Maximized Bone Purchase*  
Stable and Secure Phalanx  
Optimized Screw Design

Adjustable Bone-to-Bone Apposition  
Progressive Ratchet Tightening Mechanism

2-Piece Precision Insertion  
Intermediate Locking Before Final Closure

Reversible Assembly  
Proprietary RevLock® Adjustable Locking Feature

Natural  
Anatomically Correct Design with 10° Angulation

*“Achieving Maximum Phalangeal Fixation and Bone Contact Through Osteological Design of Hammertoe Implants”; Osteological study of bone purchase for the Nextra Hammertoe Implant.
**Nextra® Sterile Procedure Kit**

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

**Available Diameters**

3.5, 4.5, 5.5mm

**Nextra® Sterile Procedure Kit**

- 7.5mm Proximal Phalanx Reamer (cup)
- 7.5mm Middle Phalanx Reamer (cone)
- 1.6/2.8/3.5mm Step Drill
- Bone Holder

**Reversible Driver Handle**

**Reversible Driver**

**Proximal and Middle Phalanx Implant**
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.

  **Saw Cuts**
  - 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.
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.

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

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### 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.

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**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.

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**Resection - Optional Reaming Method (continued)**
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 laser-marked 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.

- **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.
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.

NOTE: Once locked together, the Proximal Implant cannot be used again.
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. Check for country product clearances and reference product-specific instructions for use.

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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ORDERING INFORMATION

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<th>Part No.</th>
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