., biologics, antibodies, cells, pharmacologic substances, biomolecules, molecules, compounds). In some embodiments, the implant comprises spaces for compressibles (e.g., gas, air). In some embodiments, the spaces comprise nanovesicles. In some embodiments, the nanovasicles comprise deliverables (e.g., biologics, antibodies, cells, pharmacologic substances, biomolecules, molecules, compounds). In some embodiments, the nanovesicles comprise compressibles (e.g., gas, air).

[0019] In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most 10 millimeters. In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most 9 millimeters. In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most 5 millimeters. In some embodiments, the implant may be configured to be introduced surgically arthroscopically as with the cannula 10 mm in diameter or may be introduced through minimal invasive surgery via a large conduit and plunger requiring a small arthrotomy several centimeters in diameter. In some embodiments routine open surgical insertion with a larger wound may be necessary depending on clinical condition, complexity and surgeon choice.

[0020] In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most 10 millimeters. In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most 9 millimeters. In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most 5 millimeters.

[0021] In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most 10 millimeters. In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most 9 millimeters. In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most 5 millimeters.

[0022] In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most 10 millimeters. In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most 9 millimeters. In some embodiments, the implant is configured to deliver by dissolution of the implant material. In some embodiments, the implant is configured to deliver by release through pores of the implant. In some embodiments, the implant is configured to deliver by release through spaces of the implant. In some embodiments, the implant is configured to deliver by release through nanovesicles of the implant. In some embodiments, the implant is configured to deliver by fracture of a vacuole by a catalyst such asultrasound or pressure or other fracturing catalyst. In some embodiments the release of contents may be over time as a function of normal cumulative limb use forces.

[0023] In some embodiments, the implant is configured to at least one of: pad cartilage, cushion the joint, deliver a pharmacologic substance, remove noxious enzymes, debride upon implantation, debride the joint following implantation, deliver a therapeutic substance, deliver a biologic substance, and deliver living stem cells. In some embodiments, the implant is configured to deliver a cell or tissue to a bone or surrounding tissue. In some embodiments, the cell is at least one of: stem cell, differentiated cell, pluripotent cell, and post-mitotic cell. In some embodiments, the implant is configured to deliver a chemotherapeutic agent to a bone or other surrounding tissues. In some embodiments, the implant is configured to deliver an anti-infectious medication to a bone or other surrounding tissues. In some embodiments, the implant is configured to deliver at least one of an antibiotic, antifungals, and analgesics agent. In some embodiments, the implant is configured to deliver an antibody. In some embodiments the implant is configured as a targeting structure for treatment of proximate pathophysiology. In some embodiments, the implant comprises a transmitter or a sensor that can emit or receive actionable instruction. In some embodiments, the implant comprises a sensor, for non-limiting example: a gauge, camera, fiberoptic, or other meter, to provide information of clinical relevance as it relates to proximate tissue. In some embodiments, the information received from the implant is transferred to the patient to enhance wound healing or other desired effects.

[0024] Provided herein is a method comprising: implanting a knee implant as described herein into a subject, wherein the implant reverses arthritis in the subject.

[0025] Provided herein is a method comprising: implanting a knee implant as described herein into a knee joint of a subject and treating a component of the knee joint of the subject with at least one of an allograph tissue, an autograph tissue, and an xenograph tissue. In some embodiments, the implanting step is at least one of: prior to the treating step, simultaneous with the treating step, and following the treating step.

[0026] Provided herein is a method comprising: implanting a knee implant as described herein into a subject, wherein the implant at least one of: restores joint function and controls arthopathies. In some embodiments, the implanting spares existing anatomy.

[0027] Provided herein is a method comprising: debriding a femur condyle of a knee joint of a subject, and implanting a knee implant as described herein into the knee joint of the subject, whereby the implant is configured to anneal to the cartilage of the subject. In some embodiments, the debriding is achieved by steam application.

[0028] Provided herein is a method comprising implanting a knee implant as described herein into a joint

previously treated with a joint replacement. In some embodiments, the method comprises removing the joint replacement prior to implanting the knee implant. In some embodiments, the method comprises clearing infectious matter from the joint and/or surrounding tissues. In some embodiments, the method comprises implanting a second implant of any implant described herein following removing the implant previously implanted in the joint. In some embodiments, the method comprises replacing the joint of the subject following removing the implant previously implanted in the joint. In some embodiments, the method comprises debriding the bone of the joint, and implanting an implant of any implant described herein. In some embodiments, the method comprises repeating the debriding and implanting steps.

[0029] In some embodiments, the implant is delivered non-arthroscopically through an incision that is at least 1 centimeter long. In some embodiments, the implant is delivered through an incision that is over about 10 centimeters long. In some embodiments, the implant is delivered through an incision that is at up to about 40 centimeters long.

[0030] In some embodiments, the implant replaces periosteum.

[0031] There may be several alternative embodiments depending upon the site in which the implant is to be deployed. For example, the polymer forming the side wall may be semi-compliant or elastic. Alternatively, the polymer forming the side wall may be non-compliant (non-elastic). The first and second walls of the implant need not have the same properties as the side wall. For example, parts of the implant such as the side wall portion may be compliant and the first and second wall portions in contact with the bone or other joint structure may be non-compliant. Additionally, the various walls or portions thereof may also be reinforced with non-compliant or semi-compliant polymer strands, beads or gel coating such as biologic or polymer latticework. The thicknesses of the first, second and side walls may be varied to accommodate for the needs of the joint structure from the standpoint of strength, elasticity and wear resistance. Moreover, the walls of the implant may be provided with joint tissue regeneration agents that rebuild the joint structure in which the implant is deployed. The regeneration agent may be incorporated into the wall of the implant prior to delivery or placed between the surface of the implant and the joint structure which it contacts after delivery. All or part of the walls of the implant may also be made of a biodegradable polymer, by minimally manipulated autograph, allograph or xenograph tissues, or a combination thereof. The method of surgery may incorporate a progressive application of the implant embodiments depending upon clinical needs. The walls of the implant may serve one or more functions, including but not limited to filling space, attachment, strengthening, and any physiological function.

[0032] The implant is preferably formed of suitable biocompatible polymeric materials, such as Chronoflex (e.g., ChronoFlexAR®, ChronoFlex AL®, ChronoFlec C®), which is a family of thermoplastic polyurethanes based on a polycarbonate structure (Al, the aliphatic version, Ar, the aromatic version and C, the casting version) available from AdvanSource Biomaterials, Corp. Other polymers include BIONATE 80, 80A, 90A, 75D, 65D, 55D, 55 or 56, BIONATE I, or BIONATE II, which are also thermoplastic polyurethane polycarbonate copolymers, available from PTG Medical LLC., an affiliate of the Polymer Technology Group located in Berkeley, CA. Other commercially available polymers include PurSil® (e.g., PurSil® 10, 20, 35, 40 80A, AL-10 75A) which is a thermoplastic silicone polyether urethane, CarboSil® (e.g., CarboSil® 10 90A, 20 55D, 20 80A, 20 90A, 40 90A, 5) which is a thermoplastic silicone polycarbonate urethane, Elasthane™ (e.g., Elasthane™ 55D, 75D, 80A) which is an aromatic biomedical polymer and Biospan which is a segmented polyurethane. These polymers are available as tubing, molded or dipped components, solution, pellets, as a casting and as a cast film for the side and first and second walls. The implant may be formed by casting, or by joining sheets of polymeric material by adhesives, laser welding and the like. Other methods of forming the implant may also be suitable. Example methods include melting beads and compression molding. The walls may also be provided with reinforcing strands which are located on the surface of the walls or incorporated within the walls. The implant material should be biocompatible, non-toxic, and non-carcinogenic and should be resistant to particulation.

[0033] The present invention provides an improved joint implant which is designed to endure variable joint forces and cyclic loads enabling reduced pain and improved function. Depending upon the particular joint involved there may be linear or curvilinear motion between the first and second walls, rotational motion between the first and second walls or both linear and curvilinear motion and rotation motion between the first and second walls. Preferably, a space is maintained between the inner surfaces of the first and second walls to avoid erosion and wear there between. The walls may be opposite sides of the same solid.

[0034] The resilient arthroplasty implant embodying features of the invention is preferably deployed as a minimally invasive procedure to deliver the implant into a prepared space in a preselected joint structure, where upon it is inflated to create a cushion, to cover damaged or arthritic cartilage and to be employed to deliver stem cells or living chondrocytes or other tissue regeneration agents. The goal of such deployment is to reduce pain and improve function, to reverse arthritis, to fill in osteochondral defects succinctly, thereby avoiding living with both dysfunctional and ablative metal/plastic prostheses or the pathophysiologic state necessitating the procedure. The operative plan is simple, systematic, and productive of new joint space with regrowth potential involving joint debridement by routine arthroscopic coblation, electronic chondroplasty methods or steam application,

followed by implantation of the implant. The implant provides three things, namely a covering or patch for the damaged or worn joint surface or compliant polymer as in normal walking in the lower extremity, and delivery of regenerative cells on the cartilage remnant surface. The stem cells may be injected as the implant is being expanded and/or directed into the adjacent hyaline cartilage via an implant coating or perfused cell template. Viscolubricants such as Synvisc or Hyalgan, analgesics such as Lidoderm, anti-inflammatory and/or antibiotic coatings as well as those stimulating cell growth may accompany the composite external implant. The implant is left in place as long as feasible, at least until regenerative cells can attach to the adjacent natural joint surface (usually in about 24 hours), or until wound healing (which may take up to 28 days or more depending on the joint structure). Preferably, the implant is designed stay within the joint structure for years, providing inert padding, cushioning and a new cell source. The implant may be used in weight bearing and non-weight bearing interfaces. Animal, such as in horses and dogs, can benefit from usage of the implant following hip and knee injuries. The implant is intended primarily for mammalian use. In humans, the implant may be used in any upper or lower extremity joint and temperomandibular joint.

[0035] These and other advantages of the invention will become more apparent from the following detailed description and the attached exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0036] The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

Figure 1 depicts an example of the knee implant having appendages including holes and tabs extending from a balloon and including slots to accommodate ligaments of the knee joint.

Figure 2 depicts an example of the knee implant having appendages including holes and tabs extending from a balloon and including slots to accommodate ligaments of the knee joint as well as side views of the same knee implant.

Figure 3 depicts an example of the knee implant having appendages including holes and tabs extending from a balloon and including slots to accommodate ligaments of the knee joint as well as side views of the same knee implant.

Figure 4A depicts an example of the knee implant having appendages including ten tabs extending from a balloon and including a slot to accommodate components of the knee joint.

Figure 4B depicts an example of the knee implant having appendages including eight tabs extending from a balloon and including a slot to accommodate components of the knee joint.

Figure 5 depicts an example of the knee implant curved to simulate curvature about the condyles of a femur, the implant having appendages extending from an uninflated balloon (not shown) and including slots to accommodate ligaments of the knee joint.

Figure 6A depicts a top-down view of an example of the knee implant curved to simulate curvature about the condyles of a femur, the implant having appendages extending from two inflated balloons and including slots to accommodate components of the knee joint.

Figure 6B depicts a bottom-up view of an example of the knee implant curved to simulate curvature about the condyles of a femur, the implant having appendages extending from two inflated balloons and including slots to accommodate components of the knee joint.

Figure 7 depicts a top-down view of an example of the knee implant curved to simulate curvature about the condyles of a femur, the implant having appendages extending from an inflated balloon and including slots to accommodate components of the knee joint.

Figure 8 depicts a side view of an example of the knee implant curved to simulate curvature about at least one condyle of a femur, the implant having appendages extending from an uninflated balloon (not shown).

Figure 9A depicts a side view of an example of the knee implant curved about at least one condyle of a femur, the implant having appendages extending from an uninflated or minimally inflated balloon.

Figure 9B depicts a side view of an example of the knee implant curved about at least one condyle of a femur, the implant having appendages extending from an inflated balloon.

Figure 9C depicts a side view of an example of the knee implant curved about at least one condyle of a femur, the implant having appendages extending from an inflated balloon and having staples or screws coupling the appendages to the femur.

Figure 10A depicts a side view of an example of the knee implant curved about at least one condyle of a femur, the implant having appendages extending from an inflated balloon and showing the inflation medium moved anteriorly toward the patella when the knee joint is flexed. Figure 10B depicts a side view of an embodiment of the knee implant curved about at least one condyle of a femur, the implant having appendages extending from an inflated balloon and having staples or screws or snaps or pins coupling the appendages to the femur and showing the inflation medium moved anteriorly toward the patella when the knee joint is flexed.

Figure 11A depicts an example of the unicompart-

ment knee implant curved to simulate curvature about one condyle of a femur, the implant having appendages extending from an uninflated balloon (not shown) and including tabs and holes which may be used with couplers to couple the implant to the femur of the knee joint.

Figure 11B depicts an example of the unicompartment knee implant curved to simulate curvature about one condyle of a femur, the implant having appendages extending from an inflated balloon and including tabs and holes which may be used with couplers to couple the implant to the femur of the knee joint.

Figure 11C depicts a bottom-up view of an example of the unicompartment knee implant curved to simulate curvature about one condyle of a femur, the implant having appendages extending from an inflated balloon and including tabs and holes which may be used with couplers to couple the implant to the femur of the knee joint.

Figure 12A depicts a bottom-up view of an example of the unicompartment knee implant or patch implant, the implant having appendages, extending from a balloon and including holes, which may be used with couplers (not shown) to couple the implant to the femur of the knee joint.

Figure 12B depicts a bottom-up view of an example of the unicompartment knee implant or patch implant, the implant having appendages, extending from a balloon and including tabs and a hole which may be used with couplers (not shown) to couple the implant to the femur of the knee joint.

Figure 12C depicts a bottom-up view of an example of the unicompartment knee implant or patch implant, the implant having appendages, extending from a balloon and including tabs and a hole which may be used with couplers (not shown) to couple the implant to the femur of the knee joint.

Figures 13A- 13D depict multiple views of a staple adapted to couple an implant to a bone of the joint.

Figure 14 depicts an embodiment of the knee implant having appendages including holes and tabs and including slots to accommodate ligaments of the knee joint as well as side views of the same knee implant.

Figures 15A, 15B, and 15C show several views of an embodiment of an implant which has no definable chamber, rather the material of the implant itself provides the cushion to the bones of the joint (at least).

Figure 16 depicts a knee implant embodiment that is generally H or V-shaped, having a slot 26b that is significantly smaller than other embodiments, and in this embodiment is effectively replaced with a tab 10i at the same location (e.g. 10i).

Figure 17 depicts a knee implant embodiment similar to Figure 16 which shows a posterior view including the location(s) 50a- 50d where a fill material such as cement may be placed.

Figure 18 is an anterior-posterior view of an example of the implant 20 attached to a knee model.

Figure 19 depicts an implant 20 which is more squarely cut for interface with a femur, for example, which has been cut square such as is done in certain total knee arthroplasty procedures.

Figures 20A and 20B depict a knee implant embodiment that is generally V-shaped or Y-shaped, and in this embodiment the notch 26b of other embodiments, or the tab 10i of other embodiments is effectively replaced with an appendage 4e at the same location.

DETAILED DESCRIPTION OF THE INVENTION

[0037] The present invention is directed to arthroplasty implants and procedures for a wide variety of joints such as, for example, hips, knees, shoulders, ankles, elbows, wrists, fingers, toes, temporomandibular joints and the like, but for clarity, as well as brevity, the discussion herein will focus on an implant for a knee joint or hip joint and an implant for replacing the talus bone of a patient's ankle.

[0038] Knee interpositional arthroplasty can replace existing total joint metal/plastic technology. It intends to fill the gap (literally in some embodiments of the implant) in cases where arthroscopic debridement fails to provide cure, since we can only 'polish arthritis' and 'clean up the joints' to date. The polymer medically inflatable implants may physiologically restore joint function. Padding is provided where cartilage is damaged, cushioning to both the femoral tibial and patella femoral joints when narrowed or pathologic. The implant in some embodiments is adapted to deliver cells, autologous (from the patient), allograph (from another member of the same species) or xenograph (from another species,) that restore articular surfaces. Since cartilage is an immunologically privileged tissue, the antigens are buried in the cartilage matrix and antibodies do not reject the refurbished surface coating.

[0039] The gap (or gaps) filled by the balloon or balloons of the implant may provide compliance between opposing joint surfaces (the femoral condyle or condyles and tibial plateau). The femur may have some portion (of not all) of the retropatellar rounded facet "V" shape of hyaline, normally about 5 mm thick, or it may not have such hyaline when the implant is inserted. The tibial plateau may have some portion of meniscal fibrocartilages, including all of said fibrocartilages, none of said fibrocartilages, or some portion thereof. When the knee is extended (straight) the implant buffers the femoro-tibial joint. When the knee is flexed, the implant balloon apposition is more between the trochlear groove portion of the anterior distal femur (groove between the condyles on the 'front of the knee') and the patella.

[0040] The knee anatomy is unique to other joint anatomies and thus has a unique set of challenges that are addressed by the implant embodiments described herein. For example, the knee is not a ball and socket joint like a hip; it is a combination of two joints-- the femoral-

tibial joint and the patellar-femoral joint. The bones of the knee have facets and irregularities that must be accommodated by a conformable implant directed to the particular shapes of the bones without impeding the joints' functions and movements, and/or which minimizes impedance to such function and movement. Not only do the joints of the knee work together to allow extension and flexion of the knee, but the joints of the knee are also designed to allow rotational movement in a screw-like manner. That is, as the tibia is twisted relative to the femur, the joints are uniquely designed to allow this twist, but to limit the twist as well. Furthermore, the knee joints are able to withstand forces that vary depending on the particular movement of the individual, not only in force strength, but in direction as well. Thus, the implants as described herein are uniquely designed to account for these factors and result in a knee having preserved natural tissues as well as preserved function and movement as compared to typical arthroplasty procedures (such as partial or full knee replacements).

[0041] As described herein, examples of an implant conform to the patient's own joint features not only in that it can be pre-molded and/or adapted to couple to the contours of the patient's bone (condyle, etc), but in that it has a balloon having an inflation medium that is conformable to the joint anatomy and allow freedom of joint movement much like natural joint while preserving the joint and bone natural tissues as much as possible. With the ability to fill various chambers of the balloon with varying materials, and to add rigid and/or semi-rigid pieces to the implant, the implant can additionally have leveling capabilities and alignment capabilities.

Diagnoses:

[0042] Patients may complain of pain and knee joint dysfunction signaled by locking, clicking, or giving way. Knees may be swollen, malaligned or show crepitus (palpable crunching on movement.) Instability of ligaments whether anterior/posterior cruciates, or medial/lateral condyles, are treated by techniques separate for those entities via allowance for healing (as for collaterals) or via cruciate repair or reconstruction.

[0043] Indications for use of implants provided herein may be those patients recognizing greater than or equal to 2 Sq cm of 3-4+/4 traumatic arthritis (ala Carticel). In such cases, the cartilage defect is often precisely locally symptomatic, with point tenderness, clicking if a loose cartilage flap exists, and may be visible on MRI and/or arthroscopic inspection and/or through palpation. The implants used herein may additionally and/or alternatively be appropriate when existing techniques such as 'picking', K wire drills, and/or allograph implants fail.

[0044] Patients with knee problems typically complain of pain and dysfunction. Pathognomonic symptoms for meniscal tearing include locking, clicking, giving way from wear or twisting the knee. Aching diffusely may arise from arthritis or synovitis; anterior knee pain is generally patella-femoral, increased with stair use due to magnified body weight forces. Diagnosis should be accurate as distinguished from pain through the knee actually arising in the back caused by L4 nerve root irritation. Physical Exam findings of pathologic knees include observed swelling, redness, or deformity. Palpation often aids focus on which compartments are involved. The patella inhibition test position connotes retropatellar pathology, and often tracking problems that warrant soft tissue or boney correct. Improved limb alignment may increase benefits, and can in part accrue from selective inflation of embodiments of the implants provided herein. X-rays of the knee are best evaluated in weight bearing views, and should be coupled with other data including MRI or CT. Relative compartment narrowing suggests cartilage degradation. Once an embodiment of an implant described herein has been successfully implanted and the knee adequately rehabilitated, the appearance of a knee with such implant should resemble a normal joint X-ray. Knee distension is from saline and/or air insufflation. Knee implant patients will benefit from tailored rehab programs, cautious weight bearing, early motion, and potential the use of constant passive motion machine regimens.

General Features

Implant Aspects

[0045] Provided herein is a resilient implant for implantation into human or animal joints to act as a cushion allowing for renewed joint motion. The implant may endure variable joint forces and cyclic loads while reducing pain and improving function after injury or disease to repair, reconstruct, and regenerate joint integrity. The implant may be deployed in a prepared debrided joint space, secured to at least one of the joint bones and expanded in the space, molding to surrounding structures with sufficient stability to avoid extrusion or dislocation. The implant may pad the damaged joint surfaces, restores cushioning immediately and may be employed to restore cartilage to normal by delivering regenerative cells.

[0046] The implant according to the invention has no inflation chamber (inner space). The implant may have varying thicknesses at different locations. The implant may have different features at different locations. Inflation may involve singular balloons for cushioning or realignment, multiple separate or connected vesicles, or small vacuoles that contain gas, fluid, gel, fluid that becomes solid, or combinations thereof. Inflation may be invoked on either both surfaces of the implant or any surface of the implant inside or between variable walls (which can be considered layers in certain embodiments). Cushioning while intending to address deficiencies in cartilage may accrue from inflation or the use of compliant materials without inflation (and without a balloon per se for that matter) or both.

[0047] Provided herein is a resilient interpositional ar-

throplasty implant for application into knee joints to pad cartilage defects, cushion joints, and replace or restore the articular surface, preserving joint integrity, reducing pain and improving function. The implant may endure variable knee joint compressive and shear forces, and millions of cyclic loads, after injury or disease requires intervention. The implant may repair, reconstruct, and regenerate knee joint anatomy in a minimally morbid fashion, with physiologic solutions that improve upon the rigid existing joint replacement alternatives of plastic and metal. In cases where cells have been used for joint resurfacing requiring massive periosteal harvesting for containment, the polymer walls of some embodiments of the implant can capture, distribute and hold living cells until aggregation and hyaline cartilage regrowth occurs. The implant may be deployed into a prepared debrided knee joint space, molding and conforming to surrounding structures with sufficient stability to avoid extrusion or dislocation. Appendages (or tabs) of the implant may serve to repair or reconstruct tendons or ligaments. There may be no defined inner chamber, however at a particular location in the device the implant may have different features to aid in cushion, therapeutic effect, wear resistance, defect correction, or the like.

[0048] Provided herein is a resilient orthopedic implant configured for deployment between a first bone and at least one second bone of a joint. In the case of a knee joint, the first bone may be a femur, a tibia, or a patella. In the case of a knee joint, the second bone may be a tibia, a patella or a femur.

[0049] In some embodiments, at least two of the first portion, the second portion, and the side portion are contiguous. In some embodiments, the first portion comprises a first wall, the second portion comprises a second wall, and the side portion comprises a side wall. As used herein, each of the terms the "first portion", the "second portion", and the "side portion" is used to describe a part of the implant and may not be separate parts in some embodiments. In some embodiments, each portion or wall is named in order to indicate the general geometry and location of each portion relative to the other of the portions and/or relative to bones and/or ligaments and/or tendons of the joint. Likewise, as used herein, each of the terms the "first wall", the "second wall", and the "side wall" is used to describe a part of the balloon or cushioning implant, and may not be separate parts of the balloon in some embodiments. Rather, in some embodiments, each of the walls is named in order to indicate the general geometry and location of each portion relative to the other of the portions and/or relative to bones and/or ligaments and/or tendons of the joint. In some embodiments, one wall may become the second wall with body movement changing the anatomy of the implant as it related to joint motion.

[0050] In some embodiments, the first portion is a term used interchangeably with the first wall. In some embodiments, the second portion is a term used interchangeably with the second wall. In some embodiments, the side portion is a term used interchangeably with the side wall. In some embodiments, a wall (whether a first wall, a second wall, and/or a side wall) of the implant may comprise a plurality of layers. The wall may comprise multiple materials to impart physical and/or therapeutic characteristics to the wall. In some embodiments, a side wall may become a first or second wall as the implant changes shape through the application of joint forces.

[0051] The distinction between the first wall and the second wall may merely be noted to show relative location, and may be a contiguous wall that has a first side (wall) and a second side (wall) where the first side is adapted to contact the first bone, and the second side is adapted to contact the second bone. Walls may be touching or be made of the same materials, or they may be made of different materials, or they may have additional materials therebetween, such as microstructures, vacuoles, therapeutic agents, padding materials, gels, liquids, solid materials, rigid or semi-rigid materials, meshes, foams, honeycombed materials, capsules, urethanes, human tissues or media, soft tissues, or the like, as described herein. Either of the walls themselves may be made of any of these materials and/or have any of these features. For example, a single sheet of BIONATE (e.g., BIONATE I, BIONATE II, BIONATE 55D, BIONATE 65D, BIONATE 75D, BIONATE 80, BIONATE 80A, BIONATE 90A) may be deemed to have a first wall that contacts the first bone, and second wall that contacts the second bone. In another example, a single sheet of Chronoflex (e.g., ChronoFlexAR®, ChronoFlex AL®, ChronoFlec C®) may be deemed to have a first wall that contacts the first bone, and second wall that contacts the second bone. Nevertheless, the single sheet may be contiguous, having no particular separation between the walls that may be deemed a chamber or balloon. Again, each of the first wall and the second wall may be, in certain embodiments, so designated only to depict relative location-i.e. in relation to the bone each wall is adapted to contact. The first wall may be so designated in order to indicate an intent that the first wall is in a position to contact the first bone, whereas the second wall may be so designated in order to indicate an intent that the second wall is in a position to contact the second bone, but the first wall and the second wall are part of a contiguous implant, without any chamber or balloon therebetween.

[0052] The implant walls (first wall and/or second wall, and/or side wall may comprise a compliant material, and there is no separation between any of the walls of the implant which could be deemed a chamber. The material of the wall itself may be compliant such that the material itself accommodates cartilage irregularity and improved alignment of the joint bodies (ligaments, bones, tissue, etc.).

[0053] In some embodiments, the implant comprises a sheet. The sheet may be solid (e.g. comprising polyurethane or another biocompatible material), complex (e.g. comprising Dyneema mesh) or with at least one chamber of any size from a micrometer, to larger cham-

bers as depicted and described elsewhere herein. The implant may comprise Dyneema mesh. The implant may comprise Dyneema fiber. In some instances, the implant comprises Dyneema Purity®. The implant may comprise a fiber. The implant may comprise a polyethylene fiber. The implant may comprise a mesh. The mesh may be a random structure or a repeating structure (such as a honeycomb). The mesh may comprise a polymer structure of interwoven or randomly interlinked fibers or a combination thereof. The mesh may comprise a metal structure of interwoven or randomly interlinked metal fibers or a combination thereof. The mesh may comprise a memory metal (e.g. Nitinol or another memory metal). The mesh may comprise a memory polymer. The mesh may aid in fixing the implant in place. The mesh may be adapted to add cushion to the bones of joint. The mesh may be adapted to add durability to implant upon cyclic loading. The mesh may be adapted to add padding to the bones of joint. The mesh may be filled in its interstices with a softer (in durometer) polymer or other material (softer than the material of the mesh itself). The mesh may be filled in its interstices with a softer (in durometer) polymer or other material (softer than the material of the mesh itself). The interstices of the mesh may comprise a pharmacologic or therapeutic agent (or both) as noted herein. The mesh may be filled with a harder material, or a material that becomes harder, such as methyl methacrylate. The mesh may comprise a biodegradable material. In some instances, the mesh does not comprise a biodegradable material. The mesh may comprise a steel wool. Alternatively, the mesh comprises DNA strands. In some embodiments, the mesh comprises intertwined DNA strands. In some embodiments, the mesh is configured to wrap a joint end.

[0054] In some embodiments there is no chamber in the implant. In such an embodiment, the implant may have a single composition throughout the implant, and shaped as noted herein with attachment features as noted herein. In such embodiments, distinction between the first wall and the second wall may be noted to indicate relative location, and may be a contiguous wall that has a first side (wall) and a second side (wall) where the first side is adapted to contact the first bone, and the second side is adapted to contact the second bone. In other embodiments of the implant, the implant comprises no chamber, however it comprises various regions which have different features than other regions-such as comprising a mesh between the first wall and the second wall (as noted above), a cushion between the first wall and the second wall, and/or comprising any aspects of the fill materials noted in the inflation mediums noted elsewhere herein, but not necessarily provided in a chamber which is filled following implantation or at the time of implantation. Rather, these aspects may be built into the implant during implant manufacture, by layering or other manufacturing processes, and not necessarily by filling a chamber. In some embodiments, there are multiple regions having different characteristics-cushioning, some therapeutic agent delivery, defect correction, padding, for non-limiting example, or some combination thereof. In some embodiments, the implant achieves these aspects by varying thickness of one of the walls at a particular region of the implant, for non-limiting example, at load-bearing locations. Implant spacing or vacuous interspace can vary at a molecular level as allowing for macromolecular sizes or macrodendritic molecules. The molecules covering the exposed or integral implant makeup may be constructed with coatings or without, that may be suspended in gas, liquid, gel, or solids with vacuoles, bubbles, balloons or bladders of a size producing a foam or trabecular framework or honeycomb that has 'inflation' not visually obvious. When encapsulating the cushioning gas or fluid in small containers, the cushioning effect may become more effective, and for a given amount of cushioning the intercell pressure can be reduced. The implant may comprise a foam between the first wall and the second wall. The implant may comprise a microvoid (i.e. a void in the implant material that is in the 1 micrometer to 1 mm size range).

[0055] The implant comprises materials without obvious or definable inflation of any sort, producing a cushioning effect usually over one primary joint surface but potentially over multiple, providing a useful cushioning via polymers of variable albeit solid material nature and reasoned compliance. In certain embodiments, the implant material per se immediately or gradually comes to conform to, accommodate, adjust and fill the indentations or defects on the side of implant in apposition to the defect. A semi-fluid tendency of certain embodiments permits both immediate post insertional and delayed joint surface alignment adjustments that may be increased by injection or cannular infusion, or deceased by aspiration or valvular evacuation.

[0056] The first wall is secured to the end of the first bone by a skirt that extends from the first wall and the second wall engages the end surface of the second bone and may also be secured thereto. In some embodiments, the skirt 18 is called an appendage. The inner surfaces of wall and skirt preferably conform to the particular surface of the head of the patient's first bone. In some embodiments, the inner surfaces of wall and skirt preferably conform to the particular surface of the patient's first bone. The outer surface of the second wall is preferably configured to conform to the end surface of the second bone. In some embodiments, the outer surface of the second wall is preferably configured to conform to a surface of the second bone.

[0057] The edge of the implant may have a depending skirt to secure or anchor the implant to the end of bone, but may have one or more depending tabs (or appendages) that may be employed for similar functions as will be discussed in other embodiments. The skirt (and/or tabs, and/or appendages) may tightly fit about the end of the first bone as shown, or the skirt can be secured by adhesive (e.g. methyl methacrylate, bone in-growth) to the supporting bone structure or be mechanically con-

nected by staples, screws and the like. Moreover, the lower portion of the skirt may be secured by a purse string suture or a suitable strand (elastic or tied) that is tightly bound about the outside of the skirt.

[0058] In some embodiments the implant comprises an in-growth patch on at least one of the first portion configured to engage the first bone, the second portion configured to engage the second bone, the side portion, and the appendage. The in-growth patch may be configured to encourage and/or promote tissue in-growth, such as bone in-growth, for non-limiting example. The patch may be as large as the portion itself (whether the first portion the second portion, the side portion, or the appendage) or may be smaller than the portion (such as in the shape of a strip or other shaped patch). The in-growth patch may comprise a surface irregularity or roughness. The in-growth patch may be Velcro-like. In some embodiments the implant comprises an in-growth patch on the first portion and/or the second portion, from (and in some embodiments including) a first appendage to a second appendage. In some embodiments, wherein the appendages loosen from attachment from the bone (by design and/or from wear and/or over time), the in-growth patch aids in securing the implant to the bone. In some embodiments, the in-growth patch comprises beads and/or bead-like elements attached to the implant. Such an in-growth patch may be configured to simulate trabecular bone space of a normally cancellous latticework. In some embodiments, the beads are sintered beads of various sizes. In some embodiments, the beads are sintered beads about 400 microns in size. With respect to bead size, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%. In some embodiments, the first bone and/or the second bone is roughened to acquire a bleeding bone to facilitate in-growth. In some embodiments, about 0.5 mm of cortical tissue is removed to facilitate in-growth.

[0059] In some embodiments, the appendage of the implant comprises a hook. In some embodiments the hook is angled. The hook may comprise a piece of metal sandwiched between two polymer pieces. The hook may comprise a piece of metal encased in polymer. In some embodiments, the hook may comprise a piece of metal and a portion of the metal piece may be encased in polymer. In some embodiments, the hook may comprise a piece of metal and a portion of the metal piece may be sandwiched between two polymer pieces. The metal of the hook may reinforce the appendage tabs for securing the implant to the bone of the joint. In some embodiments, the metal of the hook is formed of a 1 centimeter by 1 centimeter metal piece. The metal of the hook, or a portion thereof, may protrude from the appendage. The metal may be bent toward the bone to which it is configured to attach. The metal may be bent at about a 270 degree angle (as compared to the non-bent portion of the metal, or as compared to the rest of the appendage, for non-limiting example). The term about when referring to angle of bend of the metal of the hook can mean variations of 1%, 5%, 10%, 20%, and/or 25%, or variations of 1 degree, 5 degrees, 10 degrees, 15 degrees, 20 degrees, 25 degrees, 30 degrees, 40 degrees, 45 degrees, and/or up to 90 degrees. In some embodiments, the bone may be prepared to receive the hook, such as by a hole or slot into which the hook (or a portion thereof) is placed. In some embodiments, the bone is not prepared in advance to receive the hook, and the hook may self-seat into the bone by pressure applied to the hook into the bone. In some embodiments, the implant may comprise multiple appendages, and a plurality of the appendages has hooks. In some embodiment the implant may be screwed on or snapped on or secured with a combination of elements, such as stabilizers and sutures.

[0060] In some embodiments, the implant comprises a second appendage coupling the implant to the first bone of the joint. In some embodiments, the implant comprises a second appendage coupling the implant to at least one second bone of the joint. In some embodiments, the implant comprises a second appendage configured to couple at least one of the first portion, the second portion, and the side portion to at least one of the first bone and at least one second bone of the joint. In some embodiments, the first appendage and the second appendage are configured to provide ligamentary-like support to the first bone and the at least one second bone of the joint. In some embodiments, the first appendage and the second appendage are configured to provide ligamentary-like support to the joint. In some embodiments, the first appendage and the second appendage are configured to provide tendon-like support to the first bone and the at least one second bone of the joint. In some embodiments, the first appendage and the second appendage are configured to provide tendon-like support to the joint.

[0061] In some embodiments the implant may comprise vacuoles of pharmacologic substances. The vacuoles may be on a bone-engaging portion of the implant. In some embodiments, the implant comprises bubbles comprising an active substance such as a pharmacologic substance or other active substance. The implant may deliver by dissolution of the implant material (i.e. a biodegradable polymer which releases the active substance), and/or by release through pores of the implant (wherein the polymer is permeable to the active substance), and/or by fracture of the vacuole (or bubble, or space) by a catalyst such as ultrasound or pressure or other fracturing catalyst. The implant may deliver the active substance at a time after the actual implanting of the implant into the joint, for example an hour later, less than a day later, a day later, less than a week later, a week later, less than a month later, and/or a month later. In some embodiments, stem cells that are percolating in the bubble (or vacuole, or space) may be delivered to the joint space (or a constituent of the joint) after the implant is inserted into the joint. Active agents may, for non-limiting example, include cells (e.g., stem cells, differentiated cells, pluripotent cells, post-mitotic cells), growth factors, antibodies, biomolecules, biologics, chemical compounds, antibiotics, and/or viscolubricants.

In some embodiments, the implant may comprise enzyme absorptive 'microscopic sponges' that could be sucked out or evacuated at or around the time of implant delivery to the joint.

[0062] In certain embodiments the implant is a weight bearing spacer that allows joint motions to approach normal, whether filling the space left by an entirely collapsed joint bone or the space of ablated cartilage proximate surfaces diffusely as in osteoarthritis or succinctly as in osteonecrotic defects or localized trauma. The walls of the implant may be used as a membrane for holding living cells in proximity of the osteochondral defect long enough for the cells to attach (e.g. 24 hours) or to deeply adhere (up to 28 days) or return to normal (up to one year). Weight bearing may be expected to increase as distal lower extremity joints are treated.

[0063] Movement (whether linear or curvilinear) between the first and second walls of the implant as a result of movement of the femur and the tibia is illustrated in the comparison between Figures 9B and 10A, or in the comparison between Figures 9C and 10B. While not shown in the drawings, there may be slippage between a portion of the implant (whether an appendage, a wall, or some other portion of the implant) and a joint component (whether a bone, ligament, tendon or other tissue). This slippage may be in addition to wall movements within the implant per se to provide desired joint movements. While not shown in the drawings, there may be slippage between the second bone (for example, the tibia) and the second wall in addition to wall movements within the implant per se to provide desired joint movements. The appendage (or appendages) is (are) designed to secure the implant to the joint structure so as to avoid dislocation of the implant. Movement of the joint with the implant in place may be a shared function of both the moving opposing walls of the implant but also a function of the movement of the wall which may be less attached to the joint members. There may be slight movement between the appendage, first wall and the first bone. Material choices, material dimensions, and implant dimensions, placement and/or coupling may be chosen to allow for the desired amount of compression, stretching relative movement of various joint and/or implant components. For non-limiting example, the walls of the implant may be thicker is some areas to accommodate particular loads and the side wall may be thinner and more elastic to accommodate rolling and stretching thereof.

[0064] Some motion may occur between the implant and the joint surfaces. As shown in multiple Figures (including, Figures 1-7), the implant may be provided with a slot extending from the periphery of the implant toward the balloon of the implant to accommodate at least one ligament of the joint. Knee implants may have two slots leading to separate passages for receiving the anterior and posterior cruciate ligaments. Implant walls should have sufficient inherent flexibility to mold to the existing deformities imposed by either natural ligament, bone, tendon or remaining cartilage deformities of the internal joint space, and thus filled as a cushion. The wall exteriors may be flat or formed with random or specific patterns for purposes of glide or trends for traction against adjacent surfaces, or as sulci or venues for cell delivery materials.

[0065] The exterior of the implant may have a mesh material with a plurality of chords (or appendages) for securing the implant to adjacent bones or to remnant ligaments which are attached to adjacent bones. The exterior of the implant may comprise Dyneema mesh. The exterior of the implant may comprise Dyneema fiber. In some instances, the exterior of the implant comprises Dyneema Purity®. The exterior of the implant may comprise a fiber. The exterior of the implant may comprise a polyethylene fiber.

