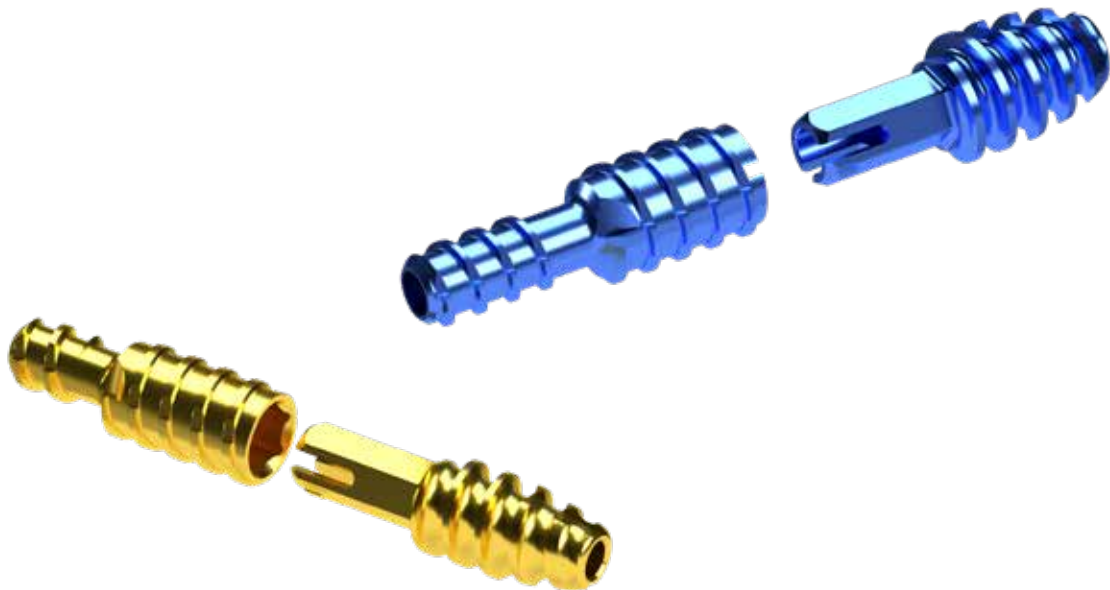


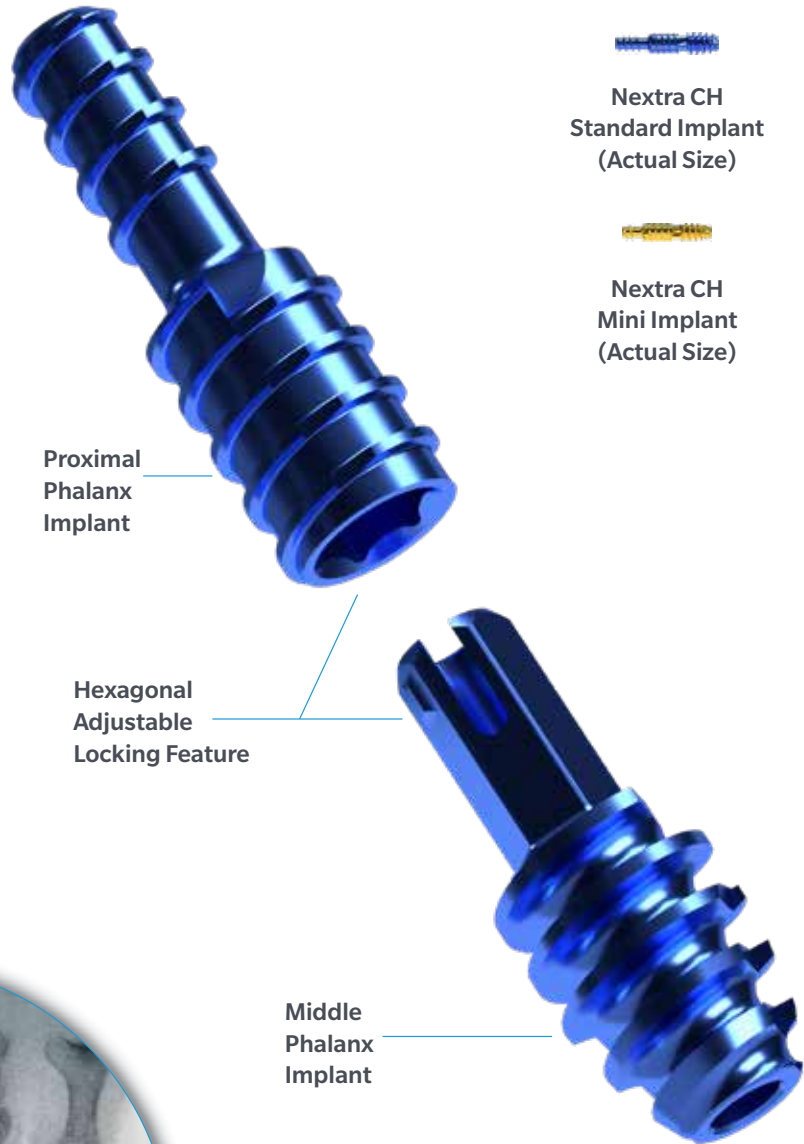
Nextra® CH Cannulated Hammertoe System

Surgical Technique



Nextra CH Cannulated Hammertoe System

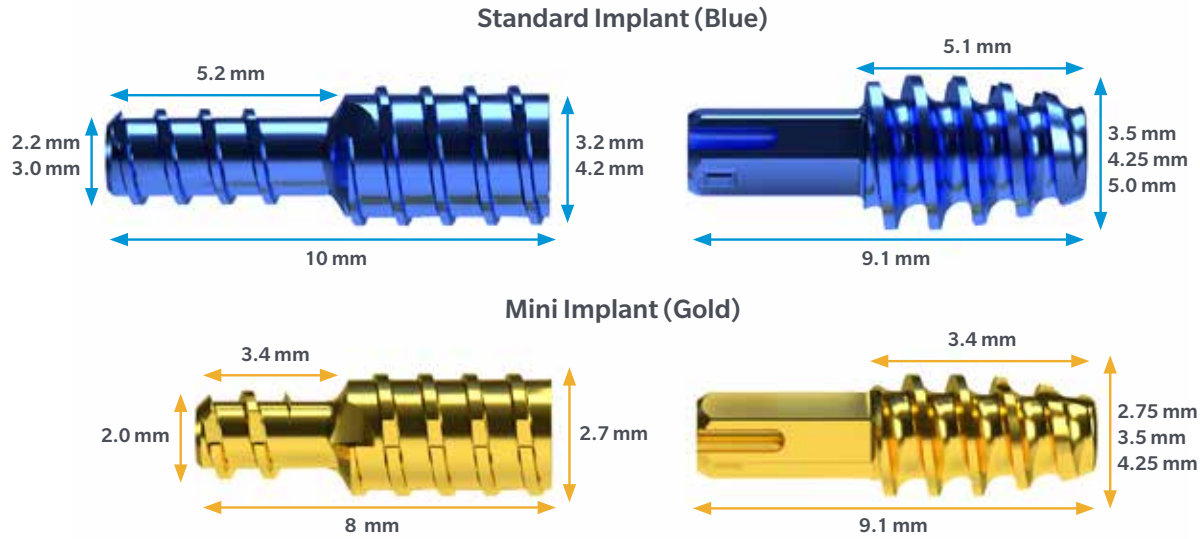
- Two-piece threaded implant construct designed for optimum bone purchase
- Cannulated implants and instruments provide targeting and technique guidance for repeatable outcomes
- Implant-to-implant rotational stability via differentiated hexagonal locking design
- Variable implant locking position provides in-situ adjustability before final closure
- Allows for optional technique to pin metatarsophalangeal joint
- Single-use sterile packed kit



Post-Op X-ray



Implant made of Ti-6Al-4V ELI



Nextra CH Sterile Instrument Kit

- Single patient use instrument tray
- Designed for precise, repeatable outcomes
- Optimized for OR efficiency

