cartimaix

COLLAGEN MEMBRANE

matricel

ALL IT TAKES TO REGENERATE

WWW.CARTIMAIX.COM

About Cartimaix

Cartimaix is a cell-free, biodegradable collagen membrane used to cover articular cartilage defects during Collagen-covered Autologous Chondrocyte Implantation (CACI) and Matrix-Assisted Bone Marrow Stimulation procedures (MA-MFX).*
During both treatments, Cartimaix supports the natural cartilage regeneration by keeping the cartilage regenerating cells within the defect area.

** In publications also described as Autologous Matrix-Induced Chondrogenesis or Nanofractured Autologous Matrix-Induced Chondrogenesis (NAMIC®)*

The open fibrous, rough side of the membrane

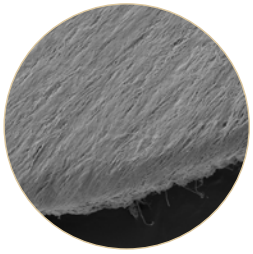
Since 2003 Matricel has accumulated broad experience in the field of collagen-supported regeneration of articular cartilage defects. For example, Matricel's ACI-Maix membrane was the first collagen scaffold approved by the European Medicines Agency as a cell carrier for MACI, the matrix-assisted tissue engineering procedure for the treatment of cartilage defects.
Since then, the therapeutic safety of the ACI-Maix membrane has been demonstrated by more than 8,000 successfully treated MACI patients. Comprehensive studies have shown the efficacy of this method for biological cartilage regeneration. [1-12]

Cartimaix – A two-sided membrane

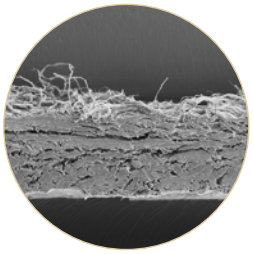
Cartimaix has a two-sided appearance: a dense, smooth side and an open fibrous, rough side. The product combines a barrier function to protect the regeneration area with an adhesion base for chondrocytes or stem cells migrating from the bone marrow.

The membrane is implanted with the dense, smooth side facing in the direction of the joint space. Like a protective shield the membrane covers the treatment area. The cells and growth-promoting factors are maintained where they are needed for an optimal regeneration of cartilage tissue.

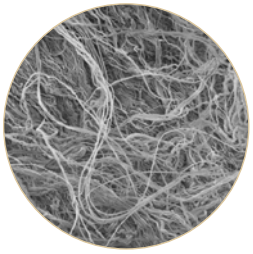
The rough side is implanted facing the cartilage defect and serves with its open fibrous structure as an ideal matrix for the adherence of the cartilage-regenerating cells.



The smooth side of Cartimaix



The two sides of Cartimaix in cross-section



The rough side of Cartimaix

Outstanding Cartimaix features

- Highly purified and safe material based on porcine collagen and elastin
- Excellent handling and mechanical stability of both the dry and the rehydrated membrane
- Creation of a protected environment for tissue regeneration where cartilage-regenerating cells and substances promoting cartilage formation are kept - consequently no loss of cells and valuable substances to the joint space
- Scientifically proven cell compatibility with cartilage-regenerating cells
- Compared with gels slower resorption and higher abrasion resistance to tangential forces
- Complete remodeling of the natural, non-crosslinked collagen during the cartilage regeneration without release of toxic or pH modifying substances

Treatment methods for cartilage regeneration

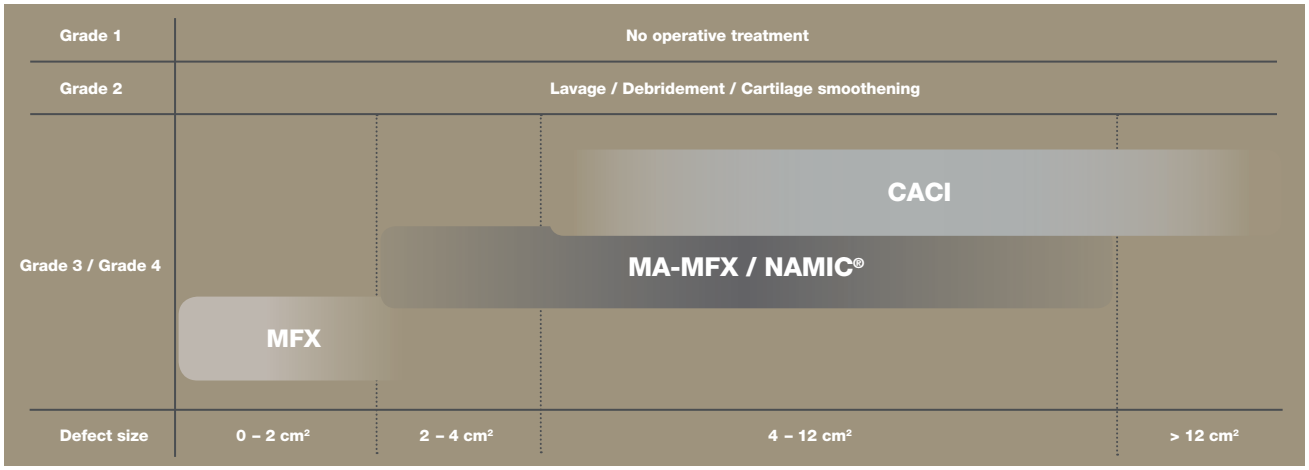
The choice of current treatment methods for the therapy of traumatic and degenerative cartilage defects is based on a scheme dependent on the size of the defect and the ICRS classification (Grade 1-4).