[0066] The dimensions of the various implant walls may vary depending upon the material properties thereof as well as the needs for a particular joint. Additionally, the first and second walls may require a thickness different from the side wall. Generally, the implant may have a wall thicknesses of about 0.125 mm to about 3 mm, preferably about 0.5 mm to about 1.5 mm. The spacing between the first and second wall within the interior can vary from about 0.5 mm to about 5 mm. Thicknesses of the fixation tabs may be at least one of: about 1mm, about 2mm, about 3mm, about 4mm, about 5mm, about 6mm, about 7mm, about 1 mm to about 6mm, about 2mm to about 4mm, 1 mm to 6mm, and 2mm to 4mm, for non-limiting example. The implant may comprise a reinforcing rim or a reinforced tab, which includes a change in tab material to make it stronger, or include a metal rim to reinforce the attachment location. The reinforcement element may be embedded in the tab or in a wall at the periphery of the implant (for example in instances where the coupler is not located at a tab per se). The inner surfaces of wall and appendage may conform to the particular surface femur, for example by being wider in particular locations and/or longer in particular areas. For example a dual compartment implant (described herein) may have a wider section to cover the medial condyle than the lateral condyle (as shown in Figures 1, 2, 3, 6A, 6B, and 7). In another example, the length of the implant the along the external edge may be longer than the length of the implant along the trochlear groove edge (as shown in Figures 11A, 11B and 11C). In yet another example, the width may vary along a single condyle, such as is shown in Figures 12A-12C, wherein the wider edge of the implant is adapted to fit over at least a portion of the anterior condyle, and the narrower portion is adapted to fit over at least a portion of the posterior condyle. In some embodiments, the inner surfaces of the first wall and appendages preferably conform to the particular surface of the patient's femur, and do so by not only dimensions of the implant (lengths, widths, location and shape), but also and/or alternatively due to appendage and/or tab and/or hole and/or coupler location and/or surface contours of the first wall. The outer surface of the second wall may be configured to conform to the end surface of the second

bone (which may be a tibia or a patella, for example). In some embodiments, the outer surface of the second wall is configured to conform to a surface of the second bone (which may be a tibia or a patella, for example). The figures provided herein are highly schematic and do not depict details of the joint surface features, since human pathology and variation reflects both the patient's immediate and evolving pathophysiology. Neither do the figures depict other joint features such as cartilage, tendons, ligaments and other soft tissues and fluids of the joint for ease of viewing that which is depicted.

[0067] In some embodiments, the implant is configured to resemble the shape of the natural hyaline of a normal knee. For example, the normal hyaline is typically "H" shaped, thus certain embodiments of the implant are generally "H" shaped. The H may be an exaggerated H form, and the notches of the H may be extended on one side, while nearly nonexistent on the other side, such as is shown in certain figures, such the "H" may look more like a "U" or "V" or contain a tab in the notch. For each joint the cartilage surface shapes, implant design, and method of surgery can vary by adapting to normal anatomy in a particular patient, to expected weight bearing, and use intent.

Implant Materials and Material Features

[0068] In some embodiments, the implant comprises polymer. Polymers may comprise at least one of: a polyurethane (such as, for example, ChronoFlex AR, ChronoFlex AL®, ChronoFlec C®), a polycarbonate urethane, a thermoplastic polycarbonate urethane (such as BIONATE, e.g., BIONATE I, BIONATE II, BIONATE 55D, BIONATE 65D, BIONATE 75D, BIONATE 80A, BIONATE 90A, BIONATE 55 or BIONATE 80), ethylene-vinyl acetate copolymer, multiblock copolymers of poly(ethylene oxide) (PEO) and poly(butylene terephthalate) (PBT), PEG, PEO, and a polyetheylene. In some embodiments the implant comprises a 125 micron thickness thermoplastic polycarbonate urethane. In some embodiments, the thermoplastic polycarbonate urethane has a low coefficient of friction. In other embodiments, the thickness of walls intends to mimic natural hyaline cartilage a the involved body location and may be one of: about 0.5mm, about 1mm, about 2mm, about 2.5mm, about 3mm, about 3.5mm, about 4mm, 0.5mm, 1mm, 2mm, 2.5mm, 3mm, 3.5mm, 4mm, 1mm-6mm, 1mm-4mm, and 1mm-3mm.

[0069] The implant may comprise to a plurality of layers of polymer (such as ChronoFlex AR, ChronoFlexAR®, ChronoFlex AL®, ChronoFlec C®) in a solvent and evaporating the solvent after applying each layer. In some embodiments, the implant comprises a polyurethane that is sprayed and dried (wherein the spraying and drying is repeated at least once) to a desired thickness.

[0070] In some embodiments, the implant is created by dip molding a mandrel having a shape of a bone of the knee joint (the medial condyle, the lateral condyle, the tibia, for non-limiting example) into a polymer solution (for non-limiting example, a urethane polymer such as Chronoflex (e.g., ChronoFlexAR®, ChronoFlex AL®, ChronoFlec C®)). Following each dip, the implant is dried for a specified time, which may be, for example, about 3 seconds, about 4 seconds, about 5 seconds, about 6 seconds, about 7 seconds, about 8 seconds, about 9 seconds, about 10 seconds, about 15 seconds, about 20 seconds, about 25 seconds, about 30 seconds, about 45 seconds, about 1 minute, about 2 minutes, about 5 minutes, about 10 minutes, about 15 minutes, and over about 15 minutes. The term "about" used herein in reference to drying time of the implant can mean variations of at least one of 5%, 10%, 25%, and 50%, In some embodiments, no drying step is used. The dipping may be repeated multiple times. In some embodiments a single dip is sufficient. In some embodiments, the dipping is repeated 2 times. In some embodiments, the dipping is repeated 3 times. In some embodiments, the dipping is repeated 4 times. In some embodiments, the dipping is repeated 5 times. In some embodiments, the dipping is repeated 6 times. In some embodiments, the dipping is repeated 7 times. In some embodiments, the dipping is repeated 8 times. In some embodiments, the dipping is repeated 9 times. In some embodiments, the dipping is repeated 10 times. In some embodiments, the dipping is repeated 11 times. In some embodiments, the dipping is repeated 12 times. In some embodiments, the dipping is repeated 13 times. In some embodiments, the dipping is repeated 14 times. In some embodiments, the dipping is repeated 15 times. In some embodiments, the dipping is repeated 16 times. In some embodiments, the dipping is repeated 17 times. In some embodiments, the dipping is repeated 18 times. In some embodiments, the dipping is repeated 19 times. In some embodiments, the dipping is repeated 20 times. In some embodiments, the dipping is repeated 21 times. In some embodiments, the dipping is repeated 22 times. In some embodiments, the dipping is repeated 23 times. In some embodiments, the dipping is repeated 24 times. In some embodiments, the dipping is repeated 25 times. In some embodiments, the dipping is repeated over 25 times. In some embodiments, the dipping is repeated a sufficient number of times to create an implant that is a prescribed thickness. The thickness may vary depending on the polymer and depending on the embodiment of the implant. The thickness may be at least one of: about 25 microns thick, about 50 microns thick, about 100 microns thick, about 125 microns thick, about 150 microns thick, about 200 microns thick, about 250 microns thick, about 300 microns thick, about 350 microns thick, about 400 microns thick, about 25-50 microns thick, about 50 - 100microns thick, about 50-200 microns thick, about 100 -150 microns thick, about 150-300 microns thick, about 100-300 microns thick, about 100-500 microns thick, about 200-500 microns thick, and about 200-1000 microns thick. The term "about" used herein in reference to thickness of the implant can mean variations of at least one of 5%, 10%, 25%, and 50%, The thickness

may vary at different locations of the implant.

[0071] The walls of the implant embodying features of the invention may be composite structures. For example, the innermost layer may be impervious to preclude escape of inflation or other filling media, a central layer may be porous or otherwise contain treatment or cell regeneration agents, and the outer layer may be a thin, but strong layer of a thermoplastic, such as a thermoplastic polyurethane for non-limiting example, which has microporosity sufficient to allow passage or egress of treatment or cell regeneration agents from the central layer (or second layer). The degree of microporosity to enable egress of treatment or cell regeneration agents from the central layer is found in polymer layers such as Chronoflex (e.g., ChronoFlexAR®, ChronoFlex AL®, ChronoFlec C®) or BIONATE (e.g., BIONATE I, BIONATE II, BIONATE 55D, BIONATE 65D, BIONATE 75D, BIONATE 80A, BIONATE 90A, BIONATE 55 or BIONATE 80).

[0072] The external wall (and/or the bone engaging surface) of the implant may be coated and/or impregnated with a latticework of polymer that is surface sprayed or layered on the outside (or bone engaging surface) of the implant to promote cartilage tissue regeneration. This most external surface coating may contain living chondrocytes (for example, as is provided in the Carticel procedure by the Genzyme company), and/or may contain stem cells with directed gene mutations to enhance adherence of the coating to the implant. Chondrocytes from companies such as Tygenix or Histogenics may be used for greater aggregation potential. The bone engaging surface may comprise peaks and troughs. The living cells may be imposed in between (and/or provided in the) troughs of the implant surface while the surface areas of prominence (the peaks of the surface) may be used for at least one of: space validation, traction, and cell protection.

[0073] The implant may be formed of suitable bioabsorbable materials so that the implant may be absorbed within a particular predetermined time frame. Suitable bioabsorbable materials include polylactic acid, polyglycolic acid, polycaprolactone, copolymers, blends and variants thereof. Suitable bioabsorbable materials may also/alternatively include poly(hydroxyalkanoate)s of the PHB-PHV class, additional poly(ester)s, and natural polymers, particularly, modified poly(saccharide)s, e.g., starch, cellulose, and chitosan. The walls of the implant may be (in whole and/or in part) bioabsorbable. The balloon may be (in whole and/or in part) bioabsorbable. As used herein the terms bioabsorbable, bioerodable, and/or bioabsorbable may be used interchangeably. The walls of the implant may release a pharmaceutical agent or an biological agent (such as stem cells, differentiated cells, pluripotent cells, post-mitotic cells, living chondrocytes, gene therapies, and the like). The release of such agents (whether biological or pharmaceutical, or a combination thereof) may occur over time, as the wall of the implant (or as the balloon) bioabsorbs in some embodiments, or as the joint is used (i.e. through pressure, for non-limiting example). In some embodiments the contents may contain targeting drugs such as gleevac that turn off tumor molecules as those in GIST. Cell-specific drugs targeting tumors by design may require nano-sized micelles with hydrophilic shells to protect core agents. In some embodiment hydrogels are used and tailored to swell thus releasing trapped molecules or cells through web like surfaces, controlled by internal or external triggers such as ph, magnetic fields, or temperature. Dendritic macromolecules may be used in implants to deliver agents en masse deploying a controllable size and structure. In some embodiments, individual agent molecules or hubs may be incorporated via covalent bonds.

[0074] In some embodiments, the implant comprises amniotic membrane (and/or a component thereof). In some embodiments, the implant comprises amniotic sac (and/or a component thereof). In some embodiments, the implant comprises amniotic tissue (and/or a component thereof). Amniotic membrane (and/or sac and/or tissue) is unique in that its mechanical properties include that it slippery on one side (lubricious, low modulus of elasticity) and sticky (adherent) on the other. In some embodiments, at least one of the first wall, the second wall and the side wall comprise amniotic membrane or a component thereof. In some embodiments, at least one of the first wall, the second wall and the side wall comprise amniotic sac or a component thereof. In some embodiments, at least one of the first wall, the second wall and the side wall comprise amniotic tissue or a component thereof. The amniotic membrane and/or amniotic sac and/or amniotic tissue may be used in conjunction with other biologic agents, pharmaceutical agents, and/or therapeutic agents. Amniotic tissue is used extensively in pleuripotential cells. It qualifies as HTBP (Human Tissue Based Product) because of the short term time span on the product and origin.

[0075] The bone engaging surface of the implant may be coated and/or impregnated with a latticework of polymer that is surface sprayed or layered on the bone engaging surface of the implant to promote cartilage tissue regeneration. This bone engaging surface coating may contain living chondrocytes (for example, as is provided in the Carticel procedure by the Genzyme company), and/or may contain stem cells with directed gene mutations to enhance adherence of the coating to the implant. The bone engaging surface may comprise peaks and troughs. The living cells may be provided in troughs while the surface peaks may be used for at least one of: space validation, traction, and cell protection.

[0076] In some embodiments, the implant is pre-molded to fit about at least one condyle of the femur. In some embodiments, the implant comprises a memory plastic. In some embodiments, the implant comprises a wire frame. In some embodiments, the wire of the wire frame comprises a memory metal. In some embodiments, the memory metal comprises nitinol. In some embodiments, the wire frame is disposed in the periphery of the implant or a portion thereof. In some embodiments, the wire

frame is configured to aid in placement against the posterior of the condyle.

[0077] In some embodiments, at least a portion of the implant comprises a slippery surface. In some embodiments the slippery surface is configured to allow for relative movement between the implant (or a portion thereof) that is coupled to the femur and the tibia. In some embodiments the slippery surface is configured to allow for relative movement between the implant (or a portion thereof) that is coupled to the femur and the patella.

[0078] In some embodiments, the implant comprises a sheet. The sheet is solid (e.g. comprising polyurethane or another biocompatible material), complex (e.g. comprising Dyneema mesh). The implant may comprise Dyneema mesh. The implant may comprise Dyneema fiber. In some instances, the implant comprises Dyneema Purity®. The implant may comprise a fiber. The implant may comprise a polyethylene fiber. The implant may comprise a mesh. The mesh may be a random structure or a repeating structure (such as a honeycomb). The mesh may comprise a polymer structure of interwoven or randomly interlinked fibers or a combination thereof. The mesh may comprise a memory polymer. The mesh may aid in fixing the implant in place. The mesh may be adapted to add cushion to the bones of joint. The mesh may be adapted to add durability to implant upon cyclic loading. The mesh may be adapted to add padding to the bones of joint. The mesh may be filled in its interstices with a softer (in durometer) polymer or other material (softer than the material of the mesh itself). The mesh may be filled in its interstices with a softer (in durometer) polymer or other material (softer than the material of the mesh itself). The interstices of the mesh may comprise a pharmacologic or therapeutic agent (or both) as noted herein.

[0079] To be clear, in some embodiments, the implant may have a single composition throughout the implant, and shaped as noted herein with attachment features as noted herein. In other embodiments of the implant, the implant comprises no chamber, however it comprises various regions which have different features than other regions-such as comprising a mesh between the first wall and the second wall (as noted above), a cushion between the first wall and the second wall, and/or comprising any aspects of the fill materials noted in the inflation mediums noted elsewhere herein, but not necessarily provided in a chamber which is filled following implantation or at the time of implantation. Rather, these aspects may be built into the implant during implant manufacture, by layering or other manufacturing processes, and not necessarily by filling a chamber. In some embodiments, there are multiple regions having different characteristics-cushioning, some therapeutic agent delivery, defect correction, padding, for non-limiting example, or some combination thereof. In some embodiments, the implant achieves these aspects by varying thickness of one of the walls at a particular region of the implant, for non-limiting example, at load-bearing locations.

[0080] In some embodiments, the features of the implant change over time. For example, prior to, at, or during implantation, the implant may comprise a powder methyl methacrylate and a liquid that becomes a slurry upon insertion or soon thereafter, and that once implanted hardens (or cures) within the implant. The methyl methacrylate (e.g. as a powder) and a catalyst liquid together become solid and are an example of a cement (or bone cement), however other cements or other materials which cure over time or with heat or with loading or by other methods (chemical or physical) are contemplated as alternatives. In certain embodiments, at least one of the powder methyl methacrylate and the liquid is part of the implant at the time of implantation. In certain embodiments, at least one of the powder methyl methacrylate and the liquid is injected into or loaded into the implant at the time of implantation or soon thereafter. In certain embodiments, both the powder methyl methacrylate and the liquid are injected into or loaded into the implant at the time of implantation or soon thereafter. In certain embodiments, at least one of the powder methyl methacrylate and the liquid is a fill material. In certain embodiments, the implant does not have a chamber prior to injection of (or loading of) a fill material between the first wall and the second wall. The injection (or loading) of a fill material between the first wall and the second wall creates a chamber. In certain embodiments, the implant comprises intersticeswhich are occupied by the fill material. In some embodiments, the methyl methacrylate powder and liquid catalyst are already inside the implant but only mix after intentional deployment in external or internal manners.

[0081] The implant in some embodiments is inserted arthroscopically through a cannula about 10 mm in diameter. Once the joint is cleaned, the implant is inserted and appropriately fixed to avoid extrusion or dislocation thereof. This may be via attachment of the implant tabs and/or by a combination of tab use plus intended friction created by implant surface coverings (analogous to Velcro) or a draw string at the smaller base of the implant.

Smart RADs

[0082] In some embodiments, the implant comprises a microminiature recorder and/or transmitter. The recorder (i.e. sensor) may collect joint loading data and comprise electronics that deliver data regarding joint loading. The recorder (i.e. sensor) may collect data regarding chemical or physiologic response at the implant location, such as the presence and composition of various biologic fluids at the sensor site. The sensor may be able to detect inflammatory responses in the joint. The sensor may be able to detect the spacing of the various joint components over time or at a particular time-such as the distance between the tibia and femur during a normal gait. The implant may comprise electronics that deliver data regarding joint loading or the other aspects of the joint sensed as listed herein or otherwise that could be

sensed. The transmitters may provide feedback to the patient or to a caregiver. The feedback may be real-time, or may be uploaded periodically, or may be uploaded upon request. The feedback may be provided wirelessly. The transmitters may provide a patient an ongoing feedback and ability to adjust the joint use based to the feedback from the transmitter. For example, the transmitter might signal to the patient that he should adjust his gait to reduce the ligamentary stress in one manner or another. In another example, the transmitter might indicate to a physical therapist that a certain ligament is being stressed during normal use, and that might indicate to the therapist that the patient should strengthen a particular muscle or muscle group to compensate for and balance the stresses in the joint. In another example, the sensor and transmitters transmits information regarding positioning, ligamentary stresses and other information to a graphic display of real-time feedback, enabling a surgeon to visualize and quantify joint loading and balance during implantation. Thus, a surgeon can make an informed choice to modify implant positioning, adjust leg alignment and optimize soft tissue balance through a full range of motion.

Attachment Elements and Couplers

[0083] In some embodiments the attachment elements of the implant comprises holes through which screws or other couplers may be placed to attach the implant to an attachment site (or connection site) in the bone of the knee. In some embodiments the attachment elements are also or alternatively called fixation elements or couplers. In some embodiments, the holes are created arthroscopically. In some embodiments the holes are prefabricated in the implant. In some embodiments, the holes may be made prior to implantation based on the patient's particular anatomy. In some embodiments, the holes are reinforced by a reinforcing material of the implant. The reinforcing material may be a polymer of sufficient durometer and/or tear resistance to reinforce the screw hole. In some embodiments, there is no preformed hole, but rather screws (or another coupler) secure the attachment tabs to the joint component (bone, etc) by creating their own hole when implanted. In some embodiments, the implant may comprise tabs that are adapted to receive staples or other couplers described elsewhere herein. In some embodiments, the elasticity of the implant may allow it to stretch over the joint end and hook or snap into place, with the tendency of the material to contract acting to hold it in place (in part or wholly).

[0084] The implants described herein may comprise attachment elements (or tabs) which may then by attached or coupled to tissue of a component of the joint (whether to a bone or a ligament or a tendon or other joint component) by a coupling device. Coupling devices (or couplers) may comprise at least one of screws, snaps, washers, pins, sutures, suture anchors (metal and/or biodegradable), rivets, staples (with and /or without teeth), stabilizers, glues, hooks of cylindrical wire or flattened sheet metal into bone holes or slots respectively. The coupling devices may be resorbable or not. Also, the coupling devices may comprise at least one of strings (i.e. drawstrings), reigns, lassos, sutures, and lanyards. The strings, reigns, lassos, sutures, and/or lanyards may join with themselves and/or other coupling devices. The strings, reigns, lassos, sutures and/or lanyards may be directed not only into bone with or without anchors, but also through ligaments, tendons or loose segments of cartilage that the surgeon intends to preserve.

[0085] The posterior of the knee can be difficult to access without disturbing joint components (or in order to minimize such disturbance) such as tendons, ligaments, etc. Thus, in some embodiments, the implant comprises strings, reigns, lassos, and/or lanyards that may pass from the posterior of the implant via the intercondylar notch anteriorly to join with themselves and/or other coupling devices. These couplers may be pre-coupled to the implant, and the implant and its couplers may be configured to be pulled (or cinched) from the anterior of the implant once the implant is in its general location relative to the condyle in order to finally position the implant about the condyle-in particular in order to cinch the implant about the posterior of the condyle. Likewise, in some embodiments where the implant is pre-molded, the coupler as described are adapted to move the implant to its final position with conformity to the condyle's posterior with minimal disturbance to the joint structures at the joint's posterior (minimal cutting, minimal moving, and or minimal detachment, for non-limiting example).

[0086] In some embodiments, the implant comprises a skirt (or sleeve) that conforms to the contours of the bone (whether a condyle of the femur, a patella, or a tibia) as a coupler.

[0087] In some embodiments, a screw through tab having reinforced center holes may be part of the implant. For example, the implant may comprise polymer covered metal washer holes. The screw may go through the holes. Another embodiment may comprise a staple having spikes as shown in Figures 13A-13D. Figures 13A- 13D depict multiple views of a staple adapted to couple an implant to a bone of the joint. Figure 13A depicts an embodiment of an implant 20 having a tab 10a that is coupled to bone using a staple 12. Figures 13B & 13C depict a staple 12 as described herein having teeth 18. Figure 13C depicts an embodiment of a tab 10a that is coupled to bone using a staple 12 having teeth 18. Combinations of spikes and screws may be used in some embodiments, or combinations of other couplers. The implant may be configured to allow a surgeon the option of several types and sizes of couplers, as each patient differs with regard to size and depth of lesion, bone stock, regrowth capability, and compliance with advised recovery, and each surgeon has his own strengths and comforts when working with such implants.

[0088] The edge of the implant may have a depending

skirt to secure or anchor the implant to the end of bone (femur), but may have one or more depending tabs (or appendages) that may be employed for similar functions as are discussed in other embodiments. The skirt (and/or tabs, and/or appendages) may tightly fit about the end of the femur, or the skirt can be secured by adhesive (e.g. HydroMed, Carbopol 934p, Polycarbophil AA1, xanthum gum, hydroxypropyl cellulose). Moreover, the lower portion of the skirt may be secured by a purse string suture or a suitable strand (elastic or tied) that is tightly bound about the outside of the skirt.

[0089] Figures 12A, 12B, and/or 12C alternatively may be used to describe a patch implant or a unicompartment knee implant described herein, having appendages 4a, 4c, extending from a balloon 6 and including holes 8a, 8b, 8c, and/or tabs 10a, 10b. 10c, 10d, 10e, 10f, which may be used with couplers (not shown) to couple the implant to a bone of the knee joint (which may be the femur, the tibia, or the patella). Features shown in Figure 12A, 12B, and or 12C are common to both the unicompartment knee implant (also discussed elsewhere herein) and the patch implant (also discussed elsewhere herein), although dimensions may differ as described elsewhere herein.

[0090] Figures 13A- 13D depict multiple views of a staple 12 adapted to couple implant 14 (such as those described herein) to a bone 16 of the joint. Figure 13A depicts a staple 12 coupling a tab 10a of an appendage 4a to the bone 16 of the joint (wherein the portion of the staple 12 embedded in the bone 16 is shown as a dashed line). Figure 13B depicts a view of a staple 12 having teeth 18 to grasp the tab 10a of the implant 14. Similarly, Figure 13C depicts a view of a staple 12 having teeth 18 to grasp the tab 10a of the implant 14. Figure 13D depicts a staple 12 attaching the tab 10a of an implant to a bone 16, the dotted lines show the portion of the tab 10a that is compressed by the staple 12 and teeth 18 thereof.

[0091] In some embodiments, the implant is configured such that the tabs and/or couplers of the implant couple to the bone where there is no natural cartilage. In some embodiments, the implant may be adapted by the surgeon at the time of surgery such that the tabs are positioned where there is no natural cartilage.

[0092] In some embodiments, the implant comprises a tab and a hook that couples to the tab by wrapping around a component of the knee and securing the tab to the hook. In some embodiments, the implant comprises a tab and a hook that couples to the tab by wrapping around a condyle of the knee and securing the tab to the hook. In some embodiments, the implant is configured to wrap around a condyle of the knee and to secure a first appendage to a second appendage of the implant. In some embodiments the appendages are secured by couplers described herein. In some embodiments, the implant is pre-formed to fit to the condyle in such a wrapping manner.

[0093] In some embodiments, the implant comprises a methyl methacrylate what is placed into a balloon chamber that fits into a bone hole. Such an embodiment would generally fix the implant to the bone once the methyl methacrylate cures to a solid.

[0094] In some embodiments, the implant can be anchored with generic available sutures and suture anchors fixing and positioning material to bone with proper tensioning.

[0095] In some embodiments, fixation may comprise various methods and elements. For example the fixation to a bone (the first, the second or the third bone) may comprise any one of or a combination of a screw, a snap, a pin, a staple, bone in-growth materials, glue, a nanocomposite, and cement. The implant may comprise a snap fit option for fixation. The implant itself may be premolded to cup the first bone of the device, or the second bone of the device. The implant may instead have a snap-like device which fixes the device to the bone (the first, second, and/or third bone). In some embodiments, fixation comprises glue. In some embodiments, fixation comprises a nanocomposite. In some embodiments, the nanocomposite comprises a polyurethane hierarchical nanocomposite. Fixation may comprise gluing a nanocomposite to the implant. In other embodiments, fixation comprises bone in-growth materials. For example, bone in-growth may be achieved as described in Vasanji A (2012). In some embodiments the patient's preoperative x-rays, MRI, CT scan, or physical measurements are coordinated with implant custom fit options providing for translation of pathophysiological data into solid works and rapid prototypes. This may provide the forum for anatomic fit of the implant to the patient. Optionally, the implant may be selected from a set of pre-selected sizes of implants and then the device may have inherent malleability which is used to couple the implant to the bone end.

[0096] The implant may be shaped to form a joint cap which is fixed to a first bone or a second bone or a combination thereof with a fixation element such as a screw or staple or cement or another means or combination of these or others as described herein. Cementing the implant in place is an alternative or may be used with other fixation elements (screws, snaps, ties, hooks, staples, etc). In some embodiments the implant is secured in place only by the nature of its location and placement within the joint space. That is, it may naturally be held in place by the surrounding structures (tissue, bone, ligaments) as well as its own geometry in three dimensions. In some embodiments, fixing of the implant to bone is achieved by combining autograph, allograph, xenograph, and/or prosthetic structures.

[0097] In some embodiments, the implant comprises a polymer joint cap that may be used similarly to the femoral component of a total knee replacement cement arthroplasty or like a hip resurfacing. In certain cases, cartilage may be sacrificed exposing more bone beneath the implant, and cement could be used as a traditional fixation technique. In certain embodiments, specific portions of cartilage can be removed to allow attachment of

the implant undersurface with the bone by localized applications of cement, bone in-growth, tacking devices, countersunk screws, or Velcro like constructs wherein opposing surfaces are set to fix. In an implant embodiment employing a cement for fixation, the anterior cruciate ligament could still be saved maintaining joint stability and proprioception.

[0098] A snap fit fixation element ("snap") may alternatively (or additionally) be used. A snap may be a protuberance off the posterior implant surface may be used. The snap may comprise a mushroom shaped peg that may insert into predrilled bone holes. The holes in some embodiments are of corresponding shape to the peg (upside-down mushroom-shaped holes, or similarly shaped holes). The holes in some embodiments are columnar shaped holes. The holes may be at the periphery (edge) of the implant as it opposes bone, or generally located as noted herein where other fixation elements are located (e.g. see Figures 1-4B, 11, 12 at least). The snap may also fit into more central posterior implant areas. With the natural effects of joint fluid and temperature on hydrophilic polymers, the snap may be designed as to increase stability by swelling beneath the joint cortical surface in the early post operative interval. Implant removal may be facilitated by placing a cooling device over the snap site to shrink or loosen the attachment. In some embodiments the peg of the snap is one of: about 1mm to about 10mm in diameter, about 2mm to about 8mm in diameter, about 3mm to about 6mm in diameter, about 4mm to about 5mm in diameter, about 4.5mm in diameter, 1mm to 10mm in diameter, 2mm to 8mm in diameter, 3mm to 6mm in diameter, 4mm to 5mm in diameter, and 4.5mm in diameter. In some embodiments the mushroom head of the snap is one of: about 1mm to about 10mm in diameter, about 2mm to about 8mm in diameter, about 3mm to about 6mm in diameter, about 4mm to about 5mm in diameter, about 4.5mm in diameter, 1mm to 10mm in diameter, 2mm to 8mm in diameter, 3mm to 6mm in diameter, 4mm to 5mm in diameter, and 4.5mm in diameter The snap or protuberances may have a narrow base that extends perpendicularly from the tabs and/or implant posterior surface. The wider sphere as compared to the diameter of the snap columnar pedestal fits into a predrilled bone hole that matches the location to be fixed. In another embodiment, the snap may be more like anchor which expands into the bone upon insertion, much like a drywall anchor acts. Material compliance allows the distal snap to enter through cortical to cancellous bone. Exposure to joint fluid and bode temperature can expand the snap wherein the snap comprises a hydrophilic polymer to secure implant apposition. In some embodiments, a mushroom shaped protuberance off the posterior of the polymer joint implant is used, with stiff pegs that push connected spheres through a predrilled cortical bone hole. The joint implant may be cap-like holding to the bone by internal elasticity of the implant and further held by the fixation elements which may be snaps or other elements. In some embodiments, a drill into cortical hole cuts a broader cancellous swath to create a location for the ball of the snap. For example the peg hole may be 5mm, while the mushroom cap head hole section diameter may be 7mm. Other sizes may be appropriate for the peg hole such as about 1mm, about 2mm, about 3mm, about 4mm, about 5mm, about 6mm, about 7mm, about 8mm. Other sizes may be appropriate for the mushroom cap head hole section, such as about 9 mm about 3mm, about 4mm, about 5mm, about 6mm, about 7mm, about 8mm, and about 9mm. A hydrophilic polymer of the snap may then swell and hold the implant into place.

[0099] Other variations of fixing an implant to a bone may be known to one of skill in the art, and may include (but is not limited to) cross pins such as those used for ACL graft fixation, whip stitches with newer strong sutures as OrthoCord, or combinations of the above or others noted herein.

[0100] It should also be recalled that whereas the usual location of implants is over the major surface of a joint, the minor surfaces of joints may be selected optionally or additionally for coverage by an implant depending on the clinical need. In another iteration for fixation, magnets inside pegs or protuberances can allow for size adjustment internally or externally so as to engage a locking mechanism of implant to bone end.

In-growth Features

[0101] In addition to the general in-growth that may occur based on the implant features described herein, the implant undersurface (adjacent the femur) may comprise an in-growth matrix. In some embodiments, at least a portion of the implant adjacent to the femur comprises bone in-growth materials. Such an implant can be attached by a series of tabs with or without holes, using screws, rivets, stabilizers, staples, tacks, washers, pins, snaps, or Sutures and suture anchors, for non-limiting example. The polymer of the implant substitutes for periosteum when the implant comprises living chondrocytes (e.g. Carticel) as the in-growth matrix on a surface of the implant. The polymer of the implant substitutes for periosteum when the implant comprises living chondrocytes (e.g. Carticel) as the in-growth matrix within an implant embodiment configured to reveal and/or release said chondrocytes over time and/or upon implantation.

[0102] The bone in-growth undersurface may be used for long term fixation of the tabs or rim. That is, whereas it is important for the surgery to secure the implant to the joint surface in the most desirable corrective location, it is also important in some embodiments to prepare the anatomic undersurface of bone by abrading it, removing about 0.5mm of cortical bone so as to expose the underlying oxygen, blood, and nutrients of the patient to the undersurface of the implant that can gradually become incorporated into the limb bone. As this healing occurs over the course of weeks and months to one year post operation, the localized tacking sites may become less

relevant and potentially inert. Thus, in some embodiments, the implant may comprise a biodegradable (bioresorbable) polymer or other material. The couplers may additionally and/or alternatively be biodegradable or durable (non-bioabsorbable). Once the implant is in place, it may serve to at least one of: pad defects, cushion the joint, and restore the original damage to the joint components. The end goal is to apply minimally morbid treatment that may refurbish arthritic limb regions, leaving only the small skin scar and remote memory of the healed physical mishap.

[0103] Undersurface implant materials may involve used of the art and science from Artelon or Gore-Tex research, as each has advantages and limitations. Several implant options per joint damage area may be available to enjoy the primary surgeons manipulation to fit the clinically recovery requirements best.

[0104] In some embodiments the implant comprises an in-growth patch on at least one of the first portion configured to engage the femur, the second portion configured to engage the second bone (whether the tibia or the patella), the side portion, and the appendage. In some embodiments, tissue is removed to facilitate in-growth.

[0105] The walls of the implant embodying features of the invention may be composite structures. For example, the innermost layer may be impervious to preclude escape of inflation or other filling media, a central layer may be porous or otherwise contain treatment or cell regeneration agents, and the outer layer may be a thin, but strong layer of a thermoplastic, such as a thermoplastic polyurethane for non-limiting example, which has microporosity sufficient to allow passage or egress of treatment or cell regeneration agents from the central layer (or second layer). The degree of microporosity to enable egress of treatment or cell regeneration agents from the central layer is found in polymer layers such as Chronoflex (e.g., ChronoFlexAR®, ChronoFlex AL®, ChronoFlec C®) or BIONATE (e.g., BIONATE I, BIONATE II, BIONATE 55D, BIONATE 65D, BIONATE 75D, BIONATE 80A, BIONATE 90A, BIONATE 55 or BIONATE 80). The external wall (and/or the bone engaging surface) of the implant may be coated and/or impregnated with a latticework of polymer that is surface sprayed or layered on the outside (or bone engaging surface) of the implant to promote cartilage tissue regeneration. This most external surface coating may contain living chondrocytes (for example, as is provided in the Carticel procedure by the Genzyme company), and/or may contain stem cells with or without directed gene mutations to enhance adherence of the coating to the implant. The bone engaging surface may comprise peaks and troughs. The living cells may be imposed in between (and/or provided in the) troughs of the implant surface while the surface areas of prominence (the peaks of the surface) may be used for at least one of: space validation, traction, and cell protection.

[0106] The implant embodying features of the invention may be used in a series of treatments wherein the first treatment involves use of autologous or minimally manipulated allograph interpositional tissues or xenograph, the second treatment involves the use of the same type of tissue added to stem cells or chondrocytes and the third treatment involving deployment of the implant if the first two fail or are ineffective.

[0107] The implant may comprise materials which allow for bone in-growth following implantation.

Pharmacologics and Therapeutic Agents & Delivery Thereof to Various Locations

[0108] In some embodiments the implant may comprise vacuoles of pharmacologic substances. The vacuoles may be on a bone-engaging portion of the implant. In some embodiments, the implant comprises bubbles comprising an active substance such as a pharmacologic substance or other active substance. In some embodiments, the implant comprises spaces filled with an active substance such as a pharmacologic substance (pharmacologic agent) or other active substance (active agent). In some embodiments, the active substance comprises iatrogenically gene mutated cells. In some embodiments, the implant may be inserted into the vacated space following removal of an infected routine total joint replacement. Current treatment of infected prostheses range from IV antibiosis, through arthroscopic washout to single or two stage replantations. With the worst infection the joint is often debrided of the prosthetic components and old cement, and then filled with new bone cement that is impregnated with antibiotics, leaving the hardened materials in place 6-12 months. During this interval 6-12 weeks IV antibiotics are typically used. In this situation if implants as noted herein were inserted with a calculated egress of antibiotics from the polymer container, both increased concentration of local antibiotics and decreased systemic side effects can benefit the patient. Further, since the polymer is both robust and compliant, use of the infected joint being treated is more realistic and comfortable, with a "bag of antibiotics and air" as opposed to a "chunk of cement."

[0109] Dendritic Macromolecules may deliver agent en masse from certain embodiments of the implant. The delivery in such situations may be via controllable size and structure, and may incorporate individual agent molecules or "hubs" via covalent bonds. Any combination of the nanoscopic developments can be created or assembled into the implants described herein and can be distributed, or oozed, or leaked, or expulsed from, or absorbed into as cleansing a noxious environment, or any combination thereof. Combined alternating forces such as materials that suck up or absorb noxious leukokynins or cathepsins while released useful viscolubricants such as Synvisc, Hyalgan or Orthovisc can be constructed to accommodate clinical need consistent with physical joint damage mandates or aligned with and consider of the natural history of disease processes so as to maximize either ones anticipated inevitable chronic deterioration or to thwart the adverse affects delaying degradation

from arthritic or pathophysiologic processes.

Patient Symptoms

[0110] Symptoms for the patient requiring an implant described herein may include, for non-limiting example, osteoarthritis or rheumatoid or gouty arthritis.

Total Knee Arthroplasty (Dual Compartment):

[0111] Provided herein is an implant for placement on both condyles (medial and lateral) of the distal femur. In some embodiments, this is called a dual compartment implant since it covers both condyles of the femur.

[0112] In some embodiments, the implant covers the "H" distal femoral cartilage segment (made up of both femoral condyles and the trochlear groove in between). The implant may absorb diffuse force, endure the millions of annual cyclic loads of both knee joints (including the patella-femur joint and the femur-tibia joints), along with rotational and shear forces up to six times body weight, at least.

[0113] In some embodiments, the implant comprises attachment tabs or attachment elements over the sides of both condyles medially and laterally. In some embodiments, the implant comprises attachment tabs or attachment elements in the intercondylar notch (or slot). In some embodiments, the implant comprises attachment tabs or attachment elements superiorly at the distal end of the femur anteriorly. In some embodiments, posterior reigns or suture-like lanyards cinch up the implant from inside the posterior intercondylar notch toward another connection site around the femur.

[0114] The posterior of the knee can be difficult to access without disturbing joint components (or in order to minimize such disturbance) such as tendons, ligaments, etc. Thus, in some embodiments, the implant comprises strings, reigns, lassos, and/or lanyards that may pass from the posterior of the implant via the intercondylar notch anteriorly to join with themselves and/or other coupling devices. These couplers may be pre-coupled to the implant, and the implant and its couplers may be configured to be pulled (or cinched) from the anterior of the implant once the implant is in its general location relative to the condyle in order to finally position the implant about the condyle-in particular in order to cinch the implant about the posterior of the condyle. Likewise, in some embodiments where the implant is pre-molded, the coupler as described are adapted to move the implant to its final position with conformity to the condyle's posterior with minimal disturbance to the joint structures at the joint's posterior (minimal cutting, minimal moving, and or minimal detachment, for non-limiting example). In some embodiments at least a portion of the ligamentary structure of the knee is spared.

