ZIMMER BIOMET
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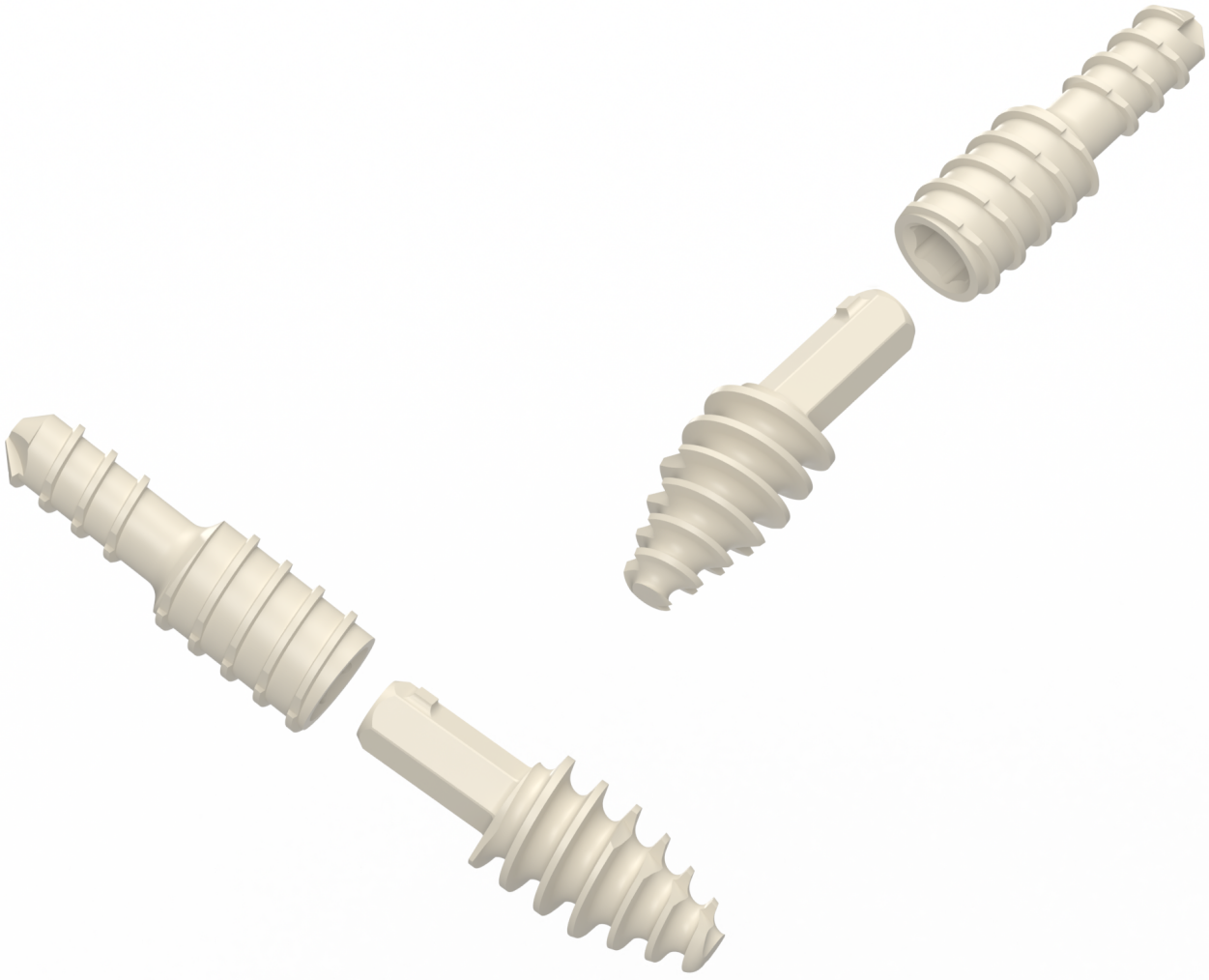
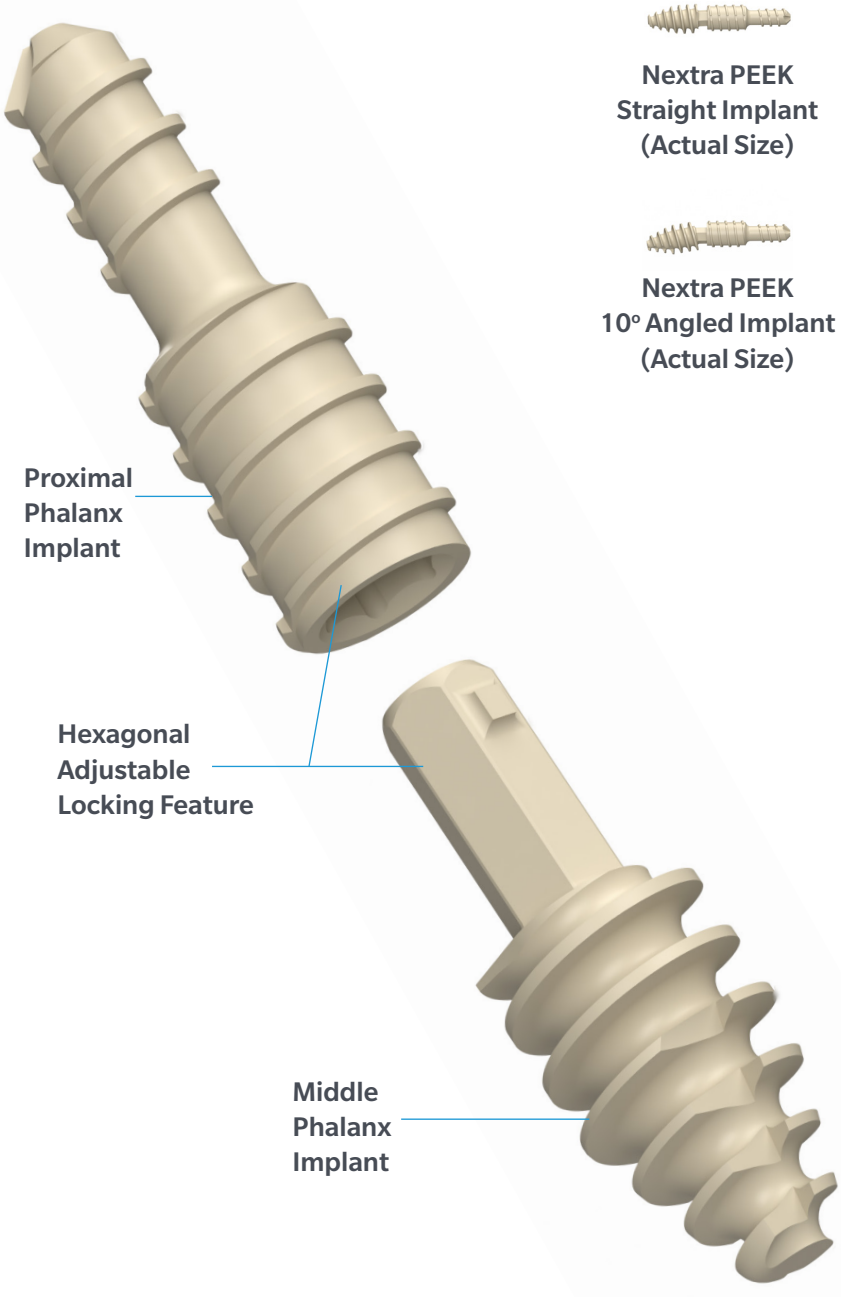
Nextra® PEEK
Hammertoe Correction System

