

TWO-STEP HAMMER TOE IMPLANT SYSTEM

The Two-Step Hammer Toe Implant is a cannulated, titanium alloy, interphalangeal joint arthrodesis implant for fusions of the DIPJ and PIPJ with temporary stabilization of the MTP joint if desired.

HAMMER TOE CORRECTION

- Self-drilling, self-tapping threaded section for rapid placement down the central axis of the phalanx
- Optional spade placement in the proximal or distal direction
- Tri-spade stem for multiplane stabilization of the joint
- Available in a wide range of extended thread lengths for combination DIPJ and PIPJ fusions with a single implant for severe hammer toe/claw toe deformities

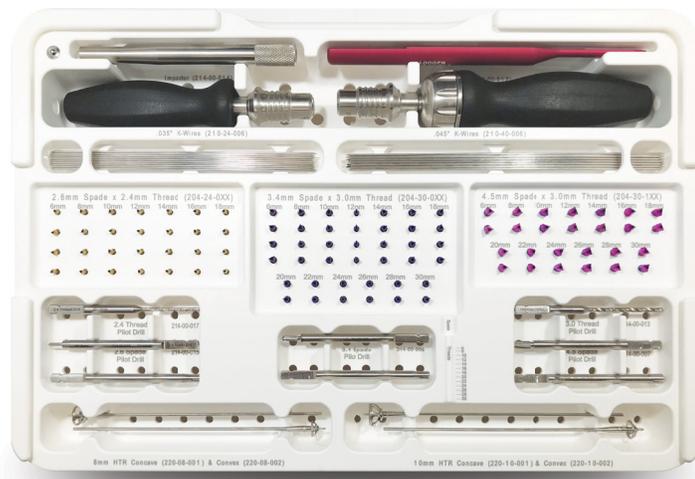


TWO-STEP HAMMER TOE IMPLANT SYSTEM



Spade Diameter	2.6mm	3.4mm	4.5mm
Spade Length	4.0mm	5.5mm	6.1mm
Thread Diameter	2.4mm	3.0mm	3.0mm
Thread Lengths*	6-18mm	6-30mm	6-30mm

*Offered in 2mm increments



All associated instrumentation included in a single system

SURGICAL TECHNIQUE



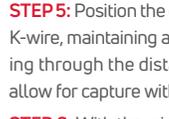
STEP 1: Expose the joint space dorsal of the proximal interphalangeal joint.



STEP 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.



STEP 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.



STEP 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.



STEP 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. Assume that the K-wire is sufficiently exposed to allow for capture with the wire pin driver.

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



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



STEP 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.



STEP 9: Manually distract the middle phalanx and align the tri-spade stem down the central axis of the head of the proximal phalanx.

STEP 10: Apply firm compression until the base of the middle phalanx fully apposes the head of the proximal phalanx.



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

ALTERNATIVE METHOD FOR HAMMER TOE IMPLANT PLACEMENT*

AFTER STEP 2: Using the drill corresponding to the chosen spade size, drill a pilot hole in the base of the middle phalanx in the proper position for implant placement. The pilot drill is self-stopping. Select the appropriate length and diameter implant and using the driver, drive the implant into the central axis of the head of the proximal phalanx until the leading edge of the tri-spade stem abuts the edge of the proximal phalanx. Make sure a fin of the tri-spade stem sits in the 12 o'clock (dorsal) position. Manually distract the middle phalanx and align the tri-spade stem down the central axis of the middle phalanx. **PROCEED WITH STEP 10.** *Use of K-Wire for placement and temporary fixation may be used per surgeon discretion.

DUAL JOINT ARTHRODESIS APPLICATION

STEP 1: Expose the joint spaces dorsal of the proximal interphalangeal joint and the distal interphalangeal joint. **STEP 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. **STEP 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. **STEP 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. **STEP 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. **STEP 6:** Measure for the desired implant length by examining the end of the guide wire in relation to the marks on the depth gauge. **STEP 7:** Continue driving the K-wire until it is protruding through the distal phalanx. Assume that the K-wire is sufficiently exposed to allow for capture with the wire pin driver. **STEP 8:** Pre-drilling the middle phalanx is recommended to reduce the axial force necessary for inserting the implant. **STEP 9:** With the wire pin driver, retract the K-wire distally until the proximal end is only exposed approximately 5mm. **STEP 10:** Select the appropriate length and diameter implant and slide the implant over the exposed proximal end of the K-wire. **STEP 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. **STEP 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. **STEP 13:** Apply firm compression until the base of the middle phalanx fully apposes the head of the proximal phalanx. **STEP 14:** Drive the K-wire to the desired depth.

FDA cleared 510(k) K181898.
Trilliant products are made in the U.S.A.



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