[0115] Although this description focuses on the distal femur as it articulates with the retropatellar and proximal tibial cartilages implants as described generally herein may be also and/or alternatively be used in conjunction with the tibia and/or the patella. Furthermore, separate and/or connected implant components may be inserted to restore natural function to the knee. In some embodiments whereas the implant caps the major joint surface and opposes remnant cartilage, the surgeon may elect to place the implant so that it opposes metal, polymer, or another surface reconstructive material.

[0116] Coupling devices to be used as part of the dual compartment implant may include any of those mentioned or described herein, for example. Such coupling devices may comprise at least one of strings (i.e. drawstrings), reigns, lassos, sutures, and lanyards. The strings, reigns, lassos, sutures, and/or lanyards may join with themselves and/or other coupling devices. The strings, reigns, lassos, sutures and/or lanyards may be directed not only into bone with or without anchors, but also through ligaments, tendons or loose segments of cartilage that the surgeon intends to preserve.

[0117] Figure 1 depicts an embodiment of the implant 20 in a 2D view configured for dual condyle (distal femur) coverage. Figure 1 depicts an embodiment of the knee implant 20 having appendages 4a, 4b, 4c, 4d, including holes 8a, 8b, 8c, 8d and tabs 10a, 10b extending from a balloon 6 and including slots 26a, 26b to accommodate ligaments (not shown) of the knee joint. Couplers as described elsewhere herein may be used to couple the implant 20 to the distal femur. In some embodiments, there may only tabs, only holes, or only appendages, or combinations thereof. In some embodiments, there may be other ways to couple the implant to the distal femur, as described elsewhere herein (sutures, drawstrings, skirts, glue, etc). In some embodiments, the tabs 10a, 10b contain holes. In some embodiments, the couplers create the holes 8a, 8b, 8c, 8d, or other holes (not shown) when the implant is placed against the distal femur 24. In some embodiments, the holes are pre-formed in the appendage prior to implantation. In some embodiments, the holes are reinforced as described elsewhere herein. In some embodiments, the holes are within the peripheral rim of the knee implant. In some embodiments, the holes are within the region of the intercondylar notch medially and/or laterally. In some embodiments, the holes are through the polymer. In some embodiments, the holes are through a reinforced rim. As shown here, the appendages in some embodiments may be different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage 4d that is intended to wrap over the medial condyle may be longer and/or wider than the appendage 4c intended to wrap over the lateral condyle. Likewise, the slots may be different in shape and/or size and/or position to accommodate the ligaments and/or tendons of the joint or other structures and functions of the joints of the knee, and to allow for placement of the implant with minimal disturbance (cutting, manipulation, for example) of the joint components such as tendons, ligaments, and other

soft or hard tissues. For example, slot 26a is shaped and positioned to accommodate the cruciate ligaments of the knee, at least. In some embodiments, the implant as shown in Figure 1 can have regions 4a, 4b, 4c, 4d where no inflation exists and may be composed of solid or compliant materials. In some embodiments, the implant comprises a Dyneema® mesh. The implant may comprise Dyneema® fiber. In some instances, the implant comprises Dyneema Purity® fiber. In some embodiments, the implant comprises a Dyneema Purity® UG fiber. In some embodiments, the implant comprises a Dyneema Purity® VG fiber. The implant may comprise a fiber. The implant may comprise a polyethylene. The implant may comprise a polyethylene fiber.

[0118] Figure 2 depicts an embodiment of the knee implant 20 having appendages 4a, 4b, 4c, 4d, including holes 8a, 8b, 8c, 8d and tabs 10a, 10b extending from a balloon 6 and including slots 26a, 26b to accommodate ligaments of the knee joint as well as side views of the same knee implant. Couplers as described elsewhere herein may be used to couple the implant 20 to the distal femur. In some embodiments, there may only tabs, only holes, or only appendages, or combinations thereof. In some embodiments, there may be other ways to couple the implant to the distal femur, as described elsewhere herein (sutures, drawstrings, skirts, glue, etc). In some embodiments, the couplers create the holes 8a, 8b, 8c, 8d, or other holes (not shown) when the implant is placed against the distal femur. In some embodiments, the holes are pre-formed in the appendage prior to implantation. In some embodiments, the holes are reinforced as described elsewhere herein. As shown here, the appendages in some embodiments are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage 4d that is intended to wrap over the medial condyle may be longer and/or wider than the appendage 4c intended to wrap over the lateral condyle. Shown in the embodiment depicted in Figure 2 are the different hole placements from the side view, showing the differences in positioning of the holes to accommodate the differences in anatomic structure and size of the condyles. Likewise, the slots may be different in shape and/or size and/or position to accommodate the ligaments and/or tendons of the joint or other structures and functions of the joints of the knee, and to allow for placement of the implant with minimal disturbance (cutting, manipulation, for example) of the joint components such as tendons, ligaments, and other soft or hard tissues. For example, slot 26a is shaped and positioned to accommodate the cruciate ligaments of the knee, at least. Additionally, as shown in the side views of the embodiment shown in Figure 2, the balloon has a first wall 28 adapted to be adjacent the femur that is of a greater thickness than the second wall 30. In some embodiments, the first wall 28 is configured to have therapeutic benefits (pharmacologic, healing, and/or in-growth properties) as described elsewhere herein. The second wall 30 may additionally and/or alternatively be configured to have a therapeutic effect (pharmacologic, healing, and/or in-growth properties).

[0119] Nevertheless, differing thicknesses of the first wall 28 and the second wall 30 are not necessarily required in order to impart the therapeutic benefits (pharmacologic, healing, and/or in-growth) described elsewhere herein. For example, Figure 3 depicts an example of a knee implant 20 having appendages 4a, 4b, 4c, 4d, including holes 8a, 8b, 8c, 8d and tabs 10a, 10b extending from a balloon 6 and including slots 26a, 26b to accommodate ligaments of the knee joint as well as side views of the same knee implant. Couplers as described elsewhere herein may be used to couple the implant 20 to the distal femur. In some embodiments, there may only tabs, only holes, or only appendages, or combinations thereof. In some embodiments, there may be other ways to couple the implant to the distal femur, as described elsewhere herein (sutures, drawstrings, skirts, glue, etc). In some embodiments, the couplers create the holes 8a, 8b, 8c, 8d, or other holes (not shown) when the implant is placed against the distal femur. In some embodiments, the holes are pre-formed in the appendage prior to implantation. In some embodiments, the holes are reinforced as described elsewhere herein. As shown here, the appendages in some embodiments are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage 4d that is intended to wrap over the medial condyle may be longer and/or wider than the appendage 4c intended to wrap over the lateral condyle. Shown in the embodiment depicted in Figure 3 are the different hole placements from the side view, showing the differences in positioning of the holes to accommodate the differences in anatomic structure and size of the condyles. Likewise, the slots may be different in shape and/or size and/or position to accommodate the ligaments and/or tendons of the joint or other structures and functions of the joints of the knee, and to allow for placement of the implant with minimal disturbance (cutting, manipulation, for example) of the joint components such as tendons, ligaments, and other soft or hard tissues. For example, slot 26a is shaped and positioned to accommodate the cruciate ligaments of the knee, at least. Additionally, as shown in the side views of the example shown in Figure 3, the balloon has a first wall 28 adapted to be adjacent the femur that is of approximately the same thickness than the second wall 30. In some examples, the first wall 28 is configured to have therapeutic benefits (pharmacologic, healing, and/or in-growth properties) as described elsewhere herein. The second wall 30 may additionally and/or alternatively be configured to have a therapeutic effect (pharmacologic, healing, and/or in-growth properties). The balloon 6 may be singular as depicted, or in certain embodiments, include a plurality of microscopic vesicular structures.

[0120] Figure 4A depicts an example of the knee implant 20 having appendages 4a-4d including ten tabs 10a-10j extending from a balloon 6 and including a slot 26a to accommodate components (such as ligaments or other tissues whether soft tissues, hard tissues, tendons, and/or others) of the knee joint (not shown). The tabs 10a-10j are not shown with holes in this embodiment, however if screws are used as couplers, such holes may be pre-drilled or formed in situ by the screws. Additionally and/or alternatively, staples, washers, pins, snaps, or sutures may be used (as described elsewhere herein) in order to couple the implant to the bone (femur, for example). Other couplers as described elsewhere herein may also and/or alternatively be used in this coupling process. Furthermore, the number of tabs may be fewer or greater than the ten depicted in order to achieve optimal placement and coupling to the bone. For example, Figure 4B depicts an embodiment of the knee implant 20 having appendages 4a-4d including eight tabs 10a- 10h extending from a balloon 6 and including a slot 26a to accommodate components (such as ligaments or other tissues whether soft tissues, hard tissues, tendons, and/or others) of the knee joint (not shown). In certain embodiments, the implant comprises 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, or 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, and/or 20 tabs. The tabs may be located on either side of the condyles, including the superior, mid, and posterior portions. Any tab may be also and/or alternatively located inside the medial and intercondylar notch.

[0121] Figure 5 depicts an example of the knee implant 32 curved to simulate curvature about the condyles of a femur, the implant having appendages 4a-4d extending from an uninflated balloon (not shown) and including slots 26a, 26b to accommodate components (such as ligaments or other tissues whether soft tissues, hard tissues, tendons, and/or others) of the knee joint (not shown). This figure also shows an implant comprising a solid compliant material, having no balloon whatsoever. The implant may comprise additional curvatures and/or slots to accommodate other ligaments and/or tissues. In some embodiments, the implant is configured to conform about various hard and/or soft tissues of the joint, such as bone, ligaments, tendons, etc. In some examples, the balloon is inflated once the implant is positioned within the joint. In other examples, the balloon is partially inflated prior to being positioned within the joint. In other examples, the balloon is at least partially inflated prior to being positioned within the joint. In some examples, the balloon is fully inflated prior to being positioned within the joint. In some examples, the implant is configured to allow an operator to adjust the amount of balloon inflation in situ (whether by adding inflation medium or removing inflation medium, or both, or neither). Couplers as described elsewhere herein may be used to couple the implant 32 to the distal femur.

[0122] Figure 6A depicts a top-down view of an example of the knee implant 32 curved to simulate curvature about the condyles of a femur, the implant having appendages 4a-4d extending from two inflated balloons 6, 34 and including a slot 26a to accommodate components of the knee joint. Figure 6B depicts a bottom-up or anterior oblique view of the same embodiment of the knee implant 32 curved to simulate curvature about the condyles of a femur, the implant having appendages 4a-4d extending from two inflated balloons 6, 32 and including a slot 26a to accommodate components of the knee joint. Couplers as described elsewhere herein may be used to couple the implant 32 to the distal femur. As shown in Figures 6A and 6B, the appendages 4a- 4d in some embodiments are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage 4d that is intended to wrap over the medial condyle may be longer and/or wider than the appendage 4c intended to wrap over the lateral condyle. Likewise, the dimensions of the balloon 34 that is adapted for placement over the medial condyle may be a different shape and/or size than the balloon 6 over the lateral condyle (the medial condyle being larger, thus the balloon 34 may be larger for that location) Alternatively and/or additionally, as described elsewhere herein, for various reasons such as injury, realignment needs, injury, etc, there may be a need for more reconstruction of one condyle than needed for the other, thus the inflation medium might be different in one balloon (or a portion thereof) than in the other balloon (or another chamber within the same balloon), or there may be need for a different shaped balloon in one location than in another location. Examples provided herein can accommodate these requirements based on materials of fillers, appendages, balloons, walls, and dimensions and chamber options of the implant and its components.

[0123] Figure 7 depicts a top-down view of an example of the knee implant 32 curved to simulate curvature about the condyles of a femur, the implant having appendages 4a-4d extending from an inflated balloon 6 and including slots to accommodate components of the knee joint. Couplers as described elsewhere herein may be used to couple the implant 32 to the distal femur. As shown here, the appendages 4a-4d in some examples are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage 4d that is intended to wrap over the medial condyle may be longer and/or wider than the appendage 4c intended to wrap over the lateral condyle. Likewise, the dimensions of the portion of the balloon that is adapted for placement over the medial condyle may be a different shape and/or size than the portion of the balloon over the lateral condyle (the medial condyle being larger, thus the balloon may be larger for that location) Alternatively and/or additionally, as described elsewhere herein, for various reasons such as injury, realignment needs, injury, etc, there may be a need for more reconstruction of one condyle than needed for the other, thus the inflation medium might be different in a portion or chamber

of an implant having a plurality of inflation chambers in a single balloon, or there may be need for a non-symmetric balloon. Examples provided herein can accommodate these requirements based on materials of fillers, appendages, balloons, walls, and dimensions and chamber options of the implant and its components.

[0124] Figure 8 depicts a side view of an example of the knee implant 32 curved to simulate curvature about at least one condyle of a femur, the implant having appendages 4b, 4d extending from an uninflated balloon (not shown). This depiction covers the maximum anticipated distal femoral contour; other iterations may be smaller, or shorter covering limited areas of the circumference of the femoral curvatures. This figure also provides a lateral view for a solid implant (without a chamber therein) wherein the material thickness and/or layering provide cushioning.

[0125] Figure 9A depicts a side view of an example of the knee implant 20 curved about at least one condyle 22 of a femur 24, the implant 20 having appendages 4b, 4d extending from an uninflated or minimally inflated balloon 6. In this view, the knee is positioned essentially in extension (straight), showing the tibia 36, fibula 38, and patella 40 of the knee. Note that although there would be other joint structures and knee structures in a true depiction of an implant positioned in the knee, this view of the implant and bones is greatly simplified for ease of understanding of the implant and the joint relative (and approximate) positions and placement. Couplers as described elsewhere herein may be used to couple the implant 20 to the distal femur 24 and/or the condyle 22 thereof (in this image the medial condyle, at least since it is primarily a one-side view of the joint and implant). For the sake of simplicity Fig 9A and the implant depicted show of the femur with opposition to the other surfaces of both knee joints (between femur and tibia, and femur and patella), the areas of contact varying according to activity, forces, and range of motion. Other implant iterations may apply to opposing surfaces.

[0126] Figure 9B depicts a side view of an example of the knee implant 20 curved about at least one condyle 22 of a femur 24, the implant 20 having appendages 4b, 4d extending from an inflated balloon 6. In this view, the knee is positioned essentially in extension (straight), showing the tibia 36, fibula 38, and patella 40 of the knee. Note that although there would be other joint structures and knee structures in a true depiction of an implant positioned in the knee, this view of the implant and bones is greatly simplified for ease of understanding of the implant and the joint relative (and approximate) positions and placement. Couplers as described elsewhere herein may be used to couple the implant 20 to the distal femur 24 and/or the condyle 22 thereof (in this image the medial condyle, at least since it is primarily a one-side view of the joint and implant). In Figure 9B wherein the balloon is inflated, as compared to Figure 9A wherein the balloon is not inflated or is minimally inflated, the balloon second wall 30 is closer to and/or contacting the tibial plateau 42 (articular surface) when the balloon 6 is inflated. Likewise, Figure 9C depicts a side view of an example of the knee implant 20 curved about at least one condyle 22 of a femur 24, the implant 20 having appendages 4b, 4d extending from an inflated balloon 6 and having couplers 44a, 44b (which may be, for non-limiting example, staples or screws, pins, or snaps) coupling the appendages 4b, 4d to the femur. In this view, the knee is positioned essentially in extension (straight), showing the tibia 36, fibula 38, and patella 40 of the knee. Where the inflated balloon as seen in Figure 9B may fill in existing pathologic defects of the joint surface, the medium of inflated and specific balloon location and durometry with the material of the implant may also be constructed so as to force the bones opposed, e.g. the femur and tibia, into a more natural limb alignment such as six (6) degrees valgus. However, if the patient being treated has variations from normal in the affected knee as illustrated by examining and measuring the opposite normal side, then the implant inflation and pressures or balloon location may be adjusted from the population norms thus customizing this implant to the clinical case under consideration. Fixation devices may be appropriately applied at various knee range of motion intervals from full extension (zero degrees) to full flexion (usually 135 degrees) as the knee is adjusted and the mplant secured under anesthesia.

[0127] Figure 10A depicts a side view of an example of the knee implant 20 curved about at least one condyle 22 of a femur 24, the implant 20 having appendages 4b, 4d extending from an inflated balloon 6 and showing the inflation medium 46 moved anteriorly toward the patella 40 when the knee joint is slightly flexed. The dynamic nature of the implant material and/or content may be responsive to body forces as a physiological rather than rigid structure. The filling of space inside the joint may add stability to the patient and to the joint. Likewise, Figure 10B depicts a side view of an embodiment of the knee implant 20 curved about at least one condyle 22 of a femur 24, the implant 20 having appendages 4b, 4d extending from an inflated balloon 6 and having couplers 44a, 44b (which may be, for non-limiting example, staples or screws, pins or snaps) coupling the appendages 4b, 4d to the femur 24 and showing the inflation medium 46 moved anteriorly toward the patella 40 when the knee joint is slightly flexed.

[0128] For example, Figure 14 depicts an embodiment of the knee implant 20 having appendages 4a, 4b, 4c, 4d, including holes 8a, 8b, 8c, 8d and tabs 10a, 10b and including slots 26a, 26b to accommodate ligaments of the knee joint as well as side views of the same knee implant. Couplers as described elsewhere herein may be used to couple the implant 20 to the distal femur. In some embodiments, there may only tabs, only holes, or only appendages, or combinations thereof. In some embodiments, there may be other ways to couple the implant to the distal femur, as described elsewhere herein (sutures, drawstrings, skirts, glue, etc). In some embodiments, the couplers create the holes 8a, 8b, 8c, 8d, or

other holes (not shown) when the implant is placed against the distal femur. In some embodiments, the holes are pre-formed in the appendage prior to implantation. In some embodiments, the holes are reinforced as described elsewhere herein. As shown here, the appendages in some embodiments are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage 4d that is intended to wrap over the medial condyle may be longer and/or wider than the appendage 4c intended to wrap over the lateral condyle. Shown in the embodiment depicted in Figure 14 are the different hole placements from the side view, showing the differences in positioning of the holes to accommodate the differences in anatomic structure and size of the condyles. Likewise, the slots may be different in shape and/or size and/or position to accommodate the ligaments and/or tendons of the joint or other structures and functions of the joints of the knee, and to allow for placement of the implant with minimal disturbance (cutting, manipulation, for example) of the joint components such as tendons, ligaments, and other soft or hard tissues. For example, slot 26a is shaped and positioned to accommodate the cruciate ligaments of the knee, at least. Additionally, as shown in the side views of the embodiment shown in Figure 14, the implant has a first wall 28 adapted to be adjacent the femur that is of approximately the same thickness than the second wall 30. In some embodiments, the first wall 28 is configured to have therapeutic benefits (pharmacologic, healing, and/or in-growth properties) as described elsewhere herein. The second wall 30 may additionally and/or alternatively be configured to have a therapeutic effect (pharmacologic, healing, and/or in-growth properties). Additionally, the thickness of the implant in certain locations is variable to add cushioning to the implant as well as to provide joint spacing. In certain embodiments, the material is not variable in thickness, but provides the same cushioning and/or joint spacing for the bones of the joint. The central region in the embodiment of Figure 14 is thicker material to add at least one of: cushioning, buffering, joint space, restore cushioning, and to respond to clinical need.

[0129] Any of the balloons described herein with regard to any of the figures may add cushioning, padding, strength, durability, flexibility, or any other aspect noted herein, and need not be a chamber per se, nor be inflatable per se. Rather they are merely distinguishable in certain embodiments from the walls which are on either side of them in composition or function or both. In some embodiments, the balloon and its interior is not materially different in composition or function from one of the walls. In some examples, they are not materially different in composition or function from either of the walls.

[0130] Figures 15A, 15B, and 15C show several views of an embodiment of an implant which has no definable chamber, rather the material of the implant itself provides the cushion to the bones of the joint (at least). The implant in 15A, 15B, and 15C is generally H or V-shaped, having a slot 26b that is significantly smaller than as shown other embodiments (for example Figures 3, 4, 5, 6A, 6B, 7, 14). In certain embodiments, an implant shaped generally like Figures 15A, 15B, and 15c may comprise a chamber which, if the implant were shown in cross section, may comprise a different material than the wall of the implant itself, or may be the same material but with different geometric or chemical or physical properties, as noted herein. Figures 15A, 15B, and 15C depict an embodiment of the knee implant 20 having appendages 4a, 4b, 4c, 4d and tabs 10a, 10b, 10c, 10d, 10e, 10f, 10g, 10h and including slots 26a, 26b to accommodate ligaments of the knee joint. Couplers as described elsewhere herein may be used to couple the implant 20 to the distal femur. In some embodiments, there may only tabs, only holes, or only appendages, or combinations thereof. In some embodiments, there may be other ways to couple the implant to the distal femur, as described elsewhere herein (sutures, drawstrings, skirts, glue, etc). In some embodiments, the couplers create holes (not shown) when the implant is placed against the distal femur. In some embodiments, the holes are pre-formed in the appendage prior to implantation. In some embodiments, the holes are reinforced as described elsewhere herein. As shown here, the appendages in some embodiments are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage 4d that is intended to wrap over the medial condyle may be longer and/or wider than the appendage 4c intended to wrap over the lateral condyle. The slots may be different in shape and/or size and/or position to accommodate the ligaments and/or tendons of the joint or other structures and functions of the joints of the knee, and to allow for placement of the implant with minimal disturbance (cutting, manipulation, for example) of the joint components such as tendons, ligaments, and other soft or hard tissues. For example, slot 26a is shaped and positioned to accommodate the cruciate ligaments of the knee, at least. The thickness of the implant in certain locations is variable to add cushioning to the implant as well as to provide joint spacing. In certain embodiments, the material is not variable in thickness, but provides the same cushioning and/or joint spacing for the bones of the joint.

[0131] Figure 16 depicts a knee implant embodiment that is generally H or V-shaped, having a slot 26b that is significantly smaller than other embodiments, and in this embodiment is effectively replaced with a tab 10i at the same location (e.g. 10i). Figure 16 depicts an embodiment of the knee implant 20 having appendages 4a, 4b, 4c, 4d and tabs 10a, 10b, 10c, 10d, 10e, 10f, 10g, 10h, 10i and including a slots 26a to accommodate ligament(s) of the knee joint. Couplers as described elsewhere herein may be used to couple the implant 20 to the distal femur. Contour lines 54a, 54b, for example, are also depicted in figure 16, however these are not necessarily significant

other than to show contour of parts of the implant 20, although they may be in the case where a mesh is provided in the implant. In some embodiments, there may only tabs, only holes, or only appendages, or combinations thereof. In some embodiments, there may be other ways to couple the implant to the distal femur, as described elsewhere herein (sutures, drawstrings, skirts, glue, etc). In some embodiments, the couplers create holes (not shown) when the implant is placed against the distal femur. In some embodiments, the holes are preformed in the appendage prior to implantation. In some embodiments, the holes are reinforced as described elsewhere herein. As shown here, the appendages in some embodiments are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage 4d that is intended to wrap over the medial condyle may be longer and/or wider than the appendage 4c intended to wrap over the lateral condyle. The slot 26a may be different in shape and/or size and/or position to accommodate the ligaments and/or tendons of the joint or other structures and functions of the joints of the knee, and to allow for placement of the implant with minimal disturbance (cutting, manipulation, for example) of the joint components such as tendons, ligaments, and other soft or hard tissues. For example, slot 26a is shaped and positioned to accommodate the cruciate ligaments of the knee, at least. The thickness of the implant in certain locations is variable to add cushioning to the implant as well as to provide joint spacing. In certain embodiments, the material is not variable in thickness, but provides the same cushioning and/or joint spacing for the bones of the joint. In certain embodiments, an implant shaped generally like Figure 16 may or may hot comprise a chamber which, if the implant were shown in cross section, may comprise a several materials which may be the same as or different from any wall of the implant itself, or may be the same material but with different geometric or chemical or physical properties, as noted herein.

[0132] Figure 17 depicts a knee implant embodiment similar to Figure 16 which shows a posterior view including the location(s) 50a- 50d where a fill material such as cement may be placed. The fill material may be added in any one location 50a, 50b, 50c, or 50d, or added in several of locations 50a, 50b, 50c, and 50d or likewise be added anywhere on the first or second wall of the implant which contacts the first, second, and/or third bone. The fill material may be used to both cushion (as do balloons 6 in other figures) and/or secure the device to the bone in the case of a bone cement or a combination of these functions. In the case where the cement is used as the fill material, the cement may be used in an element that may or may not have any, some, or all of tabs 10a-10i. The cushion, thus can act as a coupler (fixation element) and/or as a cushion and/or spacer for the joint bones. The cushion (whether a fill material such as cement or another material) may also be placed adjacent to a first wall or second wall, and not necessarily between said first wall and second wall.

[0133] Figure 18 is an anterior-posterior view of an example of the implant 20 attached to a knee model. The implant here comprises chambers 52a, 52b, 53c, at least (in this case, nano-inflated air pockets). Although sparsely shown in this embodiment, the frequency, size, etc. could be adapted to smaller chambers, larger chambers, more frequent chambers, more concentrated in particular areas of the implant, less concentrated in particular areas of the implant, or similarly adjusted. The chambers can be diffuse, of any size, containing compressible gas (air), cells, pharmacologics, liquids, beads, metals, or other materials as noted herein.

[0134] Figure 19 depicts an implant 20 which is more squarely cut for interface with a femur, for example, which has been cut square such as is done in certain total knee arthroplasty procedures. The implant in this situation may comprise a polymer alone (of soft or hard durometer) and/or metal. The walls may be contiguous or include a chamber that is optionally filled or fillable as noted herein. Although tabs are shown in Figure 19, these are optional in embodiments where another attachment element (fixation element) is used such as cement or a metal pin or screw or snap through an appendage of the device.

[0135] Figures 20A and 20B depict a knee implant embodiment that is generally V-shaped or Y-shaped, and in this embodiment the slot 26b of other embodiments, or the tab 10i of other embodiments is effectively replaced with an appendage 4e at the same location. Figure 20A depicts an embodiment of the knee implant 20 having appendages 4c, 4d, and 4e and holes 8a (not shown, in Fig. 20B), 8b (not shown, in Fig. 20B), 8c (not shown, in Fig. 20B), 8d, 8e, 8f, 8g, 8h, 8i, (not shown, substantially similarly positioned as 8e on the same edge as 8a-8c of Fig. 20A), 8j (not shown, substantially similarly positioned as 8d on the same edge as 8a-8c of Fig. 20A), and including a slot 26a to accommodate ligament(s) of the knee joint. Couplers as described elsewhere herein may be used to couple the implant 20 to the distal femur through slots 8a-8j. Contour lines are also depicted in Figures 20A and 20B, however these are not necessarily significant other than to show contour of parts of the implant 20, although they may be in the case where a mesh is provided in the implant. In some embodiments, there may only tabs, only holes, or only appendages, or combinations thereof. In some embodiments, there may be other ways to couple the implant to the distal femur, as described elsewhere herein (sutures, drawstrings, skirts, glue, etc). In some embodiments, the tabs comprise holes. In some embodiments, the couplers create holes (not shown) when the implant is placed against the distal femur. In some embodiments, the holes are within the peripheral rim of the knee implant. In some embodiments, the holes are within the region of the intercondylar notch medially and/or laterally. In some embodiments, the holes are through the polymer. In some embodiments, the holes are through a reinforced rim. In some embod-

iments, the holes are pre-formed in the appendage prior to implantation. In some embodiments, the holes are reinforced as described elsewhere herein. As shown here, the appendages in some embodiments are different in shape and/or size to accommodate the differences in condyle size and/or shape. For example the medial condyle tends to be larger than the lateral condyle, and thus appendage 4d that is intended to wrap over the medial condyle may be longer and/or wider than the appendage 4c intended to wrap over the lateral condyle. The slot 26a may be different in shape and/or size and/or position to accommodate the ligaments and/or tendons of the joint or other structures and functions of the joints of the knee, and to allow for placement of the implant with minimal disturbance (cutting, manipulation, for example) of the joint components such as tendons, ligaments, and other soft or hard tissues. For example, slot 26a is shaped and positioned to accommodate the cruciate ligaments of the knee, at least. The thickness of the implant in certain locations is variable to add cushioning to the implant as well as to provide joint spacing. In certain embodiments, the material is not variable in thickness, but provides the same cushioning and/or joint spacing for the bones of the joint. In certain embodiments, an implant shaped generally like Figures 20A or 20B may or may not comprise a chamber which, if the implant were shown in cross section, may comprise a several materials which may be the same as or different from any wall of the implant itself, or may be the same material but with different geometric or chemical or physical properties, as noted herein. As shown in Figures 20A and 20B, thickness of between the first wall (part configured to touch the femur condyle) and the second wall (part configured to touch the tibia), is shown for example in the slot 26a (which may be called a notch herein), thus showing a side wall as described elsewhere herein to provide the thickness to the implant at the condyle(s). This thickness may be a result of a thickness of a material of the implant (as in where the implant comprises a compliant polymer), or due to an inflation of a balloon that resides between the first wall and the second wall and the side wall. In some embodiments, the implant comprises a Dyneema® mesh. The implant may comprise Dyneema® fiber. In some instances, the implant comprises Dyneema Purity® fiber. In some embodiments, the implant comprises a Dyneema Purity® UG fiber. In some embodiments, the implant comprises a Dyneema Purity® VG fiber. The implant may comprise a fiber. The implant may comprise a polyethylene. The implant may comprise a polyethylene fiber.

[0136] In all descriptions provided herein of the dual compartment implant, the implant may instead be configured to couple to or emerge from the tibia and/or patella. In all descriptions provided herein of the dual compartment implant, the implant may instead be configured to couple to the tibia. It is the intention and understanding that the implant is suited for this purpose in certain embodiments with adjustments to account for dimensional differences of the tibia. Most descriptions provided herein are directed to embodiments coupling the implant to the femur, however, this is primarily for ease of description and continuity, and does not preclude embodiments wherein the implant is coupled to the tibia. Likewise, as noted elsewhere herein, there are embodiments where the implant may be coupled to two bones (at least), for example to both a tibia and a femur.

Patch

[0137] Some embodiments of the implant are configured to repair isolated lesions wherein osteochondral defects as in osteonecrosis create craters in the cartilage that need 'filling in' with a patch. Various size lesions of cartilage defects can be accommodated by the implants provided herein which may have balloons of at least one of: at most about 0.5 cm in diameter, at most about 0.75 cm in diameter, at most about 1 cm in diameter, at most about 1.25 cm in diameter, at most about 1.5 cm in diameter, at most about 1.75 cm in diameter, at most about 2 cm in diameter, at most about 2.25 cm in diameter, at most about 2.5 cm in diameter, at most about 2.75 cm in diameter, at most about 3 cm in diameter, at most about 3.25 cm in diameter, at most about 3.5 cm in diameter, at most about 3.75 cm in diameter, at most about 0.5 cm in length along the longest length of the balloon, at most about 0.75 cm in length along the longest length of the balloon, at most about 1 cm in length along the longest length of the balloon, at most about 1.25 cm in length along the longest length of the balloon, at most about 1.5 cm in length along the longest length of the balloon, at most about 1.75 cm in length along the longest length of the balloon, at most about 2 cm in length along the longest length of the balloon, at most about 2.25 cm in length along the longest length of the balloon, at most about 2.5 cm in length along the longest length of the balloon, at most about 2.75 cm in length along the longest length of the balloon, at most about 3 cm in length along the longest length of the balloon, at most about 3.25 cm in length along the longest length of the balloon, at most about 3.5 cm in length along the longest length of the balloon, at most about 3.75 cm in length along the longest length of the balloon, at most about 4 cm in length along the longest length of the balloon, at most about 4.25 cm in diameter, at most about 4.5 cm in diameter, at most about 4.75 cm in diameter, at most about 5 cm in diameter, at most about 5.25 cm in diameter, at most about 5.5 cm in diameter, at most about 5.75 cm in diameter, at most about 6 cm in diameter, at most about 6.25 cm in diameter, at most about 6.5 cm in diameter, at most about 6.75 cm in diameter, at most about 7 cm in diameter, at most about 7.25 cm in diameter, at most about 7.5 cm in diameter, at most about 7.75 cm in diameter, at most about 8 cm in diameter, at most about 3 cm in length along the longest length of the balloon, at most about 3.25 cm in length along the longest length of the balloon, at most about 3.5 cm in length along the longest length of the balloon, at most about 3.75 cm in length along the longest length of

the balloon, at most about 4 cm in length along the longest length of the balloon, at most about 4.25 cm in length along the longest length of the balloon, at most about 4.5 cm in length along the longest length of the balloon, at most about 4.75 cm in length along the longest length of the balloon, at most about 5 cm in length along the longest length of the balloon, at most about 5.25 cm in length along the longest length of the balloon, at most about 5.5 cm in length along the longest length of the balloon, at most about 5.75 cm in length along the longest length of the balloon, at most about 6 cm in length along the longest length of the balloon, 6.25 cm in length along the longest length of the balloon, at most about 6.5 cm in length along the longest length of the balloon, at most about 6.75 cm in length along the longest length of the balloon, at most about 7 cm in length along the longest length of the balloon, at most about 7.25 cm in length along the longest length of the balloon, at most about 7.5 cm in length along the longest length of the balloon, at most about 7.75 cm in length along the longest length of the balloon, and at most about 8 cm in length along the longest length of the balloon. As used herein with respect to balloon dimensions whether length or diameter, the term "about" means variations of at least one of 0.1 cm, 0.2 cm, 0.25 cm, 0.5 cm, and 1 cm.

[0138] Thus, provided herein is an implant configured to patch osteochondral defects. The defects may occur due to injury, stress, naturally occurring, and/or may created or enhanced by a medical professional during a medical procedure. In some embodiments, the implant may be called a patch having the balloon and an attachment element (or elements-which may be called appendages) described herein and may be sized to fit within a defect in a manhole-cover type manner. In some embodiments, the implant may comprise balloon and attachment elements described elsewhere herein and may be configured to lay over a defect (full defect or partial defect). In some embodiments the implant as described herein as used to patch or repair osteochondral defects may be called a patch or a patch implant.

[0139] In some examples, the size of the balloon dimensions are prechosen based on the individual patient need, and the balloon size (dimensions, geometry, length, depth, for non-limiting examples) is pre-set. In some examples, the balloon comprises multiple chambers which may be inflated (or deflated) selectively to fill the defect in situ or just prior to implantation in order to adjust the implant's balloon size (dimensions, length, width, depth, geometry, for non-limiting example) as needed at the time of implantation. The balloon (or any chamber thereof) of some examples can be secondarily inflated or deflated (or both) in situ.

[0140] Figures 11A, 11B, and/or 11C may be used to describe a patch implant described herein, having appendages 4a, 4c, extending from a balloon 6 (not shown in Figure 11A) and including holes 8a-8h, and/or tabs 10a-10f which may be used with couplers (not shown) to couple the implant to a bone of the knee joint (which may be the femur, the tibia, or the patella). Features shown in Figure 11A, 11B, and/or 11C are common to both the unicompartment knee implant (discussed elsewhere herein) and the patch implant, although dimensions may differ as described herein. Thus, Figures 11A, 11B, and/or 11C may be used to describe the unicompartment knee implant and/or the patch implant. Figure 11A depicts an example of the patch implant 2 curved to simulate curvature about one condyle of a femur, the implant 2 having appendages 4a, 4c, extending from an uninflated balloon (not shown) and including tabs 10a-10f and/or holes 8a-8h, which may be used with couplers (not shown, described elsewhere herein) to couple the implant 2 to the femur of the knee joint. Figure 11B depicts an example of the patch implant 2 curved to simulate curvature about one condyle of a femur, the implant 2 having appendages 4a, 4c, extending from an inflated balloon 6 and including tabs 10a-10f and/or holes 8a-8h, which may be used with couplers (not shown, described elsewhere herein) to couple the implant 2 to the femur of the knee joint. Figure 11A and 11B show the appearance of a compliant solid material for unicompartmental implantation. Figure 11C depicts a bottom-up of gliding surface view of an example of the patch implant 2 curved to simulate curvature about one condyle of a femur, the implant 2 having appendages 4a, 4c, extending from an inflated balloon 6 or a padded central area of the implant and including tabs 10a-10f and/or holes 8a-8h, which may be used with couplers (not shown, described elsewhere herein) to couple the implant 2 to the femur of the knee joint. In some examples, the implant is configured to couple to a tibia. In some examples, the implant is configured to couple to a trochlear groove of a femur. In some examples, the implant is configured to couple to only a portion of a condyle of a femur.

[0141] Figures 12A, 12B, and/or 12C may be used to describe a patch implant described herein, having appendages 4a, 4c, extending from a balloon 6 and including holes 8a, 8b, 8c prefabricated into an uninflated area, and/or tabs 10a, 10b. 10c, 10d, 10e, 10f which may be used with couplers (not shown) to couple the implant to a bone of the knee joint (which may be the femur, the tibia, or the patella). Features shown in Figure 12A, 12B, and/or 12C are common to both the unicompartment knee implant (discussed elsewhere herein) and the patch implant, although dimensions may differ as described herein. Thus, Figures 12A, 12B, and/or 12C may be used to describe the unicompartment knee implant and/or the patch implant. Figure 12A depicts a bottom-up view of an example of the implant 2 (unicompartment or patch), the implant having appendages 4a, 4c, extending from a balloon 6 and including holes 8a, 8b, 8c, which may be used with couplers (not shown) to couple the implant 2 to the femur of the knee joint. Figure 12B depicts a bottom-up view of an example of the implant 2 (unicompartment or patch), the implant having appendages 4a, 4c, extending from a balloon 6 and including tabs 10a, 10b and hole 8a which may be used with couplers (not shown)

to couple the implant to the femur of the knee joint. Figure 12C depicts a bottom-up view of an embodiment of the implant 2 (unicompartment or patch), the implant having appendages 4a, 4c, extending from a balloon 6 or padded weight bearing region of the implant and including tabs 10c, 10d, 10e, and 10f and hole 8a which may be used with couplers (not shown) to couple the implant to the femur of the knee joint. In some embodiments, the implant is configured to couple to a tibia. In some embodiments, the implant is configured to couple to a trochlear groove of a femur. In some examples, the implant is configured to couple to only a portion of a condyle of a femur. In some examples the implant is coupled to the patella. In any example the balloon 6 may extend from one surface of the implant as a focal protuberance to fill a defect, space, or to aide in alignment correct, or the balloon may be full thickness as differences in Figures 2 and 3 show respectively. In any example there may be a singular or multiple major balloons, if off a primary surface resembling bubble wrap, and there may be microscopic balloons or vacuoles containing gas, gel, or solid in the material matrix.

[0142] In all descriptions provided herein of the patch implant, the implant may instead be configured to couple to the tibia or to the fibula or the patella. It is the intention and understanding that the implant is suited for this purpose in certain examples with adjustments to account for dimensional differences of these bones. Most descriptions provided herein are directed to embodiments coupling the implant to the femur, however, this is primarily for ease of description and continuity, and does not preclude examples wherein the implant is coupled to the tibia (or other bones). Likewise, as noted elsewhere herein, there are examples where the implant may be coupled to two bones (at least), for example to both a tibia and a femur.

