SURGICAL TECHNIQUE

Ensemble CMC™

Pyrocarbon Interpositional Arthroplasty

ENSEMBLE ORTHOPEDICS INC

Table of Contents

Indications For Use 3

Contraindications 3

Warnings & Precautions 3

Product Description 4

Preoperative Assessment 4

Radiographic Visualization 5

Surgical Technique

Step 1: Joint Exposure 6

Step 2: Joint Space Preparation

2.1 Peripheral Rasp Insertion 7

2.2 Osteophyte Removal 8

2.3 Bone Preparation with Saddle Shaping Rasps 9

2.4 Trapezium Shaping with Bump Rasp 10

Step 3: Trial Sizing 11

Step 4: Implant Insertion 12

Step 5: Closure 14

Postoperative Rehabilitation 15

Implant & Instrument List ..... Back Cover

PLEASE NOTE:

The technique description herein is made available to the healthcare professional to illustrate the suggested treatment for the procedure. As the manufacturer of this device, Ensemble Orthopedics Inc. does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The healthcare professional who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.

Indications For Use

The Ensemble CMC™ is intended to replace the joint between the first metacarpal and the trapezium in cases of rheumatoid arthritis, traumatic arthritis, osteoarthritis, or post-fracture deformation or bone loss which present as either a painful, unstable thumb, or a thumb with limited range of motion.

Contraindications

Patient selection and sound surgical principles apply to the use of the Ensemble CMC™ in a given clinical setting. The decision to use an implant as well as the size and shape of the implant used must be based on sound medical judgment. The Ensemble CMC™ should not be used if any of the following are present:

- Evidence of deformity at the base of the metacarpal
- Infection in the joint
- Inadequate bone stock or soft tissue integrity
- Skeletal immaturity
- Patient unable or unwilling to follow preoperative and/or postoperative instructions

Warnings

Do not use the Ensemble CMC™ where the trapezium is severely compromised and the implant cannot be supported. The saddle shape of the implant requires a normal or near normal share of the distal surface of the trapezium. It also requires the restoration of the anatomic shapes of the proximal metacarpal and the distal trapezium to allow proper seating of the prosthesis.

Do not use the Ensemble CMC™ in a joint where soft tissue reconstruction cannot provide adequate stabilization throughout the functional range of motion. Similar to the natural joint, the Ensemble CMC™ attains stabilization from the surrounding capsuloligamentous structures. If soft tissue reconstruction cannot provide adequate stabilization, the device may dislocate or loss of motion may occur.

Do not modify the Ensemble CMC™ in any manner. Reshaping the implant using cutters, grinders, burrs, or other means will damage the structural integrity of the device and could result in implant fracture and/or particulate debris.

Do not grasp the Ensemble CMC™ with metal instruments, or instruments with teeth, serrations, or sharp edges. Contact implants only with instruments provided in the Ensemble CMC™ Instrument Set. Mishandling implants could cause surface damage, reduced strength, implant fracture, and/or particulate debris.

Do not use excessive force to seat the final implant. Excessive force may cause implant fracture. If having difficulty inserting the implant, re-insert the sizing trial to verify proper sizing, and re-rasp the bone surfaces if necessary.

Do not use the Ensemble CMC™ in combination with components from other implant products. Use in combination with other materials or products could damage the structural integrity of the device and could result in implant fracture and/or particulate debris.

Do not re-sterilize the Ensemble CMC™. Re-sterilization may cause surface damage that could result in implant fracture and/or particulate debris.

Precautions

(*A comprehensive list of precautions is located in the Instructions For Use.)*

Surgeons should be thoroughly familiar with the recommended surgical technique and specialized instrumentation available to facilitate implantation of the Ensemble CMC™. Use of other instruments, or deviation from the recommended surgical technique, may result in improper fit or installation of the device.

Improper sizing may result in instability of the implant or limited range of motion leading to excessive stress on the capsulo-ligamentous structures.

Patients should be informed of the importance of following the postoperative rehabilitation prescribed in order to fully understand the possible limitations in activities of daily living. Potential Ensemble CMC™ construct failures such as stress fractures of the bones, subsidence, soft tissue irritation, or incomplete healing may occur as a result of non-compliance to postoperative rehabilitation, strenuous loading, excessive mobility, or construct overloading.

The Ensemble CMC™ is intended for single use only. Violation of this warning may result in loss of performance, function, fit, infection, or device failure.

Product Description

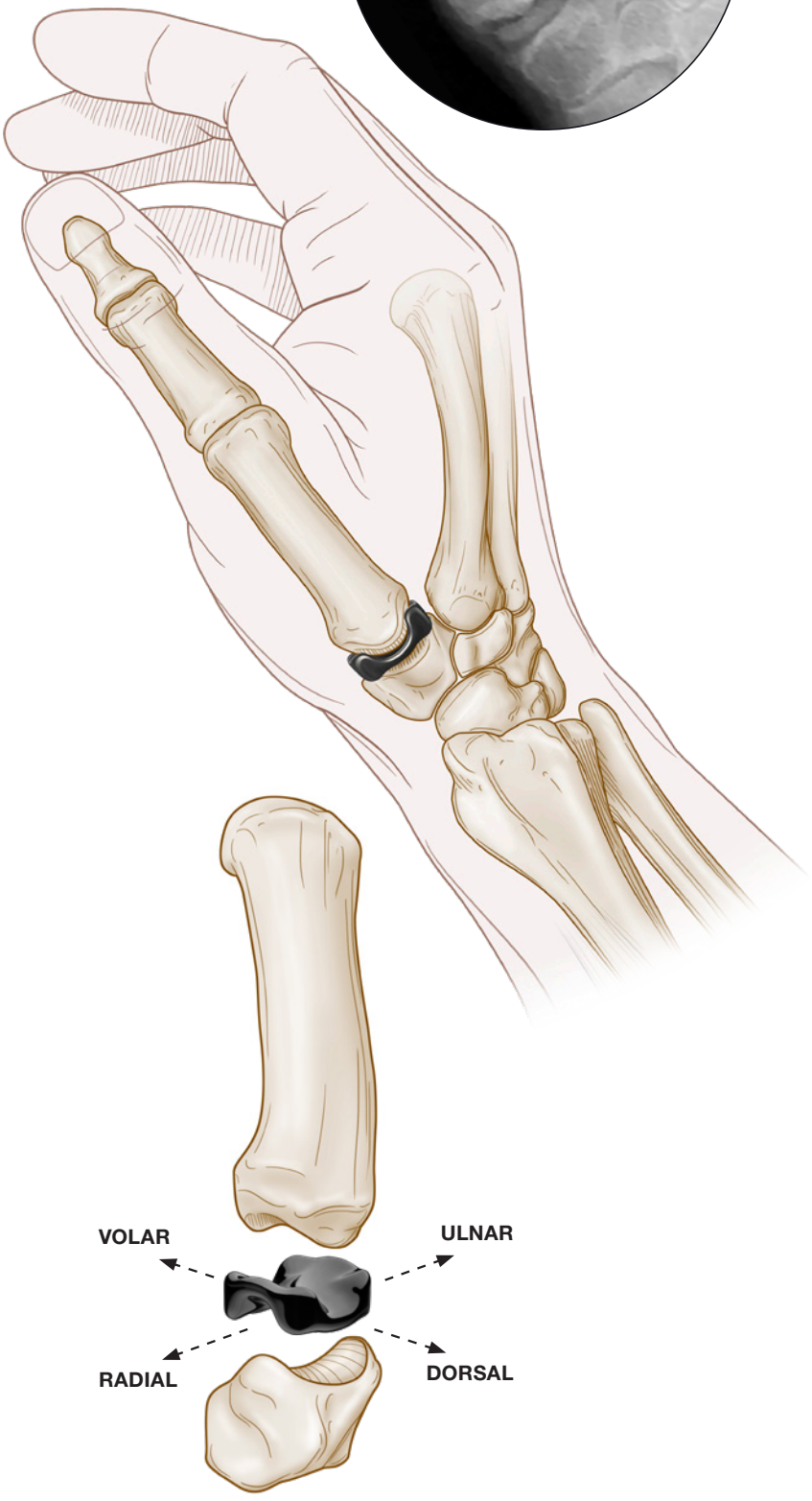
The Ensemble CMC™ is a single-use, one-piece, interpositional joint prosthesis designed to fit into the space between the trapezium and first metacarpal for patients with early stage arthritis of the carpometacarpal joint (CMC). The Ensemble CMC™ implant has upper and lower surfaces that are saddle (toroidal) shaped to match the anatomy of the base of the first metacarpal and trapezium. This design allows for flexion-extension, abduction-adduction, and circumduction motions. The implant is manufactured with an On-X® Carbon layer encasing a graphite core and comes in three sizes. Each device is provided sterile in packaging containing a single implant, Instructions for Use, and patient chart labels.

