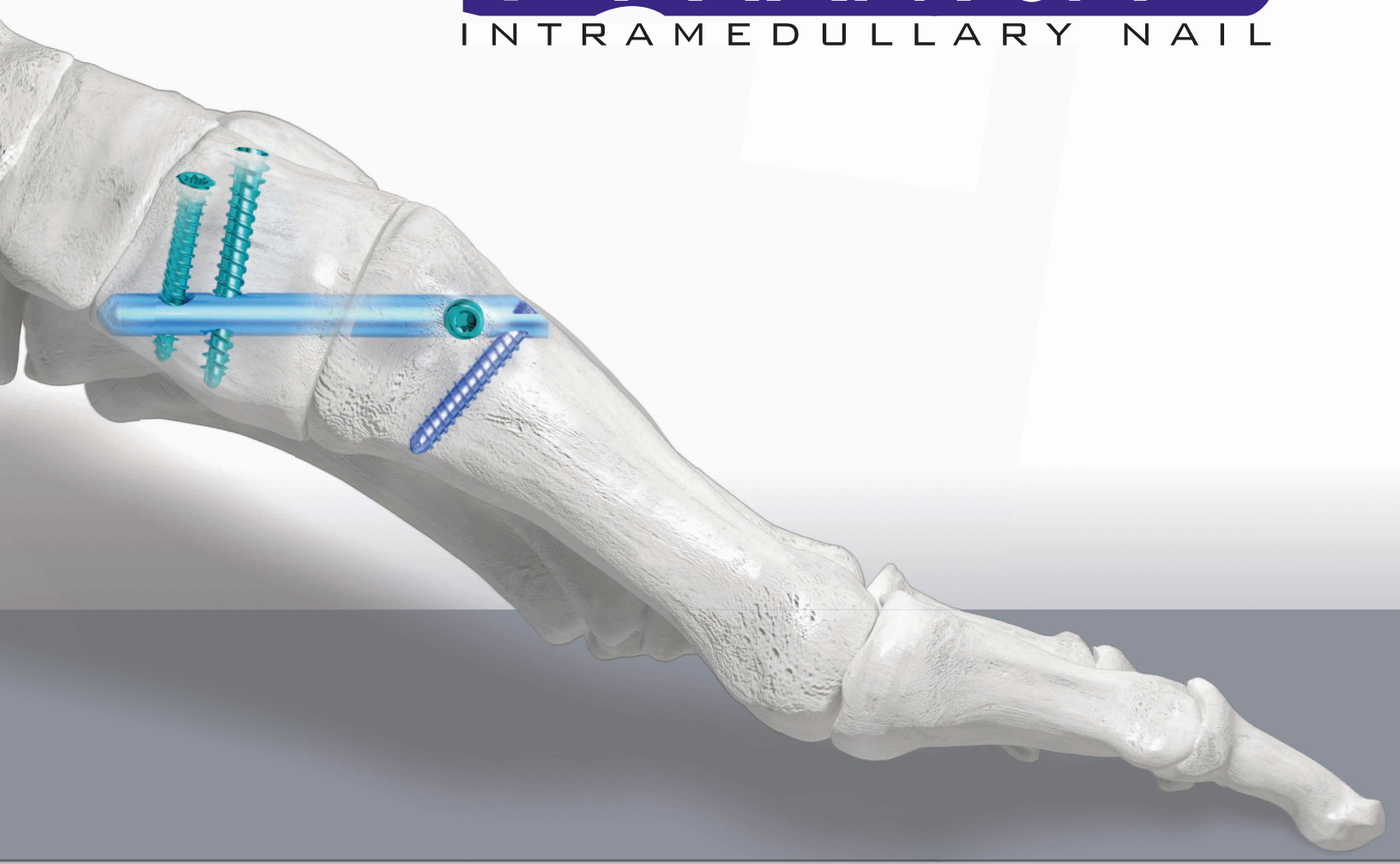
SURGICAL TECHNIQUE GUIDE:

LAPIDUS ARTHRODESIS USING THE PHANTOM® INTRAMEDULLARY **NAIL**

PHANTOM®
INTRAMEDULLARY NAIL



Exclusively foot & ankle

Paragon 28®

Acknowledgment:

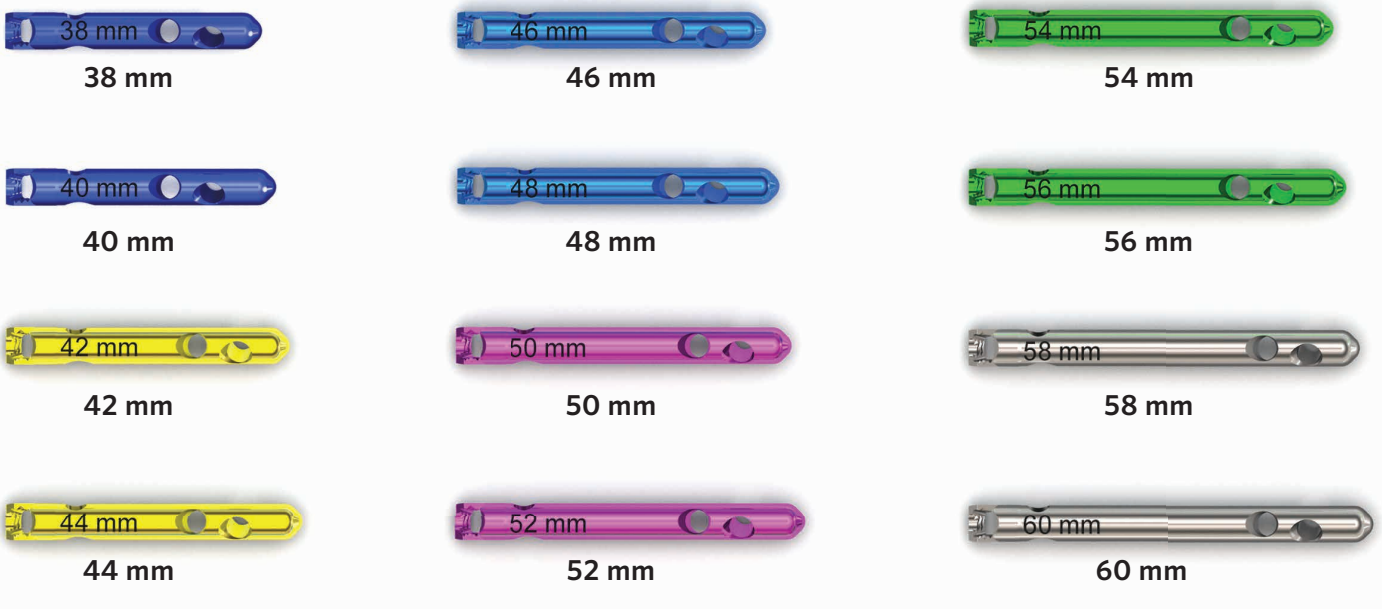
Paragon 28® would like to thank James T. Clancy, DPM and Thomas San Giovanni, MD for their contribution to the development of the surgical technique guide.