Partial Knee Arthroplasty (Unicompartment)

[0143] In addition to the total knee-type (dual condyle) and patch implants are implants that serve to cover and adjust alignment for either the medial or lateral condyle of the femur with varus or valgus knees requiring added cushioning to recreate the natural six degrees of knee valgus.

[0144] Thus, provided herein is an implant for placement on at least one condyle of the distal femur (a unicompartment implant-- named so due to their coverage of a single condyle of the femur). The implant may be configured to be placed over the lateral condyle. The implant may be configured to be placed over the medial condyle. The implant may be configured to be placed over either the medial condyle or the lateral condyle. Two unicompartment implants may be placed in the same knee, one over the medial condyle, one over the lateral condyle.

[0145] Figures 11A- 12C depict example examples of unicompartment implants. In some examples, the unicompartment implant comprises a balloon that is at least one of: at most about 1.5 cm in diameter, at most about 1.75 cm in diameter, at most about 2 cm in diameter, at most about 2.25 cm in diameter, at most about 2.5 cm in diameter, at most about 2.75 cm in diameter, at most about 3 cm in diameter, at most about 3.25 cm in diameter, at most about 3.5 cm in diameter, at most about 3.75 cm in diameter, at most about 4 cm in diameter, at most about 4.25 cm in diameter, at most about 4.5 cm in diameter, at most about 4.75 cm in diameter, at most about 5 cm in diameter, at most about 5.25 cm in diameter, at most about 5.5 cm in diameter, at most about 5.75 cm in diameter, at most about 6 cm in diameter, at most about 6.25 cm in diameter, at most about 6.5 cm in diameter, at most about 6.75 cm in diameter, at most about 7 cm in diameter, at most about 7.25 cm in diameter, at most about 7.5 cm in diameter, at most about 7.75 cm in diameter, at most about 8 cm in diameter, at most about 3 cm in length along the longest length of the balloon, at most about 3.25 cm in length along the longest length of the balloon, at most about 3.5 cm in length along the longest length of the balloon, at most about 3.75 cm in length along the longest length of the balloon, at most about 4 cm in length along the longest length of the balloon, at most about 4.25 cm in length along the longest length of the balloon, at most about 4.5 cm in length along the longest length of the balloon, at most about 4.75 cm in length along the longest length of the balloon, at most about 5 cm in length along the longest length of the balloon, at most about 5.25 cm in length along the longest length of the balloon, at most about 5.5 cm in length along the longest length of the balloon, at most about 5.75 cm in length along the longest length of the balloon, at most about 6 cm in length along the longest length of the balloon, 6.25 cm in length along the longest length of the balloon, at most about 6.5 cm in length along the longest length of the balloon, at most about 6.75 cm in length along the longest length of the balloon, at most about 7 cm in length along the longest length of the balloon, at most about 7.25 cm in length along the longest length of the balloon, at most about 7.5 cm in length along the longest length of the balloon, at most about 7.75 cm in length along the longest length of the balloon, and at most about 8 cm in length along the longest length of the balloon. As used herein with respect to balloon dimensions whether length or diameter, the term "about" means variations of at least one of 0.1 cm, 0.2 cm, 0.25 cm, 0.5 cm, and 1 cm.

[0146] In some examples, the implant comprises attachment tabs or attachment elements over the anterior and/or posterior and/or medial side, and/or lateral side (and/or some combination thereof) of a condyle. In some examples, the implant comprises attachment tabs or attachment elements in the intercondylar notch. In some examples, the implant comprises attachment tabs or attachment elements superiorly at the distal end of the femur anteriorly.

[0147] The posterior of the knee can be difficult to ac-

cess without disturbing joint components (or in order to minimize such disturbance) such as tendons, ligaments, etc. Thus, in some examples, the implant comprises strings, reigns, lassos, and/or lanyards that may pass from the posterior of the implant via the intercondylar notch anteriorly to join with themselves and/or other coupling devices. In some examples, posterior reigns or suture-like lanyards cinch up the implant from inside the posterior intercondylar notch toward another connection site around the femur. These couplers may be pre-coupled to the implant, and the implant and its couplers may be configured to be pulled (or cinched) from the anterior of the implant once the implant is in its general location relative to the condyle in order to finally position the implant about the eondyle-in particular in order to cinch the implant about the posterior of the condyle. Likewise, in some examples where the implant is pre-molded, the coupler as described are adapted to move the implant to its final position with conformity to the condyle's posterior with minimal disturbance to the joint structures at the joint's posterior (minimal cutting, minimal moving, and or minimal detachment, for non-limiting example). In some embodiments at least a portion of the ligamentary structure of the knee is spared.

[0148] Figure 10A depicts a side view of an example of the knee implant 20 curved about at least one condyle 22 of a femur 24, the implant 20 having appendages 4b, 4d extending from an inflated balloon 6 and showing the inflation medium 46 moved anteriorly toward he patella 40 when the knee joint is slightly flexed. Likewise, Figure 10B depicts a side view of an example of the knee implant 20 curved about at least one condyle 22 of a femur 24, the implant 20 having appendages 4b, 4d extending from an inflated balloon 6 and having couplers 44a, 44b (which may be, for non-limiting example, staples or screws, pins or snaps) coupling the appendages 4b, 4d to the femur 24 and showing the inflation medium 46 moved anteriorly toward the patella 40 when the knee joint is slightly flexed.

[0149] Figures 11A, 11B, and/or 11C may be used to describe a unicompartment implant 2 (or unicompartment knee implant, terms which may be used interchangeably) described herein, having appendages 4a, 4c, extending from a balloon 6 (not shown in Figure 11 A) and including holes 8a-8h, and/or tabs 10a-10f which may be used with couplers (not shown) to couple the implant to a bone of the knee joint (which may be the femur, the tibia, or the patella). Features shown in Figure 11A, 11B, and/or 11C are common to both the unicompartment knee implant and the patch implant (discussed elsewhere herein), although dimensions may differ as described herein. Thus, Figures 11A, 11B, and/or 11C may be used to describe the unicompartment knee implant and/or the patch implant. Figure 11A depicts an example of the unicompartment knee implant 2 curved to simulate curvature about one condyle of a femur, the implant 2 having appendages 4a, 4c, extending from an uninflated balloon (not shown) and including tabs 10a-10f and/or holes 8a-8h, which may be used with couplers (not shown, described elsewhere herein) to couple the implant 2 to the femur of the knee joint. Figure 11B depicts an example of the unicompartment knee implant 2 curved to simulate curvature about one condyle of a femur, the implant having appendages 4a, 4c, extending from an inflated balloon 6 and including tabs 10a-10f and/or holes 8a-8h, which may be used with couplers (not shown, described elsewhere herein) to couple the implant 2 to the femur of the knee joint. Figure 11C depicts a bottom-up view of an example of the unicompartment knee implant 2 curved to simulate curvature about one condyle of a femur, the implant 2 having appendages 4a, 4c, extending from an inflated balloon 6 and including tabs 10a-10f and/or holes 8a-8h, which may be used with couplers (not shown, described elsewhere herein) to couple the implant 2 to the femur of the knee joint.

[0150] In some examples, the unicompartment implant including attachment tabs is at least one of: at most about 15 cm in length along the longest length of the implant, at most about 15.25 cm in length along the longest length of the implant, at most about 15.5 cm in length along the longest length of the implant, at most about 15.75 cm in length along the longest length of the implant, at most about 16 cm in length along the longest length of the implant, at most about 16.25 cm in length along the longest length of the implant, at most about 16.5 cm in length along the longest length of the implant, at most about 16.75 cm in length along the longest length of the implant, at most about 17 cm in length along the longest length of the implant, at most about 17.25 cm in length along the longest length of the implant, at most about 17.5 cm in length along the longest length of the implant, at most about 17.75 cm in length along the longest length of the implant, at most about 18 cm in length along the longest length of the implant, 18.25 cm in length along the longest length of the implant, at most about 18.5 cm in length along the longest length of the implant, at most about 18.75 cm in length along the longest length of the implant, at most about 19 cm in length along the longest length of the implant, at most about 19.25 cm in length along the longest length of the implant, at most about 19.5 cm in length along the longest length of the implant, at most about 19.75 cm in length along the longest length of the implant, at most about 20 cm in length along the longest length of the implant, at most about 20.25 cm in length along the longest length of the implant, at most about 20.5 cm in length along the longest length of the implant, at most about 20.75 cm in length along the longest length of the implant, at most about 21 cm in length along the longest length of the implant, at most about 21.25 cm in length along the longest length of the implant, at most about 21.5 cm in length along the longest length of the implant, at most about 21.75 cm in length along the longest length of the implant, at most about 22 cm in length along the longest length of the implant, at most about 22.25 cm in length along the longest length of the implant, at most about 22.5 cm in length along the longest length of the implant, at most about 22.75 cm in length along

the longest length of the implant, at most about 23 cm in length along the longest length of the implant, 23.25 cm in length along the longest length of the implant, at most about 23.5 cm in length along the longest length of the implant, at most about 23.75 cm in length along the longest length of the implant, at most about 24 cm in length along the longest length of the implant, at most about 24.25 cm in length along the longest length of the implant, at most about 24.5 cm in length along the longest length of the implant, at most about 24.75 cm in length along the longest length of the implant, at most about 25 cm in length along the longest length of the implant, at most about 25.25 cm in length along the longest length of the implant, at most about 25.5 cm in length along the longest length of the implant, at most about 25.75 cm in length along the longest length of the implant, and at most about 26 cm in length along the longest length of the implant. As used herein with respect to implant length dimensions, the term "about" means variations of at least one of 0.1 cm, 0.2 cm, 0.25 cm, 0.5 cm, and 1 cm.

[0151] In some examples, the unicompartment implant is longer than it is wide, and the longer portion of the implant wraps from the anterior of the condyle to the posterior of the condyle. In some embodiments, the length of the implant is longer on the outer edge of the implant than on the inner edge nearest the trochlear groove (whether used on the lateral or medial condyle). In some examples, the trochlear groove per se rather than either the medial or lateral compartment is reconstructed with the implant anatomically to oppose the undersurface of the patella.

[0152] Figures 12A, 12B, and/or 12C may be used to describe a unicompartment knee implant (unicompartment implant) described herein, having appendages 4a, 4c, extending from a balloon 6 and including holes 8a, 8b, 8c, and/or tabs 10a, 10b. 10c, 10d, 10e, 10f which may be used with couplers (not shown) to couple the implant to a bone of the knee joint (which may be the femur, the tibia, or the patella). Features shown in Figure 12A, 12B, and/or 12C are common to both the unicompartment knee implant and the patch implant (discussed elsewhere herein), although dimensions may differ as described herein. Thus, Figures 12A, 12B, and/or 12C may be used to describe the unicompartment knee implant and/or the patch implant. Figure 12A depicts a bottom-up view of an embodiment of the implant 2 (unicompartment or patch), the implant having appendages 4a, 4c, extending from a balloon 6 and including holes 8a, 8b, 8c, which may be used with couplers (not shown) to couple the implant 2 to the femur of the knee joint. Figure 12B depicts a bottom-up view of an example of the implant 2 (unicompartment or patch), the implant having appendages 4a, 4c, extending from a balloon 6 and including tabs 10a, 10b and hole 8a which may be used with couplers (not shown) to couple the implant to the femur of the knee joint. Figure 12C depicts a bottom-up view of an example of the implant 2 (unicompartment or patch), the implant having appendages 4a, 4c, extending from a balloon 6 and including tabs 10c, 10d, 10e, and 10f and hole 8a which may be used with couplers (not shown) to couple the implant to the femur of the knee joint.

[0153] In all descriptions provided herein of the unicompartment implant, the implant may instead be configured to couple to the tibia or to the fibula or the patella. It is the intention and understanding that the implant is suited for this purpose in certain examples with adjustments to account for dimensional differences of the particular bones. Most descriptions provided herein are directed to examples coupling the implant to the femur, however, this is primarily for ease of description and continuity, and does not preclude examples wherein the implant is coupled to the tibia (or other bones). Likewise, as noted elsewhere herein, there are examples where the implant may be coupled to two bones (at least), for example to both a tibia and a femur.

Meniscal Replacement or Repair, and Solid, Rigid, or Semi-Rigid Components:

[0154] Provided herein is an implant having a balloon having a first and second chamber. The implant may be any of the Dual Compartment, Unicompartment, and Patch implants described herein. The second chamber may be configured to replace and/or partially replace fibrocartilage meniscal loss. The implant may have two lobes of chambers which may be alternatively described as two superimposed balloon radii in apposition to each other. The implant may be configured to provide stability between the femur and tibia by providing a meniscus wedge. In some examples the implant comprises a portion configured to replace and/or partially replace fibrocartilage meniscal loss. Such an example may not require a second chamber.

[0155] In some examples a chamber of the implant is configured to receive a solid piece configured to restore joint and/or bone alignment. In some examples, the chamber is configured to receive a plurality of solid pieces, each of which can be used to increase the space between a first bone and a second bone in order to restore and/or improve joint and/or bone alignment. The solid pieces may be wedge-shaped, or be provided in various sizes and/or shapes. The solid pieces may individually or together be used in a chamber or multiple chambers of the implant. The solid piece (or pieces) may be used to ratchet adjacent bones to a desired distraction and/or alignment to restore and/or improve joint and/or bone alignment. The solid piece may be put in a chamber of the implant, which may enclose or partially enclose the piece to hold the piece in place. In some embodiments, a block of biocompatible material (such as PMMA or another bone-like substitute) may be provided and may be formed (by carving or other forming method) by the surgeon to a desired shape. The formed piece may then be put in a chamber of the implant, which may enclose or partially enclose the piece to hold the piece in place.

[0156] In some examples, the inflation medium is a me-

thyl methacrylate or other biocompatible hardening substance which can flow when initially put into the chamber, and hardens to become a rigid piece (or solid piece). The methyl methacrylate or other biocompatible hardening substance may conform to the shape of the chamber, or may conform to the shape of a space between bones and/or other joint structures. The methyl methacrylate or other biocompatible hardening substance may conform to a form chosen by the surgeon using tools and/or pressure to influence the final shape of the rigid piece formed by the methyl methacrylate or other biocompatible hardening substance upon hardening.

[0157] The solid piece (whether formed in situ or by a surgeon or pre-formed) may be cushioned by the implant. The implant may comprise an inflatable chamber between the solid piece and the first bone. In some examples, the first bone is a femur. The implant may comprise an inflatable chamber between the solid piece and the tibia. The implant may comprise an inflatable chamber between the solid piece and the patella. The implant may comprise an inflatable chamber between the solid piece and the second bone. The implant may comprise a pad between the solid piece and the first bone as a cushion. In some examples, the first bone is a femur. The implant may comprise a pad between the solid piece and the second bone as a cushion. In some examples, the second bone is a tibia. In some embodiments, the second bone is a patella.

[0158] The solid piece may provide at least one of about 1 degree of joint correction, about 2 degrees of joint correction, about 3 degrees of joint correction, about 4 degrees of joint correction, about 5 degrees of joint correction, about 6 degrees of joint correction, about 7 degrees of joint correction, about 8 degrees of joint correction, about 9 degrees of joint correction, and about 10 degrees of joint correction. With respect to degrees of joint correction, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%.

[0159] The implant can be used in a variety of joints where the implant replaces a bone on bone surface and cushions the interaction between the articular ends of any two bones, such as at the femoral tibial and patella femoral knee interfaces. The implant can be used in a variety of joints where the implant replaces a bone on bone surface and cushions the interaction between the articular ends of any two bones, such as at the femoral-acetabular interspace of a patient's hip, the humerus and glenoid scapular component in the shoulder, the replacement of talus bone in the human ankle between the tibia and calcaneus and the like. Where the implant is substituting or enhancing articular cartilage, the rigidity can be reduced or enhanced to maximize conformation changes that arise during motion as enabled by the two opposing walls and intended inner space, coupled with considerations in any joint surgical reconstruction with accommodation to or amplification of the existing joint ligaments, tendons or dearth thereof. The implant 10 may be deflated and removed by minimally invasive surgery, for example, after the implant has served its purpose of regenerating tissue or if another clinical condition warrants its removal. However, it may not be clinically necessary to remove the implant even if inflation is lost, since the two remaining functions of patching the injured cartilage, and delivering restorative cells may justify implant retention.

[0160] In many examples the implant (or a portion thereof, such as the balloon or balloon) is a weight bearing spacer that allows joint motions to approach normal, whether filling the space left by an entirely collapsed peripheral joint bone or the space of ablated cartilage proximate surfaces diffusely as in osteoarthritis or succinctly as in osteonecrotic defects or localized trauma. The walls may be used as a membrane for holding living cells in proximity of the osteochondral defect long enough for the cells to attach (e.g. 24 hours) or to deeply adhere (up to 28 days) or return to normal (up to one year). Weight bearing may be expected to increase as distal lower extremity joints are treated.

Additional Locations for Use

[0161] Shoulder subacromical bursa may be a target joint for an implant as described herein. Rotator cuff tears may be addressed using an implant as described herein-as adjusted for the particular features, loading profile, and geometries of the joint. In shoulders, 85% of octagenians have massive rotator cuff tears and often less than half normal upper extremity abduction and flexion capabilities. There may not be sufficient remnant supraspinatus and other rotator cuff tissues to pull together. Then the humeral head rides up, in a cephalad direction, rubbing the superior bone surface on a frequently spurred and downward sloping acromion. If a subacromial implant as described herein were implanted beneath the lateral (arthroscopically decompressed and prepared) acromion, the pain of bone on bone could be reduced, and the structural anatomy between the ball and socket (humeral head and glenoid fossa) could be improved. In essence then a shoulder implant could cover the humeral head analogous to the hip redundant membrane wherein that membrane replaces a normal subacromial bursa. Optionally, a singular bladder beneath the acromion per se could pad the ball beneath it. For virtually every joint in the body (arms and legs, at least) there are similar potential implant uses.

[0162] The distal femur of the knee, and the distal humerus of the elbow are regions that interface each with two opposite joints. That is, an implant for the knee as designed with polymer capping of the femoral condyles and trochlear groove to provide cushioning of the femorotibial and patellafemoral joints. Analogously, in the humerus the distal coverage enables padding restoration of the humeral-olecranon as well as the radio-capitellar (part of the humerus) joint interfaces. Whereas generally the implant may cover the main or primary joint surface of the surgeon's choice contributing to arthritis, consequently reducing symptoms when treated, another alter-

native would be that the implant can cover any singular surface entirely or partially. It is generally desired that the implant may cover one surface allowing remnant cartilages in other usually opposing or opposite surfaces to glide against the implant polymer with smooth gliding joint motion. This principle allows for retained joint linings or synovium to produce lubricating substances including enzymes for facile joint movement. It also avoids the wear debris that would accrue from polymer rubbing on polymer, as recently recognized in metal on metal prostheses. In certain embodiments, the implant can cover more than one surface in a joint, such as the radiocapitallar joint wherein the distal humerus and the radial head receive prosthetic capping or interpositional application of polymers.

[0163] The surgical techniques may be individualized to fit patient need. The implants may be combined with or comprise autologous or allograph tissues such as fascia lata. Surgeons may implant fascia lata above unreconstructable rotator cuff with consequent symptom relief. Polymers can interface with any human tissue and/or with metals or polyethylenes or polyurethanes. Living tissues that can be combined with implants provided herein for repair or reconstruction may be from the same patient (autograph), and cadaver or other member of the same species (allograph) or from another species (xenograph.) Virtually any combination of polymer interpositioning is feasible with the implant concepts provided herein, as anatomy varies among patients in need, and clinical conditions differ with each person. Therefore, although the general or most common construct is expected to cover just one singular and the primary surface of a joint with an implant, any combination of surfaces can be involved allowing versatile custom applications of this implant and method of surgery.

[0164] Additionally, whereas implants as noted herein may be available in specified sizes, the material membrane elastic deformation and resilience may allow for calculated malleability toward goodness of fit. In other iterations the fit of implant over the affected joint surface is customized as paring preoperative findings of MRI or CT or PET imaging pathophysiology with intraoperative reconstructive need. Ultimately best fit implants may serve patient restorative requirement with least morbidity.

[0165] Locations wherein implants described herein may be additionally or alternatively applicable include all the limb joints of mammals. In the shoulder mainly the glenohumeral joint, though as discussed above the subacromial space are useful loci for renewed padding when pathophysiologies warrant. In the AC or acromioclavicular joint of the shoulder, a Mumford procedure (resection of the distal clavicle) can be avoided by inserted an implant as described herein. Even the TMJ in the jaw may be amenable to therapy using the implants noted herein. Proceeding distally in the arm, the elbow has two relevant joints mentioned earlier, radiocapitellar and ulnohumeral. Depending on 'where the arthritis forms' (as from fracture or disease) the padding should be restored toward normal. Wrist, thumb and finger joints are many and may respond to vesicular implants with better durometry and vicsolubricant delivery than tradition metal or silicon prostheses. Legs started at the hip joint have been shown via Hip implant prototypes to be amenable to polymer capping. Variations per surgeon's choice could evoke special uses as for coverage of trochanteric bursae.

[0166] Additionally, the many functions of the implants noted herein may be coupled with cosmetic aspects in order to restore bulk and soft tissue balance after scarring, injury or atrophy, or for purely cosmetic purposes. Treatment for cosmesis especially when coupled with functional or visual injury deficits can provide a reduction in physiological as well as physical pain and discomfort. Therefore the extent minimally invasive implants restore the injured or diseased patient recipient to become hole, they are being used purposefully and as intended.

[0167] The knee joint is an initial focus of the figures wherein application to the largest bone (the distal femur) accommodates padding needs for the opposing patella and tibia. The potential use of implants, however, over the contralateral surfaces is an option that should not be ruled out. In the ankle the supratalar, or tibia talar joint will be a useful location as may the subtalar area, depending on pathology present. Indications for use may depend on the patients symptoms, from the history and physical exam, based on studies such as roentgenograms, MRI or CT imaging, and may depend on test result from localized injections. For example, if a talus fracture pain were alleviated by sinus tarsi injection then implant insertion into the subtalar joint would be preferred. The talonavicular and other foot/toe joints are all amenable to renewed padding via an implant noted herein..

[0168] Pets, or other animals, such as cows, dogs, and horses, may be served better by polymer joint capping than hip replacement for congenital dysplasia. The successful treatment and rehabilitation of animals can favorably affect the implant recipient and animal's owner, as pets can provide functions necessary for activities of daily living (as a horse helping to plow a field) or an animal relieved of pain from injury or arthritis can also be a comfort to its owner.

Kits

[0169] Provided herein are kits comprising multiple implants described herein. A kit may comprise multiple sizes of a single type of implant. A kit may comprise various implant types, such as the patch, the unicompartment, and/or the dual compartment types of implants described herein. A kit may comprise various couplers, which may be selected by the surgeon depending on his comfort and expertise, and/or based on the particular patient anatomy and/or needs. The kit may further comprise any insertion tools and/or surgery tools that may uniquely assist in implanting the implant in the patient.

[0170] In addition to kits involving reparative implants, and insertional tools, there may also be included software for translation of pre-injury data and/or postoperative data collection and analysis, as well as custom implants may be provided.

Implantation Methods

[0171] Implantation of implants provided herein may depend on the size of joint surface intended for reconstruction by use of the implant. This may be based upon the nature and extent of injury, and upon the expectations of the patient and surgeon. In some embodiments, an arthroscope can be inserted in one side of the knee joint through a 0.5 cm wound, while the implant is inserted into the opposite joint line wound from 1 -10 cm in size. The joint may be first inspected and debrided, performing an arthroscopic synovectomy, chondroplasty, and meniscectomy as needed. Additional distraction under general anesthesia with the knee at variable degrees of flex may allow for implant introduction, systematic peripheral attachment, balancing, and inflation, if warranted.

[0172] In some examples, the implant may be selectively inflatable depending on the particular needs of the patient. In some examples, the filler of the interior of the implant may be rigid, semi-rigid, fluid, air, or combinations thereof, as described herein. In some examples, the implant may be used in conjunction with fibrocartilage repair or replacement. In some examples, the implant may be used without fibrocartilage repair or replacement. In some examples, the implant may be used in conjunction with boney osteotomy. In some examples, the implant may be used without boney osteotomy.

[0173] The posterior of the knee can be difficult to access without disturbing joint components (or in order to minimize such disturbance) such as tendons, ligaments, etc. Thus, in some examples, the method comprises providing an implant comprising strings, reigns, lassos, and/or lanyards that may pass from the posterior of the implant via the intercondylar notch anteriorly to join with themselves and/or other coupling devices. In some examples, posterior reigns or suture-like lanyards cinch up the implant from inside the posterior intercondylar notch toward another connection site around the femur. In some examples, the methods comprise conforming the implant posterior to the condyle by pulling the strings (or reigns, or lassos, or lanyards or the like) of the implant. Such couplers (strings, reigns, lassos, lanyards, etc) may comprise suture materials and/or wire materials.

[0174] These couplers (i.e. strings, reigns, lassos, lanyards, etc) may be pre-coupled to the implant, and the implant and its couplers may be configured to be pulled (or cinched) from the anterior of the implant once the implant is in its general location relative to the condyle in order to finally position the implant about the condyle-in particular in order to cinch the implant about the posterior of the condyle. Likewise, in some examples, where the implant is pre-molded, the coupler as described are adapted to move the implant to its final position with conformity to the condyle's posterior with minimal disturbance to the joint structures at the joint's posterior (minimal cutting, minimal moving, and or minimal detachment, for non-limiting example). In some examples at least a portion of the ligamentary structure of the knee is spared.

[0175] In some instances, the implant is inserted arthroscopically through a cannula about 10 mm in diameter with the implant in the deflated construct, and once inside the prepared joint space and secured therein by the skirt or tabs, the implant is distended or inflated with gas, gel, fluid or fluid that becomes a resilient solid to fill the original natural space of about 0.5 cm between the bones of the joint (between at least two bones of the joint). If the implant is not inserted through a cannula, it may be inserted through an open incision from one to forty centimeters in length at the surgeon's discretion. Tensioning may be by the surgeon's sense of proper pressure application aided by a gauged syringe for insertion of viscolubricants such as Synvisc, Hyalgan, Supartz and/or analgesics such as lidocaine gel. The insertion of liquids to the joint per se may be directly, through a cannula to the joint space previously in place for debridement, and or via a cannula or tube that is not part of the original implant assembly. Once the joint is cleaned, the implant is inserted and appropriately fixed to avoid extrusion or dislocation thereof. This may be via attachment of the implant tabs and/or by a combination of tab use plus intended friction created by implant surface coverings (analogous to Velcro) or a draw string at the smaller base of the implant.

[0176] In some examples the attachment tabs are positioned on the implant to both secure the implant to the joint components, and to enable a physician to ensure the implant has a minimum amount of slack that could create wrinkles or loose areas to avoid unnecessary friction and/or wear of the implant of the patient's anatomy. Figures depicted herein show examples of properly situated attachment tabs configured for these dual purposes. In some examples, fewer tabs are needed to achieve these goals.

[0177] In some examples, where slack or voids exist, the balloon under compression may fill such areas. The implant in some examples is configured to allow hyaline and/or cartilage cells to fill any irregularities or craters in the joint components and grow to refurbish natural joint contour. When the implant implantation is combined with, for example, movement of the treated joint in a constant passive motion machine for 12 hrs a day for 6 weeks after surgery implanting the implant, cell growth may create renewed hyaline cartilage, and/or blood/fibrin and scar to create fibrocartilage filler material.

[0178] Each attachment tab insert site may be clinically determined centripitally around the implant during surgery, driving slots or holes sequentially with an osteotome or drill immediately followed by insertion of the triangled tab extension into the bone slots or screw re-

spectively. For example, if the implant were viewed like a clockface the first tab could be tacked/tapped in a 2 o'clock, then 7, 10, 4, 11,5, 12, 6 (wherein # 2, 7, 10, 4 are over the bilateral femurs superior/inferior to collateral ligaments, 11, 12 are superior at the distal anterior femur beneath the upper patella, and 5, 6 are inside the intercondylar notch anterior to cruciates). This can be like putting a saddle on a horse, going around the knee end with a grasper, to tug the polymer toward fit, tapping a slot over the side of the femur with a thin one-half inch osteotome, angling cuts distally, one by one, as if to pull the implant (or saddle) into its angle of repose, seating ideally over the condyles and ridings nicely in the trochlear groove.

[0179] In some examples, the metal clips could be set angled at about 120 degrees, as greater than 90 can favorably distract/hold the implant to tighter fit analogous to a mylar compliant balloon or stretch sock fitting over a protuberance as opposed to a piece of (non-compliant) paper that results is wrinkles and areas of incongruence between the implant and bone end. Reducing dislodgement tendency and snugging the polymer once stretched to best fit may avoid the failure history as illustrated in the Danish Polymer hip cap solid crescent shaped hip resurfacing implants which lacked inflation, surface stability, accommodation, and fixation.

[0180] Inflation may also be specified by clinical need, and modifications in the implant multi-cell (multi-compartment) construction allows for selective inflation with substances ranging from gas to solid, including gels or semi-solids that can as part of material layered integrity either provide calculated hardness (durometer) to overcome and resist limb adjacent bone mal-alignment, and/or to deliver new regenerative tissues for restoration of natural anatomy of time. That is, certain sections of the implant may be electively inflated of left without expansion, to adjust to fit as matching a normal or uninjured contralateral limb for the involved patient.

[0181] Indeed, patient interaction and feedback may be sought so as to bring to orthopedic conceived art and science the individual's own needs and concerns. It is said that for patients who have anterior cruciate injuries, one third require reconstruction for knee joint stabilizer, one third do not-- living with a reduced activity level, and one third deliberate extensively until a choice between the two continuum options is made.

[0182] A goal of embodiments of implants described herein is to maintain remnant living tissue by using minimally invasive technologies, smaller incisions when they serve the patient equally to larger, sacrificing the least normal tissue as possible. Implants described herein assist and improve on current treatment options available by avoiding as much as possible the ablative bone and cartilage resecting, ligament removing total knee arthroplasty and instead to restore the padding lost in injury or disease or surgery.

[0183] Examples from within the techniques include electing to repair rather than reconstruct anterior cruciate ligaments in certain situations, proved warranted and effective at a $p<0.3$ statistical level. Whereas Carticel chondrocyte implantation is useful to enable articular surface regrowth with hyaline, rather than scar/fibrocartilage from picking/drilling, the massive morbidity from periosteal harvesting is unnecessary. This is because it takes only 24 hours for the cartilage cloned chondrocytes to attach to the prepared joint surface, and the polymer membrane (patch implant described herein, for example, or use of chondrocytes on surfaces of the dual compartment implant or the unicompartment implant) over the prepared defect (like a manhole cover) can adeptly substitute for periosteum.

[0184] With these concepts in mind in is the overall intent to do what is necessary to restore function and nothing more in order to spare the patient removal of injured tissues that may recover or regrow, by implementing a common sense approach to limb repair and reconstruction with the implant and methods of use thereof. In animals as horses and dogs, where recovery instructions are even less likely to be followed than with humans, implanting secure restorative implants for joint surface refurbishment may offer renewed function and save lives that would have otherwise been sacrificed.

[0185] Rehabilitation of knee implant treated patients may engage prudent early motion. The amount of weight bearing allowed may be analogous to the procedures written by this primary surgery for Carticel implanted cases, following the principles that excessive amounts and repetitions of stress upon reconstructed areas should be avoided for 6-12 weeks after surgery. However, the knee implant surgeries per se are expected to take less than one hour, involve less than 1 cc blood loss, require wounds less than or equal to 10 cm overall (depending on the embodiment of the implant), and the end result intends to permit early full weight bearing. Zealous sports activities may be restricted until the bone in-growth and cartilage renewal is reasonably expected, between 2 and 12 months after surgery depending upon the amount of joint tissue replaced.

[0186] In some situations, the removal of the implant may be needed, and embodiments of the implants described herein are configured for removal arthroscopically, and with the allowance to perform all regular older routine accepted techniques ranging from joint debridement to drilling, partial or total replacement. In some embodiments the implant is configured for removal and replacement with a replacement implant-either immediately (within a week), or after a period of longer time (for example, after about 6 weeks to 1 year in the case of infection once all foreign bodies are removed and depending upon the surgeon's and/or infectious disease consultant's opinion

[0187] Specific surgical decisions related to size matching, fixation and or concomitant osteotomy warranted reconstruction are left to the primary surgeon and patient in each case.

[0188] The implant is inserted by minimally invasive

surgery, in some embodiments; however, in other embodiments, the implant may not be inserted minimally invasive surgery. In some embodiments, the implant is delivered through an incision that is about 12,7mm (0.5 inches) long. In some embodiments, the implant is delivered through an incision that is about 1 centimeter long. In some embodiments, the implant is delivered through an incision that is at most about 25,4mm (1 inch) long. In some embodiments, the implant is delivered non-arthroscopically through an incision that is at least 1 centimeter long. In some embodiments, the implant is delivered through an incision that is at most about 19,0mm (0.75 inches) long. In some embodiments, the implant is delivered through an incision that is at most about 12,7mm (0.5 inches) long. In some embodiments, the implant is delivered through an incision that is about 8 centimeters long. In some embodiments, the implant is delivered through an incision that is about 9 centimeters long. In some embodiments, the implant is delivered through an incision that is about 10 centimeters long. In some embodiments, the implant is delivered through an incision that is about 11 centimeters long. In some embodiments, the implant is delivered through an incision that is about 12 centimeters long. In some embodiments, the implant is delivered through an incision that is over about 10 centimeters long. In some embodiments, the implant is delivered through an incision that is at up to about 40 centimeters long. In some embodiments, the implant is delivered through multiple incisions. In some embodiments, the implant is delivered non-arthroscopically. In other embodiments, the implant is delivered arthroscopically. With respect to incision length, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%.

[0189] In some embodiments the implant is configured to be delivered to the joint arthroscopically. In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most about 10 millimeters. In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most about 9 millimeters. In some embodiments, the implant is configured to fit within a cannula having a distal end inner diameter of at most about 5 millimeters. With respect to cannula distal end inner diameter, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%.

[0190] In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most about 10 millimeters. In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most about 9 millimeters. In some embodiments, the implant is configured to fold in order to fit within a cannula having a distal end inner diameter of at most about 5 millimeters. With respect to cannula distal end inner diameter, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%.

[0191] In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most about 10 millimeters. In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most about 9 millimeters. In some embodiments, the implant is configured to be delivered to a joint through a cannula having a distal end inner diameter of at most about 5 millimeters. With respect to cannula distal end inner diameter, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%.

[0192] In some examples the implant may be provided as a deflated balloon for insertion into the joint space. In some examples the implant may be provided as folded balloon that may be collapsed like an umbrella for insertion into the joint space. In some examples the implant may be provided as collapsed balloon that is of an irregular folded pattern to minimize its folded (or collapsed) size for insertion into the joint space. In some examples, the implant is configured to blow up (or expand) to take the form of the expanded, distracted, debrided joint.

[0193] In some embodiments, the implant replaces periosteum.

[0194] In some embodiments, the implant is implanted to preserve bone as compared to a typical arthroplasty procedure of the joint. In some embodiments, the implant is implanted to preserve cartilage as compared to a typical arthroplasty procedure of the joint. In some embodiments, the implant is implanted with minimal soft tissue dissection as compared to a typical arthroplasty procedure of the joint. In some embodiments, the implant is implanted without joint dislocation. In some embodiments, once implanted, the joint is adaptable to revision surgery. In some embodiments once implanted, the joint retains at least one of: about 90% of normal joint function, about 95% of normal joint function, about 85% of normal joint function, about 80% of normal joint function, about 75% of normal joint function, about 70% of normal joint function, about 65% of normal joint function, about 60% of normal joint function, about 55% of normal joint function, about 50% of normal joint function, at least 95% of normal joint function, at least 90% of normal joint function, at least 85% of normal joint function, at least 80% of normal joint function, at least 75% of normal joint function, at least 70% of normal joint function, at least 65% of normal joint function, at least 60% of normal joint function, at least 55% of normal joint function, at least 50% of normal joint function, about 50%- about 75% of normal joint function, about 50%- about 70% of normal joint function, about 60- about 70% of normal joint function, about 70%- about 80% of normal joint function, about 70%- about 90% of normal joint function, about 80%- about 95% of normal joint function, about 80%- about 90% of normal joint function, and about 90%- about 95% of normal joint function. As used herein with respect to percentage of normal joint function, the term "about" can be ranges of 1%, 5%, 10%, or 25%. For example, a range of 1% with respect to about 90% of normal joint function covers 89% to 90% of normal joint function.

[0195] In an example of a hip implant, an upper portion

of the implant has a first wall, a second wall and a side wall which define at least in part the interior. A skirt depends from the first wall and secures the first wall to the end of the patient's femur. An upper portion may be configured to engage the corresponding acetabulum of the patient's pelvic bone. The skirt surrounds the head of the patient's femur and secures the implant thereto. In this example, the upper portion of the implant creates overlapping layers, like a redundant membrane, in the side wall between the first and second walls and to accommodate the normal movement of the first or second. This provides greater motion between the femur and the acetabulum and also provides implant stabilization over the head of the femur. This structure also accommodates variation in individual joints that occur from patient to patient.

[0196] In an example, the first wall does not extend across the entire end of the patient's femur. However, the implant may be designed so that first wall may extend over the head of the femur. The second wall and the side wall tend to roll as the femur moves within the acetabulum.

[0197] In some examples, prior to deploying the implant embodying features of the invention, the cartilage lining the joint is prepared by removing hyaline or fibro cartilage flaps or tears, and areas of chondral advanced fissuring are excised or debrided to create precisely defined defects surrounded by stable normal remnant hyaline cartilage with vertical edges in relation to the damaged surface. It is these defects of the cartilage previously normal surface into which new living cells may be injected or otherwise inserted, and allowed to aggregate by the implant interpositional arthroplasty proximate expanded compressive external wall material. Synovitis invading the joint periphery may be vaporized and extracted conventionally or by the use of steam. Areas of greater cartilage damage are removed for subsequent regeneration and the less afflicted areas having stable cracks are treated to seal or weld the cracks. Areas where the tugor or consistency or minimally damaged cartilage can be preserved are intentionally saved rather than destroyed so as to support the normal spacing and gliding opportunity of the more normal joint interface. Thus, normal cartilage is left behind and abnormal cartilage is removed with the implant making up for the deficiencies. With the present invention, it is preferred in some embodiments to avoid joint dislocation so as to preserve natural innervations and vascularity and thus preserving the blood supply.

