ENSEMBLE ORTHOPEDICS INC

Facility Approval Packet

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Revision: January 2026

Minimally Invasive
Joint Replacement for the Hand

ENSEORT-01 JBLANK

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 12/29/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME: Joann Blank
Acrisure Great Lakes Partners Insurance Services, LLC 223 West Grand River Ave #1 Howell, MI 48843	PHONE (A/C, No, Ext): (216) 658-7830 FAX (A/C, No): E-MAIL ADDRESS: joblank@acrisure.com

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
Ensemble Orthopedics, Inc 2621 Ridgepoint Dr, Suite 100 Austin, TX 78754	INSURER A : Hartford Underwriters Insurance Company	30104
	INSURER B : Hartford Insurance Company (USE ONLY FOR MULTIPLE HARTFO	00914
	INSURER C : ProAssurance Specialty Insurance Company	17400
	INSURER D :	
	INSURER E :	
	INSURER F :	

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			45SBMAJ7UTX	12/31/2025	12/31/2026	EACH OCCURRENCE	$ 1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 1,000,000
							MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 2,000,000
	POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ Included
	OTHER: Business Liability General Aggre							$
A	AUTOMOBILE LIABILITY			45SBMAJ7UTX	12/31/2025	12/31/2026	COMBINED SINGLE LIMIT (Ea accident)	$
	ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
A	X UMBRELLA LIAB OCCUR			45SBMAJ7UTX	12/31/2025	12/31/2026	EACH OCCURRENCE	$ 4,000,000
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$
	DED X RETENTION $ 10,000						Umbrella Covera	$
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N	N / A		45WECAT9WY4	11/8/2025	11/8/2026	PER STATUTE OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH)						E.L. EACH ACCIDENT	$ 1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
							E.L. DISEASE - POLICY LIMIT	$ 1,000,000
C	Products Liability			N23TX380038	12/31/2025	12/31/2026	Each Occurrence	5,000,000
C				N23TX380038	12/31/2025	12/31/2026	Aggregate	500,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

For Record Purposes Only

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Form **W-9**
(Rev. March 2024)
Department of the Treasury
Internal Revenue Service

Request for Taxpayer Identification Number and Certification

Go to *www.irs.gov/FormW9* for instructions and the latest information.

Give form to the requester. Do not send to the IRS.

Before you begin. For guidance related to the purpose of Form W-9, see *Purpose of Form*, below.

Print or type. See *Specific Instructions* on page 3.

1 Name of entity/individual. An entry is required. (For a sole proprietor or disregarded entity, enter the owner's name on line 1, and enter the business/disregarded entity's name on line 2.)

Ensemble Orthopedics, Inc.

2 Business name/disregarded entity name, if different from above.

3a Check the appropriate box for federal tax classification of the entity/individual whose name is entered on line 1. Check only **one** of the following seven boxes.

☐ Individual/sole proprietor ☑ C corporation ☐ S corporation ☐ Partnership ☐ Trust/estate

☐ LLC. Enter the tax classification (C = C corporation, S = S corporation, P = Partnership) . . . . .

Note: Check the "LLC" box above and, in the entry space, enter the appropriate code (C, S, or P) for the tax classification of the LLC, unless it is a disregarded entity. A disregarded entity should instead check the appropriate box for the tax classification of its owner.

☐ Other (see instructions)

4 Exemptions (codes apply only to certain entities, not individuals; see instructions on page 3):

Exempt payee code (if any)

Exemption from Foreign Account Tax Compliance Act (FATCA) reporting code (if any)

(Applies to accounts maintained outside the United States.)

3b If on line 3a you checked "Partnership" or "Trust/estate," or checked "LLC" and entered "P" as its tax classification, and you are providing this form to a partnership, trust, or estate in which you have an ownership interest, check this box if you have any foreign partners, owners, or beneficiaries. See instructions . . . . . ☐

5 Address (number, street, and apt. or suite no.). See instructions.

PO Box 143987

6 City, state, and ZIP code

Austin, TX 78714

Requester's name and address (optional)

7 List account number(s) here (optional)

Part I Taxpayer Identification Number (TIN)

Enter your TIN in the appropriate box. The TIN provided must match the name given on line 1 to avoid backup withholding. For individuals, this is generally your social security number (SSN). However, for a resident alien, sole proprietor, or disregarded entity, see the instructions for Part I, later. For other entities, it is your employer identification number (EIN). If you do not have a number, see *How to get a TIN*, later.

Note: If the account is in more than one name, see the instructions for line 1. See also *What Name and Number To Give the Requester* for guidelines on whose number to enter.

Social security number

			–		–				

or

Employer identification number

2	7	–	4	1	8	4	6	3	1

Part II Certification

Under penalties of perjury, I certify that:

1. The number shown on this form is my correct taxpayer identification number (or I am waiting for a number to be issued to me); and
2. I am not subject to backup withholding because (a) I am exempt from backup withholding, or (b) I have not been notified by the Internal Revenue Service (IRS) that I am subject to backup withholding as a result of a failure to report all interest or dividends, or (c) the IRS has notified me that I am no longer subject to backup withholding; and
3. I am a U.S. citizen or other U.S. person (defined below); and
4. The FATCA code(s) entered on this form (if any) indicating that I am exempt from FATCA reporting is correct.

Certification instructions. You must cross out item 2 above if you have been notified by the IRS that you are currently subject to backup withholding because you have failed to report all interest and dividends on your tax return. For real estate transactions, item 2 does not apply. For mortgage interest paid, acquisition or abandonment of secured property, cancellation of debt, contributions to an individual retirement arrangement (IRA), and, generally, payments other than interest and dividends, you are not required to sign the certification, but you must provide your correct TIN. See the instructions for Part II, later.

Sign Here **Signature of U.S. person** W Oyden **Date** January 6, 2026

General Instructions

Section references are to the Internal Revenue Code unless otherwise noted.

Future developments. For the latest information about developments related to Form W-9 and its instructions, such as legislation enacted after they were published, go to *www.irs.gov/FormW9*.

What's New

Line 3a has been modified to clarify how a disregarded entity completes this line. An LLC that is a disregarded entity should check the appropriate box for the tax classification of its owner. Otherwise, it should check the "LLC" box and enter its appropriate tax classification.

New line 3b has been added to this form. A flow-through entity is required to complete this line to indicate that it has direct or indirect foreign partners, owners, or beneficiaries when it provides the Form W-9 to another flow-through entity in which it has an ownership interest. This change is intended to provide a flow-through entity with information regarding the status of its indirect foreign partners, owners, or beneficiaries, so that it can satisfy any applicable reporting requirements. For example, a partnership that has any indirect foreign partners may be required to complete Schedules K-2 and K-3. See the Partnership Instructions for Schedules K-2 and K-3 (Form 1065).

Purpose of Form

An individual or entity (Form W-9 requester) who is required to file an information return with the IRS is giving you this form because they

Ensemble Orthopedics, LLC
Sandie Roth
VP, Regulatory Affairs
107 Redbud Trail, Suite 11
Austin, Texas 78746

December 2, 2020

Re: K201072
Trade/Device Name: Ensemble CMC, Size 141, Ensemble CMC, Size 151, Ensemble CMC, Size 161
Regulation Number: 21 CFR 888.3770
Regulation Name: Wrist Joint Carpal Trapezium Polymer Prosthesis
Regulatory Class: Class II
Product Code: KYI
Dated: October 30, 2020
Received: November 2, 2020

Dear Sandie Roth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vesa Vuniqi -S

Vesa Vuniqi
Assistant Director
DHT6A2: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

ENSEMBLE ORTHOPEDICS INC

Ensemble Implant GTIN Numbers

Catalog Number	Description	GTIN
101-CMC-141	Ensemble CMC, Size 141	0100810063560003
101-CMC-151	Ensemble CMC, Size 151	0100810063560010
101-CMC-161	Ensemble CMC, Size 161	0100810063560027

INSTRUCTIONS FOR USE

Ensemble CMC™

CAUTION: Federal Law restricts this device to sale by or on the order of a Physician.

DEVICE 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 the trapezium. This design allows for flexion-extension, abduction-adduction, and circumduction motions. The implant is manufactured with an On-X® Carbon (pyrocarbon) 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.

A series of non-powered, hand-held manual surgical instruments can be used to prepare the joint space before implantation of the Ensemble CMC™.

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 CMC should not be used if any of the following are present:

1. Evidence of deformity at the base of the metacarpal
2. Infection in the joint
3. Inadequate bone stock or soft tissue integrity
4. Skeletal immaturity
5. Patients unwilling or unable to follow post-operative care instructions

Contraindications may be relative or absolute. Surgeons must carefully weigh the advantages against possible complications and consider the patient's entire clinical exam in addition to the items listed above.

WARNINGS:

1. 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. The saddle shape of the implant requires that the restoration of the anatomic shapes of the proximal metacarpal and the distal trapezium can be achieved to allow proper seating of the prosthesis.
2. 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.
3. 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.
4. Do not grasp the Ensemble CMC™ with metal instruments or instruments that have teeth, serrations, or sharp edges. Contact implants only with instruments provided in the Ensemble CMC™ Instrument Set. Mishandling implants could cause surface damage and reduced strength, implant fracture, and/or particulate debris.
5. Do not use excessive force to seat the final implant. Excessive force may cause implant to fracture. If having difficulty inserting the implant, re-insert the sizing trial to verify proper sizing, and re-rasp the bone surfaces if necessary.
6. 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.
7. Do not re-sterilize the Ensemble CMC™. Re-sterilization may cause surface damage that could result in implant fracture and/or particulate debris.

PRECAUTIONS:

1. Surgeons should be thoroughly familiar with the recommended surgical technique and 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.
2. Improper sizing may result in instability of the implant or limited range of motion leading to excessive stress on the capsuloligamentous structures.
3. Patients should be informed about the importance of following the post-operative 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 post-operative rehabilitation, strenuous loading, excessive mobility or construct overloading.
4. The Ensemble CMC™ has been sterilized by gamma irradiation at a minimum dose of 25kGy. If either the implant or package appears damaged, or if sterility is questioned for any reason, the implant should not be used. Re-sterilization of this implant is not recommended.
5. 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.
6. To maintain product traceability, record the Lot number for each implanted device.

7. The benefits from implant surgery may not meet the patient's expectations or may deteriorate over time, requiring revision surgery to replace the implant or to carry out alternative procedures.
8. Dispose of contaminated implants and instruments per established facility guidelines and protocols.
9. Any adjacent soft tissue structures should be checked to ensure that abrasive rubbing against the implant will not occur.
10. Size and position of components should be checked radiographically prior to completion of the surgical procedure.

POTENTIAL ADVERSE EVENTS:

In any surgical procedure, the potential for adverse reactions exist. Possible adverse events specific to orthopedic implants used to treat the carpometacarpal joint are listed below. These are not specific to the Ensemble CMC™ but have been observed with CMC implants. Additionally, these do not include all adverse events which can occur with surgical procedures.

