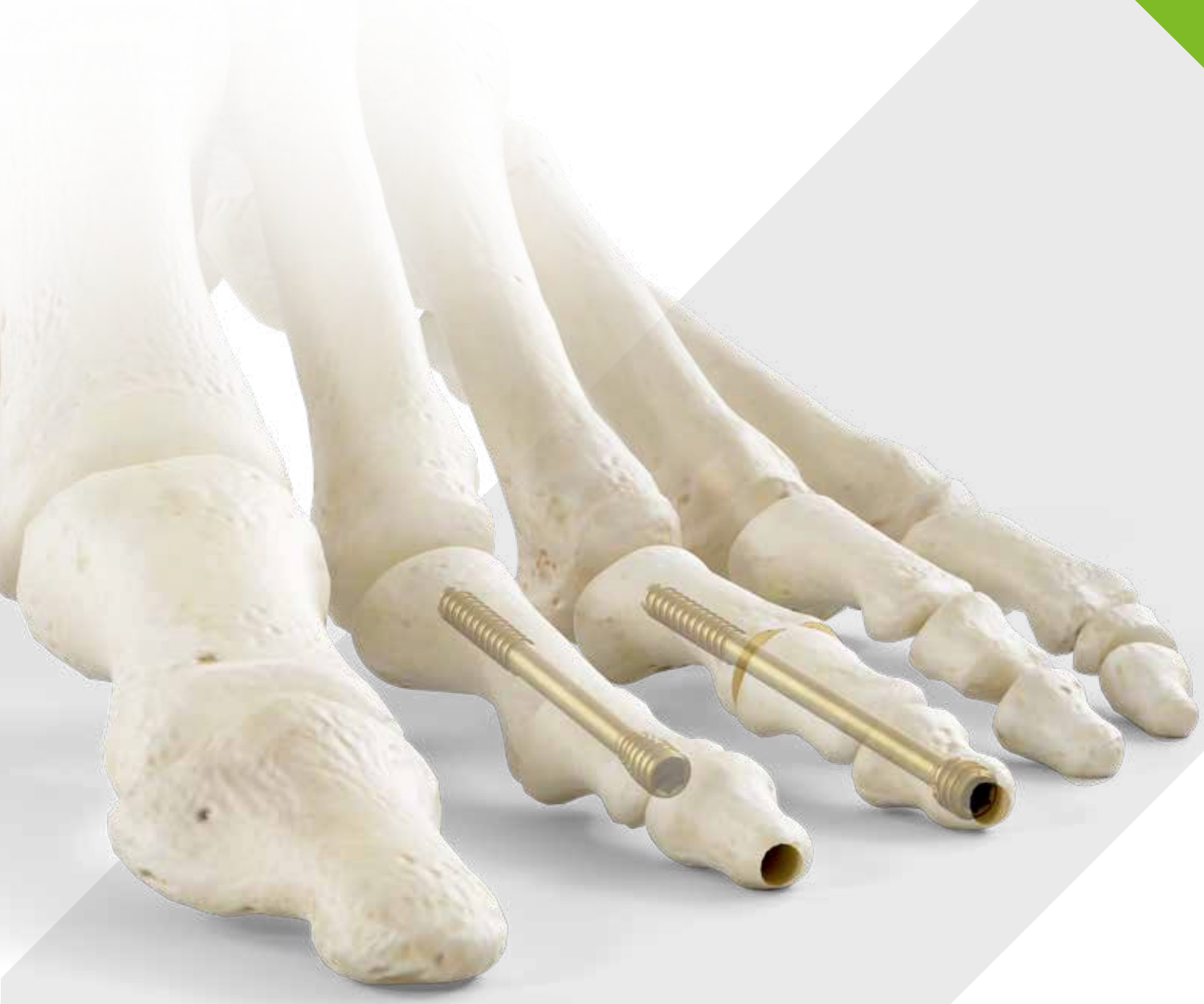
GLW Foot & Ankle

hammer thread™

Lesser toe deformity correction

Operative Technique

Ø2.5mm PIP & DIP Implants
Hammertoe Fixation System



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Lesser toe deformity correction

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This document offers technical guidance pertaining to the HammerThread Implants. As with any medical device, surgeons should rely on their training, making any necessary adjustments based on the needs of the patient.

Indications

Indications for Use and Intended Use:

HammerThread Implants are intended to maintain alignment and fixation of bone fractures, comminuted fractures in the presence of appropriate additional immobilization such as rigid fixation implants, cast or brace, non-unions, osteotomies, arthrodesis or bone grafts in the hand, foot, and ankle including distal tibia and fibula. These implants are not intended for spinal use.

Contraindications

Severe muscular, neurological or vascular deficiency in the extremity concerned.

Bone destruction or poor bone quality, likely to impair implant stability.

Surgical procedures other than those listed in the Indications section.

Known or suspected allergy to any of the device components.

Use of this implant together with implants of another origin not recommended by GLW.

Precautions

If either the implant or the package appears damaged the implant should not be used.

Meticulous preparation of the implant site and selection of the proper size implant increase the potential for a successful outcome.

Design Rationale

The HammerThread implants were designed to provide surgeons with a minimally invasive and reliable solution to address smaller toe deformities. The system is comprised of Ø2.5mm titanium Ti64 implants that accept Ø1.3 K-Wires.

This combination results in superior precision during predrilling and insertion and ample stability during the reduction of proximal and distal interphalangeal joints (PIPJ-DIPJ). The double stinger tip design of the K-Wires also allows for retrograde insertion of the HammerThread implants for both PIPJ and DIPJ fixation.

The streamlined system of implants offers appropriate length options for the compression of the DIPJ and PIPJ and offers design options for the compression of the PIPJ only. The instrumentation is provided in a sterile, ready-to-use instrument kit designed specifically for the correction of smaller toe deformities.

The instrument kit includes 4x double stinger tip Ø1.3 K-Wires, a mini depth gauge, an AO-handle and a cannulated T8 driver with a tapered shaft that matches the implants outer diameter and allows the compression of the PIPJ only without requiring additional hole preparation.