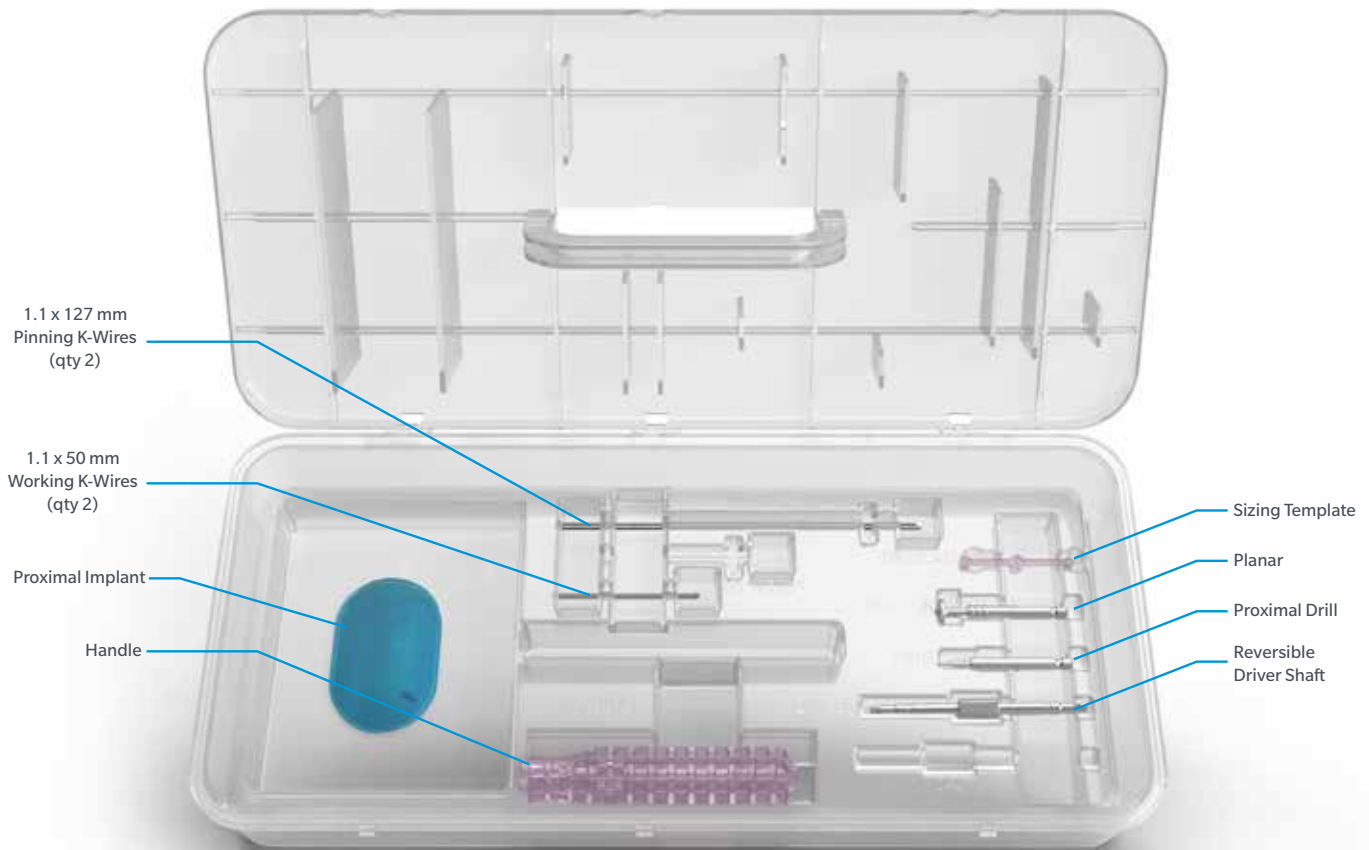




Figure 1



Figure 2

Introduction

The following surgical technique describes the steps necessary to perform hammertoe surgery using the Nextra CH Cannulated Hammertoe System. This system includes both Standard and Mini implants. Please follow the outlined steps for both sized implants. Differences in procedures for Standard or Mini are noted.

Preparation – PIP Joint Exposure

Prepare the insertion site using standard surgical techniques. A typical approach involves a 2 cm dorsolateral incision over the target joint. Access to the bone is gained via a transverse capsulotomy with release of the collateral ligaments from the head of the proximal phalanx. Release tendon to allow for joint exposure.

K-Wire Placement – Proximal Phalanx

Based on pre-operative implant sizing determine the appropriate **Working K-Wire** (Standard 1.1 mm or Mini 0.9 mm). Align the **Working K-Wire** to the center of the proximal phalanx head along the IM canal (Figure 1).

ⓘ **Note:** K-Wire placement can be checked using fluoroscope.