Healthy Cartilage

Grade 1 / Grade 2 Defect
light fissures of the cartilage tissue

Grade 3 Defect
lesion of more than 50% of the cartilage thickness

Grade 4 Defect
complete lesion of the cartilage, extending into subchondral bone



IN GRADE 3-4 DEFECTS AND WITH INCREASING DEFECT SIZE, MORE COMPLEX REGENERATION METHODS ARE REQUIRED:

- For defect sizes up to 2 cm², usually no matrix is used. The typical treatment relies on a perforation of the subchondral bone, e.g. Microfracturing (MFX) or Nanofracturing.
- For defect sizes between 2 and 12 cm² Cartimaix is used for Matrix-Assisted Bone Marrow Stimulation (MA-MFX) or advanced developments of this, for example NAMIC®.
- For very large defects Cartimaix is used in Collagen-covered Autologous Chondrocyte Implantation (CACI) procedures.

Hydrated Cartimaix membrane

MATRIX-ASSISTED BONE MARROW STIMULATION:

Since the first description of Microfracturing (MFX) by Steadman in the early 1990s, bone marrow stimulating techniques are the most common and accepted treatments of articular cartilage defects. Today, excellent results can be achieved in particular when these techniques are used in combination with collagen membranes.

Decisive for the success of the treatment are factors such as the effective protection of the regeneration area, a matrix scaffold that serves as an adhesion base for cartilage formation with a sufficient stability during the regeneration phase and a natural and residue-free resorption of the collagen membrane.

Studies on the regeneration of articular cartilage tissue show significantly better results when implementing Matrix-Assisted Bone Marrow Stimulation techniques compared to Microfracturing without the use of a collagen membrane. These results are also reflected in improved clinical scores.[13–19]

As a further advancement of conventional Matrix-Assisted Microfracturing* the Nanofractured Autologous Matrix Induced Chondrogenesis (NAMIC®) represents a standardized procedure with a defined depth of the bone marrow perforation.[20–22]

COLLAGEN-COVERED AUTOLOGOUS CHONDROCYTE IMPLANTATION (CACI):

For larger defects, the Collagen-covered Autologous Chondrocyte Implantation (CACI) is recommended. Compared with a periosteum-covered ACI, the collagen-covered ACI offers a significantly lower risk of hypertrophy.

This therapy uses the regeneration potential of a patient‘s own chondrocytes, expanded in certified GMP laboratories under controlled conditions. There is no need to perforate the subchondral bone plate.
In CACI treatments Cartimaix is placed with the open fibrous side facing the prepared defect site and sutured with interrupted sutures on the insides of the healthy cartilage.
A waterproof seam is applied with fibrin glue at the edges – only a small opening remains. In this manner, a protected environment is generated above the defect area, into which the chondrocyte suspension is injected in accordance to the manufacturers instructions. Finally, the remaining opening is sutured and glued with fibrin glue.

As part of the CACI treatment Cartimaix also offers an excellent adhesion base for tissue-regenerating cells and protects the valuable cell suspension from a loss of the cells into the joint space.

In publications also described as Autologous Matrix-Induced Chondrogenesis.