Design Features

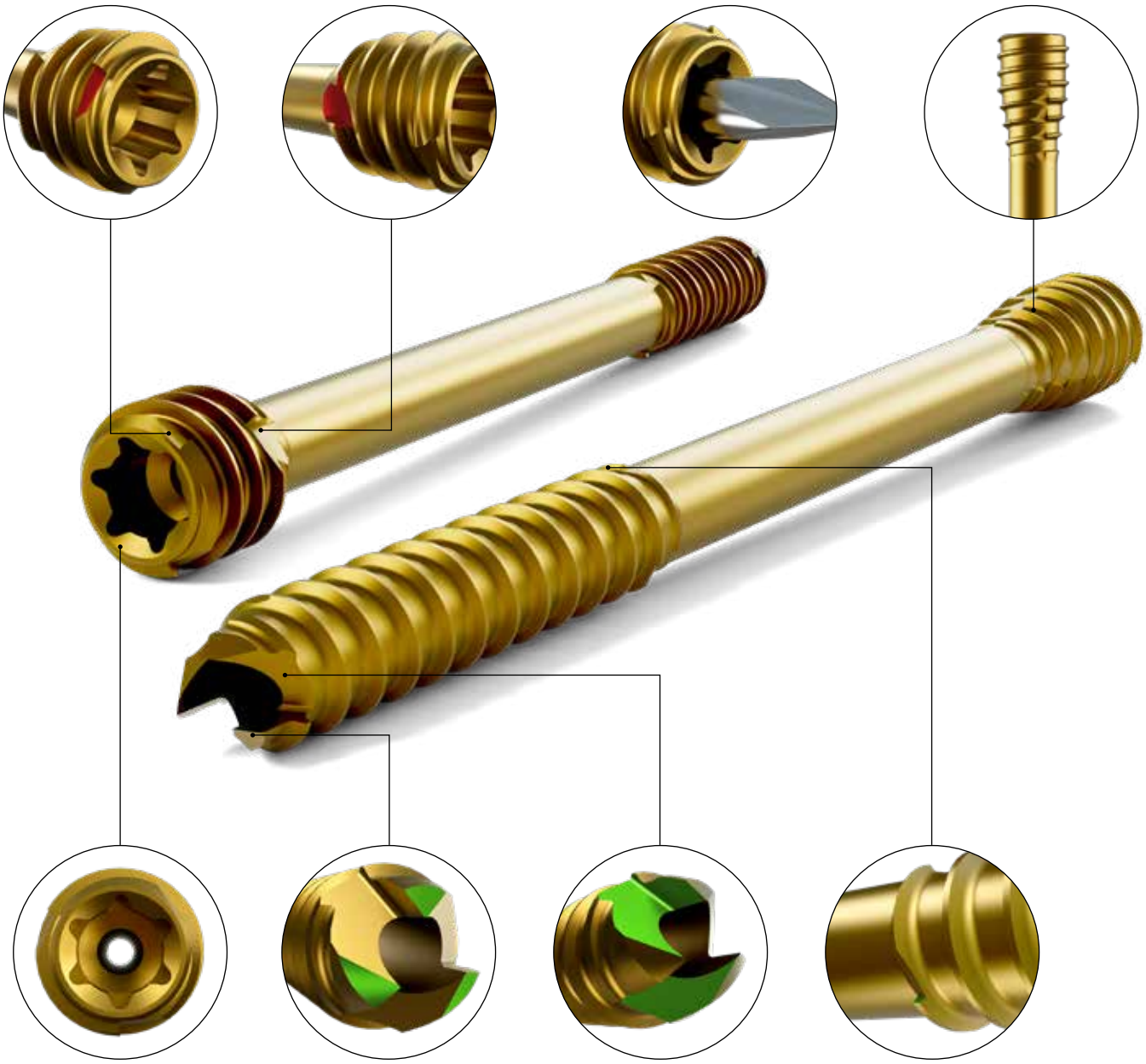
Created in conjunction with foot and ankle specialists, the HammerThread Implants are designed to deliver maximum compression with minimum torque to address smaller toe deformities.

Reverse-Cutting Design
Expedites implant extraction

Forward-Cutting Design
Accelerates screwhead countersinking

Large Cannulation
Accepts Ø1.3mm K-Wires

Tapered Head Design of PIP Implants
Seamless fixation of PIPJ



Torx Interface
Promotes a sturdy driver / implant interface

Self-Drilling Tip Design

Self-Tapping Tip Design

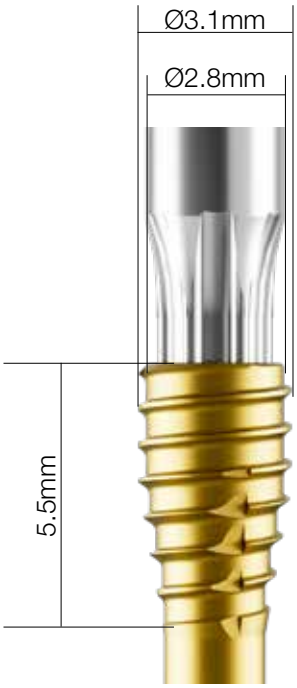
Aggressive Tri-tip design for unmatched cutting performance

Reverse-Cutting Feature
Facilitates removal of implant

Design Features – Technical Specifications

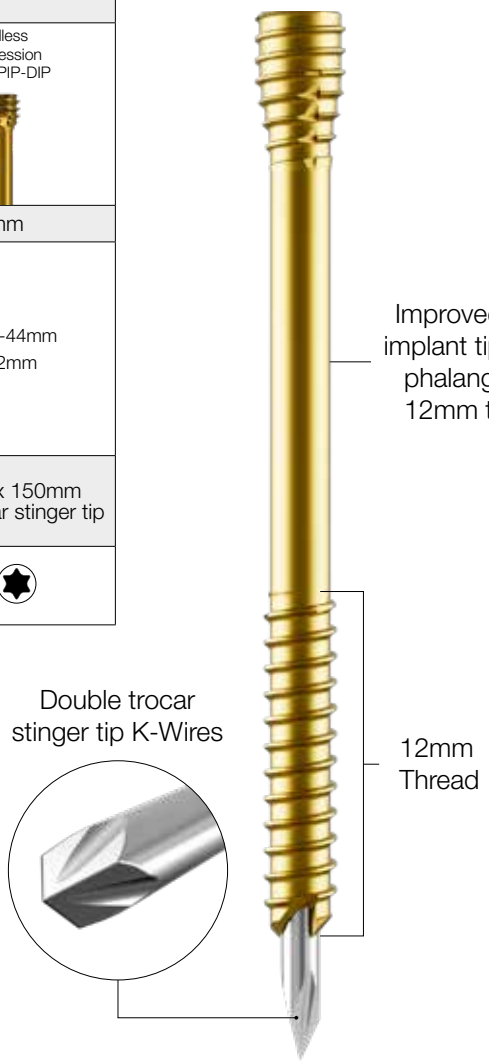
HammerThread PIPJ Implants are available in Ø2.5mm diameters and offer a wide range of lengths with 2mm increments:

Ø Size Range	2.5mm	2.5mm
Material	Ti6Al4V	
Type	Headless Compression Implant PIP 	Headless Compression Implant PIP-DIP 
Thread	12mm	12mm
Length	From 20-32mm each 2mm	From 32-44mm each 2mm
K-wire	Ø1.3mm x 150mm Double trocar stinger tip	Ø1.3mm x 150mm Double trocar stinger tip
Torx Tip	T8	T8

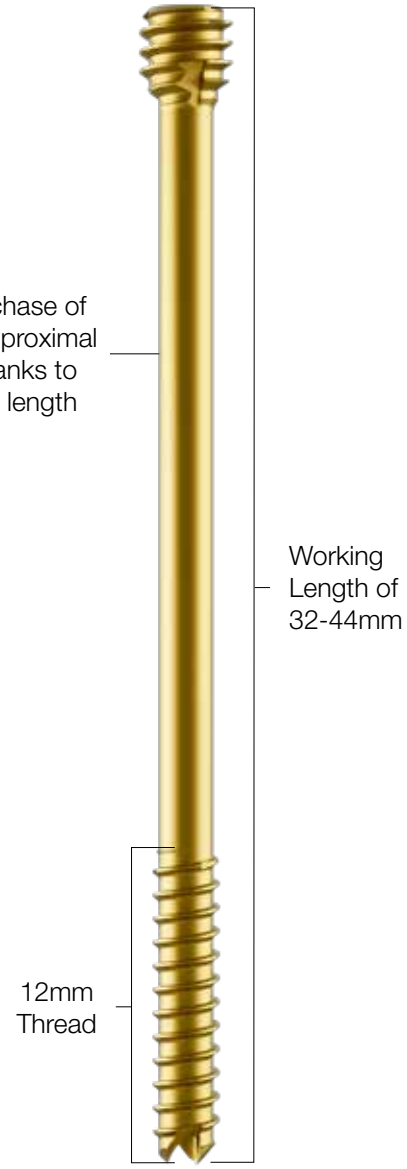


Novel tapered head design of PIP Implants allows fixation of the PIPJ only placed in retrograde manner.

Hammerhead

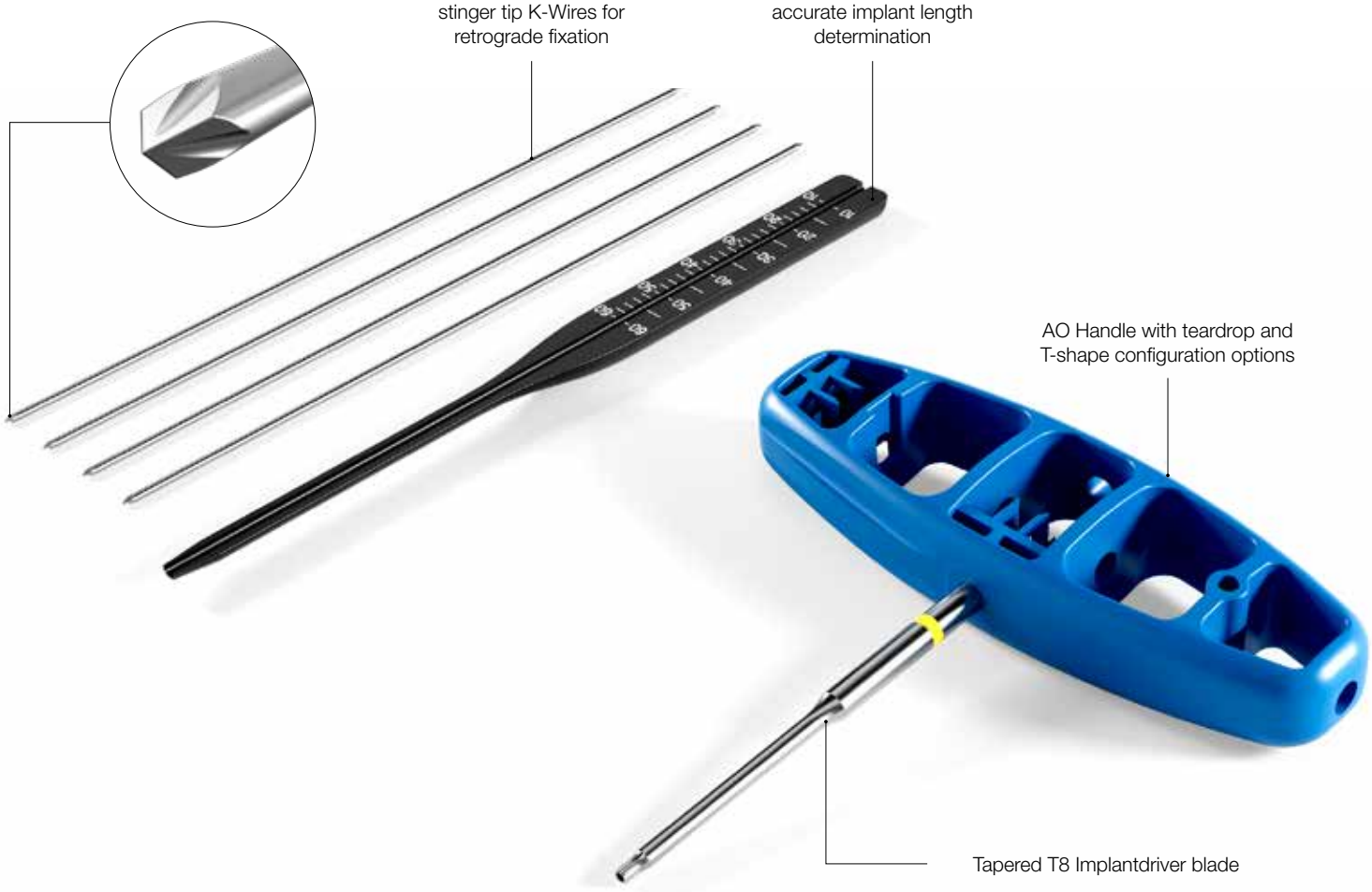


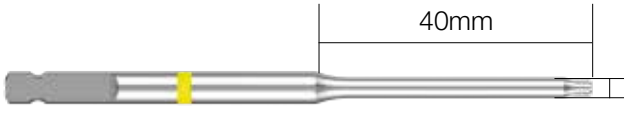
Mallethead



The length span of 32–44mm allows the appropriate fixation of PIP and DIP joints for a wide range of anatomies.

