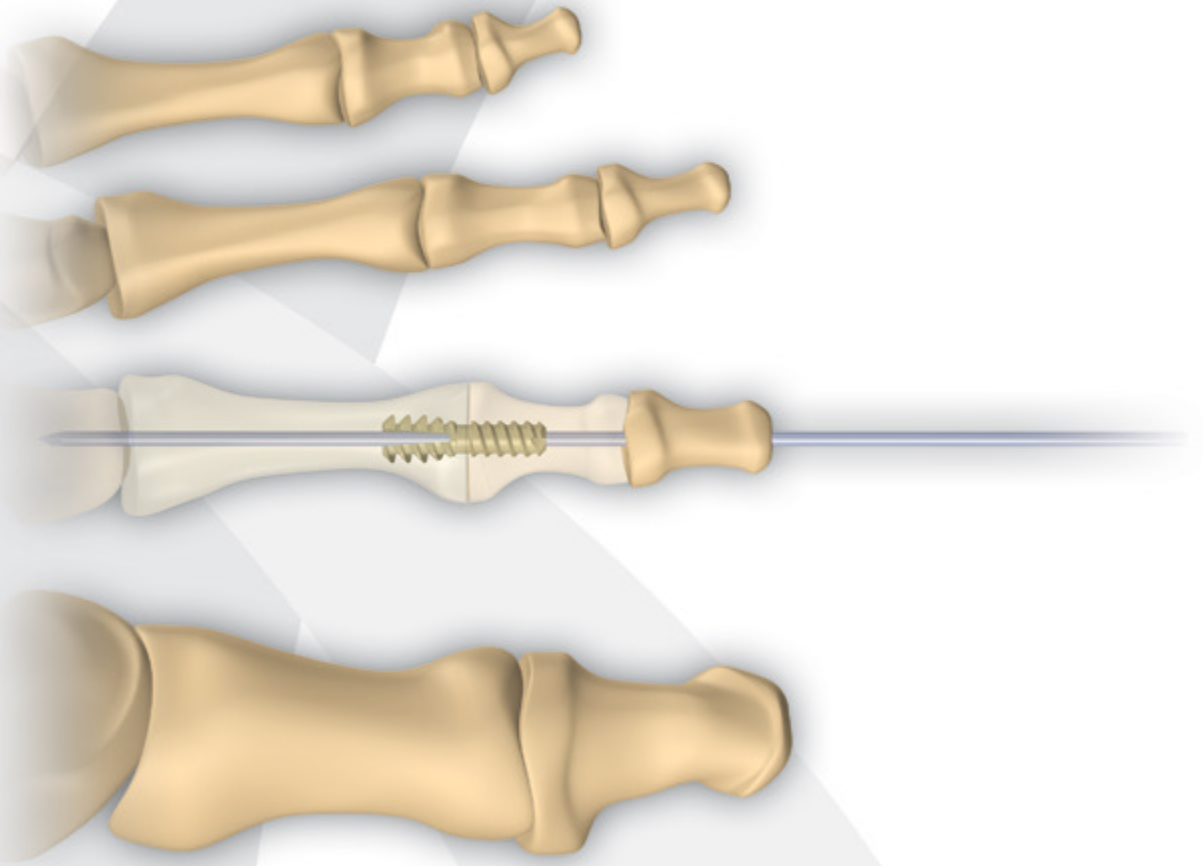
HammerFix™
IP FUSION SYSTEM

Hammertoe Deformity
Surgical Technique



CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

EXTREMITY MEDICAL™

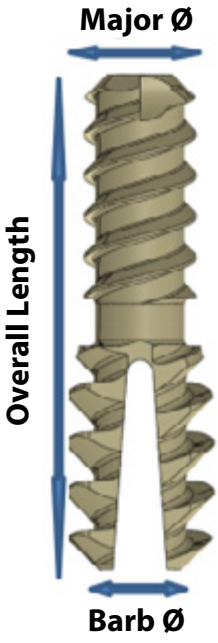
Customer Service: 888.499.0079
www.extremitymedical.com

