3S Hemi Toe Implant System
Instructions for Use

900-01-009 Rev I
July 2018

Description
The 3S Hemi Toe Implant consists of one component to replace the articulation of the proximal phalanx of the first metatarsophalangeal joint and corresponding instrumentation to facilitate insertion. The 3S Hemi Toe Implant is fixed by means of a stem, which is inserted into the medullary canal of the phalanx. The profile of the metal base plate articulates with the metatarsal head. Instrumentation is provided to assist in the surgical implantation of this great toe system. It is important that the instruments and trial implants used are those specifically designed for this device to ensure accurate installation. The implants are intended for single use only.

Implant Materials
The 3S Hemi Toe Implant is manufactured from cobalt chromium (ASTM F-799, ASTM F-75, or ASTM F-1537). The instrumentation is made from medical grades of anodized titanium, stainless steel, and plastic.

Indications
The 3S Hemi Toe Implant is designed to supplement first metatarsal phalangeal joint arthroplasty. Indications include hallux limitus or hallux rigidus, painful hallux valgus, revision of failed previous surgery and painful arthritis. This device is for uncemented use.

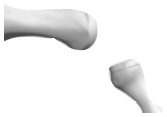
Contraindications
Contraindications for the use of the 3S Hemi Toe Implant include any condition, which would contraindicate the use of joint replacement in general, including:
- Poor bone quality, which may affect the stability of the implant
- Severe tendon, neurological, or vascular deficiencies, which could compromise the affected extremity
- Any concomitant disease, which may compromise the function of the implant

Warnings
For safe and effective use of this implant system, the surgeon should be familiar with the recommended implantation procedure for this device. Improper selection, placement, positioning, or fixation of implant may result in unusual loading conditions, which could affect the long-term service of the implant. In every case, accepted surgical practices should be followed in post-operative care. The patient should be made aware of the limitations of joint reconstruction and cautioned to govern his/her activities accordingly to protect the joint from unreasonable stresses. Excessive physical activity and trauma affecting the replaced joint have been implicated in premature failure by loosening, fracture, or wear of the implant. Patient sensitivity to implant materials should be considered and assessed prior to surgery.

Adverse Effects
- Loosening of similar implant components has been reported. Early loosening may result from improper fixation or latent infection. Late loosening may result in bone resorption or pain due to biological complications or mechanical problems.
- Dislocation and subluxation of similar implant components have been reported due to improper positioning of the prostheses. Soft tissue laxity can also contribute to these conditions. Metal sensitivity reactions in patients following joint replacement have been reported infrequently. The significance and effects of sensitization await further clinical evidence for evaluation and may be avoided by preoperative sensitivity testing.
- Implantation of foreign material in the tissues can result in histological reaction involving various sized macrophages and fibroblasts, or heterotopic bone formation. The actual clinical significance of this effect is uncertain, as similar changes may occur as a normal precursor to, or during, the normal wound healing process.
- Peripheral neuropathies may occur, possibly as a result of surgical trauma. Reoperation may be required to repair adverse affects. Infrequent complications, such as infections, have been reported which have resulted in implant revision, arthrodesis or amputation.

Instructions for Use, 3S Hemi Implant System

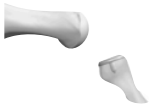
1. Expose the 1st Metatarsal Phalangeal Joint with a 4cm to 5cm slightly curved dorsal incision just medial to the EHL tendon, allowing proper dissection to expose the joint capsule.
2. Retract the tissues, then incise the capsule with a “T” incision at the MPJ for exposure of the phangeal base and the metatarsal head. Carefully release the capsular structures from the medial, dorsal, and anteriolateral aspects of the joint.



3. Resect the articular surface of the phalanx with an oscillating or sagittal saw, making the cut perpendicular to the long axis of the phalanx. Resect only enough bone to avoid prosthetic overspacing and excessive joint tension by accommodating for proper implant head thickness (generally 2mm-8mm).
4. Remove any osteophytes from the lateral, dorsal, and medial aspects of the metatarsal head to allow for normal range of motion.

5. Determine implant size by application of implant sizers. Care should be taken to select sizer which approximates the dimensions of the osteotomized phalanx and does not extend beyond the margins of the cut surface.

