SURGICAL TECHNIQUE GUIDE:

LAPIDUS ARTHRODESIS USING THE PHANTOM INTRAMEDULLARY NAIL

PHANTOM
INTRAMEDULLARY NAIL

Exclusively foot & ankle

Paragon 28®

SURGICAL TECHNIQUE GUIDE:

LAPIDUS ARTHRODESIS USING THE PHANTOM INTRAMEDULLARY NAIL

Acknowledgment:

Paragon 28® would like to thank James T. Clancy, DPM and Mark Myerson, MD for their contribution to the development of the surgical technique guide.

PRODUCT DESCRIPTION

The Paragon 28® Phantom™ Intramedullary Nail System was designed to improve on existing technology for the Lapidus Arthrodesis procedure by providing a structurally sound implant that minimizes hardware prominence, improves on compression capability and preserves the periosteum. The Intramedullary Nail can be used in primary arthrodesis or for revision Lapidus procedures. An extensive offering of sizes of Intramedullary Nails are available to fit variations in patient anatomy and allow for use of a bone graft to restore the length of the first ray.

PRODUCT OFFERING

Intramedullary Nail-Available in right (shown) and left

38 mm

46 mm

54 mm

40 mm

48 mm

56 mm

42 mm

50 mm

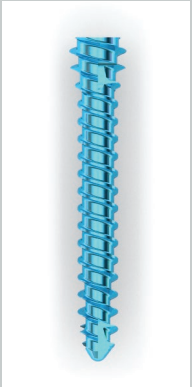
58 mm

44 mm

52 mm

60 mm

Intramedullary Nail Threaded Pegs



Size: 3.5 mm diameter
Length: 10-46 mm lengths, 2 mm increments
Color: Teal
Use: Three per Lapidus Intramedullary Nail, inserted at the 3 most proximal holes in nail through the outrigger construct

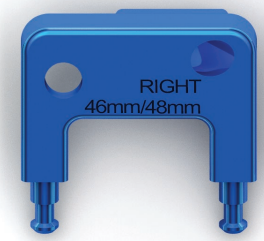
Intramedullary Nail Locking Screws

Size: 3.5 mm diameter
Length: 10-26 mm lengths, 2 mm increments
Color: Dark Blue
Use: One per Lapidus Intramedullary Nail, inserted at the most distal hole of nail

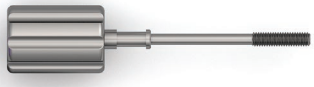
INSTRUMENTS

Outrigger
Attaches to selected outrigger slider to form an outrigger construct

Outrigger Slider
Size is color matched to Lapidus Intramedullary Nail

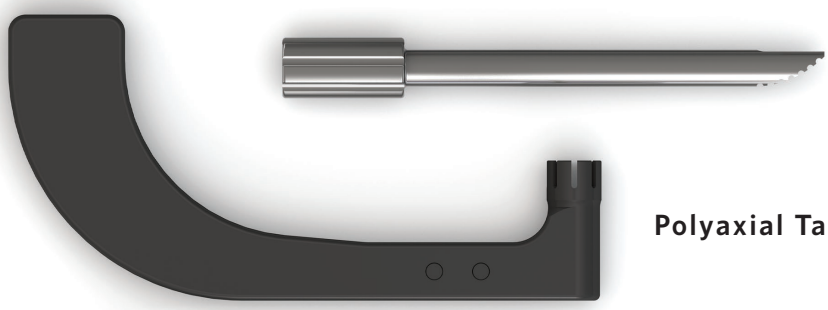


Thumb Screw
Inserts into the outrigger and attaches to the Lapidus Intramedullary Nail



Sphere Wire

Nail Positioning Guide



Polyaxial Targeting Guide Sleeve Insert

Polyaxial Targeting Guide

Ø2.3mm K-wire

Nail Depth Gauge

Ø5.5mm Cannulated Nail Drill

Screw Guide

Ø2.3mm Guide

Drill Guide

Obturator

SURGICAL TECHNIQUE GUIDE:

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INSTRUMENTS

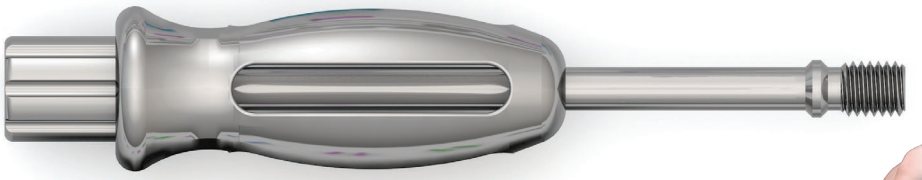
Ø2.75mm K-wire

Depth Gauge

AO Mini Ratcheting Handle

Solid Driver

Locking Guide



Slaphammer

INCISION/EXPOSURE

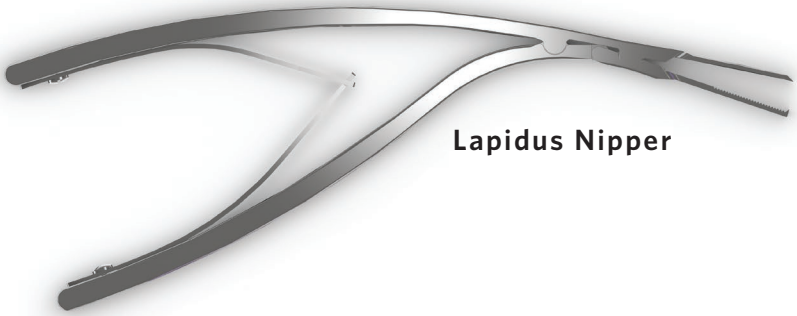
The procedure described can be performed on its own or combined with resection of the medial eminence and lateral release at the 1st metatarsophalangeal joint at the discretion of the surgeon.

Supine patient positioning with fluoroscopy available is recommended for this procedure.

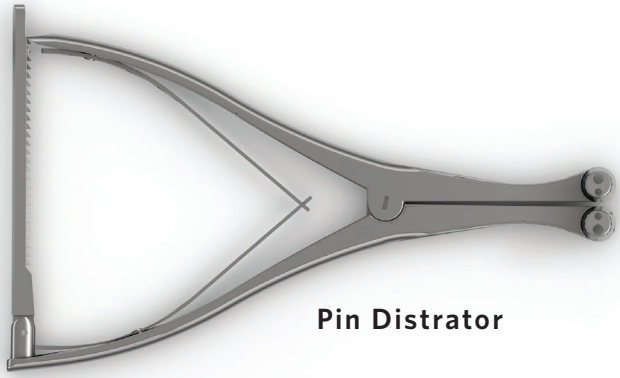
A medial or dorsomedial incision over the 1st tarsometatarsal joint is recommended. Soft tissue dissection is continued to expose the 1st tarsometatarsal joint (1st TMTJ).

JOINT PREPARATION

After exposure of the joint surfaces at the 1st TMTJ, cartilage resection is performed according to surgeon preference. The patent-pending Paragon 28 Lapidus Nipper is available for removal of fragments from the joint created by sagittal saw resection. A pin distractor is available in the system to allow for joint access.



Lapidus Nipper



Pin Distrator

Subchondral bone preparation can be performed following joint resection using the Paragon 28 subchondral perforating drill, joint preparation chisel or surgeon's preferred technique.