[0198] Joint preparation is usually performed under a brief general anesthetic of outpatient surgery. A muscle relaxant combined with traction (e.g. 267N (60 pounds force) for a hip implant) may be employed to opens the joint wider to permit improved visualization for joint preparation and implant installation, increasing the space between the remnant cartilage from about 3 up to about 12 mm. Increasing the joint space may be necessary and allows the surgeon to wash out noxious enzymes, to remove invasive synovitis, to remove loose bodies, to prepare osteochondral defects ideally and otherwise prepare the joint for the implant. Partial or complete inflation of the implant may precede release of traction in some embodiments. In some embodiments, regeneration agents or cells are inserted with the implant or as a fluid or 3-D template prior to release of traction and wound closure. It is preferred, in some examples, to perform joint debridement, implant deployment and application of cell regeneration agent, e.g. stem cell application, under the same anesthetic. As described by several companies in the Stem Cell Summit held in New York, New York on February 17, 2009, it is desirable to obtain an aspiration of the patient's bone marrow from the iliac crest after anesthesia sterilely at the beginning of the operation. The intraoperative technologist may "dial in the cells" to regenerate areas of maximum pathophysiology while the surgeon debrides or otherwise prepares the joint and inserts the implant, placing the cells at the best time. Cell implantation may also occur as a secondary or tertiary reconstructive treatment adjunct. An example resilient implant may be deployed within a patient's hip structure comprising the head of the patient's femur and the acetabulum of the patient's pelvic hip bone. The resilient implant embodying features of the invention is disposed within the space between the femur and the acetabulum. The implant is shaped like a half an orange rind or a hemisphere for a hip joint. The implant has a first wall which is secured to the head of the femur by a plurality of depending tabs (or appendages). The tabs may be attached to the femur by a suitable adhesive or mechanically such as by a screw or pin or snap. The second wall the implant engages the acetabulum, but it also may be provided with tabs and the like for securing the second wall the acetabulum.

[0199] The side wall extends between the first and second walls to form an interior which receives filling material through tube (also called a conduit herein, or may be called an inflation port).The implant would also be appropriate for the humeral head in the shoulder or one condyle of the knee or of the humerus, but other shapes may be desired for other joint configurations whether relatively flat as in the thumb base, or more inflated toward a ballooning construct as in the ankle when the talus bone is collapsed.

[0200] In many examples the implant (or a portion thereof), is a weight bearing spacer that allows joint motions to approach normal, whether filling the space left by an entirely collapsed peripheral joint bone or the space of ablated cartilage proximate surfaces diffusely as in osteoarthritis or succinctly as in osteonecrotic defects or localized trauma. The walls may be used as a membrane for holding living cells in proximity of the osteochondral defect long enough for the cells to attach (e.g. motion is believed to be primarily between the spaced walls (or portions) of the implant peripherally secured to joint structures, although some motion may occur between the implant and the joint surfaces (as with current bipolar hip

hemiarthroplasties)). The implant may be provided with a slot extending from the periphery of the implant to a centrally located passage through the implant to accommodate the ligament of the head of the femur for hip implants. Knee implants may have two slots leading to separate passages for receiving the anterior and posterior cruciate ligaments. Implants for other locations may have similar variable structures to accommodate anatomical features. Implant walls should have sufficient inherent flexibility to mold to the existing deformities imposed by either natural ligament, bone, tendon or remaining cartilage deformities of the internal joint space, and thus filled as a cushion. A separate portal or tube (not shown) or the existing conduit (tube or valve), may be used to extract noxious inflammatory enzymes that can be aspirated at appropriate clinical intervals. Viscolubricants can be injected into the interior of the resilient arthroplasty device through existing conduit or through a long needle to aide in distension, expansion, and/or lubrication (with predetermined microporosity).

[0201] The ankle version of the arthroplasty implant comprises a square transverse cross-section that must take into account supratalar ankle dorsi/plantar flexion, subtalar eversion/inversion motions, ligament fixation-needs, and the accommodation to existing bony architecture as implant variables accounting for the ipsilateral joint pathophysiology. The implant has a first wall, a second wall and a side wall which extends between the first and second wall. The exterior of the implant may have a mesh material with a plurality of chords (or appendages) for securing the implant to adjacent bones or to remnant ligaments which are attached to adjacent bones.

[0202] The implant may be inflated with gas and/or liquid to open wider the space between the tibia above and the calcaneus below to accommodate collapse of the talus bone as in the flattening which succeeds talus fracture with avascular necrosis, or it may be filled with a liquid that becomes a resilient solid. The instant center of the implant's rotation will be constantly changing, with the talus implant mainly stable and with the tibia moving over it. Deformation with weight bearing during the average human's 10,000 daily steps or 2 - 4 million annual gait cycles required by the stance and walking of normal activities of daily living, must be balanced between sufficient solidarity of the implant to maintain axial load, avoiding circumferential stress, and shear forces imposed by the tibia distal plafond on the dorsal ankle implant allowing stance and gait of the patient while avoiding implant migration or failure. Further accommodation to lateral forces imposed by the boney medial and lateral malleoli need to be endured through the cyclic load of walking, while collapsing with enough give to absorb shock and to match the shape of surrounding structures of bone and ligament tissue. Whereas the axial load between the distal tibia through the talar implant to the dorsal calcaneus may be loaded during stance and especially while walking on a level plane for supratalar motion, the lateral forces may be loaded particularly with subtalar motion while walking on an uneven plane or with inversion/eversion.

[0203] In some examples, the first inflation medium imparts rigidity in the implant. In some examples, the first inflation medium imparts cushion in the implant. In some examples, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in examples having multiple chambers) filled with such first inflation medium aligns the joint. In some examples, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in examples having multiple chambers) filled with such first inflation medium aligns the bones of the joint. In some examples, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in examples having multiple chambers) filled with such first inflation medium changes the bone alignment. In some examples, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in examples having multiple chambers) filled with such first inflation medium improves joint alignment. In some examples, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in examples having multiple chambers) filled with such first inflation medium restores, at least in part, joint alignment. In some examples, individual chambers of the interior are selectively inflated with a first inflation medium and/or a second inflation medium. In some examples, individual chambers of the interior are selectively inflated with a first inflation medium and/or a second inflation medium in order to reconstruct the joint and/or bones of the joint.

[0204] In some examples, the interior comprises a honeycomb structure. In some examples, the interior comprises a mesh structure. In some examples, the interior comprises a sponge structure.

[0205] The dimensions of the various implant walls may vary depending upon the material properties thereof as well as the needs for a particular joint. The spacing between the first and second wall within the interior can vary from about 0.5 mm to about 5 mm for most joints (except for the implant for an ankle when an entire collapsed bone space is being replaced), preferably about one to five centimeters to fill between the tibia and calcaneus. In the ankle version of the implant, the amount of inflation of the implant per se may be directly proportional to the amount of talus bone collapse between the distal tibia and proximal calcaneus - thus as much as 5 cm implant distension or expansion may be required to be maintained between superior and inferior surfaces of the talus, while as much as 10 cm anterior and posterior expansion may be required for the ankle implant between the posterior soft tissues such including the Achilles tendon and the anterior navicular bone as relates to the talus.

[0206] The method of insertion for the hip joint invention may be a minimally invasive approach, ideally arthroscopically facilitated, as long as the surgical timing and result quality permit smaller incisions. The hip patient may be placed in the lateral decubitus position (lying non-

operative side down on the operating table) with a stabilizing operating table pole and pad apparatus positioned to fix the pelvis. The external stabilizing table and attachments may include a padded metal pole beneath the pubis or pelvic bone from posterior to anterior, along with other external anterior and posterior pelvic stabilizing paddles. The affected leg may be attached beneath the knee with a distracting mechanism that applies about 267N (60 pounds) of distal force to open the hip joint about 1 cm once the patient is under general anesthesia. The hip joint is arthroscopically debrided through at least one anterior 0.5 cm incision and one posterior 0.5 cm incision, to remove from the femoral head acetabular (ball and socket) joint arthritic debris such as synovitis, loose bodies and noxious inflammatory enzymes. In certain cases a larger open incision may be needed. A smoothing or electronic/ultrasonic/steam or other chondroplasty method may be performed to make the remaining cartilage smoother to better accommodate the hip implant, and protuberant osteophytes or lateral bone overgrowths may be arthroscopically removed or if needed by open excision. A lateral hip incision may be required between 2 and 10 centimeters in length to deal with deformities and/or to insert the implant. In cases of major deformities appropriate reconstruction may add to the basic procedure.

[0207] Once the joint is open and cleared, the hip implant may be inserted laterally and fixed via the skirt or tabs or at least one appendage to the adjacent structures including the peripheral femoral head and/or acetabular rim. Preferably, the implant is inserted arthroscopically through a cannula about 10 mm in diameter with the implant in the deflated construct, and once inside the prepared joint space and secured therein by the skirt or tabs, the implant may be distended or inflated with gas, gel, fluid or fluid that becomes a resilient solid to fill the original natural space of about 0.5 cm between the upper acetabulum and lower femoral head, covering as much of the upper hip joint as required as the implant expands to fit the space.

[0208] The method of insertion of the ankle implant generally may be through an anterior surgical ankle approach or tendon separating incision from the distal tibia to the proximal talus (or calcaneus if the talus is absent), removing and reconstructing portions of the superior and inferior ankle extensor retinacula only to the extent required to gain access to the cleared tibiotalar space. Analogous to the hip joint insertional method, the ankle joint may be prepared arthroscopically under general anesthesia, and may benefit from distal distraction as in total ankle joint replacement surgeries with the DePuy Agility technique pinning above and below the ankle joint and then distracting it. The degree of distraction required in all joints to which this invention is applied, including but not limited to those of all appendicular skeletal structures such as the shoulder, elbow, wrist, phalanges, hip, knee, and ankle, may depend both on the nature anatomy and located pathophysiology that must be accommodated on a case by case basis and said distraction may be a combination of body position using gravitational forces and/or superimposed distracting devices. In the ankle, the surgeon may be developing the interval between the extensor hallucis longus and anterior tibial tendons. Injury tissue is removed, and the implant inserted fitting as preplanned. The implant surface may be provided with roughness, e.g. external mesh, to control movement by friction as described above for the hip joint, and/or attached fixation cords or tabs to connect to proximate ligaments or adjacent boney structures may be used at the surgeon's discretion to balance implant location stability and integrity, with the need for functional joint movements.

[0209] Provided herein is a method for restoring a joint comprising: providing an implant configured for deployment between a first bone and at least one second bone of a joint, the implant further comprising a balloon comprising a first portion that is configured to engage the first bone of the joint, a second portion that is configured to engage at least one second bone of the joint, a side portion connecting the first portion and the second portion, in which the side portion facilitates relative motion between the first portion and the second portion, and an interior that is optionally inflatable with a first inflation medium; and coupling a first appendage of the balloon to the first bone of the joint. In the case of a knee device, the first bone may be one of a tibia, a femur and a patella. In the case of a knee device, the second bone may be one of a tibia, a patella and a femur.

[0210] In some examples, at least two of first portion, the second portion, and the side portion are contiguous. In some examples, the first portion comprises a first wall, the second portion comprises a second wall, and the side portion comprises a side wall.

[0211] In some examples the method comprises providing an in-growth patch on at least one of the first portion configured to engage the first bone (e.g. a femur, a tibia, or a patella, in the case of the knee device), the second portion configured to engage the second bone, the side portion, and the appendage. The in-growth patch may be configured to encourage and/or promote tissue in-growth, such as bone in-growth, for non-limiting example. The patch may be as large as the portion itself (whether the first portion the second portion, the side portion, or the appendage) or may be smaller than the portion (such as in the shape of a strip or other shaped patch). The in-growth patch may comprise a surface irregularity or roughness. The in-growth patch may be Velcro-like. In some examples the implant comprises an in-growth patch on the first portion and/or the second portion, from (and in some examples including) a first appendage to a second appendage. In some embodiments, wherein the appendages loosen from attachment from the bone (by design and/or from wear and/or over time), the in-growth patch aids in securing the implant to the bone. In some examples, the in-growth patch comprises beads and/or bead-like elements attached to the implant. Such an in-

growth patch may be configured to simulate trabecular bone space of a normally cancellous latticework. In some examples, the beads are sintered beads of various sizes. In some embodiments, the beads are sintered beads about 400 microns in size. With respect to bead size, the term "about" can mean ranges of 1%, 5%, 10%, 25%, or 50%. In some examples, the first bone and/or the second bone is roughened to acquire a bleeding bone to facilitate in-growth. In some examples, about 0.5 mm of cortical tissue is removed to facilitate in-growth.

[0212] In some examples, the method comprises coupling a second appendage of the balloon to the first bone of the joint. In some examples, the method comprises coupling a second appendage of the balloon to at least one second bone of the joint. In some examples, the method comprises coupling a second appendage of at least one of the first portion, the second portion, and the side portion to at least one of the first bone and at least one second bone of the joint. In some examples, coupling at least one of the first appendage and the second appendage provides ligamentary-like support to the first bone and at least one second bone of the joint. In some examples, coupling at least one of the first appendage and the second appendage provides ligamentary-like support to the joint. In some examples, the first appendage and the second appendage are configured to provide tendon-like support to the first bone and the at least one second bone of the joint. In some examples, the first appendage and the second appendage are configured to provide tendon-like support to the joint.

[0213] In some examples, the method comprises providing an inflation port in communication with the interior of the balloon for inflation of the interior of the balloon with the first inflation medium. In some examples, the method comprises using an inflation port of the implant that is in communication with the interior of the balloon to inflate the interior of the balloon with the first inflation medium. In some examples, the method comprises puncturing the balloon to inflate the interior of the balloon with the first inflation medium. In some examples, the method comprises providing a balloon having self-sealing capability. In some examples, the method comprises providing a balloon having self-sealing capability upon inflation of the interior of the balloon with the first inflation medium. In some examples, the method comprises providing a balloon comprising a seal capable of closing the interior of the balloon.

[0214] In some examples, the method comprises providing a balloon having an interior comprising a plurality of inflatable chambers. In some examples, the interior comprises a plurality of individually inflatable chambers. In some examples, the method comprises inflating a first chamber of the plurality of inflatable chambers with a first inflation medium. In some examples, the first chamber and the inflation medium is selected based on the particular needs of the patient. For non-limiting example, if the patient has bone loss due to an injury, the chamber may be selected at the location of the missing bone, and may be filled with a rigid inflation medium (or one that becomes rigid once in the chamber) in order to replace the missing and/or damaged bone. Alternatively, or in addition, a chamber may be chosen to restore alignment of the joint, and inflated with an appropriate inflation medium to impart both alignment and cushion to the joint. In some examples, the method comprises inflating a second chamber of the plurality of individually inflatable chambers with a second inflation medium.

[0215] In some examples, the balloon is a composite structure. In some examples, the balloon comprises layers of porous and/or non-porous materials, or otherwise contains treatment or cell regeneration agents. In some examples, a first layer of the balloon is a thin, but strong layer of a thermoplastic, such as a thermoplastic polyurethane, for non-limiting example, which has microporosity sufficient to allow passage or egress of treatment or cell regeneration agents from a second layer. The second layer may be a central layer (which lies between the first layer and a third layer or a fourth layer or more layers). The first layer may comprise a bone engaging surface in some embodiments. The degree of microporosity to enable egress of treatment or cell regeneration agents from the second layer is found in polymer layers such as Chronoflex (e.g., ChronoFlexAR®, ChronoFlex AL®, ChronoFlec C®) or BIONATE (e.g., BIONATE I, BIONATE II, BIONATE 55D, BIONATE 65D, BIONATE 75D, BIONATE 80A, BIONATE 90A, BIONATE 55 or BIONATE 80). The bone engaging surface of the implant may be coated and/or impregnated with a latticework of polymer that is surface sprayed or layered on the bone engaging surface of the implant to promote cartilage tissue regeneration. This bone engaging surface coating may contain living chondrocytes (for example, as is provided in the Carticel procedure by the Genzyme company), and/or may contain stem cells with directed gene mutations to enhance adherence of the coating to the implant. The bone engaging surface may comprise peaks and troughs. The living cells may be provided in troughs while the surface peaks may be used for at least one of: space validation, traction, and cell protection.

[0216] In some examples, the first inflation medium imparts rigidity in the implant. In some examples, the first inflation medium imparts cushion in the implant. In some examples, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in examples having multiple chambers) filled with such first inflation medium aligns the joint. In some examples, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in embodiments having multiple chambers) filled with such first inflation medium aligns the bones of the joint. In some examples, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in examples having multiple chambers) filled with such first inflation medium changes the bone alignment. In some examples, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in examples hav-

ing multiple chambers) filled with such first inflation medium improves joint alignment. In some examples, the inflation medium chosen for the first inflation medium, and/or the particular choice of chamber (in examples having multiple chambers) filled with such first inflation medium restores, at least in part, joint alignment. In some examples, individual chambers of the interior are selectively inflated with a first inflation medium and/or a second inflation medium. In some examples, individual chambers of the interior are selectively inflated with a first inflation medium and/or a second inflation medium in order to reconstruct the joint and/or in order to reconstruct bones of the joint.

[0217] Over time, in-growth of repair tissue aids in fixation and stability externally to the implant, while the soft cushioning implant interior may absorb forces across the joint surfaces and permit proper motion. The turgor or wall tension of the implant as well as the inside distension of the implant per se can be adjusted by adding or removing the inflation substance to the implant's interior space.

[0218] Accordingly, the present invention provides a new approach to arthroplasty that involves a resilient implant deployed between bones of the knee joint. In some instances, a joint is comprised of the interface between (a) a first bone and a first cartilage; and (b) a second bone and a second cartilage, wherein the first cartilage is separated from the second cartilage by a space (e.g., joint space) and the cushion expands to fit the joint space. In some instances, where the first cartilage and/or second cartilage is damaged or absent, the cushion expands to fit the joint space between the first bone and second cartilage or the first bone and second bone. In certain joint spaces such as the knee, the cushion expands to fit the spaces of the "knee joint" or "knee joints". For example, the cushion may expand to fit the spaces of the femoral tibial involved on standing or walking on a level plane, and the cushion may expand to fit the spaces of the patella femoral bones of the knee more involved on stair ascent and descent. For example, pressures behind the knee cap or patella when lying are zero, when standing are 0.7 times body weight, and when going up and down the patella femoral pressures are 3 - 4 times body weight. Thus, in some instances, the implants accommodate some or all of the normal body functional pressures and complex space movements, as described above, and can also be used in other joints such as the elbow, ankle, or hip. When in the hip joint, the normal flexion up to 120 degrees, extension of 20 degrees, abduction of 50 degrees, internal and external rotation of 45 degrees may produce variable axial, shear, and cyclic loads which the implant by design may accommodate and endure as up to 6 times body weight, consistent with a tire on a car that allows for cyclic loads different when driving straight or turning corners. The implant embodying features of the present invention provides more physiologic motion and shock absorption within the joint and has combined characteristics of anatomic design symmetry, balanced rigidity with sufficient attachment connections to adjacent normal structures, and durability that meet the needs of joint reconstruction.

[0219] The opposing internal surfaces of the first and second walls of the invention may either move together in synchrony or in opposite directions from one another (e.g. the superior wall moving medially in the hip and the inferior wall moving laterally). Optionally, the implant may be fixed to a concave surface of the joint (e.g., the acetabular hip cup) or to a convex surface of the joint (e.g. the dorsal femoral head surface), to both, or to neither (e.g., having an interference fit within the joint with an expanding balloon or cushion that fills the existing space). The implant may be inserted arthroscopically like a deflated balloon and then inflated through a cannula into the ankle or hip (or other joint structure) to act as a cushion or renewed interface for painless and stable limb motion. When feasible, joint capsular and adjacent ligament tissue as well as bone may be left in place to preserve the natural body, unless interfering with reconstructed limb function.

[0220] The application of steam in addition to removing damaged debris, can smooth out and reform the joint surface. The high temperature of the steam tends to weld cracks or fissures which can be present in the cartilage surface of a damaged joint. Smoothing of joint surface cartilage with steam welds or seals existing cracks or flaps in the cartilage, especially superficially as the lamina splendors, which melt together to provide a white shiny gliding joint surface. In cases where bone is exposed, the steam can be used to stabilize the periphery of the defect in the joint surface via capsulorrhaphy or joint tightening. Open mechanical and chemical debridement may also be employed to prepare the surfaces for the implant.

[0221] Once the implant is secured to the femur by means of the skirt or tabs or using other couplers, an impregnated transfer medium or cell template may be used, as described by Histogenics and Tygenix chondrocytes delivery systems wherein the position of concentrated cells is mechanically placed about the implant at areas of greatest cartilage damage to promote regrowth, or as in Carticel wherein watery cells are implanted beneath a periosteal membrane (a wall of the implant serving as the membrane), prior to completion of the inflation or expansion of the implant. A syringe or gauged device with measured screw-home pressure is used to inflate the implant.

[0222] Once the joint is ready to receive the implant, the deflated implant is advanced through the diaphragm of a delivery cannula (such as the Acufex from Smith & Nephew) or through the open incision site into the joint. It can be inflated by the attached cannula using a common syringe, inserting several cc's of filler material. Inserted contents and locations of cell placements depend on areas of need and joint size. In some embodiments of the methods several cc's of filler material and a viscol-ubricant in the interior of the implant allows distension,

cushioning, and gliding movements. Cell regeneration agents are placed in the areas of greatest need.

[0223] Methods of living cell (e.g., stem cell, differentiated cell, pluripotent cell, post-mitotic cell) or chondrocyte placement depend on the lesions and specific implant construct. Direct infusion into the joint with completion of implant inflation may press the cells into the hyaline surface, whereupon they attach within the first 24 hours. As a result, the patient may be forced to remain sedentary and the joint where the implant is deployed, non-weight bearing for the first day after surgery. Deeper osteochondral defects can be treated by 'hyper-perfusion of cells' via either 3-D cell transfer templates, or microneedle injection as used in treatment of diabetic patients for blood sugar testing and insulin/transdermal drug delivery. In cases of osteochondritis dissecans or localized both cartilage and bone lose, bone graft may be packed into the base of the defect followed by addition of a cell/tissue application. The cannula attached to the implant may be sealed and detached, or left in place for periodic aspiration of noxious enzymes as for the Cox-1, Cox-2, and 5-Lox systems, followed by reinsertion of activated substances including viscolubricants, or even more cells (e.g., stem cells, differentiated cells, pluripotent cells, post-mitotic cells).

[0224] Implants embodying features of the invention may be designed for permanent or temporary deployment within a joint structure. Moreover, the implant may be formed of suitable bioabsorbable materials so that the implant may be absorbed within a particular predetermined time frame. Suitable bioabsorbable materials include polylactic acid, polyglycolic acid, polycaprolactone, copolymers, blends and variants thereof. One present method of forming the implant is to apply numerous layers of polymer such as ChronoFlex (e.g., ChronoFlexAR®, ChronoFlex AL®, ChronoFlec C®), ChronoPrene™, ChronoSil®, ChronoThane P™, ChronoThane T™, HydroMed™, HydroThane™, or PolyBlend™ in a solvent and evaporating the solvent after applying each layer.

[0225] The coupling aspects (couplers) including but not limited to skirting or fixation tabs of the present implant prevent joint migration during use.

[0226] In some embodiments, the implant is adapted to restore natural joint function. In some embodiments, the implant is adapted to preserve viable joint tissue. In some embodiments, the implant is adapted to be placed with minimal surgery as compared to joint replacement therapy currently marketed. In some embodiments, the implant is adapted to permit weight bearing post surgery within at least one of: about 1 week, within about 1 day, within about 2 days, within about 3 days, within about 4 days, within about 5 days, within about 6 days, within about 10 days, within about 2 weeks, within about 3 weeks, within about 4 weeks, within about 5 weeks, within about 6 weeks. In some embodiments, the implant is adapted to permit weight bearing post surgery after about 1 day wherein full weight bearing is allowed in about 6 weeks. As used herein with respect to weight bearing timing, the term "about" can be a range of 1 day, 2 days, or 3 days, in some embodiments. In some embodiments, the implant is adapted to allow for faster recovery and resumption of normal activities as compared to joint replacement therapy currently marketed.

[0227] In some examples the balloon (or a portion thereof) is adapted to conform to the patient's anatomy. In some examples, the implant (or a portion thereof) is adapted to conform to the patient's anatomy. In some examples, the inflation medium is adapted to absorb a force (or forces) exerted on the joint. In some examples, the inflation medium is adapted to absorb a force (or forces) exerted on the bones of the joint. In some examples, the inflation medium is adapted to absorb a force (or forces) exerted on at least one bone of the joint. In some examples, the balloon is adapted to absorb shocks exerted on at least one of a bone, multiple bones, a ligament of the joint, ligaments of the joint, a tendon of the joint, tendons of the joint, and the joint in general. In some examples, the implant is adapted to restore natural cartilage cushion with cells (e.g., stem cells, differentiated cells, pluripotent cells, post-mitotic cells). In some examples, the implant is adapted to restore natural cartilage cushion with stem cells.

[0228] In some examples, the balloon (or a portion thereof) is adapted to renew joint space. In some examples, the balloon (or a portion thereof) is adapted to reduce pain as compared to the pain felt prior to the implantation of the implant. In some examples, the balloon (or a portion thereof) is adapted to restore joint function. In some examples, the implant (or a portion thereof) is adapted to renew joint space. In some examples, the implant (or a portion thereof) is adapted to reduce pain as compared to the pain felt prior to the implantation of the implant. In some examples, the implant (or a portion thereof) is adapted to restore joint function.

[0229] In some embodiments, the implant is adapted to reverse arthritis in the joint. In some embodiments, the implant is adapted to prevent, reduce, or ameliorate arthritis in the joint. In some embodiments, the implant is adapted to reduce pain associated with arthritis in the joint.

[0230] In some examples, the balloon (or a portion thereof) is adapted to be placed into a debrided limb joint arthroscopically. In some examples, the balloon is adapted to pad cartilage defects. In some examples, the balloon is inflated to cushion the joint. In some examples the implant is adapted to deliver stem cells to at least one of the joint and a bone of the joint. In some examples the implant is adapted to deliver living chondrocytes to at least one of the joint and a bone of the joint. In some examples, the implant is adapted to deliver cells to at least one of the joint and a bone of the joint. In some examples, the cells are at least one of stem cells, differentiated cells, pluripotent cells, and post-mitotic cells. In some examples, the implant is adapted to provide a new articular surface for the joint. In some examples, the implant is adapted to act as a spacer in the joint. In some

examples, the implant is adapted to space the bones of the joint apart for proper joint articulation. In some examples, the implant is adapted to space the bones of the joint apart for reduced bone-on-bone rubbing.

[0231] In some examples, the implant is configured to at least one of: pad cartilage, cushion the joint, deliver a pharmacologic substance, remove noxious enzymes, debride upon implantation, debride the joint following implantation, deliver a therapeutic substance, deliver a biologic substance, and deliver living stem cells. In some examples, the implant is configured to deliver a chemotherapeutic agent to a bone or other surrounding tissues. In some examples, the implant is configured to deliver an anti-infectious medication to a bone or other surrounding tissues. In some examples, the implant is configured to deliver at least one of an antibiotic antifungals, and analgesics agent.

[0232] In some examples, the implant is configured to be selectively inflated to realign limbs.

[0233] Provided herein is a method comprising: implanting a knee implant as described herein into a subject, wherein the implant reverses arthritis in the subject. Provided herein is a method comprising: implanting a knee implant as described herein into a subject, wherein the implant prevents, reduces, or ameliorates arthritis in the subject. Provided herein is a method comprising: implanting a knee implant as described herein into a subject, wherein the implant reduces pain associated with arthritis in the subject.

[0234] Provided herein is a method comprising: implanting a knee implant as described herein into a knee joint of a subject and treating a component of the knee joint of the subject with at least one of an allograph tissue, an autograph tissue, and an xenograph tissue. In some examples, the tissue comprises a cell. In some examples, the tissue comprises a plurality of cells. In some examples, the cell is a stem cell, differentiated cell, pluripotent cell, or post-mitotic cell. In some examples, the implanting step is at least one of: prior to the treating step, simultaneous with the treating step, and following the treating step.

[0235] Provided herein is a method comprising: implanting a knee implant as described herein into a subject, wherein the implant is configured to at least one of: restore joint function and control arthopathies. In some examples, the implanting spares existing anatomy.

[0236] Provided herein is a method comprising: debriding a femur condyle of a knee joint of a subject, and implanting a knee implant as described herein into the knee joint of the subject, whereby the implant is configured to anneal to the cartilage of the subject. In some examples the debriding is achieved by steam application.

[0237] Provided herein is a method comprising implanting a knee implant as described herein into a joint previously treated with a joint replacement. In some examples, the method comprises removing the joint replacement prior to implanting the knee implant. In some examples, the method comprises clearing infectious matter from the joint and/or surrounding tissues. In some examples, the method comprises implanting a second implant of any implant described herein following removing the implant previously implanted in the joint. In some examples, the method comprises replacing the joint of the subject following removing the implant previously implanted in the joint. In some examples, the method comprises debriding the bone of the joint, and implanting an implant of any implant described herein. In some examples, the method comprises repeating the debriding and implanting steps.

[0238] The surgical techniques may be individualized to fit patient need. The implants may be combined with or comprise autologous or allograph tissues such as fascia lata. Surgeons may implant fascia lata above unreconstructable rotator cuff with consequent symptom relief. Polymers can interface with any human tissue and/or with metals or polyethylenes or polyurethanes. Living tissues that can be combined with implants provided herein for repair or reconstruction may be from the same patient (autograph), and cadaver or other member of the same species (allograph) or from another species (xenograph.) Virtually any combination of polymer interpositioning is feasible with the implant concepts provided herein, as anatomy varies among patients in need, and clinical conditions differ with each person. Therefore, although the general or most common construct is expected to cover just one singular and the primary surface of a joint with an implant, any combination of surfaces can be involved allowing versatile custom applications of this implant and method of surgery.

[0239] Additionally, whereas implants may be available in specified sizes, the material membrane elastic deformation and resilience may allow for calculated malleability toward goodness of fit. In other iterations the fit of implant over the affected joint surface can be customized as paring preoperative findings of MRI or CT or PET imaging pathophysiology with intraoperative reconstructive need. Ultimately best fit implants may serve patient restorative requirement with least morbidity.

[0240] The implants may be implanted typically during an outpatient surgery, wherein the joint is first arthroscopically debrided and cartilage prepared, similar to the methods used in a Carticel procedure. Cartilage or osteochondral size defects and alignment problems are studied, and measurements taken. Considerations to materials stretch are acknowledged as polyurethanes gain 50% pliability with 100 hours exposure to serum, and 30% additional malleability by heating to 37 degrees C. Thus, implant presentation in the OR may aim for best fit and accommodate patient need.

[0241] Intraoperative hyaline cartilage biopsy acquiring e.g. 400 mg of normal hyaline articular tissue from the intercondylar notch (as would be wasted with notchplasty) or from the joint periphery (outside articulating regions) may allow for chondrocytes autologous acquisition. Currently such specimens may be sent to Genzyme Corp. for 2-4 weeks cloning of cells whereupon 2-3

bottles containing e.g. 1 cc of cells, 93% viability, 12 million cells per bottle, are delivered on an exact day to the operating room for placement in the Carticel cartilage regenerative procedure securing the liquid cells beneath a harvested periosteal membrane. In implant surgery contemplated in certain embodiments, the polymer may substitute for the periosteum thus reducing surgical morbidity markedly and changing an otherwise major open procedure into an arthroscopically facilitated outpatient treatment option through a small arthrotomy.

[0242] With outpatient surgeries the intraoperative biopsy may be given to the technician in the operating room in early surgery, for insertion into the stem cells generation machine. In 30-40 minutes living autologous chondrocytes may be 'spun down' and separated, then returning the living cells to the primary surgeon. By this time, the implant has been pulled up over the prepared defects and sufficient fixation sites have been locked into place so that the implant is secure in its general location over the distal femoral surface, for example. An unattached portion of the implant is lifted, the newly procured cells inserted potentially on a soft matrix to hold cells inside the prepared defect, and the implantation is completed sealing the living cells for the purpose of articular surface regeneration. After 24 hours the cells are fixed as the aggregate to the surface of the defect into which they were introduced. This begins a one year period of regrowth of the new joint surface. Concurrently the arthritis osteochondral defect so treated is padded by the implant, and the joint cushioned is mechanically restored. Said cushioning is by nano and/or macro inflation and/or by use of polymers with variable compliance. Immediate fixation and the opportunity for a regenerated joint are thus accomplished in the operating room. This may use either the implant matched to size by preoperative planning via X-rays considering the magnification factors, by using one of the other scanning methods available, or by custom generation ultimately of implant partial or entire coverage options in the same surgery.

[0243] Once the implant is secured circumferentially and solidly in place with multiple fixation sites verified as patent, one or two forms of orthobiologic activity proceed. Specifically, if chondrocytes were implanted (autologous or potentially allograph) they may mature and in the course of a year the durometry may come to resemble normal hyaline articular cartilage. The other biologic activity promoted during implantation surgery is the bone in-growth onto the tab undersurface and/or periphery. This fixation at the secondary level in proposed to decrease the probability of loosening of the prosthetic implant, one of the two most common causes of implant failure. With the normal 10,000 steps people take per day during normal gait, or 2-4 million cycles per annum, the compressive and shear forces, and cyclic loads can cause micromotion between the implant and natural underlying tissue. This may lead to implant shift, dislocation, and/or hardware backing out if not appropriately secured to the bones. In the implant technique the immediate fixation is achieved through multiple robust circumferential fixation of implant tabs to bone. Each screw and washer secures the mechanically adequate implant tab to bone at over 1334N (300 pounds force) to failure. Since, depending on the example, there may be ten (10) tab sites intended the sum of 3,3kN (3000 pounds) In some example, fixation comprises bone in-growth. In some examples, fixation comprises bone in-growth as described in Vasanji A, In vivo bone growth assessment in preclinical studies and clinical trials, Bonezone, 2012, p. 12-17.

[0244] The methods of surgery may have certain constants and other variables mandated by materials and fixation management versus altering anatomies and joint forces. In each joint a standardized implant method of surgery may be recommended with variations to be determined by the responsible surgeon.

[0245] While particular forms of the invention have been illustrated and described herein, it will be apparent that various modifications and improvements can be made to the invention. One alternative implant construction involves the use of an upper portion of the implant having a net-like construction and filled with balls or ball bearing like elements that are larger than the openings in the netting. The balls or ball bearing like elements provide motion to the implant. The netting and ball bearing like elements may include regeneration agents as previously discussed, and the bearing construction may be directed toward favorable implant movement balanced with content disbursement.

[0246] The invention is intended primarily for human use but may be extended to mammalian use. Examples of mammals include, but are not limited to, cats, dogs, sheep, horses, pigs, goats, cows, mice, and rats. To the extent not otherwise disclosed herein, materials and structure may be of conventional design.

[0247] Moreover, individual features of embodiments of the invention may be shown in some drawings and not in others, but those skilled in the art will recognize that individual features of one embodiment of the invention can be utilized in another embodiment. Moreover, individual features of one embodiment may be combined with any or all the features of another embodiment. Accordingly, it is not intended that the invention be limited to the specific embodiments illustrated. It is therefore intended that this invention be defined by the scope of the appended claims as broadly as the prior art will permit.

[0248] Terms such as "element", "member", "component", "device", "means", "portion", "section", "steps" and words of similar import when used herein shall not be construed as invoking the provisions of 35 U.S.C §112(6) unless the following claims expressly use the terms "means for" or "step for" followed by a particular function without reference to a specific structure or a specific action.

[0249] While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous varia-

tions, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention.

Claims

1. An implant (20) configured for deployment between a femur and a tibia of a knee joint, the implant comprising

   a first surface that is configured to engage a medial condyle and a lateral condyle of the femur of the knee joint,
   a second surface that is configured to engage the tibia of the knee joint,
   a first appendage (4c) configured to couple the first surface to a first condyle of the femur of the knee joint,
   a second appendage (4d) configured to couple the first surface to a second condyle of the femur of the knee joint, and
   a slot between the first appendage and the second appendage, wherein the first appendage and the second appendage cushion the femur and tibia,

   characterized by the first surface, second surface, first appendage (4c) and second appendage (4d) together consisting of a single polymer sheet having essentially no separation between the first surface and the second surface.

2. The implant of claim 1, comprising at least one attachment element in the intercondylar notch.

3. The implant of claim 1, comprising at least one attachment element configured to couple with the distal end of the femur anteriorly.

4. The implant of claim 1, comprising at least one posterior reign configured to cinch up the implant from inside a posterior intercondylar notch toward a connection site around the femur.

5. The implant of claim 1, comprising at least one suture-like lanyard configured to cinch up the implant from inside a posterior intercondylar notch toward a connection site around the femur.

6. The implant of claim 1, comprising an in-growth matrix on at least a portion of the implant adjacent the femur.

7. The implant of claim 6, wherein the in-growth matrix comprises living chondrocytes.

8. The implant of claim 7, wherein the implant comprises a bioabsorbable polymer configured to release the chondrocytes over time.

9. The implant of claim 1, comprising a pharmacologic agent on a surface of the implant adjacent the femur.

10. The implant of claim 1, wherein the implant comprises vacuoles of pharmacologic substances.

Patentansprüche

1. Implantat (20), das für den Einsatz zwischen dem Femur und der Tibia eines Kniegelenks konfiguriert ist, wobei das Implantat Folgendes umfasst:

   eine erste Oberfläche, die konfiguriert ist, um einen medialen Condylus und einen lateralen Condylus des Femurs des Kniegelenks zu erfassen,
   eine zweite Oberfläche, die konfiguriert ist, um die Tibia des Kniegelenks zu erfassen,
   ein erster Fortsatz (4c), der konfiguriert ist, um die erste Oberfläche mit einem ersten Condylus des Femurs des Kniegelenks zu verbinden,
   ein zweiter Fortsatz (4d), der konfiguriert ist, um die erste Oberfläche mit einem zweiten Condylus des Femurs des Kniegelenks zu verbinden, und
   eine Aussparung zwischen dem ersten Fortsatz und dem zweiten Fortsatz, wobei der erste Fortsatz und der zweite Fortsatz das Femur und die Tibia polstern,
   dadurch gekennzeichnet, dass die erste Oberfläche, die zweite Oberfläche, der erste Fortsatz (4c) und der zweite Fortsatz (4d) zusammen aus einer einzigen Kunststoffplatte bestehen, die im Wesentlichen keine Trennung zwischen der ersten Oberfläche und der zweiten Oberfläche aufweist.

2. Implantat nach Anspruch 1, umfassend mindestens ein Befestigungselement in der Fossa intercondylaris.

3. Implantat nach Anspruch 1, umfassend mindestens ein Befestigungselement, das konfiguriert ist, um sich vorderhalb mit dem distalen Ende des Femurs zu verbinden.

4. Implantat nach Anspruch 1, umfassend mindestens einen hinteren Kupplungsstrang, der konfiguriert ist, um das Implantat aus dem Inneren einer hinteren Fossa intercondylaris hin zu einer Verbindungsseite um das Femur zu verengen.

5. Implantat nach Anspruch 1, umfassend mindestens ein nahtartiges Band, um das Implantat aus dem Inneren einer hinteren Fossa intercondylaris hin zu einer Verbindungsseite um das Femur zu verengen.