Resection – Planning Proximal Phalanx

Insert the 9 mm **Planar** over the **Working K-Wire** and resect the desired amount of proximal phalanx. (Figure 2).

ⓘ **Note:** If the resected bone surface created by the **Planar** did not cover the entire bone face, a curette or rongeur can complete the resection to ensure a flat surface is achieved.

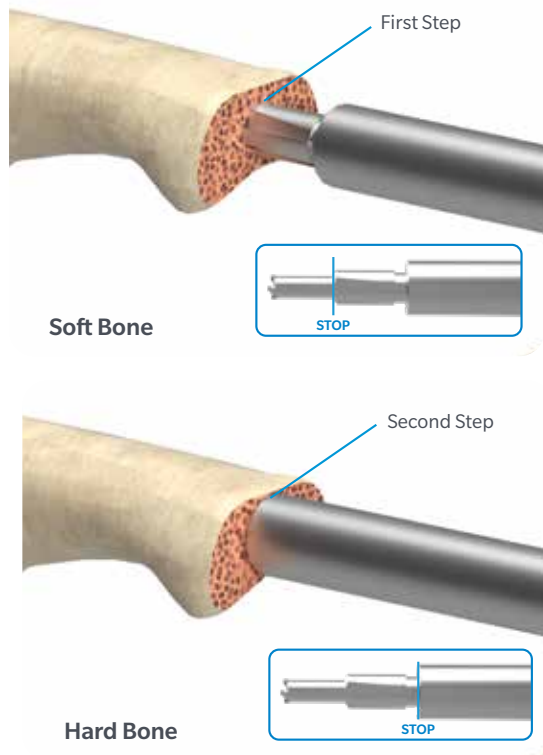


Figure 3



Figure 4

Proximal Phalanx Pilot Drilling

Insert the **Proximal Drill** over the **Working K-Wire** and drill the bone until the cutting flutes are no longer visible. For soft bone, drill only until the first step is no longer visible. For hard bone, drill until hard stop (Figure 3).

Proximal Implant Insertion

Assemble the desired size **Proximal Implant** onto the **Driver Shaft** end labeled "1 PROX". Insert the construct over the **Working K-Wire**. Thread the **Proximal Implant** into the proximal phalanx bone by turning the driver clockwise until the end of the proximal implant is flush or slightly countersunk with the cut surface. The final position of the **Driver Handle** should have one of the six flat sides oriented horizontally at the 12 o'clock position (Figure 4).

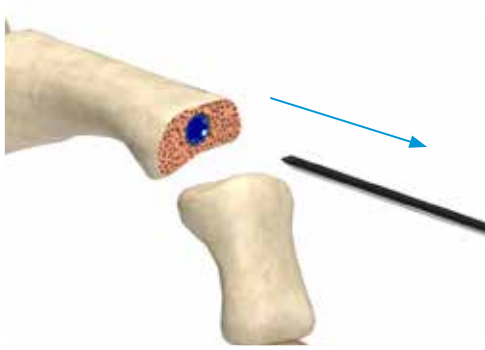


Figure 5



Figure 6

K-Wire Transition

Once the **Proximal Implant** has been inserted, the **Working K-Wire** will need to be removed from the proximal phalanx in preparation for the middle phalanx implant insertion. Either the existing or new **Working K-Wire** should now be inserted into the center of the middle phalanx (Figure 5).

ⓘ **Note:** K-Wire placement can be checked using fluoroscope.

OPTIONAL: Temporary Stabilization with K-Wire Method

ⓘ **Note:** This technique only applies to the standard size implants (1.1 mm cannula).

Place the **Pinning K-Wire** (1.1 mm X 127 mm) into the center of the middle phalanx, driving it through the distal phalanx until 4-5 mm remain exposed (Figure 6).