PRODUCT DESCRIPTION

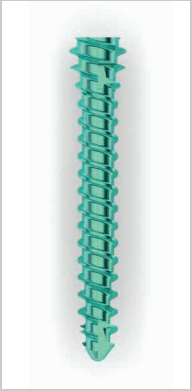
The patent-pending Paragon 28® Small Bone Phantom® Intramedullary Nail System was designed to improve on existing technology for the Lapidus Arthrodesis procedure by providing a structurally sound implant that minimizes hardware prominence, improves compression capability and helps to preserve the periosteum. The Phantom® Nail can be used in primary arthrodesis or for revision Lapidus procedures. An extensive offering of sizes of Phantom® 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

Phantom® Nail - Right (shown) and Left Side Specific Nails



Phantom® Nail Threaded Pegs



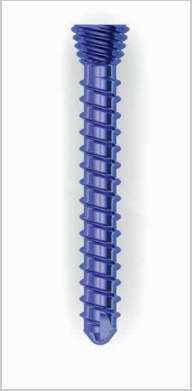
Size: 3.5 mm diameter

Length: 10-60 mm lengths, 2 mm increments

Color: Teal

Use: Three per Phantom® Nail, inserted at the 3 most proximal holes

Phantom® Nail Locking Screws



Size: 3.5 mm diameter

Length: 10-30 mm lengths, 2 mm increments

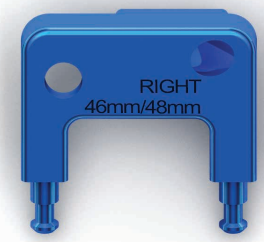
Color: Dark Blue

Use: One per Phantom® Nail, inserted at the most distal hole of the nail

INSTRUMENTS

Outrigger
- Attaches to selected outrigger slider to form an outrigger construct
- Right and Left

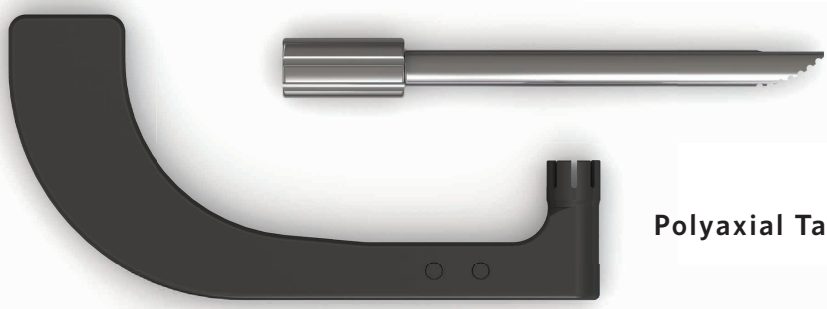
Outrigger Slider
- Size is color matched to Phantom Nail
- Right and Left



Thumb Screw
- Inserts into the outrigger and attaches to the Phantom Nail

Sphere Wire

Nail Positioning Guide



Polyaxial Targeting Guide - Sleeve Insert

Polyaxial Targeting Guide

Ø2.75mm Drill Depth Gauge

Ø2.75mm Drill-Pin

Nail Depth Gauge

Ø2.3mm K-wire

Ø5.5mm Cannulated Nail Drill

Screw Guide

Drill-Pin Guide

Obturator

INSTRUMENTS

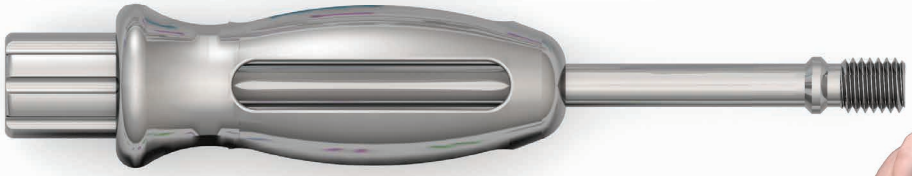
Depth Gauge

Tissue Protector

Torque Indicating Driver

Solid Driver

Locking Guide



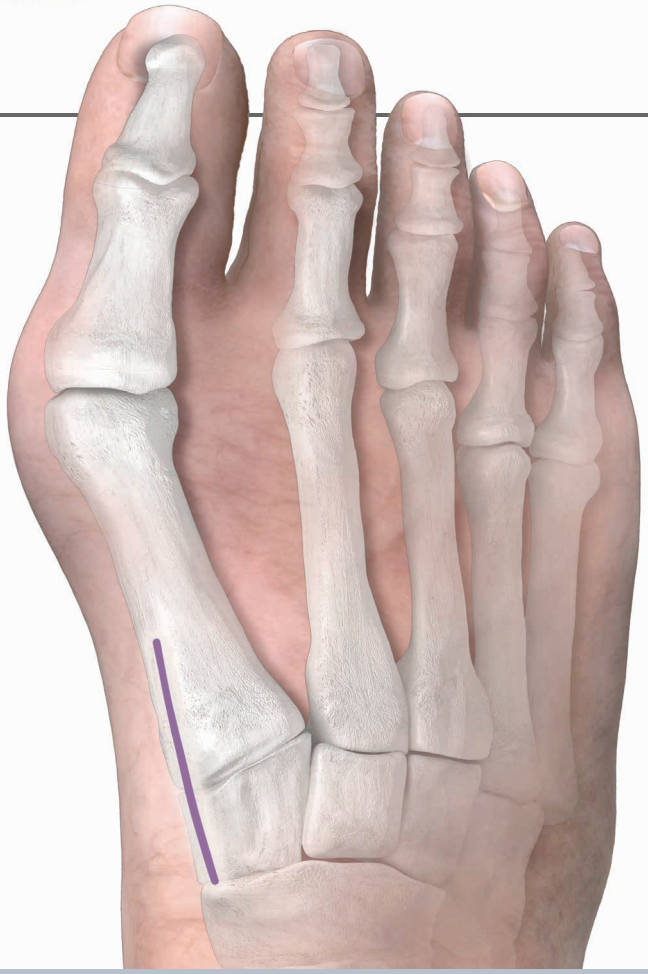
Slaphammer

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.

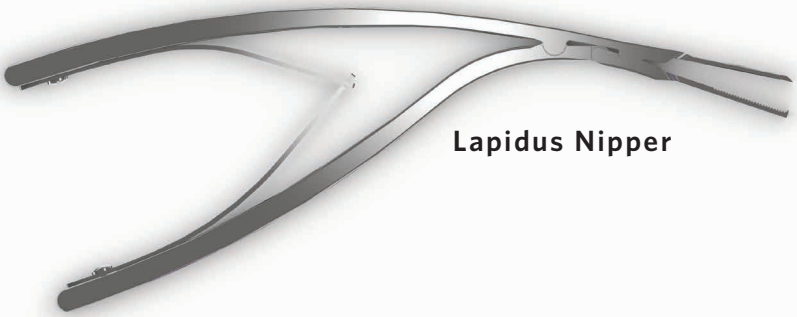
Patient is positioned supine. Intraoperative fluoroscopy is highly recommended.

A medial or dorsomedial incision over the 1st tarsometatarsal joint is recommended. Soft tissue dissection is continued to expose the 1st tarsometatarsal joint (1st TMT joint). Care should be taken to avoid disruption of the tibialis anterior tendon insertion.