Design Features – Instruments





The Tapered T8 Implantdriver blade matches the implant major diameter and allows the insertion of implants past the distal phalanx without requiring a larger hole.

The Ø3.2mm Drill is available individually.

The Ø3.2mm Drill allows the insertion of PIP Implants without compression of the DIP.

Operative Technique

HammerThread Ø2.5mm PIP–DIP Implants
PIPJ–DIPJ Arthrodesis

Step 1 – Incision

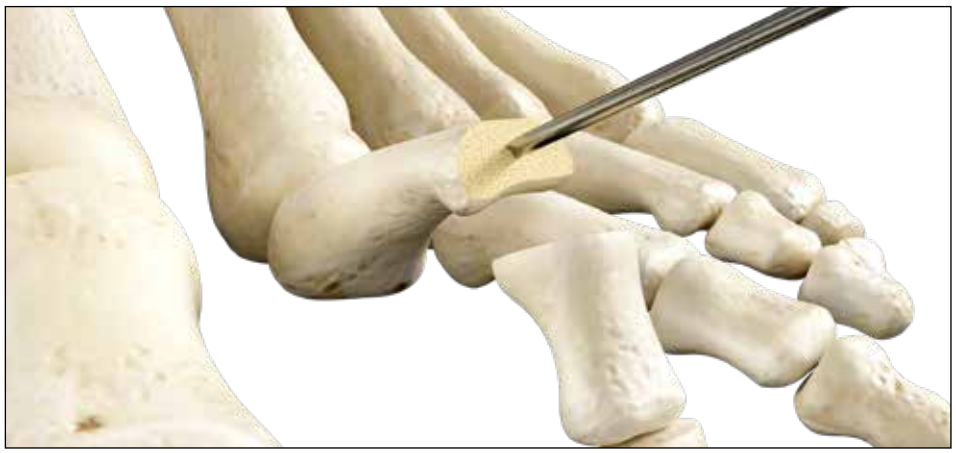
Longitudinal or transverse skin incision per surgeon preference. Expose PIP and DIP joints. Release collateral ligaments. Resect the distal aspect of proximal phalanx and proximal aspect of middle phalanx and distal aspect of middle phalanx and base of distal phalanx

Step 2 – Predrilling

Predrilling of proximal phalanx using Ø1.3mm K-Wire.

Insert the supplied K-wire to the proper depth. If necessary, utilize fluoroscopy to control K-wire position.

Note:
Please ensure there is no visible bending of the K-wire before inserting the implant. Correct K-wire placement if required.



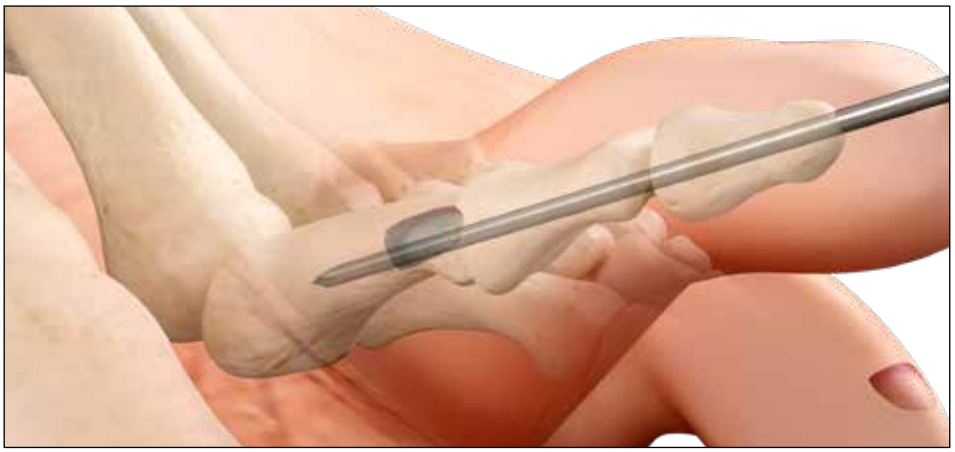
Operative Technique

HammerThread Ø2.5mm PIP–DIP Implants PIPJ–DIPJ Arthrodesis

Step 3 – K-Wire insertion

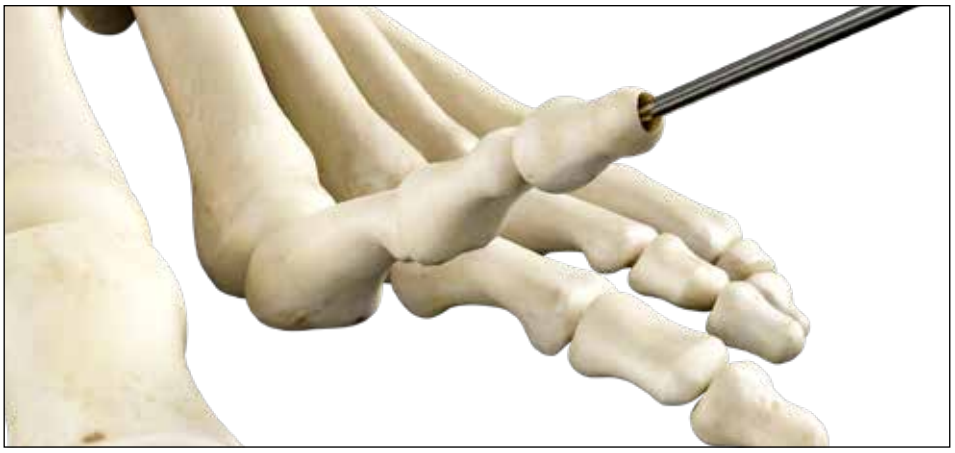
Insertion of Ø1.3 K-Wire into middle and distal phalanx.

Confirm good placement of the wire in the distal phalanx on the lateral view to avoid implant insertion that is too dorsal or plantar.



Step 4 – Retrograde K-Wire insertion

Leave the tip of the wire proud at the middle phalanx, and reduce the PIP joint so the tip of the wire is inserted into the pre-drilled pilot hole in the proximal phalanx. Advance the wire to the base of the proximal phalanx and confirm on fluoroscopy.