1. Migration or subsidence of the implant
2. Infection, erosion, and devascularization of the trapezium
3. Undesirable shortening or lengthening of the thumb
4. Stiffness of the CMC joint
5. Dislocation or subluxation of the implant due to improper positioning or insufficient capsuloligamentous structure
6. Wear and deformation of the articular surfaces
7. Intra-operative and post-operative bone fracture
8. Post-operative pain and/or infection
9. Intra-operative and post-operative device fracture

MRI SAFETY INFORMATION:

The Ensemble CMC™ has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the Ensemble CMC™ in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

DIRECTIONS FOR USE:

A surgical technique manual is available which outlines the basic procedure for device implantation and the use of Ensemble surgical instrumentation (LBL-73-101-06). It is the responsibility of the surgeon to be familiar with the pre-operative and operating procedures before using the Ensemble CMC™.

STORAGE CONDITIONS:

The Ensemble CMC™ should be stored in the original unopened packaging, away from moisture and should not be used after the Use-by date.

STERILIZATION:

Ensemble CMC™ implants have been pouched in a sterile barrier system then sterilized by gamma irradiation. If the implant or package appears damaged, the Use-by date has been exceeded, or if sterility is questionable, the implant should not be used. Do not re-sterilize the implantable components.

RECOMMENDATIONS FOR INSTRUMENT CLEANING AND STERILIZATION:

The procedure for cleaning, and sterilization of Ensemble instruments is described in the Ensemble Instruments Instructions for Use (See IFU, LBL-73-103-01).

SYMBOLS GLOSSARY:

For product shipped, the following symbols may be indicated on the labels placed on the packaging:

SYMBOL	SYMBOL DESCRIPTION	EXPLANATORY TEXT
Standard Development Organization: ISO 15223-1: 2021– Symbols to be used with medical device labels, labelling and information to be supplied		
	Manufacturer (Ref # 5.1.1)	Indicates the medical device manufacturer
	Date of Manufacture (Ref # 5.1.3)	Indicates the date when the medical device was manufactured
	Use-by-date (Ref # 5.1.4)	Indicates the date after which the medical device is not to be used
	Lot Number (Ref # 5.1.5)	Indicates the manufacturer's batch code so that the batch or lot can be identified
	Catalog Number (Ref # 5.1.6)	Indicates the manufacturer's catalog number so that the medical device can be identified
	Sterilized Using Irradiation (Ref # 5.2.4)	Indicates a medical device has been sterilized using irradiation
	Do Not Resterilize (Ref # 5.2.6)	Indicates that a medical device is not to be resterilized
	Do Not Use If Package Is Damaged (Ref # 5.2.8)	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
	Double Sterile Barrier System (Ref # 5.2.12)	Indicates two sterile barrier system
	Do Not Re-use (Ref # 5.4.2)	Indicates a medical device that is intended for one single use only
	Consult Instructions for Use (Ref # 5.4.3)	Indicates the need for the user to consult the instructions for use
	Medical Device (Ref # 5.7.7)	Indicates an item is a medical device
Symbols not from Standards		
	Prescription Only (21 CFR 801.15 (c)(1)(i); 21 CFR 801.109)	Caution: Federal law restricts this device to sale by or on the order of a physician

ENSEMBLE
ORTHOPEDICS INC

2621 Ridgepoint Drive, Suite 100
Austin, Texas 78754 USA
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email: info@ensembleortho.com
www.ensembleortho.com

INSTRUCTIONS FOR USE
Ensemble Orthopedics Surgical Instruments

Caution: Federal Law restricts this device to sale by or on the order of a Physician.

General Instrument Description:

Ensemble Orthopedics ("Ensemble") surgical instruments are an array of generic and unique instruments designed specifically for orthopedic surgery. Such tools facilitate orthopedic surgeons achieve, enable or expedite specific tasks related to surgical techniques and implant systems. All Ensemble surgical instruments are reusable devices manufactured from medical-grade stainless steel and/or common medical device polymers. Instruments are hand-held and manually operated. Instruments should only be used with the appropriate Ensemble devices (i.e. interacting instruments and implants) per the associated surgical technique.

Indications for Use:

Ensemble surgical instruments are manual surgical instruments intended to be used in surgical procedures to assist in the implantation of Ensemble implants.

Contraindications:

Ensemble surgical instruments shall only be used for their intended purpose. Ensemble surgical techniques provide instructions on the use of the instrumentation. The decision to use an instrument must be based on sound medical judgement that takes into consideration factors such as surgical application, physical and mechanical properties. Medical personnel are encouraged to contact their Ensemble representative(s) if a more comprehensive understanding of the instrument mechanics or its method of use is required.

Warnings and Precautions:

1. Ensemble surgical instruments have been designed for use with Ensemble implantable devices. Use of these instruments to implant other devices may result in non-optimal patient outcomes.
2. Failure to thoroughly clean the instruments in accordance with the validated cleaning method may prevent adequate disinfection or sterilization, posing a risk of infection to the patient.
3. Instruments should be rinsed of cleaning agents to prevent residue.
4. Do not use mineral oil or silicone lubricants on instruments.
5. Neutral pH enzymatic and cleaning agents are recommended for cleaning instruments. It is important that alkaline cleaning agents are thoroughly neutralized and rinsed from instruments.
6. Prior to sterilization, instruments should be inspected for cleanliness of surfaces, joints, lumens, proper function, wear and tear.
7. Instruments are subject to wear with repeated use. Inspect instruments for damage or malfunction prior to use to verify condition and do not use if damaged or worn.
8. A full inventory of instruments and implants should be available prior to initiating a surgical procedure. Components should be tested in trial assembly prior to the actual operation.
9. Use caution in the handling and storage of instruments. After sterilization, instruments should be stored in the sterilization wrapped rigid container in a dry and dust-free environment. Instruments should be stored away from environments and agents that may cause contamination and deterioration.

Cleaning:

The recommended manual cleaning instructions are described below. Ensemble surgical instruments supplied to the user non-sterile must be cleaned and steam sterilized prior to surgical use. Other cleaning methods that differ from the instructions below are not recommended must be validated by the user.

Point of Use Processing:

Cleaning should begin at the point of use, prior to processing. Throughout the surgical procedure, blood and/or debris should be wiped from the instruments using a disposable gauge pad or cloth to prevent it from drying on the surface. Additionally, a towel moistened with sterile or distilled water should be draped over the used instruments. Contaminated instruments should not be allowed to dry prior to cleaning/reprocessing. Excess blood or debris should be wiped off to prevent it from drying. All subsequent cleaning and sterilization steps are facilitated by not allowing blood, body fluids and tissue debris to dry on the instruments.

Cleaning Instructions:

For non-sterile, reusable instruments, Ensemble recommends cleaning devices within 30 minutes of use or after removal from solution to minimize the potential for drying prior to cleaning. Ensemble recommends using the following validated cleaning procedure. Due to variations in conditions and environments, the user has final responsibility for the implementation and verification of procedures to achieve cleanliness.

Recommended Manual Cleaning Instructions

Process	Water Quality/Temp	Time	Cleaning Instructions
Pre-Wash	Tap Water 15-25 °C	Minimum 1 minute	Rinse with clean, cool, running tap water. Use soft-bristled brush to clean instrument thoroughly.
Soaking	Tap Water 27-44 °C	20-25 minutes	Submerge instruments in proteolytic enzymatic cleaning solution diluted per manufacturer recommendations. Remove visible soil with soft-bristled brush.
Rinse	Tap Water 27-44 °C	Minimum 1 minute	Remove instruments from enzyme solution and thoroughly rinse with running tap water.
Inspect	N/A	N/A	After rinsing, visually inspect instruments to ensure debris removal. If debris remains, thoroughly and aggressively flush the device or repeat rinsing until debris is removed.
Ultrasonic Clean	Tap Water 25-30 °C	10-15 minutes	Prepare proteolytic cleaning solution diluted according to manufacturer's recommendations in ultrasonic cleaner. Completely submerge instruments and sonicate.
Rinse	Purified Water 22-43 °C	Minimum 1 minute	Fully immerse and gently agitate the instruments in a basin of purified water.
Dry	N/A	N/A	Dry with a clean, lint-free or low lint cloth.
Inspect	N/A	N/A	Visually inspect each instrument for remaining soil and moisture. If soil remains, repeat the cleaning process.

Additional Inspection:

Visually inspect each device for completeness, damage and excessive wear. If damage or wear is observed that might compromise the function of the device, do not process them further and contact your Ensemble representative for a replacement.

- When inspecting devices look for the following:
  - Cutting edges should be free of nicks and have a continuous edge.
  - Long thin instruments should be free of bending or distortion.

Sterilization Instructions:

Ensemble recommends the following sterilization procedures for non-sterile instruments. These instruments are intended for steam sterilization at the healthcare facility. Due to variations in conditions and environments, the user has final responsibility for the implementation and verification of procedures to achieve sterility.

1. Place properly cleaned and dried instruments into the designated slots or arranged to ensure instruments do not touch inside the sterilization tray. Disassemble instruments and place components inside the sterilization tray.
2. Wrap the instrument tray with commercially available CSR wrap.
3. Place wrapped instrument tray in steam sterilizer, sterilize for 4 minutes in 132°C pre-vacuum cycle with 20-minute dry time.
4. Upon cycle completion, remove the wrapped instrument tray from sterilizer and place tray on a padded surface to prevent condensation during cooling.
5. Store the sterilized instrument tray in a clean and dry area.

Steam Sterilization Cycle Parameters

Parameters	Cycle Parameters
Cycle type	Pre-vacuum with 4 pulses
Temperature	132°C
Exposure Time	4 minutes
Dry Time	20 minutes

Additional Ensemble recommendations are as follows:

- Follow ANSI/AAMI ST79:2006 - Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.
- Flash sterilization is not recommended, but if used, should only be performed according to the requirements of ANSI/AAMI ST79:2006 - Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.
- Usage of an FDA cleared wrap is recommended to ensure the instruments are sterile prior to use.