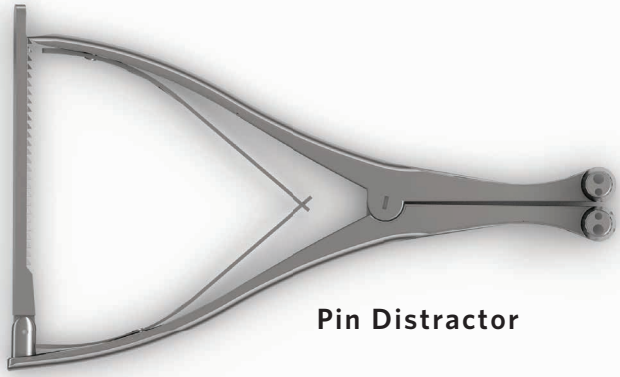


JOINT PREPARATION

After exposure of the joint surfaces at the 1st TMT joint, 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 Distractor

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

Subchondral Perforating Drill

Joint Preparation Chisel

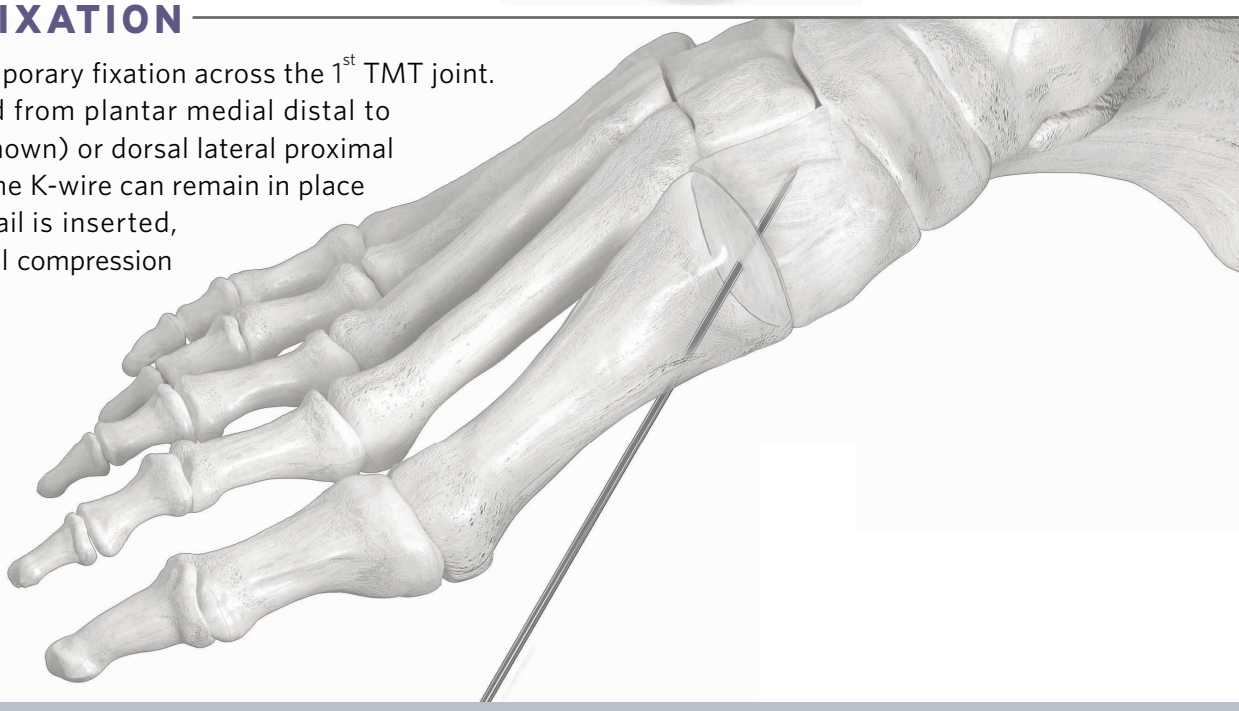
If necessary, bone grafting material can be inserted in the joint at this time.

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 patented bone graft is anatomically shaped to the joint and features biplanar correction to plantarflex and abduct the 1st metatarsal. The Phantom Nail has sizes to accommodate a bone graft in the 1st TMT joint.

Lapidus Wedge
NOTE:
Not available for sale in Canada

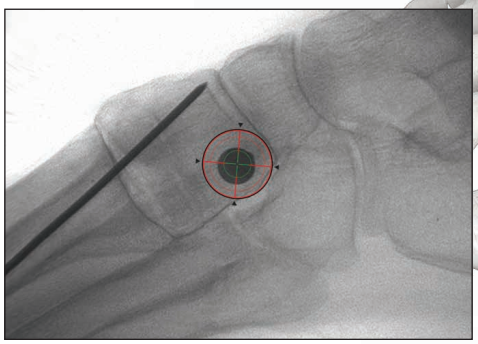
TEMPORARY FIXATION

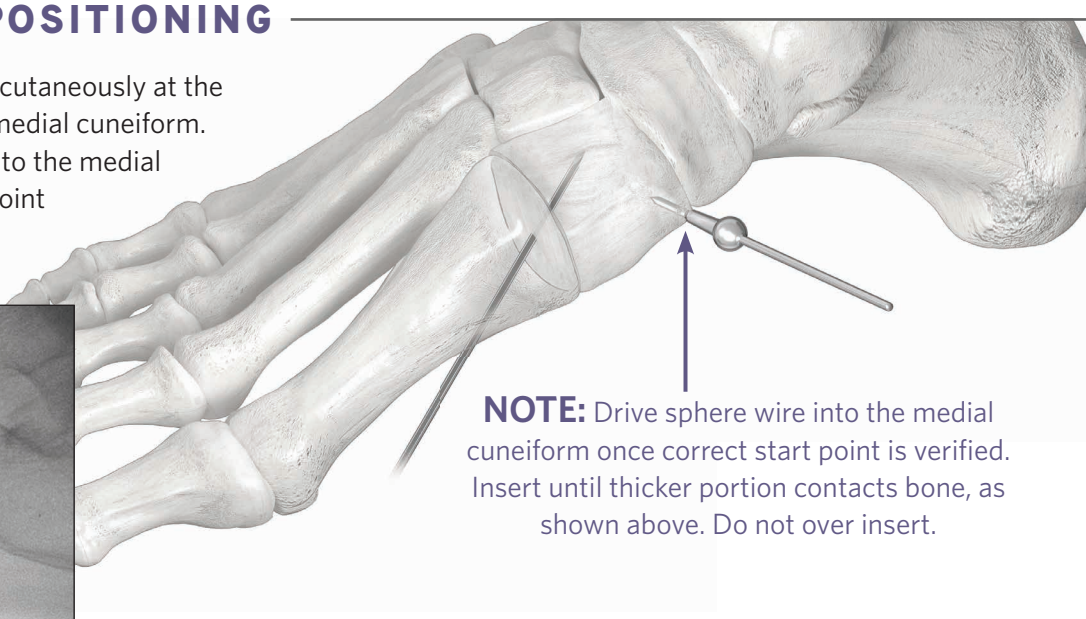
A K-wire is placed for temporary fixation across the 1st TMT joint. The K-wire can be placed from plantar medial distal to dorsal lateral proximal (shown) or dorsal lateral proximal to plantar lateral distal. The K-wire can remain in place until after the Phantom Nail is inserted, but prior to applying final compression across the 1st TMT joint.