Step 5 – Implant Insertion

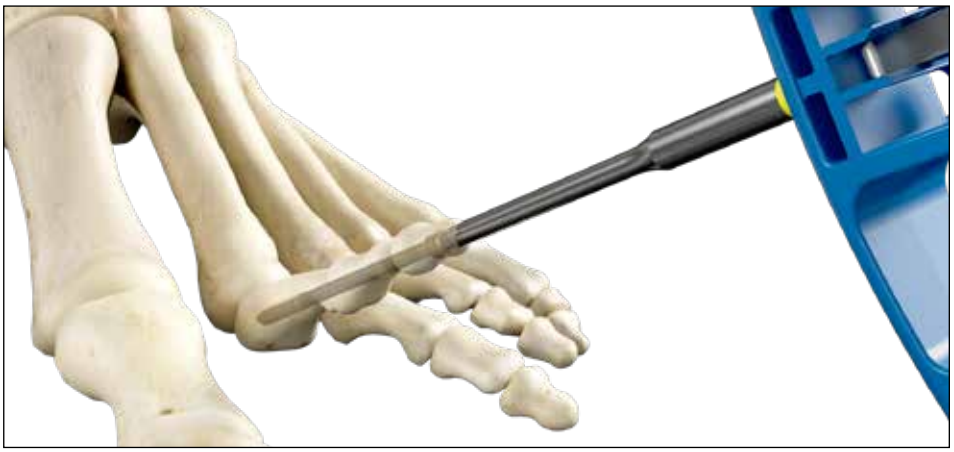
Use the provided Mini Depth Gauge to determine the appropriate implant length.

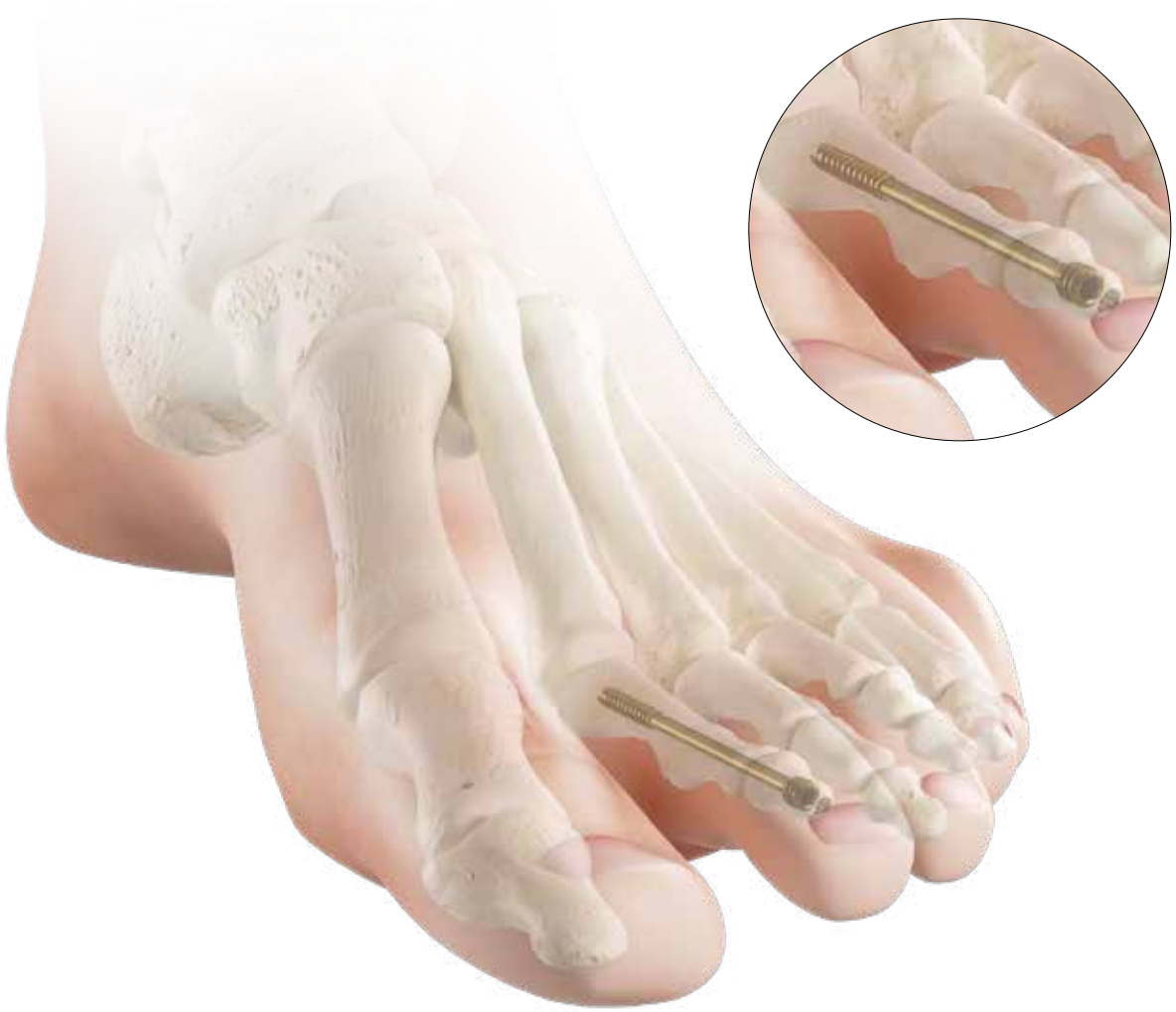
Attach the provided Cannulated T8 Implantdriver Bit to the Universal Handle, to insert the appropriate Ø2.5mm implant over the previously placed Ø1.3mm K-wire. If power insertion is preferred the drivers are compatible.

Step 6 – Final Compression

Final compression of PIPJ and DIPJ using handle and T8 tapered screwdriver.

Final position of the reduction and implant should be verified. The K-wire is removed and discarded. Repeat these steps as needed for additional implants.





Operative Technique

HammerThread Ø2.5mm PIP Implants
PIPJ Arthrodesis

Step 1 – Incision

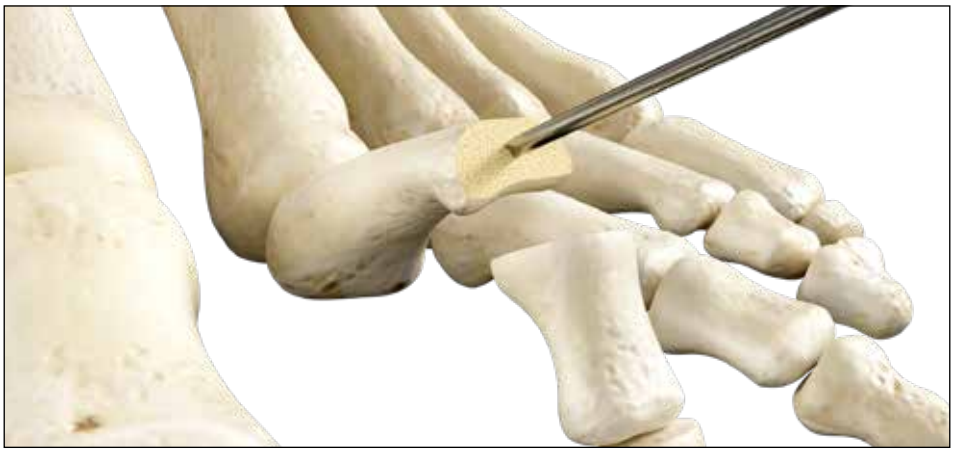
Longitudinal or transverse skin incision per surgeon preference. Expose PIP joint. Release collateral ligaments. Resect the distal aspect of proximal phalanx and proximal aspect of middle phalanx.