Joint Preparation Chisel

Subchondral Perforating Drill

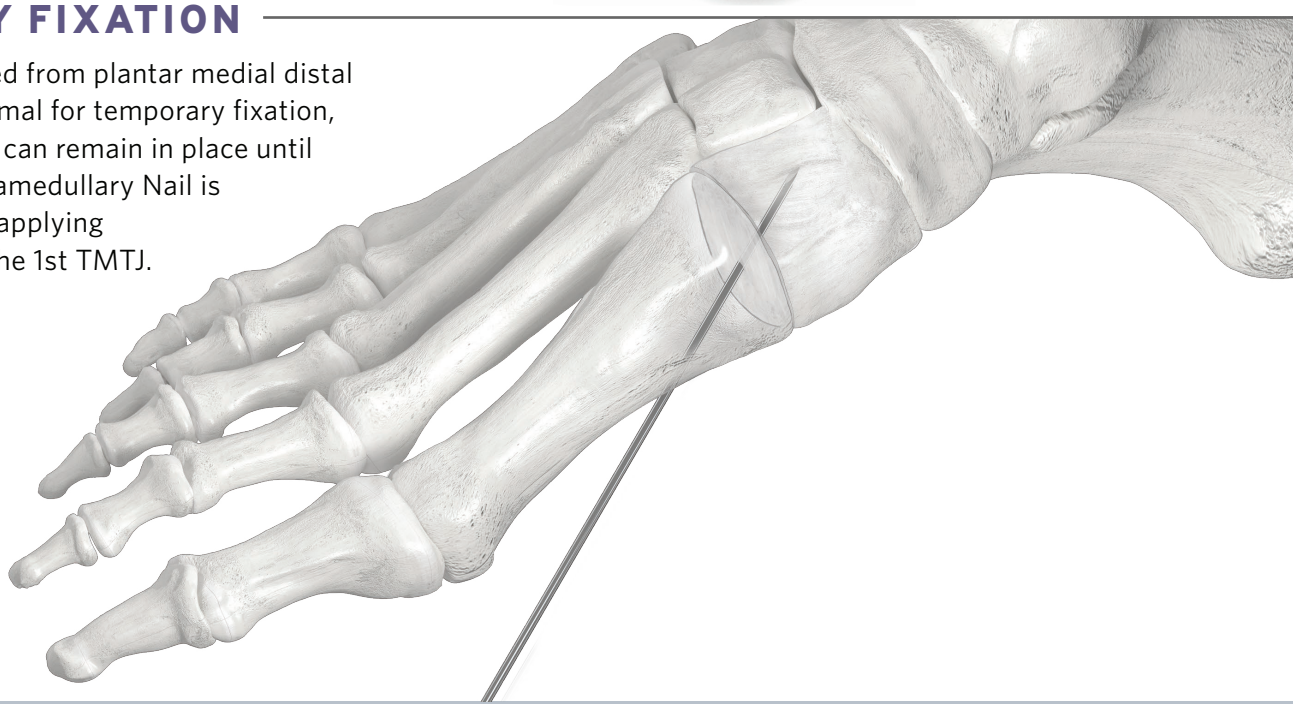
If used, bone grafting material can be inserted in the joint at this time.

TIP: The PRESERVE™ Lapidus Angular Length Restoring Bone Graft can help restore length for a patient with a short 1st metatarsal, in a case with over-shortening or for revision procedures. This bone graft is anatomically shaped to the joint and features biplanar correction to plantarflex and abduct the 1st metatarsal. The Lapidus Intramedullary Nail sizing has the optionality to accommodate a bone graft in the 1st TMTJ.

Lapidus Wedge

TEMPORARY FIXATION

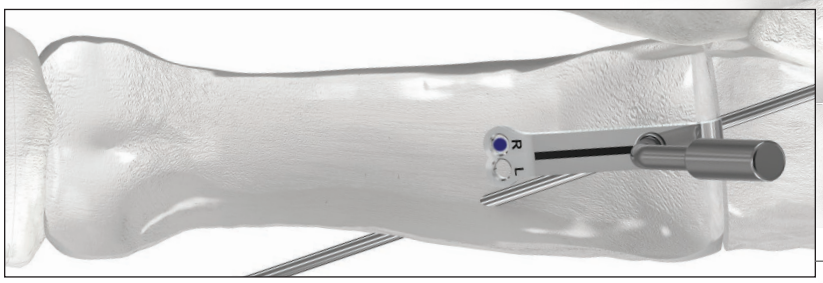
A K-wire can be placed from plantar medial distal to dorsal lateral proximal for temporary fixation, if desired. The K-wire can remain in place until after the Lapidus Intramedullary Nail is inserted, but prior to applying compression across the 1st TMTJ.



TEMPORARY FIXATION

Obtain the sphere wire and place it at the proximal plantar medial aspect of the medial cuneiform.

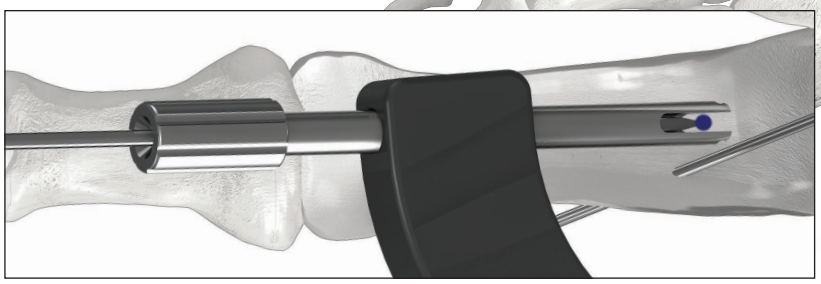
TIP: A nail positioning guide is available to help provide the correct 2.3 mm K-wire starting position. By placing the 90° side of the polyaxial targeting guide into the central lateral aspect of the 1st TMT joint, the hole on the nail positioning guide is positioned to receive the tip of the 2.3 mm K-wire at the desired start position of just lateral to the mid-line of the first metatarsal and 23 mm distal to the 1st TMTJ. A pilot hole can be made using the 2.3 mm K-wire at this location so that the 2.3 mm K-wire can be appropriately lined up for insertion.



Place the "claw" end of the polyaxial targeting guide on the sphere wire so that it "clicks" into place to allow circular motion on the sphere wire but does not disengage.

TEMPORARY FIXATION

Insert the sleeve insert into the distal end of the polyaxial targeting guide. Align the trajectory of the sleeve inserter to achieve desired start position. The goal of the start position of the 2.3 mm K-wire is just lateral to the mid-line and 23 mm distal to the 1st TMTJ.