Symbols Glossary:

For product shipped, the following symbols may be indicated on the labels placed on the packaging:

Symbol	Symbol Description	Explanatory Text
Standard Development Organization: ISO 15223-1: 2021 – Symbols to be used with medical device labels, labelling and information to be supplied		
	Manufacturer (Ref # 5.1.1)	Indicates the medical device manufacturer
	Date of Manufacture (Ref # 5.1.3)	Indicates the date when the medical device was manufactured
	Use-by-date (Ref # 5.1.4)	Indicates the date after which the medical device is not to be used.
	Lot Number (Ref # 5.1.5)	Indicates the manufacturer's batch code so that the batch or lot can be identified
	Catalog Number (Ref # 5.1.6)	Indicates the manufacturer's catalog number so that the medical device can be identified
	Non-sterile (Ref # 5.2.7)	Indicates a medical device that has not been subjected to a sterilization process.
	Consult Instructions for Use (Ref # 5.4.3)	Indicates the need for the user to consult the instructions for use.
Symbols not from Standards		
	Prescription Only (21 CFR 801.15 (c)(1)(i); 21 CFR 801.109)	Caution: Federal law restricts this device to sale by or on the order of a physician

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Implants & Instruments

ITEM DESCRIPTION	CATALOG NUMBER
Ensemble CMC™ Implant, Size 141	101-CMC-141
Ensemble CMC™ Implant, Size 151	101-CMC-151
Ensemble CMC™ Implant, Size 161	101-CMC-161

ITEM DESCRIPTION	CATALOG NUMBER
Ensemble CMC™ Instrument Set	103-INS-001
Ensemble CMC™ Rasp, Peripheral	103-RSP-001
Ensemble CMC™ Rasp, Saddle	103-RSP-002
Ensemble CMC™ Rasp, Bump	103-RSP-003
Ensemble CMC™ Rasp, Trapezium	103-RSP-005
Ensemble CMC™ Trial, Size 141	103-TRL-141
Ensemble CMC™ Trial, Size 151	103-TRL-151
Ensemble CMC™ Trial, Size 161	103-TRL-161

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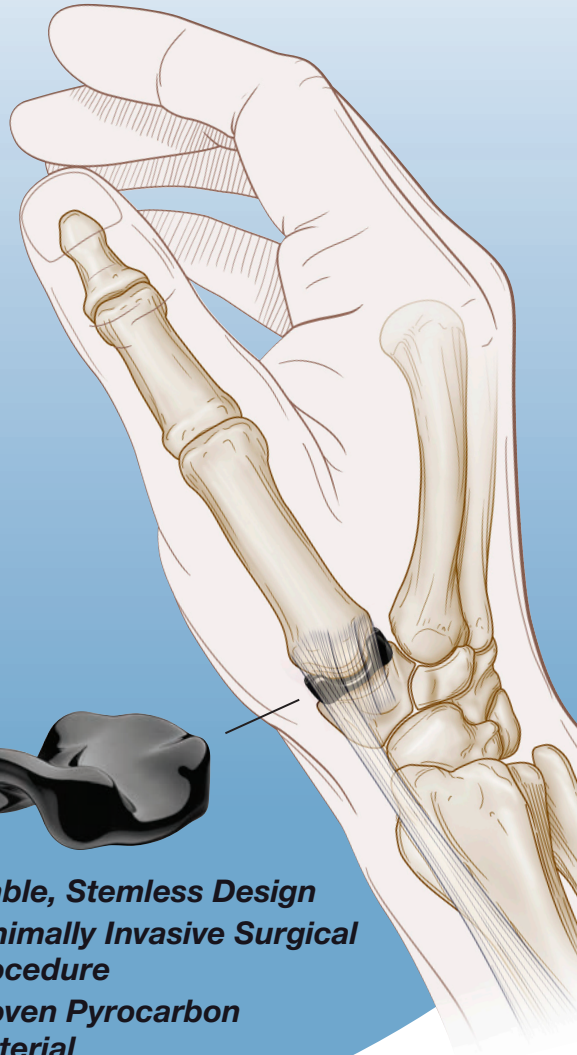
MK-72-101-01 rev F

Ensemble CMC™

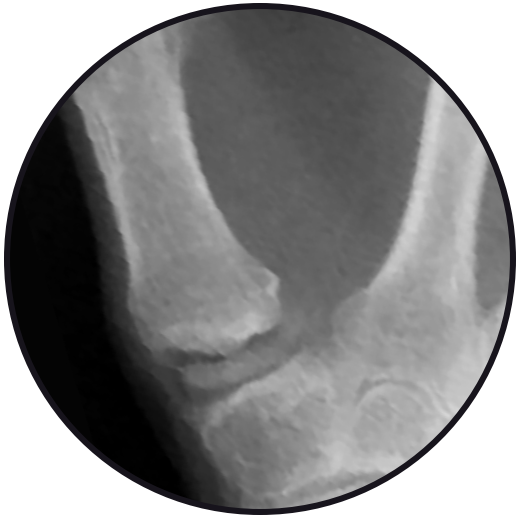
Pyrocarbon Interpositional Arthroplasty



- ***Stable, Stemless Design***
- ***Minimally Invasive Surgical Procedure***
- ***Proven Pyrocarbon Material***

ENSEMBLE ORTHOPEDICS INC

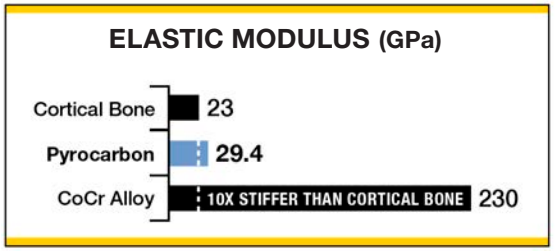
Bringing Minimally Invasive Joint Replacement To The Hand



Ensemble CMC™

The Ensemble CMC™ is an interpositional device that is inserted in the joint space between the first metacarpal and the trapezium. The slim profile of the implant allows for separation of the damaged articular surfaces without extensive bone resection or disruption of surrounding soft tissues. The proprietary saddle-shaped design of the Ensemble CMC™ allows for stable, natural thumb motion.

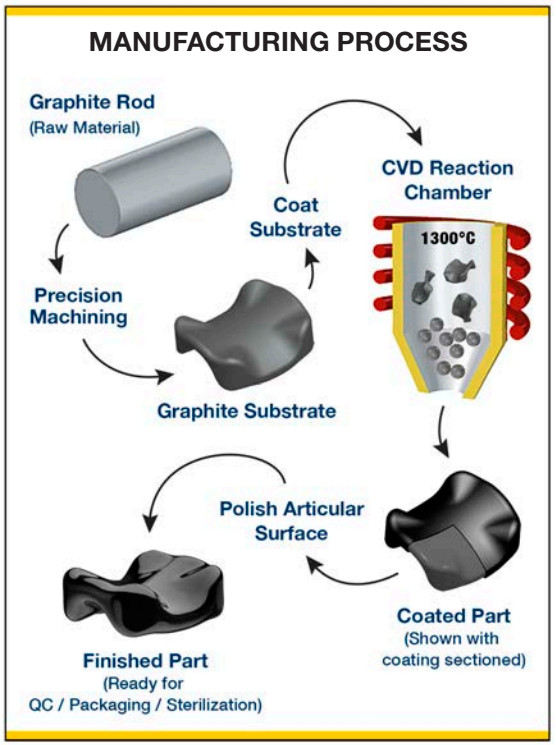
The Ensemble CMC™ is manufactured from On-X® Carbon – a proven biocompatible, low modulus, and durable material that has been shown to cause less bone wear compared to metal or ceramic devices. A simple instrument set is available, and the implant has three size options.

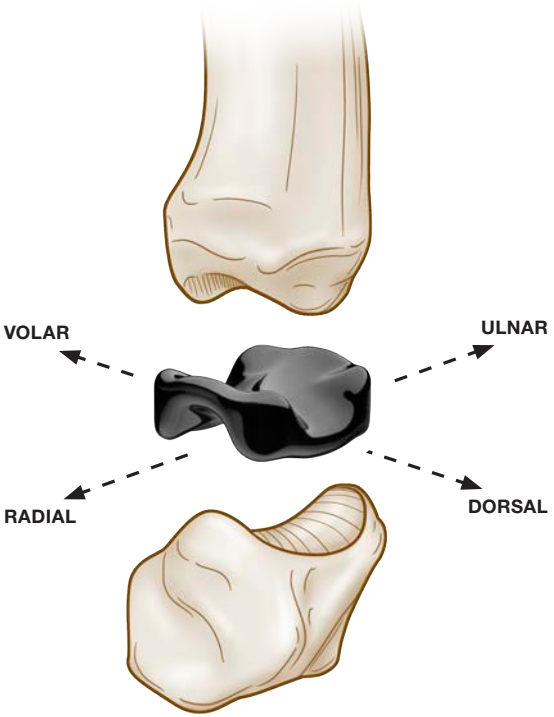


Pyrocarbon Material

- Elastic Modulus Similar to Cortical Bone
- Durable with Low Wear Properties
- Extensive History as Medical Implant

Pyrocarbon has an elastic modulus similar to that of cortical bone and is both strong and wear resistant. Extensive laboratory and pre-clinical testing has demonstrated that pyrocarbon, bearing against bone, exhibits superior wear properties to either metal or ceramic surfaces.





Interpositional Design

- Replaces Damaged Bearing Surfaces
- Stemless Implant = Minimally Invasive
- Limited Disruption of Soft Tissues

The design philosophy behind the Ensemble CMC™ is to minimize bone-on-bone contact by implanting a stemless device that matches the natural anatomy of the joint and preserves critical stabilizing soft tissues. The Ensemble CMC™ achieves stability through the shape of the implant, including the peripheral protrusions that act to keep the implant centered in the joint space.

ENSEMBLE ORTHOPEDICS INC

SURGICAL TECHNIQUE

Ensemble CMC™

Pyrocarbon Interpositional Arthroplasty

ENSEMBLE
ORTHOPEDICS INC

Table of Contents

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

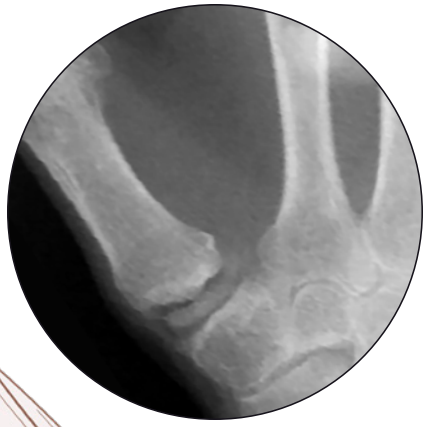
The Ensemble CMC™ is a single-use, one-piece, interpositional joint prosthesis designed to fit into the space between the trapezium and first metacarpal for patients with early stage arthritis of the carpometacarpal joint (CMC). The Ensemble CMC™ implant has upper and lower surfaces that are saddle (toroidal) 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.