NAIL ALIGNMENT & POSITIONING

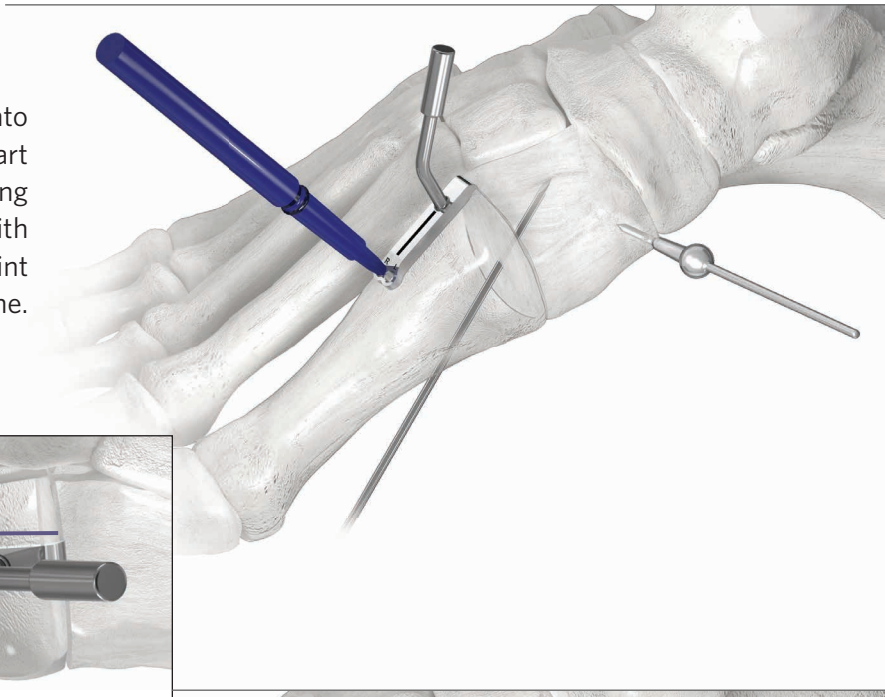
Obtain the sphere wire and place it percutaneously at the proximal plantar medial aspect of the medial cuneiform. Position the sphere wire perpendicular to the medial cuneiform. Confirm sphere wire start point under fluoroscopy using a lateral and dorsal view.

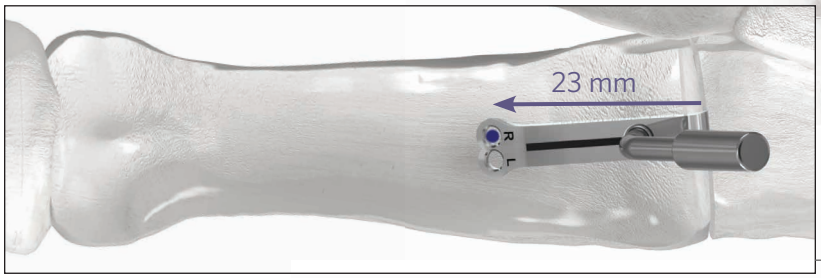




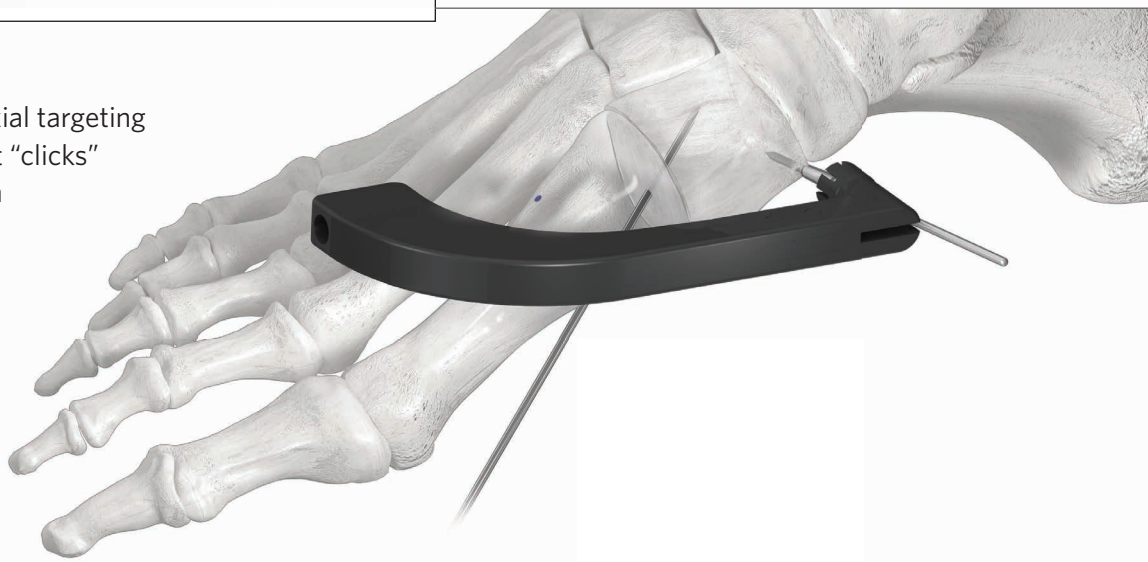
NOTE: Drive sphere wire into the medial cuneiform once correct start point is verified. Insert until thicker portion contacts bone, as shown above. Do not over insert.

Place the hook side of the nail positioning guide into the TMT joint resection site and mark the desired start position for the nail. When aligning the nail positioning guide, the laser marked line should align centrally with the dorsal aspect of the metatarsal to ensure a start point 23 mm distal to the TMT joint, just lateral to the mid-line. A pen mark can be made at this location.



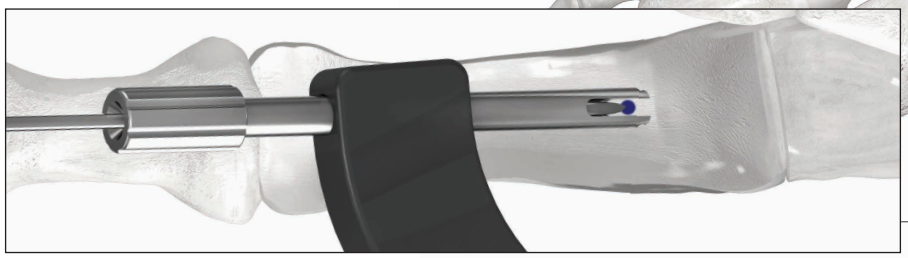


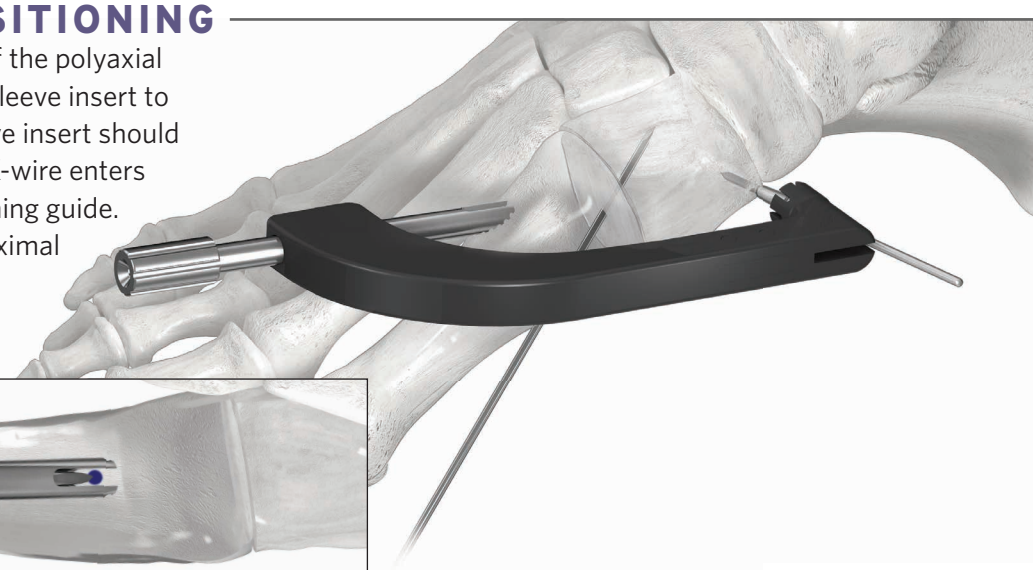
Place the "claw" end of the polyaxial targeting guide on the sphere wire so that it "clicks" into place to allow circular motion on the sphere wire but does not disengage.