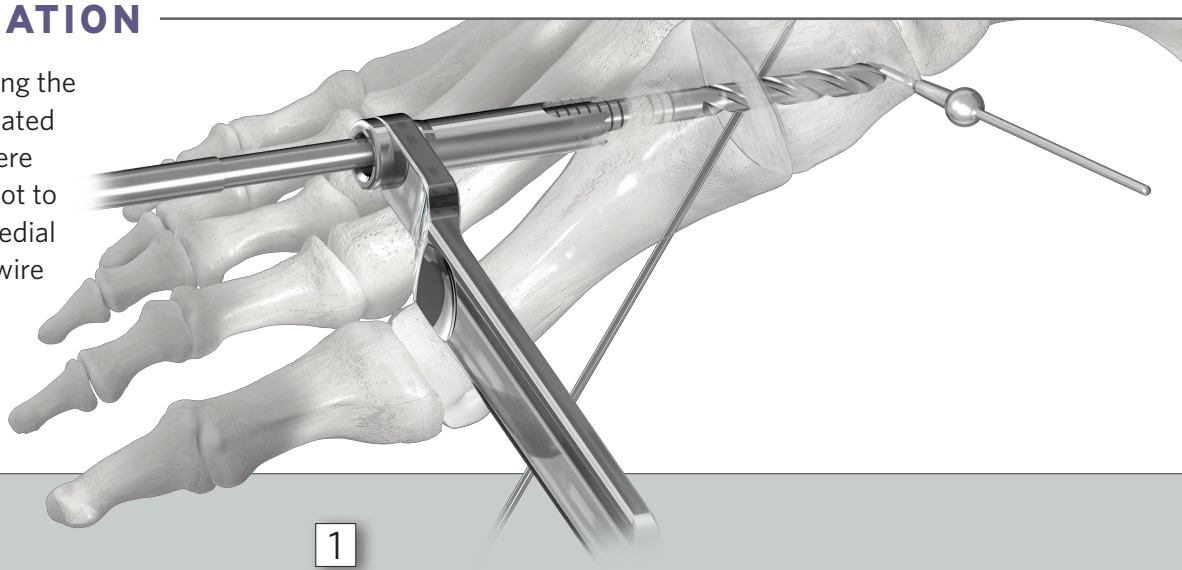


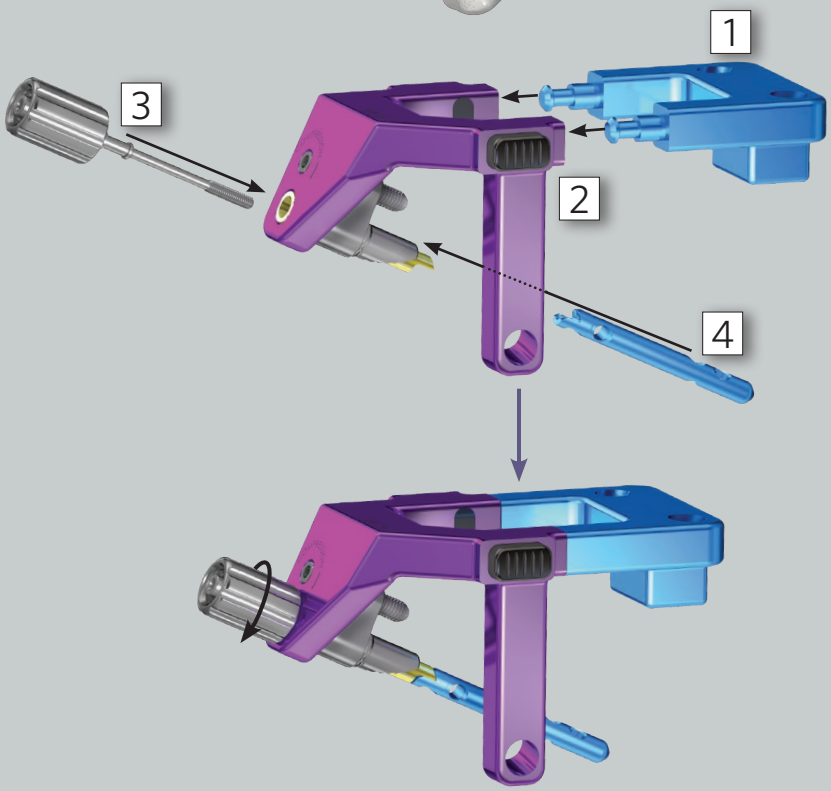
Drive the 2.3 mm K-wire into the sleeve insert until it contacts the sphere wire or reaches the proximal plantar aspect of the medial cuneiform. Confirm placement and length using fluoroscopy. Slide the sleeve insert off of the 2.3 mm K-wire. Remove the polyaxial targeting guide from the sphere wire.

Measure the 2.3 mm K-wire length using the provided nail depth gauge.

TEMPORARY FIXATION

Drill over the 2.3 mm K-wire using the cannulated nail drill. The cannulated nail drill should stop on the sphere wire, but care should be taken not to drill past the far cortex of the medial cuneiform. Remove the sphere wire and 2.3 mm K-wire.



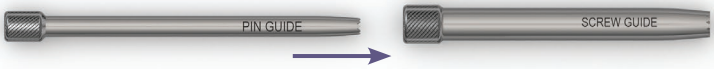


1. Obtain the Intramedullary Nail according to patient operative side and length. Select the outrigger slider by matching color and side. The outrigger sliders are laser marked to correspond with specific Intramedullary Nail sizes and sides.
2. Insert the outrigger slider into the right or left outrigger by inserting the two arms of the outrigger slider into the outrigger until no further advancement of the outrigger slider can be achieved and disengagement of the outrigger slider can only occur with depressing the buttons on the outside of the outrigger.
3. Retrieve the thumb screw and insert it into the outrigger.
4. Attach the desired size of Intramedullary Nail to the outrigger by turning the thumb screw in a clockwise direction to thread into the inside of the Intramedullary Nail until tightened.

Insert the Intramedullary Nail/outrigger construct into the drill hole. Continue insertion until the contoured piece on the outrigger is flush with the dorsal aspect of the first metatarsal. Confirm Intramedullary Nail size and placement using fluoroscopy.

PERMANENT FIXATION

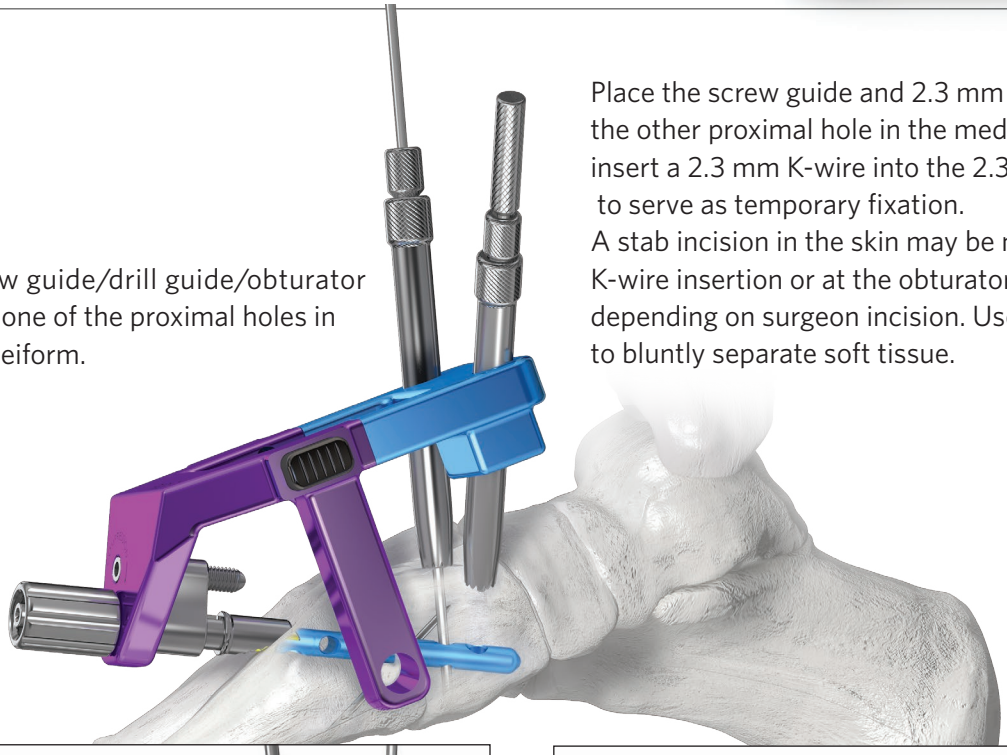
Assemble an obturator, drill guide and screw guide.