Surgical Technique



Nextra PEEK
Hammertoe System

- Two-piece threaded implant construct designed for optimum bone purchase
- Cannulated instruments provide targeting and technique guidance for repeatable outcomes
- Implant-to-implant rotational stability via innovative hexagonal locking design
- Variable implant locking position provides in-situ adjustability before final closure
- Radiolucent image under fluoroscopy
- Single-use sterile packed kit

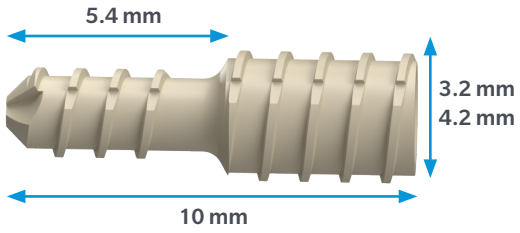


Nextra PEEK Straight Implant (Actual Size)

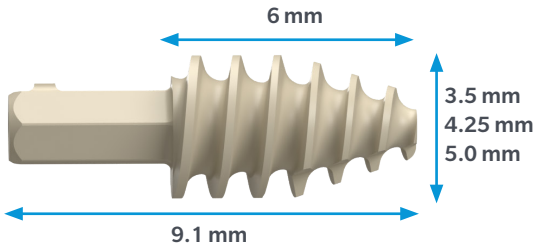
Nextra PEEK 10° Angled Implant (Actual Size)

Implants made of implant-grade polyetheretherketone (PEEK)

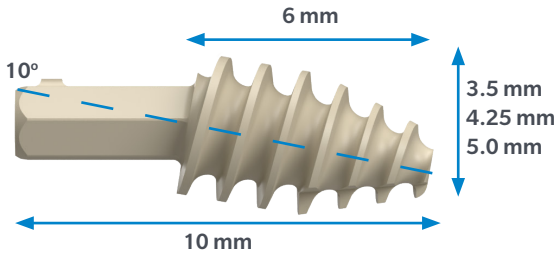
Proximal Implant



Straight Middle Implant

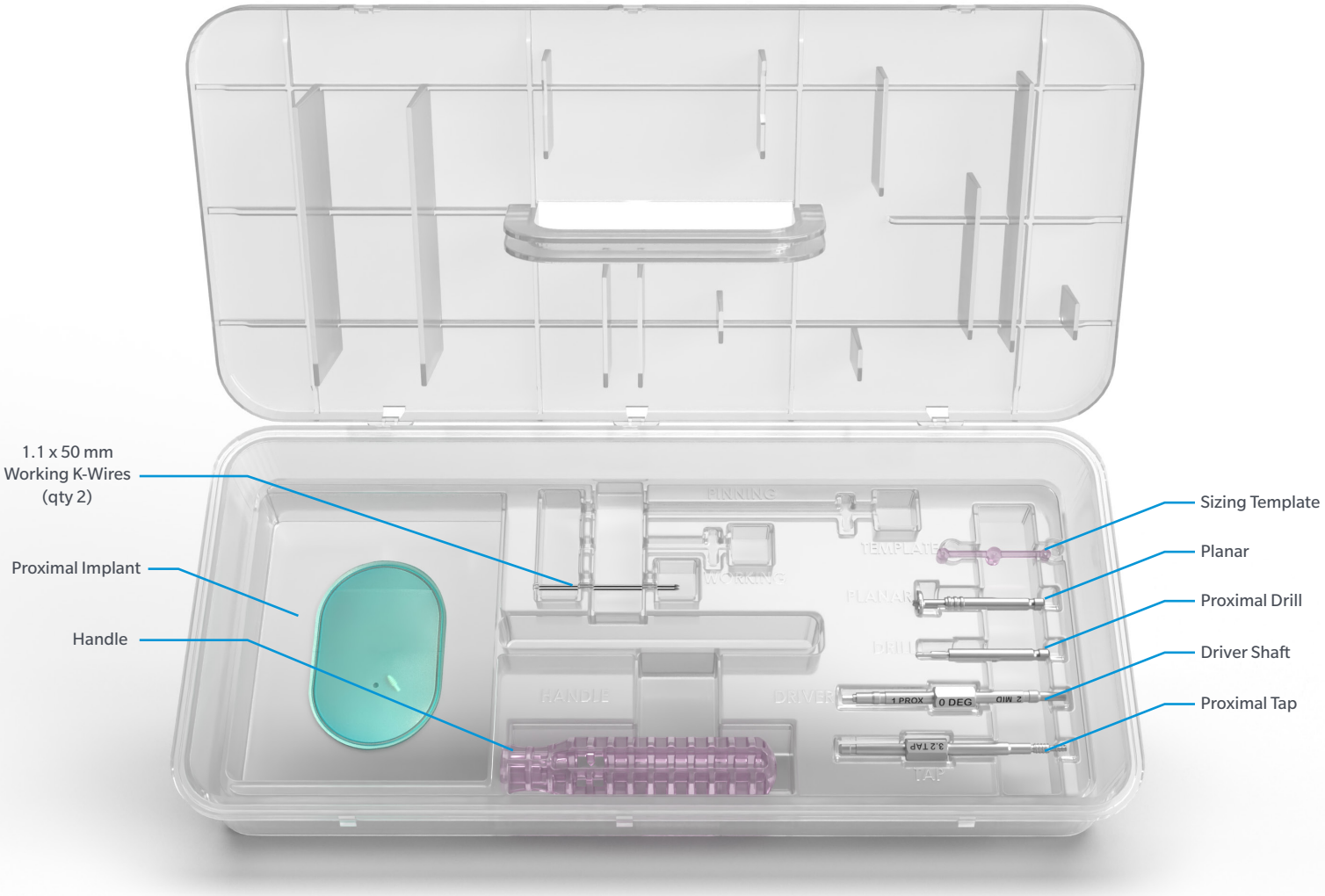


10° Angled Middle Implant



Nextra PEEK Sterile Instrument Kit

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



Surgical Technique

The following surgical technique describes the steps necessary to perform hammertoe surgery using the Nextra PEEK Correction Hammertoe System. This system includes both Straight and 10° Angled implants. Please follow the outlined steps for both type of implants. Differences in procedures for Straight and 10° Angled are noted.

