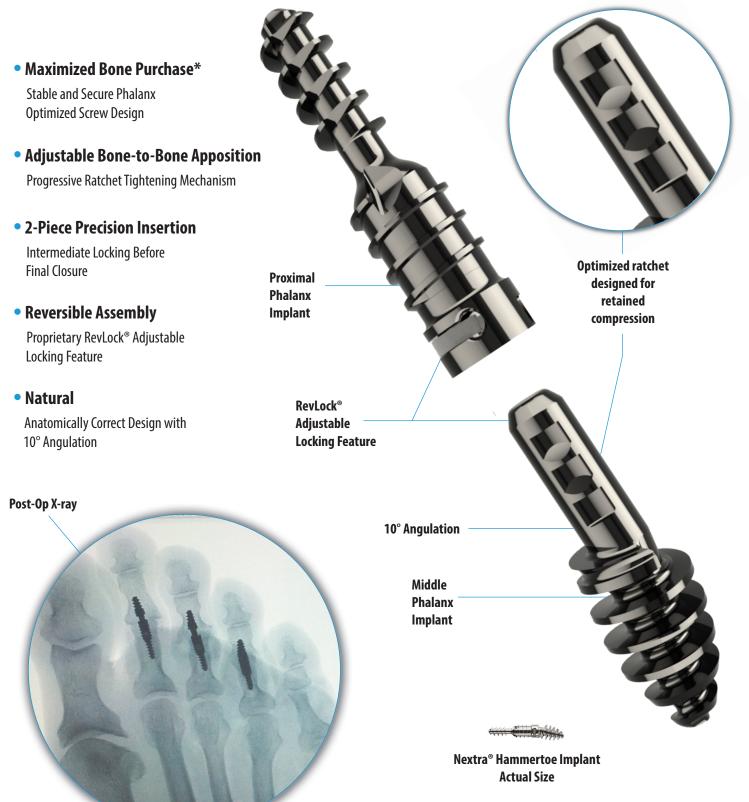


Nextra[®] Hammertoe Correction System

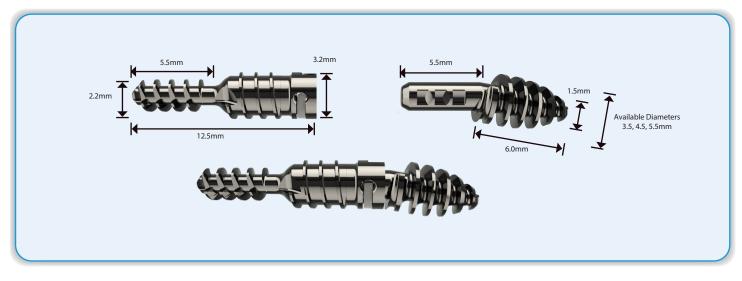
Surgical Technique

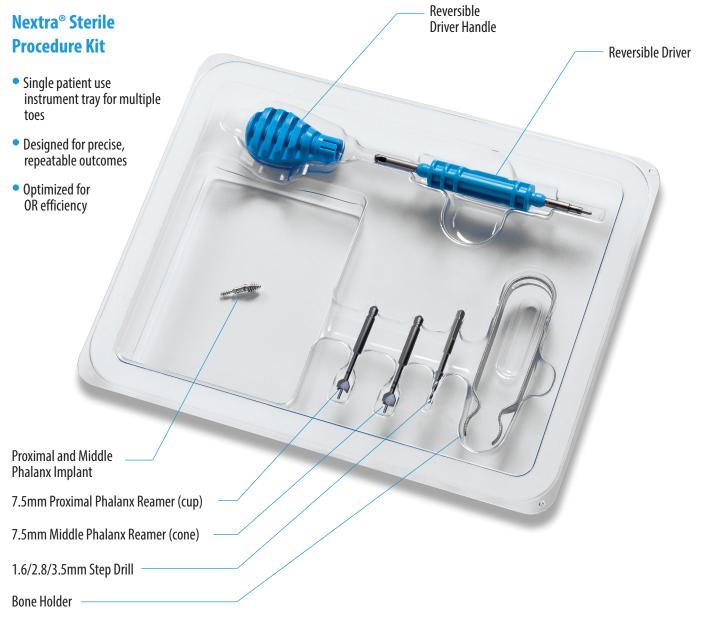






Product Information





Surgical Technique

1. Preparation

PIP Joint Exposure

Prepare the insertion site using standard surgical techniques. A typical approach involves a 2cm 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. Resection - Saw Cuts Method

Utilize optional **Bone Holder** to secure bone during resection. It is important that necessary shortening be done on the proximal and not the middle phalanx. Enough bone should be resected to allow for the implant.



