Part No. 030-1333
Rev. N

OSTEOMED
TALAR FIT
SUBTALAR IMPLANT SYSTEM
ESSENTIAL PRESCRIBING INFORMATION

Device Description
The *OSTEOMED Talar-Fit Subtalar Implant System* is comprised of implants in diameters of 8.0mm to 12.0mm and lengths of 15.0mm. Instrumentation includes guide wires, cannulated screw drivers and trial sizers.

Material
The implants are made from Titanium Alloy (ISO 5832-3). Instruments are made of stainless steel, anodized aluminum, and/or medical grade plastic.

Indications for Use
The *OSTEOMED Talar-Fit Subtalar Implant System* is indicated for use in the treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block the anterior and inferior displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela. *OSTEOMED Talar-Fit Subtalar Implant 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.

Contraindications
The *OSTEOMED Talar-Fit Subtalar Implant System* is not intended for use in and is contraindicated: in cases of active or suspected infection or in patients who are immunocompromised; in patients previously sensitized to titanium. The Talar-Fit Subtalar Implant System is further contraindicated in patients with rigid flatfoot (unreduciable); in patients with vertical talus; in patients with a structural forefoot varus as the primary condition; in patients with a degenerative joint valgus, osseous ankle equines, excessive ligamentous laxity, previous subtalar joint infection or tumor; in patients with track-bound tarsal joints, superstructural torsional problems, frontal plane knee deformity, skewfoot condition (unless complex osseous structural surgical procedures are included); in patients with severe obesity and in patients younger than 4 years of age.

Warnings
1. Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
2. 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.
3. The *OSTEOMED Talar-Fit Subtalar Implant 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.

Maintaining Device Effectiveness
1. The Surgeon should have specific training, experience and thorough familiarity with the use of implant devices.
2. Surgeon should familiarize him/her self with the surgical instruction manual.
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 condition. 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.

Attention: Instructions for Use are in the Surgical Technique Guide (030-1332)

Instructions for use
1. Create a 2-3cm incision over the sinus tarsi along the relaxed skin tension lines, avoiding the intermediate dorsal cutaneous nerves and sural nerve.
2. Identify the deep fascia and bluntly dissect, allowing entrance into the tarsal canal. The fibro-fatty plug maybe removed, if necessary, from the canal.
3. The guide pin should be inserted into the sinus tarsi from lateral to medial.
   CAUTION: If the surgeon chooses to insert the guide wire until tenting is seen on the medial aspect of the foot, care should be taken to avoid the tibialis posterior tendon and neurovascular bundle. The guide pin should be superior to the tibialis posterior tendon and anterior and slightly inferior to the medial malleoulus.
4. Optional: Prepare the Talar-Fit instrument probe by pulling the spring loaded sleeve toward the handle and placing the probe's keyed slot on to the distal end of the Talar-Fit instrument shaft. Release the sleeve. Introduce the probe into the sinus tarsi. If the surgeon preference is to pass the instrument through to the medial side of the foot, care should be taken to avoid the tibialis posterior tendon and neurovascular bundle. To remove the probe from the Talar-Fit instrument, pull back on the spring loaded sleeve and rotate the keyed probe.
5. Choose the appropriate trial based on the size and the anatomy of the patient. The size indicator is located at the proximal end of the trial. Attach the trial to the distal end of the Talar-Fit instrument shaft using the method discussed in Step 4. Slide the Talar-Fit instrument and trial over the guide wire and thread the trial into the sinus tarsi. The trial should be at least 1cm medial to the lateral wall of the calcaneous.
6. Assess range of motion of the Subtalar joint and clinical correction. The handle of the Talar-Fit instrument can be removed from the instrument shaft at this time by pulling the black collet toward the handle to release the instrument shaft. Intra-operative radiographics are recommended to evaluate the degree of correction and final placement of the trial. The sleeve of the Talar-Fit instrument is calibrated in 10mm increments as a reference point of the final position of the trial.
7. Once the trial size is determined, remove the trial and instrument from the sinus tarsi. Remove the trial from the Talar-Fit Instrument by pulling back on the spring loaded sleeve and rotate the keyed trial to release the trial from the instrument shaft.
   WARNING: The trial is not designed as a permanent implant and must be removed and replaced with the corresponding titanium Talar-Fit Implant.
8. Place the determined implant over the exposed hex head of the instrument. Slide the sterile implant over the guide pin and thread into place with the Talar-Fit instrument.
9. The implant should be at least 1cm medial to the lateral wall of the calcaneous. Intra-operative x-rays are recommended to determine the exact location of the implant. The location can be further assessed using the calibration marks on the Talar-Fit instrument as a reference.
10. Once proper location of the implant is obtained, remove the Talar-Fit instrument and guide pin.
11. Irrigate and reevaluate the subtalar joint motion.
12. Close incision.

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 biomechanic implications of the procedure as well as the patients post operative goals and compliance.

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
OSTEOMED Talar-Fit Subtalar Implant System implants and instruments are packed STERILE (Gamma Sterilized). DO NOT USE IF STERILE PACKAGE IS DAMAGED. DO NOT USE IMPLANTS OR INSTRUMENTS AFTER EXPIRATION DATE.

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	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
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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