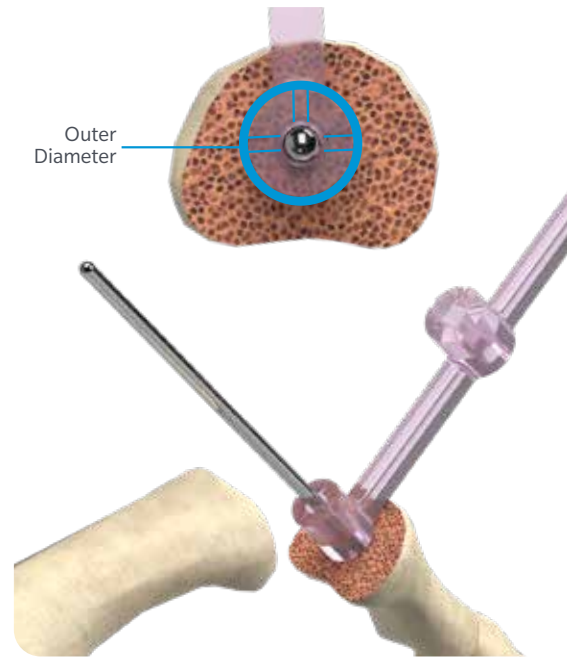


Figure 7

Resection – Planning Middle Phalanx

Insert the 9 mm **Planar** over the **Working K-Wire** or the **Pinning K-Wire** if optional technique was used. Using the Planar, resect the desired amount of middle phalanx (Figure 7).

ⓘ **Note:** If the resected bone surface created by the **Planar** did not cover the entire middle phalanx bone face, a curette or rongeur can finish the resection to ensure a flat surface is achieved.



Standard sizing template shown with 4 notches, indicating a 4.25 mm Middle Phalanx Implant should be used.

Figure 8

Middle Phalanx Sizing Template

Insert the Sizing Template over the K-Wire to determine the optimal Middle Phalanx Implant size. The outer diameter of the Sizing Template cylinders represent the outer diameter of the Middle Phalanx Implant threads (Figure 8).

Sizing Template Notch ID	Standard Middle Phalanx Implant
3	Middle 3.5 mm
4	Middle 4.25 mm
5	Middle 5.0 mm

Sizing Template Notch ID	Mini Middle Phalanx Implant
2	Mini Middle 2.75 mm
3	Mini Middle 3.5 mm
4	Mini Middle 4.25 mm



Figure 9

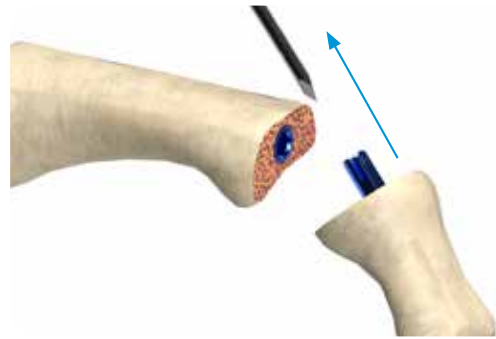


Figure 11

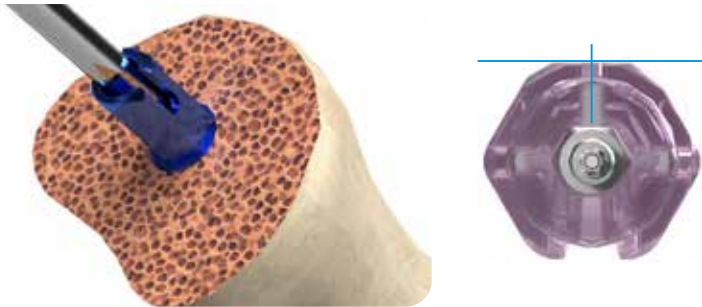


Figure 10

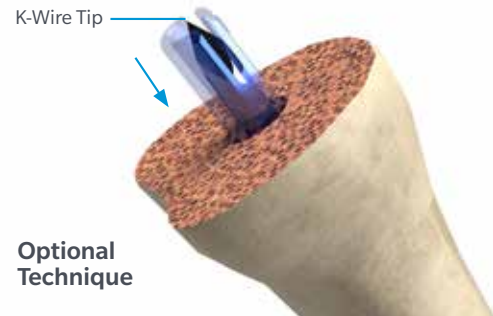
Optional
Technique

Figure 12

Middle Implant Insertion

Assemble the desired **Middle Implant** onto the **Driver Shaft** end labeled “2 MID”. **Ensure that the tab on the implant is visible in the window of the driver.** (Figure 9). Insert the construct over the **K-Wire**. Thread the **Middle Implant** into the middle phalanx bone by turning the driver clockwise until the threads are buried or are slightly countersunk in the cut surface. The final position of the **Driver Handle** should have one of the six flat sides oriented horizontally at the 12 o'clock position.