The choice of implant size is based on the geometry of the joint. The three Ensemble CMC™ sizes correspond to the anatomic variations in the cross-section of the trapezium and first metacarpal of the joint, specifically the Radial/Ulnar dimension and the Dorsal/Volar dimension.

Preoperative Assessment

Initial physical and radiographic evaluations should be performed to determine if the patient is a candidate for the Ensemble CMC™, including:

- Obtain thorough history for optimal patient selection including determination of whether patient has responded to conservative treatment.
- Perform physical assessment of the thumb joint including pinch/grip strength and a grind test.
- Obtain radiographic views of the trapezium to assess the level of basal thumb arthritis in the joint as well as the location and size of any osteophytes present.



Radiographic Visualization

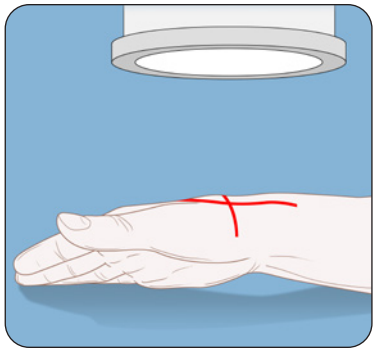
Optimal radiographic visualization of the CMC joint is key to the success of the Ensemble CMC™ procedure.

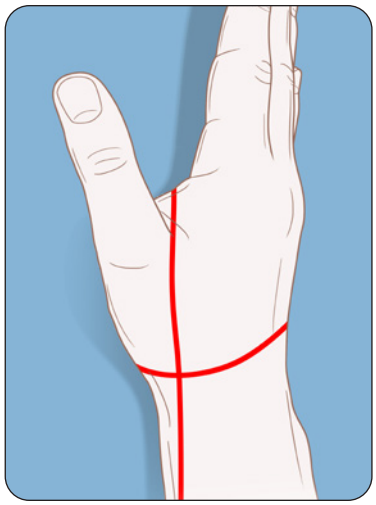
Throughout this technique, two views of the CMC joint shall be referenced that will adequately allow visualization of the CMC joint: the peritrapezial (A/P) view of the trapezium and the lateral view of the trapezium. The goal of each is to obtain a clear, unobstructed view of the trapezium and the joint space between the parallel radiopaque sclerotic areas of the joint.

How to Obtain a Peritrapezial or A/P View of the Trapezium:

From the neutral forearm position:

- pronate the forearm 40°,
- ulnarly deviate the wrist 30°, and
- radially abduct the thumb 30°.

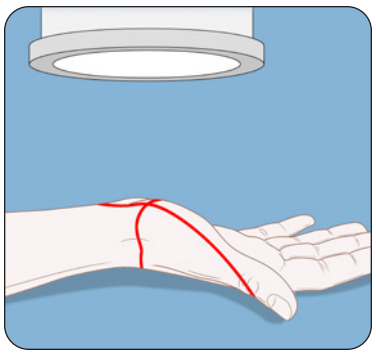


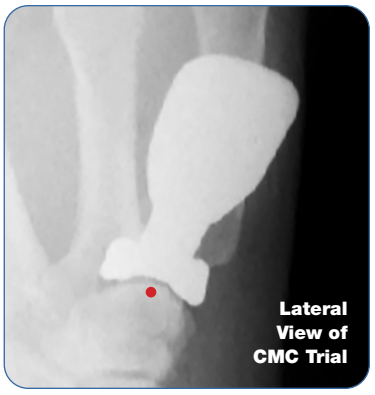


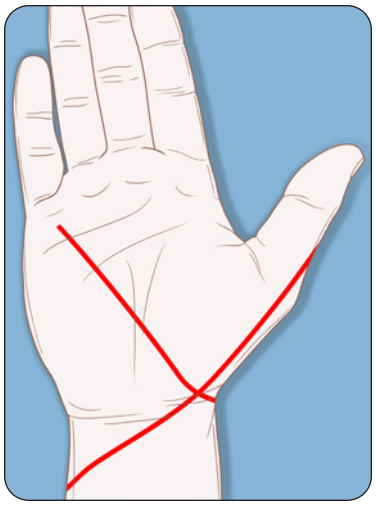
How to Obtain the Lateral View of the Trapezium:

From the neutral forearm position:

- supinate the forearm approx. 60° and position plane of thumbnail perpendicular to plane of the table
- ulnarly deviate wrist approx. 20°, and
- extend the wrist 15°.







Step 1: Joint Exposure

Surgical Insights:

- → *The location of the incision is crucial to the success of the procedure.*
- → *To enhance implant stability, ensure that – aside from the incision made to access the joint space – the joint capsule remains intact.*

Confirm the location of the CMC joint under fluoroscopy. Make a 2 cm glabrous skin incision centered on the CMC joint exposing the palmar edge of APL **(FIGURE 1).**

During dissection, retract small cutaneous branches of the radial nerve dorsally and reflect thenar muscles sharply off the CMC joint capsule, in a palmar direction.

Make a capsular incision along the APL, avoiding disruption of dorsal and volar ligaments. **(FIGURE 2).** Elevate capsule edges and APL to expose the radial horn of the trapezium and identify its peak **(FIGURES 3-4).** Elevate the APL and thenar muscle along the midline of this point. This is generally 90° to the plane of the thumbnail.

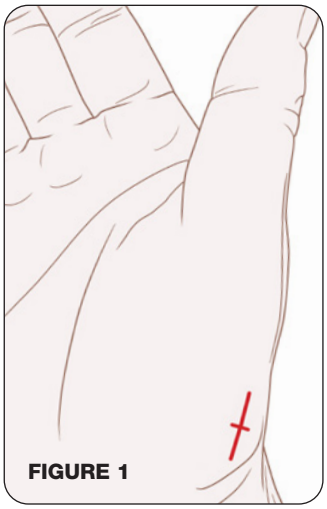


FIGURE 1

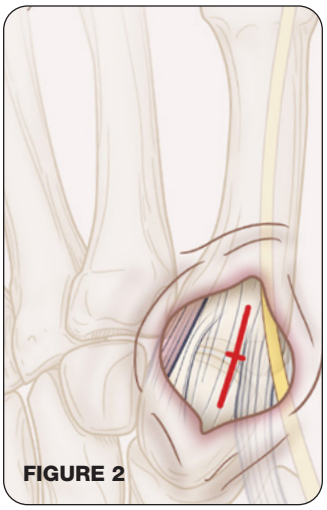


FIGURE 2

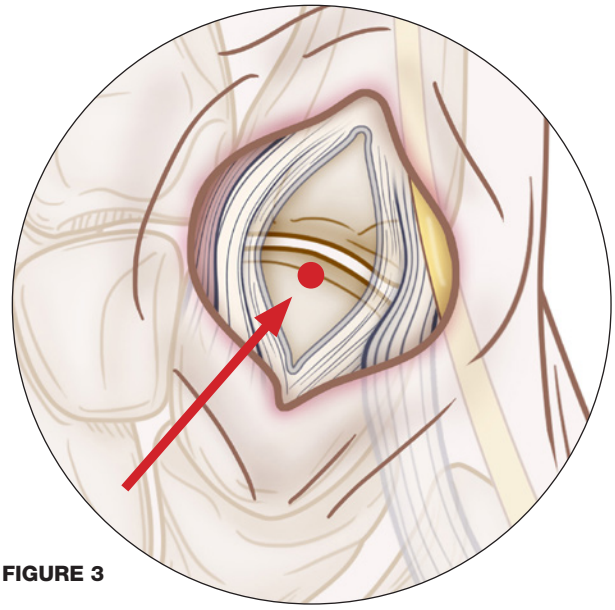
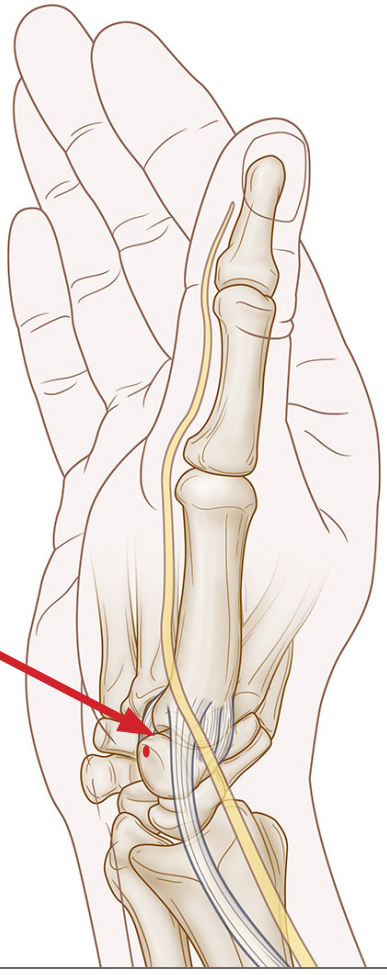


FIGURE 3



Surgical Window:
Open Capsule under the APL, between AOL and DRL.