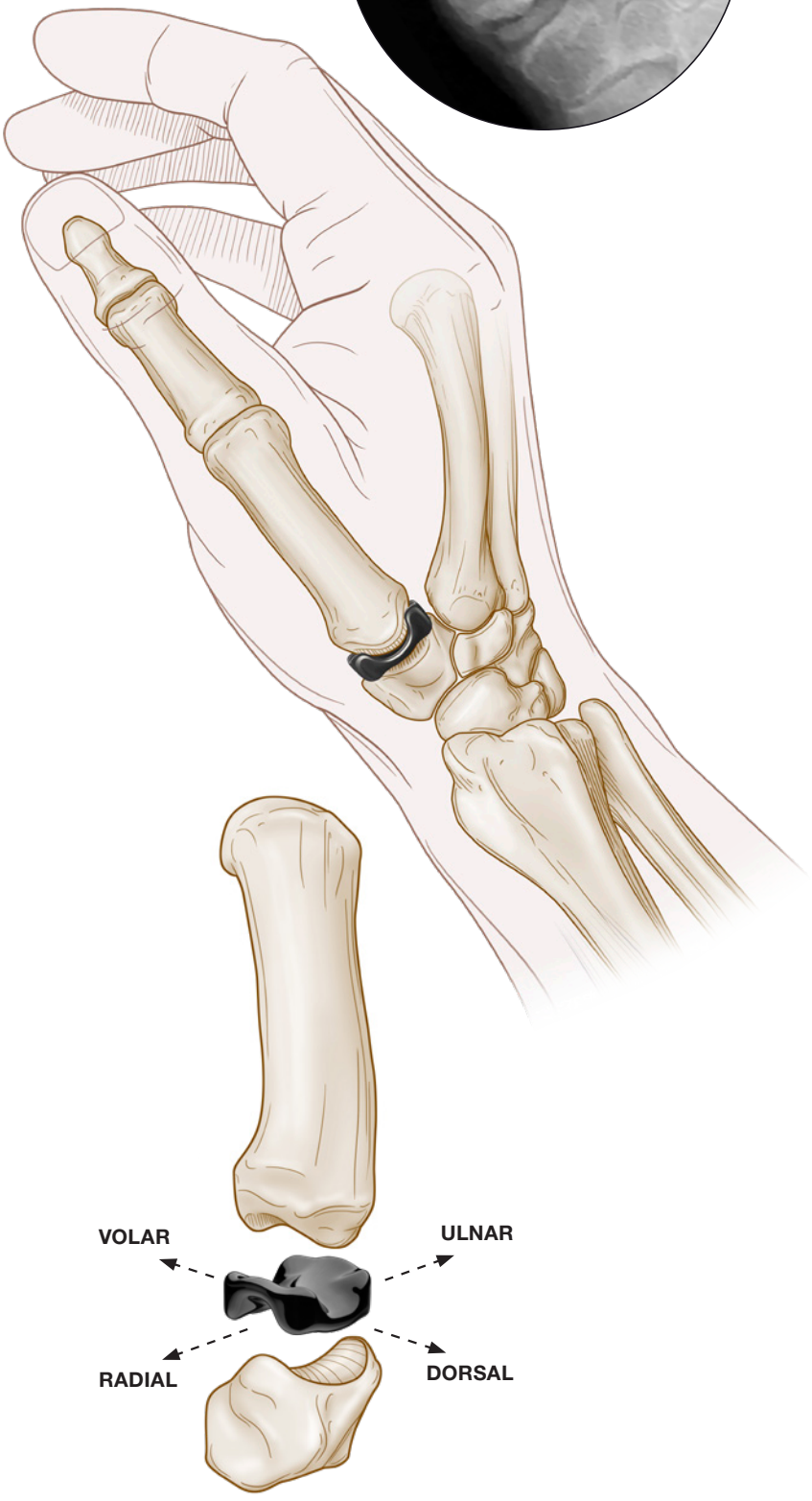
The choice of implant size is based on the geometry of the joint. The three Ensemble CMC™ sizes correspond to the anatomic variations in the cross-section of the trapezium and first metacarpal of the joint, specifically the Radial/Ulnar dimension and the Dorsal/Volar dimension.

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

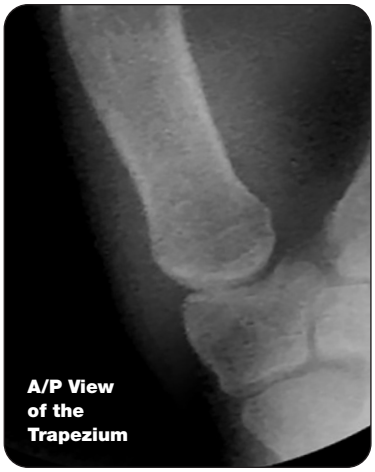
Optimal radiographic visualization of the CMC joint is key to the success of the Ensemble CMC™ procedure.

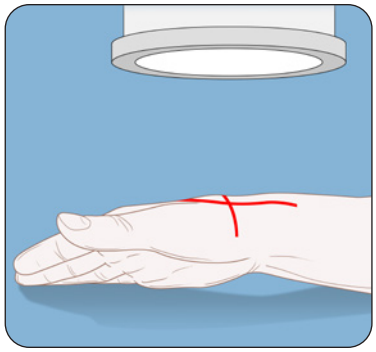
Throughout this technique, two views of the CMC joint shall be referenced that will adequately allow visualization of the CMC joint: the peritrapezial (A/P) view of the trapezium and the lateral view of the trapezium. The goal of each is to obtain a clear, unobstructed view of the trapezium and the joint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

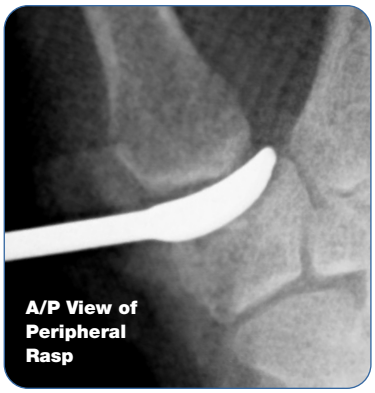
How to Obtain a Peritrapezial or A/P View of the Trapezium:

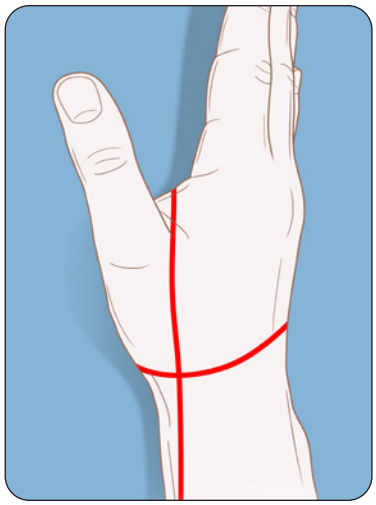
From the neutral forearm position:

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





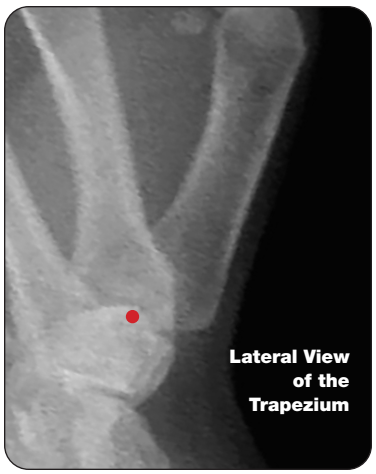


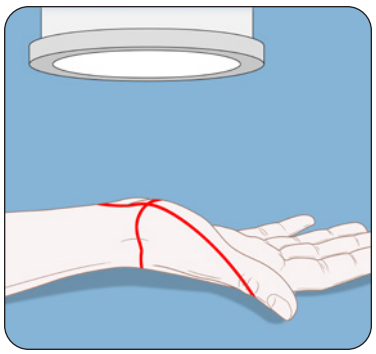


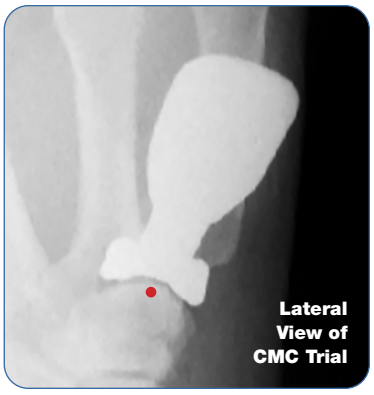
How to Obtain the Lateral View of the Trapezium:

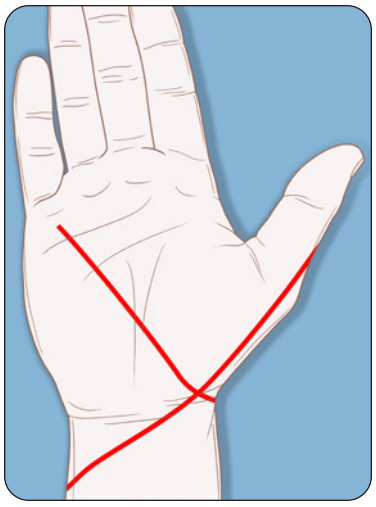
From the neutral forearm position:

- 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.

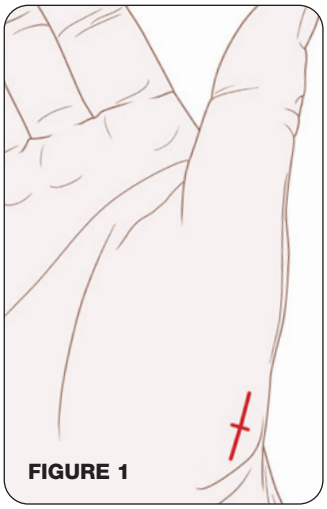


FIGURE 1

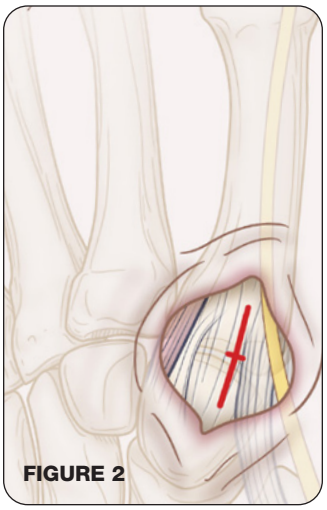


FIGURE 2

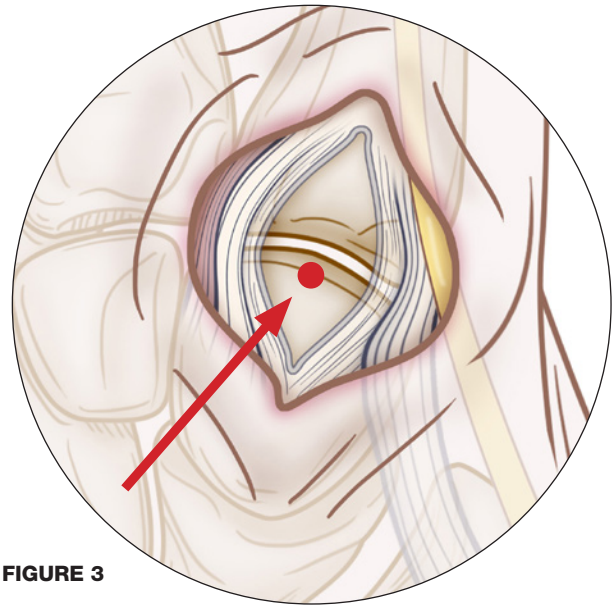
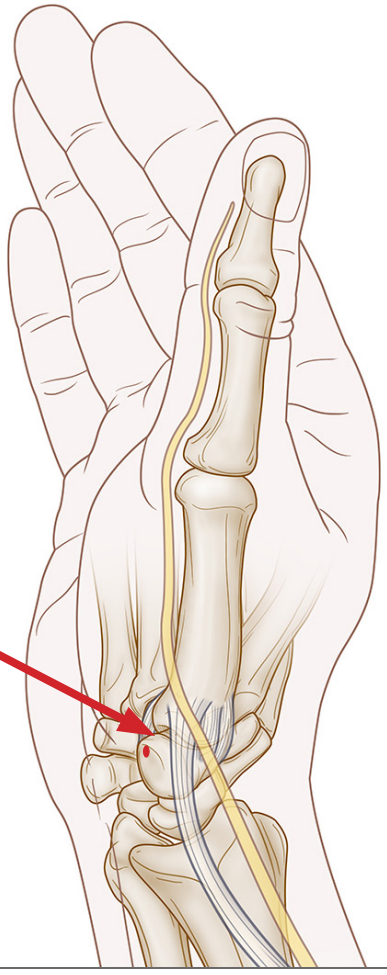