Assemble a 2.3 mm K-wire guide and screw guide.

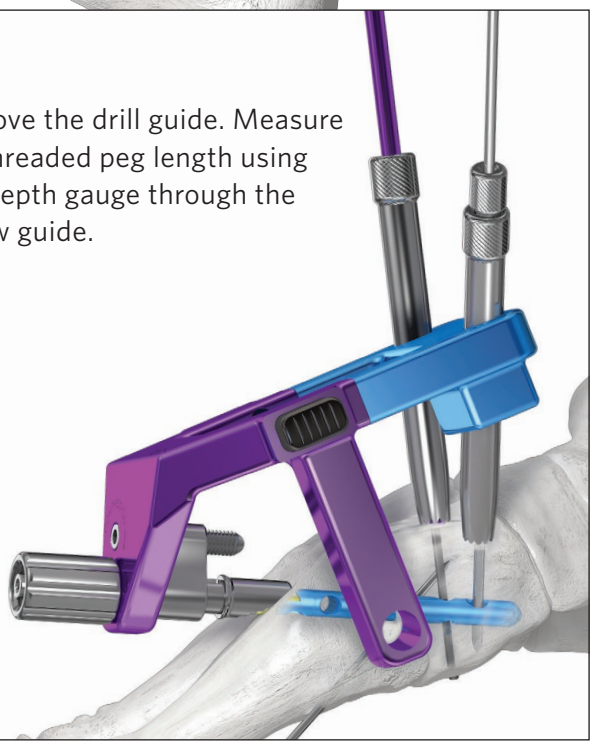
Place the screw guide/drill guide/obturator assembly into one of the proximal holes in the medial cuneiform.

Place the screw guide and 2.3 mm K-wire guide into the other proximal hole in the medial cuneiform and insert a 2.3 mm K-wire into the 2.3 mm K-wire guide to serve as temporary fixation.
A stab incision in the skin may be necessary prior to K-wire insertion or at the obturator location depending on surgeon incision. Use the obturator to bluntly separate soft tissue.



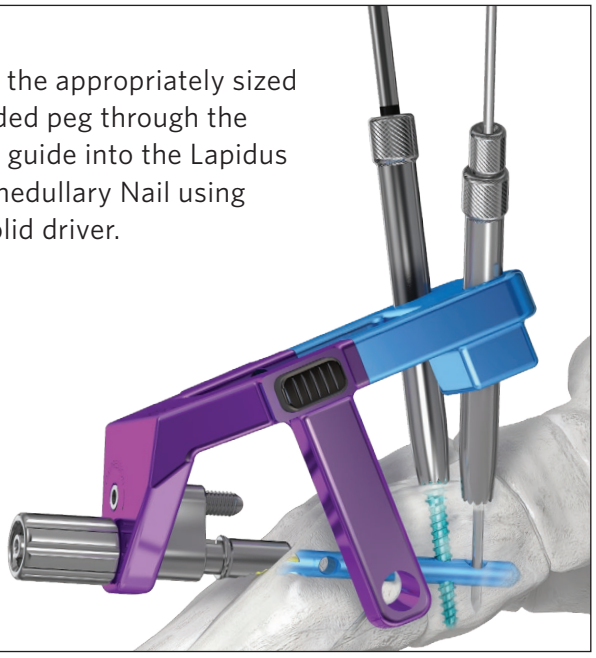
Remove the obturator.
Using the 2.75 mm k-wire, drill through the drill guide.

Remove the drill guide. Measure for threaded peg length using the depth gauge through the screw guide.