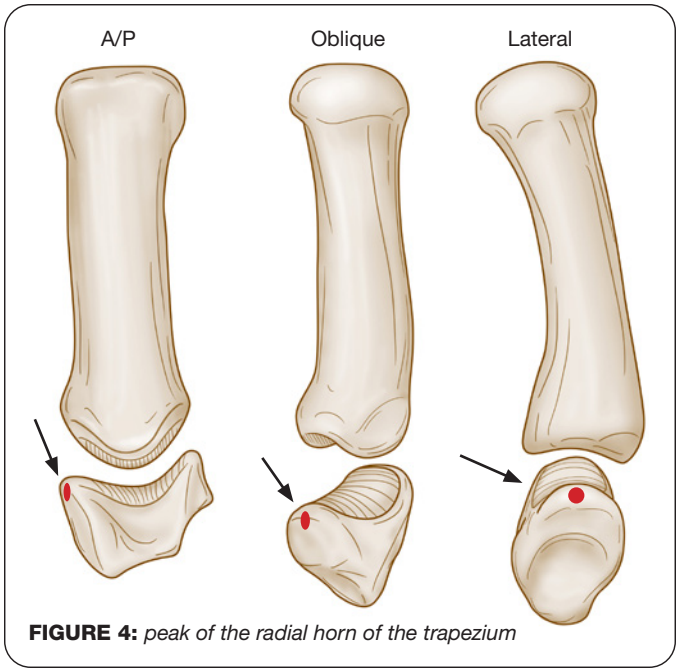


FIGURE 4: *peak of the radial horn of the trapezium*

Step 2: Joint Space Preparation

2.1 Peripheral Rasp Insertion

NOTE: To aid in orientation, all Ensemble CMC™ instruments have a handle that points distally towards the metacarpal. The path of each instrument should follow the natural curvature of the joint.

Surgical Insight:

→ *Prior to any bone preparation, remove all loose bodies from within the joint space.*

The **Peripheral Rasp** is used to determine the presence of osteophytes and initially assess the shape of the articular surfaces. It can also be used to identify medial osteophytes. The Peripheral Rasp is thinner than the other rasps allowing for easier insertion into the wound to access the joint space.

Assess Trapezial Curvature

Under fluoroscopy, gauge the A/P curvature of the distal articular surface of the trapezium.

Insert the Peripheral Rasp into joint space (**FIGURE 5).** Using fluoroscopy, visualize the A/P view of the trapezium and assess whether the rasp can be inserted across the joint to the medial side of trapezium. If the Peripheral Rasp cannot cross the joint, there may be too much trapezial curvature. The trapezium should be flattened, using a rongeur, until the rasp can cross the joint space (**FIGURE 6).**

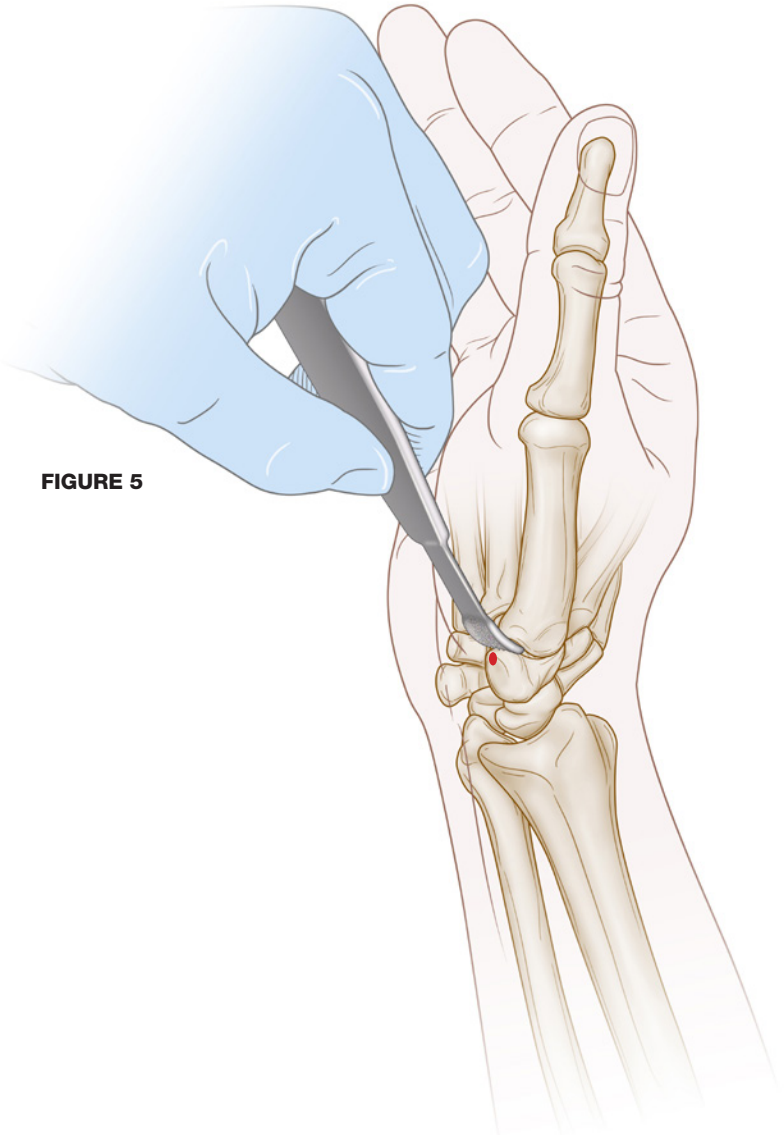


FIGURE 5

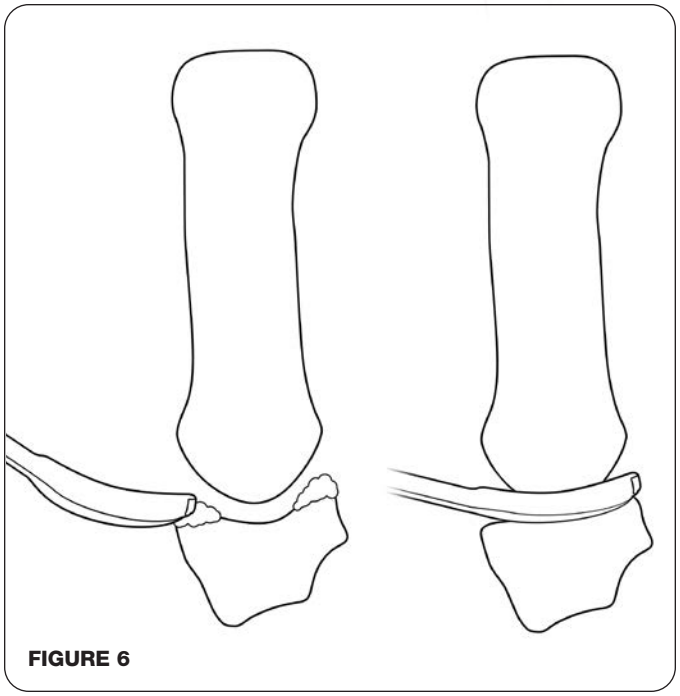


FIGURE 6

Joint Space Preparation (cont'd.)

2.2 Osteophyte Removal

Obtain A/P and Lateral radiographic views of the trapezium to assess the location and size of any osteophytes present.