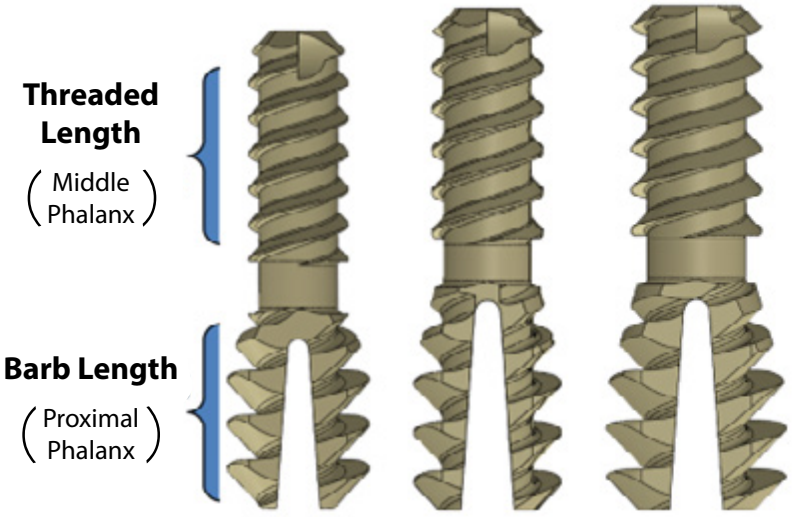
INDICATIONS FOR USE

The Extremity Medical Hammertoe Device is indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe and mallet toe.

HammerFiX™ Implants Description:

- Made of PEEK (Polyetheretherketone)
  - *A non-resorbable polymer that has been shown to be highly biocompatible with a long track record in orthopaedics*
- Cannulated
  - *Provides an option to temporarily pin the corrected phalanx across the MPJ with a guidewire*
- Available in 3 sizes to accommodate size variations of the lesser toes

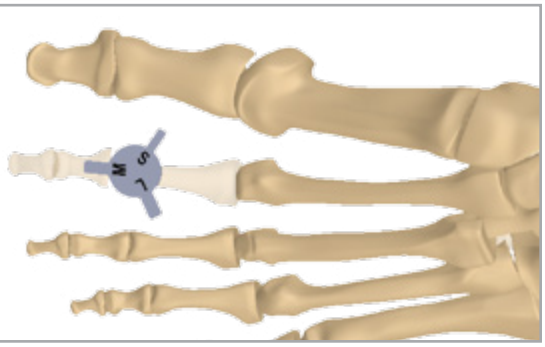




Size	Small – 2.8	Medium – 3.4	Large – 4.0
Overall Length (mm)	13.5	15	15
Major Diameter Screw (mm)	2.8	3.4	4.0
Major Diameter Barb (mm)	4.0	4.5	5.5
Barb Length (mm) Proximal	5.5	6.8	6.8
Threaded Length (mm) Middle	6.5	7.0	7.0
Guidewire (mm) Compatibility	1.1 (.045 in)	1.4 (.054 in)	1.6 (.062 in)

STEP 1 - Pre-Operative Planning (Templating with Sizing Key)

An intra-operative template may be used to determine the optimal implant size. This template is radiopaque and can be used with fluoroscopy. The length and width of the template correspond to the length and major diameter of the threaded end of the implant for the middle phalanx.