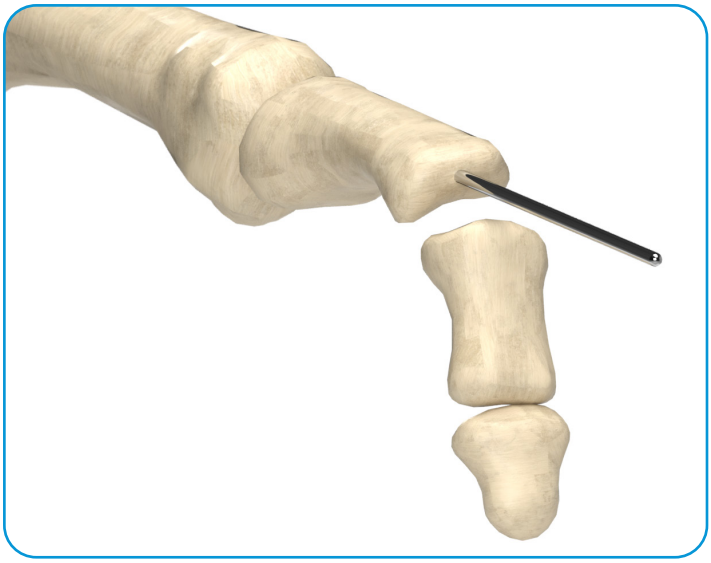
1. Preparation – PIP Joint Exposure

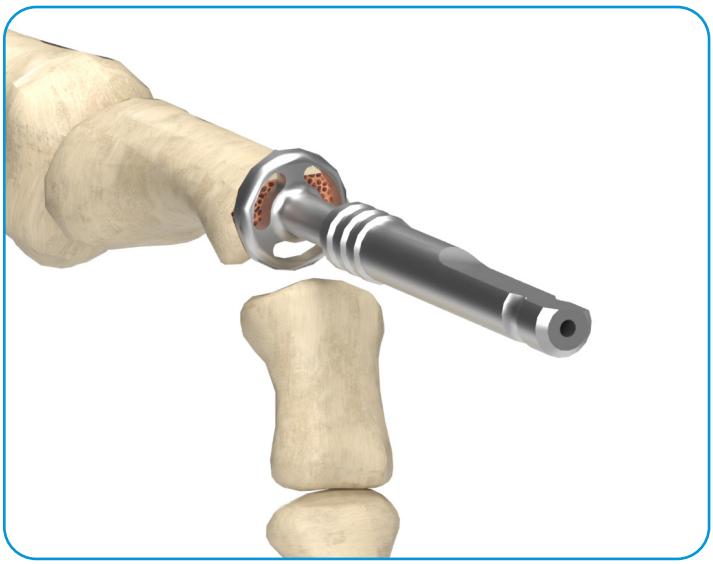
Prepare the insertion site using standard surgical techniques. A typical approach involves a 2 cm dorsolinear incision over the target joint. Access to the bone is gained via a transverse capsulotomy with release of the collateral ligaments from the head of the proximal phalanx. Release tendon to allow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

2. K-Wire Placement – Proximal Phalanx

Align the **Working 1.1mm K-Wire** to the center of the proximal phalanx head along the IM canal.

NOTE: K-Wire placement can be checked using fluoroscope.





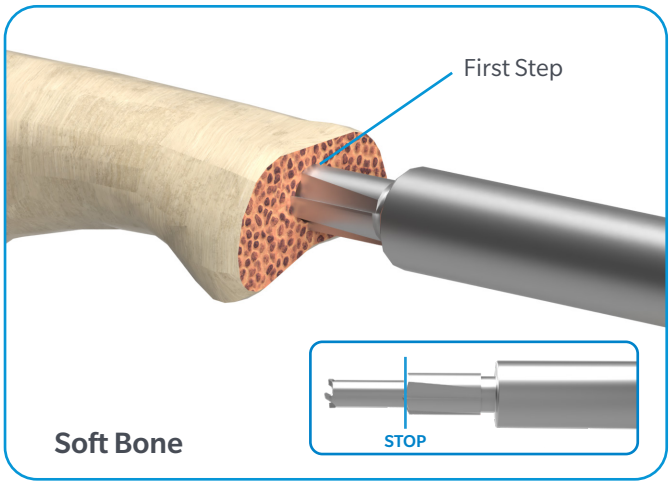
3. Resection – Planning Proximal Phalanx

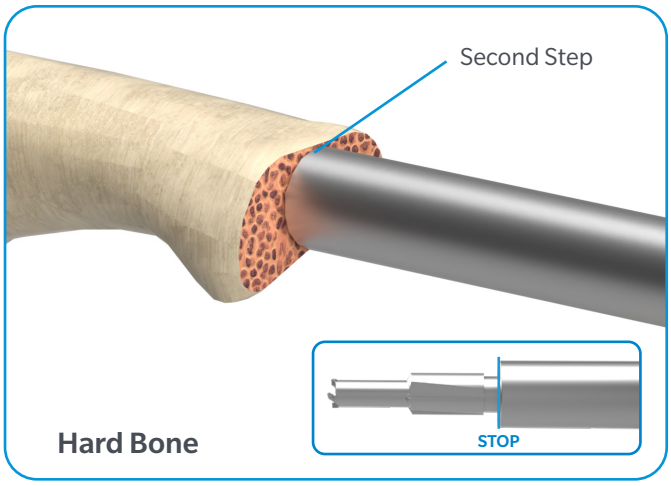
Insert the 9 mm **Planar** over the **Working 1.1mm K-Wire** and resect the desired amount of proximal phalanx.

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.

4. Proximal Phalanx Pilot Drilling

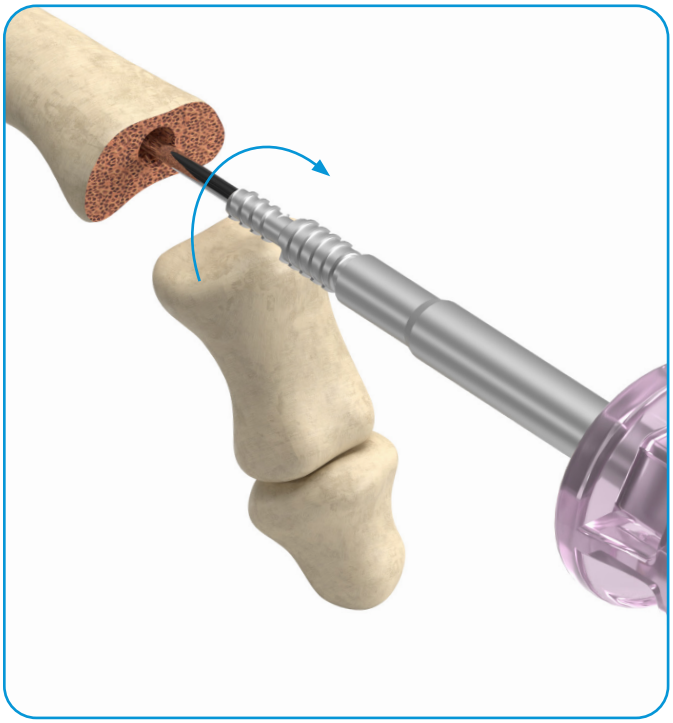
Insert the **Proximal Drill** over the **Working 1.1mm K-Wire** and drill the bone until the cutting flutes are no longer visible. For *soft bone*, drill only until the first step is no longer visible. For *hard bone*, drill until hard stop.