10° flat cuts, to approximate a natural position, may be used. The proximal surface should be resected on a 10° angle to allow for optimal contact of the proximal and middle bone surfaces during fusion.

Resection - Optional Reaming Method

Proximal and middle reamers may be used instead of traditional saw cuts.

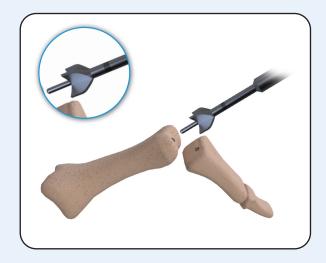
When using the optional reaming method, there must be a pilot hole in the center of the middle and proximal phalanx. This is achieved using the 1.6mm portion only of the **Step Drill**, indicated with one laser mark.

Proximal Reaming

The Proximal Phalanx Reamer has one laser mark ring.

Insert the centering reamer pin into the pilot hole. Ream to suitable depth to prepare the bone surface for optimal fusion.





Resection - Optional Reaming Method (continued)

Reaming of the Middle Phalanx

The Middle Phalanx Reamer has two laser mark rings.

Insert the centering reamer pin into the pilot hole. Ream to suitable depth to prepare the bone surface for optimal fusion.

Post Reaming

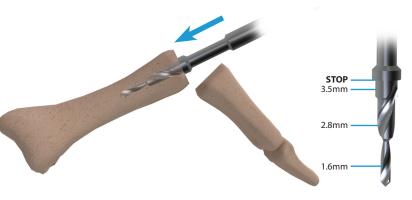
Trim excess bone of middle and proximal phalanx edges, if present, with rongeur.



3. Pilot Drilling

Proximal Drill Positioning

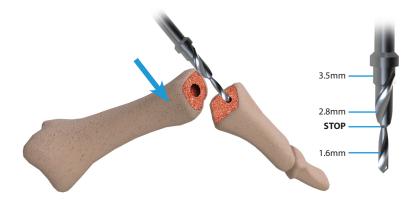
When drilling the proximal phalanx, using the **Step Drill**, drill the bone into the 2.8mm and 3.5mm portions of the **Step Drill** until the stop on the drill makes contact with the surface of the bone. For soft bone, only the 1.6mm portion should be used. For hard bone, drill until a dead stop.



Step Drill aligned with center of the intramedullary canal in both bones.

Middle Pilot Positioning

When drilling the middle phalanx, it is important to **NOT** countersink the bone, and to stop prior to the tapered portion of the **Step Drill** or the DIP cortical wall, whichever occurs first. Only the 1.6mm portion of the **Step Drill** should be used.



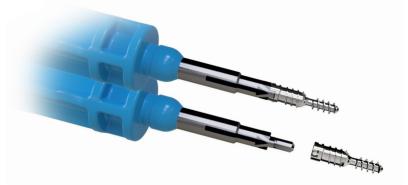
4. Implant Insertion

Set up of Reversible Driver

Reversible Driver has a middle (female) and proximal (male) side. Slide handle over shaft to expose the end of the proximal driver.



Load Proximal Phalanx Implant onto Reversible Driver by placing notch on implant into key on Reversible Driver.



Insert Proximal Phalanx Implant



Turn Proximal Phalanx Implant in until end is flush with cut surface. The leading edge of the black laser-marked ring should be flush with the bone surface. It is acceptable to slightly countersink the Proximal Phalanx Implant.



4. Implant Insertion (continued)

In its final position, the arrow should be in the 12 o'clock position.

In the rare case when the surgeon desires more implant purchase in the proximal phalanx, a larger proximal phalanx implant should be used.

The **Proximal Phalanx Implant Grasper** can be used to remove an undersized implant. This can be achieved by inserting the **Grasper**, under fluoroscopy, into the proximal phalanx until a connection with the implant is made.