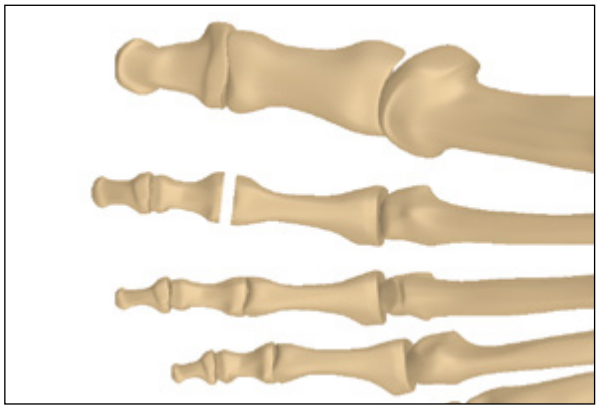


STEP 2 - Exposure and Joint Preparation

Create an incision over the dorsal aspect of the PIP joint. Perform soft tissue releases as necessary. The joint dissection and access should provide complete visualization of the articular surfaces of the middle and proximal phalanges.

STEP 3 - Joint Preparation

Prepare the joint surface of both the proximal and middle phalanx. Resect the distal aspect of the proximal phalanx just posterior to the head of the phalange. Denude the articular cartilage of the middle phalanx. If you choose to resect the middle phalanx, take care to avoid excessive resection which may result in a shortened digit.

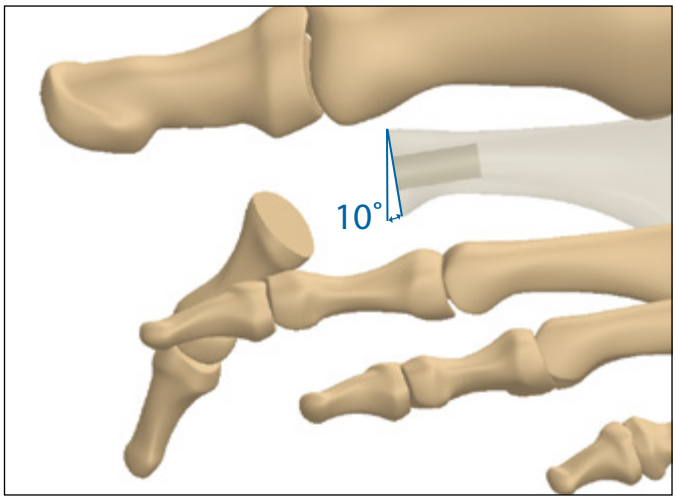


Straight Cut

10˚ Plantar Flexion Option

Resect the distal aspect of the proximal phalanx at a 10˚ angle.

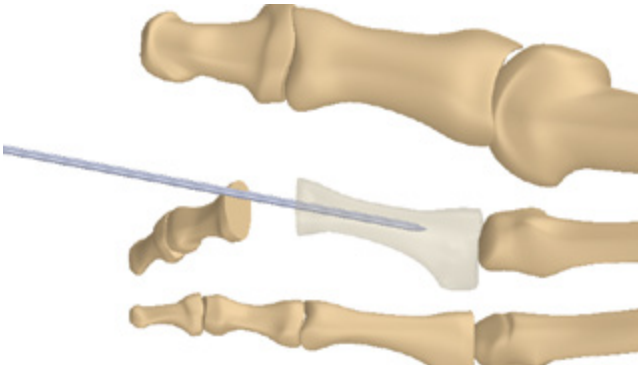
Note: It may not be possible to utilize the Guidewire for fixation of the MP joint with this option (step 8).



10˚ Option

STEP 4 - Prepare the Proximal Phalanx (Guidewire Placement & Drill)

Place the Guidewire into the proximal phalanx along its central axis, approximately 10mm. Verify proper positioning with AP and lateral fluoroscopic views.