6. Implantat nach Anspruch 1, umfassend eine Einwachsmatrix in mindestens einem Abschnitt des Implantats, der am Femur angrenzt.

7. Implantat nach Anspruch 6, wobei die Einwachsmatrix lebende Knorpelzellen umfasst.

8. Implantat nach Anspruch 7, wobei das Implantat ein bioabsorbierbares Polymer umfasst, das konfiguriert ist, um die Knorpelzellen im Laufe der Zeit freizusetzen.

9. Implantat nach Anspruch 1, umfassend einen pharmakologischen Wirkstoff auf einer Oberfläche des Implantats, die an das Femur angrenzt.

10. Implantat nach Anspruch 1, wobei das Implantat Vakuolen mit pharmakologischen Substanzen umfasst.

Revendications

1. Implant (20) configuré pour se déployer entre le fémur et le tibia d'une articulation du genou, l'implant comprenant
une première surface qui est configurée pour s'engager dans un condyle médial et un condyle latéral du fémur de l'articulation du genou,
une deuxième surface qui est configurée pour s'engager dans le tibia de l'articulation du genou,
un premier appendice (4c) configuré pour accoupler la première surface à un premier condyle du fémur de l'articulation du genou,
un deuxième appendice (4d) configuré pour accoupler la première surface à un deuxième condyle du fémur de l'articulation du genou, et
une fente entre le premier appendice et le deuxième appendice, où le premier appendice et le deuxième appendice amortissent le fémur et le tibia,
caractérisé en ce que la première surface, la deuxième surface, le premier appendice (4c) et le deuxième appendice (4d) sont constitués ensemble d'une seule feuille de polymère pratiquement sans séparation entre la première surface et la deuxième surface.

2. Implant selon la revendication 1, comprenant au moins un élément d'attache dans l'encoche intercondylaire.

3. Implant selon la revendication 1, comprenant au moins un élément accessoire configuré pour s'accoupler avec l'extrémité distale du fémur au niveau antérieur.

4. Implant selon la revendication 1, comprenant au moins une rêne postérieure configurée pour remonter l'implant depuis l'intérieur d'une encoche intercondylaire postérieure vers un site de raccordement autour du fémur.

5. Implant selon la revendication 1, comprenant au moins une lanière de type suture configurée pour remonter l'implant depuis l'intérieur d'une encoche intercondylaire postérieure vers un site de raccordement autour du fémur.

6. Implant selon la revendication 1, comprenant une matrice de croissance sur au moins une partie de l'implant adjacent au fémur.

7. Implant selon la revendication 6, où la matrice de croissance comprend des chondrocytes vivants.

8. Implant selon la revendication 7, où l'implant est composé d'un polymère bioabsorbable configuré pour libérer les chondrocytes au fil du temps.

9. Implant selon la revendication 1, comprenant un agent pharmacologique sur au moins une partie de l'implant adjacent au fémur.

10. Implant selon la revendication 1, où l'implant est composé de vacuoles de substances pharmacologiques.

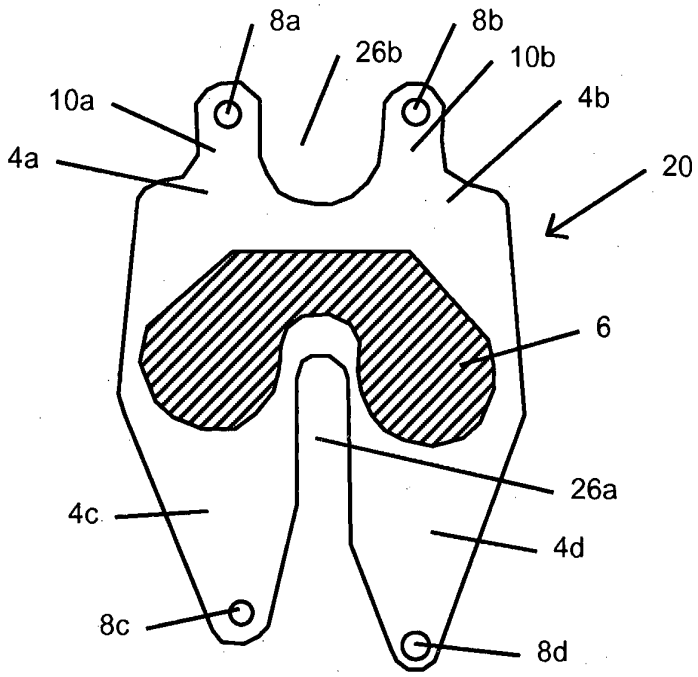
8a
26b
8b
10b
10a
4b
4a
20
6
26a
4c
4d
8c
8d

FIG. 1

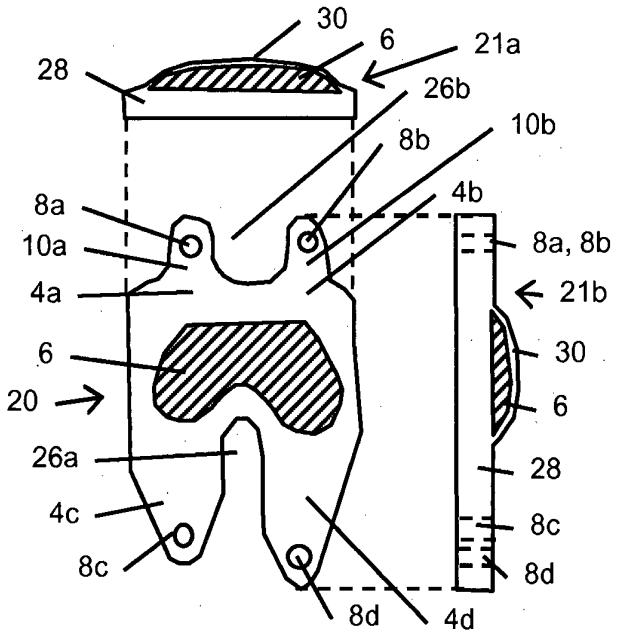
30
6
21a
28
26b
10b
8b
4b
8a
10a
8a, 8b
4a
21b
6
30
20
6
26a
28
4c
8c
8c
8d
8d
4d

FIG. 2

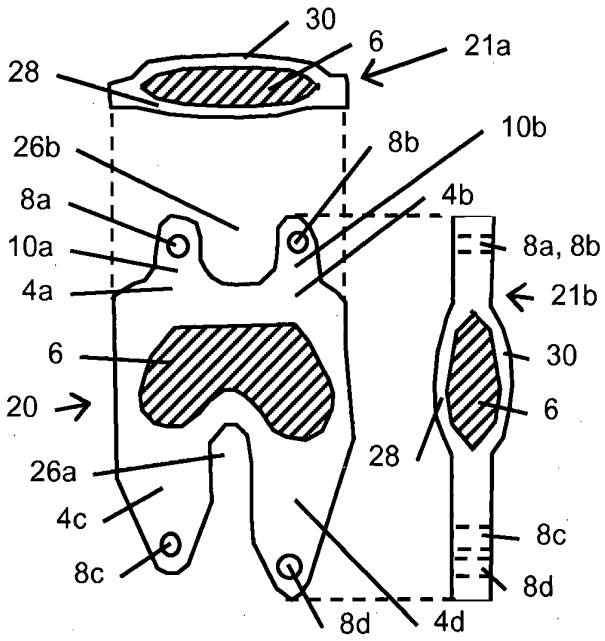
30
6
21a
28
26b
8b
10b
8a
4b
10a
8a, 8b
4a
21b
6
30
20
6
28
26a
4c
8c
8c
8d
8d
4d

FIG. 3

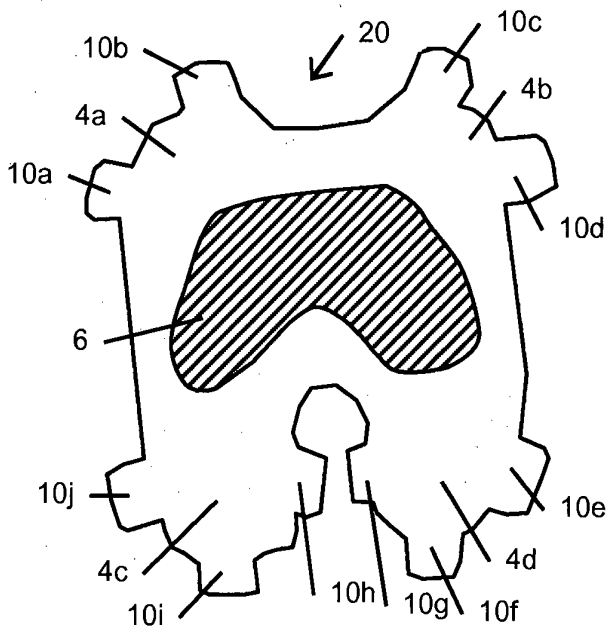
20
10c
10b
4b
4a
10a
10d
6
10j
10e
4c
4d
10h
10g
10f
10i

FIG 4A

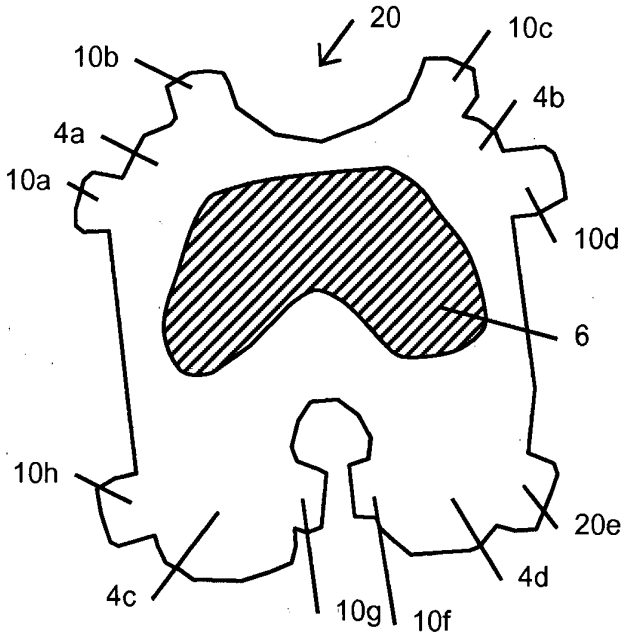
20
10b
10c
4b
4a
10a
10d
6
10h
20e
4c
10g
10f
4d

FIG 4B

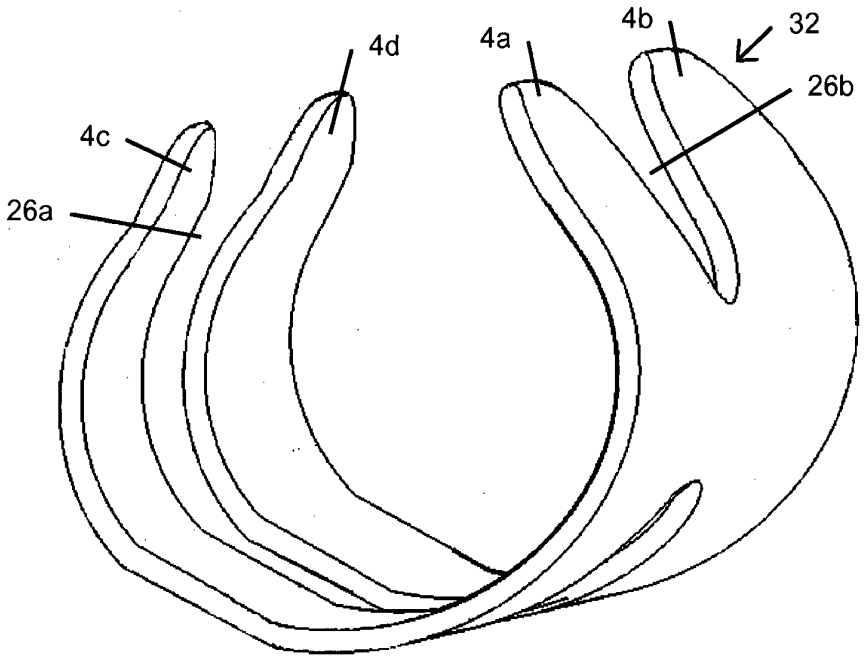
4d
4a
4b
32
26b
4c
26a

FIG 5

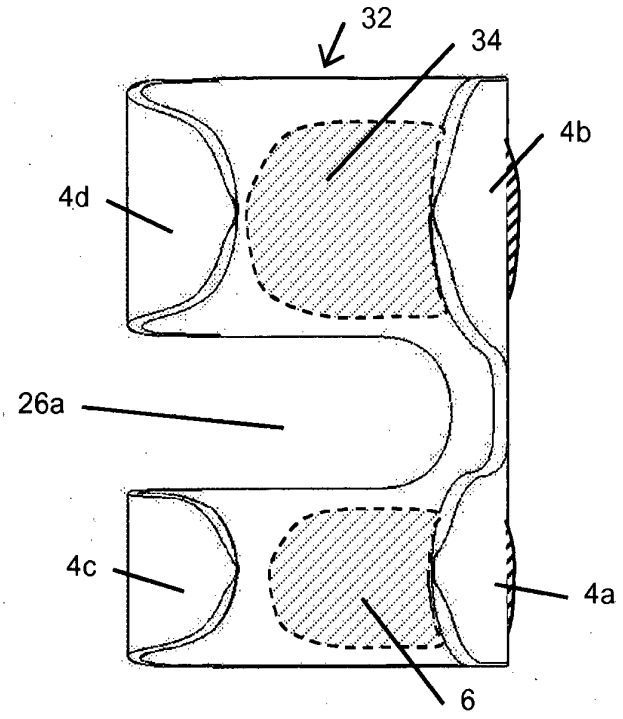

FIG. 6A

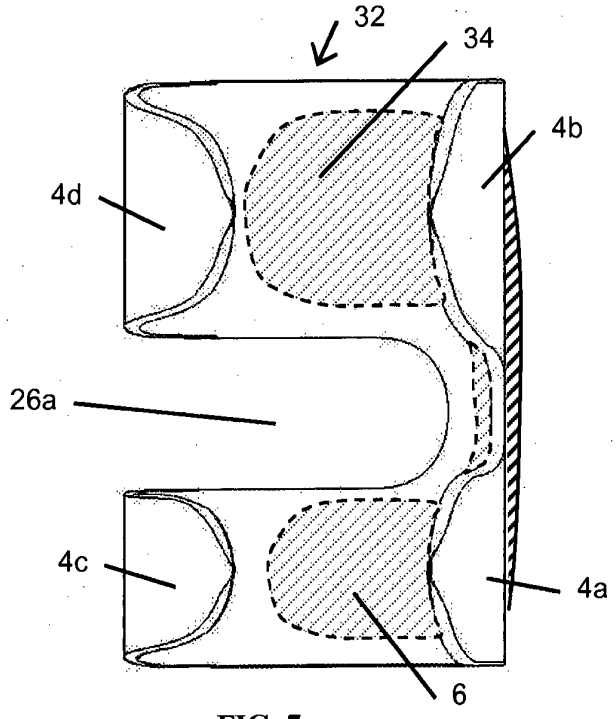

FIG. 7

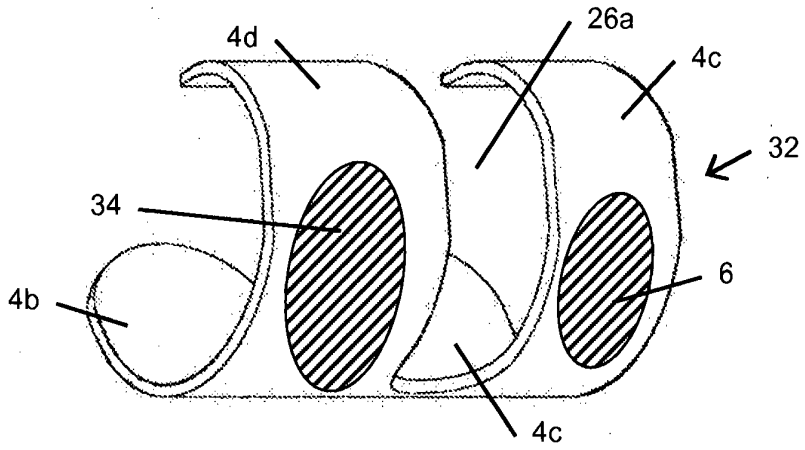

FIG 6B

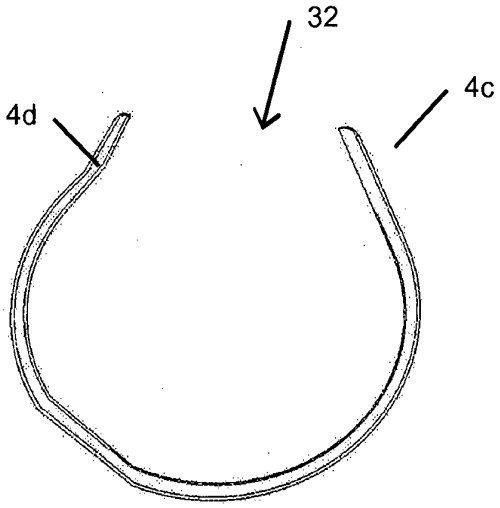

FIG 8

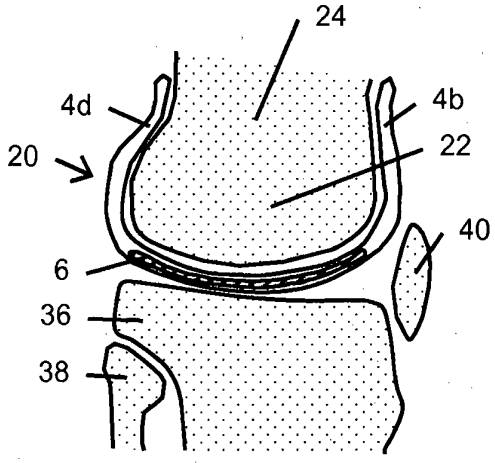

FIG 9A

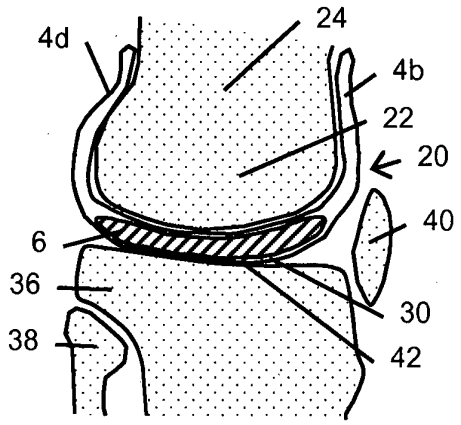

FIG 9B

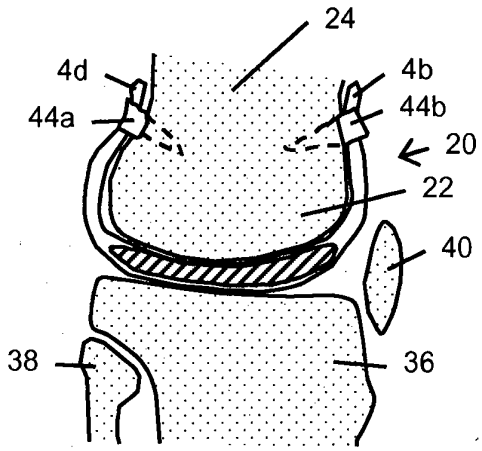

FIG 9C

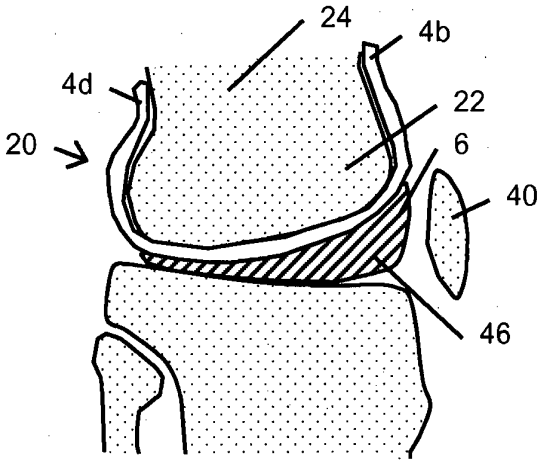

FIG 10A

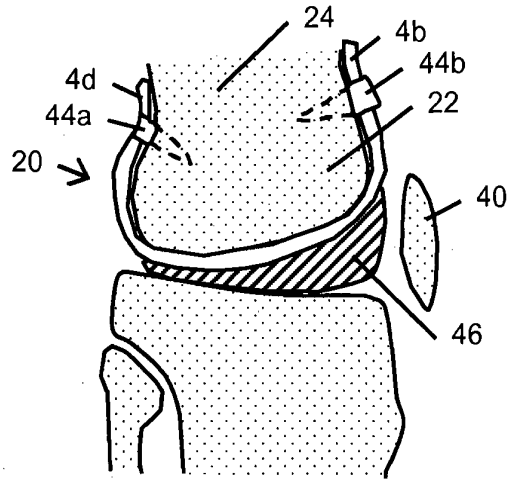

FIG 10B

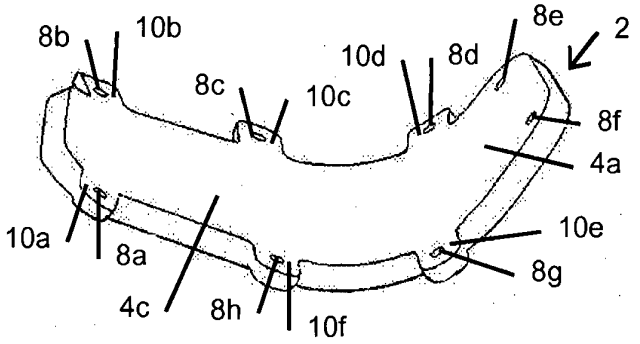

FIG 11A

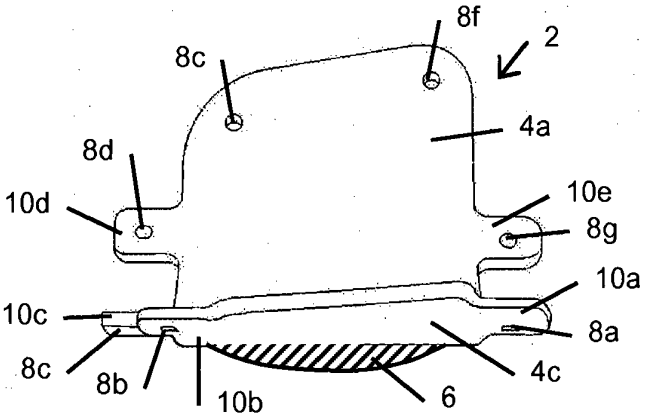

FIG 11B

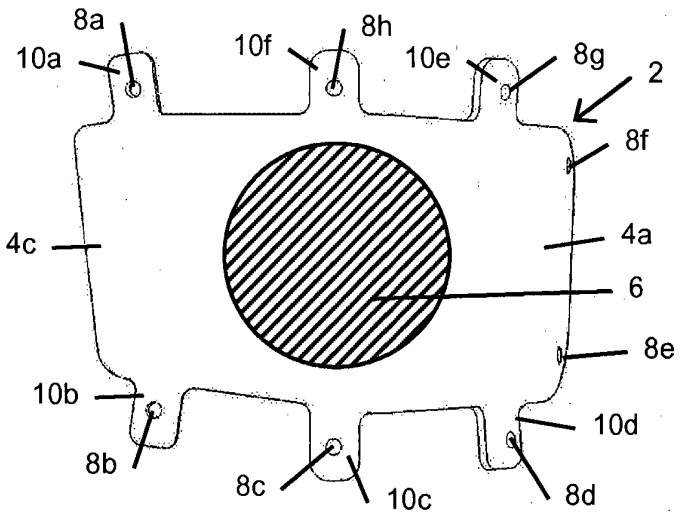

FIG 11C

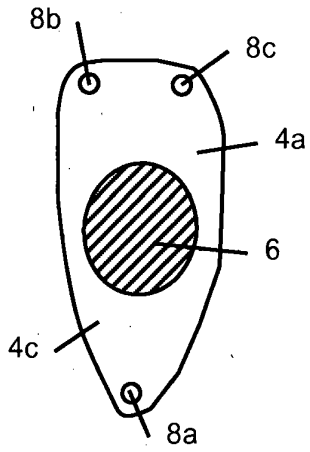

FIG 12A

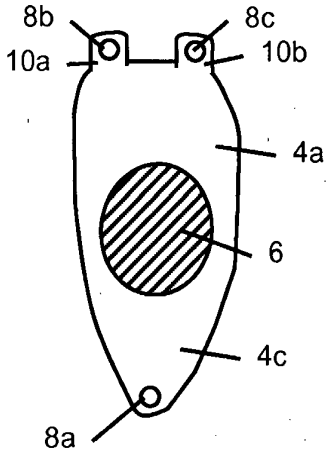

FIG 12B

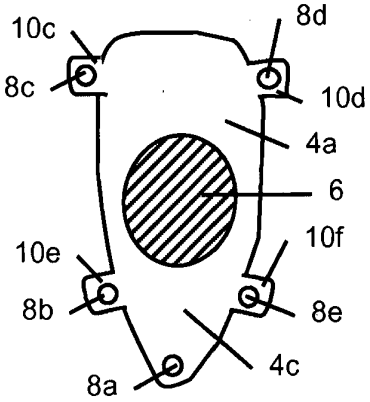

FIG 12C

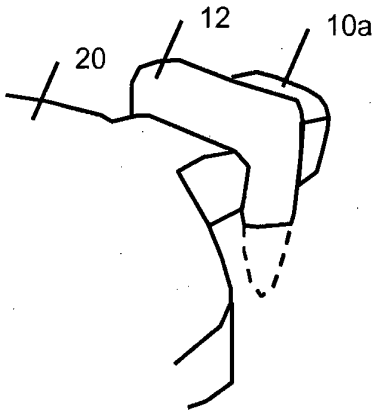

FIG 13A

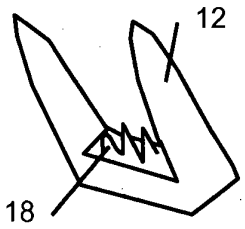

FIG 13B

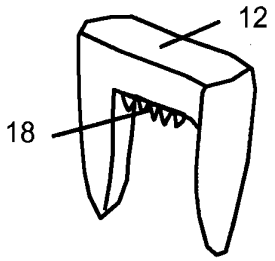

FIG 13C

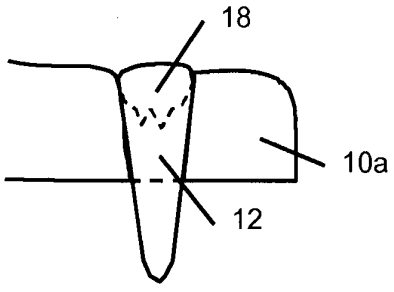

FIG 13D

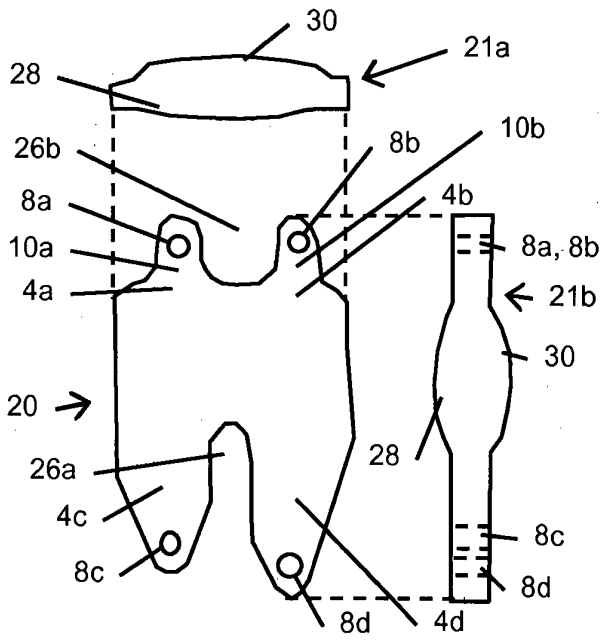

FIG 14

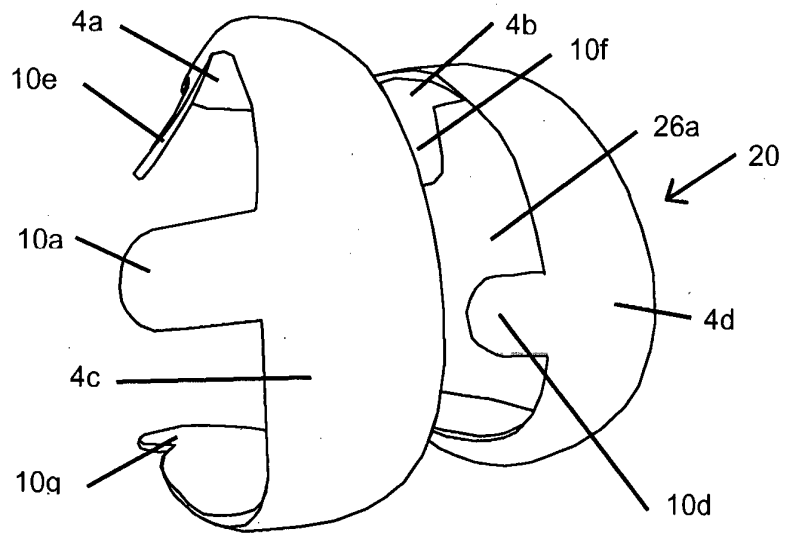

FIG 15A

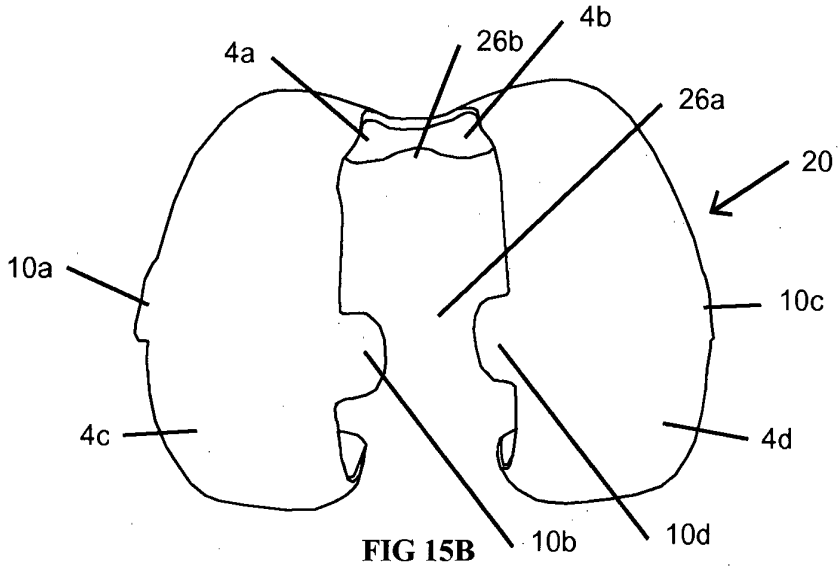

FIG 15B

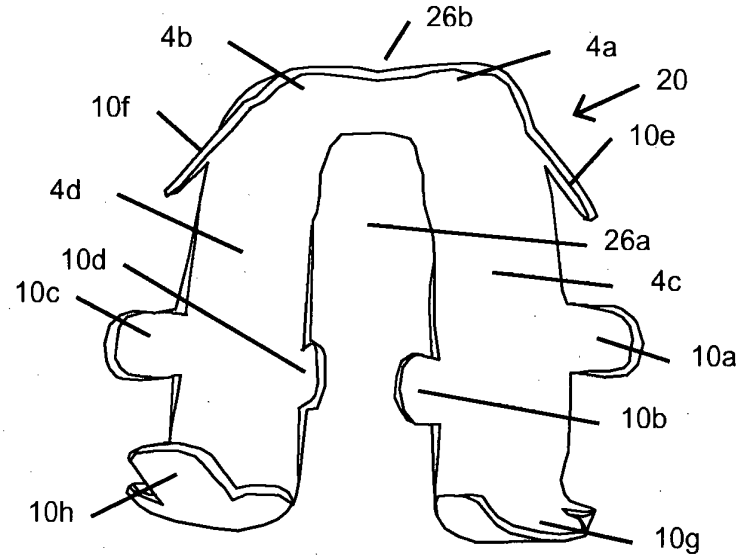

FIG 15C

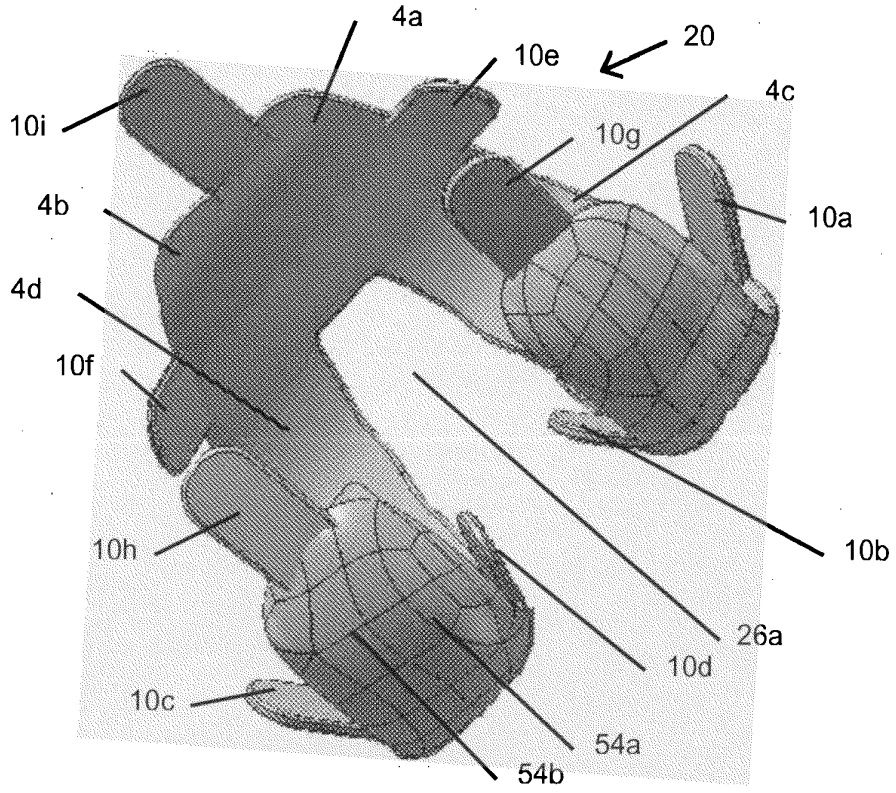

FIG. 16

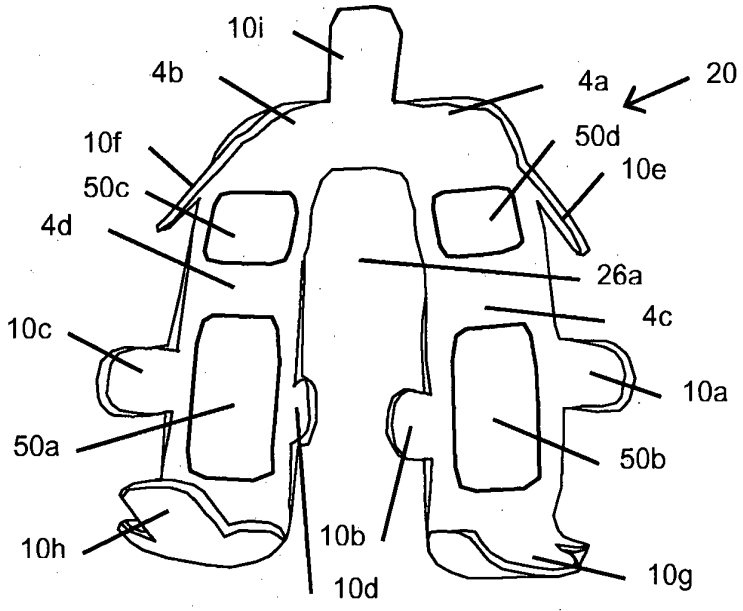
10i
4b
4a
20
10f
50d
50c
10e
4d
26a
4c
10c
10a
50a
50b
10h
10b
10d
10g

