HAMMERTECH

Reaming Implant Kit

Fusion ORTHOPEDICS

Surgical Technique

DESCRIPTION OF THE MEDICAL DEVICE

The HammerTech Reaming Implant Kit is designed to facilitate reproducible joint preparation and fixation for fusions in HammerToe, claw toe, and mallet toe repair. The system is comprised of Kirschner wires (K-wires) used for bone fixation and a concave and convex reamer set to create a matching hemispherical joint interface.

The implants and instruments are manufactured of Surgical Grade Stainless Steel per ASTM F899. All Implants and instruments are intended for single use only.

INDICATIONS FOR USE

The HammerTech device is indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe and mallet toe.

CONTRAINDICATIONS

- Local or systemic, acute or chronic inflammation;
- Active infection or inflammation;
- Growing patients with open epiphyses;
- Physiologically or Psychologically inadequate patients;
- Patients with high levels of activity.

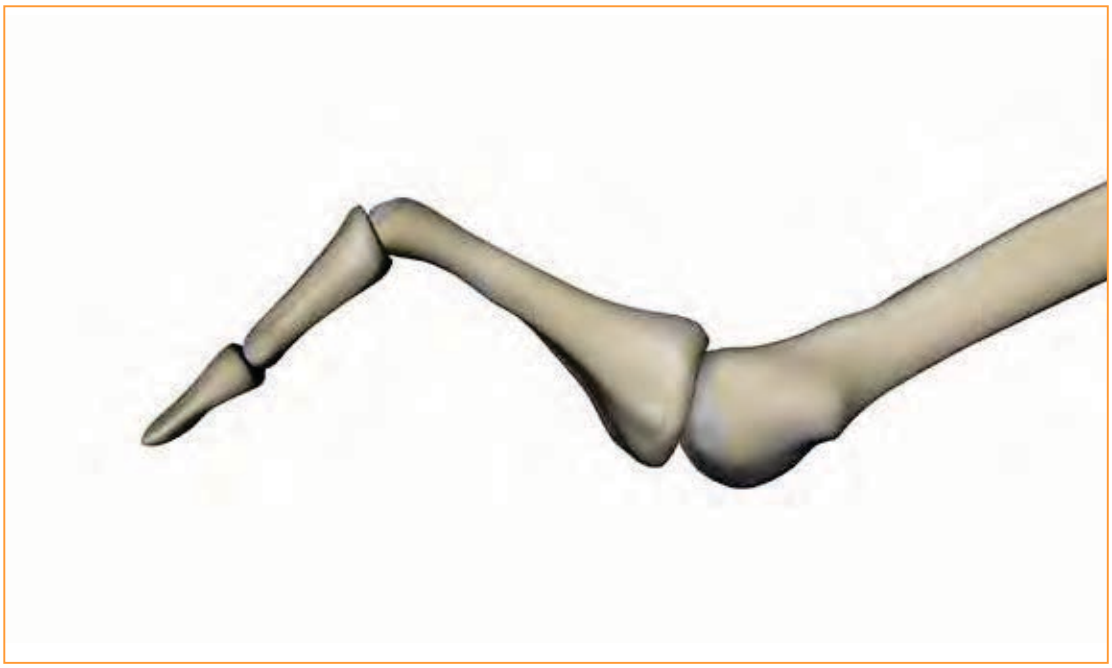
DIRECTIONS FOR USE

To implant the HammerTech device, use only the specialized HammerTech instrumentation. Do not use implants or instruments from any other system or manufacturer.

All HammerTech System components should be carefully inspected to ensure proper working condition. Critical areas, including joint surfaces, should be checked for wear, damage or irregularities. Damaged or broken HammerTech System devices must not be used and should be returned to Fusion Orthopedics for evaluation.

Before using the HammerTech System, the surgeon should be thoroughly familiar with the HammerTech System Surgical Technique Manual. Pre-Operative planning by the surgeon should determine the size of implant required and an adequate supply of the implant sizes should be available prior to surgery, including larger and smaller sizes than those expected to be used.