The site of the most common osteophytes in the CMC joint are on the radial horn of the trapezium, the volar/ulnar (or medial) quadrant of the articular surface of the trapezium, and the ulnar side of the metacarpal base **(FIGURE 7).**

Based on fluoroscopy and joint anatomy assessment with the Peripheral Rasp, remove identified osteophytes in the recommended order **(FIGURE 8):**

1. Using a small rongeur, trim off 1-2 mm of the radial horn of the trapezium to open up the joint space for visualization and instrument insertion.
2. Trim off the ulnar (or medial) horn of the trapezium. If the Peripheral Rasp cannot cross the base of the metacarpal, assess the presence of any medial osteophytes. Remove using a rongeur, burr*, or osteotome. Reinsert the Peripheral Rasp and assess whether the rasp can be moved across the entire width of the metacarpal and trapezium.

   Perform burring under fluoroscopy – recommended burr size 2.5 – 3.0.
3. Assess the osteophyte presence in the volar/ulnar (or medial) portion of the metacarpal.

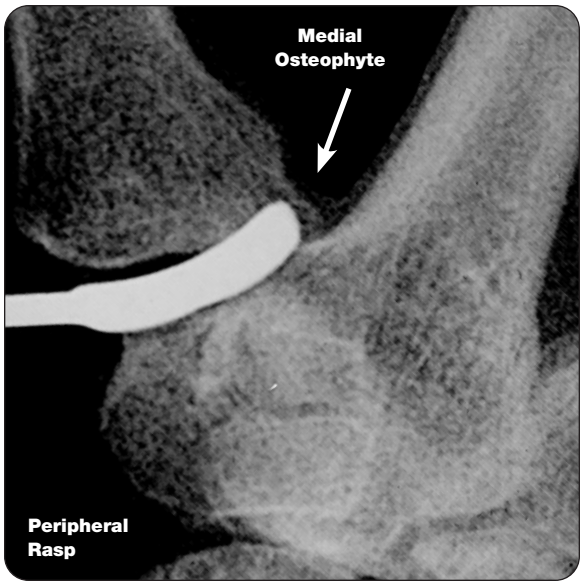


FIGURE 7:
shotgun view of the CMC joint space

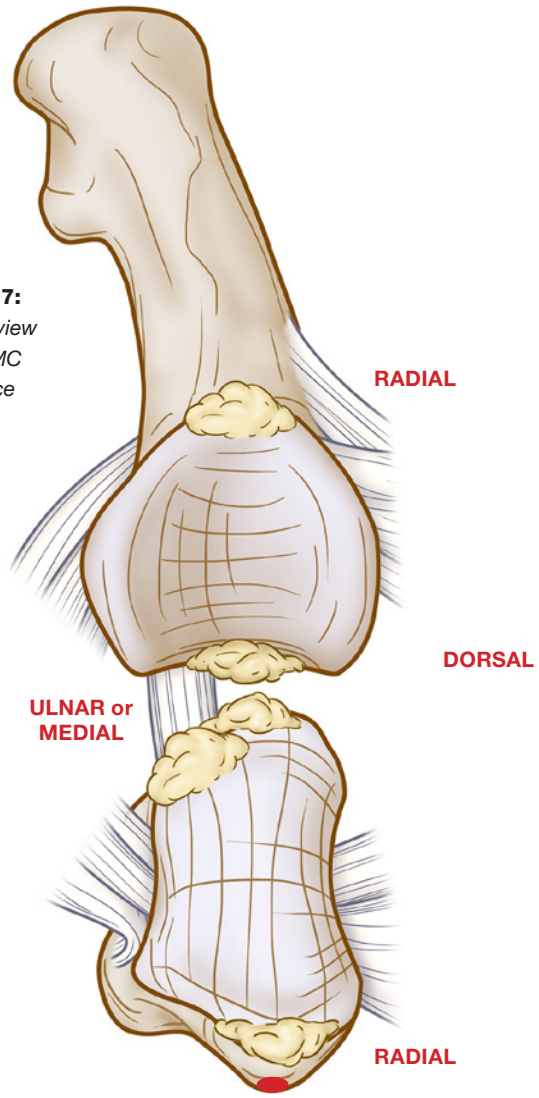
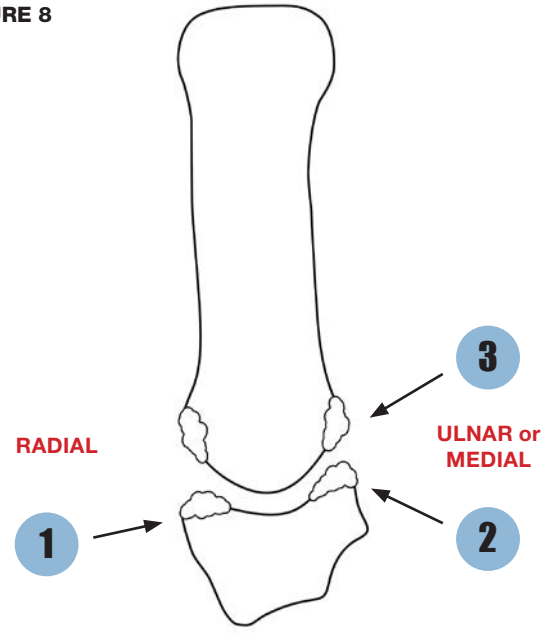


FIGURE 8



Joint Space Preparation
(cont'd.)

2.3 Bone Preparation with Saddle Shaping Rasps

The **Trapezium Rasp** is used to shape the trapezium to approximate the proximal curvature of the Ensemble CMC™ device. There are teeth on the trapezial side of the instrument only.

The **Saddle Rasp** is used to shape the base of the metacarpal and the trapezium to approximate the curvatures of the Ensemble CMC™ device. There are teeth on both sides of the instrument that can remove bone across the entire articular surface of the joint.

Bone Shaping in A/P View of Trapezium

Confirm the Saddle Rasp can be inserted freely across the width of the metacarpal base and trapezium (similar to assessment done with Peripheral Rasp), **FIGURE 9.**

If the joint space is too tight to insert the Saddle Rasp, use the Trapezium Rasp to shape the trapezium and allow insertion of the Saddle Rasp.

Remove any osteophytes that are interfering with the Saddle Rasp, using a rongeur or burr*. Shape the base of the metacarpal with arcing pull strokes of the rasp **(FIGURE 10)**.

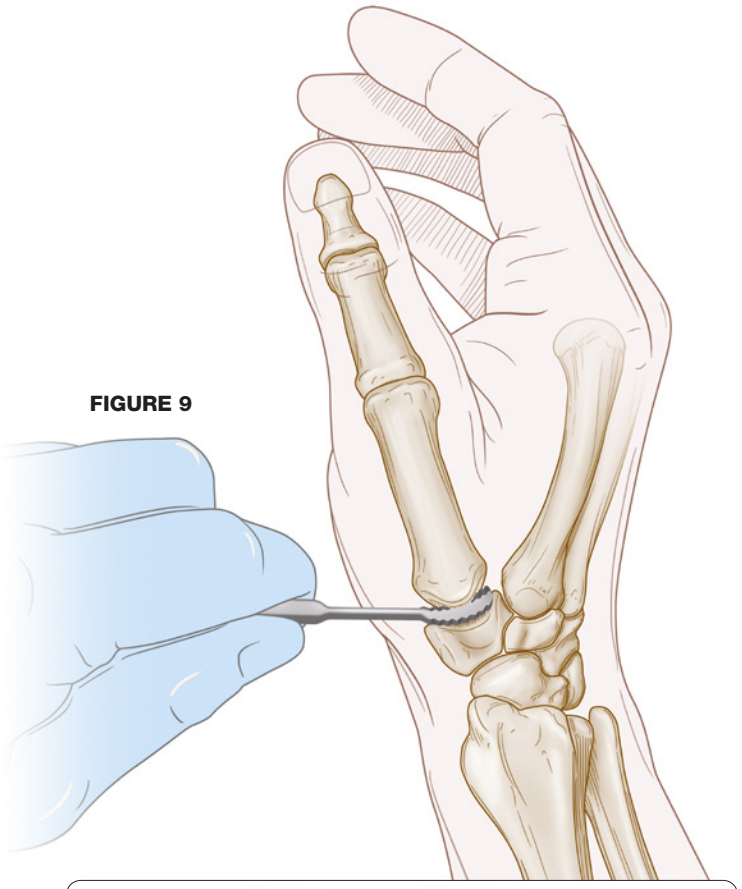
NOTE: Perform burring under fluoroscopy – recommended burr size 2.5 – 3.0.