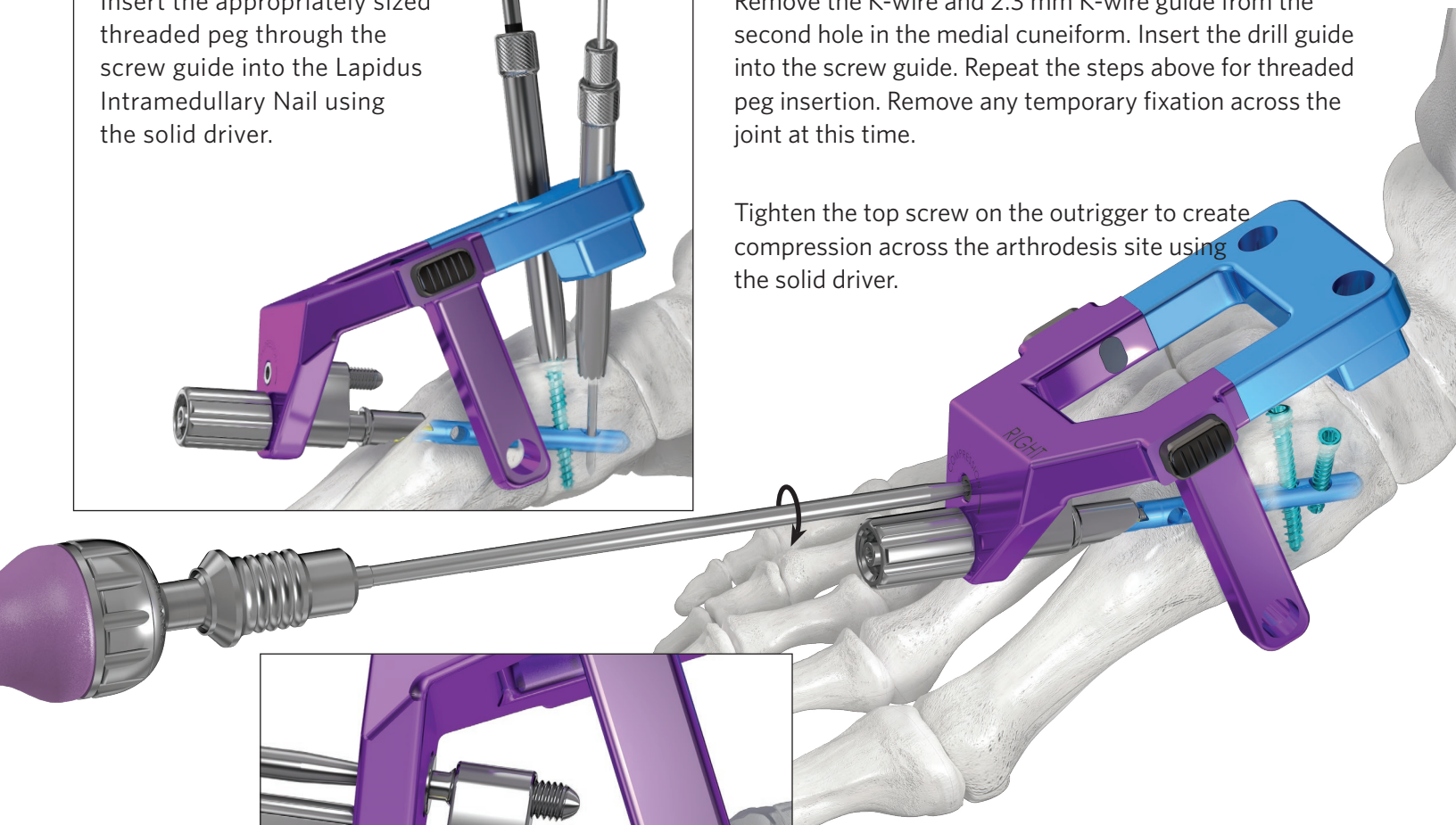
PERMANENT FIXATION

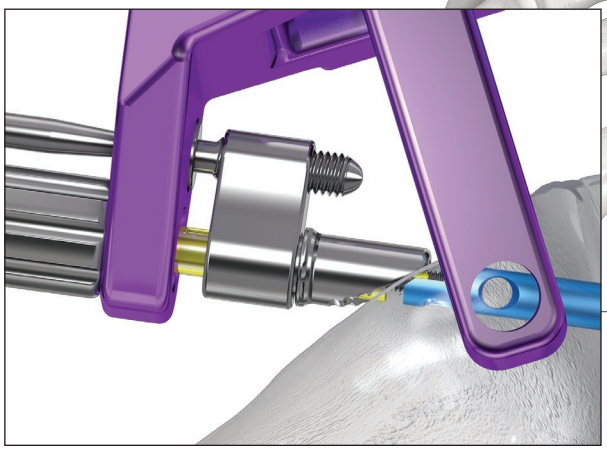
Insert the appropriately sized threaded peg through the screw guide into the Lapidus Intramedullary Nail using the solid driver.



Remove the K-wire and 2.3 mm K-wire guide from the second hole in the medial cuneiform. Insert the drill guide into the screw guide. Repeat the steps above for threaded peg insertion. Remove any temporary fixation across the joint at this time.

Tighten the top screw on the outrigger to create compression across the arthrodesis site using the solid driver.

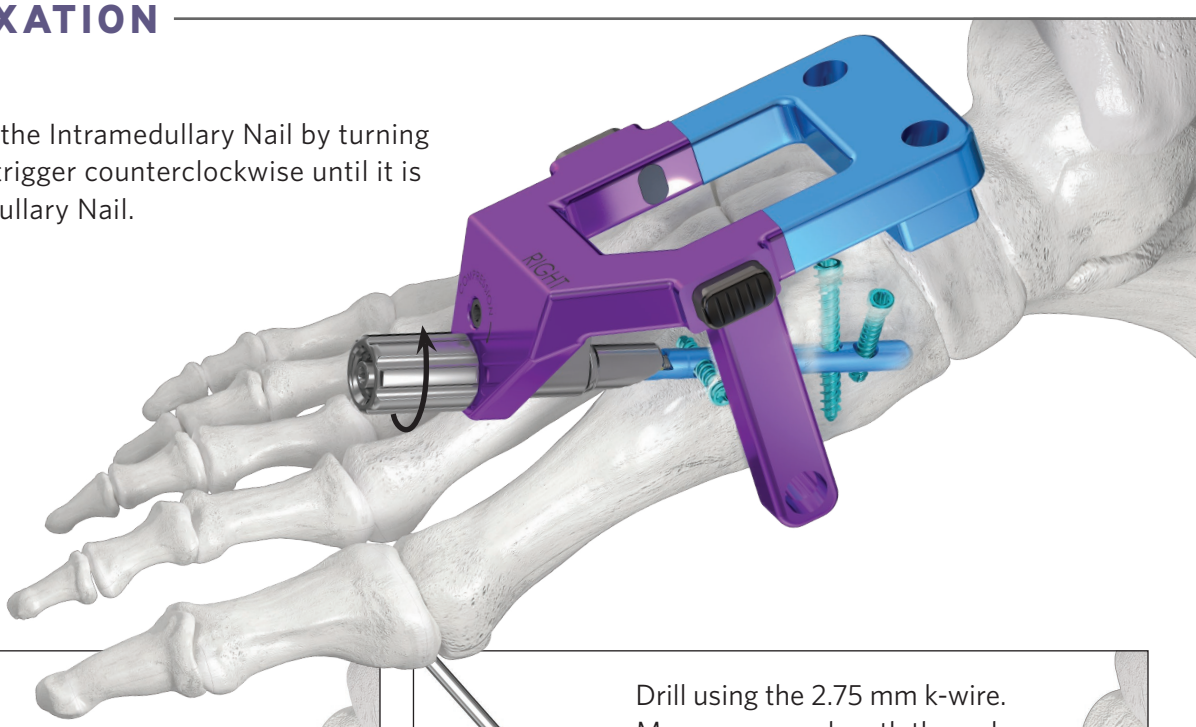


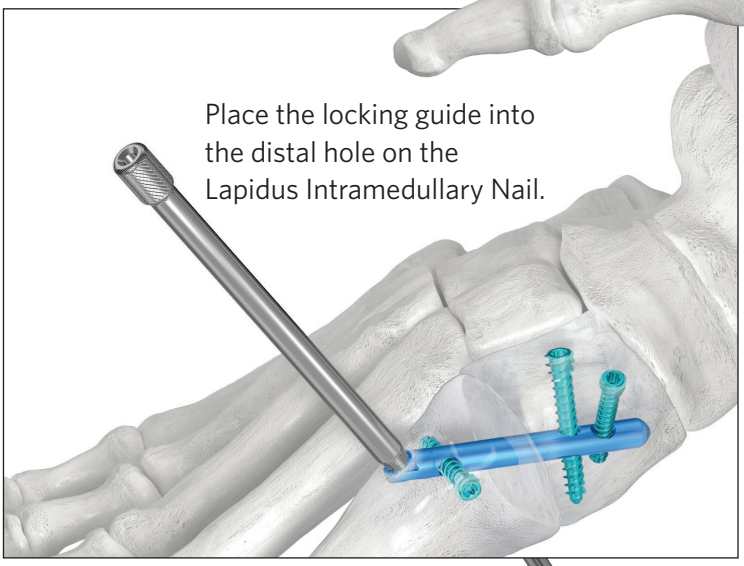


Repeat the steps of placing a threaded peg into the final outrigger hole.

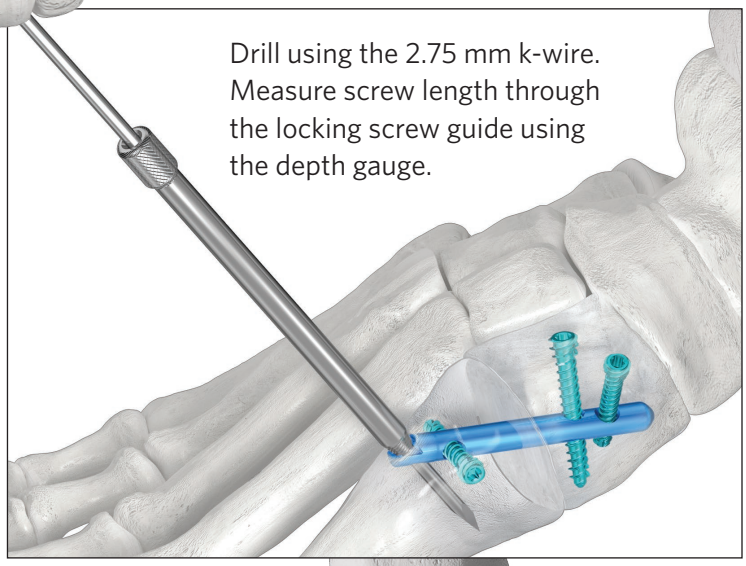
PERMANENT FIXATION

Remove the outrigger from the Intramedullary Nail by turning the thumb screw on the outrigger counterclockwise until it is released from the Intramedullary Nail.