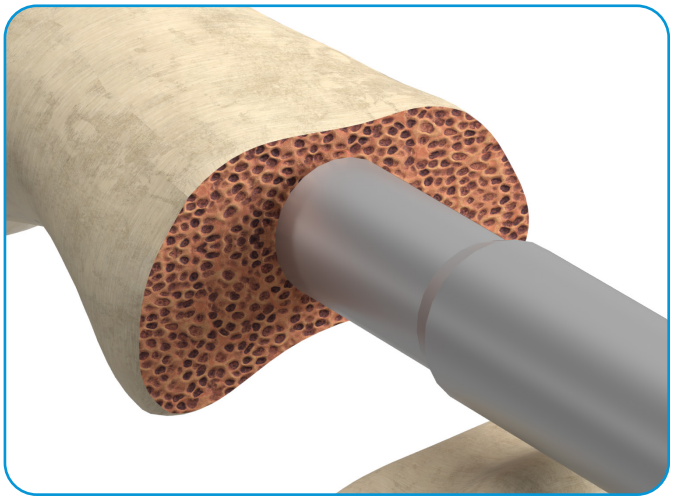




5. Proximal Phalanx Bone Tap

Insert the appropriately-sized **Proximal Phalanx Bone Tap** over the **Working 1.1mm K-Wire**. Thread the **Proximal Phalanx Bone Tap** into the proximal phalanx bone by turning the driver clockwise until the end of the **Proximal Phalanx Bone Tap** threads are slightly countersunk or at a hard stop with the prepeared surface.

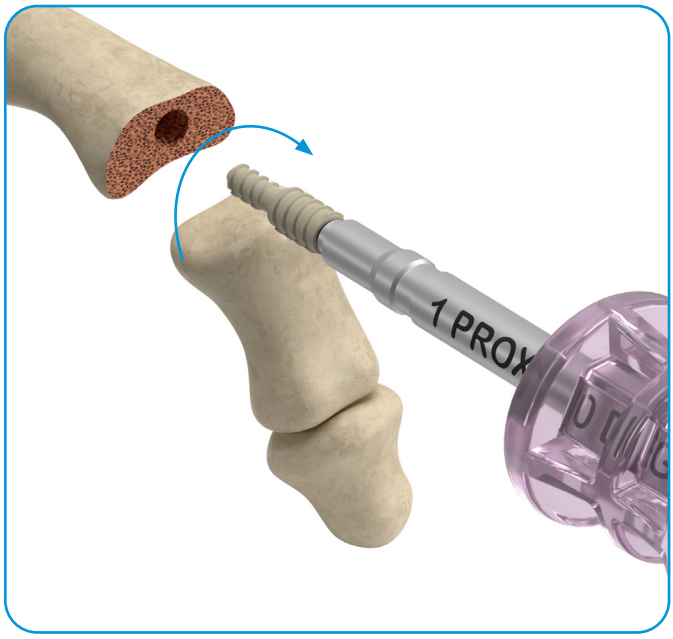


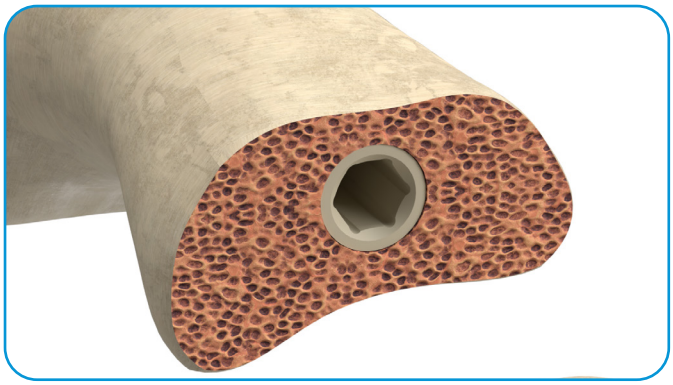


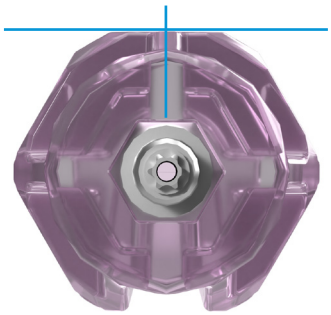
Surgical Technique

6. Proximal Implant Insertion

Prior to implant insertion, remove the **K-Wire**. Assemble the desired size **Proximal Implant** onto the **Driver Shaft** end labeled "1 PROX". 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 prepared surface. The final position of the **Driver Handle** should have one of the six flat sides oriented horizontally at the 12 o'clock position.



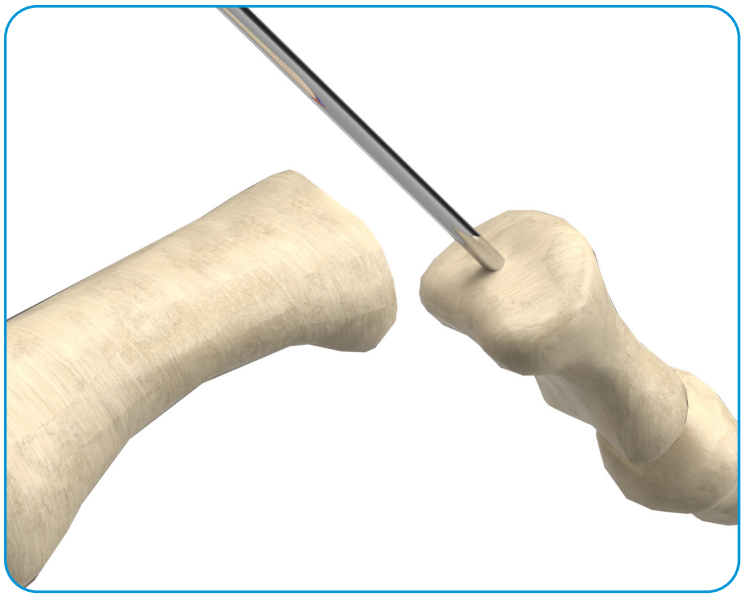




7. K-Wire Transition

Once the **Proximal Implant** insertion has been completed, the **Middle Implant** preparation can begin. Using either the existing or new **Working 1.1mm K-Wire,** insert the **Working 1.1mm K-Wire** into the center of the middle phalanx.

