Part No. 030-1607
Rev. J

OSTEOMED
EnCompass Metatarsal Resurfacing Implant System
Product Insert

Device Description

The *OSTEOMED ENCOMPASS METATARSAL RESURFACING IMPLANT* is a one piece implant designed to replace the distal head of the metatarsal and provides a smooth articular surface for the adjacent phalangeal base. The implant is available in several sizes in direct proportion to the anatomic construct of the metatarsal head (implant head sizes range from 10mm to 19mm).

The implant has a spherical end (concave spherical inner surface), that is coated with Ti plasma coating and hydroxylapatite coating. The implant is characterized by a single, proximal stem which is press fit or fixated via bone cement into the intramedullary canal of the distal metatarsal.

The instrumentation for the system includes drill guides, guide pins, reamers, trials, broach and impactor for placement of the device.

Material

The *OSTEOMED ENCOMPASS METATARSAL RESURFACING IMPLANT System* is comprised of implants made from cobalt chromium (ASTM F-1537). Implants are coated with Ti Plasma coating and hydroxylapatite coating.

The instrumentation is made from various grades of stainless steel, TiN coated stainless steel, anodized aluminum, and/or medical grade polymers.

Indications for Use

The *OSTEOMED ENCOMPASS METATARSAL RESURFACING IMPLANT*, a hemi-arthroplasty implant for the metatarsophalangeal (MTP) joint, is indicated for use in the treatment of patients with degenerative and post-traumatic arthritis in the MTP joint in the presence of good bone stock and integrity of the phalangeal base, along with the following clinical conditions; hallux limitus, hallux valgus, hallux rigidus, and an unstable or painful MTP joint. The *OSTEOMED ENCOMPASS METATARSAL RESURFACING IMPLANT* is intended to be used with bone cement or press fit without bone cement. The *OSTEOMED ENCOMPASS METATARSAL RESURFACING IMPLANT* is intended for single use only.

OsteoMed single use devices/instruments cannot be reused and/or reprocessed. The product has been labeled as single use only for patient safety. The design of the device and the intricacies of the surfaces may not facilitate cleaning and sterilization after contact with body tissues or fluids, so there is an increased risk of contamination if reused. This may lead to potential risks of cross infection/contamination associated with using inadequately cleaned and sterilized devices. For cutting instruments the cutting efficacy may be reduced requiring the surgeon to use increased force that might cause patient harm and/or increase the risk of thermal necrosis. Because these products have not been validated for multiple use, OsteoMed cannot guarantee the safety and effectiveness of the device if it is used on more than one patient.

Contraindications

1. Use of the *OSTEOMED ENCOMPASS METATARSAL RESURFACING IMPLANT System* is contraindicated
   a) in cases of active or suspected infection or in patients who are immunocompromised;
   b) in patients previously sensitized to the implant materials, ie. cobalt chromium or titanium;
   c) in patients with certain metabolic diseases; or
   d) in patients exhibiting disorders which would cause the patient to ignore the limitations of artificial joint replacement.
2. This system is further contraindicated in serious systemic diseases.
3. The *OSTEOMED ENCOMPASS METATARSAL RESURFACING IMPLANT System* should not be used in cases where the remaining bone is too diminished to provide adequate width or height to surround the implant.
4. Implant failure may occur in cases where there is insufficient available bone or poor bone quality or in patients with blood supply limitations.
5. Use of the implant is further contraindicated in cases of significant angular or biomechanical deformities or in cases which would subject the implant to excessive stress or wear due to patient weight and/or activity level.