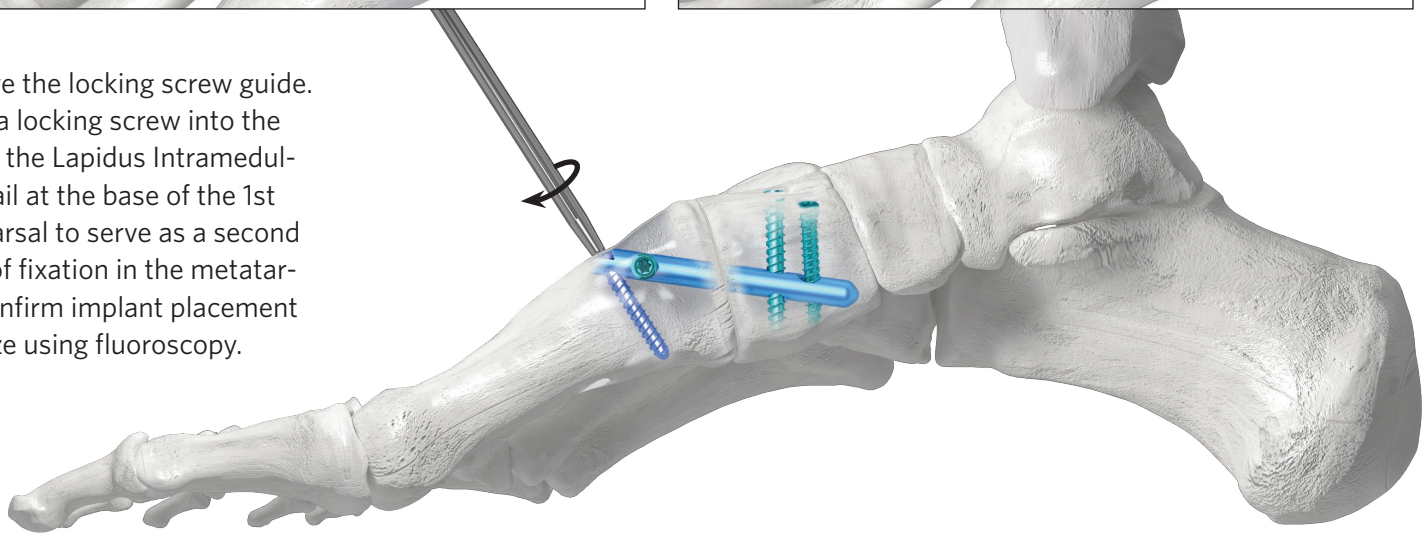


Place the locking guide into the distal hole on the Lapidus Intramedullary Nail.



Drill using the 2.75 mm k-wire. Measure screw length through the locking screw guide using the depth gauge.

Remove the locking screw guide. Insert a locking screw into the hole in the Lapidus Intramedullary Nail at the base of the 1st metatarsal to serve as a second point of fixation in the metatarsal. Confirm implant placement and size using fluoroscopy.



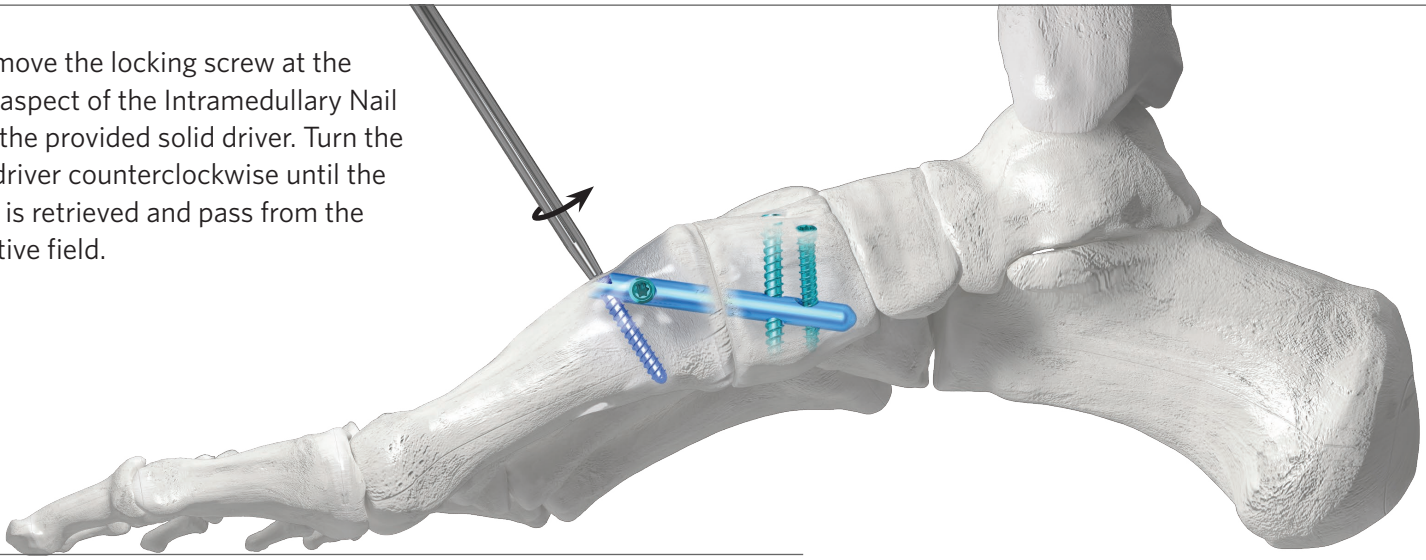
CLOSURE

Proceed to incision closure or concomitant procedures at this time.

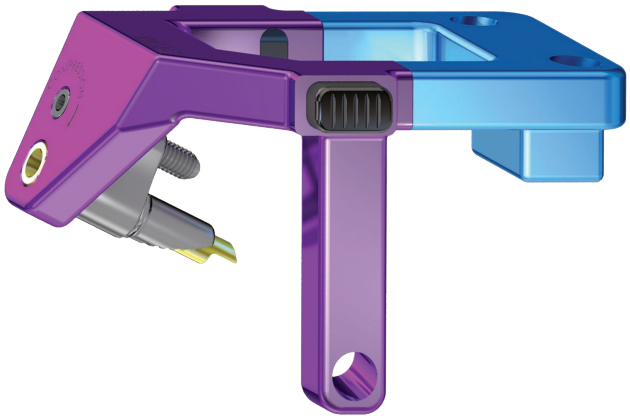
REMOVAL/REVISION

If removal of the Lapidus Intramedullary Nail is necessary, the following steps should be followed:

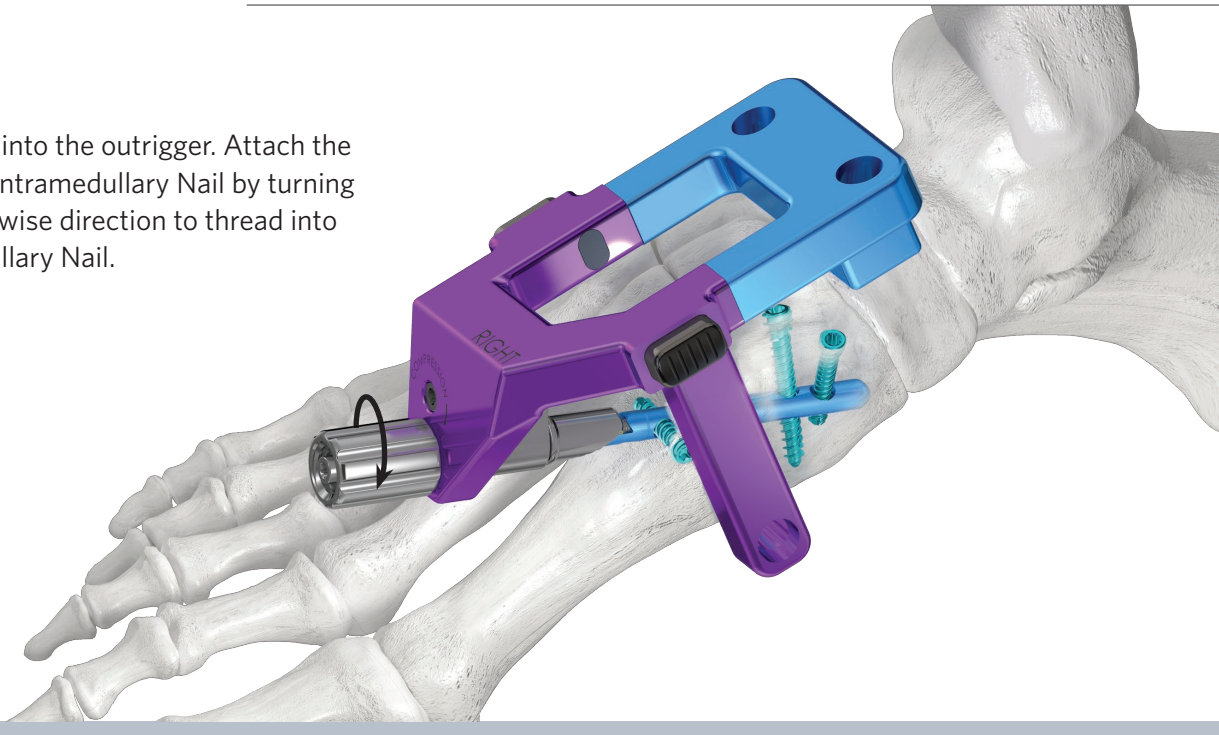
1. Remove the locking screw at the distal aspect of the Intramedullary Nail using the provided solid driver. Turn the solid driver counterclockwise until the screw is retrieved and pass from the operative field.



2. Retrieve the outrigger for the Intramedullary Nail. Retrieve the outrigger slider that corresponds to the color of the implanted Intramedullary Nail and patient side. If size is unknown and color is unable to be determined, use fluoroscopy to determine Intramedullary Nail length using a measuring device or by matching perfect circles of the outrigger slider and screw head location. Attach the outrigger slider to the outrigger by inserting the arms of the outrigger slider into the outrigger until no further advancement can be achieved and disengagement of the outrigger slider can only occur with depressing the buttons on the outside of the outrigger.

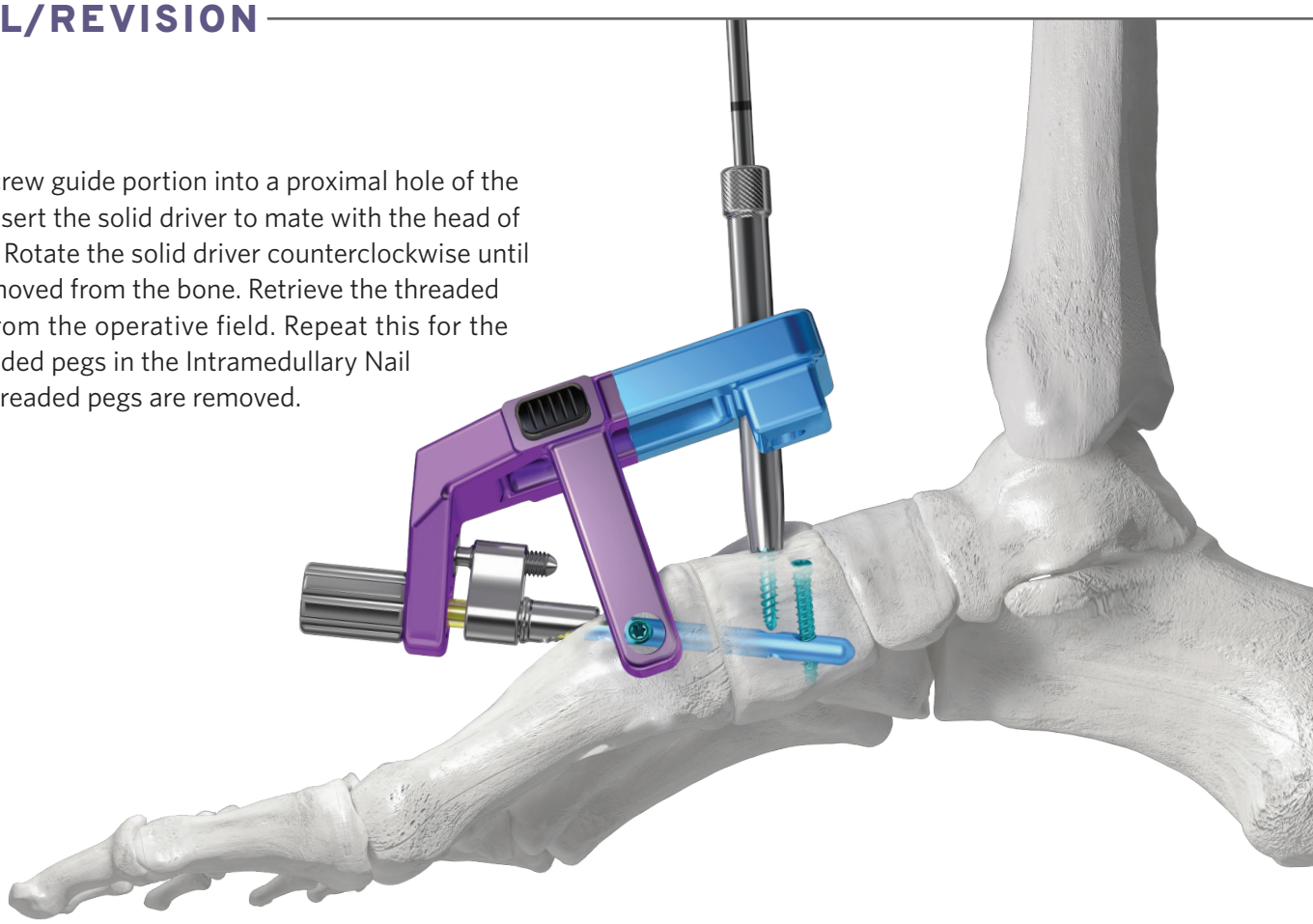


3. Insert the thumb screw into the outrigger. Attach the outrigger construct to the Intramedullary Nail by turning the thumb screw in a clockwise direction to thread into the inside of the Intramedullary Nail.