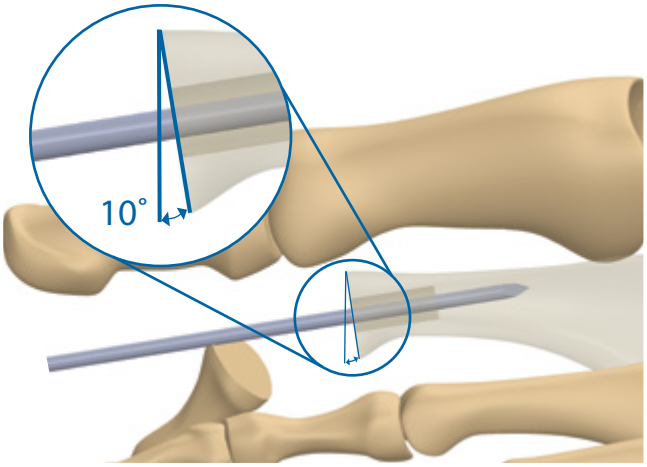


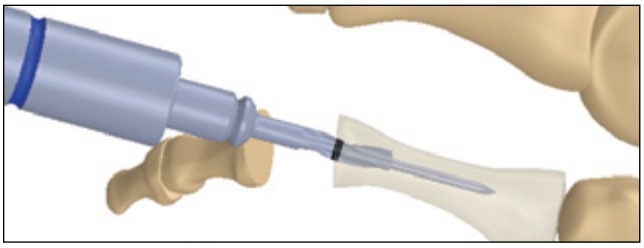
Hand drill over the Guidewire and advance until the depth line on the cannulated Drill is no longer visible. This will create space for the barbed end of implant.

Remove the Drill and Guidewire.

10˚ Option

Place the Guidewire perpendicular to the 10˚ resection of the proximal phalanx



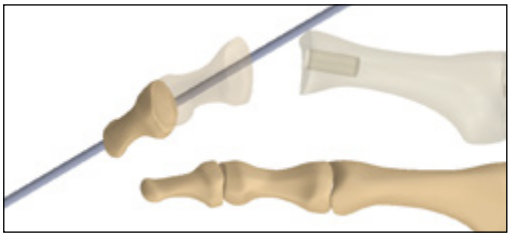


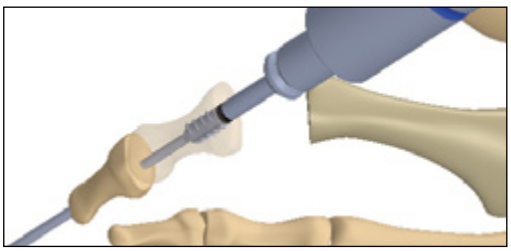
STEP 5 - Prepare the Middle Phalanx (Guidewire Placement & Tap)

Insert the Guidewire into the central axis of the middle phalanx. After verifying proper positioning with AP and lateral fluoroscopic views, continue to drive the Guidewire distally through both the middle and distal phalanx until it exits the toe, leaving a minimum of 10mm to guide the Tap.

Advance the cannulated Tap by hand over the Guidewire to prepare the middle phalanx for the threaded side of the implant. Advance the Tap until the depth line is no longer visible.

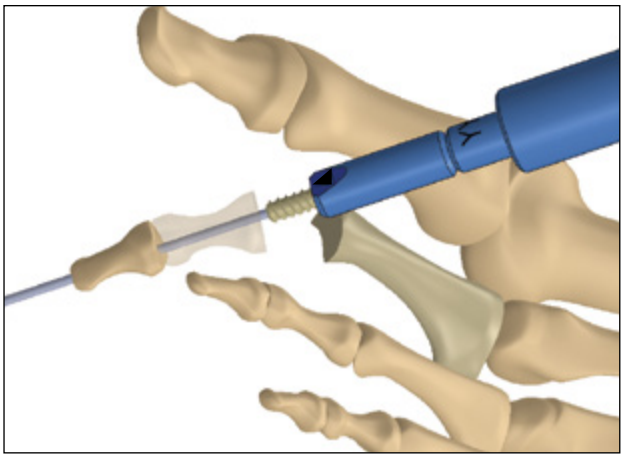
NOTE: Tap Removal – rotate the Tap counterclockwise to remove. Never pull the Tap straight out.