FIGURE 3



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

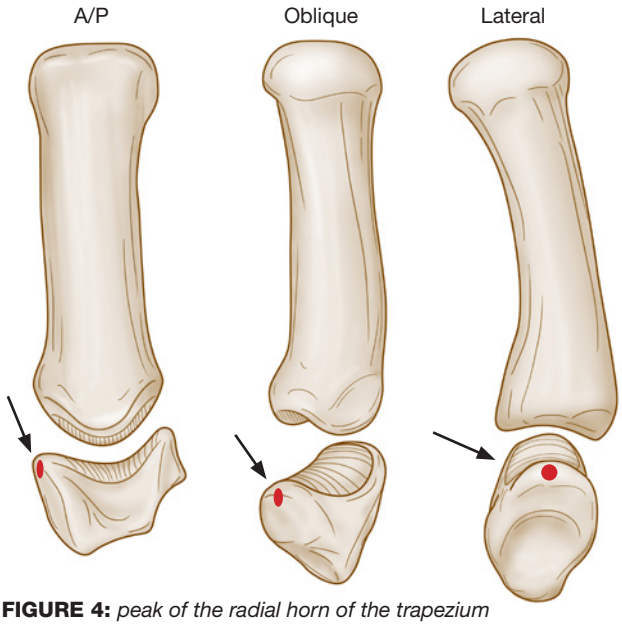


FIGURE 4: *peak of the radial horn of the trapezium*

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).**

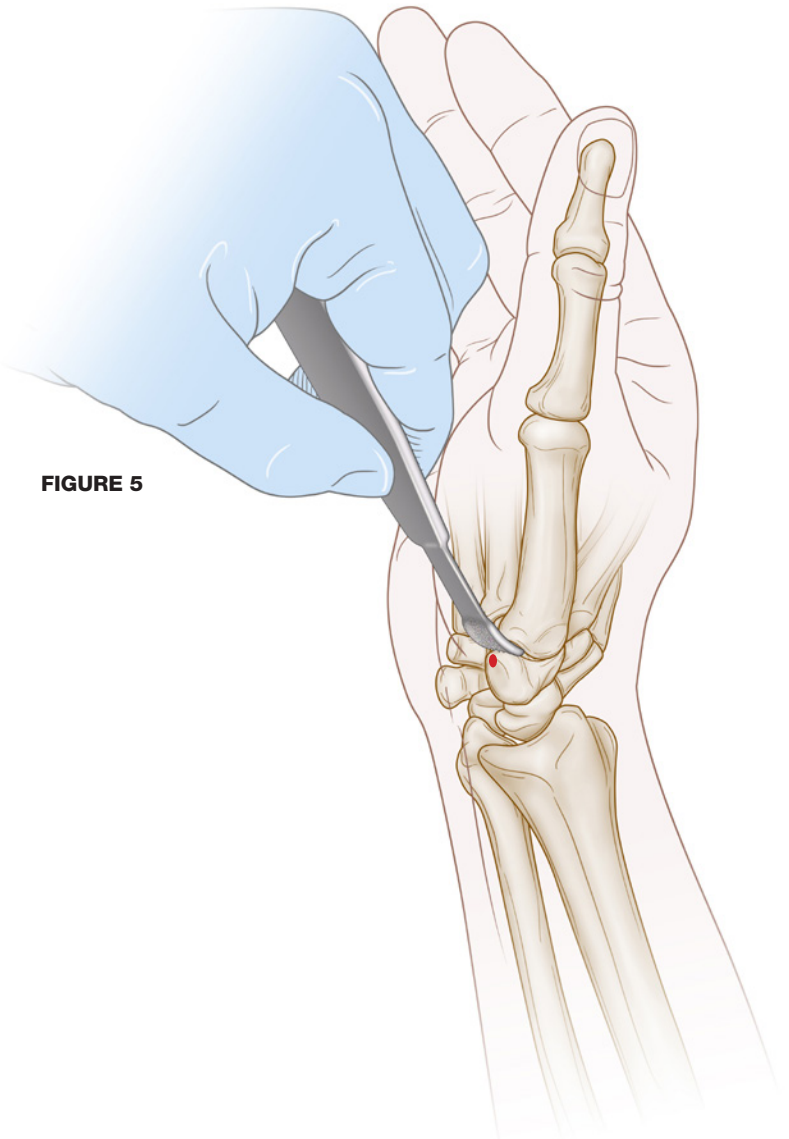


FIGURE 5

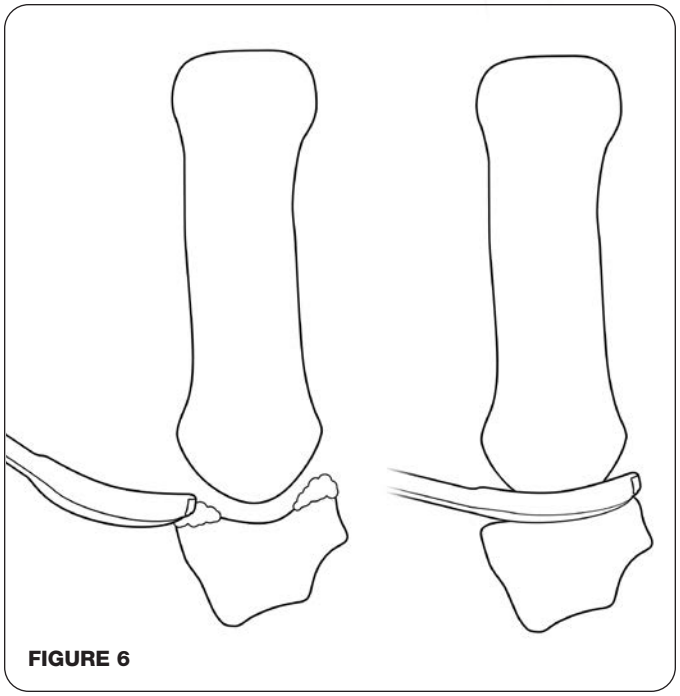


FIGURE 6

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.

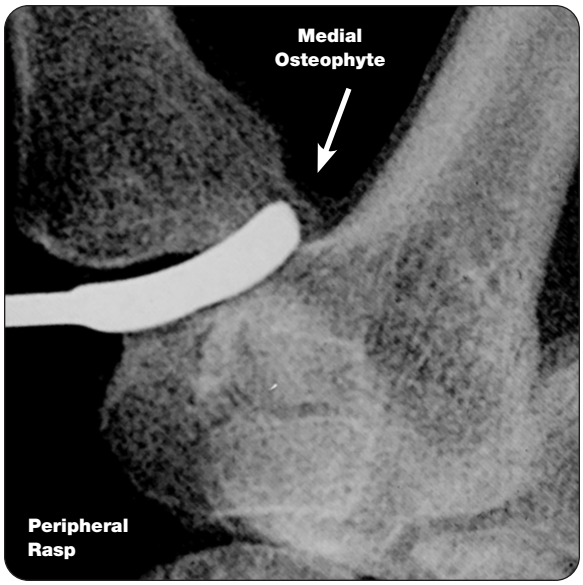


FIGURE 7:
shotgun view of the CMC joint space

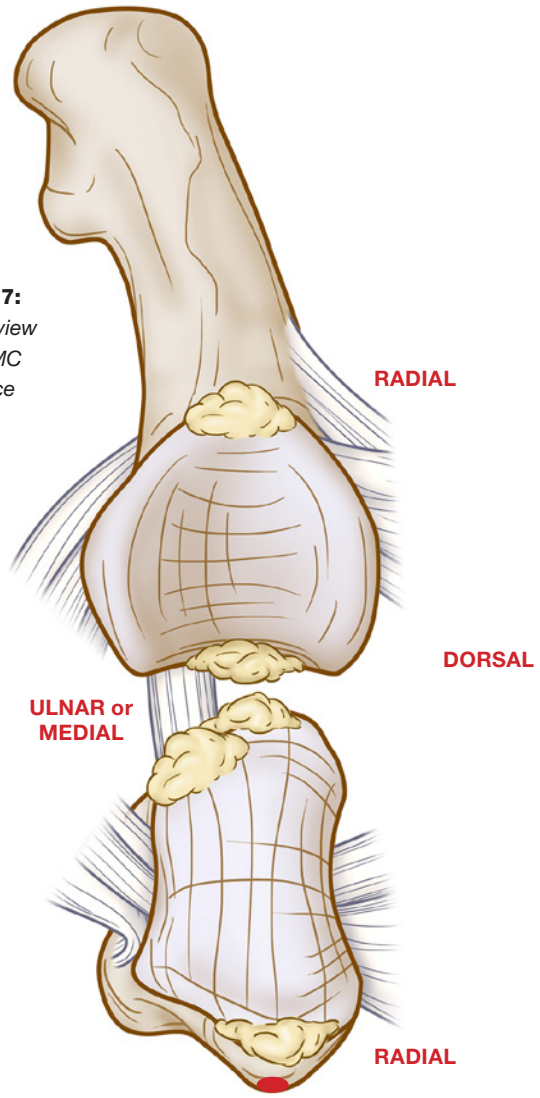
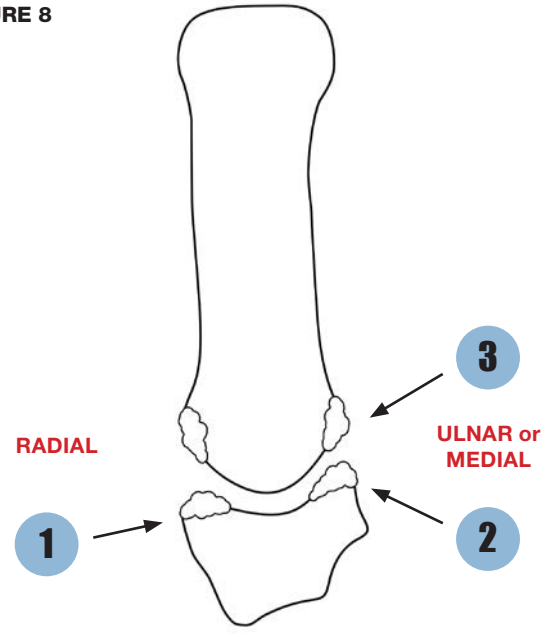


FIGURE 8



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)**.