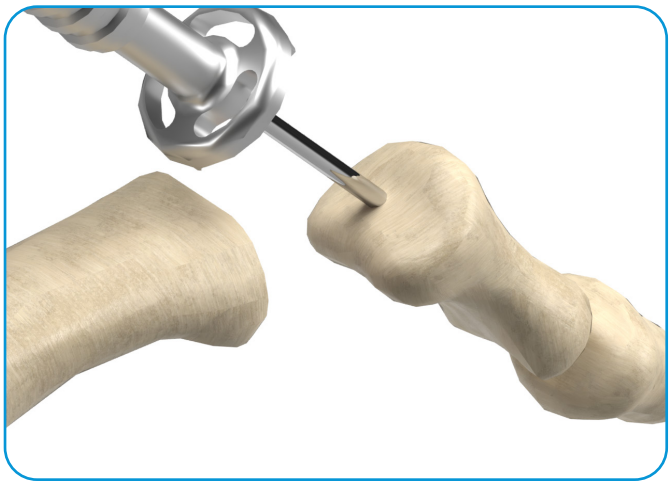
NOTE: K-Wire placement can be checked using fluoroscope.

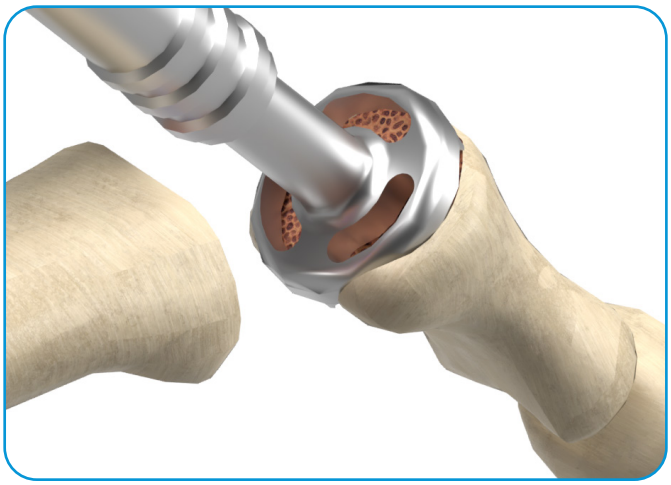


8. Resection – Planning Middle Phalanx

Insert the 9mm **Planar** over the **Working K-Wire**. Using the **Planar**, resect the desired amount of middle phalanx.

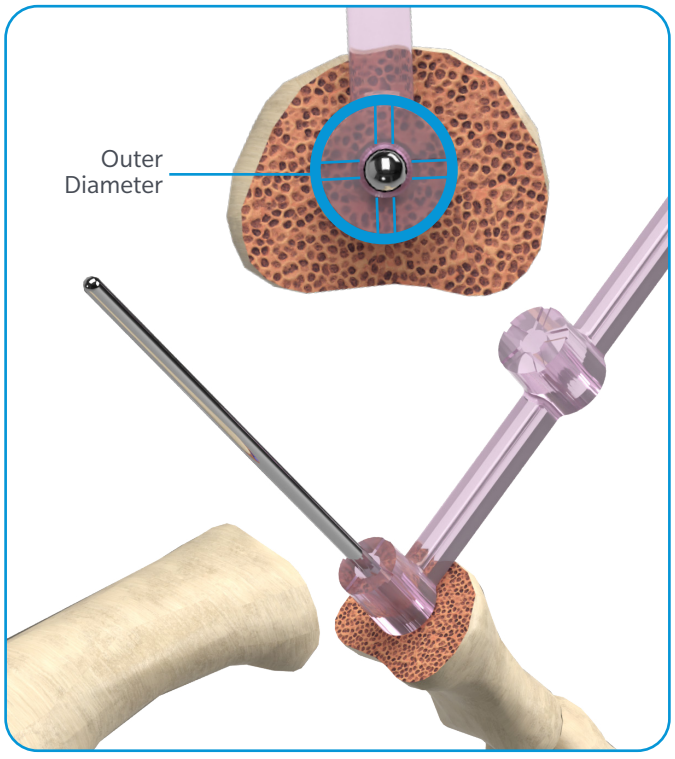
NOTE: If the resected bone surface created by the **Planar** did not cover the entire middle phalanx bone face, a curette or rongeur can finish the resection to ensure a flat surface is achieved.





9. 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.



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

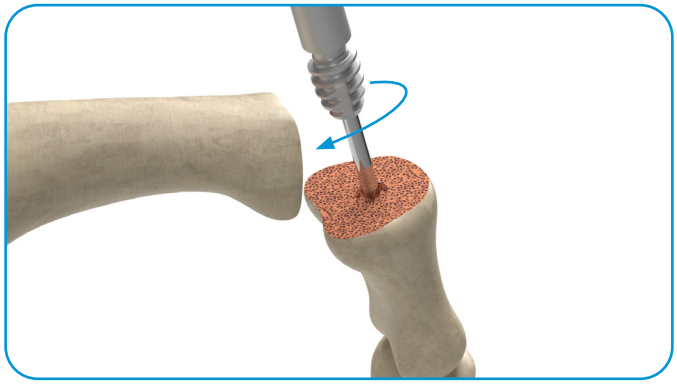
Sizing Template Notch ID	Straight or Angled Middle Phalanx Implant
3	Middle 3.5 mm
4	Middle 4.25 mm
5	Middle 5.0 mm

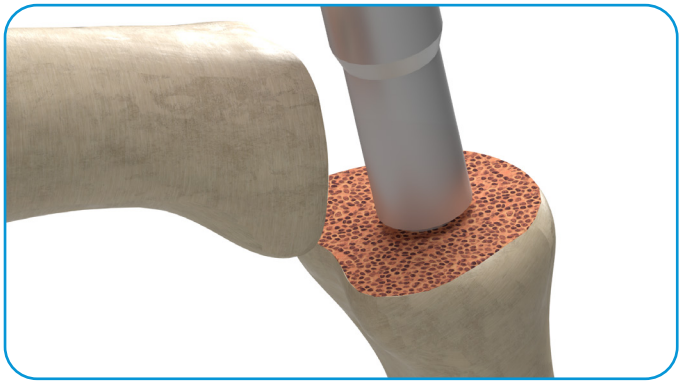
Surgical Technique

10. Middle Phalanx Bone Tap

Insert the appropriate-sized **Middle Phalanx Bone Tap** over the **Working 1.1mm K-Wire**. Thread the **Middle Phalanx Bone Tap** into the middle phalanx bone by turning the tap clockwise until the threads are slightly countersunk or until at a hard stop in the prepared surface.

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.