FIG 17

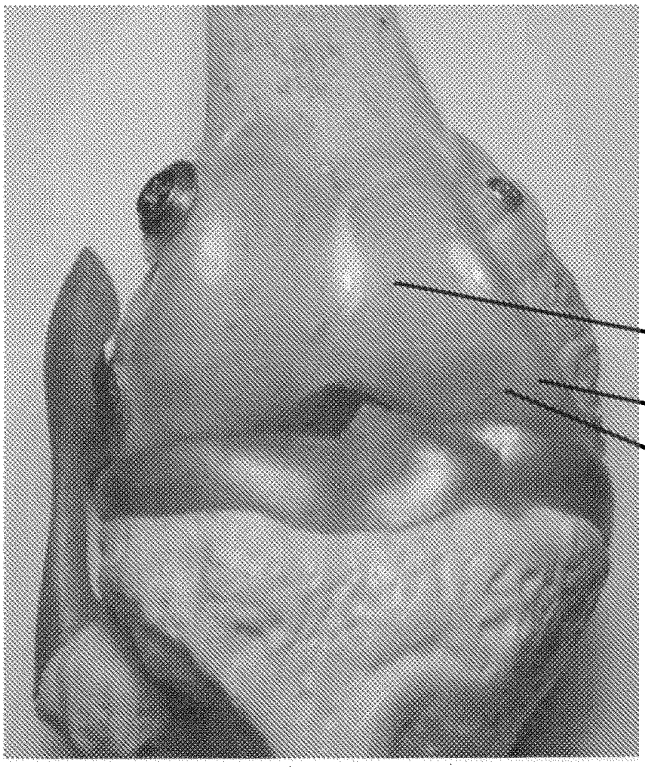
20
52a
52b
52c

FIG 18

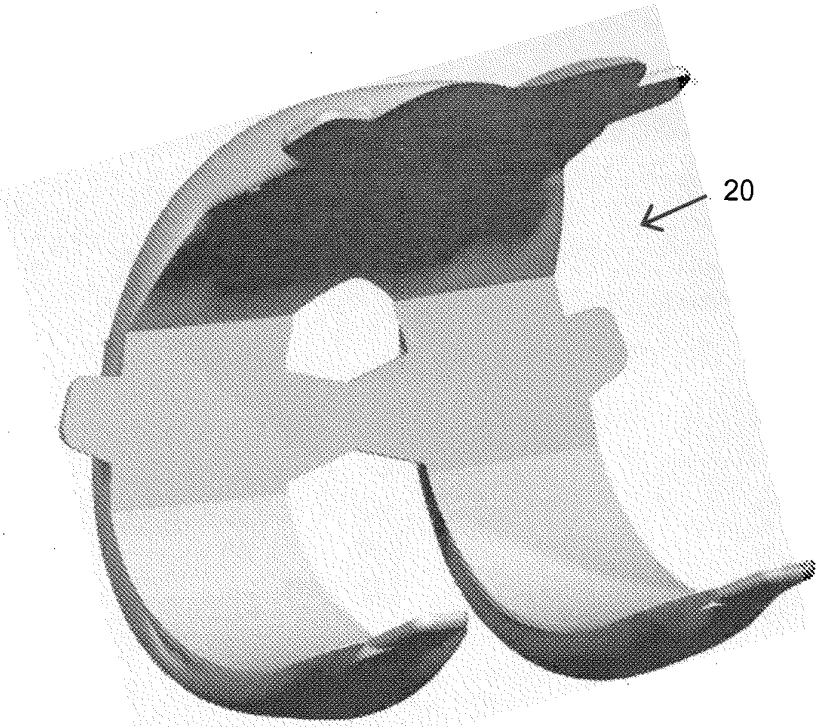

FIG 19

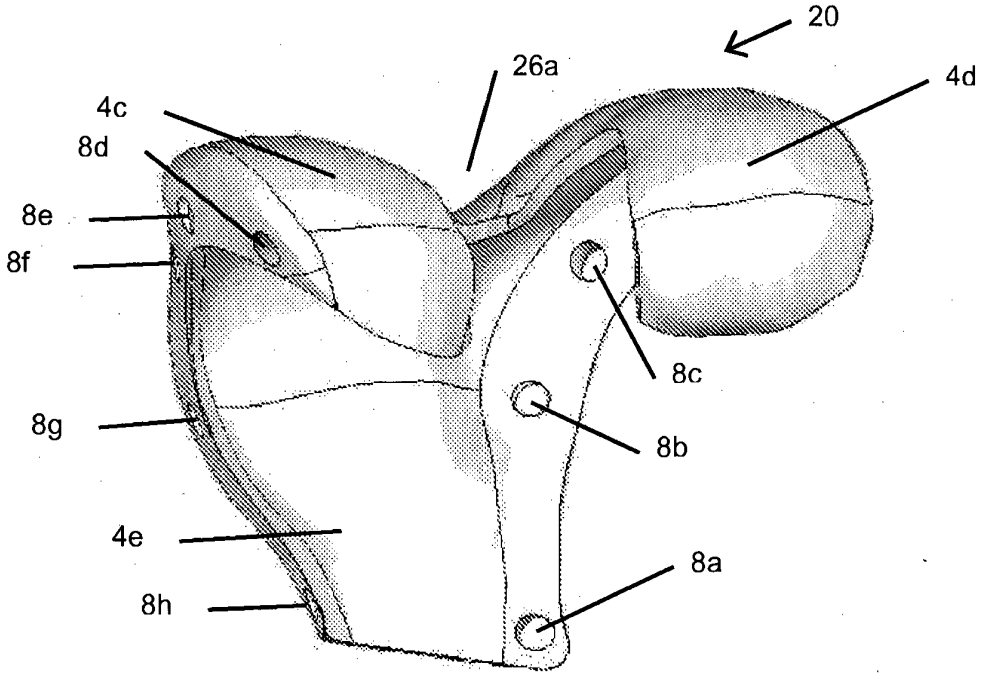

FIG 20A

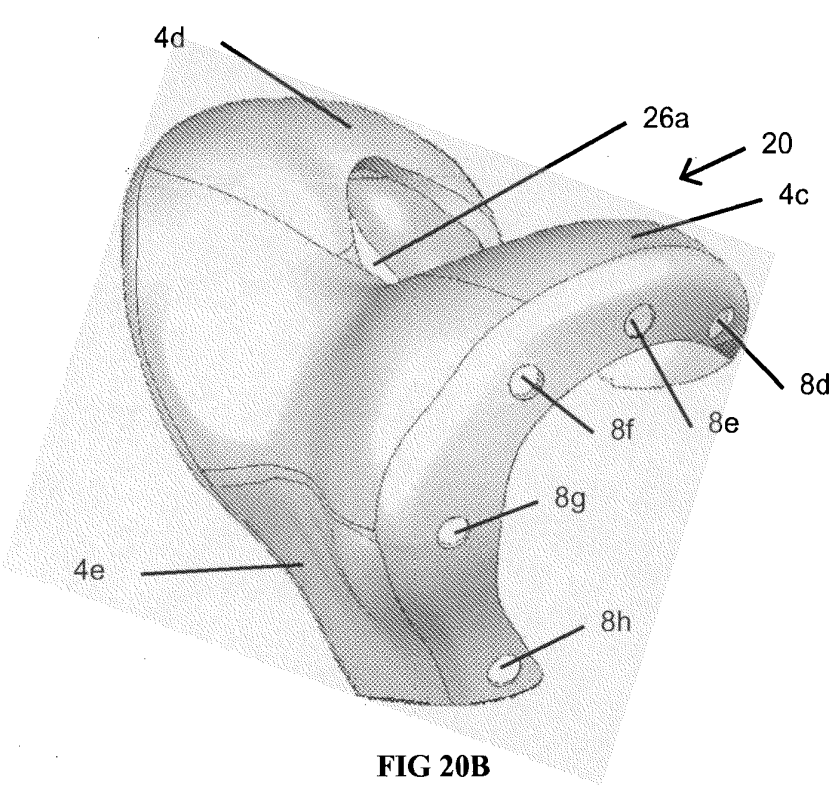

FIG 20B

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

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- *the Stem Cell Summit held in New York, New York,* 17 February 2009 **[0198]**

US005782865A

United States Patent [19]

Grotz

[11] Patent Number: 5,782,865

[45] Date of Patent: Jul. 21, 1998

[54] **STABILIZER FOR HUMAN JOINTS**

[76] Inventor: **Robert Thomas Grotz**, 1001 Valleja St., San Francisco, Calif. 94133

[21] Appl. No.: **712,635**

[22] Filed: **Aug. 21, 1996**

Related U.S. Application Data

[60] Provisional application No. 60/

[51] **Int. Cl.**[6] **A61B 17/04**

[52] **U.S. Cl.** **606/232**; 606/72; 606/104

[58] **Field of Search** 606/232, 66, 67, 606/68, 72, 73, 76, 77, 104

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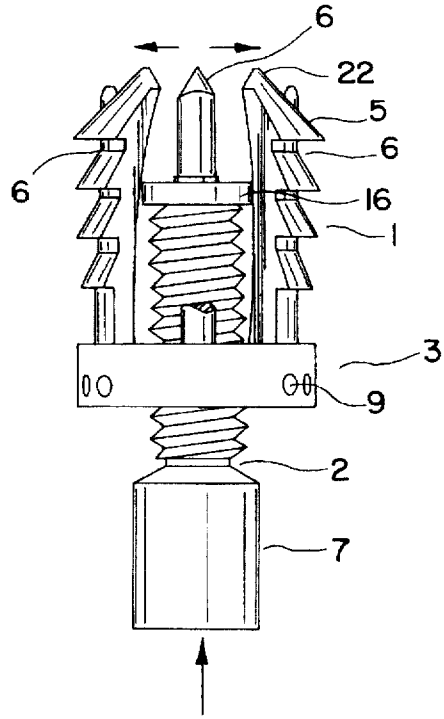
Primary Examiner—Gary Jackson

Attorney, Agent, or Firm—Townsend and Townsend and Crew LLP

[57] **ABSTRACT**

This invention pertains to a medical device for securing bodily tissues to bone, and more particularly to a triangular shaped joint stabilizer comprising sharpened, toothed bone anchors that are forcibly spread into the bone by a central plug.

20 Claims, 2 Drawing Sheets



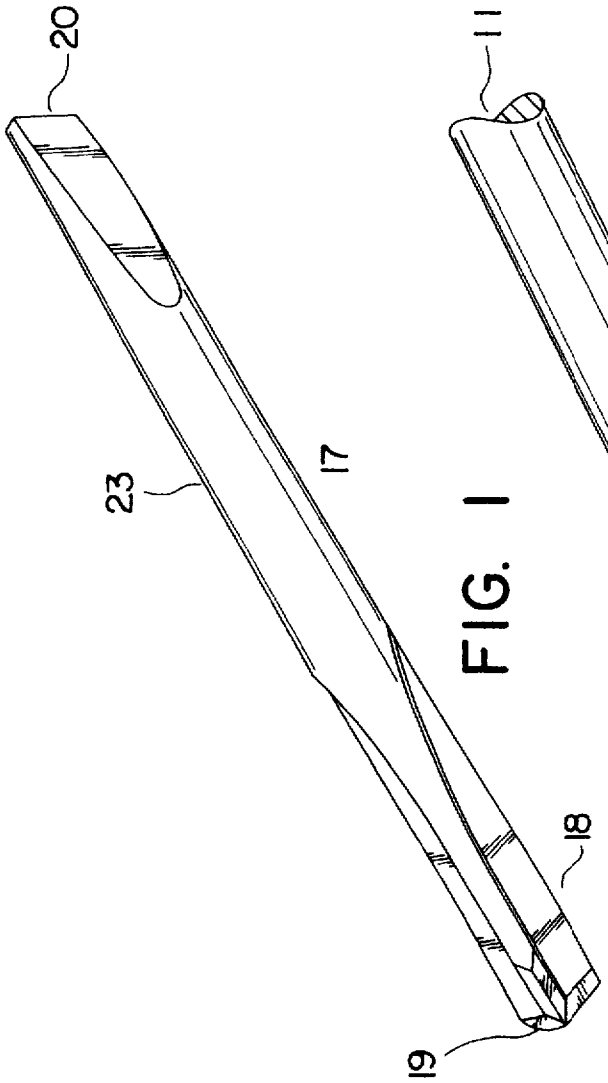


FIG. 1

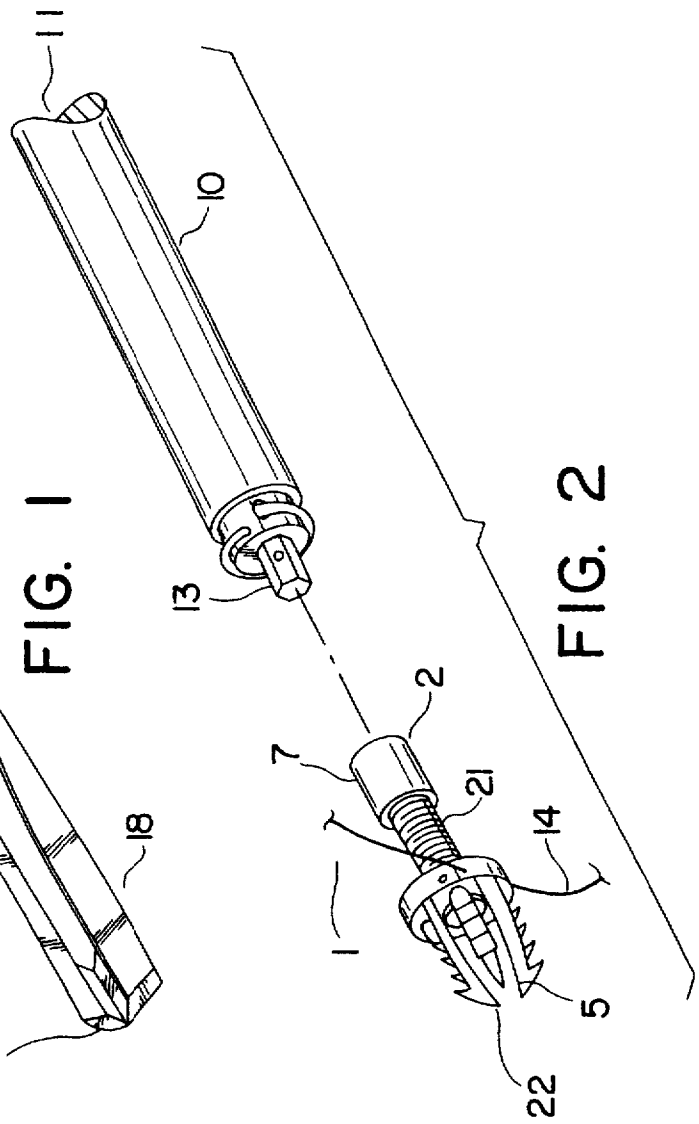


FIG. 2

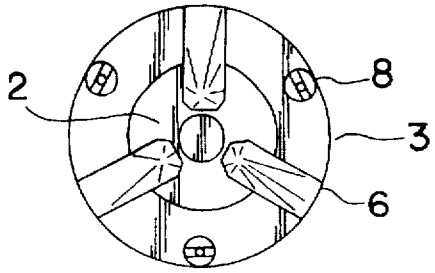


FIG. 3

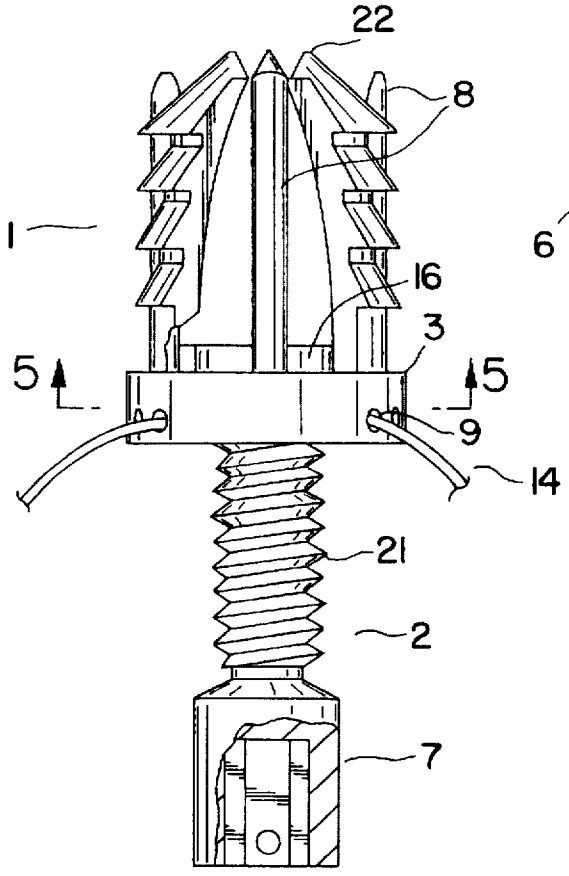


FIG. 4A

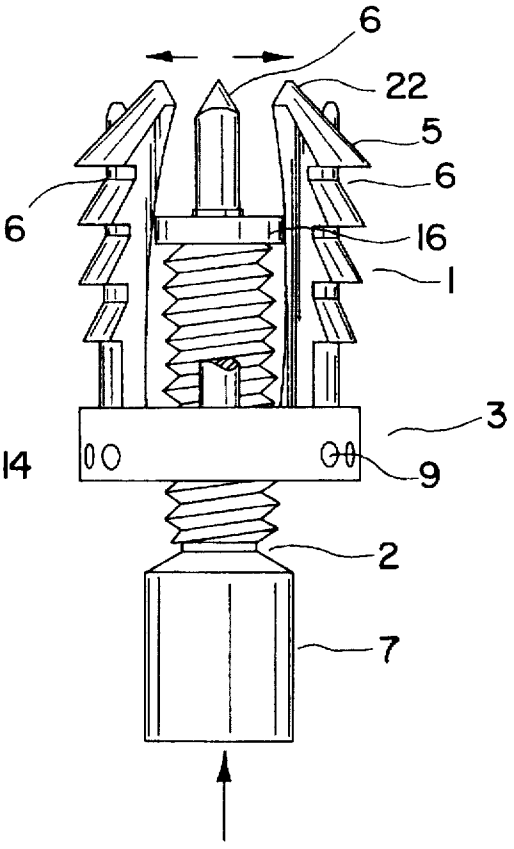


FIG. 4B

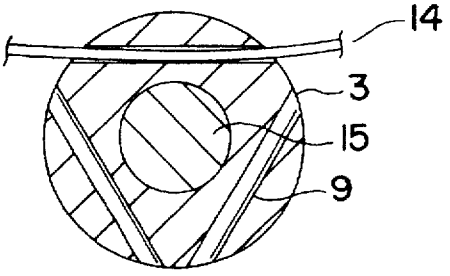


FIG. 5

STABILIZER FOR HUMAN JOINTS

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of U.S. provisional application Ser. No. 60/002,794, filed Aug. 25, 1995.

FIELD OF THE INVENTION

This invention pertains to an improved medical device for securing soft body tissues to bone, and more particularly to a joint stabilizer comprising toothed bone anchors that are forcibly spread into the bone by a central plug. The specific improvements include the ability of the invention to gather soft tissue, to retain the tissue by multiple sutures, and to secure itself to bone by distal penetration of its moveable legs.

BACKGROUND

Currently there are various staples and anchor devices for attaching soft tissue to bone. None of the tissue stabilizing devices known to the inventor provide multiple sutures to be anchored, distally expand in contrast to proximal expansion or an equal expansion along their long axis, and collect soft tissue into the receiving hole of the bone. Alternative devices also suffer from low pull-out strength, a lack of adequate suture attachment sites, a failure to assist the surgeon in positioning soft tissue into contact with bone prior to suturing to maximize bonding of the soft tissue to bone (tissue gathering capabilities), and an overall difficulty in physically handling the devices during surgery.

Generally, injury to joints such as the shoulder and knee involve the tearing or separation of ligaments from their natural position on the bone. The injury leads to a chronic instability in the joint which requires surgical intervention. Modernly, the surgery involves use of one or more arthroscopic devices. These devices include surgical cannulas through which a camera or surgical device are passed. The arthroscopic methods involve less iatrogenic trauma to the patient than previous methods and predict a faster recovery.

In brief, the surgical procedures involve visualization and localization of the damage, preparation of the bone surface, implantation of a soft tissue anchor, and suturing of the tissue to the bone to tighten up the joint and restabilize it. By tightly contacting the ligament or other soft tissue to a properly prepared bone surface, the two materials bond during the healing process.

SUMMARY OF THE INVENTION

It is an objective of this invention to provide a device with an increased pull-out strength relative to currently available joint stabilizers, and to provide a device which affords the capacity to use multiple sutures for gathering up a maximum amount of soft tissue for rejoining with bone. This invention further provides for sharp bone anchors and ligament combs that direct and draw ligaments, tendons, or other soft tissues to the bone to better facilitate and maximize the amount of soft tissue that is placed in contact with the bone during the reparative steps.

The present invention is generally characterized by first and second parts wherein the first part is a central body forming a hollow core or opening which defines a longitudinal axis, said body having laterally positioned (horizontal) proximal and distal faces, with bone anchors extending along the long axis from the distal face, said anchors symmetrically positioned about the face and in a first

position that is internally angled from the vertical to form a triangular shape (toward the center of the horizontal), each anchor having at least one bone engaging tooth and sharp ends to penetrate or gather soft tissue; and, wherein the second part of said system comprises a central plug positioned within the hollow core of the central body, and said plug having a generally elongate shape forming a head, a shank and a distal portion where the head forms a receptor for receiving a complementary driver device, the shank connects the head to the distal portion of the peg, and where the core is threaded, the central peg has an optionally threaded shank wherein the shank diameter and thread complement and engage threads of the central core, and the distal portion of the plug has a diameter that permits it to contact the bone anchors when the anchors are in the first internal lateral (unexpanded) position, said distal portion placing an increasing lateral force on the anchors as the central peg is driven by impact force along its elongate axis or is threaded by torque force through the threaded hollow core whereby the lateral force moves the bone anchors into a second external lateral (expanded) position in which the teeth penetrate into bone that is about equal to or outside of the diameter of the central body.

Preferred embodiments of the central body include devices as described above where the distal face of the central body further comprises ligament combs that are rigid projections that extend laterally (distally) from the face and where the combs are symmetrically positioned about the face. The central body is preferably circular as in the form of a washer, and preferably includes suture fasteners that are optionally hollow passages cut through the central body.

Preferred embodiments of the central plug include embodiments where the head of the central plug sits nearly flush with or is internal to the proximal face of the central body. A preferred head shape includes a receptacle for receiving a driver that is capable of transmitting impact along the elongate (vertical) axis or torque force in instances when the shank and core are complementarily threaded.

The invention further includes a system having as one of its components the above-described stabilizer and further includes a driver that is generally an elongate rod having a head, a shank and a distal portion. The head is formed to receive impact force. The shank is of a diameter that fits within an arthroscopic cannula and is of a length that permits the head and distal portion to be delivered through the cannula. The distal portion can be designed to mate with the receptor formed by the head of the central plug. The driver is optionally modified to include a snap fitting that complements the head of the peg to prevent accidental separation during surgery. The snap fitting may be based on a detent and dimple connection or wire and groove connection.

Alternatively, the driver can be contained within a holder that is designed to prevent slippage of the driver from the central plug. By controlling the distance the driver is permitted to travel, one can prevent over-striking or impacting of the central peg. The driver/holder assembly would resemble a hollow cylinder which would function as the holder where the driver is internal to the cylinder and has a safety stop or projection to control its extension upon impact. This assembly can also be used as an inserter/suture organizer which can be used to direct the stabilizer to its target site.

The invention further includes a system having as one of its components the above-described stabilizer and further including a trocar or drill bit for penetrating bone. The trocar or drill bit having a generally elongate or rod shape com-

prising a head, a shank and a distal portion. The head of the trocar is shaped to receive an axial impact force and transfer said force evenly along the length of the trochar device to the distal portion. In the case of a drill bit, the head is formed to be connected to a drill chuck. The shank is of a diameter that fits within an arthroscopic cannula and has a length that permits the head and distal portions to extend beyond the cannula. The distal portion of the trocar comprises a sharpened end having multiple cutting edges that match the number of bone anchors of the central body and having size that will create a concavity that complements the external shape of the stabilizer when its bone anchors are in the first position.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1**. is a side view of a trocar that matches a joint stabilizer having three bone anchors.

FIG. **2** is side view of the stabilizer made according to this invention and a driver.

FIG. **3** is a view of the distal end of the stabilizer.

FIG. **4A** is a side view of the stabilizer of FIG. **2** with the bone anchors in the first position. FIG. **4B** is a side view of the stabilizer of FIG. **2** with the bone anchors in the second position.

FIG. **5** is a cross-sectional view of the central body along line **5**—**5** of FIG. **4A**.

DESCRIPTION OF THE PREFERRED EMBODIMENT

A soft tissue stabilizer **1** in accordance with this invention is described in FIGS. **2**–**5**. The stabilizer is preferably made of biocompatible or physiologically inert materials. Such materials include titanium and its alloys, stainless steel, and cobalt based alloys. Bioabsorbable materials can also be used and include aliphatic polyesters of alpha-hydroxy acid derivatives as described in Rokkanen, P. V. (1991) "Absorbable Materials in Orthopedic Surgery," *Annals of Med.* 23:109–115.

The precise dimensions of the stabilizer can vary with its intended use and the patient size. The following overall dimensions are suited for the shoulder and knee joints of an adult human of average size, and can be modified for specific patients or uses. Along the axis defined by the core **15** of the central body **3**, reaching from the proximal face of the body **3** to the distal ends of the bone anchors **6**, the device is from 2 to 20 mm. The width of the stabilizer is from 2 to 15 mm. The thickness of the central body **3** between the distal and proximal faces is preferably from 0.8 to 4.0 mm.

The central body **3** can be circular, or a polygon of three or more sides. The central core **15** can be circular or a polygon. Circular forms are preferred. The proximal surface of body **3** is preferably flat or concave to minimize any surface extending above the cortex of the bone in situations where such surface might interfere with function, as in joints.

The distal surface of the body **3** in FIG. **2** has three bone anchors **6** as shown in side view in FIG. **4A**. It is preferred that the body **3** have from 2–4 anchors. The bone anchors **6** are attached to the central body **3** by a variety of conventional means, including welding, casting from a single mold, screwing, riveting, or pressure-fitted together by means of a tapered insert into a hole. The anchors are tapered to a sharp point and have at least one bone engaging tooth **5**, and preferably several teeth **5**. The teeth are attached to the outer surface of the anchors to be directed into bone when the anchors are expanded. The teeth **5** act as barbs to increase the pull-out strength of the stabilizer. Where multiple teeth **5** are present, they may increase in size as they are positioned more distal from the central body **3**. The teeth **5** are preferably tapered to sharpened points that are able to penetrate the interior matrix (cancellous portion) of the bone, specially prepared with the matching kit drill.

The anchors **6** are preferably symmetrically positioned about the central body **3**. When the distal ends **22** of anchors **6** are in the first internal lateral position, see FIG. **4A**, they are parallel to or angled internal to the longitudinal axis, the preferred internal angle being 8 to 15 degrees. When in the internal lateral position, the teeth **5** are at or within the cylindrical, axially extending region defined by the body **3**. As the distal ends **22** of the anchors **6** are moved to their second or external, more lateral position, the distance between the ends **22** and the long axis of the stabilizer **1** will increase to place the teeth **5** at or just beyond the cylindrical axially extending region defined by the body **3**, see FIG. **4B**.

In addition to having bone anchors **6**, the body **3** may optionally bear ligament combs **8**, which are elongate pins that are positioned between the anchors **6**, preferably symmetrically about the anchors **6**. As shown in FIG. **4A**, the combs **8** are approximately the same length as the anchors **6**. The combs are rigid and tapered to a sharp end for gathering ligament and other soft tissue, and for penetrating the bone.

The central body **3** may optionally comprise suture fasteners **9** which are depicted in FIGS. **4** and **5** as internal, laterally directed passages cut or drilled out of the central body **3**. Alternatively, the fasteners could be holes drilled along the longitudinal axis through the distal and proximal faces of the central body **3**, or loop-like means or hook-like means which could be cut into or mounted to the central body **3**. Prior to implantation of the stabilizer **1**, the suture threads can be attached or threaded through the central body **3**. Alternatively, the suture fasteners might be located on the central plug **2** or bone anchors **6**.

Positioned within the central core **15** is a central plug **2**. The central plug **2** is an elongate structure comprising a head **7** that is designed to receive a driver device—termed a central plug driver **10**. If the plug **2** is pressure fitted into the hollow core **15**, the head **7** has a generally symmetric surface for receiving impact force and transmitting the force equally down the length of the plug **2**. The head **7** can be flat or slightly concave to prevent slippage of the driver **10** during use. When the central plug **2** is threaded, as in FIG. **4A**, and positioned by torque force, the head **7** can be single or multiply slotted, or cut out to form a socket such as a hexagonal socket for receiving a complementary central plug connector **13**.

The shank **21** of the central plug **2** is either smooth or threaded. The nature of the thread is not critical and 8–36 inch thread is useful and provides suitable control. As the central plug **2** is moved from a first upper position to a second lower position, the distal end of the central plug **16** is designed to spread or force the bone anchors **6** from a first internal lateral position, as depicted in FIG. **4A**, to a second external lateral position, as depicted in FIG. **4B**.

The diameter of the head **7** is not critical. The diameter can be larger or smaller or equal to the diameter of the shank **21**. To facilitate assembly, the head **7** may preferably be of sufficient size to pass through the opening **15** or the central body **3**. In a similar vein, and although the diameter of the distal end **16** of the central plug **2** of FIG. **4A** is larger than

the central opening **15**, it would be apparent to those of skill that the diameter of end **16** is not critical and could be equal or slightly smaller than the opening **15** to accommodate assembly.

The bone surface is optionally prepared with a trocar **17** that has a cutting surface that matches the stabilizer **1** (see FIG. 1). More particularly, the trochar **17** is comprised of a head **20** connected to an elongate shank **23** which is connected to distal end **19** having cutting edges **18**. This distal end **19** has an external size and configuration to create a concavity in bone that complements the external configuration of the central body **3** when its bone anchors **6** are in the first position. The concavity created by the trochar **17** should be the same size or just slightly smaller than the external size of the stabilizer **1** when in the position of FIG. **4A**. The trochar **17** can be made of any material that can be sterilized, be formed into a cutting edge **18**, and withstand the impact force needed to penetrate bone. Metal alloys such as stainless steel are preferred. The overall diameters of the trochar are not critical and need only be long enough to reach into the joint and extend outside a suitable distance for receiving the impact force, or for drill attachment to a chuck. An overall length of eight to twelve inches with an outside diameter of 0.5 to 1.5 cm is suitable for the anticipated uses.

Alternatively, the bone surface may be prepared with a drill bit that creates a hole in the bone large enough to receive the tissue stabilizer. The cut hole can be either straight or angled to walls to form a Morse taper.

The central plug driver **10** is illustrated in FIG. **2** and is designed to transfer either axillary impact force or torque force to the central plug head **7** to move the central plug **2** from its first to its second position. If impact force is used to move the central plug **2**, the central plug connector **13** is a blunt tapered end or a flat end. If torque force is used to move the central plug **2**, the central plug connector **13** can be flat or be formed into a socket or a hex shape or a cut to shape that will fit into a slot or Phillip's type of head. The handle **11** comprises an elongate shank and a head that is shaped to either receive impact force and transfer that force equally down the shank to the connector **13** such as a flat surface, or shaped to facilitate frictional grasping for application of torque force such as a flattened surface for twisting between the thumb and forefinger or a spherical ball. The overall dimensions of the driver are the same as those provided above for the trochar **17**.

The central plug driver **10** may be used to position the stabilizer **1** into the concavity created by the trochar **17**. To facilitate the positioning of the stabilizer through tissue to bone, the driver and device can be held together by the sutures or the driver **10** can be snap fitted to the stabilizer **1**. The means for snap fitting is not critical. Typical examples include tension wire and groove fittings or dimple, detent fittings. The strength of the fitting should be such that accidental separations are minimized while deliberate separations are possible after insertion into bone without inadvertent pull-outs. Pull-out strengths can be measured according to Shall, et al., "Soft Tissue Reconstruction in the Shoulder: Comparison of Suture Anchors, Absorbable Staples and Absorbable Tacks, *Amer. J. Sports Med.*, 22:715–718 (1994) or Hecker, et al., "Pull-Out Strength of Suture Anchors for Rotator Cuff and Bankart Lesion Repairs," *Amer. J. of Sports Med.*, 21:874–879 (1993). The FDA has also issued recent guidelines.

It should be noted that the claimed stabilizer expands at its distal end. This is in contrast to other expanding anchors that expand equally along their longitudinal axis or at their proximal end as an arrowhead shape. Distal expansion provides improved pullout strength by maximizing overlying bone contact.

Multicomponent kits are also a part of this invention. The kits will include at a minimum the tissue stabilizing device as described herein as a first component. Other components include the drill, sutures and the inserter/suture organizer.

The surgical procedures for which the device is particularly suited are repairs to the shoulder and knee joints such as reconstructing anterior cruciate ligament (ACL) deficiencies and for repairing dislocating shoulders and torn rotator cuffs. However, the stabilizer is universally applicable to most efforts which warrant reattachment of soft tissue to bone. The following, brief description of surgical procedures are not intended to be the only way the inventions described herein could be used and are presented for illustration purposes and not by way of limitation.

For repairing shoulder injuries, the patient is prepared for surgery and within a sterile field two or three incisions are made. The first incision is anterior superior on the shoulder 1 cm lateral to the anterior glenohumeral joint line, and 1 cm beneath the inferior acromion's palpable cortex. This incision is 1.0 cm in length and vertically positioned. The next two incisions are 0.5 cm in length and horizontal to the body axis. The second incision is posterior superior, 1 cm lateral to the posterior glenohumeral joint line, 1 cm beneath the acromion palpable cortex. The third incision is lateral to the acromion just posterior to the greater tuberosity of the humerus and supraspinatus attachment, 1 cm beneath the inferior acromion palpable cortex. All incisions are made just to the depth of superficial subcutaneous tissue. The newer arthroscopic devices allow the posterior incision to be omitted.

The arthroscopic camera equipment is positioned by driving a sharp trocar inside a cannula to the synovium, and then a blunt trocar through the synovium. A scope cannula is positioned through either the lateral or posterior incision. A pressure pump cannula is then posteriorly or laterally positioned and the stabilizer cannula containing a smooth trocar is placed into the anterior glenohumeral joint. The joint is examined to study the effusion and synovium before arthroscopic fluid enters (unless pre-infusion is needed for instrument insertion). One next washes out the joint with Ringer's lactate and checks the labrum for tears and/or detachment. Good practice includes looking at the biceps tendon and inferior cuff from the posterior or lateral position. This process allows one to identify any Bankart lesion or other anterior inferior glenohumeral ligament maladies, or any capsular laxity.

The joint repair is conceptualized to locate the point of stabilizer placement that will maximize joint stability. Selecting a stabilizer with a threaded or smooth cylindrical central plug, one assembles, if not already assembled, the two parts of the stabilizer so that the central plug is approximately 50% of the way into the central body and just contacting the bone anchors. The stabilizer is then snap fitted on the central plug driver, or fixed by the inserter/suture organizer. The tissue to be captured and re-attached is revisualized with usual attention paid to the anterior inferior shoulder and inside the joint. The surgeon then probes the pathology with a smooth trocar through the cannula.

The glenoid rim is prepared either by using a sharp, pointed trocar, by pre-drilling to expose bone, by burring, or by use of the star-tipped trocar as in FIG. **1**. The stabilizer is placed into the anterior shoulder through an accommodating cannula. The stabilizer is then used to pierce the tissue

inside the joint, "teasing it" onto the anchors and optimal combs, and the stabilizer is then driven into bone while the assistant surgeon holds the arm up against the glenoid. Next, the central plug is tightened down to expand the bone anchors into their second position for extra fixation security.

In cases where sutures are required, the sutures are attached to the suture fasteners prior to insertion and used in conventional ways to tie additional soft tissue to the bone. A suture-passing device can be used here.

In the final step, the surgeon checks the joint motion, implant and joint stability, and rules out any impingement of the implant against mobile surfaces.

For repairs to the knee, one follows an analogous protocol. Two or three incisions are made to a patient's knee after appropriate external site preparation steps are completed. The first incision is at the femorotibial joint line 1 cm above the tibial plateau palpable surface just medial to the patella tendon, 1 cm in length, and horizontal. The second incision is horizontal, 0.5 cm in length, and along the joint line just lateral to the patella tendon. The third incision is about 3 cm above the top of the patella superolaterally. The incision depths are to subcutaneous tissue. The third incision can usually now be omitted with newer arthroscopic equipment.

The arthroscopic equipment is positioned inferolaterally using the sharp trocar to the synovium and blunt trocar through the synovium. The surgeon then places a stabilizer cannula along the inferior medial 1 cm incision through the skin, and then vertically into the intercondylar notch along the medial parapatellar tendon with a smooth tipped trocar inside a cannula. A pressure pump cannula is then placed above and lateral to the patella, about 3 cm superior to the upper patella border, or attached to new scope equipment. Good practice mandates that all four compartments of the knee joint are then examined to study the effusion and synovium before arthroscopic fluids enter. Care is taken to avoid iatrogenic cartilage injury.

The joint is then washed out with Ringer's lactate, checking the anterior cruciate ligament for location of tear, degree of strand compromise, concomitant ligament conduit attenuation, and remnant attachment tissue qualities.

To place the stabilizer in its optimal position, one must first conceptualize the goals of repair to identify the location on the condyle where the stabilizer will provide maximum security and adequate (isometric) function. The stabilizer is then prepared as above for the shoulder. The pathology is then reprobed to locate tissue to be captured. Most common is damage to the femoral ACL remnant, in repair cases. The stabilizer also provides for secure fixation in reconstruction cases, wherein autografts or allografts are used.

The surgeon then prepares the concavity for implanting the stabilizer by a limited synovectomy, burr notchplasty, and then by exposing bone inside the notch at the inner lateral femoral condyle. A pointed tipped trocar may be used if the upper ligamentous remnant is sufficient, or otherwise the bone can be prepared with the trocar of FIG. 1 used by impact or by drill.

The surgeon then places the joint stabilizer into the anteromedial knee wound through an accommodating cannula. One pierces the anterior cruciate ligament fibers toward the mid and upper section of the remaining attenuated or torn conduit for distal to proximal ACL fixation, teasing as many strands and fibers onto the implant device as can be gathered. The ligament combs are designed to help organize the strands, and the combination of toothed bone anchors and ligament combs or pins will comb, or align, the remaining anterior cruciate fibers before bringing them up to and into bone.

The stabilizer is then driven into the prepared concavity, while the knee is flexed at about 30 degrees, and the assistant surgeon holds the tibia up towards the femur. The central plug is then impacted down, thus expanding the prongs inside the bone, locking the stabilizer into place. The optional use of sutures completes the repair. The surgeon ties the knots if pre-secured using bioabsorbable (#1) PDS suture, or with the suture of choice, and checks the joint clinically for stability and impingement.

All publications and patent applications cited in this specification are herein incorporated by reference as if each individual publication or patent application were specifically and individually indicated to be incorporated by reference.

Although the foregoing invention has been described in some detail by way of illustration and example for purposes of clarity of understanding, it will be readily apparent to those of ordinary skill in the art in light of the teachings of this invention that certain changes and modifications may be made thereto without departing from the spirit or scope of the appended claims.

What is claimed is:

1. A soft tissue stabilizing device for securing soft tissue to bone which comprises first and second parts:

(i) wherein the first part comprises a central body defining an opening, the opening defining an axis, said body having proximal and distal faces that extend in a lateral direction with the distal face having bone anchors having distal ends, said ends being movable between a first internal and a second external lateral position, each anchor having a plurality of bone engaging teeth, the teeth increasing in size as they are positioned more distally from the distal face of the central body; and,

(ii) wherein the second part of said device comprises a central plug positioned within the opening of the central body and said plug has a generally elongate shape forming a head, a shank and a distal portion, wherein the shank is movable through the opening of the central body so that the distal portion of the plug is positionable between a first upper and second lower axial position, and wherein the distal portion of the plug is sized to contact the bone anchors so that when the distal portion of the plug is moved into the second axial position, the distal ends of the bone anchors are moved towards the second lateral position.

2. The device of claim **1** wherein the distal face of the central body further comprises ligament combs that are rigid pins that extend axially from the distal face.

3. The device of claim **1** wherein the bone anchors have sharp distal ends.

4. The device of claim **1** wherein the central body is circular.

5. The device of claim **1** wherein said body defines a cylindrical axially extending region, said bone anchors lying substantially completely within the region when the distal ends of the anchors are in the first lateral position with substantial portions of the teeth lying outside the cylindrical region when said distal ends of the anchors are in the second lateral position.

6. The device of claim **1** wherein the central body comprises at least one suture fastener.

7. The device of claim **1** wherein the suture fasteners are more than one and include hollow passages formed in the central body.

8. The device of claim **1** having more than one suture anchor.

9. The device of claim **1** wherein the number of bone anchors is three.

10. The device of claim 1 wherein the opening of the central body and the shank of the central peg are frictionally mated without threads using smooth surfaces to position the central peg along the axis defined by the opening.

11. The device of claim 1 wherein the head of the central plug sits flush with or is internal to the proximal face of the central core when in the second position.