6. Use the awl along with a mallet to create the guidehole.



7. Reduce the joint and examine for tension and motion. A normal range of concentric, unimpinged motion particularly in dorsiflexion should be demonstrated. If the joint is too tight, remove the trial and resect the appropriate amount of bone from the proximal phalanx to relieve tension. An overly tight joint may result in limited motion and contraction hallux deformity post surgery. Final remodeling is performed to assure that the entire bone is covered by the trial.

8. Optional (for dense bone only): Place the appropriately sized broach into handle. Broach bone by aligning the spade tip with the center of the pilot hole created by the awl; "DORSAL" marking on broach bit indicates orientation. Use mallet if necessary.

9. Once the appropriate size implant has been determined, the trial removed, and the metatarsal head remodeled, use the impactor to place the implant into phalanx until it is flush with the bone.

10. Once implant is placed, perform a final check of alignment and range of motion to ensure proper fit.
11. Irrigate and remove any debris from the joint space and close using standard closure techniques.

Implant Removal (if necessary)

1. Expose the 1st Metatarsal Phalangeal Joint with a 4cm to 5cm slightly curved dorsal incision just medial to the EHL tendon, allowing proper dissection to expose the joint capsule.
2. Remove implant by most appropriate method as chosen by surgeon preference.
3. Once implant is removed, it should be treated as medical waste and disposed of accordingly.

Cleaning

Non-sterile 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. For validated cleaning instructions, please reference document 900-06-008, 3S Hemi Implant System Cleaning and Sterilization Protocol.

Packaging and Sterility

NON-STERILE PRODUCT

The 3S Hemi Toe Implant System (instruments and implants) can be packaged non-sterile and therefore must be sterilized prior to surgical use. Use of the sterilizer shall comply with the manufacturer's user instructions. The user facility must clean and disinfect instruments prior to sterilization per standard hospital procedures. Non-sterile devices are sterilizable by steam sterilization (autoclaving). The following parameters should be followed:

Sterilization Method	Pre-Vacuum Steam	Gravity Steam
Condition	Wrapped*	Wrapped*
Temperature	270°F (132°C)	270°F (132°C)
Time	4 minutes	15 minutes
Dry Time	Recommended 40 minutes**	Recommended 30 minutes**

* The system shall be packaged for sterilization by double wrapping in standard central supply wrap (i.e. Bio-Shield® Sterilization Wrap).
** Trilliant Surgical has validated the recommended sterilization cycle and dry time for trays. The dry time varies due to load configuration, wrapping method, and material.

CAUTION

Federal Law (USA) restricts this device to sale by or on the order of a physician.
Do not attempt a surgical procedure with faulty, damaged or suspect Trilliant Surgical instruments or implants.
Inspect all components preoperatively to assure utility.

Product Handling

Store implants unopened in their respective protective packages until use. When removing the implant from its package, observe all relevant aseptic instructions. Protect the prosthesis from contact with objects, which may damage the surface finish. Inspect each implant prior to use and return the 3S Hemi Toe Implants that exhibit surface or configuration damage. Contouring or clamping of implants should be avoided if possible. It is recommended that implants should not be cut, sharply bent or re-bent, notched or scratched. These alterations can produce defects or stresses, which may lead to failure of the implant.

MRI Safety Information

The 3S Hemi Toe Implant System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of 3S Hemi Toe Implant System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Symbols Glossary

Symbol	Description	Designation Number, ISO 15223-1:2016
REF	Catalog Number	5.1.5
LOT	Batch Code	5.1.6
	Do not use if package is damaged	5.2.8
	Do not reuse	5.4.2
NON STERILE	Non-Sterile	5.2.7
Rx only	Device only to be sold on or by the order of a physician	N/A*
	Manufacturer	5.1.1
	Caution	5.4.4
	Consult instructions for use	5.4.3

*Symbol allowed under 21 CFR 801. The above symbols are outlined in ISO 15223-1:2016 Medical devices -- Symbols to be used with medical device labels, labeling and information to be supplied -- Part 1: General requirements. Note: QTY is an abbreviation of "QUANTITY".

Please contact company for product inquiries and surgical techniques, or to report any adverse experience.

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