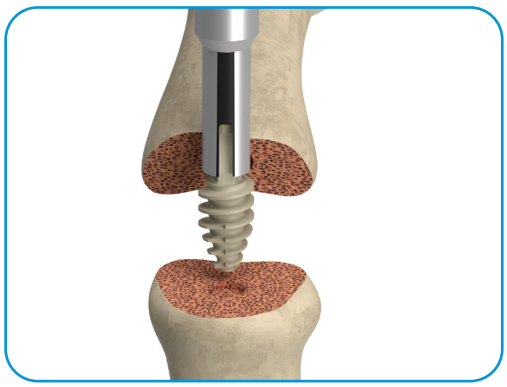


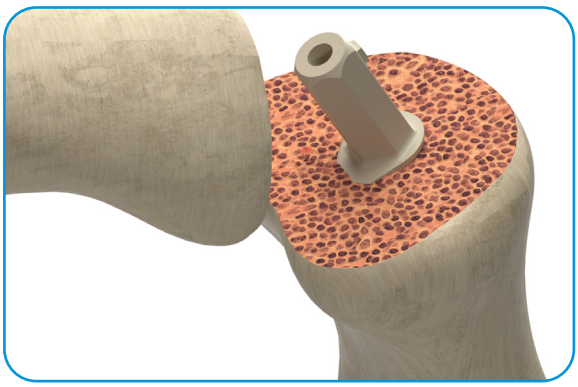


11. Middle Implant Insertion

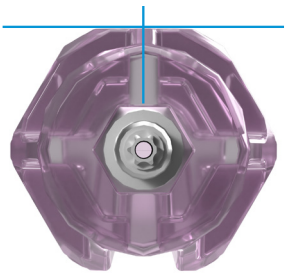
Prior to implant insertion, remove the **K-Wire**. Assemble the desired **Middle Implant** onto the **Driver Shaft** end labeled "2 MID". Thread the **Middle Implant** into the middle phalanx bone by turning the driver clockwise until the threads are buried or or slightly countersunk in the prepared surface. When using the **Straight Middle Implants**, the final position of the **Driver Handle** should have one of the six flat sides oriented horizontally at the 12 o'clock position. When using the **Angled Middle Implants**, the **Driver** laser line and slot should end at the 12 o'clock position.

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





10-degree Angled Middle Implant final position shown



Straight Middle Implant final position of driver

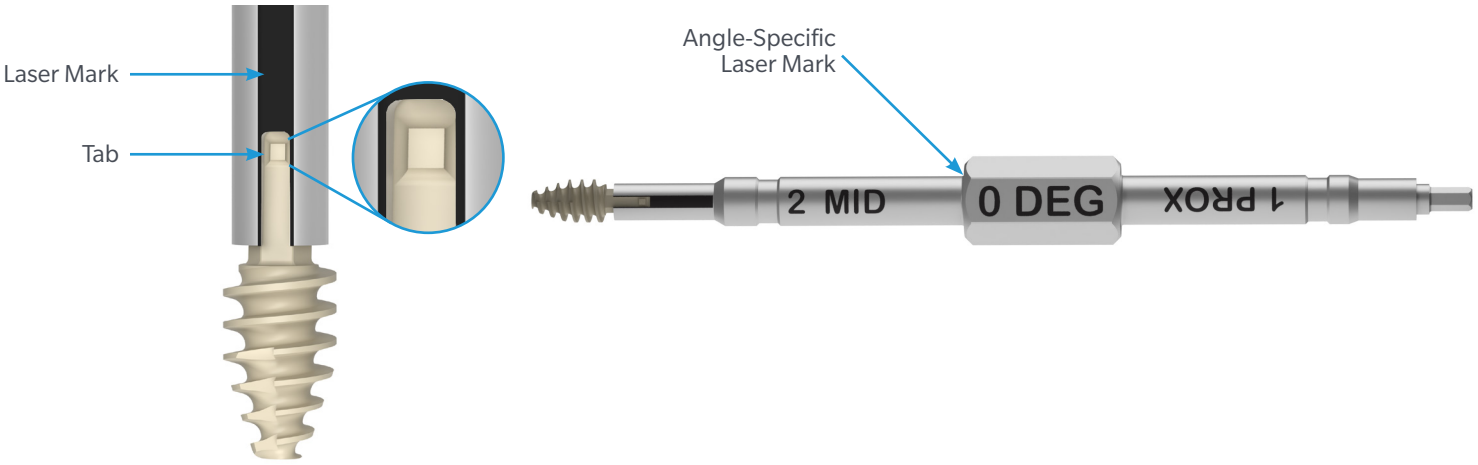
Surgical Technique

Middle Implant & Corresponding Driver

The Nextra PEEK Hammertoe System delivers two different options for **Middle Implants**; a straight 0º option and an angled 10º option. Each option requires a specific **Driver** for insertion which is laser etched according to its corresponding **Middle Implant**.

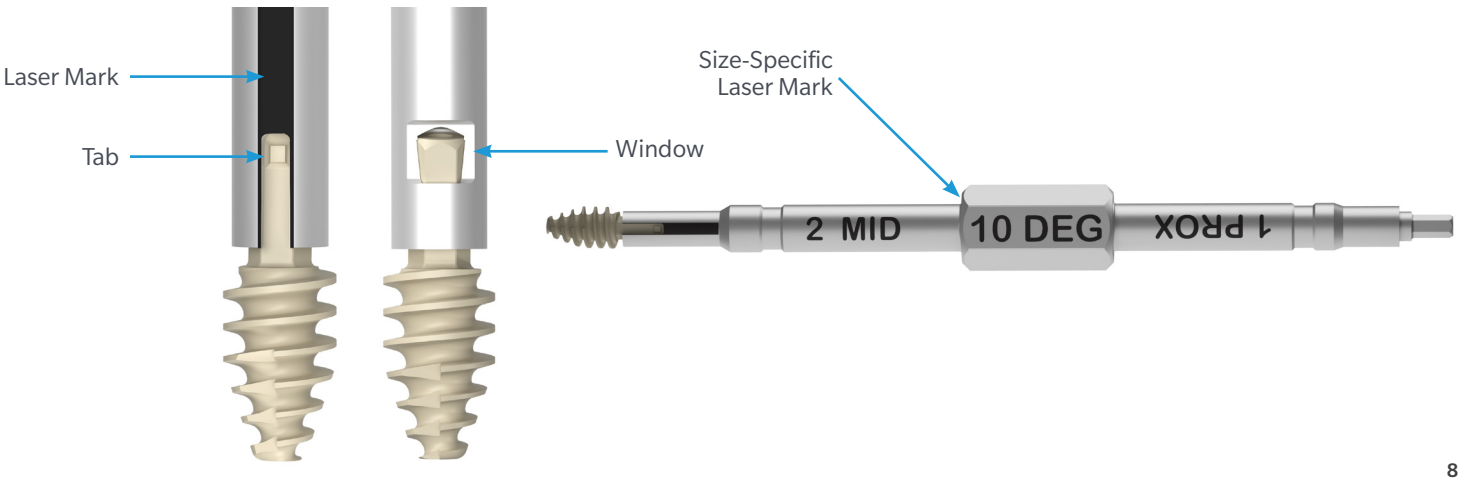
0-Degree Straight Middle Implant & Driver

The **Straight Driver** is indicated by the "0 DEG" laser mark on the driver. The **Straight Middle Implant** should be inserted into the **Straight Driver** by lining up the small tab on the implant shaft with the laser mark on the driver as indicated below. Once the tab and laser mark are aligned, seat the **Straight Middle Implant** into the driver and proceed with insertion of the implant into the middle phalanx (Step 11).