Bone Shaping in Lateral View of Trapezium

In the lateral view, assess if the shape of the trapezium matches the curvature of the Saddle Rasp. Rasp the trapezium until the Saddle Rasp uniformly contacts the articular surface **(FIGURE 11).**

Visually assess the position of the rasp looking into the wound **(FIGURE 11 – INSET).**

FIGURE 9



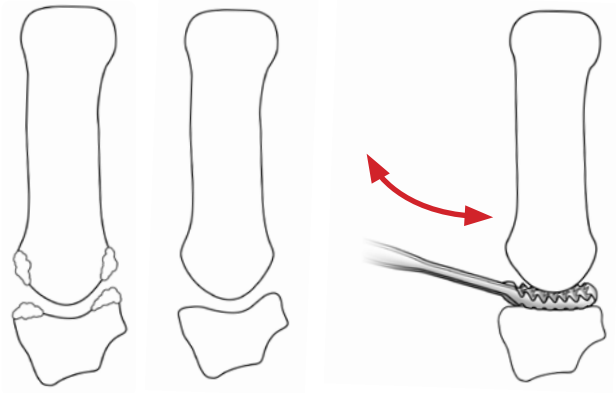


FIGURE 10: *Use arcing, pull strokes of the Saddle Rasp to shape the metacarpal and trapezium.*

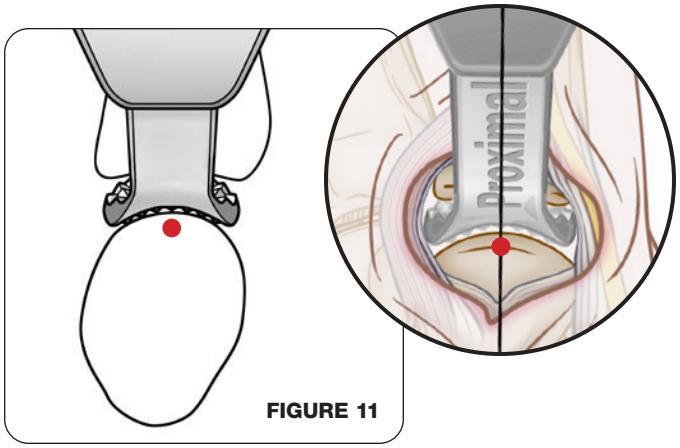


FIGURE 11

Joint Space Preparation
(cont'd.)

2.4 Trapezium Shaping with Bump Rasp

The **Bump Rasp** is used to create clearance channels for the peripheral protrusions of the Ensemble CMC™ device to assure that the proximal surface of the implant contacts the trapezium in the center. The teeth of the Bump Rasp are used on the trapezium only.

Create Implant Bump Clearance

Confirm the Bump Rasp can be inserted freely across the width of the trapezium (similar to assessment done with Saddle Rasp). Visually assess the position of the rasp looking into the wound **(FIGURE 12)**.

Shape the distal articular surface of the trapezium with radial-to-medial flat pull/push strokes of the Bump Rasp **(FIGURE 13 – INSET)** to create two separate radial-to-medial grooves – one dorsal and one volar – across the trapezial surface **(FIGURE 13)**. This aids in implant insertion, providing clearance for the peripheral bumps, as well as the dorsal-volar positioning of the implant.

Bone Shaping in Lateral View of Trapezium

Under fluoroscopy, assess the fit of the Bump Rasp with the curvature of the lateral side of the trapezium. If there is no center contact of rasp on the trapezium, continue shaping until center contact is achieved **(FIGURE 14)**.

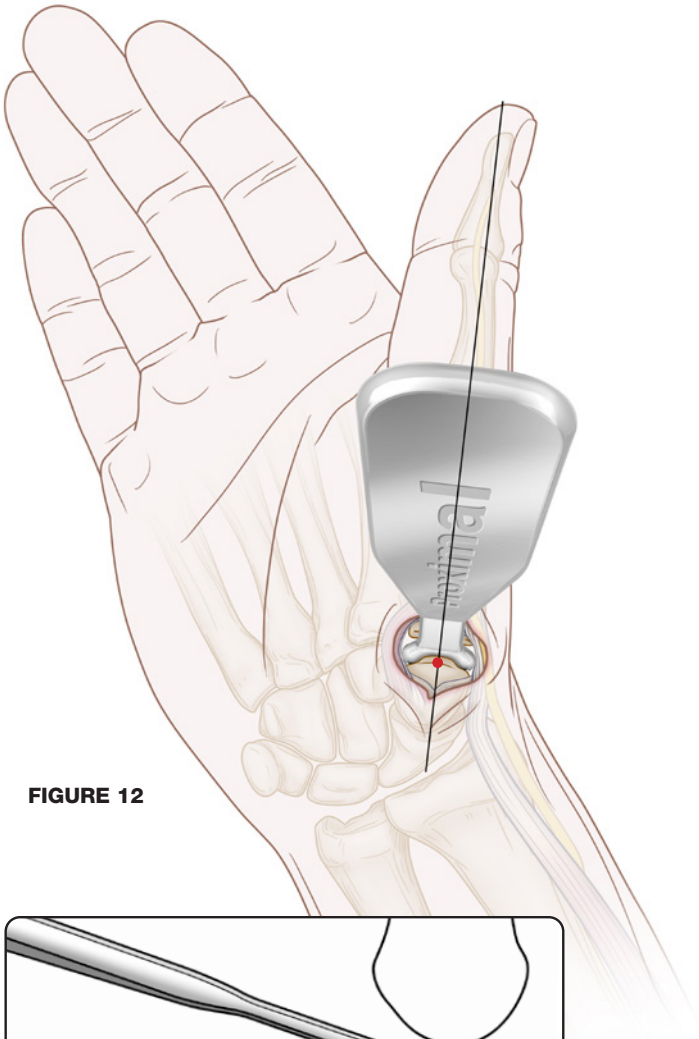
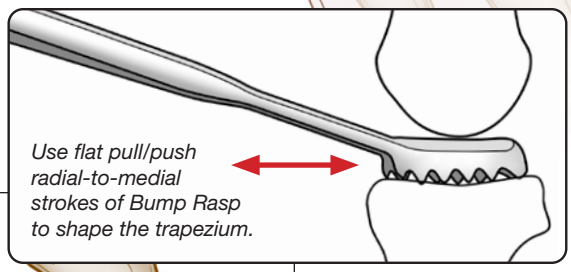


FIGURE 12



Use flat pull/push radial-to-medial strokes of Bump Rasp to shape the trapezium.

FIGURE 13

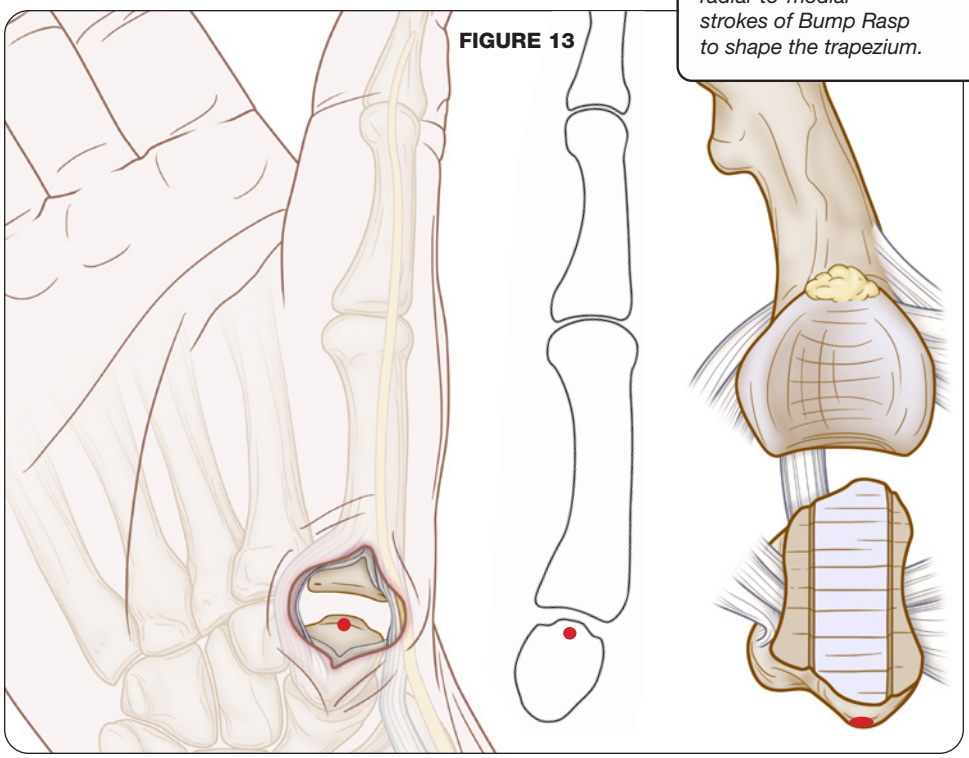
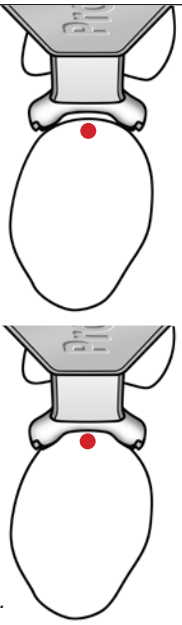


