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 and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Ensemble CMC™ in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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: 2016 – 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
	Non-sterile (Ref # 5.2.7)	Indicates a medical device that has not been subjected to a sterilization process
	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
	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
	Caution (Ref # 5.4.4)	Indicates the need for the user to consult the instructions for use for important, cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself
Symbols not from Standards		
R_X Only	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
phone: +1 (512) 638-3598
email: info@ensembleortho.com
www.ensembleortho.com