10-Degree Angled Middle Implant & Driver

The **Angled Driver** is indicated by the "10 DEG" laser mark on the driver. The **Angled Middle Implant** should be inserted into the **Angled Driver** by lining up the small tab on the implant shaft with the laser mark on the driver as indicated below. The **Angled Driver** is equipped with a small window on the opposite side of the driver. This window allows the **Angled Middle Implant** to retain its 10º angle while seated in the **Angled Driver**. Once the tab and laser mark are aligned, seat the **Angled Middle Implant** into the driver and proceed with insertion of the implant into the middle phalanx (Step 11).



Surgical Technique

12. Alignment & Reduction

Align the stem of the **Middle Implant** axially with the **Proximal Implant** (Figure 1).

Reduce the proximal phalanx and middle phalanx by compressing the implants (Figure 2).

Seat the implants to achieve bone-to-bone contact for final apposition (Figure 3).

Close the wound in conventional manner. Extensor tendon repair is recommended.

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

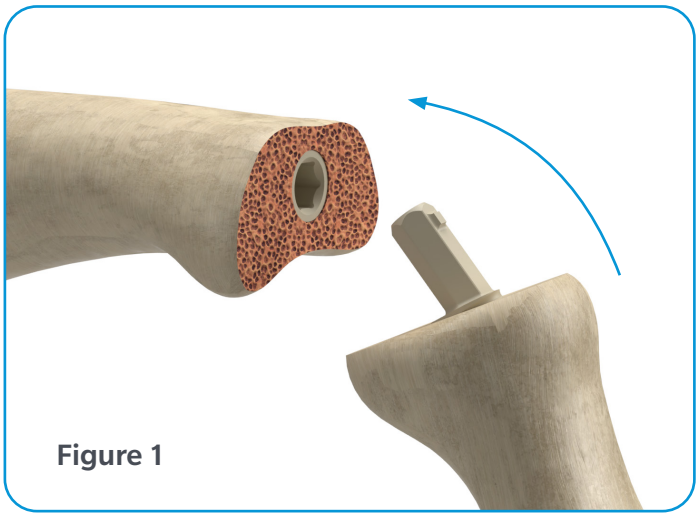


Figure 1

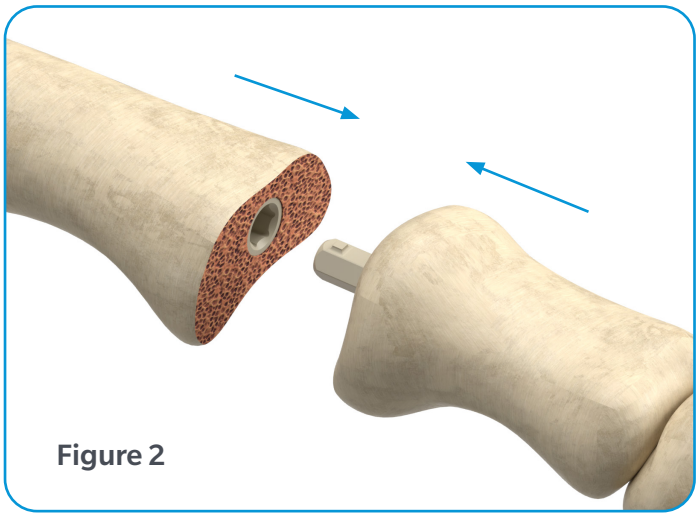


Figure 2

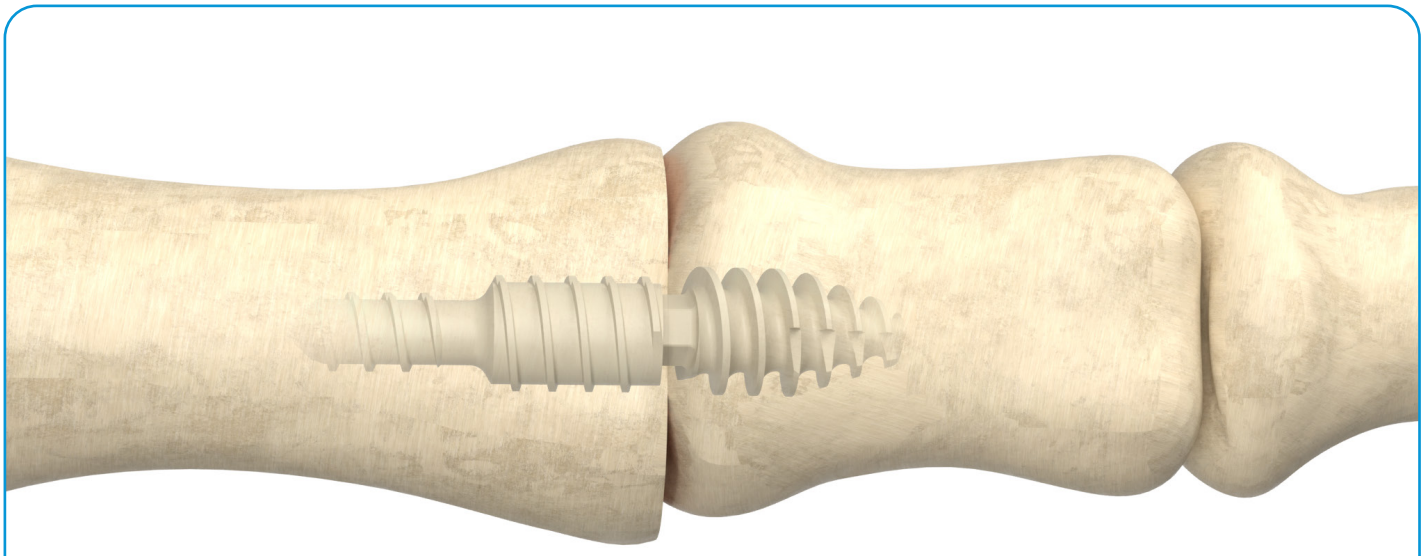


Figure 3

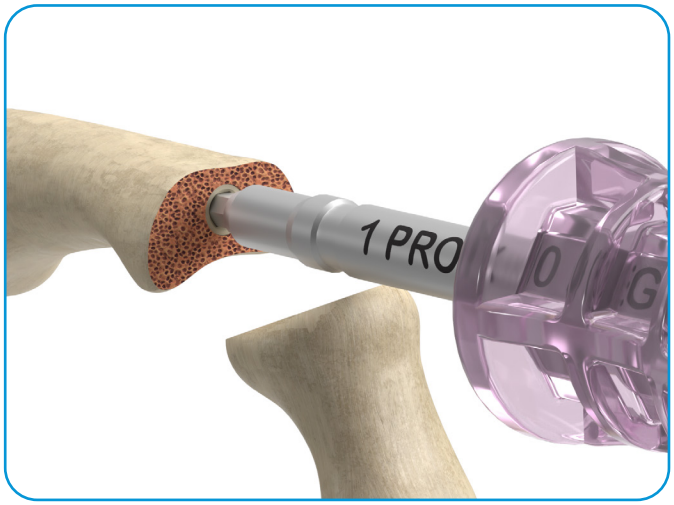
Revision Surgical Technique

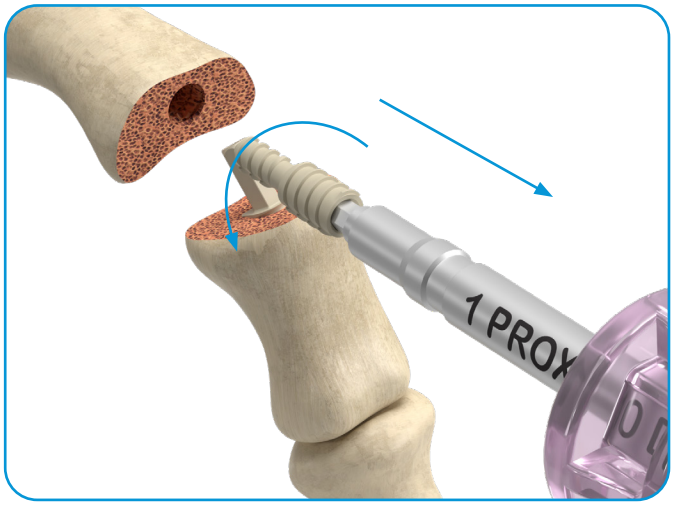
The following surgical technique describes the steps necessary to perform revision surgery of the Nextra PEEK Hammertoe Correction System. The following steps can be applied to both straight and angled implants. Please follow the outlined steps for both sized implants.

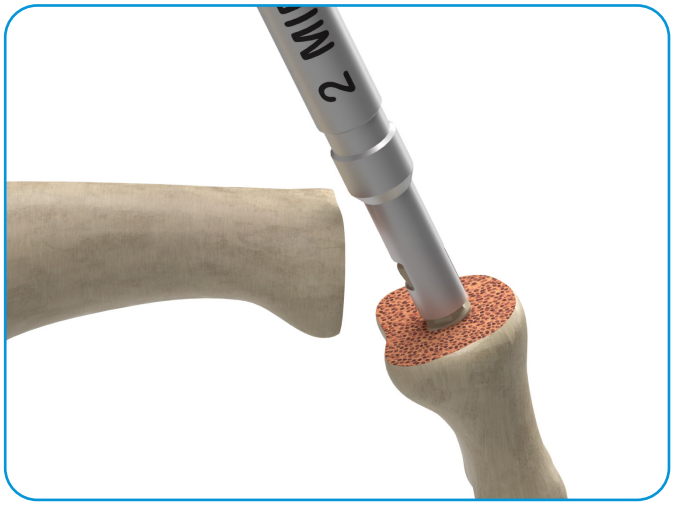
Implant Removal Using Driver Handle

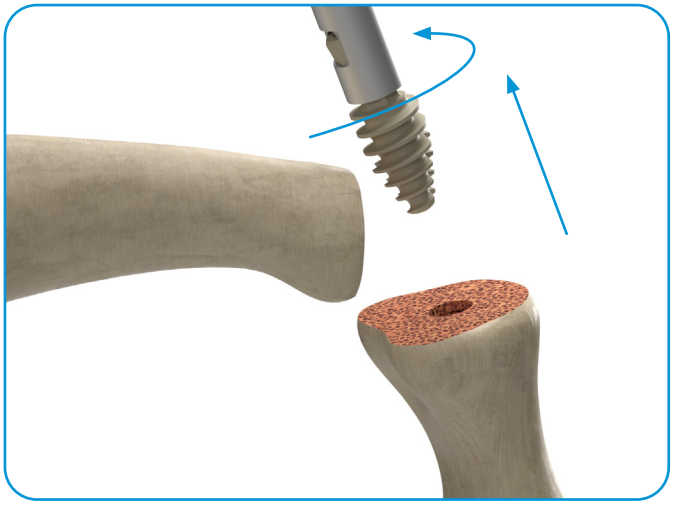