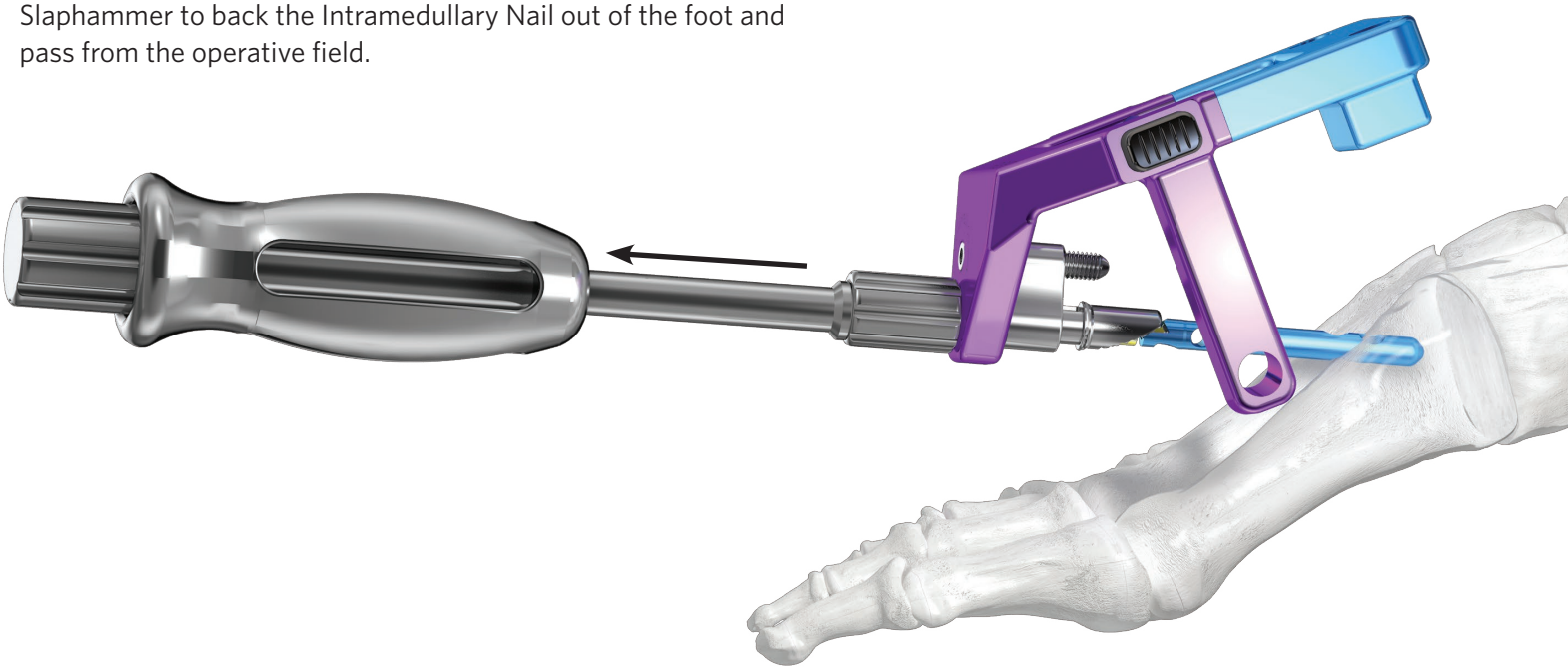


REMOVAL/REVISION

4. Insert the screw guide portion into a proximal hole of the outrigger and insert the solid driver to mate with the head of a threaded peg. Rotate the solid driver counterclockwise until the screw is removed from the bone. Retrieve the threaded peg and pass from the operative field. Repeat this for the remaining threaded pegs in the Intramedullary Nail until all three threaded pegs are removed.



5. Attach the Slaphammer to the thumb screw of the outrigger by rotating the Slaphammer in a clockwise direction. Use the Slaphammer to back the Intramedullary Nail out of the foot and pass from the operative field.



INDICATIONS FOR USE

The Phantom™ Small Bone Intramedullary Nail System is indicated for use in stabilization and fixation of the small bones of the feet and ankle for the treatment of fractures, osteotomies, arthrodesis, nonunions, pseudoarthroses and malunions caused by revision, joint fusion or reconstruction procedures.

CONTRAINDICATIONS

The Paragon 28® Phantom™ Small Bone Intramedullary Nail System implants are not designed or sold for any use except as indicated. Use of the Phantom™ Small Bone Intramedullary Nail System is contraindicated in the following situations:

- Active, suspected or latent infection in the affected area
- Patients who are physiologically or psychologically inadequate
- Patients previously sensitized to titanium
- Longitudinal splits or longitudinal fractures
- Insufficient quantity or quality of bone to permit stabilization, conditions that retard healing (not including pathological fractures) and conditions causing poor blood supply
- Open epiphyseal plates
- In patients where there is a possibility for conservative treatment
- Indications not included in the INDICATIONS FOR USE

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

In any surgical procedure, the potential for complications and adverse reactions exist.
The risks and complications with these implants include:

- Loosening, deformation or fracture of the implant
- Acute post-operative infections and late infections with possible sepsis
- Migration, subluxation of the implant with resulting reduction in range of movement
- Fractures resulting from unilateral joint loading
- Thrombosis and embolism
- Wound hematoma and delayed wound healing
- Temporary and protracted functional neurological perturbation
- Tissue reactions as a result of allergy or foreign body reaction to dislodged particles
- Corrosion with localized reaction and pain
- Pain, a feeling of malaise or abnormal sensations due to the implant used
- Bone loss due to stress shielding

All possible complications listed here are not typical of Paragon 28®, Inc. products but are in principle observed with any implant. Promptly inform Paragon 28®, Inc. as soon as complications occur in connection with the implants or surgical instruments used. In the event of premature failure of an implant in which a causal relationship with its geometry, surface quality or mechanical stability is suspected, please provide Paragon 28®, Inc. with the explant(s) in a cleaned, disinfected and sterile condition. Paragon 28®, Inc. cannot accept any other returns of used implants. The surgeon is held liable for complications associated with inadequate asepsis, inadequate preparation of the osseous implant bed in the case of implants, incorrect indication or surgical technique or incorrect patient information and consequent incorrect patient behavior.

WARNINGS AND PRECAUTIONS

- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- Use of an undersized implant in areas of high functional stresses may lead to implant fracture and failure.
- Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- The implants and guide wires are intended for single use only.
- Instruments and K-wires are to be treated as sharps.
- **Do not use other manufacturer's instruments or implants in conjunction with the Phantom™ Small Bone Intramedullary Nail System**

PHANTOM
INTRAMEDULLARY NAIL

PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

Exclusively foot & ankle
Paragon 28®

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DISCLAIMER

The purpose of the Phantom™ Intramedullary Nail System Surgical Technique Guide is to demonstrate the optionality and functionality of the Phantom™ Intramedullary Nail implants and instrumentation. Although variations in placement and use of the Intramedullary Nail can be performed, the fixation options demonstrated in this technique were chosen to demonstrate the functionality of the system and for simplicity of explanation. Other uses for the Intramedullary Nail can be employed, appropriate for the size of the device.