For difficult insertion or hard cancellous bone cases, the **Proximal Drill** may be used. Be sure to stop prior to the second step of the **Proximal Drill** or the DIP cortical wall, whichever occurs first (Figure 10).

Note: In the rare case where more implant purchase on the middle phalanx is desired, a larger middle phalanx implant should be used.

Removal of K-Wire

After the **Middle Implant** is in place, remove the **Working K-Wire** from the middle phalanx (Figure 11).

OPTIONAL

If the **Pinning K-Wire** optional technique was used, retract the **K-Wire** distally until just the tip of the **K-Wire** is visible or slightly inside the **Middle Implant** to prepare for final reduction (Figure 12).

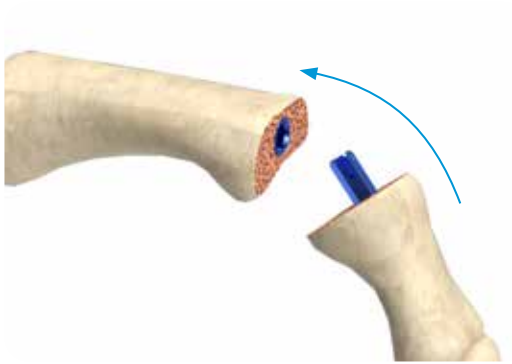


Figure 13

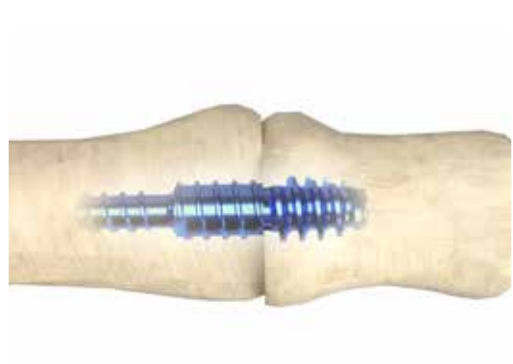


Figure 15

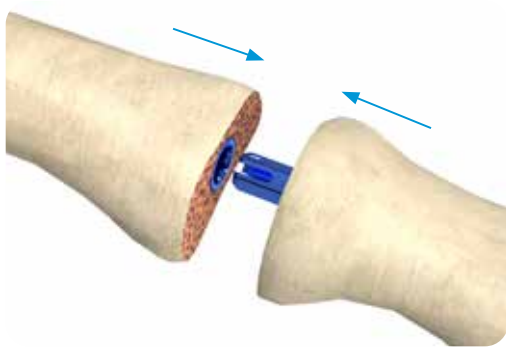


Figure 14

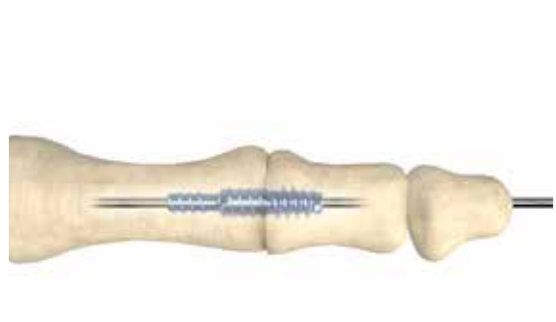


Figure 16

Alignment & Reduction

Align the stem of the Middle Implant axially with the Proximal Implant (Figure 13).

Reduce the proximal phalanx and middle phalanx by compressing the implants (Figure 14).

Seat the implants to achieve bone-to-bone contact for final apposition (Figure 15).

Close the wound in the conventional manner.*

In-Situ Repositioning: In the case that the final reduction or implant position is not satisfactory, the implant construct can be disassembled for in-situ adjustments.

OPTIONAL

If the **Pinning K-Wire** technique was used, additional joint stabilization can be achieved by driving the **Pinning K-Wire** in a retrograde manner under fluoroscope until the MTP joint is adequately crossed. Trim and cap the remaining **Pinning K-Wire** in the conventional manner (Figure 16).

*Extensor tendon repair is recommended.