NAIL ALIGNMENT & POSITIONING

Insert the sleeve insert into the distal end of the polyaxial targeting guide. Align the trajectory of the sleeve insert to achieve the desired start position. The sleeve insert should be aligned such that the tip of the 2.3 mm K-wire enters the pen mark created using the nail positioning guide. Ensure that the K-wire start point is not proximal to this mark, as this can create a stress riser in the metatarsal.





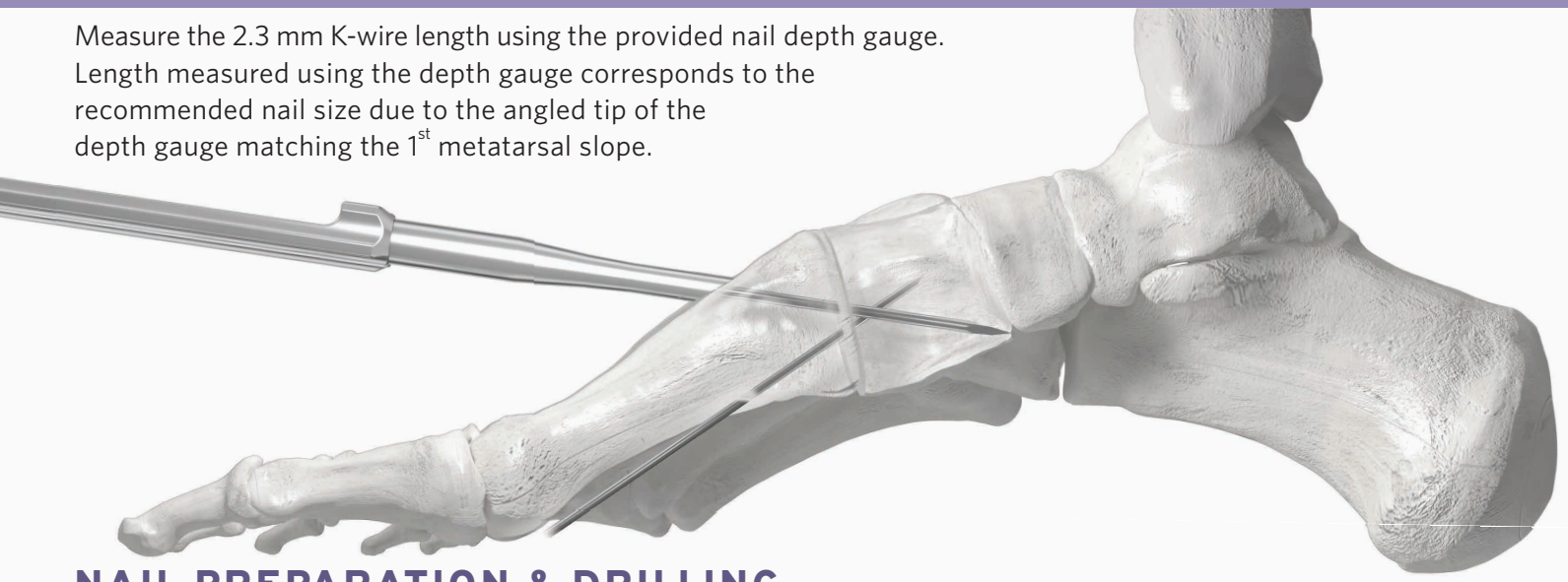
NOTE: Apply downward pressure to the sleeve insert claw guide as the k-wire enters the dorsal cortex of the 1st metatarsal to prevent skiving.

Drive the 2.3 mm K-wire into the sleeve insert until it contacts the sphere wire. If sphere wire is not contacted, check fluoroscopy to ensure that re-pinning is not necessary due to major deflection. Minor deflection may occur due to length of the K-wire.

Confirm K-wire position using fluoroscopy. Slide the sleeve insert off of the 2.3 mm K-wire. Remove the polyaxial targeting guide from the sphere wire and slide off the 2.3 mm K-wire. Remove the sphere wire.

Continue driving the K-wire into the medial cuneiform until the K-wire reaches the cortex, but does not penetrate the cortex.

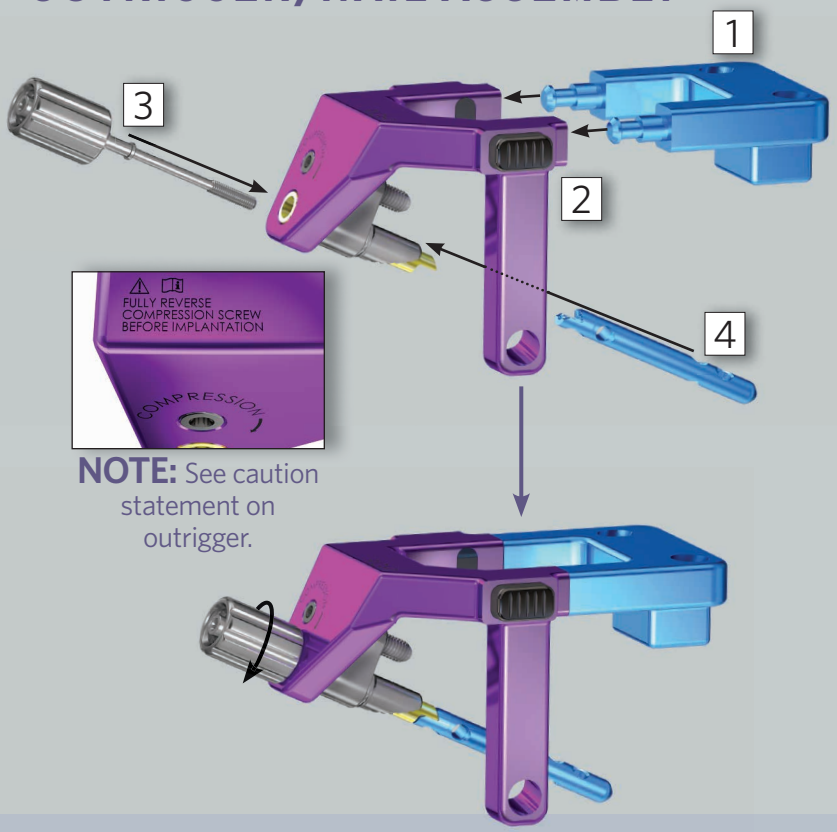
Measure the 2.3 mm K-wire length using the provided nail depth gauge. Length measured using the depth gauge corresponds to the recommended nail size due to the angled tip of the depth gauge matching the 1st metatarsal slope.



NAIL PREPARATION & DRILLING

Drill over the 2.3 mm K-wire using the cannulated nail drill and tissue protector. The tissue protector is designed such that the sloped surface matches the slope of the 1st metatarsal and the handle will point either medial or lateral. Care should be taken not to drill past the far cortex of the medial cuneiform with final drilling being performed under fluoroscopy. Remove the drill and 2.3 mm K-wire.

OUTRIGGER/NAIL ASSEMBLY



NOTE: See caution statement on outrigger.

PERFORM ON BACK TABLE:

1. Obtain the Phantom 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 Phantom 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.