FIGURE 14



Continue shaping to achieve center contact of Bump Rasp on trapezium.

Step 3: Trial Sizing

Surgical Insight:

→ *If the Trials are positioned well in the joint space, there are no obstructive osteophytes, and the joint can move through a full range of motion, no additional preparation is required and the final implant can be inserted.*

Select the **Size 151 Trial** initially. Insert the trial, first introducing one corner of the trial **(FIGURE 15)** and then straightening the trial to align with the radial-to-medial curvature of the trapezium in an arcing motion **(FIGURE 16).**

The trial should insert easily across the joint and be stable. If not, assess the A/P radiograph, then continue to remove osteophytes and shape joint surfaces to create more joint space **(FIGURE 17).**

Under fluoroscopy, evaluate trial sizing, ensuring that:

a. The trial does not interfere with the range of motion of the joint.

b. The metacarpal base is wrapped with the trial.

c. There is center contact of the implant on both the metacarpal and trapezium (**FIGURE 18).**

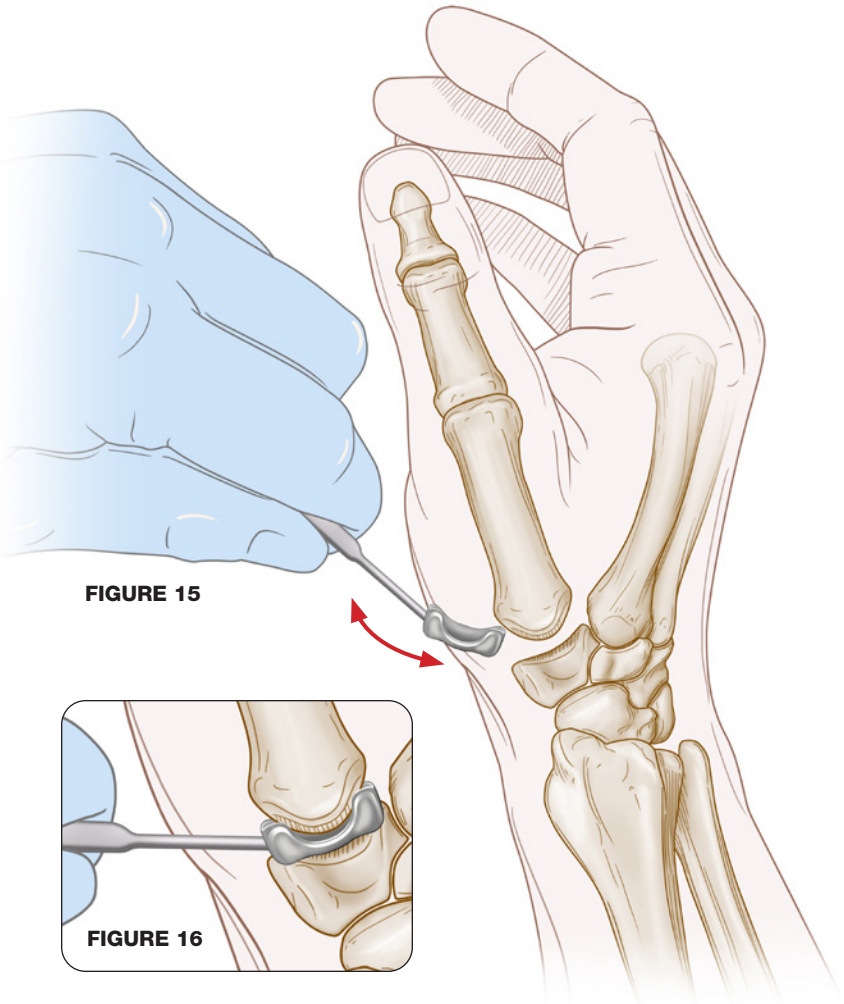


FIGURE 15

FIGURE 16

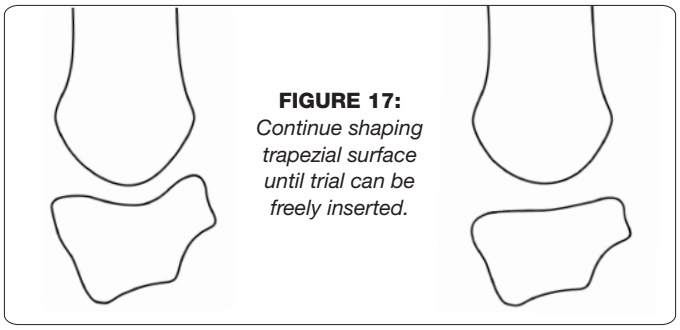


FIGURE 17: *Continue shaping trapezial surface until trial can be freely inserted.*

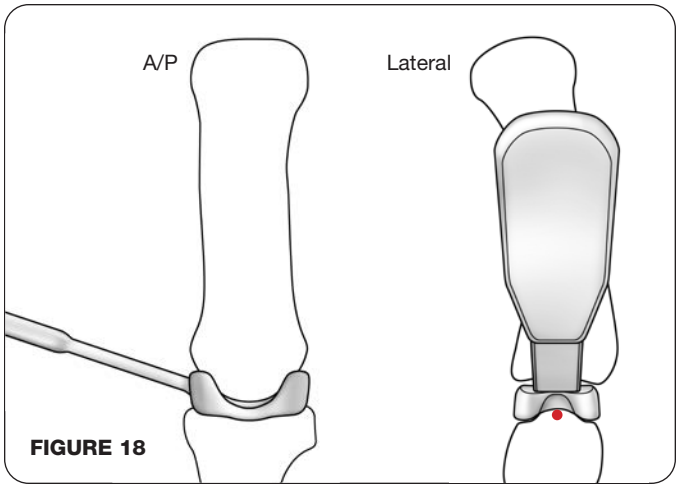


FIGURE 18

Step 4: Implant Insertion

Surgical Insights:

- → *Sizing and positioning of the implant should be confirmed using fluoroscopy. It is important to have the correct orientation of the trials and implants upon insertion.*
- → *The implant should be centered on the saddle of the trapezium with contact through the center of the joint.*
- → *The implant should provide adequate trapezial coverage without inhibiting joint range of motion.*

Open the **Ensemble CMC™** that corresponds to the selected trial size. Use the trial to confirm orientation of the implant before insertion, matching long edges and curvature **(FIGURE 19).**

Pinch the short edge of the implant. Similar to the introduction of the trial, use a corner to introduce the implant into the joint space **(FIGURE 20)** and then push the implant in using your thumb **(FIGURE 21).**