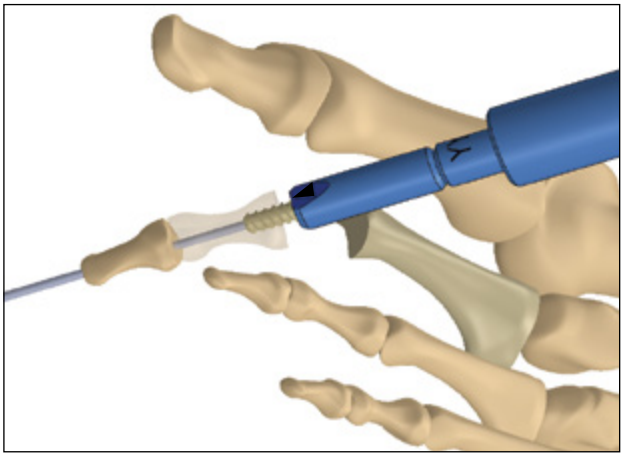


STEP 6 - Implant Insertion into the Middle Phalanx

Attach the Driver to the barbed segment of the HammerFiX implant.

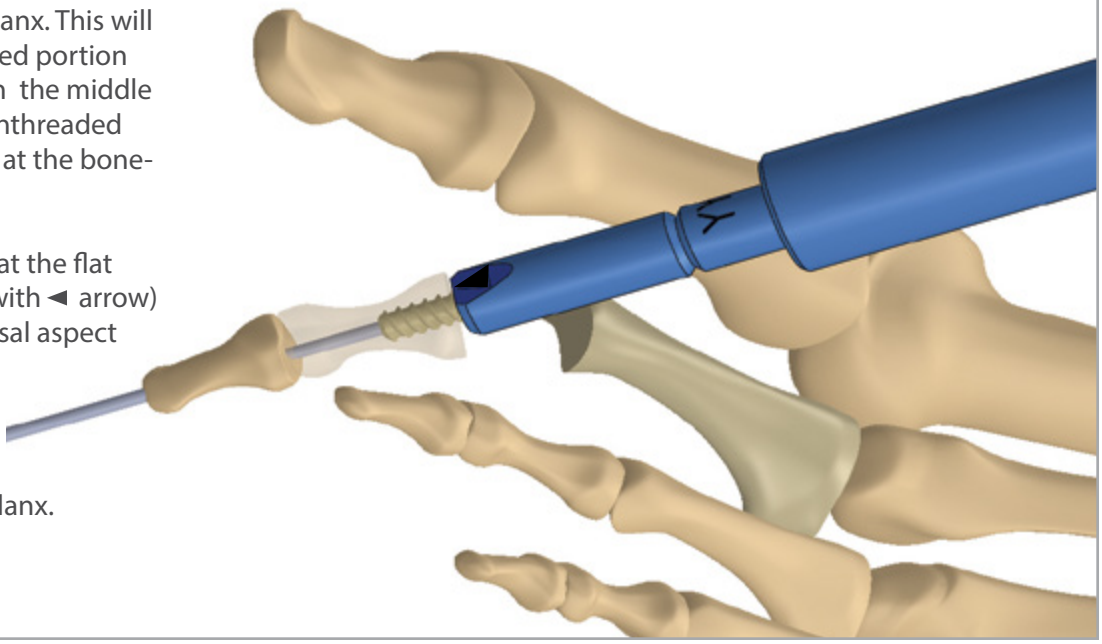


Insert the threaded screw segment of the HammerFiX implant into the middle phalanx.



