

OSTEOMED
ReFlexion Toe System
Product Information and Instructions for Use

Description

The *OSTEOMED ReFlexion Toe System* consists of a metatarsal component, a metatarsal head and a phalangeal base. Each component is available in small, medium and large configuration and the different sizes are interchangeable. The instruments include reamers, planers, guide pins and preparation instruments.

Material

The *OSTEOMED ReFlexion Toe System* is comprised of implants made from Titanium Alloy (ASTM F-136), Cobalt-Chromium Alloy (ASTM F-799), Ultra-High-Molecular-Weight-Polyethylene (ASTM F-648) and instrumentation made of stainless steel, anodized aluminum, and/or medical grade plastic.

Indications for Use

For reconstruction of severely disabled and/or painful metatarsal-phalangeal joints resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis or failure of previous arthroplasty. **Device is intended for cemented use only.** *OSTEOMED ReFlexion Toe System* implants are intended for single patient 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. System Instruments are reusable.

Contraindications

Use of the Implants is contraindicated in cases of active or suspected infection; in patients sensitive to the implant materials or in patients with bone quality or joint mechanics which would be insufficient to support the implants. Use of the Implants is further contraindicated in cases of significant angular or biomechanical deformities or in cases which would subject the implants to excessive stress or wear due to patient weight and/or activity level or in patients who may ignore the limitations of artificial joint replacement.

Warnings

1. The ReFlexion Toe System components are 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. The *OSTEOMED ReFlexion Toe System* 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.
4. 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.
2. Surgeon should familiarize him/her self with the surgical instruction manual 030-1123.
3. 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.
4. Carefully inspect the OsteoMed implants prior to use. Inspect the instruments before and after each procedure to assure they are in proper operating conditions. Instruments which are faulty, damaged, or suspect should not be used. They should be replaced or sent to OsteoMed for disposition and repair.
5. OsteoMed recommends the use of OsteoMed products in a sterile environment.

Individualization of Treatment

The Surgeon must exercise reasonable judgment when selecting the type and size of implant to use for specific indications and should consider the quality of bone, bone type, functional loads, soft tissue constraints and biomechanic 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.

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.

Cleaning (instruments)

- Products must be carefully cleaned prior to sterilization. Trained personnel must perform cleaning and mechanical inspection prior to sterilization.
- Compliance is required with the equipment manufacturer's user instructions (manual and/or machine cleaning, ultrasound treatment, etc.) and recommendations for chemical detergents.
- *OSTEOMED* recommends the following cleaning and sterilization instructions for Instrumentation:
 1. Clean all instruments thoroughly using mild detergent, soft brush and warm water. Ensure that dried blood, bone chips and other deposits are removed from the instruments and sterilization tray.
 2. Thoroughly rinse all instruments and the sterilization tray with water.
 3. Arrange all the instruments in the sterilization case and ensure that the lid is in place and properly closed.
 4. Steam Autoclave per the following Sterilization Instructions.

Sterility

- *OSTEOMED ReFlexion Toe System* implants are packed **STERILE** (Gamma Sterilized). **DO NOT USE IF STERILE PACKAGE IS DAMAGED. DO NOT USE AFTER EXPIRATION DATE.**
- Instruments are supplied **NON-STERILE** and **MUST** be sterilized prior to use.
- Use of the sterilizer shall comply with the manufacturer's user instructions for sterilizers.
- The user facility must clean and disinfect devices prior to sterilization per standard hospital procedures.
- Non-sterile instruments are sterilizable by steam sterilization (autoclaving). For sterilization of *OSTEOMED* ReFlexion Toe system instruments, the following parameters should be used.

Pre-Vacuum Steam Sterilization:

Temperature: 270°F (132°C)
Time: 8 minutes
Dry Time: 20 minutes
Configuration: Individually wrap 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 wraps 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. stearotherophilus* 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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Symbols and Definitions

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