

# Two-Step Hammer Toe Implant System

## Instructions for Use

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### Description

The Two- Step Hammer Toe Implant is a device used for bone fixation in the phalanges of the lesser digits in the foot and hand. The implant is a cannulated, threaded, spaded device that is offered in 3.0mm and 4.0mm threaded diameters. The 3.0mm threaded implants are available in 3.4mm and 4.5mm diameter spade sizes with lengths of 6 – 30mm in the threaded section. The 4.0mm threaded implant is available in a 5.5mm diameter spade size with lengths of 6 – 10mm in the threaded section. Available implants and instrumentation can be packaged as a single system or the implants may be offered in a single sterile packaged offering. System instrumentation includes k-wires, spade drills, drivers, a thread drill and handles to facilitate the placement of the implants. The Hammer Toe Implants and K-wires are intended for single use only.

### Implant Materials

All Hammer Toe Implants are made from Titanium Alloy (ASTM F-136). The instrumentation is made from medical grades of stainless steel, anodized aluminum, and silicone.

### Indications

The Hammer Toe System implants are intended for fixation of osteotomies and reconstruction of the lesser phalanges during procedures to correct deformities of the lesser toes and fingers. Indications include: hammer toe deformity, claw toe deformity, mallet toe deformity, and other deformities of the foot and hand.

### Contraindications

Use of the Hammer Toe Implant System is 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; or in patients with certain metabolic diseases. It is further contraindicated in patients exhibiting disorders, which would cause the patient to ignore the limitations of internal fixation.

### 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. Use of an undersized implant in areas of high functional stresses may lead to implant fracture and failure.
3. Plates, screws, or other appliances of dissimilar metals should not be used together in or near the implant site.
4. Implants and guide wires are to be treated as sharps.

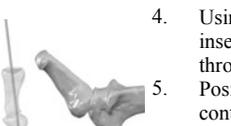
### Maintaining Device Effectiveness

1. The surgeon should have specific training, experience, and thorough familiarity with the use of the Hammer Toe Implant System.
2. The surgeon must exercise reasonable judgment when deciding which implant type to use for specific indications.
3. The Hammer Toe Implants are not intended to endure excessive abnormal functional stresses.
4. The Hammer Toe Implants are intended for temporary fixation only until osteogenesis occurs.
5. All Hammer Toe Implant System implants and instrumentation may be required for each surgery. Failure to use dedicated, unique Trilliant Surgical 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.
6. Carefully inspect the 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.
7. The Two-Step Hammer Toe Implant System should be used in a sterile environment.

### Instructions for use, Hammer Toe Implant System

 <ol style="list-style-type: none"> <li>1. Expose the joint space dorsal of the proximal interphalangeal joint.</li> <li>2. Prepare the joint for arthrodesis by resurfacing the head of the proximal phalanx and the base of the middle phalanx until the desired correction is achieved.</li> </ol>	 <ol style="list-style-type: none"> <li>7. Select the appropriate length and diameter implant and slide the implant over the exposed proximal end of the K-wire.</li> </ol>
 <ol style="list-style-type: none"> <li>3. Using the drill corresponding to the chosen spade size, drill a pilot hole in the head of the proximal phalanx in the proper position for implant placement. The pilot drill is self-stopping.</li> </ol>	 <ol style="list-style-type: none"> <li>8. Using the driver, drive the implant into the middle phalanx until the leading edge of the tri-spade stem abuts the edge of the middle phalanx. Make sure a fin of the tri-spade stem sits in the 12 o'clock (dorsal) position.</li> </ol>
 <ol style="list-style-type: none"> <li>4. Using a wire pin driver and the appropriate size K-wire, insert the K-wire centrally into the middle phalanx, drilling towards the distal phalanx.</li> <li>5. Position the distal phalanx in the desired position and continue inserting the K-wire, maintaining a central position. Continue driving the K-wire until it is protruding through the distal phalanx. Assure that the K-wire is sufficiently exposed to allow for capture with the wire pin driver.</li> <li>6. With the wire pin driver, retract the K-wire distally until the proximal end is exposed approximately 5mm.</li> </ol>	 <ol style="list-style-type: none"> <li>9. Manually distract the middle phalanx and align the tri-spade stem down the central axis of the head of the proximal phalanx.</li> <li>10. Apply firm compression until the base of the middle phalanx fully apposes the head of the proximal phalanx.</li> </ol>  <ol style="list-style-type: none"> <li>11. Drive the K-wire to the desired depth.</li> </ol>