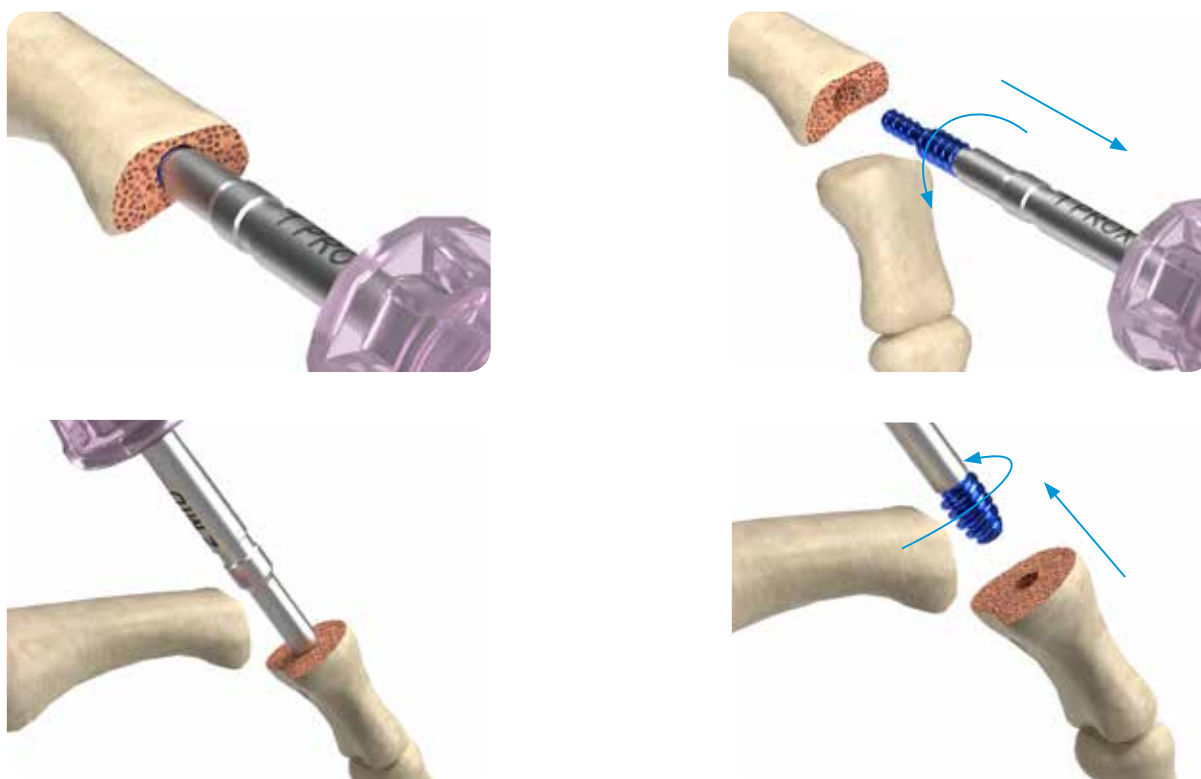


Figure 17

Revision Surgical Technique

The following surgical technique describes the steps necessary to perform revision surgery of the Nextra CH Cannulated Hammertoe System. The following steps can be applied to both Standard and Mini implants. Please follow the outlined steps for both sized implants.

Implant Removal Using Driver Handle

Make a dorsolateral incision over the joint to be revised. Clear any bone growth from around the implant construct that has filled the joint space. Using an osteotome or other surgical tool, distract the proximal and middle phalanges until the **Proximal Implant** and **Middle Implant** have disengaged (approximately 4 mm).

Insert the **Driver Shaft** into the **Driver Handle** with "1 PROX" displayed and insert into the **Proximal Implant**. Rotate counter-clockwise to remove the **Proximal Implant**. Remove the **Driver Shaft** from the **Driver Handle** and re-insert so "2 MID" is displayed. Insert the Driver into the **Middle Implant** and rotated counter-clockwise until the implant is fully removed (Figure 17).