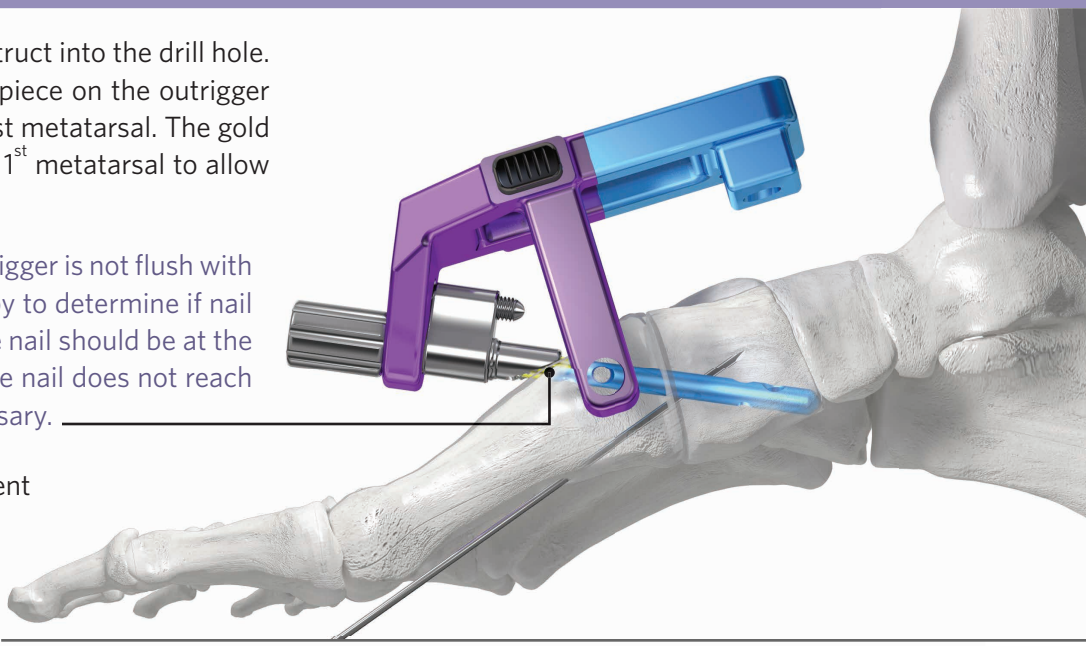
3. Retrieve the thumb screw and insert it into the outrigger.

4. Attach the desired size of the Phantom Nail to the outrigger by turning the thumb screw in a clockwise direction to thread into the inside of the Phantom Nail until two-finger tightness is achieved.

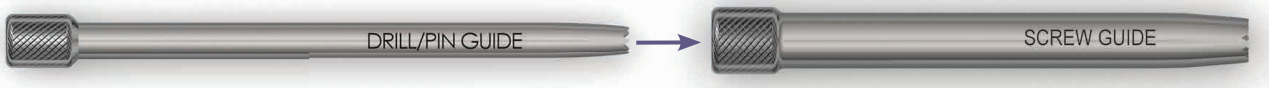
Insert the Phantom Nail/outrigger construct into the drill hole. Continue insertion until the contoured piece on the outrigger is flush with the dorsal aspect of the first metatarsal. The gold portion of the outrigger is buried in the 1st metatarsal to allow for compression.

NOTE: If the contoured piece of the outrigger is not flush with the dorsal 1st metatarsal, use fluoroscopy to determine if nail position is under inserted. The tip of the nail should be at the far cortex of the medial cuneiform. If the nail does not reach this location, additional drilling is necessary.

Confirm Phantom Nail size and placement using fluoroscopy.

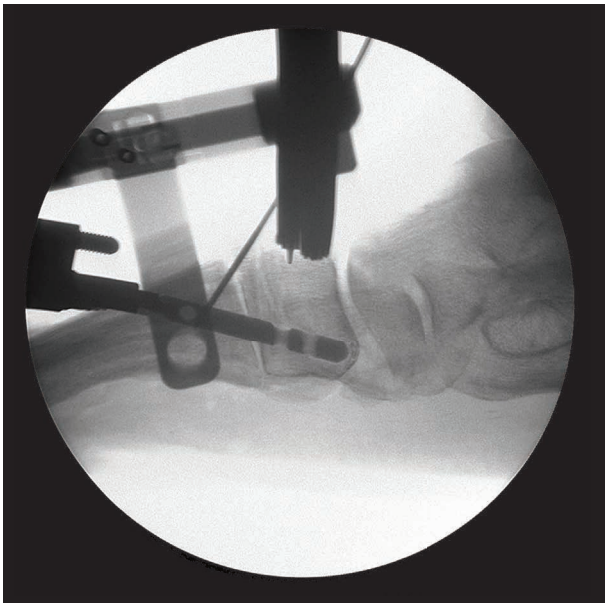


PROXIMAL FIXATION



Assemble two drill-pin guides and screw guides.

Place a screw guide/drill-pin guide assembly into each of the proximal holes in the medial cuneiform.



As an additional sizing check, fluoroscopy can be used to determine appropriate position of the most proximal threaded peg placement by reviewing the screw/drill-pin guide assembly placement. The tip of the proximal guide assembly should be just distal to the N-C joint, but not penetrating it. Sufficient space should be seen between the distal screw/drill-pin guide position and the 1st TMT.

PROXIMAL FIXATION

Insert a 2.75 mm drill-pin bi-cortically into the lateral drill-pin guide first, aligning the guide and drill-pin with the tibial crest. This drill-pin serves as both temporary fixation and drills for a threaded peg.

TIP: A stab incision in the skin may be necessary prior to K-wire insertion when inserted percutaneously. An obturator (shown medially) may be used for blunt dissection.

Using a second 2.75 mm drill-pin, drill bi-cortically through the medial drill-pin guide, retaining the drill-pin in the medial cuneiform.

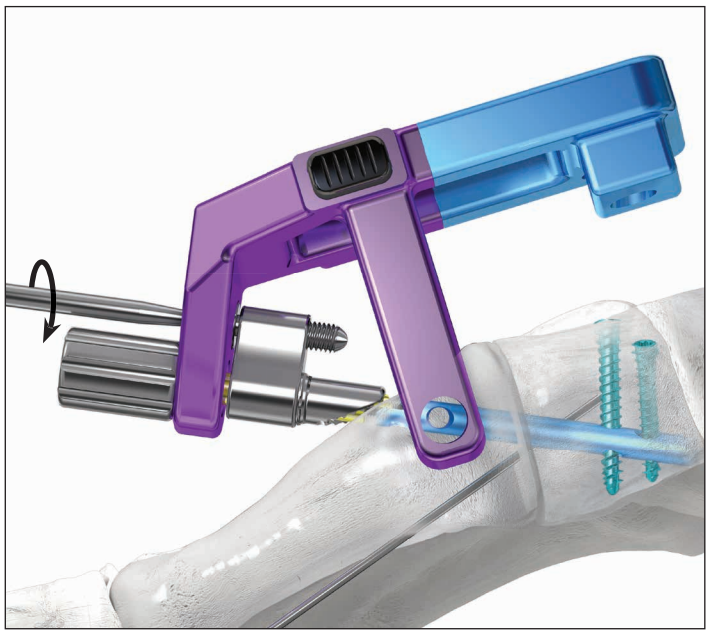
Remove the lateral drill-pin guide. Measure for threaded peg length using the depth gauge through the screw guide. Remove screw guide to measure, if necessary.

