INSTRUCTIONS FOR USE
Two-Step Hammer Toe Implant System

TRILLIANT SURGICAL

900-01-008 Rev P | February 2023

Description
The Two-Step Implant System is used for fixation of the bones of the foot and hand. The system includes a cannulated, threaded, spaded implant that is offered in multiple threaded diameters, lengths, and spade diameters. The system includes k-wire implants in multiple sizes. Available implants and instrumentation can be packaged in a sterilization tray as a single system. System instrumentation includes spade pilot drills, spade drivers, thread pilot drills, reamers, impactor, and handles to facilitate the placement of the implants. The Two-Step Implant System Implants and K-wires are intended for single use only.

Implant Materials
All Two-Step Hammer Toe Implants are made from Titanium Alloy (ASTM F136). All K-wires are made from 316L Stainless Steel (ASTM F138). The instrumentation is made from medical grades of stainless steel, anodized aluminum, and silicone.

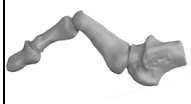
Indications
The Two-Step Hammer Toe Implant System is intended for fixation of osteotomies and reconstruction of the bones of the foot and hand during procedures to correct deformities of the toes and fingers. Indications include: hammer toe deformity, claw toe deformity, mallet toe deformity, and other deformities of the foot and hand.

Contraindications
Use of the Two-Step 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.

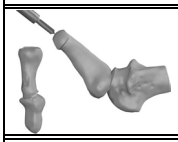
Warnings
1. Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
2. Use of an undersized implant in areas of high functional stresses may lead to implant fracture and failure.
3. Plates, 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.
5. Re-use of devices indicated as single use can result in decreased mechanical and clinical performance of devices.

Maintaining Device Effectiveness
1. The surgeon should have specific training, experience, and thorough familiarity with the use of the Two-Step Hammer Toe Implant System.
2. The surgeon must exercise reasonable judgment when deciding which implant type to use for specific indications.
3. The Two-Step Hammer Toe Implants are not intended to endure excessive abnormal functional stresses.
4. The Two-Step Hammer Toe Implants are intended for temporary fixation only until osteogenesis occurs.
5. All Two-Step 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, Two-Step Hammer Toe Implant System

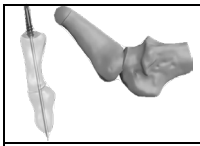


1. Expose the joint space dorsal of the proximal interphalangeal joint.
2. Prepare the joint for arthrodesis by resurfacing the head of the proximal phalanx and the base of the middle phalanx until the desired correction is achieved.

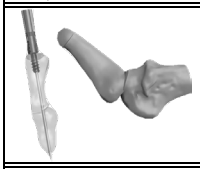


3. Using the drill corresponding to the chosen spade size, drill a pilot hole in the head of the proximal phalanx in the proper position for implant placement. The pilot drill is self-stopping.

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.
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.
6. With the wire pin driver, retract the K-wire distally until the proximal end is exposed approximately 5mm.



7. Select the appropriate length and diameter implant and slide the implant over the exposed proximal end of the K-wire.

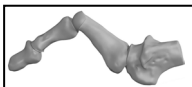


8. Using the corresponding spade driver, drive the implant into the middle phalanx until the leading edge of the tri-spade stem abuts the edge of the middle phalanx. Make sure a fin of the tri-spade stem sits in the 12 o'clock (dorsal) position.

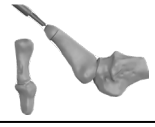
9. Manually distract the middle phalanx and align the tri-spade stem down the central axis of the head of the proximal phalanx.
10. Apply firm compression until the base of the middle phalanx fully apposes the head of the proximal phalanx.

11. Drive the K-wire to the desired depth.

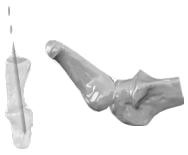
Instructions for Use, Two-Step Hammer Toe Implant System Dual Joint Arthrodesis



1. Expose the joint spaces dorsal of the proximal interphalangeal joint and the distal interphalangeal joint.
2. 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.



3. Using the spade pilot 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.



4. 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.
5. 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.

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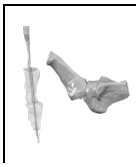
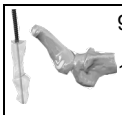
6. Measure for the desired implant length by examining the end of the guide wire in relation to the marks on the depth gauge.



7. 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.
8. Pre-drilling the middle phalanx with the thread pilot drill is recommended to reduce the axial force necessary for inserting the implant.



9. With the wire pin driver, retract the K-wire distally until the proximal end is only exposed approximately 5mm.
10. Select the appropriate length and diameter implant and slide the implant over the exposed proximal end of the K-wire.

11. Using the appropriate spade 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.

12. Manually distract the distal/middle phalanx segment and align the tri-spade stem down the central axis of the head of the proximal phalanx.
13. Apply firm compression until the base of the middle phalanx fully apposes the head of the proximal phalanx.

14. Drive the K-wire to the desired depth.

Removal of K-wire Implant
Engage the distal percutaneous K-wire segment with a wire pin driver while retracting the K-wire distally until fully removed.*

Removal of Two-Step 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.*

*Removed implants should be treated as medical waste and disposed of accordingly.

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
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. Trays shall be thoroughly cleaned and visually inspected to ensure cleanliness. Repeat cleaning if visual inspection shows any contaminants or debris. For validated cleaning instructions, please reference document 900-06-020, Two-Step Hammer Toe Implant System Cleaning and Sterilization Protocol.

Packaging and Sterility
NON-STERILE PRODUCT
The Trilliant Surgical Two-Step Hammer Toe Implant System (instruments and implants) are 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 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	30 minutes
Recommended Dry Time	50 minutes**	60 minutes**

*The system shall be packaged for sterilization by double wrapping in in an FDA cleared wrap and wrapping techniques outlined per ANSI/AAMIST79, then adhered with FDA cleared chemical indicator autoclave tape.
**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.
Note: Do not stack trays during sterilization.

The proposed sterilization cycle (Gravity - 132°C exposure time 30 min.) is not considered by the United States Food and Drug Administration (US FDA) to be a standard sterilization cycle. Users should only use sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization containers) that have been cleared by the US FDA for the selected sterilization cycle specifications (time and temperature).

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.

Symbols Glossary

Symbol	Description	Designation Number, ISO 15223-1:2021
REF	Catalog Number	5.1.6
LOT	Batch Code	5.1.5
	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 15223-1:2021 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 for "QUANTITY".

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

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