For complete instructions regarding the proper use and application of HammerTech System implants and instruments, please refer to the HammerTech System Surgical Technique Manual. A comprehensive manual can be found at www.fusionorthopedics.com/surgicaltechnique



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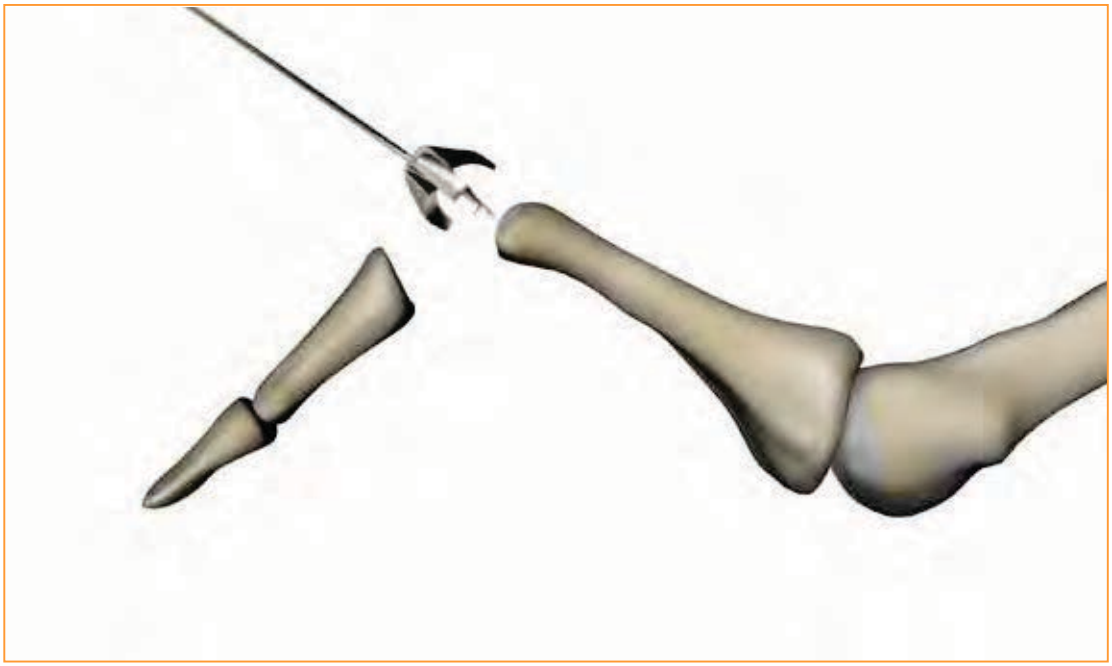
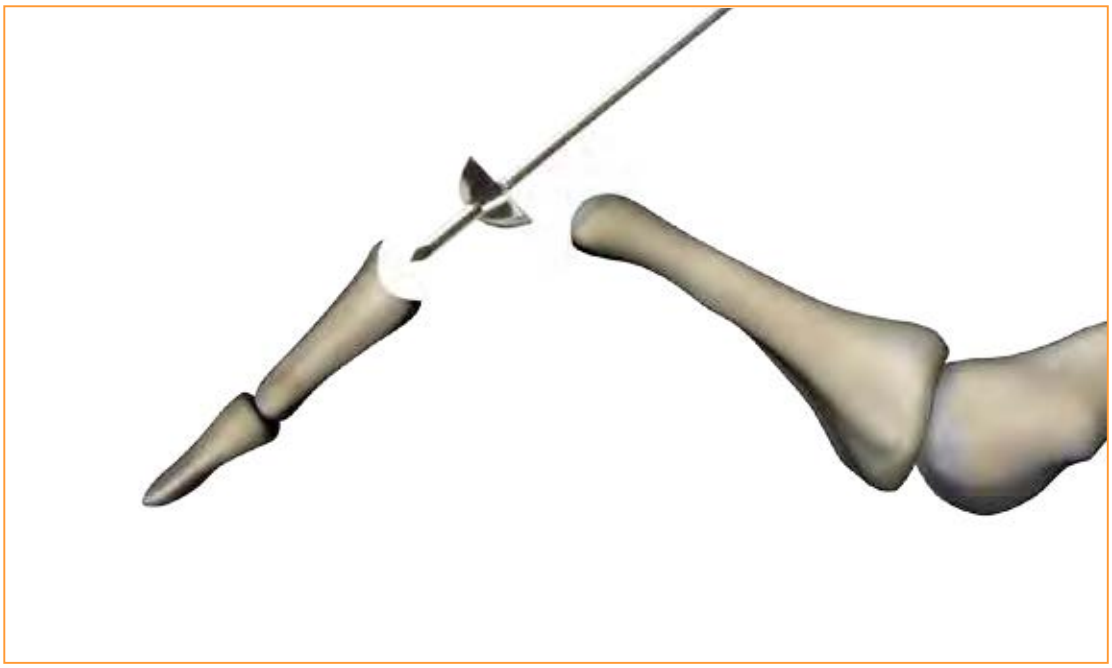
After creating an incision over the dorsal aspect of the PIP joint, perform soft tissue releases as necessary.