NOTE: Alternatively, a cannulated depth gauge can be used over the drill-pin to determine length. Fluoroscopy should be used to ensure that the depth of the drill-pins drills are correct prior to measuring.

Insert the appropriate sized threaded peg through the lateral screw guide into the Phantom Nail using the solid driver. When the laser marking on the driver is at the top of the screw guide, the threaded peg should be fully seated.

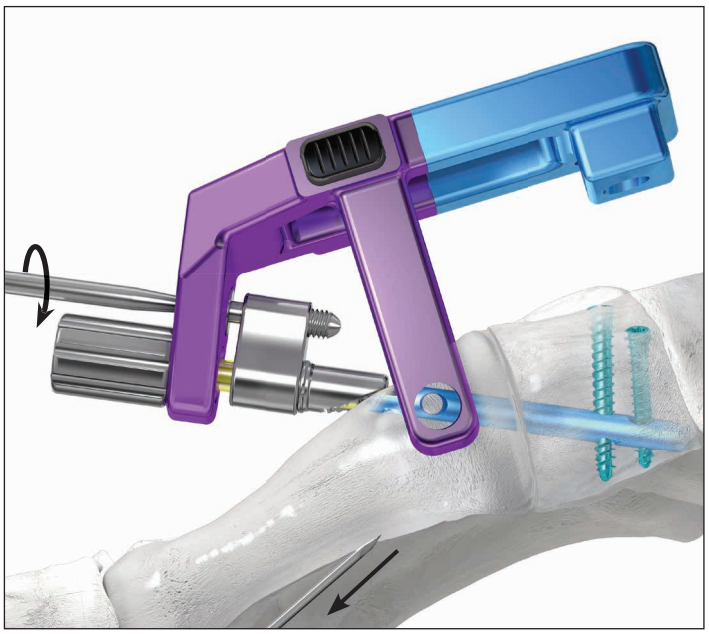
Remove the drill-pin and drill-pin guide from the medial hole in the medial cuneiform. Repeat the steps above for threaded peg insertion and confirm the threaded proximal peg placement on fluoroscopy.

COMPRESSION



Tighten the top screw on the outrigger to create a slight amount of compression.

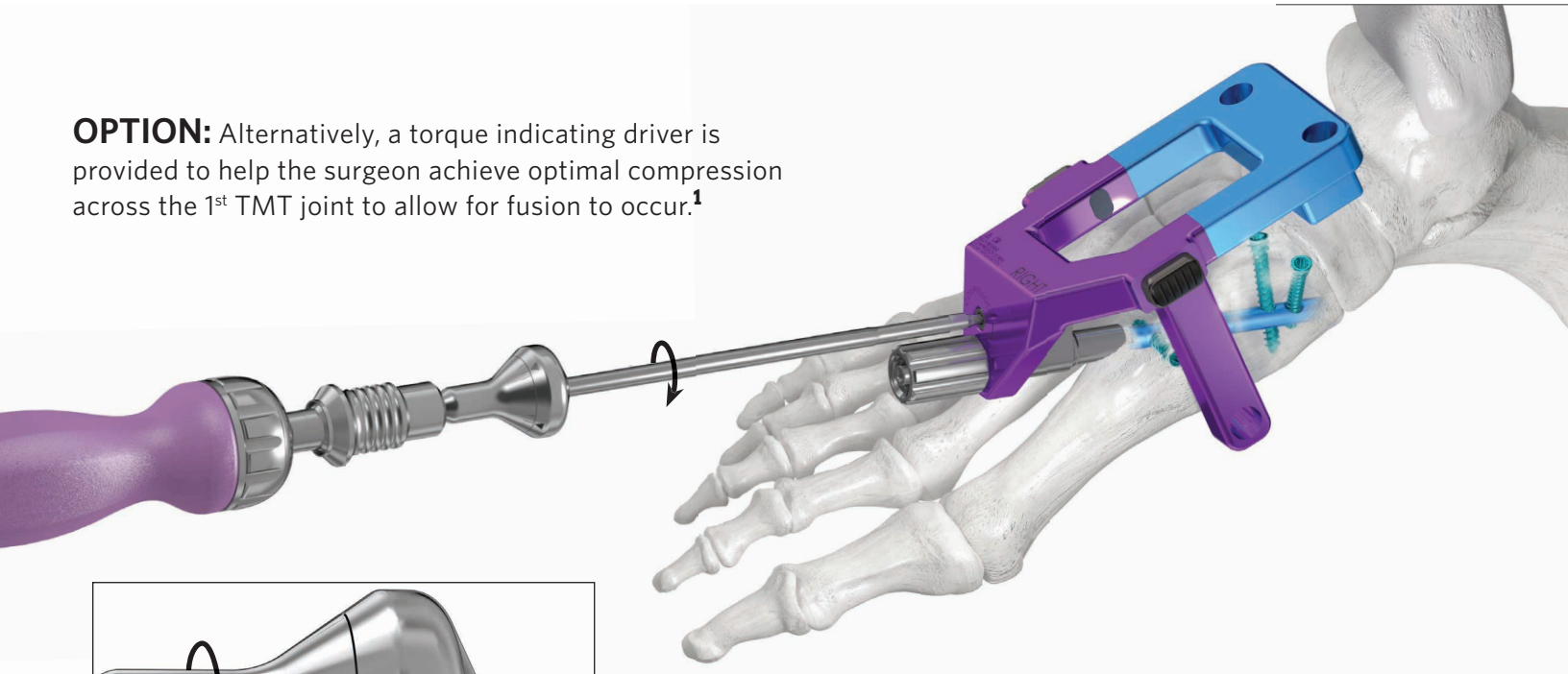
NOTE: The temporary fixation across the joint should be kept in until a slight amount of compression is applied to help prevent rotation of the 1st metatarsal.

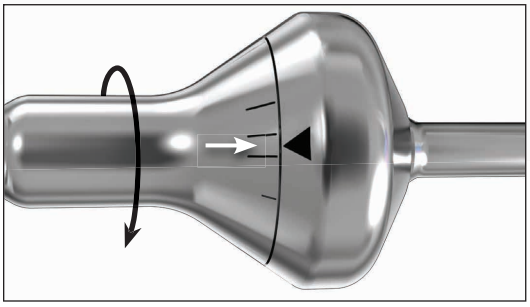


Remove any temporary fixation across the joint. Tighten the top screw on the outrigger to create a slight amount of compression. Continue tightening until two-finger tightness is achieved.

NOTE: Even with use of a PRESERVE™ Lapidus Wedge, two finger tightness should be achieved.