12. The device of claim 10 wherein the head forms a receptor for receiving a driving tool.

13. The device of claim 1 wherein the device is made of a bioabsorbable material.

14. The device of claim 1 wherein the device is made of a stainless steel.

15. The device of claim 1 wherein the device is made of an alloy of titanium.

16. A system for stabilizing soft tissue to bone comprising: (a) a soft tissue stabilizing device for securing soft tissue to bone which comprises a first and second part:

(i) wherein the first part is a circular central body forming a ring with an opening defining a long axis and further forming three hollow passages that symmetrically traverse the lateral or vertical plane of the central body to serve as suture securing anchors, said body having lateral proximal and distal planar faces with the distal face comprising three bone anchors extending axially from the face said bone anchors symmetrically positioned about the face and having distal ends that are movable from a first internal, lateral position to a second external lateral position, each bone anchor having at least one bone engaging tooth and where said distal face further comprises ligament combs,

(ii) wherein the second part of said system comprises a generally elongate central plug positioned within the opening so that it is movable from a first upper axial position to a lower axial position and said plug having a head, a shank and a distal portion, the shank connects the head and the distal portion, and the distal portion of the plug is sized to contact the bone anchors when the anchors are moved from the first to second lateral positions and move the bone anchors into a second position in which the teeth penetrate into bone; and,

(b) a driver that is generally elongate having a head, shank and distal portion wherein the head is formed into a handle for applying torque force, the shank is of a diameter that fits within a arthroscopic cannula and of a length that permits the head and proximal portion to extend outside the cannula wherein the distal portion contacts the head of the central plug.

17. A system of claim 16 wherein the distal portion of the driver and the head of the central plug are held in contact by the sutures to prevent separation.

18. A system of claim 17 wherein the distal portion of the driver bears a detent.

19. A system of claim 16 wherein the bone anchors have sharp distal ends.

20. A system of claim 16 which further comprises a trochar for penetrating bone said trochar having a generally elongate shape having a head, shank and distal portion wherein the head is generally planar or concave to accept an axial force and transfer said force evenly along the length of the shank to the distal portion, the distal portion comprising a sharpened end having multiple cutting edges that have an external size and configuration to create a concavity in bone that complements the external configuration of the central body when its bone anchors are in the first position.

* * * * *

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United States Patent [19]

Grotz

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[45] Date of Patent: Oct. 19, 1999

[54] **STABILIZER FOR HUMAN JOINTS**

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[73] Assignee: **Ultraortho, Inc.**, San Francisco, Calif.

[21] Appl. No.: **09/104,814**

[22] Filed: **Jun. 25, 1998**

Related U.S. Application Data

[63] Continuation of application No. 08/712,635, Aug. 21, 1996, Pat. No. 5,782,865.

[60] Provisional application No. 60/002,794, Aug. 25, 1995.

[51] **Int. Cl.**[6] **A61B 17/04**

[52] **U.S. Cl.** **606/232**; 606/72; 606/104

[58] **Field of Search** 606/232, 72, 73, 606/76, 77, 104

[56] **References Cited**

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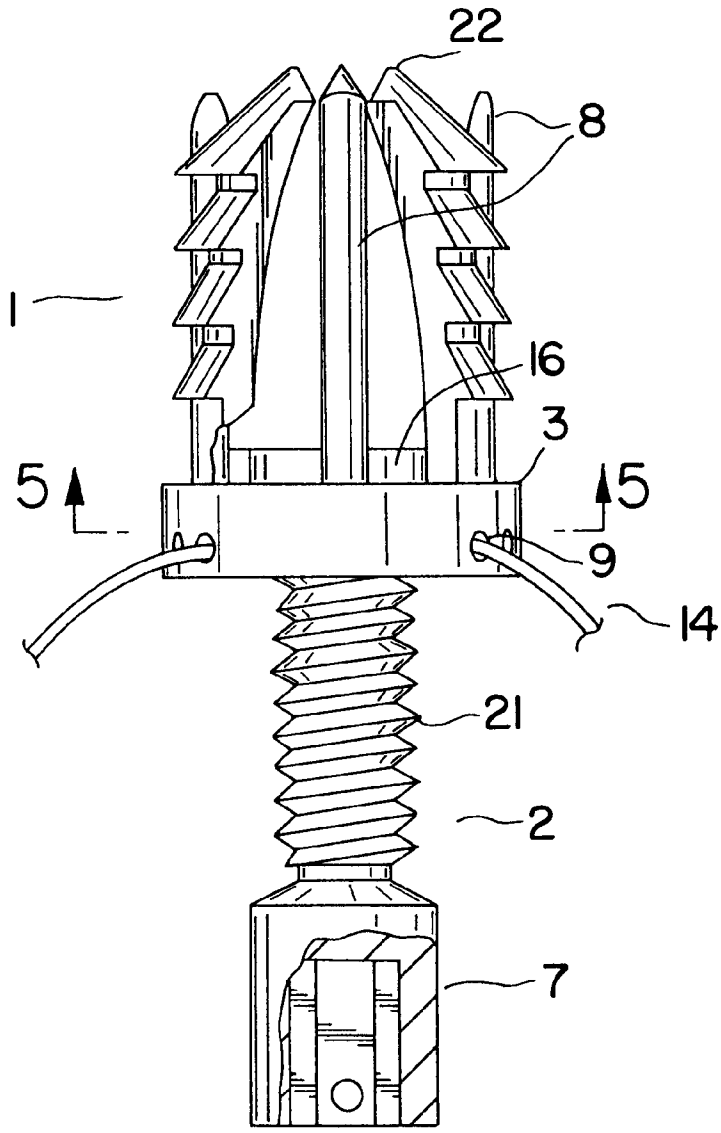
Primary Examiner—Gary Jackson

Attorney, Agent, or Firm—Townsend and Townsend and Crew LLP

[57] **ABSTRACT**

This invention pertains to a medical device for securing bodily tissues to bone, and more particularly to a triangular shaped joint stabilizer comprising sharpened, toothed bone anchors that are forcibly spread into the bone by a central plug.

23 Claims, 2 Drawing Sheets



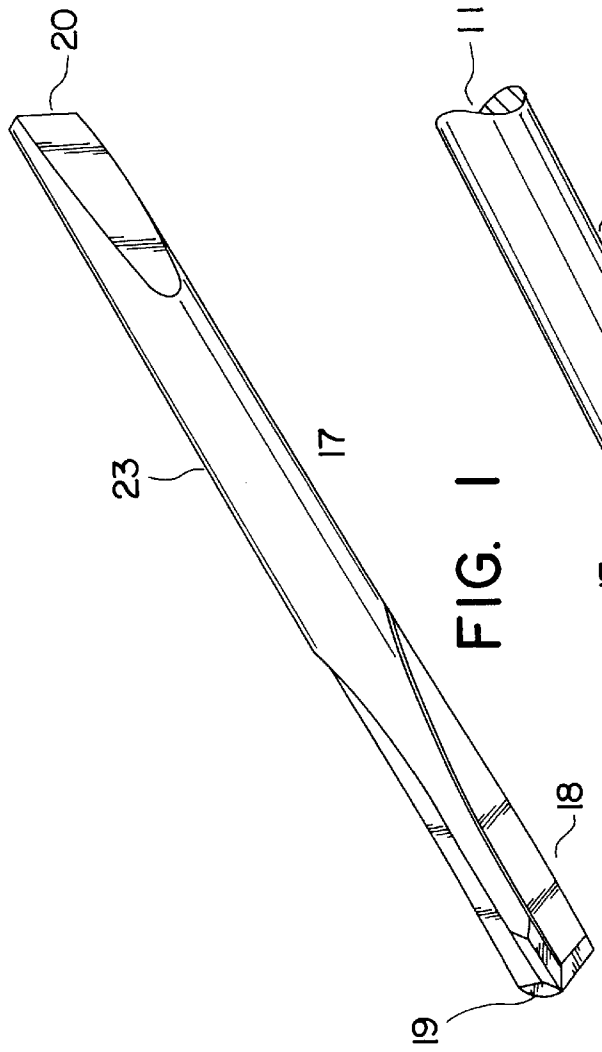


FIG. 1

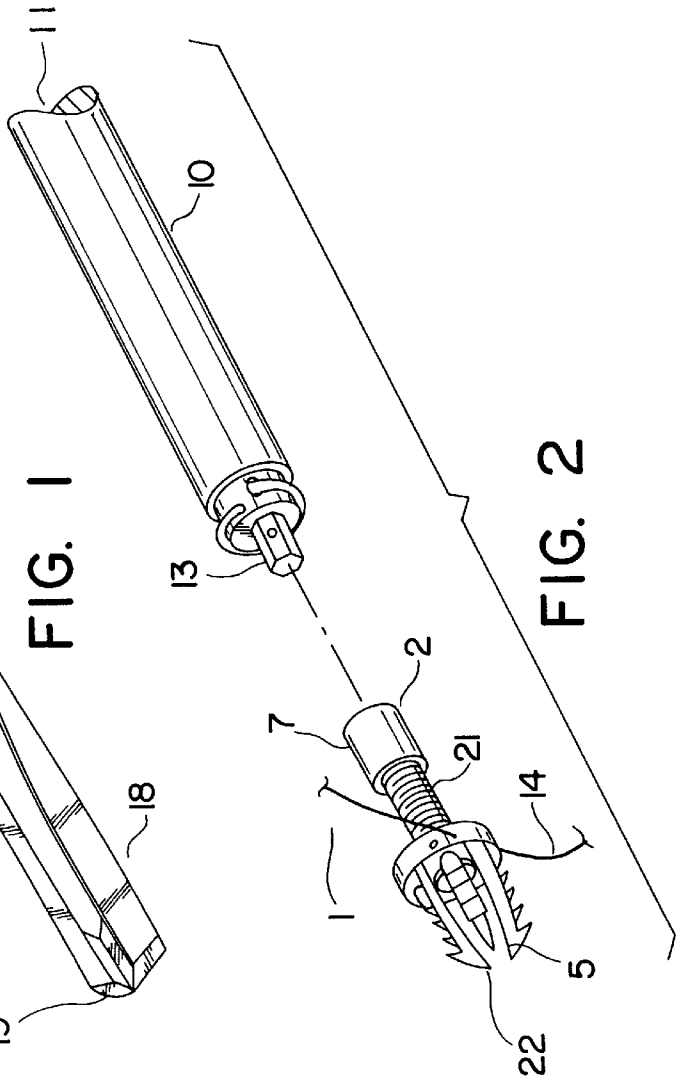


FIG. 2

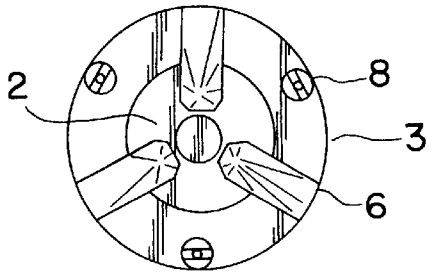


FIG. 3

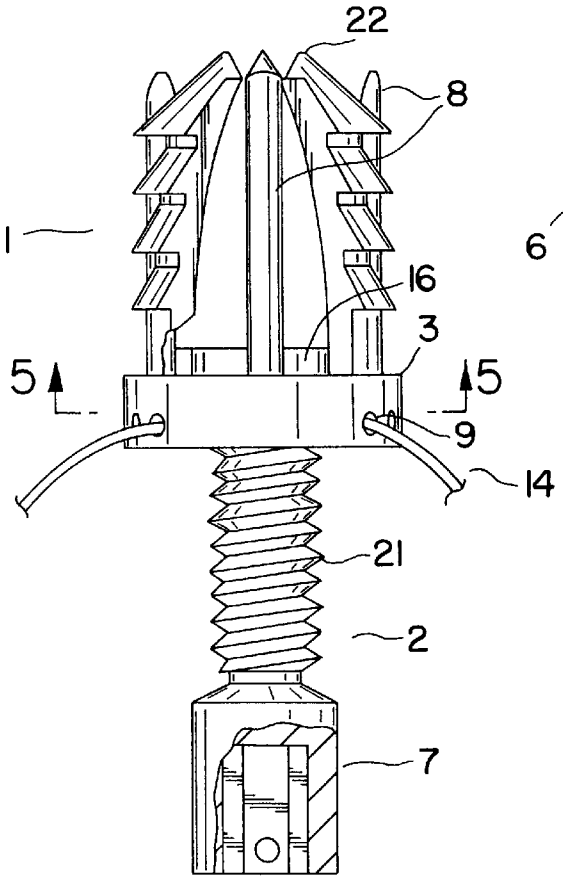


FIG. 4A

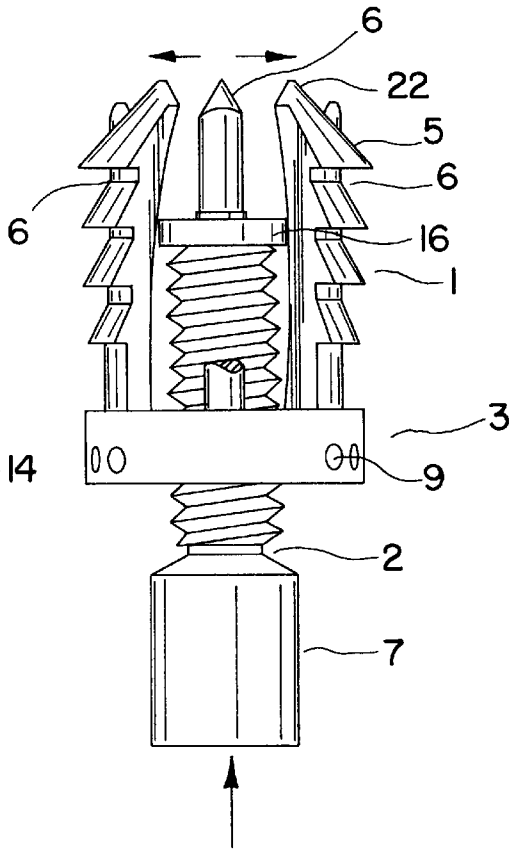


FIG. 4B

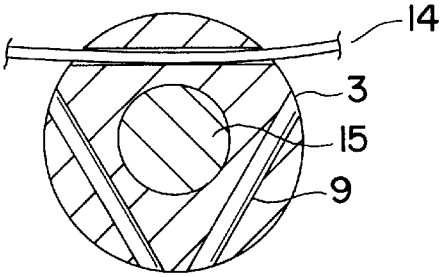


FIG. 5

STABILIZER FOR HUMAN JOINTS

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 08/712,635, filed Aug. 21, 1996, now U.S. Pat. No. 5,782,865, which is a continuation-in-part of U.S. provisional application No. 60/002,794, filed Aug. 25, 1995.

FIELD OF THE INVENTION

This invention pertains to an improved medical device for securing soft body tissues to bone, and more particularly to a joint stabilizer comprising toothed bone anchors that are forcibly spread into the bone by a central plug. The specific improvements include the ability of the invention to gather soft tissue, to retain the tissue by multiple sutures, and to secure itself to bone by distal penetration of its moveable legs.

BACKGROUND

Currently there are various staples and anchor devices for attaching soft tissue to bone. None of the tissue stabilizing devices known to the inventor provide multiple sutures to be anchored, distally expand in contrast to proximal expansion or an equal expansion along their long axis, and collect soft tissue into the receiving hole of the bone. Alternative devices also suffer from low pull-out strength, a lack of adequate suture attachment sites, a failure to assist the surgeon in positioning soft tissue into contact with bone prior to suturing to maximize bonding of the soft tissue to bone (tissue gathering capabilities), and an overall difficulty in physically handling the devices during surgery.

Generally, injury to joints such as the shoulder and knee involve the tearing or separation of ligaments from their natural position on the bone. The injury leads to a chronic instability in the joint which requires surgical intervention. Modernly, the surgery involves use of one or more arthroscopic devices. These devices include surgical cannulas through which a camera or surgical device are passed. The arthroscopic methods involve less iatrogenic trauma to the patient than previous methods and predict a faster recovery.

In brief, the surgical procedures involve visualization and localization of the damage, preparation of the bone surface, implantation of a soft tissue anchor, and suturing of the tissue to the bone to tighten up the joint and restabilize it. By tightly contacting the ligament or other soft tissue to a properly prepared bone surface, the two materials bond during the healing process.

SUMMARY OF THE INVENTION

It is an objective of this invention to provide a device with an increased pull-out strength relative to currently available joint stabilizers, and to provide a device which affords the capacity to use multiple sutures for gathering up a maximum amount of soft tissue for rejoining with bone. This invention further provides for sharp bone anchors and ligament combs that direct and draw ligaments, tendons, or other soft tissues to the bone to better facilitate and maximize the amount of soft tissue that is placed in contact with the bone during the reparative steps.

The present invention is generally characterized by first and second parts wherein the first part is a central body forming a hollow core or opening which defines a longitudinal axis, said body having laterally positioned (horizontal) proximal and distal faces, with bone anchors extending

along the long axis from the distal face, said anchors symmetrically positioned about the face and in a first position that is internally angled from the vertical to form a triangular shape (toward the center of the horizontal), each anchor having at least one bone engaging tooth and sharp ends to penetrate or gather soft tissue; and, wherein the second part of said system comprises a central plug positioned within the hollow core of the central body, and said plug having a generally elongate shape forming a head, a shank and a distal portion where the head forms a receptor for receiving a complementary driver device, the shank connects the head to the distal portion of the peg, and where the core is threaded, the central peg has an optionally threaded shank wherein the shank diameter and thread complement and engage threads of the central core, and the distal portion of the plug has a diameter that permits it to contact the bone anchors when the anchors are in the first internal lateral (unexpanded) position, said distal portion placing an increasing lateral force on the anchors as the central peg is driven by impact force along its elongate axis or is threaded by torque force through the threaded hollow core whereby the lateral force moves the bone anchors into a second external lateral (expanded) position in which the teeth penetrate into bone that is about equal to or outside of the diameter of the central body.

Preferred embodiments of the central body include devices as described above where the distal face of the central body further comprises ligament combs that are rigid projections that extend laterally (distally) from the face and where the combs are symmetrically positioned about the face. The central body is preferably circular as in the form of a washer, and preferably includes suture fasteners that are optionally hollow passages cut through the central body.

Preferred embodiments of the central plug include embodiments where the head of the central plug sits nearly flush with or is internal to the proximal face of the central body. A preferred head shape includes a receptacle for receiving a driver that is capable of transmitting impact along the elongate (vertical) axis or torque force in instances when the shank and core are complementarily threaded.

The invention further includes a system having as one of its components the above-described stabilizer and further includes a driver that is generally an elongate rod having a head, a shank and a distal portion. The head is formed to receive impact force. The shank is of a diameter that fits within an arthroscopic cannula and is of a length that permits the head and distal portion to be delivered through the cannula. The distal portion can be designed to mate with the receptor formed by the head of the central plug. The driver is optionally modified to include a snap fitting that complements the head of the peg to prevent accidental separation during surgery. The snap fitting may be based on a detent and dimple connection or wire and groove connection.

Alternatively, the driver can be contained within a holder that is designed to prevent slippage of the driver from the central plug. By controlling the distance the driver is permitted to travel, one can prevent over-striking or impacting of the central peg. The driver/holder assembly would resemble a hollow cylinder which would function as the holder where the driver is internal to the cylinder and has a safety stop or projection to control its extension upon impact. This assembly can also be used as an inserter/suture organizer which can be used to direct the stabilizer to its target site.

The invention further includes a system having as one of its components the above-described stabilizer and further

including a trocar or drill bit for penetrating bone. The trocar or drill bit having a generally elongate or rod shape comprising a head, a shank and a distal portion. The head of the trocar is shaped to receive an axial impact force and transfer said force evenly along the length of the trochar device to the distal portion. In the case of a drill bit, the head is formed to be connected to a drill chuck. The shank is of a diameter that fits within an arthroscopic cannula and has a length that permits the head and distal portions to extend beyond the cannula. The distal portion of the trocar comprises a sharpened end having multiple cutting edges that match the number of bone anchors of the central body and having size that will create a concavity that complements the external shape of the stabilizer when its bone anchors are in the first position.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1**. is a side view of a trocar that matches a joint stabilizer having three bone anchors.

FIG. **2** is side view of the stabilizer made according to this invention and a driver.

FIG. **3** is a view of the distal end of the stabilizer.

FIG. **4**A is a side view of the stabilizer of FIG. **2** with the bone anchors in the first position. FIG. **4**B is a side view of the stabilizer of FIG. **2** with the bone anchors in the second position.

FIG. **5** is a cross-sectional view of the central body along line **5**—**5** of FIG. **4**A.

DESCRIPTION OF THE PREFERRED EMBODIMENT

A soft tissue stabilizer **1** in accordance with this invention is described in FIGS. **2**–**5**. The stabilizer is preferably made of biocompatible or physiologically inert materials. Such materials include titanium and its alloys, stainless steel, and cobalt based alloys. Bioabsorbable materials can also be used and include aliphatic polyesters of alpha-hydroxy acid derivatives as described in Rokkanen, P.V. (1991) "Absorbable Materials in Orthopedic Surgery," *Annals of Med.* 23:109–115.

The precise dimensions of the stabilizer can vary with its intended use and the patient size. The following overall dimensions are suited for the shoulder and knee joints of an adult human of average size, and can be modified for specific patients or uses. Along the axis defined by the core **15** of the central body **3**, reaching from the proximal face of the body **3** to the distal ends of the bone anchors **6**, the device is from 2 to 20 mm. The width of the stabilizer is from 2 to 15 mm. The thickness of the central body **3** between the distal and proximal faces is preferably from 0.8 to 4.0 mm.

The central body **3** can be circular, or a polygon of three or more sides. The central core **15** can be circular or a polygon. Circular forms are preferred. The proximal surface of body **3** is preferably flat or concave to minimize any surface extending above the cortex of the bone in situations where such surface might interfere with function, as in joints.

The distal surface of the body **3** in FIG. **2** has three bone anchors **6** as shown in side view in FIG. **4**A. It is preferred that the body **3** have from 2–4 anchors. The bone anchors **6** are attached to the central body **3** by a variety of conventional means, including welding, casting from a single mold, screwing, riveting, or pressure-fitted together by means of a tapered insert into a hole. The anchors are tapered to a sharp point and have at least one bone engaging tooth **5**, and preferably several teeth **5**. The teeth are attached to the outer surface of the anchors to be directed into bone when the anchors are expanded. The teeth **5** act as barbs to increase the pull-out strength of the stabilizer. Where multiple teeth **5** are present, they may increase in size as they are positioned more distal from the central body **3**. The teeth **5** are preferably tapered to sharpened points that are able to penetrate the interior matrix (cancellous portion) of the bone, specially prepared with the matching kit drill.

The anchors **6** are preferably symmetrically positioned about the central body **3**. When the distal ends **22** of anchors **6** are in the first internal lateral position, see FIG. **4**A, they are parallel to or angled internal to the longitudinal axis, the preferred internal angle being 8 to 15 degrees. When in the internal lateral position, the teeth **5** are at or within the cylindrical, axially extending region defined by the body **3**. As the distal ends **22** of the anchors **6** are moved to their second or external, more lateral position, the distance between the ends **22** and the long axis of the stabilizer **1** will increase to place the teeth **5** at or just beyond the cylindrical axially extending region defined by the body **3**, see FIG. **4**B.

In addition to having bone anchors **6**, the body **3** may optionally bear ligament combs **8**, which are elongate pins that are positioned between the anchors **6**, preferably symmetrically about the anchors **6**. As shown in FIG. **4**A, the combs **8** are approximately the same length as the anchors **6**. The combs are rigid and tapered to a sharp end for gathering ligament and other soft tissue, and for penetrating the bone.

The central body **3** may optionally comprise suture fasteners **9** which are depicted in FIGS. **4** and **5** as internal, laterally directed passages cut or drilled out of the central body **3**. Alternatively, the fasteners could be holes drilled along the longitudinal axis through the distal and proximal faces of the central body **3**, or loop-like means or hook-like means which could be cut into or mounted to the central body **3**. Prior to implantation of the stabilizer **1**, the suture threads can be attached or threaded through the central body **3**. Alternatively, the suture fasteners might be located on the central plug **2** or bone anchors **6**.

Positioned within the central core **15** is a central plug **2**. The central plug **2** is an elongate structure comprising a head **7** that is designed to receive a driver device—termed a central plug driver **10**. If the plug **2** is pressure fitted into the hollow core **15**, the head **7** has a generally symmetric surface for receiving impact force and transmitting the force equally down the length of the plug **2**. The head **7** can be flat or slightly concave to prevent slippage of the driver **10** during use. When the central plug **2** is threaded, as in FIG. **4**A, and positioned by torque force, the head **7** can be single or multiply slotted, or cut out to form a socket such as a hexagonal socket for receiving a complementary central plug connector **13**.

The shank **21** of the central plug **2** is either smooth or threaded. The nature of the thread is not critical and **8**-**36** inch thread is useful and provides suitable control. As the central plug **2** is moved from a first upper position to a second lower position, the distal end of the central plug **16** is designed to spread or force the bone anchors **6** from a first internal lateral position, as depicted in FIG. **4**A, to a second external lateral position, as depicted in FIG. **4**B.

The diameter of the head **7** is not critical. The diameter can be larger or smaller or equal to the diameter of the shank **21**. To facilitate assembly, the head **7** may preferably be of sufficient size to pass through the opening **15** or the central

body **3**. In a similar vein, and although the diameter of the distal end **16** of the central plug **2** of FIG. **4**A is larger than the central opening **15**, it would be apparent to those of skill that the diameter of end **16** is not critical and could be equal or slightly smaller than the opening **15** to accommodate assembly.

The bone surface is optionally prepared with a trocar **17** that has a cutting surface that matches the stabilizer **1** (see FIG. **1**). More particularly, the trochar **17** is comprised of a head **20** connected to an elongate shank **23** which is connected to distal end **19** having cutting edges **18**. This distal end **19** has an external size and configuration to create a concavity in bone that complements the external configuration of the central body **3** when its bone anchors **6** are in the first position. The concavity created by the trochar **17** should be the same size or just slightly smaller than the external size of the stabilizer **1** when in the position of FIG. **4**A. The trochar **17** can be made of any material that can be sterilized, be formed into a cutting edge **18**, and withstand the impact force needed to penetrate bone. Metal alloys such as stainless steel are preferred. The overall diameters of the trochar are not critical and need only be long enough to reach into the joint and extend outside a suitable distance for receiving the impact force, or for drill attachment to a chuck. An overall length of eight to twelve inches with an outside diameter of 0.5 to 1.5 cm is suitable for the anticipated uses.

Alternatively, the bone surface may be prepared with a drill bit that creates a hole in the bone large enough to receive the tissue stabilizer. The cut hole can be either straight or angled to walls to form a Morse taper.

The central plug driver **10** is illustrated in FIG. **2** and is designed to transfer either axillary impact force or torque force to the central plug head **7** to move the central plug **2** from its first to its second position. If impact force is used to move the central plug **2**, the central plug connector **13** is a blunt tapered end or a flat end. If torque force is used to move the central plug **2**, the central plug connector **13** can be flat or be formed into a socket or a hex shape or a cut to shape that will fit into a slot or Phillip's type of head. The handle **11** comprises an elongate shank and a head that is shaped to either receive impact force and transfer that force equally down the shank to the connector **13** such as a flat surface, or shaped to facilitate frictional grasping for application of torque force such as a flattened surface for twisting between the thumb and forefinger or a spherical ball. The overall dimensions of the driver are the same as those provided above for the trochar **17**.

The central plug driver **10** may be used to position the stabilizer **1** into the concavity created by the trochar **17**. To facilitate the positioning of the stabilizer through tissue to bone, the driver and device can be held together by the sutures or the driver **10** can be snap fitted to the stabilizer **1**. The means for snap fitting is not critical. Typical examples include tension wire and groove fittings or dimple, detent fittings. The strength of the fitting should be such that accidental separations are minimized while deliberate separations are possible after insertion into bone without inadvertent pull-outs. Pull-out strengths can be measured according to Shall, et al., "Soft Tissue Reconstruction in the Shoulder: Comparison of Suture Anchors, Absorbable Staples and Absorbable Tacks, *Amer. J. Sports Med.,* 22:715–718 (1994) or Hecker, et al., "Pull-Out Strength of Suture Anchors for Rotator Cuff and Bankart Lesion Repairs," *Amer. J. of Sports Med.,* 21:874–879 (1993). The FDA has also issued recent guidelines.

It should be noted that the claimed stabilizer expands at its distal end. This is in contrast to other expanding anchors that expand equally along their longitudinal axis or at their proximal end as an arrowhead shape. Distal expansion provides improved pullout strength by maximizing overlying bone contact.

Multicomponent kits are also a part of this invention. The kits will include at a minimum the tissue stabilizing device as described herein as a first component. Other components include the drill, sutures and the inserter/suture organizer.

The surgical procedures for which the device is particularly suited are repairs to the shoulder and knee joints such as reconstructing anterior cruciate ligament (ACL) deficiencies and for repairing dislocating shoulders and torn rotator cuffs. However, the stabilizer is universally applicable to most efforts which warrant reattachment of soft tissue to bone. The following, brief description of surgical procedures are not intended to be the only way the inventions described herein could be used and are presented for illustration purposes and not by way of limitation.

For repairing shoulder injuries, the patient is prepared for surgery and within a sterile field two or three incisions are made. The first incision is anterior superior on the shoulder 1 cm lateral to the anterior glenohumeral joint line, and 1 cm beneath the inferior acromion's palpable cortex. This incision is 1.0 cm in length and vertically positioned. The next two incisions are 0.5 cm in length and horizontal to the body axis. The second incision is posterior superior, 1 cm lateral to the posterior glenohumeral joint line, 1 cm beneath the acromion palpable cortex. The third incision is lateral to the acromion just posterior to the greater tuberosity of the humerus and supraspinatus attachment, 1 cm beneath the inferior acromion palpable cortex. All incisions are made just to the depth of superficial subcutaneous tissue. The newer arthroscopic devices allow the posterior incision to be omitted.

The arthroscopic camera equipment is positioned by driving a sharp trocar inside a cannula to the synovium, and then a blunt trocar through the synovium. A scope cannula is positioned through either the lateral or posterior incision. A pressure pump cannula is then posteriorly or laterally positioned and the stabilizer cannula containing a smooth trocar is placed into the anterior glenohumeral joint. The joint is examined to study the effusion and synovium before arthroscopic fluid enters (unless pre-infusion is needed for instrument insertion). One next washes out the joint with Ringer's lactate and checks the labrum for tears and/or detachment. Good practice includes looking at the biceps tendon and inferior cuff from the posterior or lateral position. This process allows one to identify any Bankart lesion or other anterior inferior glenohumeral ligament maladies, or any capsular laxity.

The joint repair is conceptualized to locate the point of stabilizer placement that will maximize joint stability. Selecting a stabilizer with a threaded or smooth cylindrical central plug, one assembles, if not already assembled, the two parts of the stabilizer so that the central plug is approximately 50% of the way into the central body and just contacting the bone anchors. The stabilizer is then snap fitted on the central plug driver, or fixed by the inserter/suture organizer. The tissue to be captured and re-attached is revisualized with usual attention paid to the anterior inferior shoulder and inside the joint. The surgeon then probes the pathology with a smooth trocar through the cannula.

The glenoid rim is prepared either by using a sharp, pointed trocar, by pre-drilling to expose bone, by burring, or by use of the star-tipped trocar as in FIG. **1**. The stabilizer is placed into the anterior shoulder through an accommo-

dating cannula. The stabilizer is then used to pierce the tissue inside the joint, "teasing it" onto the anchors and optimal combs, and the stabilizer is then driven into bone while the assistant surgeon holds the arm up against the glenoid. Next, the central plug is tightened down to expand the bone anchors into their second position for extra fixation security.

In cases where sutures are required, the sutures are attached to the suture fasteners prior to insertion and used in conventional ways to tie additional soft tissue to the bone. A suture-passing device can be used here.

In the final step, the surgeon checks the joint motion, implant and joint stability, and rules out any impingement of the implant against mobile surfaces.

For repairs to the knee, one follows an analogous protocol. Two or three incisions are made to a patient's knee after appropriate external site preparation steps are completed. The first incision is at the femorotibial joint line 1 cm above the tibial plateau palpable surface just medial to the patella tendon, 1 cm in length, and horizontal. The second incision is horizontal, 0.5 cm in length, and along the joint line just lateral to the patella tendon. The third incision is about 3 cm above the top of the patella superolaterally. The incision depths are to subcutaneous tissue. The third incision can usually now be omitted with newer arthroscopic equipment.

The arthroscopic equipment is positioned inferolaterally using the sharp trocar to the synovium and blunt trocar through the synovium. The surgeon then places a stabilizer cannula along the inferior medial 1 cm incision through the skin, and then vertically into the intercondylar notch along the medial parapatellar tendon with a smooth tipped trocar inside a cannula. A pressure pump cannula is then placed above and lateral to the patella, about 3 cm superior to the upper patella border, or attached to new scope equipment. Good practice mandates that all four compartments of the knee joint are then examined to study the effusion and synovium before arthroscopic fluids enter. Care is taken to avoid iatrogenic cartilage injury.

The joint is then washed out with Ringer's lactate, checking the anterior cruciate ligament for location of tear, degree of strand compromise, concomitant ligament conduit attenuation, and remnant attachment tissue qualities.

To place the stabilizer in its optimal position, one must first conceptualize the goals of repair to identify the location on the condyle where the stabilizer will provide maximum security and adequate (isometric) function. The stabilizer is then prepared as above for the shoulder. The pathology is then reprobed to locate tissue to be captured. Most common is damage to the femoral ACL remnant, in repair cases. The stabilizer also provides for secure fixation in reconstruction cases, wherein autografts or allografts are used.

The surgeon then prepares the concavity for implanting the stabilizer by a limited synovectomy, burr notchplasty, and then by exposing bone inside the notch at the inner lateral femoral condyle. A pointed tipped trocar may be used if the upper ligamentous remnant is sufficient, or otherwise the bone can be prepared with the trocar of FIG. **1** used by impact or by drill.

The surgeon then places the joint stabilizer into the anteromedial knee wound through an accommodating cannula. One pierces the anterior cruciate ligament fibers toward the mid and upper section of the remaining attenuated or torn conduit for distal to proximal ACL fixation, teasing as many strands and fibers onto the implant device as can be gathered. The ligament combs are designed to help organize the strands, and the combination of toothed bone anchors and ligament combs or pins will comb, or align, the remaining anterior cruciate fibers before bringing them up to and into bone.

The stabilizer is then driven into the prepared concavity, while the knee is flexed at about **30** degrees, and the assistant surgeon holds the tibia up towards the femur. The central plug is then impacted down, thus expanding the prongs inside the bone, locking the stabilizer into place. The optional use of sutures completes the repair. The surgeon ties the knots if pre-secured using bioabsorbable (#1) PDS suture, or with the suture of choice, and checks the joint clinically for stability and impingement.

All publications and patent applications cited in this specification are herein incorporated by reference as if each individual publication or patent application were specifically and individually indicated to be incorporated by reference.

Although the foregoing invention has been described in some detail by way of illustration and example for purposes of clarity of understanding, it will be readily apparent to those of ordinary skill in the art in light of the teachings of this invention that certain changes and modifications may be made thereto without departing from the spirit or scope of the appended claims.

What is claimed is:

1. A soft tissue anchor device for securing soft tissue to bone, the device comprising:

a central body defining an opening, the body having proximal and distal faces that extend in a lateral direction;

at least two bone anchors extending from the distal face and having distal ends, the distal ends being movable between a first internal and a second external lateral position, each anchor having at least one bone engaging tooth;

means for engaging and gathering soft tissue; and,

a central plug positioned within the opening of the central body and including a head, a shank and a distal portion;

wherein the shank is movable through the opening of the central body so that the distal portion of the plug is positionable between a first upper and second lower axial position; and,

wherein the distal portion of the plug is sized to contact the bone anchors so that when the distal portion of the plug is moved into the second axial position, the distal ends of the bone anchors are moved towards the second lateral position.

2. The device of claim **1** wherein the means for engaging and gathering soft tissue comprises ligament combs that are rigid pins that extend axially from the distal face.

3. The device of claim **1** wherein the means for engaging and gathering soft tissue comprises sharp distal ends on the bone anchors and each engaging tooth is configured to engage and gather soft tissue.

4. The tissue anchor device of claim **1** wherein the central plug is integral with the tissue anchor device.

5. The tissue anchor device of claim **4** wherein the central plug is pressure fitted within the opening.

6. The tissue anchor device of claim **4** wherein the central plug is threaded within the opening.

7. The device of claim **1** wherein the central body is circular.

8. The device of claim **1** wherein said body defines a cylindrical axially extending region, said bone anchors lying substantially completely within the region when the distal ends of the anchors are in the first lateral position with substantial portions of the teeth lying outside the cylindrical region when said distal ends of the anchors are in the second lateral position.

9. The device of claim **1** wherein the number of bone anchors is three.

10. The device of claim 1 wherein the opening of the central body and the shank of the central peg are frictionally mated without threads using smooth surfaces to position the central peg along the axis defined by the opening.

11. The device of claim 10 wherein the head forms a receptor for receiving a driving tool.

12. The device of claim 1 wherein the head of the central plug sits flush with or is internal to the proximal face of the central core when in the second position.

13. The device of claim 1 wherein the device is made of a bioabsorbable material.

14. The device of claim 1 wherein the device is comprised of stainless steel alloy, titanium alloy and cobalt alloys.

15. A method of attaching soft tissue to a bone, the method comprising:

providing a soft tissue anchor device including a bone engaging surface;

providing a bore within the bone;

gathering soft tissue upon the bone engaging surface;

placing the bone engaging surface and gathered tissue within the bore; and

engaging the bone engaging surface with the bone.

16. A soft tissue anchor device configured to be placed within a bore defined within a bone for securing soft tissue to the bone, the device comprising:

a central body having an opening defined therein, the central body comprising a distal face;

at least two bone anchors extending from the distal face, each anchor including at least one bone engaging tooth, each of the at least two anchors being configured to move from an internal position to an external position relative to the central body; and

means for engaging and gathering soft tissue;

wherein when the means for engaging and gathering soft tissue engages soft tissue and the device is within the bore, some tissue is gathered into the bore; and

wherein when the at least two bone anchors are moved from the internal position to the external position when the device is within the bore, the device is secured within the bore.

17. The tissue anchor device of claim 16 wherein each anchor further comprises a sharp distal end that terminates proximally into a bone engaging tooth configured to engage and gather tissue.

18. The tissue anchor device of claim 16 further comprising means for spreading the anchors outwardly, the means for spreading the anchors outwardly comprising a central plug positioned within the opening.

19. The tissue anchor device of claim 18 wherein the central plug is pressure fitted within the opening.

20. The tissue anchor device of claim 18 wherein the central plug is threaded within the opening.

21. A soft tissue anchor device in accordance with claim 16 wherein the means for engaging and gathering soft tissue comprises a sharp distal tip at a distal end of each of the at least two bone anchors.

22. A soft tissue anchor device in accordance with claim 16 wherein the means for engaging and gathering soft tissue comprises the at least one bone engaging tooth included on the at least two bone anchors.

23. A soft tissue anchor device in accordance with claim 22 wherein the means for engaging and gathering soft tissue further comprises a sharp distal tip at a distal end of each of the at least two bone anchors.

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