Warnings

1. The *OSTEOMED ENCOMPASS METATARSAL RESURFACING IMPLANT* is not intended to endure excessive functional stresses. Such stresses may lead to accelerated implant wear and/or failure.
2. Protect implant surfaces from scratching or other surface damage. Such damage may lead to accelerated implant failure. Avoid direct impact on implants with hammers or other instruments.
3. Ensure proper size instrumentation is used to avoid removing insufficient or excessive amounts of bone.
4. Removing insufficient amounts of bone prior to final implant seating may result in prosthetic over spacing, excessive joint tension, and/or possible implant failure.
5. It is recommended to remove any fractured device from surgical site during surgery. If unable to remove, notify patient.
6. The *OSTEOMED ENCOMPASS METATARSAL RESURFACING IMPLANT* has not been tested for safety and compatibility in the MR environment, nor has it been tested for heating or migration in the MR environment.
7. Evaluation of the safety and compatibility of the device in the MR environment, the following concerns were determined based on the implant material, MDD 93/42/EEC and ISO14630: magnetically induced displacement force and torque, radio frequency (RF) heating and image artifacts.

Maintaining Device Effectiveness

1. The surgeon should have specific training, experience and thorough familiarity with the use of joint replacement implant devices. Surgeon should familiarize himself/herself with the surgical technique guide.
2. All *OSTEOMED* implants and instrumentation may be required for each surgery. Failure to use dedicated, unique *OSTEOMED* instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
3. Carefully inspect the *OSTEOMED* implants prior to use. Inspect the instruments before use to assure they are in proper operating condition. Instruments which are faulty, damaged, or suspect should not be used. They should be replaced or sent to *OSTEOMED* for disposition.
4. *OSTEOMED* products are to be used in a sterile environment.
5. Inspect hydroxylapatite coating on implant for fractures.
6. Guide Pin marking tolerance: ±.010"=.254mm.

Individualization of Treatment

The surgeon must exercise reasonable judgment when selecting the size of implant to use for specific indications and should consider the quality of bone, bone type, functional loads, soft tissue constraints and biomechanical implications of the procedure as well as the patients post operative goals and compliance.

Patient Information

Patients should be informed and cautioned in writing regarding the limitations of artificial joint replacement.

Attention: Instructions for Use are in the Surgical Technique Guide (030-1608)

Instructions for Use

1. Expose the metatarsophalangeal joint using a dorsal incision.
2. If necessary, remove any bony eminence or osteophytes from the metatarsal head.
3. Use the drill guides to determine the appropriately sized implant for the metatarsal head. The drill guide should cover the metatarsal head from medial to lateral and dorsal to plantar without extending beyond the margins of the bone.
4. Drive the appropriately sized guide pin into the metatarsal shaft through the drill guide until the first calibration mark in the grouping is flush with the drill guide. Remove the drill guide, and drive the guide pin until the distal laser mark line is flush with the metatarsal bone.
5. Select the corresponding spherical reamer and place over the guide pin. Once the reamer is fully seated against the metatarsal head, the zero calibration mark on the guide pin will be visible. Ream the metatarsal several additional millimeters until all articular cartilage is removed and bleeding bone is present.
6. Remove the guide pin and reamer and place the corresponding trial. Remove any excess bone if necessary.
7. Check the joint for range of motion and confirm that the metatarsal length has been adjusted properly.
8. Mark the location of the trial alignment groove on the dorsal aspect of the metatarsal head with a marking pen and remove the trial.
9. Align the groove of the appropriately sized broach with the dorsal mark made with the pen. Place the broach into the reamed canal and use a mallet to insert until the broach bottoms out on the metatarsal head. Remove the broach with a slaphammer.
10. Select the corresponding implant and insert into the metatarsal. The implant is marked "DOR" to indicate the dorsal side. Use the impactor to fully seat the implant against the metatarsal bone.
11. Check implant alignment, range of motion, fixation, and joint spacing.
12. Close using standard closure techniques.

Storage

- Sterile packaged implants should be stored at controlled room temperature out of direct sunlight.
- Product package should be inspected prior to use for signs of damage or tampering.
- Sterile implants have a shelf life of 4 years.