Step 2 – Predrilling

Predrilling of proximal phalanx using Ø1.3mm K-Wire.

Insert the supplied K-wire to the proper depth. If necessary, utilize fluoroscopy to control K-wire position.

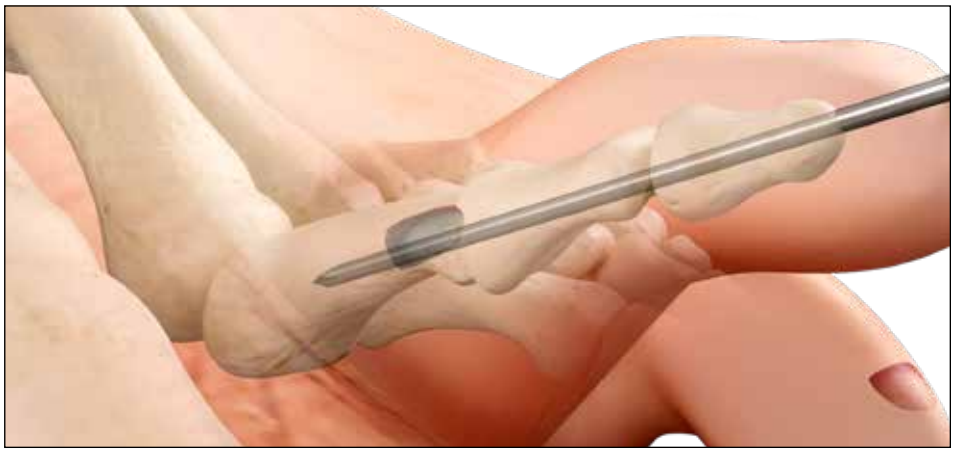
Note:
Please ensure there is no visible bending of the K-wire before inserting the implant. Correct K-wire placement if required.



Step 3 – K-Wire insertion

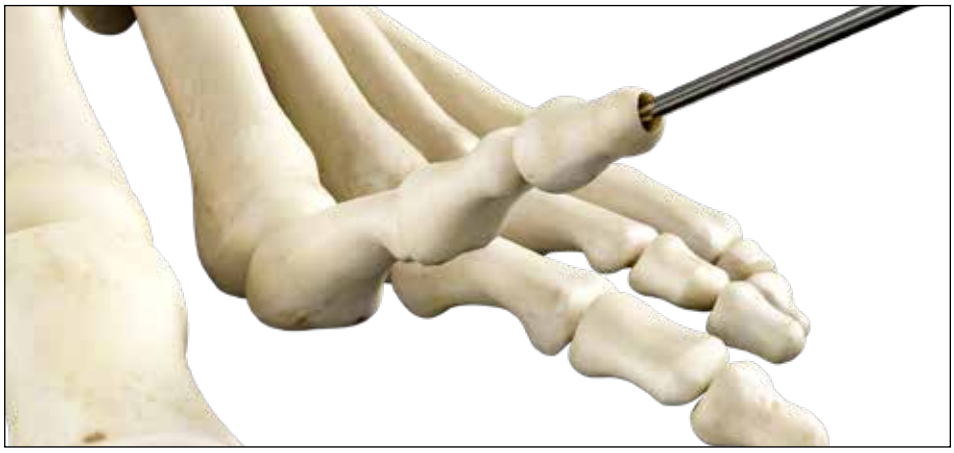
Insertion of Ø1.3 K-Wire into middle and distal phalanx.

Confirm good placement of the wire in the distal phalanx on the lateral view to avoid implant insertion that is too dorsal or plantar.



Step 4 – Retrograde K-Wire insertion

Leave the tip of the wire proud at the middle phalanx, and reduce the PIP joint so the tip of the wire is inserted into the pre-drilled pilot hole in the proximal phalanx. Advance the wire to the base of the proximal phalanx and confirm on fluoroscopy.



Step 5 – Implant Insertion

Attach the provided Cannulated T8 Screwdriver Bit to the Universal Handle, to insert the appropriate Ø2.5mm implant over the previously placed Ø1.3mm K-wire. If power insertion is preferred the drivers are compatible.