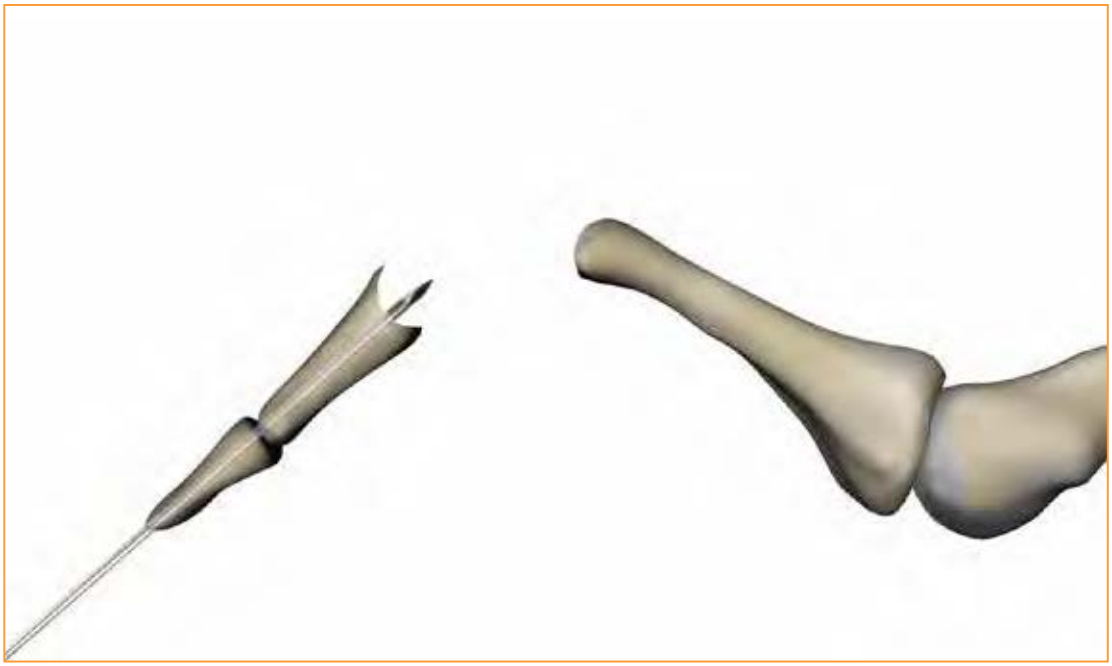


2

Prepare the joint surface beginning with the head of the proximal phalanx. Using a wire pin driver, place the concave reamer on full power before bone contact to reduce the axial force placed on the digit. The distal aspect of the proximal phalanx should be resurfaced until the desired correction has been achieved. Take care to avoid excessive reaming.



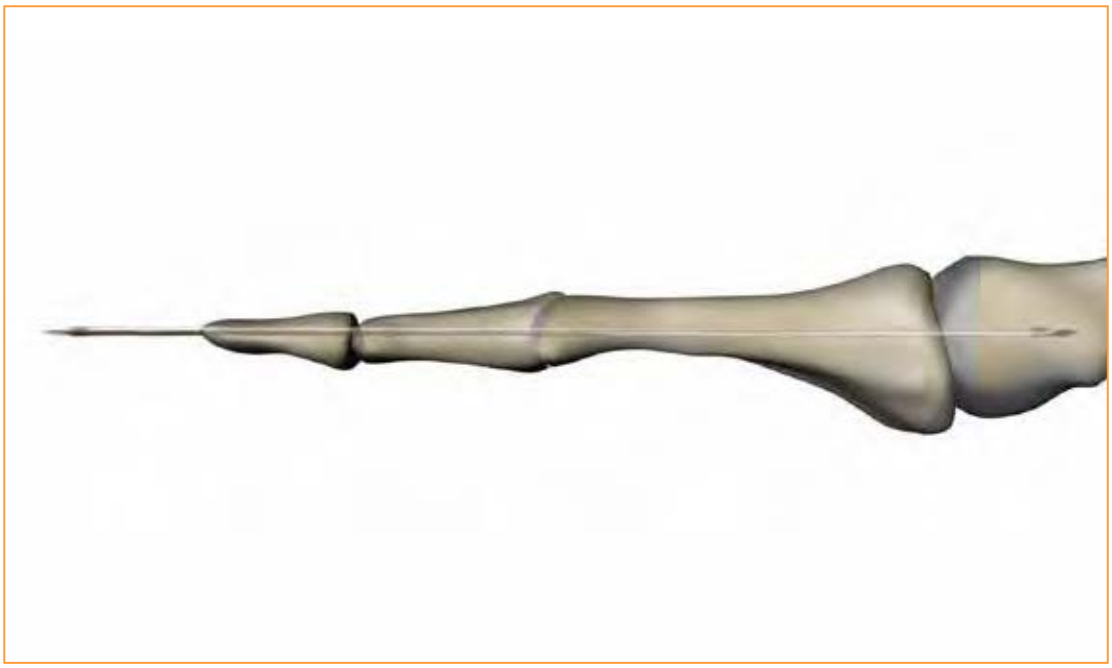
3 Load the convex reamer into the wire pin driver and prepare the middle phalanx. Place the Convex reamer on full power before resurfacing and ensure the alignment of the reamer down the center axis of the joint.