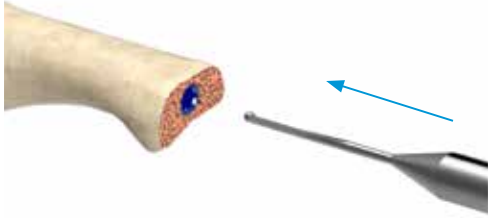


Figure 18

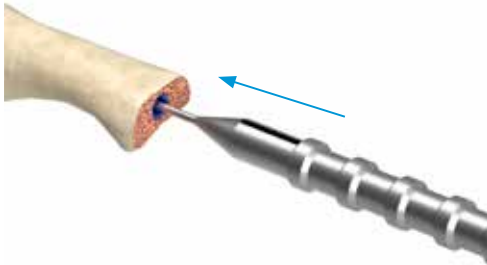


Figure 19

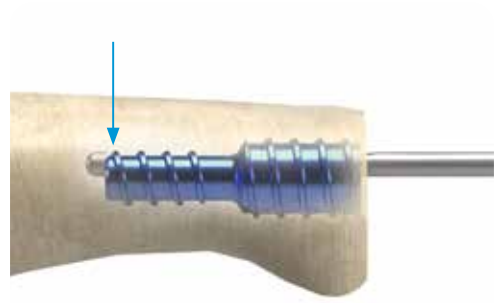


Figure 20

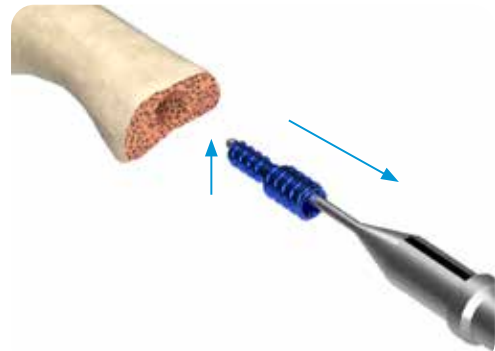


Figure 21

Implant Removal Using Retriever

In the rare case that the **Proximal Implant** cannot be unthreaded, the **Retriever** may be used. Insert the hooked end of the **Retriever** through the cannulation of the **Proximal Implant** (Figures 18 & 19) until the hook can grab the tip (Figure 20). Keep the laser line in the 12 o'clock position and apply upward force when pulling until the **Proximal Implant** is completely removed from the proximal phalanx (Figure 21).

Ordering Information

Kits

Description	Part Number
NEXTRA CH Cannulated Hammertoe Proximal 2.75mm Instrument Kit w/ Implant	CH-275P-KT
NEXTRA CH Cannulated Hammertoe Proximal 3.2mm Instrument Kit w/ Implant	CH-32P-KT
EXTRA CH Cannulated Hammertoe Proximal 4.2mm Instrument Kit w/ Implant	CH-42P-KT

Implants

Description	Part Number
NEXTRA CH Mini Middle Cannulated Hammertoe Implant 2.75 mm	CH-M275M
NEXTRA CH Mini Middle Cannulated Hammertoe Implant 3.5 mm	CH-M35M
NEXTRA CH Mini Middle Cannulated Hammertoe Implant 4.25 mm	CH-M425M
NEXTRA CH Standard Middle Cannulated Hammertoe Implant 3.5 mm	CH-35M
NEXTRA CH Standard Middle Cannulated Hammertoe Implant 4.25 mm	CH-425M
NEXTRA CH Standard Middle Cannulated Hammertoe Implant 5.0 mm	CH-50M
NEXTRA CH Mini Proximal Cannulated Hammertoe Implant 2.75 mm	CH-M275P
NEXTRA CH Standard Proximal Cannulated Hammertoe Implant 3.2 mm	CH-32P
NEXTRA CH Standard Proximal Cannulated Hammertoe Implant 4.2 mm	CH-42P

Disposables

Description	Part Number
NEXTRA CH Retriever	CH-RTR
NEXTRA CH Driver Set	CH-DRIVERS

INDICATIONS:

The Nextremity Solutions Nextra® CH Cannulated Hammertoe System is indicated for small bone reconstruction limited to interphalangeal repair and fusion of the lesser toes.

CONTRAINDICATIONS:

The Nextremity Solutions Nextra® CH Cannulated Hammertoe System is NOT intended for use in procedures involving the great toe. In addition, the device is contraindicated in the following: (1) Patient conditions including insufficient quantity or quality of bone; (2) Blood supply limitations and previous or active infections that may inhibit healing; (3) Surgical procedures other than for the indications listed; (4) Patients with conditions that limit their ability or willingness to follow postoperative care instructions; (5) The device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopedic surgery on patients who are skeletally immature; (6) Where material sensitivity is suspected, appropriate testing should be performed, and sensitivity ruled out prior to implantation.

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Zimmer Biomet is the exclusive distributor of the Nextra® CH Cannulated Hammertoe System

The Nextra CH Cannulated Hammertoe System is manufactured using Ti-6Al-4V ELI.

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