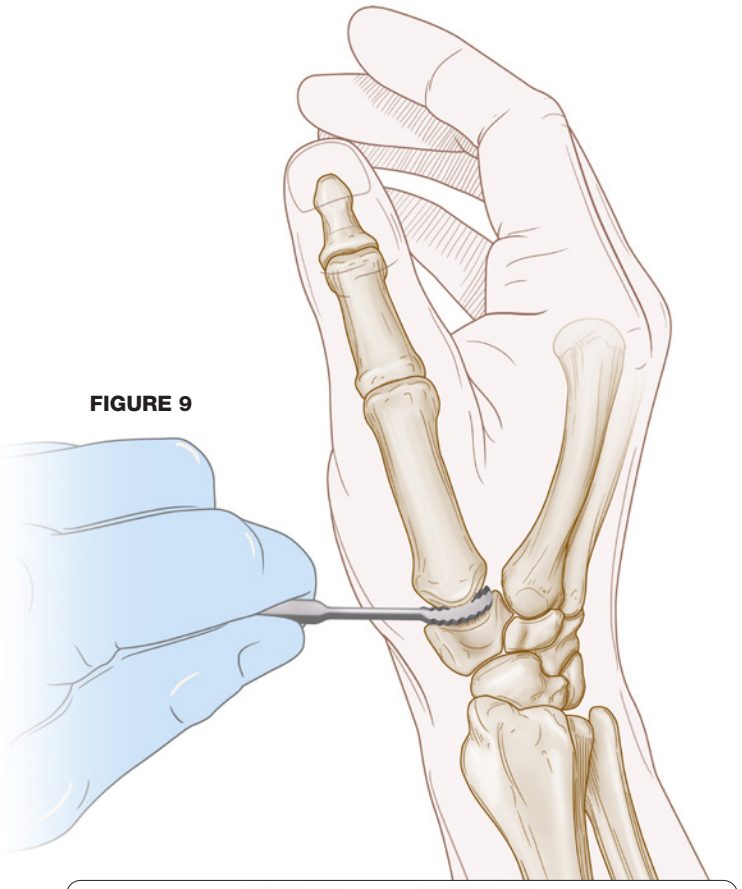
NOTE: Perform burring under fluoroscopy – recommended burr size 2.5 – 3.0.

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



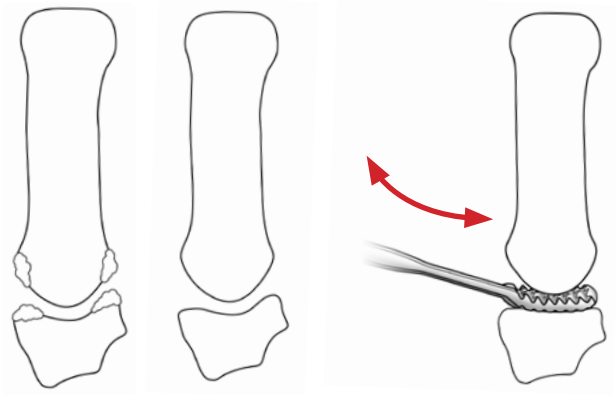


FIGURE 10: *Use arcing, pull strokes of the Saddle Rasp to shape the metacarpal and trapezium.*

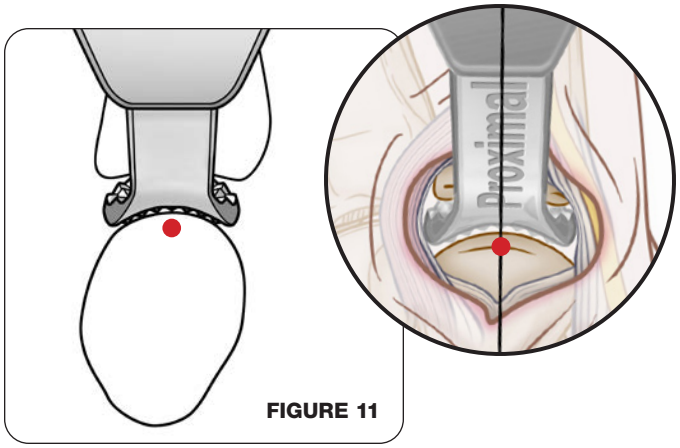


FIGURE 11

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)**.

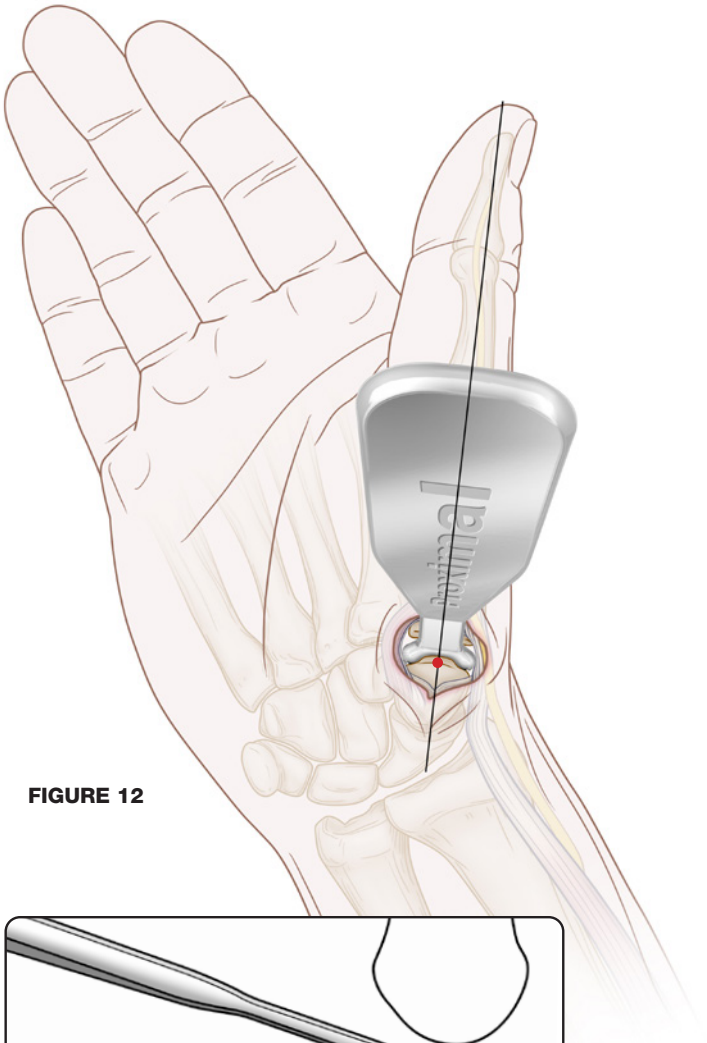
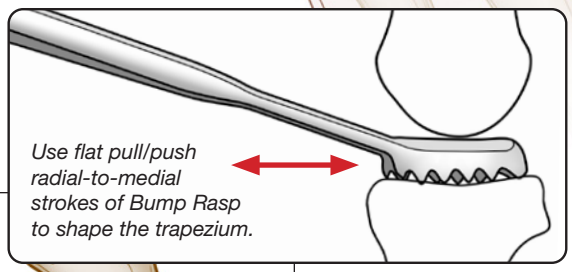


FIGURE 12



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

FIGURE 13

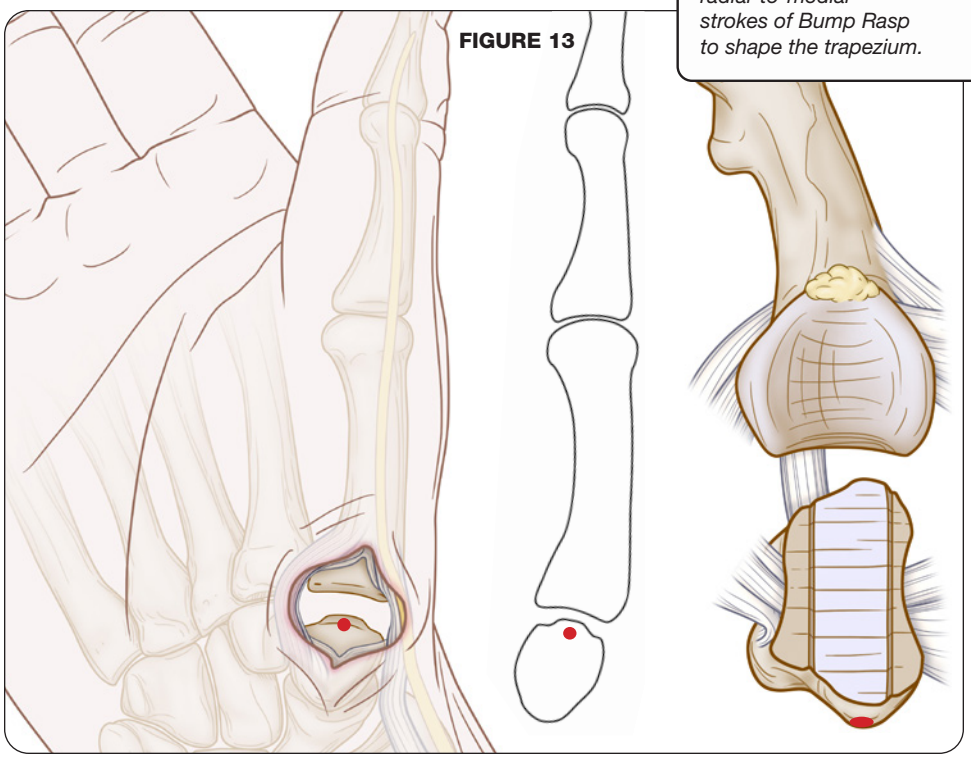
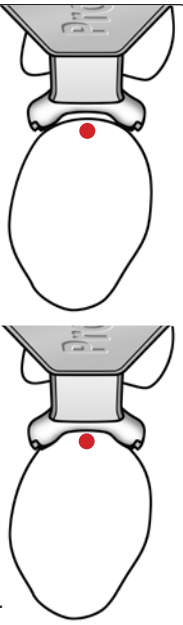