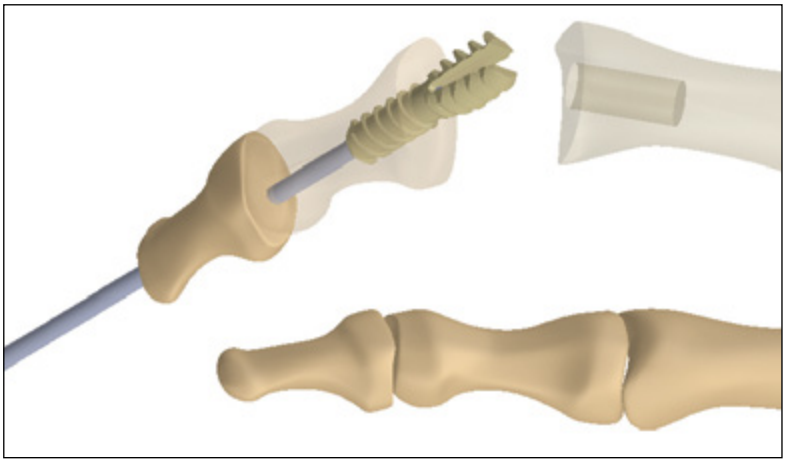
Advance the implant until the Driver meets the middle phalanx. This will ensure that the threaded portion of the implant is within the middle phalanx, leaving the unthreaded portion of the implant at the bone-to-bone interface.

Orient the Driver so that the flat surface of the Driver (with ◄ arrow) is aligned with the dorsal aspect of the middle phalanx (12 o'clock position). This will ensure the proper orientation of the implant in the phalanx.



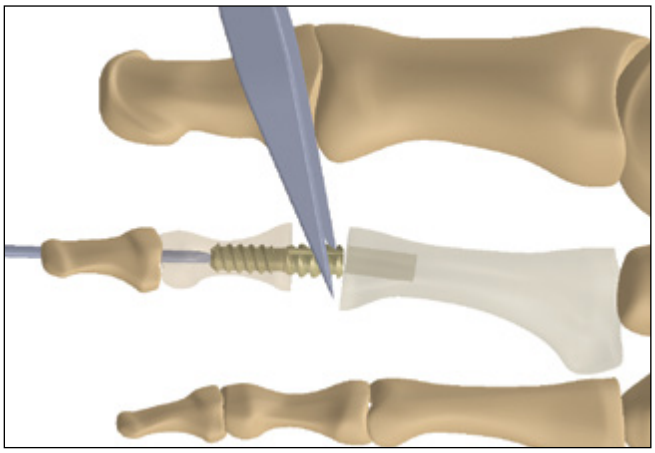
STEP 7 - Implant Insertion into the Proximal Phalanx

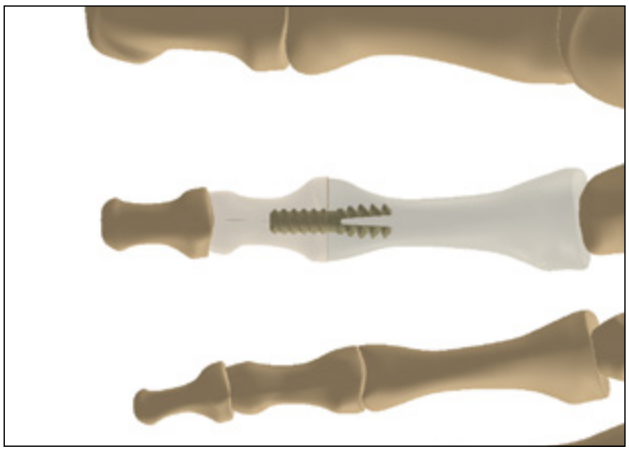
Withdraw the Guidewire distally until it is housed within the threaded screw segment of the implant.



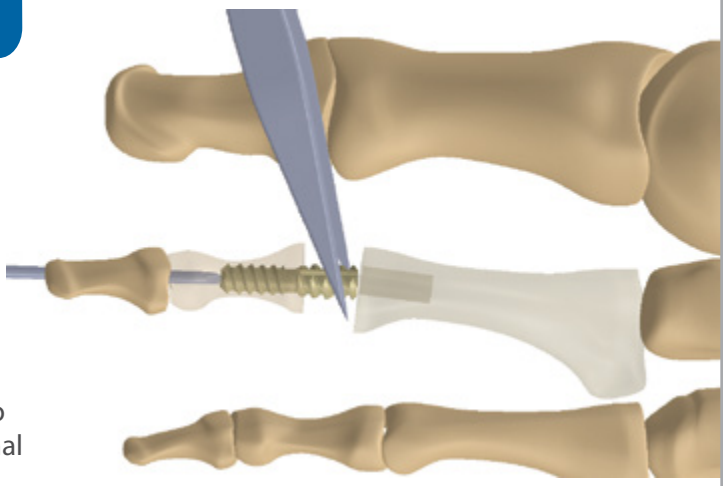
Align the implant with the proximal phalanx. Compress the barbed segment of the implant with the provided Forceps and insert the barbed portion of the implant into the pre-drilled hole in the proximal phalanx. Firmly compress the joint until the implant is completely buried and the surfaces of the resectioned joint are fully opposed.