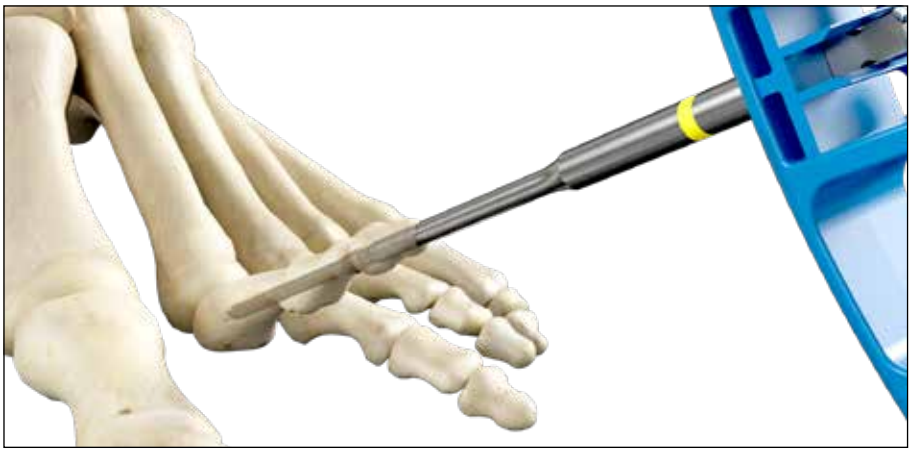
Operative Technique

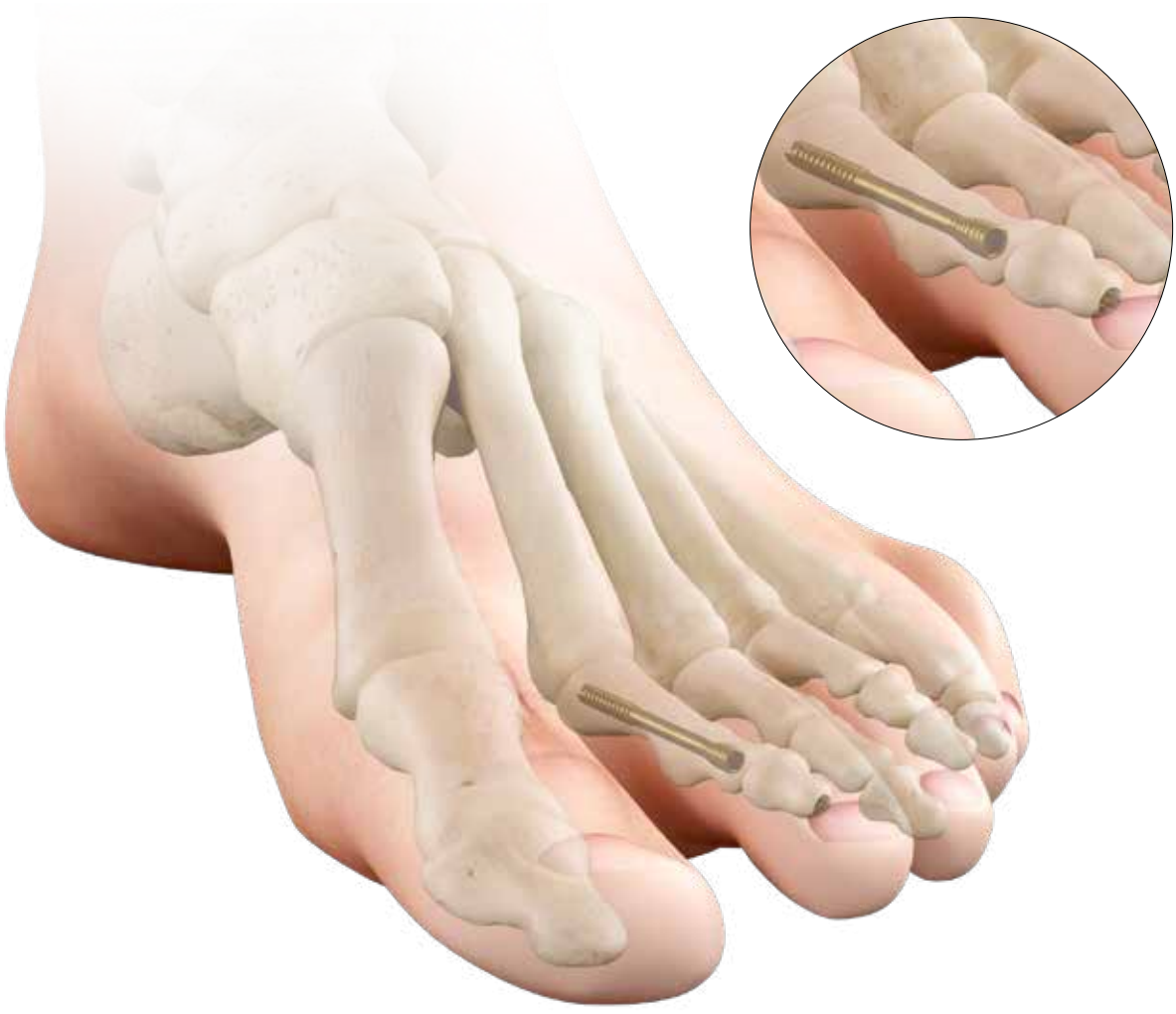
HammerThread Ø2.5mm PIP Implants
PIPJ Arthrodesis

Step 6 – Final Compression

Final compression of PIPJ and DIPJ using handle and T8 tapered screwdriver.

Final position of the reduction and implant should be verified. The K-wire is removed and discarded. Repeat these steps as needed for additional implants.





Operative Technique

Percutaneous PIPJ Fusion

Step 1 – Patient Positioning

Patient is positioned supine with the operative foot hanging off the bed and resting on the mini c-arm. The non operative leg may be placed in a frog leg position.

Position the mini c-arm at the contralateral side of the extremity & the power equipment at the ipsilateral side of the surgical extremity.

Positioning of OR equipment is a recommendation & may be modified to the surgeon's preference.

Step 2 – Osteotomy

Osteotomies performed with a burr should always be powered with high torque, low rpm motor, and kept at safe speeds. Be mindful to avoid pulling on the skin by rotating around the fulcrum by supinating and pronating to perform osteotomies.

Depending on the dominant hand of the surgeon, using a beaver blade a 2mm incision can be made on either the medial or lateral side of the PIP joint. The blade is spanned across the joint, creating a portal for access.

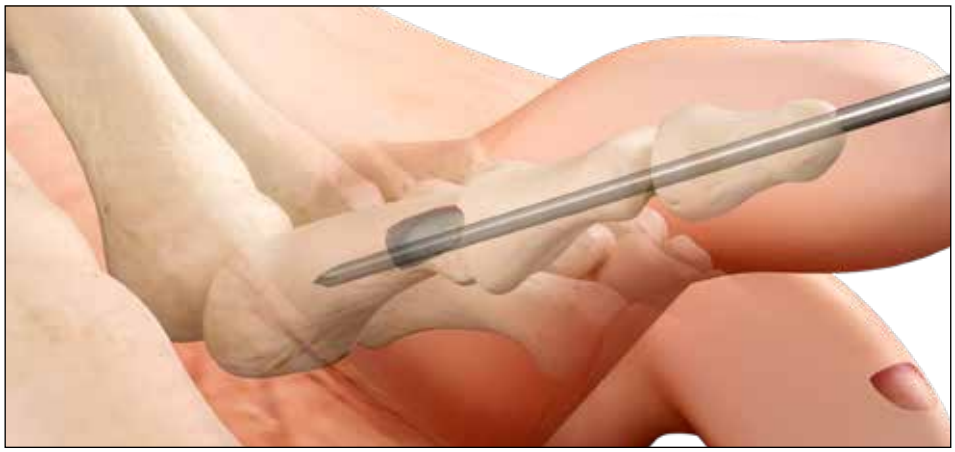
Introduce a cutting burr into the portal and debride the PIP joint, removing cartilage on both sides of the joint. Be mindful to continuously irrigate the surgical site to prevent complications to the skin.

An 18-gauge angiocath can be introduced through the portal to irrigate any residual bone paste left behind in the joint.

Operative Technique
Percutaneous PIPJ Fusion

Step 3 – K-wire insertion

Insert the 1.3mm K-wire into the distal phalanx and cross the DIP & PIP Joints. Confirm proper placement of the wire using image intensification.