Use of the K-wire for placement and fixation may be according to surgeon preference.

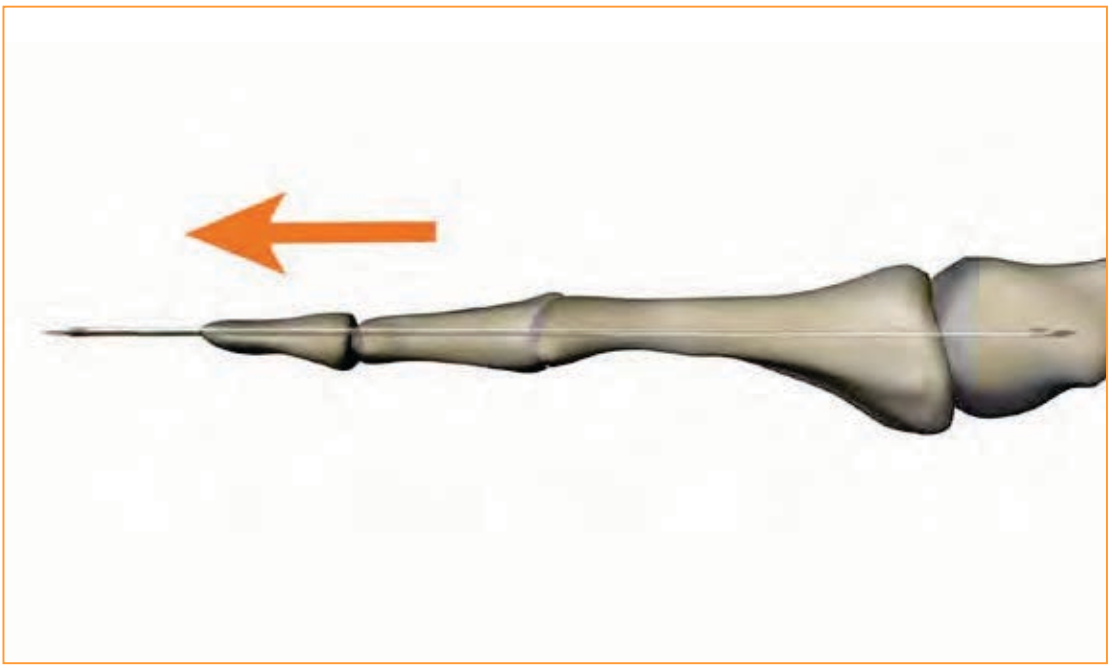
4 Insert the K-wire into the central axis of the middle phalanx. After verifying proper positioning with AP and lateral fluoroscopic views continue to drive the K-wire distally through both the middle and distal phalanx until it exits the toe leaving 1-2mm exposed for positioning into the proximal phalanx.

Confirm under floroscopy for adequate joint reduction and final placement. The K-wire is not indicated for permananent implantation and may be left in place for less than 30 days according to surgeon preference. Postoperative protocol is the responsibility of the medical professional.



5

Position the distal phalanx and continue advancing the K-wire through the metatarsophalangeal joint. Surgeons should use judgment to ensure sagittal plane stability and proper toe purchase.
*The Reaming Implant Kit is indicated for single use only.
Additional toes will require the use of additional instrument kits.



1

The K-wire is not indicated for permananent implantation and may be left in place for less than 30 days according to surgeon preference. Postoperative protocol is the responsibility of the medical professional. Pull on the K-wire distally, removing it from the phalanx once adequate healing has occured (3-4 weeks).

Implant Kits	Description	Sterile
	Reamer Implant Kit 8mm	HT-60-0808-S
	Reamer Implant Kit 10mm	HT-60-1010-S
	Reamer Implant Kit 12mm	HT-60-1212-S

K-Wires	Description	Sterile
	K-Wire Double Ended 1.1mm	HT-KW-4011-S
	K-Wire Double Ended 1.4mm	HT-KW-4014-S
	K-Wire Double Ended 1.6mm	HT-KW-4016-S

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. Fusion Orthopedics 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 the breadth of Fusion Orthopedics' product offerings. A surgeon must always refer to the package insert, product label, and instructions for use before using any Fusion Orthopedics product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your representative if you have questions about the availability of products in your area.

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FDA Cleared

D-4018-STG-2
9-24-18 Rev A