Note: It is recommended to advance the Guidewire through the barb segment of the implant as this will enhance the barb deployment in the proximal phalanx. The Guidewire can then be removed.





STEP 7b - Implant Insertion with Added Compression



For added compression: rotate the middle phalanx counter clockwise prior to insertion into the proximal phalanx.

Optional Technique

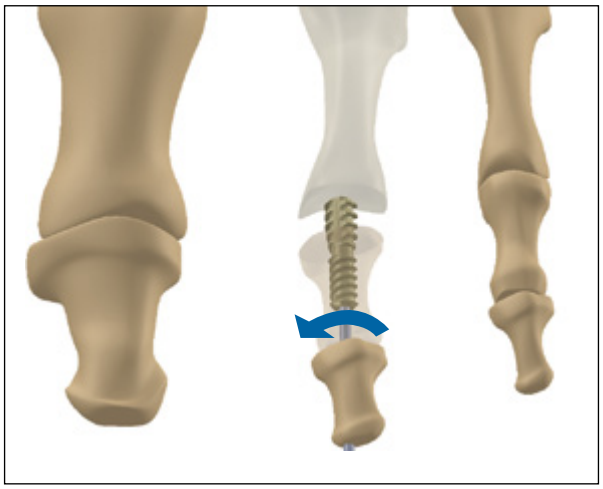
The reverse helical thread pattern of the barbed segment of the implant (opposing threads) allows for the ability to generate added compression upon the insertion of the device.

To generate compression:

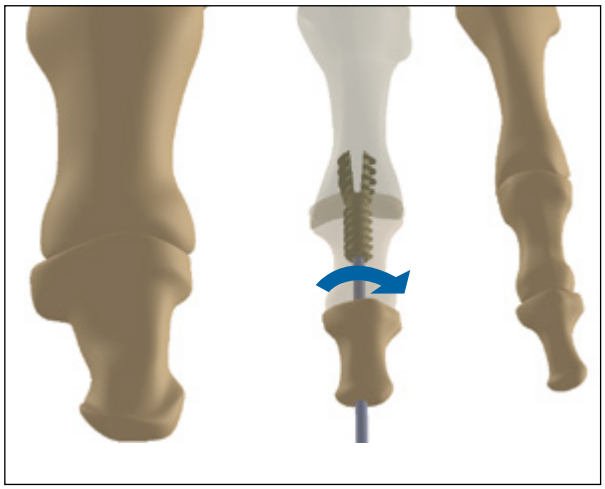
- Compress the barbed segment with the provided Forceps as in Step 7.
- Rotate the middle phalanx counterclockwise prior to the insertion of the barbed segment into the proximal phalanx.
- Firmly compress the joint until the implant is completely buried and the surfaces of the joint are fully opposed.
- Rotate the middle phalanx back to a neutral position.

The opposing threads of the barbed segment of the implant allow for ~ .25mm of compression for every 30˚ of counter-rotation.