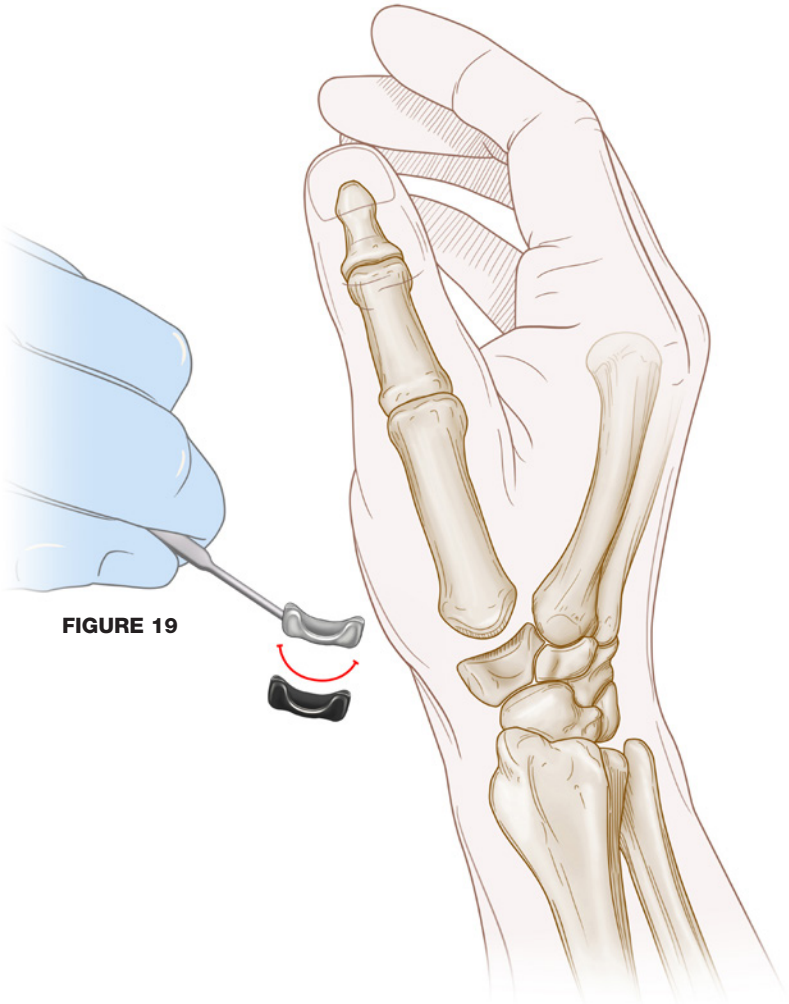


FIGURE 19

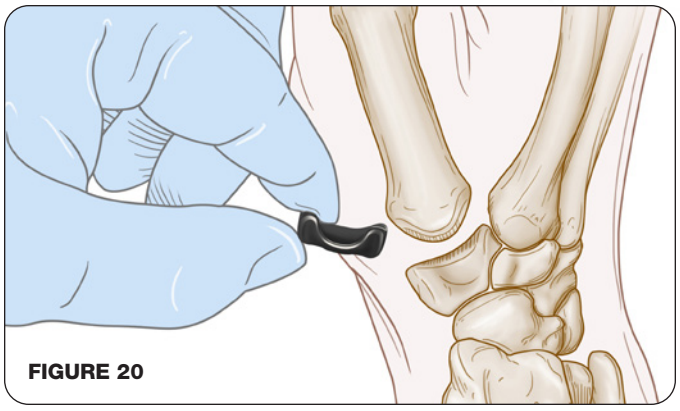


FIGURE 20

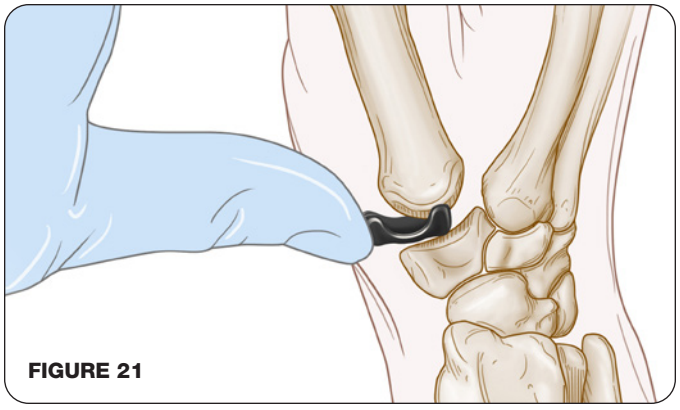


FIGURE 21

Implant Insertion
(cont'd.)

Under fluoroscopy, assess the placement of the implant in both the A/P and lateral views of the trapezium **(FIGURE 22).** The implant should allow the metacarpal to settle into the center of the implant without inhibiting the range of motion **(FIGURE 23).**

Circumduct the thumb and touch the tip of the thumb to the tip of the 5th digit.

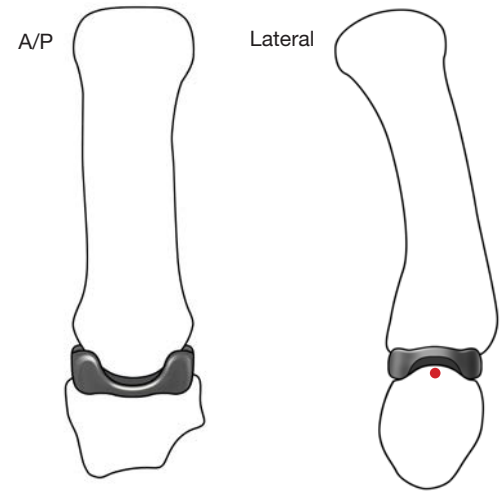


FIGURE 22: *center contact of the implant*

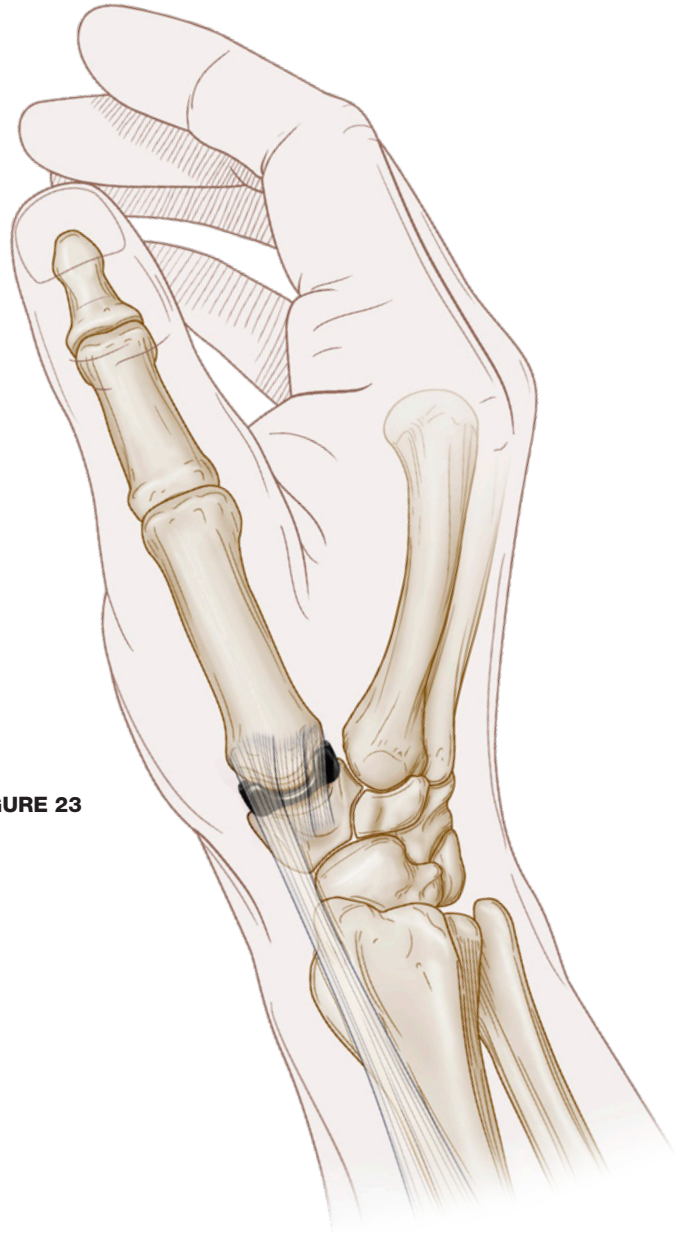


FIGURE 23

Step 5: Closure

Suture the two edges of the capsule together using a non-cutting needle **(FIGURE 24).**

Reposition the radial nerve and thenar muscle over the capsule.

