Part No. 030-1787
Rev. D

OSTEOMED
EXTREMIFUSE HAMMERTOE FIXATION SYSTEM
Product Information and Instructions for Use

Description
The *OsteoMed* ExtremiFuse System is indicated for small bone reconstruction limited to inter-digital repair and fusion of the phalanges. The implant is a one piece implant with a threaded portion and a barbed portion that hold together the resected faces of the two phalanges. The implant is offered in 3 diameter sizes of 2.0mm, 2.4mm, and 3.0mm. For each size, the implant is available in angle configurations of 0° and 10°.

Material
The *OsteoMed* ExtremiFuse implants are made from implant grade titanium alloy (Ti6Al4V) per ASTM F136. The instrumentation is made from various grades of surgical grade stainless steel, anodized aluminum, and/or medical grade plastic.

Clinical Indications
The *OsteoMed* ExtremiFuse System is indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, and mallet toe.

Contraindications
Use of the ExtremiFuse implants are contraindicated in cases of:
- Active or suspected infection or in patients who are immunocompromised;
- In patients previously sensitized to titanium;
- In patients with inadequate bone stock;
- In patients with irreparable tendon system;
- In patients with certain metabolic diseases;
- In patients with high levels of activity;
- In patients who are unable to comply with post-operative treatment protocols;
- Possible conservative treatment;
- Growing patients with open epiphyses

Warnings
1. The *OsteoMed ExtremiFuse System* is recommended for use in patients with sufficient bone quality to sustain effectiveness and benefits of rigid fixation.
2. Ensure the proper implant size is selected via comparison with the Pre-Op X-ray template.
3. Use of an incorrectly sized implant in areas of high functional stresses may lead to implant failure.
4. DO NOT use broach for 2.0mm implants. Broach is only intended for use with the 2.4mm and 3.0mm implants.
5. When evaluating for the safety and compatibility of these devices 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.
6. The *OsteoMed ExtremiFuse System* implants have not been tested for safety and compatibility in the MR environment, nor have they been tested for heating or migration in the MR environment.

Maintaining Device Effectiveness
1. The surgeon must have specific training, experience, and thorough familiarity with the use of internal rigid fixation devices, surgical techniques and post-operative care.
2. The surgeon must exercise reasonable judgment when deciding which ExtremiFuse implant type to use for specific indications.
3. The *OsteoMed ExtremiFuse System* implants are not intended to endure excessive abnormal functional stresses.
4. All *OsteoMed ExtremiFuse System* 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.
5. Carefully inspect the *OsteoMed ExtremiFuse System* implants prior to use. Inspect the instruments before and after each procedure to assure they are in proper operating condition. Instruments which are faulty or damaged and/or suspected to be faulty or damaged should not be used. These instruments should be replaced and sent back to *OsteoMed* for disposition and repair.
6. Post-operative instructions should be given to the patient by the surgeon, including the potential for secondary injuries to a surgical site if the patient is non-compliant. Patients should be instructed to closely follow the post-operative instructions.
7. *OsteoMed* recommends the use of *OsteoMed* products in a sterile environment.

Instructions for Use
Refer to the *OsteoMed ExtremiFuse System* Surgical Technique Guide (030-1788) for detailed guidelines on surgical techniques. Available upon request at no charge from OsteoMed Customer Service.

1. Prepare joint for fusion
   - Make incision on the dorsal surface of PIP joint.
   - Resect soft tissue around PIP joint.
   - Cut base of middle phalanx perpendicular to central canal. Cut head of proximal phalanx at either 0° or 10° based on implant selected.

   Note: For a 10° fusion implant, resect the proximal phalanx with a 10° cut.

2. Drill Middle Phalanx
   - Place a Ø.035" K-wire axially into middle phalanx and check position under fluoroscopy.
   - Drill over K-wire with Ø2.7mm drill to marked line. If using a 2.4mm implant, drill to distal line. If using a 3.0mm implant, drill to proximal line.
   - Remove K-wire.
3. Broach the middle phalanx.
   - Position broach so tip is in drilled hole and a marked line is aligned with dorsal aspect of bone. By pushing on end, fully insert broach until shoulder hits bone. If desired, a mallet may be used.

   NOTE: Broach is only intended for use with the 2.4mm and 3.0mm implants. DO NOT use broach for 2.0mm implants.

4. Insert implant into proximal phalanx.
   - Insert Ø.035" K-wire axially into proximal phalanx and check placement under fluoroscopy.
   - In cases of dense bone, pre-drill over K-wire with Ø1.7mm drill.
   - Place threaded portion of implant and driver handle over K-wire. Assure implant is in correct end of driver handle marked with 0° or 10°.
   - Drive implant into phalanx until flat surface of barbs is touching bone and dorsal marking on handle is aligned with dorsal surface of bone.
   - Remove Driver Handle.
5. Remove Driver Handle and K-Wire
   - Remove driver handle from implant and pull off of K-wire.
   - For 10° implants, handle will shift plantar slightly and K-wire will slide through dorsal side of handle.
   - Remove K-wire. Insert implant into middle phalanx.
6. Insert Implant into Middle Phalanx
   - Manually distract middle phalanx. Place implant barb into hole in middle phalanx. Using firm pressure, press proximal and middle phalanges together.
   - Check both dorsal and lateral placement under fluoroscopy. If implant will not fully insert to provide bone to bone contact, distract middle phalanx off barb and broach before reinserting (see step 3).
7. Check placement under fluoroscopy
   - Do not pull on toe.
   - Check for surface contact under fluoroscopy; if more contact is desired continue to push bones together for further implant insertion.

   The device is not intended to be removed.

If removal is necessary before fusion has occurred:
1. Remove the barbed sections from the middle phalanx by pulling on the toe.
2. Unscrew the proximal thread with the ExtremiFuse driver handle.

If removal is necessary after fusion has occurred:
1. Using a sagittal saw or an osteotome, make an osteotomy at the joint line.
2. Remove the barbed sections from the middle phalanx by pulling on the toe.
3. Unscrew the proximal threaded with the ExtremiFuse driver handle.

Cleaning
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. *OsteoMed* recommends the following cleaning and sterilization instructions for re-usable Instrumentation:
4. Rinse the articles to be cleaned under running cool tap water (<40°C) to remove visible soil until visibly clean.
5. Prepare an enzymatic cleaner, Klenzyme®, or equivalent, 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.
6. 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.
7. Prepare a mild detergent such as Renu-Klenz™, or equivalent, 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.
8. Rinse the articles under running reverse osmosis/deionized (RO/DI) water until all evidence of detergent is removed.
9. Steam Autoclave per the following Sterilization Instructions.

Sterility
- NON-STERILE implants and instruments 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 devices are sterilizable by steam sterilization (autoclaving). For sterilization of *OSTEOMED* implant systems, the following parameters should be used.

Pre-Vacuum Steam Sterilization	
Minimum Temperature:	270°F (132°C)
Full Cycle Time:	4 minutes
Minimum Dry Time:	25 minutes
Configuration:	Individually wrapped 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.	

Storage – Non-Sterile Implants and Instruments
- Non-sterile implants and instruments should be stored out of direct sunlight.

Caution
- Federal (United States) law restricts this device for 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	REF	Catalogue Number
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.		

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