Treatment procedure

*The typical Matrix-Assisted Bone Marrow Stimulation treatment is depicted below for the knee.**

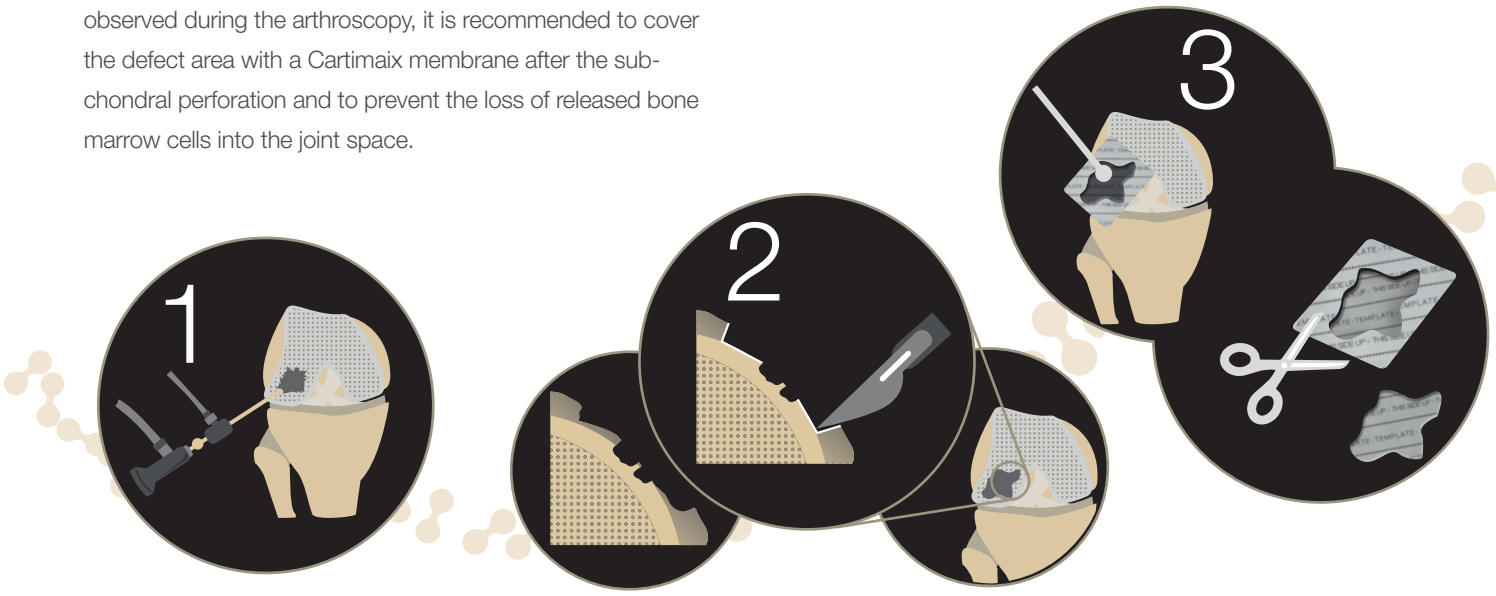
1. INITIAL ARTHROSCOPY

Typically, an initial arthroscopic examination is carried out to assess the extent of joint damage. Size and grade of the cartilage defect can be diagnosed and necessary accompanying interventions, such as the treatment of meniscal damage, can be performed.

For defects smaller than 2 cm^2, debridement of the cartilage defect and a standard Micro- or Nanofracturing is usually a sufficient treatment. In case a defect size larger than 2 cm^2 is observed during the arthroscopy, it is recommended to cover the defect area with a Cartimaix membrane after the subchondral perforation and to prevent the loss of released bone marrow cells into the joint space.

3. OUTLINE IMPRINTING WITH THE TEMPLATE

To facilitate exact cutting of the Cartimaix membrane to the shape of the prepared defect site, each Cartimaix package contains a sterile aluminium foil (“Template”). The outline of the prepared defect can be imprinted by pressing the Template with the blank side into the lesion until the imprint mirrors the defect. According to the shaped contour the Template is cut to size. Finally, the size of the cut-to-size Template can be verified by fitting it into the defect.



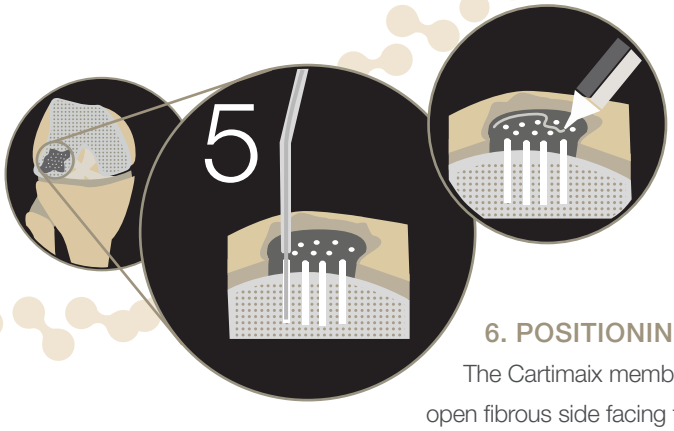
2. PREPARING THE DEFECT

Depending on the cartilage defect localization the knee joint is typically opened by a small incision (miniarthrotomy). The defect is circumscribed with a scalpel to expose healthy cartilage leaving a vertical cartilage wall. Loose and damaged cartilage is debrided down to the subchondral bone plate using a ring curette or osteotome.