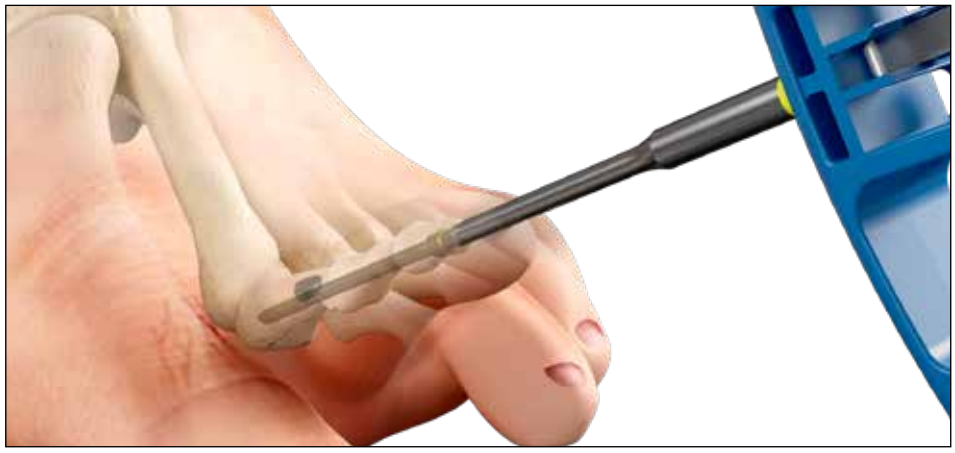


Step 4 – Screw insertion

Measure to confirm the appropriate implant length and insert using the tapered driver.

The Mallet Head Implant: was designed with a shorter stout head to fully seat into the distal phalanx to increase the purchase and maintain compression.

The Hammer Head Implant: was designed with a longer tapered head to fully seat in the middle phalanx to increase the purchase and maintain compression.



Post-Operative Protocol

The post-operative protocol for HammerThread implants is under the discretion of the surgeon. Protected weight-bearing is generally recommended after surgery for the correction of smaller toe deformities for 4-6 weeks.

Explant Information

In the exceedingly rare case that implant removal is desired or required due to an adverse event, the HammerThread implants have been designed to facilitate removal.

To remove the implants, re-create the distal incision used for implantation to grant access to the T8 torx interface of the implants. The implant can be then backed out using any T8 driver. All HammerThread implants have reverse cutting capabilities at the proximal and distal threads to facilitate implant removal.

In case of implant failure, the surgeon should contact the distributor using the contact information in the Operative Technique, the implant box or patient label.

Catalog Information – Implants

Ø2.5mm HammerThread Implant PIP-DIP

HammerThread Ø2.5mm PIP-DIP (REF)	Length (mm)	Thread (mm)
F1-1225-032S	32mm	12mm
F1-1225-034S	34mm	12mm
F1-1225-036S	36mm	12mm
F1-1225-038S	38mm	12mm
F1-1225-040S	40mm	12mm
F1-1225-042S	42mm	12mm
F1-1225-044S	44mm	12mm

Ø2.5mm HammerThread Implant PIP

HammerThread Ø2.5mm PIP (REF)	Length (mm)	Thread (mm)
F1-1225-P20S	20mm	12mm
F1-1225-P22S	22mm	12mm
F1-1225-P24S	24mm	12mm
F1-1225-P26S	26mm	12mm
F1-1225-P28S	28mm	12mm
F1-1225-P30S	30mm	12mm
F1-1225-P32S	32mm	12mm

Ø2.5mm Creed Headless Compression Implant (CREED Ø2.5 Headless compression Implants are available on request)

Headless Ø2.5mm (REF)	Length (mm)	Thread (mm)
F1-0825-014S	14mm	8mm
F1-0825-016S	16mm	8mm
F1-0825-018S	18mm	8mm
F1-0825-020S	20mm	8mm
F1-0825-022S	22mm	8mm
F1-0825-024S	24mm	8mm
F1-0825-026S	26mm	8mm
F1-0825-028S	28mm	8mm
F1-0825-030S	30mm	8mm

Catalog Information – Instruments

REF	Description
F4-P025-000S	HammerThread Instrument Kit for Lesser Toe Deformities
F4-1332-100S	Sterile Ø3.2 Drill Kit

S = items are sterile

		Qty.
	K-wire Ø1.3 x 150mm Double Stinger Trocar Tip	4
	Universal Handle, AO Small	1
	Tapered Implantdriver Blade T8 x 85mm	1
	Mini Depth Gauge for Ø1.3mm K-wire Length 150mm, Scale 10 - 60mm	1
	Drill Ø3.2 x 100mm (Available Individually)	1

Catalog Information – Implant Caddy

REF	Description	Qty.
F1-1225-032S	HammerThread Ø2.5x32mm, PIP-DIP	4
F1-1225-034S	HammerThread Ø2.5x34mm, PIP-DIP	5
F1-1225-036S	HammerThread Ø2.5x36mm, PIP-DIP	5
F1-1225-038S	HammerThread Ø2.5x38mm, PIP-DIP	5
F1-1225-040S	HammerThread Ø2.5x40mm, PIP-DIP	5
F1-1225-042S	HammerThread Ø2.5x42mm, PIP-DIP	5
F1-1225-044S	HammerThread Ø2.5x44mm, PIP-DIP	4
F1-1225-P20S	HammerThread Ø2.5x20mm, PIP	4
F1-1225-P22S	HammerThread Ø2.5x22mm, PIP	5
F1-1225-P24S	HammerThread Ø2.5x24mm, PIP	5
F1-1225-P26S	HammerThread Ø2.5x26mm, PIP	5
F1-1225-P28S	HammerThread Ø2.5x28mm, PIP	5
F1-1225-P30S	HammerThread Ø2.5x30mm, PIP	5
F1-1225-P32S	HammerThread Ø2.5x32mm, PIP	4
F4-P025-000S	HammerThread Instrument Kit	3

Notes

Notes

hammerthread™

Lesser toe deformity correction

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a surgeon. Rx only.

This document is intended solely for the use of healthcare professionals. This technique was developed in conjunction with healthcare professionals. A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. GLW, Inc. does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery. The information presented is intended to demonstrate a GLW, Inc. product. A surgeon must always refer to the package insert, product label and/or instructions for use, including the instructions for Cleaning and Sterilization (if applicable), before using any GLW, Inc. product.

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Patents: www.glwmed.com/patents/

Scan for more product information

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