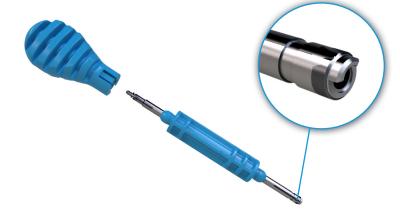


Final Position of the Proximal Phalanx Implant



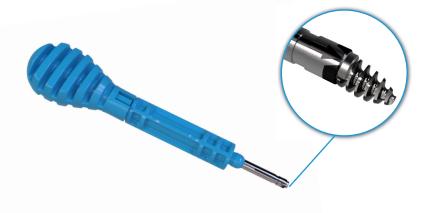
Load Middle Phalanx Implant

Reverse the handle to expose the middle (female) side of the Reversible Driver. Do this by pulling handle off one end and sliding it over the other. It will snap when fully seated.



Load the Middle Phalanx Implant onto the Reversible Driver.

The **Middle Phalanx Implant** will only engage in one orientation.



4. Implant Insertion (continued)

Middle Phalanx Insertion

For the **Middle Phalanx Implant** final position, the screw threads should go into bone fully.

As in the proximal side, the leading edge of the black lasermarked ring should be flush with the bone surface. In its final position, the slot and arrow should be in the 12 o'clock position. It is acceptable to slightly countersink the Middle Phalanx Implant, as long as the *final position is in the 12 o'clock position*.

In the rare case where the surgeon desires more implant purchase on the middle phalanx, a larger middle phalanx implant should be used.

CAUTION: Use care to properly align the implant and **Reversible Driver** during insertion. Do not use a bent or damaged implant.

Both Segments Implanted

5. Alignment & Reduction

Alignment of Implants & Reduction

Reduce the bones until surface-to-surface contact is achieved. The Nextra® RevLock® adjustable locking feature will click at 1.1mm intervals. It is acceptable for the implant's RevLock® adjustable locking feature to be seated on the 1st, 2nd, or 3rd notch, as long as bone-to-bone contact is achieved.

Fully Reduced Device is Shown at Right

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

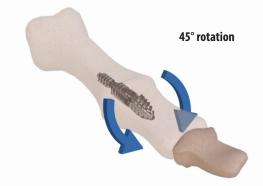




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5. Alignment & Reduction (continued)

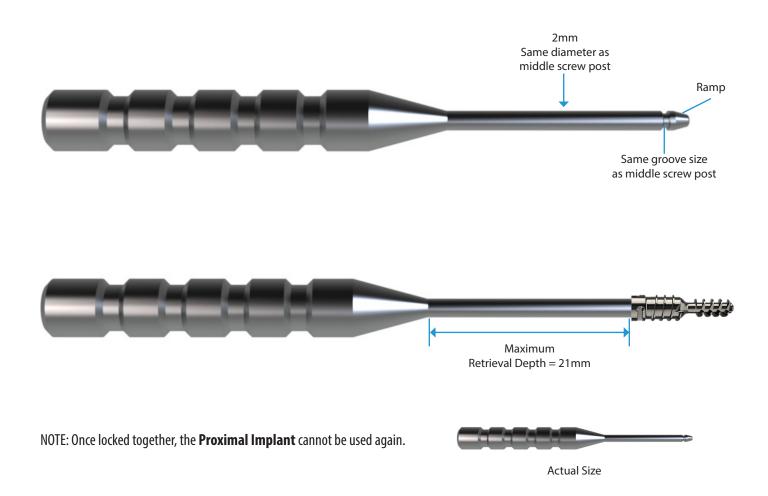
In the rare instance that the segments are too shallow or too deep, the implant can be disengaged and repositioned. This is done by holding the proximal phalanx rigidly, and rotating the middle phalanx approximately 45°, as allowed by soft tissue. The implant can then be retracted from its locked position. Rotation can be done in either direction.