4. PREPARATION AND CUT-TO-SIZE OF CARTIMAIX

The Cartimaix membrane is removed from the sterile packaging and can be cut to size either dry or rehydrated. If the dry membrane is cut to size, a slight increase of the membrane surface after rehydration should be considered. The cut-to-size Template is now placed on the Cartimaix membrane, the unprinted side facing the smooth, dense side of Cartimaix. The membrane is cut out along the Template exactly to the contour of the prepared cartilage defect.

After removal of the Template, the cut-to-size Cartimaix membrane can be fitted into the defect area. Due to the excellent handling characteristics of Cartimaix in rehydrated state a correction of the pre-cut after fitting is easily possible. To ensure a secure fixation of the membrane, Cartimaix should be placed within the healthy, vertical cartilage walls and should not overlap them.
Please pay attention to Cartimaix orientation during handling.



5. ESTABLISHING ACCESS TO THE SUBCHONDRAL BONE MARROW

After debridement and preparation of Cartimaix access to the subchondral bone marrow will be established by perforating the subchondral bone plate with a sharp awl or pick.
Recent studies show improved results for thinner and deeper perforations.[20-24] Innovative instruments such as the NanoFX® system generate particularly small perforations of a defined depth to access the subchondral bone marrow. In order to maintain the mechanical stability of the remaining bone bridges, the minimum distance between perforations should not be smaller than 3-5 mm.
Finally, fibrin glue is applied to the perforated area to prepare the wound bed for the subsequent fixation of the membrane within the defect.

6. POSITIONING OF CARTIMAIX

The Cartimaix membrane is placed with its open fibrous side facing the prepared lesion site. Cartimaix is fixed by digitally pressing to the fibrin glue. Additional fixing by interrupted sutures is usually not necessary, but the decision is depending on the respective operating situation and left to the preference of the surgeon. Subsequently after adhesion by the fibrin glue (about 5 minutes), the correct placement of the membrane is checked by moving the joint 10 times.
If required a redon drainage can be applied for 24 hours (without suction). Wound closure and if indicated the application of an immobilizing orthesis complete the surgery.

References regarding the treatment procedure [16, 19-22, 25-27]

** The individual treatment by the surgeon may vary partially from this described procedure. The general principles of sterile handling, applicable patient medication and the general surgical techniques must be followed. Please note the Instructions For Use accompanying the product and the Limitations of Use contained therein.*

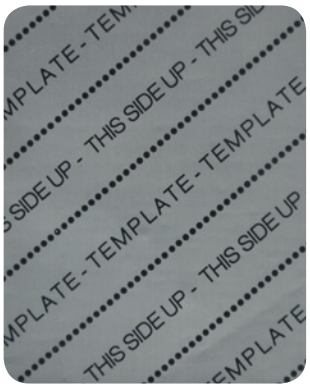
About Matricel

Matricel is a manufacturer of medical devices and starting materials for pharmaceuticals, which are certified e.g. in Europe, Canada and the United States and are used as degradable implants in the field of Regenerative Medicine. The clinical application spectrum of Matricel products ranges from orthopedics and trauma surgery to plastic surgery, dermatology and the dental field.

Cleanroom production at Matricel

Order information

Cartimaix is available in the following product sizes and is supplied in double sterile packaging. Each product contains a Cartimaix membrane and a sterile aluminium Template in the size 40 mm x 50 mm.



Aluminium Template

Order-No.	CAR2530	CAR3040	CAR4050
Product size	25 mm x 30 mm	30 mm x 40 mm	40 mm x 50 mm
Packaging unit	1 Cartimaix Membrane + 1 Template	1 Cartimaix Membrane + 1 Template	1 Cartimaix Membrane + 1 Template

CAR2530

CAR3040

CAR4050

Ordering and further information on Cartimaix and literature references are available on the internet at www.cartimaix.com or www.matricel.com and by phone +49 (0)2407 - 56 44 20.

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