FIGURE 14



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).**

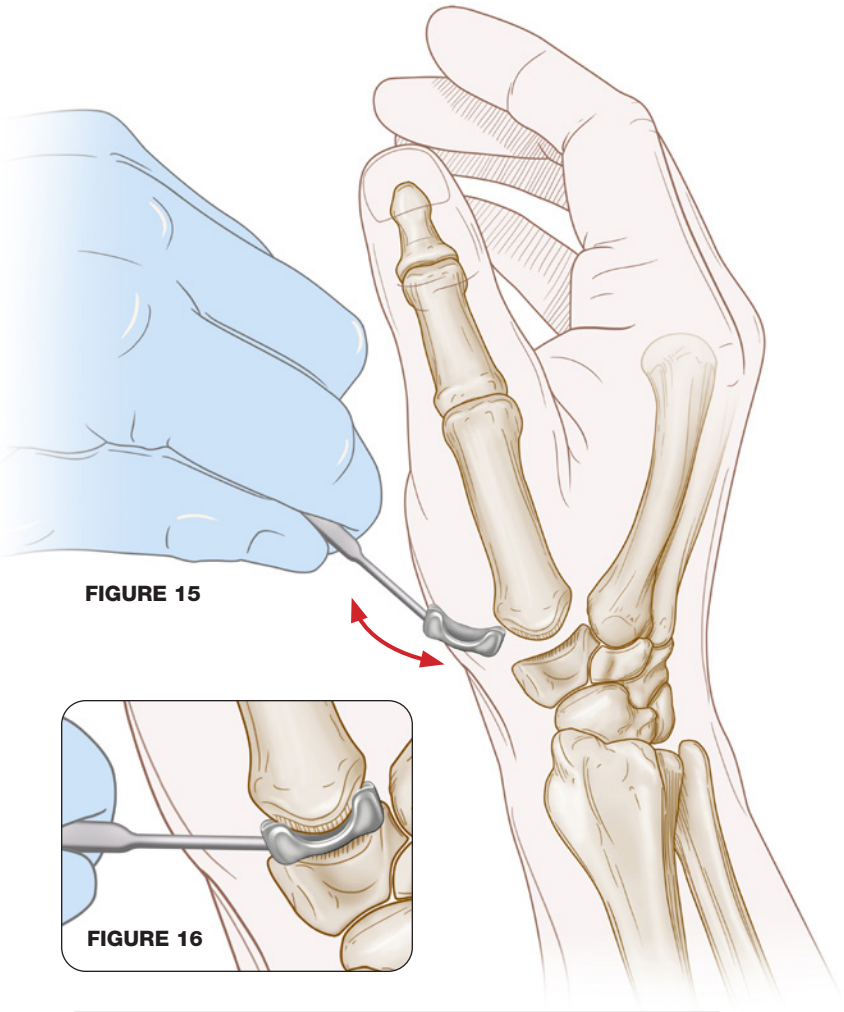


FIGURE 15

FIGURE 16

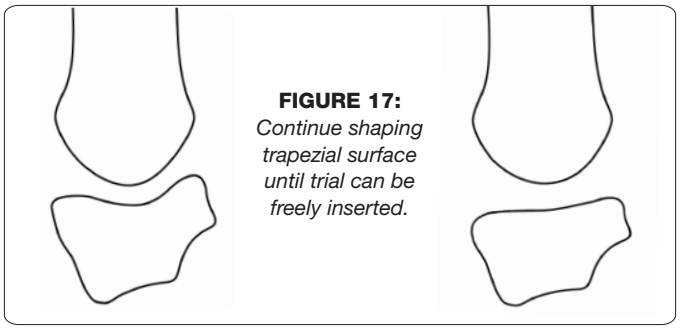


FIGURE 17: *Continue shaping trapezial surface until trial can be freely inserted.*

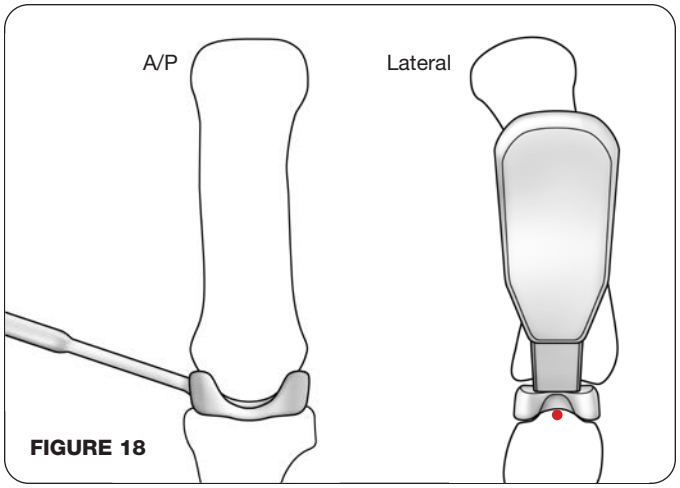


FIGURE 18

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).**

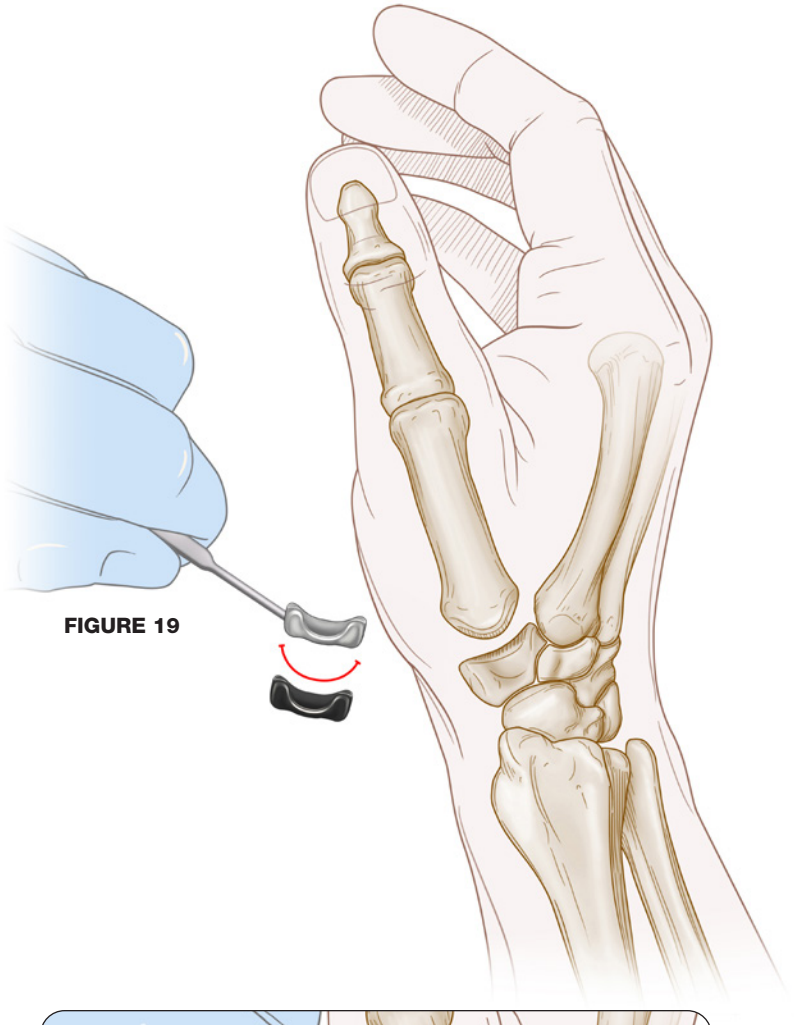


FIGURE 19

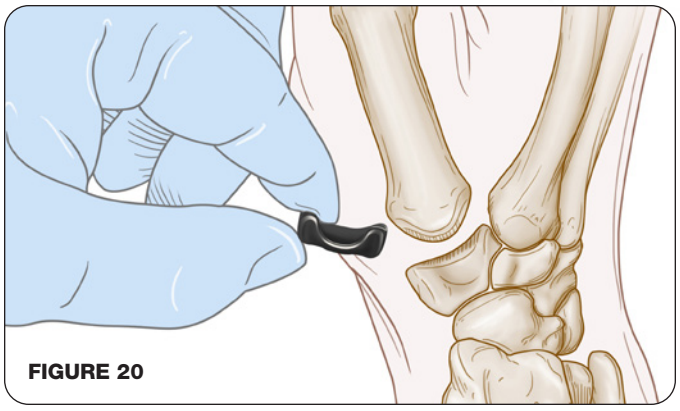


FIGURE 20

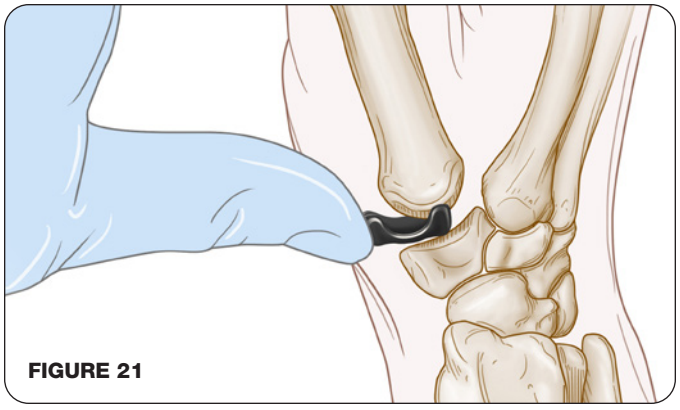


FIGURE 21

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.