Rotate counterclockwise prior to insertion

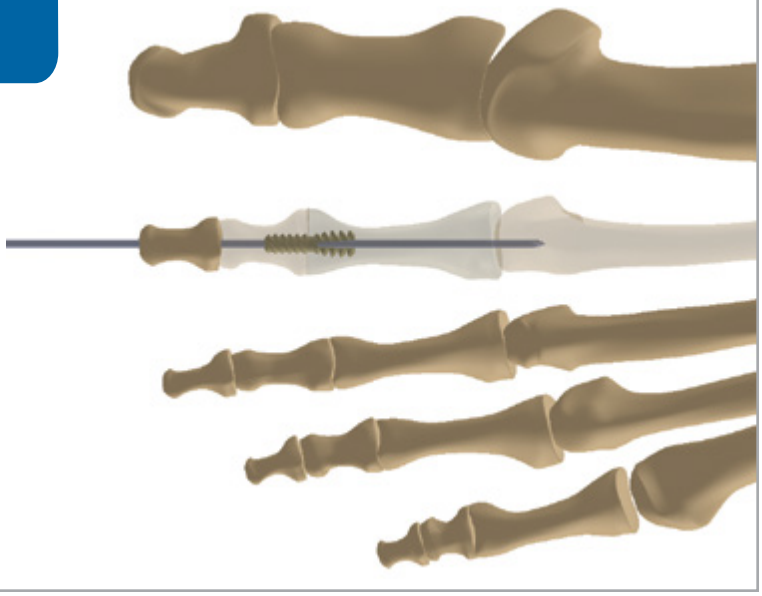


Compress joint and rotate clockwise to neutral



Note: It is recommended to advance the Guidewire through the barbed segment of the implant as this will enhance the barb deployment in the proximal phalanx. The Guidewire can then be removed.

STEP 8 - MTP Joint Stabilization (Optional)



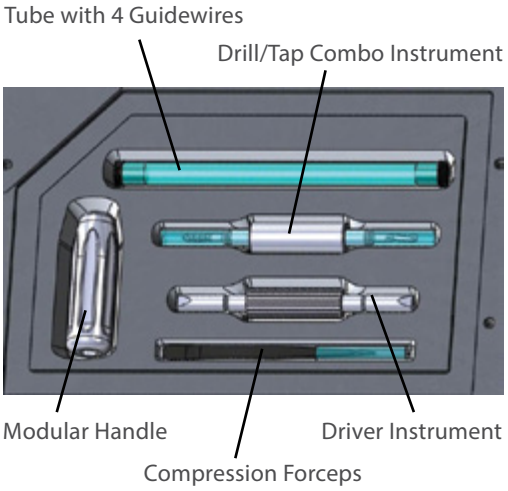
MTP Joint Stabilization

This cannulated device allows for the Guidewire to be driven proximally into the metatarsal to stabilize the MTP joint. This step is based on the surgeon's discretion, and may be left in place for the initial recovery period (up to 30 days) to allow the soft tissue to heal and prevent MTP subluxation. This step is optional. If not desired, remove the Guidewire.

REMOVAL

Expose the proximal interphalangeal joint. Distract the joint space until the barbed end of implant is exposed. Using surgical Forceps, grasp and compress the barbed side of the implant to remove from the proximal phalanx. Back implant out of the middle phalanx by turning implant counterclockwise.

Each HammerFiX Implant utilizes a size specific Instrument Set (sterile packed) that consists of the following items:



Reference Number	Description
HammerFiX™ Small	
132-28013-S	HammerFiX™ Implant - Small
132-02800-S	HammerFiX™ Instrument Kit - Small
132-28000-S	HammerFiX™ Set - Small (Implant & Instruments)
HammerFiX™ Medium	
132-34015-S	HammerFiX™ Implant - Medium
132-03400-S	HammerFiX™ Instrument Kit - Medium
132-34000-S	HammerFiX™ Set - Medium (Implant & Instruments)
HammerFiX™ Large	
132-40015-S	HammerFiX™ Implant - Large
132-04000-S	HammerFiX™ Instrument Kit - Large
132-40000-S	HammerFiX™ Set - Large (Implant & Instruments)
Sizing Key	
132-00050-S	Sizing Key

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