Part No. 030-1295
Rev.M

OSTEOMED
INTERPHLEX FLEXIBLE STABILIZATION RODS
Interphalangeal (IPJ) System
ESSENTIAL PRESCRIBING INFORMATION

Device Description
The *OSTEOMED Interphlex IPJ System* is a stemmed flexible implant specifically designed for replacement of the interphalangeal joints of the lesser toes. The *OSTEOMED Interphlex IPJ System* is comprised of implants made from medical grade silicone and instrumentation, consisting of drills and trials.

Indications for Use
Intended for indications commonly found in the interphalangeal joints; semi-rigid or rigid hammertoe deformity; angular deformity; impaired function and stability; pain; impaired toe length ratio. *OSTEOMED Interphlex IPJ System* implants and instruments 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.

Target Population: Adults

Contraindications
Use of the Implants is not intended for use in and 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 or inadequate skin coverage or in patients with bone quality insufficient to support the implants; in patients previously sensitized to silicone; in patients with significant muscle dysplasia creating malalignment of the MP joint; in patients exhibiting disorders which would cause the patient to ignore the limitations of rigid fixation.

Warnings
1. The *Interphlex IPJ* System components are not intended to endure excessive functional stresses. Such stresses may lead to accelerated implant wear and/or failure.
2. The implant should be handled with a blunt instrument to avoid implant damage.

Maintaining Device Effectiveness
- The Surgeon should have specific training, experience and thorough familiarity with the use of joint replacement implant devices. Surgeon should familiarize him/her self with the surgical instruction manual.
- 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.
- 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.
- OsteoMed recommends the use of OsteoMed products in a sterile environment.
- UNCEMENTED: Implants are intended to be used without bone cement

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 and instruments 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.

Sterility
Interphlex IPJ System implants and instruments are packed STERILE (Gamma Sterilized). DO NOT USE IF STERILE PACKAGE IS DAMAGED.

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.

Instructions for Use
1. A straight longitudinal or short curvilinear skin incision is made over the dorsum of the interphalangeal joint.
2. Retract the skin bilaterally and deepen the wound to the extensor expansion.
3. The extensor tendon is incised and reflected. Dorsal veins should be carefully retracted.
4. A longitudinal capsulotomy is performed, exposing the interphalangeal joint.
5. The interphalangeal joint is excised.
6. The drill included in the sterile surgical pack is used to prepare the medullary canals for implant placement.
   Note: Laser marking on drill flutes is in 5mm increments.
7. The sizers are used to determine the correct size and final fit of each implant. The size of the implant depends on amount of bone resected and size of the patient. The implant can be further modified by trimming the stems if necessary.
8. Thoroughly irrigate the wound for final implant placement.
9. Place implant.
10. Flush implant site with copious irrigation.
11. Reattach the capsule of the interphalangeal joint, suture the extensor tendon, close the subcutaneous tissue, and close the skin.

Recommendations for Implant Handling
1. Contact with gowns, drapes, gloves, sponges, or any other possible source of foreign body contaminants should be avoided.
2. Excessive handling of the implant should be avoided; Acute bends (greater than 90°) during insertion may cause implant damage.
3. The implant should be handled with a blunt instrument.
4. The implant should be kept immersed in sterile antibiotic solution after introduction to the operative field.
5. After trimming, rinse the implant thoroughly to remove any free particles.

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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 (MFG Date)		Manufacturer (MFR)
	Attention, See Instructions for Use Caution, Consult Accompanying Documents	EC REP	Authorized Representative in the European Community
	Keep Away from Sunlight	STERILE R	Sterile, Method of Sterilization Using Irradiation
		Rx ONLY	Federal Law (U.S.A) Restricts this device to sale by or on the order of a physician.

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