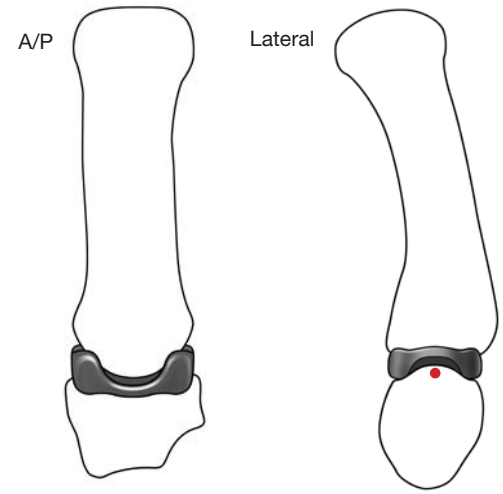


FIGURE 22: *center contact of the implant*

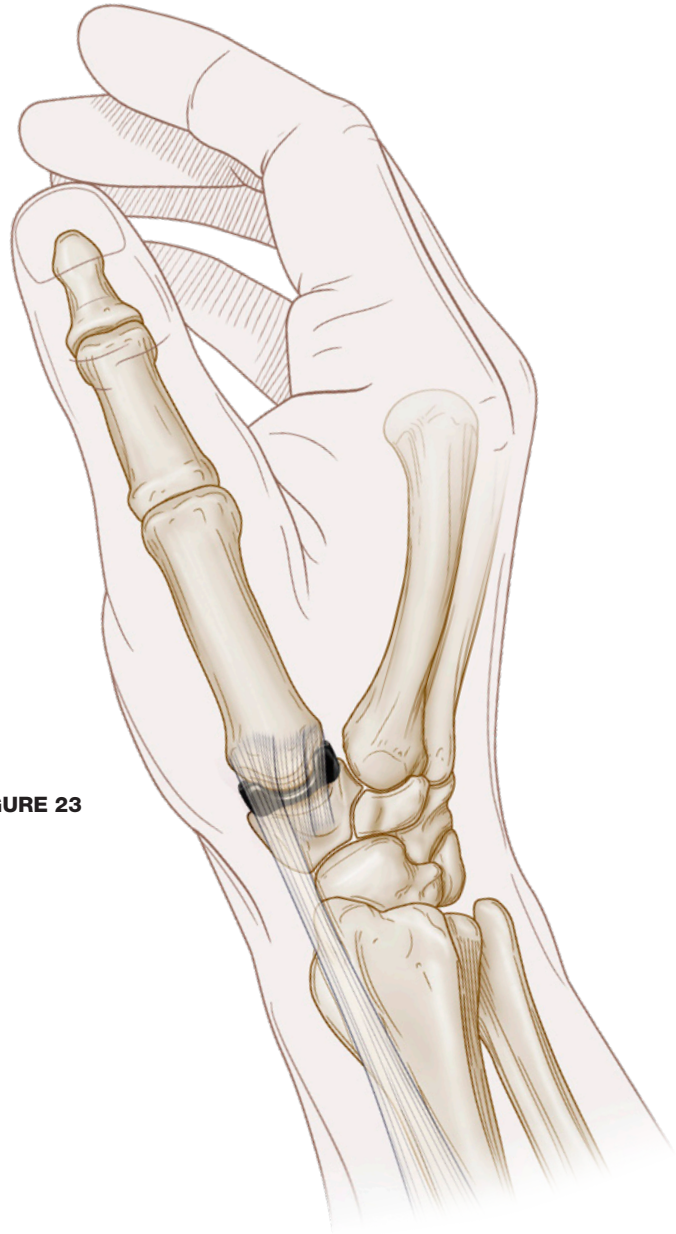


FIGURE 23

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).**

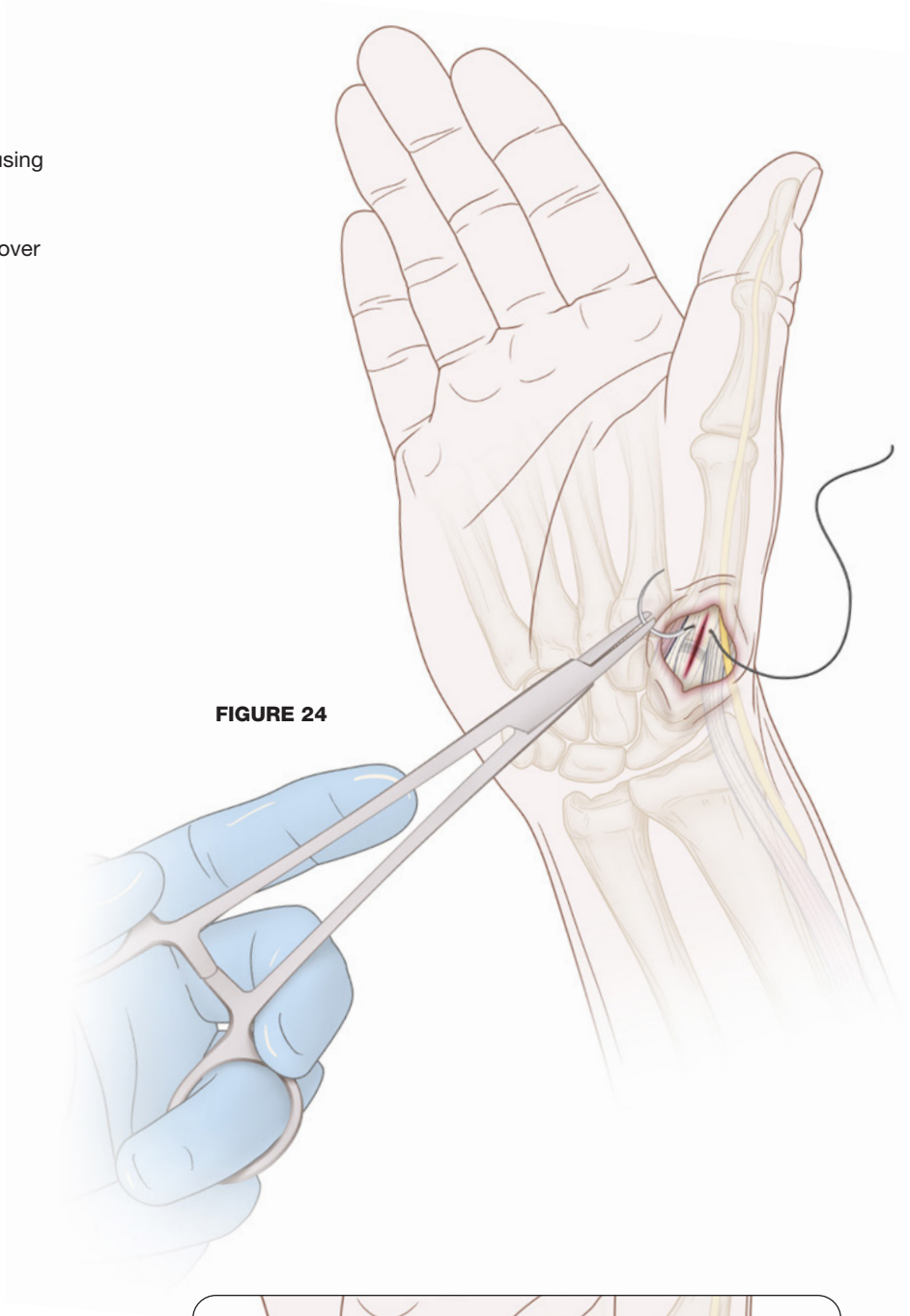


FIGURE 24

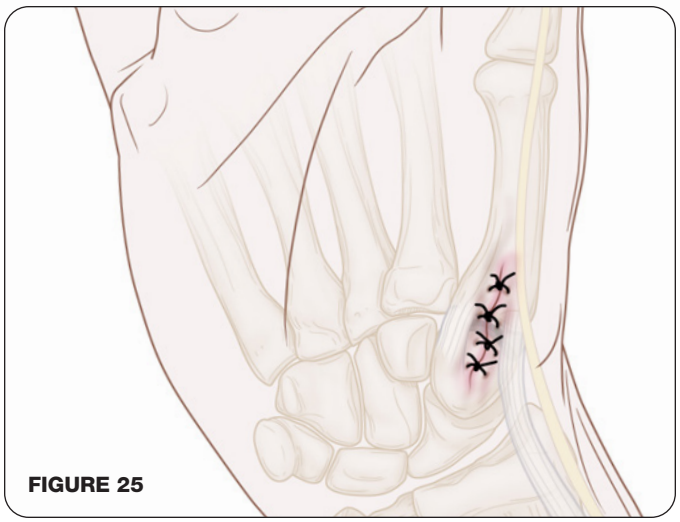


FIGURE 25

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.

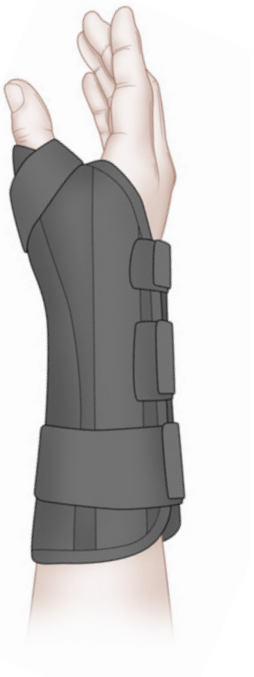
Phase 1 – Immediate Post-surgical Phase, Weeks 0-2:
Start CMC immobilization with wrist-based cast.

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

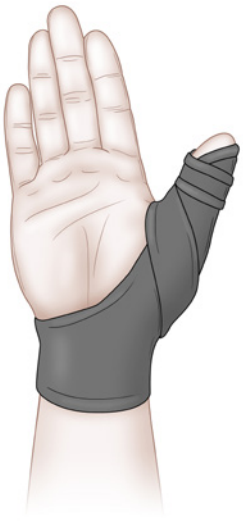
Phase 3 – Intermediate Phase, Weeks 4-12:
Initiate CMC mobilization. Light activities as tolerated. Wear thumb spica splint as needed during high demand activities.

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

Phase 1: Wrist-based Cast

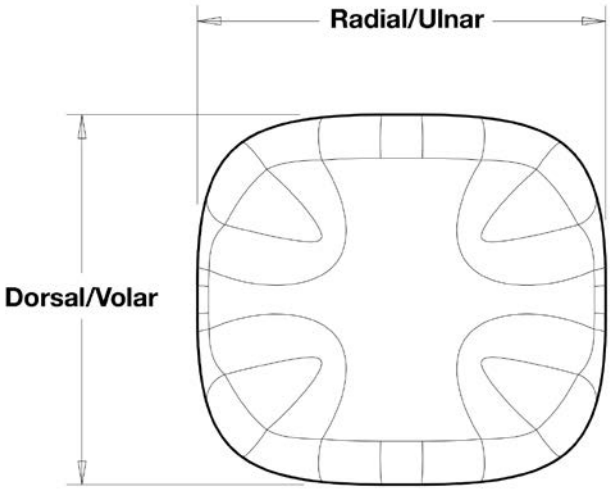


Phase 2: Removable Wrist-based Splint



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

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PRICE LIST

Effective January 1, 2026

THIS INFORMATION IS PROPRIETARY AND CONFIDENTIAL

Ensemble CMC™ Implant Pricing

CATALOG NUMBER	DESCRIPTION	SIZE	LIST PRICE
101-CMC-141	CMC Interpositional Implant	141	$ 6095.00
101-CMC-151		151	$ 6095.00
101-CMC-161		161	$ 6095.00

Instrument Replacement Costs in Case of Loss or Damage

CATALOG NUMBER	DESCRIPTION	SIZE	PRICE
103-RSP-001	CMC Rasp, Peripheral	—	$ 495.00
103-RSP-002	CMC Rasp, Saddle	—	$ 495.00
103-RSP-003	CMC Rasp, Bump	—	$ 495.00
103-RSP-005	CMC Rasp, Trapezium	—	$ 495.00
103-TRL-141	CMC Trial	141	$ 395.00
103-TRL-151		151	$ 395.00
103-TRL-161		161	$ 395.00
003-INS-001	CMC Tray / Lid / Mat	—	$ 295.00
103-INS-001	**Ensemble CMC™ Instrument Set**	**—**	**$ 3460.00**

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