## Instructions for use, Hammer Toe Implant System Dual Joint Arthrodesis

	<ol style="list-style-type: none"> <li>Expose the joint spaces dorsal of the proximal interphalangeal joint and the distal interphalangeal joint</li> <li>Prepare the joints for arthrodesis by resurfacing the head of the proximal phalanx, base of the middle phalanx, head of the middle phalanx, and base of the distal phalanx until the desired correction is achieved.</li> </ol>	 <ol style="list-style-type: none"> <li>Continue driving the K-wire until it is protruding through the distal phalanx. Assure that the K-wire is sufficiently exposed to allow for capture with the wire pin driver.</li> <li>Pre-drilling the middle phalanx is recommended to reduce the axial force necessary for inserting the implant.</li> </ol>
	<ol style="list-style-type: none"> <li>Using the spade drill corresponding to the chosen spade size, drill a pilot hole in the head of the proximal phalanx in the proper position for implant placement. The spade drill is self-stopping.</li> </ol>	 <ol style="list-style-type: none"> <li>With the wire pin driver, retract the K-wire distally until the proximal end is only exposed approximately 5mm.</li> <li>Select the appropriate length and diameter implant and slide the implant over the exposed proximal end of the K-wire.</li> </ol>
	<ol style="list-style-type: none"> <li>Using a wire pin driver and the appropriate size K-wire, insert the K-wire centrally into the middle phalanx, drilling through the middle phalanx and towards the distal phalanx.</li> <li>Position the distal phalanx in the desired position and continue inserting the K-wire, maintaining a central position. Drive the K-wire under image intensification to the center of the distal phalanx or until the desired depth is achieved in the distal phalanx.</li> </ol>	 <ol style="list-style-type: none"> <li>Using the appropriate driver, drive the implant through the middle phalanx and into the distal phalanx until the leading edge of the tri-spade stem abuts the edge of the middle phalanx and the distal tip of the implant sits inside the distal phalanx. Make sure a fin of the tri-spade stem sits in the 12 o'clock (dorsal) position. It is recommended to stabilize the phalanges while placing the implant.</li> </ol>
	<ol style="list-style-type: none"> <li>Measure for the desired implant length by examining the end of the guide wire in relation to the marks on the depth gauge.</li> </ol>	 <ol style="list-style-type: none"> <li>Manually distract the distal/middle phalanx segment and align the tri-spade stem down the central axis of the head of the proximal phalanx.</li> <li>Apply firm compression until the base of the middle phalanx fully apposes the head of the proximal phalanx.</li> </ol>
		 <ol style="list-style-type: none"> <li>Drive the K-wire to the desired depth.</li> </ol>

### Removal of Hammer Toe Implant

Expose proximal interphalangeal joint. Distract the joint space until tri-spade stem is fully exposed. Using the driver, back implant out by turning counter-clockwise.

### Postoperative Precautions

Postoperative care is according to surgeon preference and should follow protocol for fusions/reconstructions of a similar nature. The patient should be advised of the limitations of the reconstruction. The reconstruction will need to be protected from full weight bearing until adequate healing has occurred.

### Possible Adverse Effects

The following are specific adverse effects, which should be understood by the surgeon and explained to the patient

- Pain, discomfort or abnormal sensations
- Metal sensitivity, allergic reaction to a foreign body
- Dislocation or migration of components from improper position, trauma, loss of fixation and/or muscle and fibrous tissue laxity
- Infection
- Delayed wound healing; deep wound infection which may necessitate the removal of the implant
- Fracture of the device can occur as the result of non-compliance, trauma, strenuous activity, improper alignment, incomplete implant seating, non-union, or excessive weight

### 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 900-06-016, HTR® Hammer Toe Implant System and Two-Step Hammer Toe Implant System Cleaning and Sterilization Protocol.

### Packaging and Sterility

#### NON-STERILE PRODUCT

The Trilliant Surgical Subtalar 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 40 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.

### STERILE PRODUCT

Trilliant Surgical Hammer Toe Implants can be supplied sterile (Gamma Sterilized). In accordance with ISO 11137:2006, two methods of sterilization are allowed. Both provide a sterility assurance level (SAL) of 10<sup>-6</sup>. These are "Method 1" and "VDmax". Prior to use, inspect package for damage, which may compromise sterility.

### 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.

### MRI Safety Information

The Two-Step Hammer 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 Two-Step Hammer Toe Implant System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

### Symbol Definitions

Batch Code Catalogue Number Quantity Caution

Non-Sterile Manufacturer Date of Manufacture

Device only to be sold on or by the order of a physician

Do not use if package is damaged Caution

Do not re-use Device has no expiration Consult Instructions for Use

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