Close the skin incision **(FIGURE 25).**

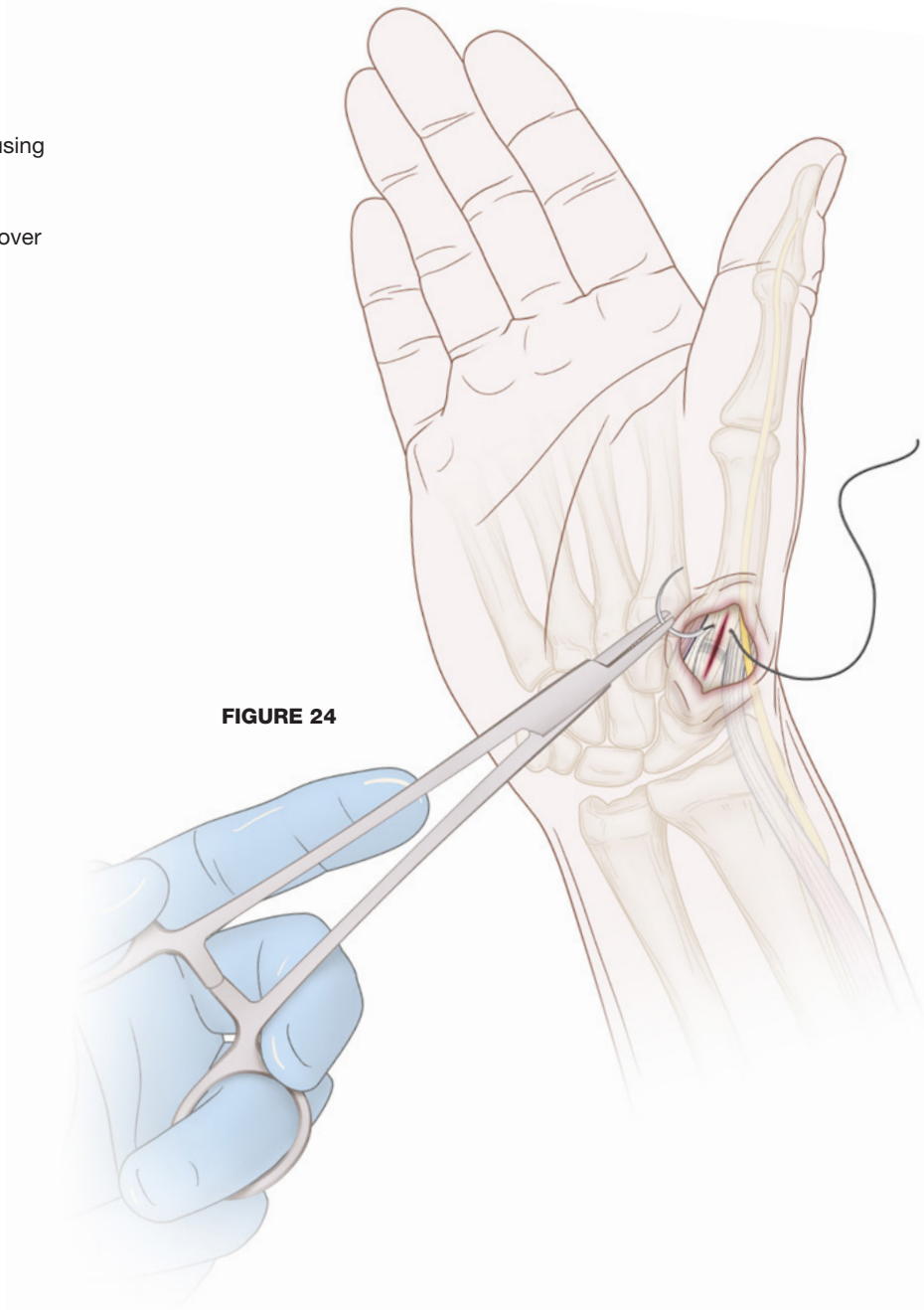


FIGURE 24

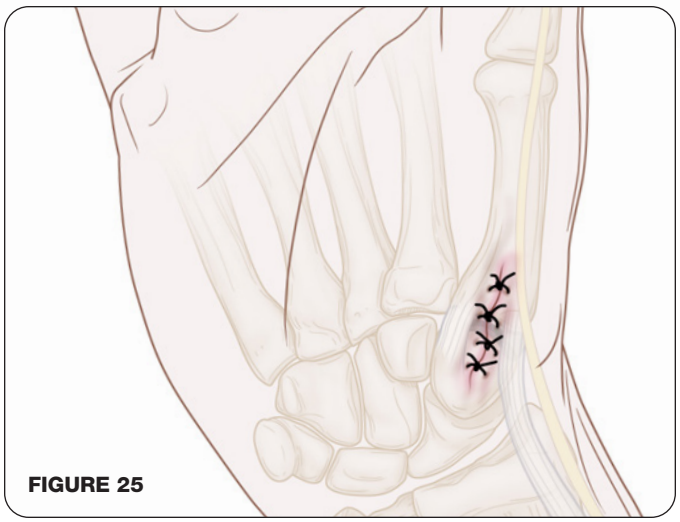


FIGURE 25

Postoperative Rehabilitation

For optimal outcomes, immobilize CMC joint for a minimum of 4 weeks.

The Ensemble CMC™ surgical procedure minimizes disruption of critical, stabilizing soft-tissue structures, which may allow for quicker recoveries. Providing careful postoperative guidance in terms of timing and activity level can help manage patient expectations.

Based on users' reported postoperative protocols, we recommend the following guidelines, which can be tailored on a case-by-case basis.

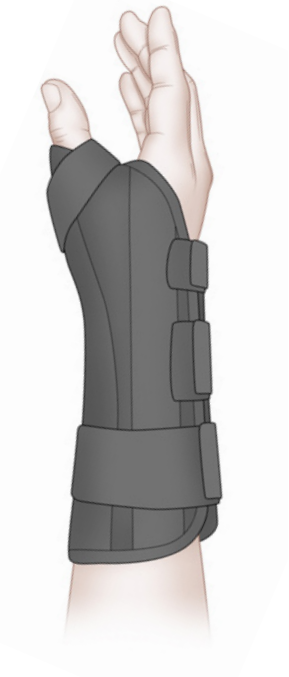
Phase 1 – Immediate Post-surgical Phase, Weeks 0-2:
Start CMC immobilization with wrist-based cast.

Phase 2 – Protection Phase, Weeks 2-4:
Continue CMC immobilization with hard, removable wrist-based splint.

Phase 3 – Intermediate Phase, Weeks 4-12:
Initiate CMC mobilization. Light activities as tolerated. Wear thumb spica splint as needed during high demand activities.

Phase 4 – Final Phase, Weeks 12+:
Advanced activities as tolerated.

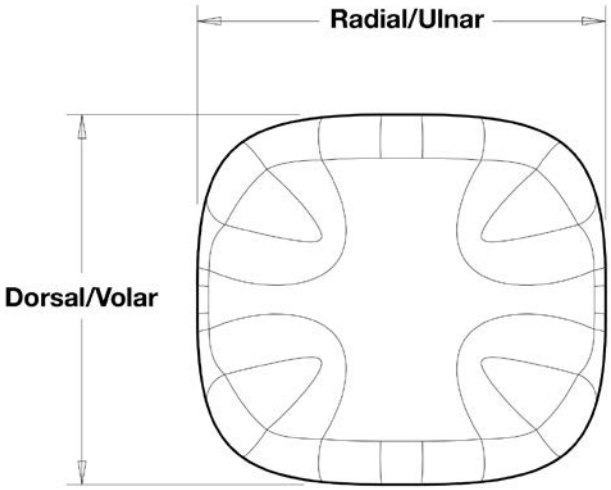
Phase 1: Wrist-based Cast



Phase 2: Removable Wrist-based Splint

Phase 3: Thumb Spica Splint

Implant & Instrument List



Implant Catalog Number	Dimensions (mm)		
	Radial/ Ulnar	Dorsal/ Volar	Center Thickness
101-CMC-141	14.5	13.0	3.0
101-CMC-151	15.6	14.0	3.0
101-CMC-161	16.6	15.0	3.0

Catalog Number	Description	Type / Size
103-RSP-001	CMC Rasps	Peripheral
103-RSP-002		Saddle
103-RSP-003		Bump
103-RSP-005		Trapezium
103-TRL-141	CMC Trials	141
103-TRL-151		151
103-TRL-161		161

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LBL-73-101-06 Rev E