Sterility

1. *OSTEOMED ENCOMPASS METATARSAL RESURFACING IMPLANT System* implants are packed STERILE (Gamma Sterilized). DO NOT USE IF STERILE PACKAGE IS DAMAGED. DO NOT USE AFTER EXPIRATION DATE.
2. Instruments are supplied NON-STERILE and MUST be sterilized prior to use.
3. Use of the sterilizer shall comply with the manufacturer's user instructions for sterilizers.
4. Non-sterile instruments are sterilizable by steam sterilization (autoclaving). For sterilization of *OSTEOMED ENCOMPASS METATARSAL RESURFACING IMPLANT System* instruments, the following Cleaning and Sterilization Instructions should be followed.

Cleaning (instruments)

1. Products must be carefully cleaned prior to sterilization. Trained personnel must perform cleaning and mechanical inspection prior to sterilization.
2. Compliance is required with the equipment manufacturer's user instructions (manual and/or machine cleaning, ultrasound treatment, etc.) and recommendations for chemical detergents.
3. It is the responsibility of the facility/user to qualify any deviations from the recommended method of processing.
4. *OSTEOMED* recommends the following cleaning and sterilization instructions for Instrumentation:
   1. Rinse the articles to be cleaned under running cool tap water (<40°C) to remove visible soil until visibly clean.
   2. Prepare an enzymatic cleaner, Klenzyme®, per manufacturer's recommendations. Fully immerse the articles in the solution and soak for a minimum of 10 minutes. Actuate the articles while immersed in the solution to ensure complete penetration of cleaning solution.
   3. Using a soft bristled brush, clean the entire article paying close attention to hard to reach areas until all evidence of soil is removed. A syringe may be used to clean the lumens and other hard to reach areas. Actuate the articles while brushing in order to clean matted surfaces and movable parts.
   4. Prepare a mild detergent such as Renu-KlenzTM, per manufacturer's recommendations. Fully immerse the articles in the prepared solutions and sonicate the articles for a minimum of 10 minutes. Following sonication, remove the articles and proceed to the rinse step.
   5. Rinse the articles under running reverse osmosis/deionized (RO/DI) water until all evidence of detergent is removed.
   6. Steam Autoclave per the following Sterilization Instructions.

Encompass Case with one Tray system and pin matt

Pre-Vacuum Steam Sterilization

Temperature:	270°F (132°C)
Time:	4 minutes
Dry Time:	55 minutes

Configuration: Indivigually wrapped the case in two layers of 1-ply polypropylene wrap (Kimguard KC600 – 510(k) K082554) using sequential envelope folding techniques with a surgical towel placed between the warps and the bottom of the case.

Do not exceed 275°F (135°C), to avoid compromising functions of polymeric instrumentation.

Note: Biological Indicator of *G. stearothermophilus* was used in sterilization validation.

Encompass Case with Two Tray system and No pin matt

Pre-Vacuum Steam Sterilization

Temperature:	270°F (132°C)
Time:	4 minutes
Dry Time:	25 minutes

Configuration: Indivigually wrapped the case in two layers of 1-ply polypropylene wrap (Kimguard KC600 – 510(k) K082554) using sequential envelope folding techniques with a surgical towel placed between the warps and the bottom of the case.

Do not exceed 275°F (135°C), to avoid compromising functions of polymeric instrumentation.

Note: Biological Indicator of *G. stearothermophilus* was used in sterilization validation.

Caution

- Federal Law (USA) restricts this device to sale by or on the order of a medical practitioner licensed to do so.
- Do not attempt a surgical procedure with faulty, damaged, or suspect OsteoMed instruments or implants. Inspect all components preoperatively to assure utility. Alternate fixation methods should be available intraoperatively.

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CE 0086

Symbols and Definitions

	Single Use Only	REF	Catalogue Number
	Use By (Date)		Do not use if sterile package is damaged
LOT	Batch Code (Lot Number)		Consult Instructions for Use
	Date of Manufacture		Manufacturer
	Attention, See Instructions for Use Caution, Consult Accompanying Documents	EC REP	Authorized Representative in the European Community
Rx ONLY	Federal Law (U.S.A.) Restricts this device to sale by or on the order of a physician.	STERILE R	Sterile, Method of Sterilization Using Irradiation

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