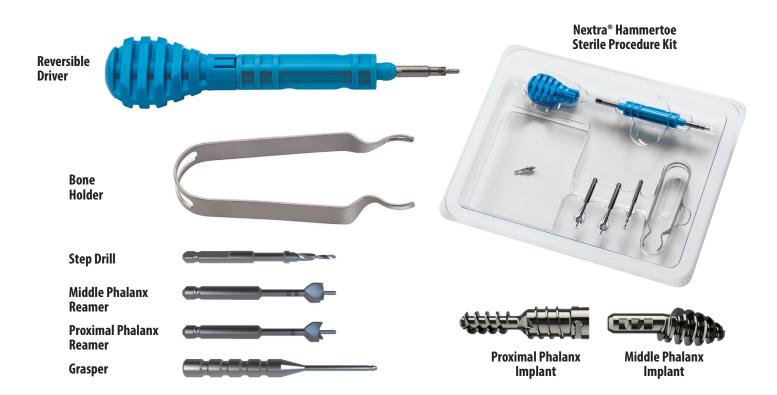


Proximal Implant Retrieval

If it becomes necessary to retrieve the proximal Nextra[®] implant and the Reversible Driver will not back it out, the Proximal Grasper can be inserted into the open end of the Proximal Implant.

When the implant locks onto the Proximal Grasper, pull axially to gently remove the Proximal Implant.





ORDERING INFORMATION	
Part No.	Description
NX-3532K-SC	Nextra® Hammertoe Sterile Procedure Saw Cut Kit (No Reamers) Nextra® Hammertoe Implant (3.5mm Middle Phalanx Implant / 3.2mm Proximal Implant),1.6/2.8/3.5mm Step Drill, Implant Handle & Driver
NX-3532K	Nextra® Hammertoe Sterile Procedure Kit Nextra® Hammertoe Implant (3.5mm Middle Phalanx Implant / 3.2mm Proximal Implant),1.6/2.8/3.5mm Step Drill, 7.5mm Proximal and Middle Phalanx Reamers, Bone Holder, Implant Handle & Driver
NX-4532K-SC	Nextra® Hammertoe Sterile Procedure Saw Cut Kit (No Reamers) Nextra® Hammertoe Implant (4.5mm Middle Phalanx Implant / 3.2mm Proximal Implant),1.6/2.8/3.5mm Step Drill, Implant Handle & Driver
NX-4532K	Nextra® Hammertoe Sterile Procedure Kit Nextra® Hammertoe Implant (4.5mm Middle Phalanx Implant / 3.2mm Proximal Implant),1.6/2.8/3.5mm Step Drill, 7.5mm Proximal and Middle Phalanx Reamers, Bone Holder, Implant Handle & Driver
NX-3532MP	Nextra® Hammertoe Sterile Implant: 3.5mm Middle Phalanx Implant / 3.2mm Proximal Implant
NX-4532MP	Nextra® Hammertoe Sterile Implant: 4.5mm Middle Phalanx Implant / 3.2mm Proximal Implant
NX-45M	Nextra® Sterile Middle Phalanx Implant: 4.5mm Middle Phalanx Implant
NX-55M	Nextra® Sterile Middle Phalanx Implant: 5.5mm Middle Phalanx Implant
NX-45P	Nextra® Sterile Proximal Phalanx Implant: 4.5mm Proximal Phalanx Implant
NX-GRA	Nextra® Sterile Proximal Grasper
NX-DR	Nextra® Sterile Driver

INDICATIONS: The Nextra® Hammertoe Correction Implant is indicated for small bone reconstruction limited to inter- phalangeal repair and fusion of the lesser toes. CONTRAINDICATIONS: The Nextra® Hammertoe Correction Implant is NOT intended for use in procedures involving the great toe. In addition, the device is contraindicated in the following: (1) Pathological conditions of bone, such as cystic changes or severe osteopenia, osteoporosis, bony deficiencies, or comminuted bone surface which would adversely affect the Nextra® Hammertoe Correction Implant; (2) Physical conditions that would eliminate, or tend to eliminate, adequate implant support or retard healing, including inadequate soft tissue coverage; (3) Conditions which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period; (4) Sensitivity or allergy to the metal implant. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation; (5) Blood supply limitations and previous infections that may retard healing; (6) Presence of an active infection; (7) Pediatric patients with open epiphyseal plates.

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The Nextra Hammertoe Correction system is manufactured using 316L Stainless Steel.

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