Part No. 030-1252
Rev. M

OSTEOMED

Bio-Action Great Toe System

Product Information and Instructions for Use

Description

The *OSTEOMED Bio-Action Great Toe System* consists of a metatarsal component and a phalangeal component. Both the metatarsal and phalangeal components are offered in two sizes and in neutral, right and left configurations. The instruments include broaches, impactors, awl, drill guides and preparation instruments.

Material

The implants are made from Titanium Alloy (ASTM F-136), Cobalt-Chromium Alloy (ASTM F-90) and Ultra High Molecular Weight Polyethylene (ASTM F-648). Instruments are made of stainless steel, anodized aluminum, and/or medical grade plastic.

Indications for Use

The *OSTEOMED Bio-Action Great Toe System* is indicated for reconstruction of painful and/or severely disabled toe joints, resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis, or previously failed prosthesis. The device is intended for cement fixation only. OsteoMed Bio-Action Toe implants are 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. System instruments are reusable.

Contraindications

Use of the *OSTEOMED Bio-Action Great Toe System* is contraindicated in cases of active or suspected infection or in patients who are immunocompromised; in cases where there is limitation of the blood supply; in patients previously sensitized to titanium; or in patients with certain metabolic diseases or in patients with bone quality 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 Bio-Action Great 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* Bio-Action Great 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 joint replacement implant devices.
2. Surgeon must familiarize him/her self with the surgical instruction manual 030-1251.
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 BioAction Great 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* BioAction Great Toe system instruments, the following parameters should be used.

Pre-Vacuum Steam Sterilization: Plastic Tray:
Temperature: 270°F (132°C)
Time: 8 minutes
Dry Time: 30 minutes
Configuration: Tray wrapped with a towel in two layers of 1-ply polypropylene wrap (Kimguard KC600 – 510(k) K082554), using sequential wrapping techniques.

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.

Pre-Vacuum Steam Sterilization: Metal Tray:
Temperature: 270°F (132°C)
Time: 8 minutes
Dry Time: 30 minutes
Configuration: Tray wrapped with a towel in two layers of 1-ply polypropylene wrap (Kimguard KC600 – 510(k) K082554), using sequential wrapping techniques.

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.

Read manual prior to use

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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

Printed in U.S.A
OSTEOMED August 2014