Make a dorsolinear incision over the joint to be revised. Clear any bone growth from around the implant construct that has filled the joint space. Using an osteotome or other surgical tool, distract the proximal and middle phalanxes until the **Proximal Implant** and **Middle Implant** have disengaged (approximaly 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 corresponding **Driver** (straight or angled) into the **Middle Implant** and rotate counter-clockwise until the implant is fully removed.









Ordering Information

Part No.	Description
INSTRUMENT KITS (INCLUDES PROXIMAL IMPLANT)	
PH32PKT	NEXTRA PEEK Instrument Kit with 3.2mm Proximal Implant
PH42PKT	NEXTRA PEEK Instrument Kit with 4.2mm Proximal Implant
IMPLANTS	
PH35M	NEXTRA PEEK 3.5mm Middle Straight Implant w/ Tap
PH425M	NEXTRA PEEK 4.25mm Middle Straight Implant w/ Tap
PH50M	NEXTRA PEEK 5.0mm Middle Straight Implant w/ Tap
PH35AM	NEXTRA PEEK 3.5mm Middle 10º Angled Implant w/ Tap
PH425AM	NEXTRA PEEK 4.25mm Middle 10º Angled Implant w/ Tap
PH50AM	NEXTRA PEEK 5.0mm Middle 10º Angled Implant w/ Tap
PH32P	NEXTRA PEEK 3.2mm Proximal Implant w/ Tap
PH42P	NEXTRA PEEK 4.2mm Proximal Implant w/ Tap
DISPOSABLES	
PHSTRD	NEXTRA PEEK Sterile Straight Driver
PHANGD	NEXTRA PEEK Sterile Angled Driver

INDICATIONS: Nextra® PEEK Hammertoe Correction System is indicated for small bone reconstruction limited to interphalangeal repair and fusion of the lesser toes.

CONTRAINDICATIONS: Nextra® PEEK Hammertoe Correction 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.

This material is intended for health care professionals. Distribution to any other recipient is prohibited. For product information, including indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert.

This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure. Caution: Federal (USA) law restricts this device to sale by or on the order of a surgeon. Rx only.

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The Nextra PEEK Hammertoe Correction System is manufactured using implant-grade polyetheretherketone (PEEK).

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