OPTION: Alternatively, a torque indicating driver is provided to help the surgeon achieve optimal compression across the 1st TMT joint to allow for fusion to occur.[1]

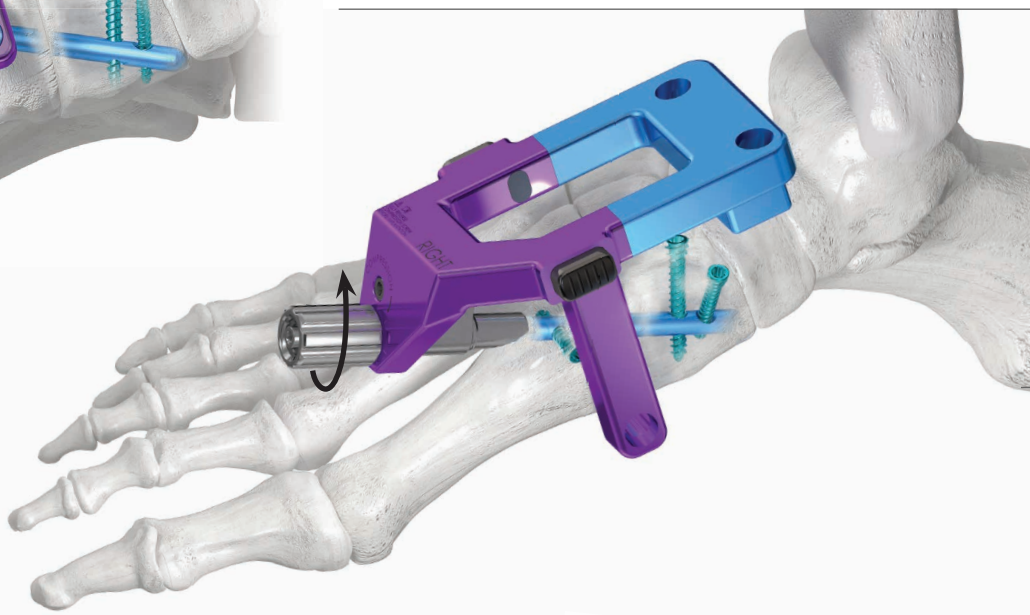




Compressing the outrigger using the torque indicating driver allows the surgeon to read when they are in the correct zone of compression by turning the driver until the triangular indicator is centered between the longer central markings.

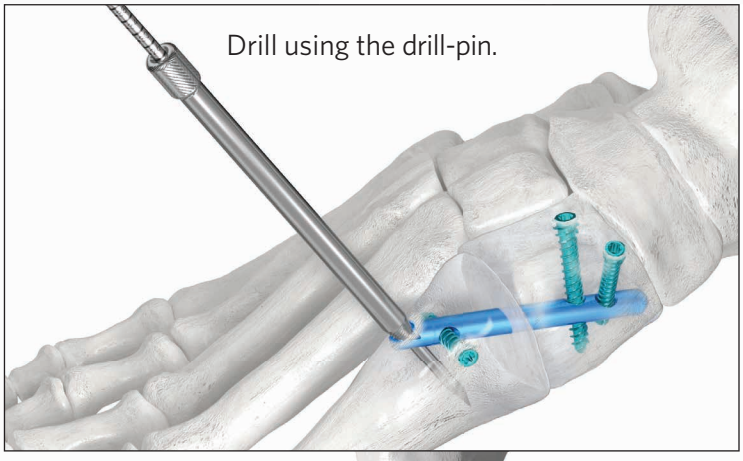
DISTAL FIXATION

Repeat the steps of placing a threaded peg into the final outrigger hole. Confirm placement using fluoroscopy.

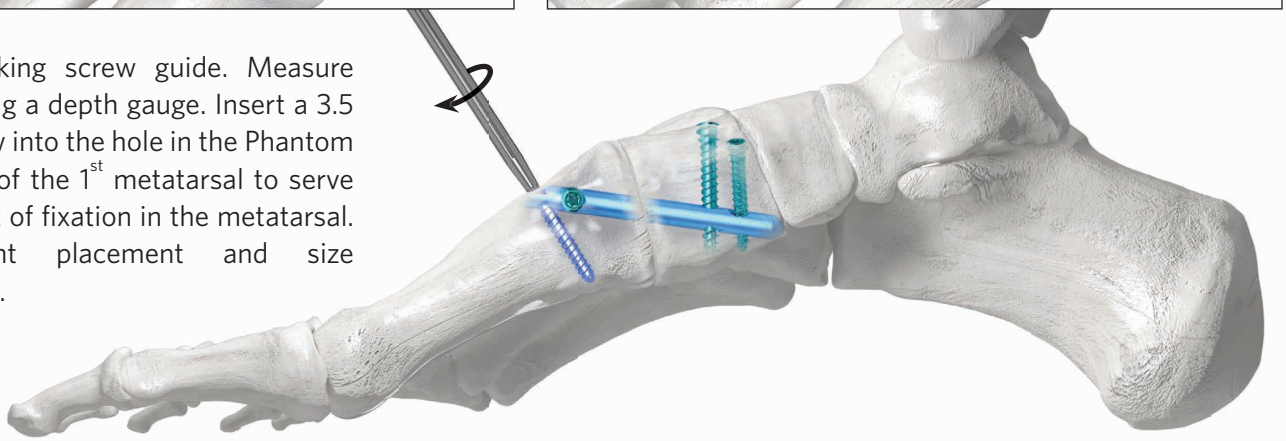


Remove the outrigger from the Phantom Nail by turning the thumb screw on the outrigger counterclockwise until it is released from the Phantom Nail.

Place the locking guide into the distal hole on the Phantom Nail.



Drill using the drill-pin.



Remove the locking screw guide. Measure screw length using a depth gauge. Insert a 3.5 mm locking screw into the hole in the Phantom 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.

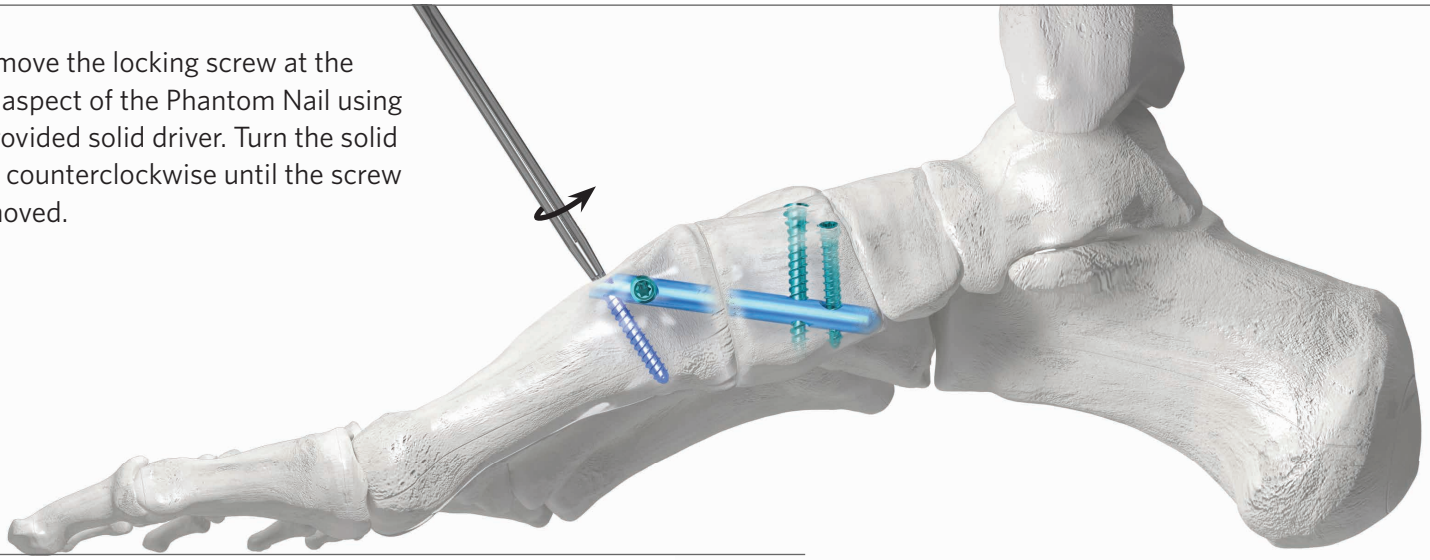
CLOSURE

Proceed to incision closure or concomitant procedures at this time.

REMOVAL/REVISION

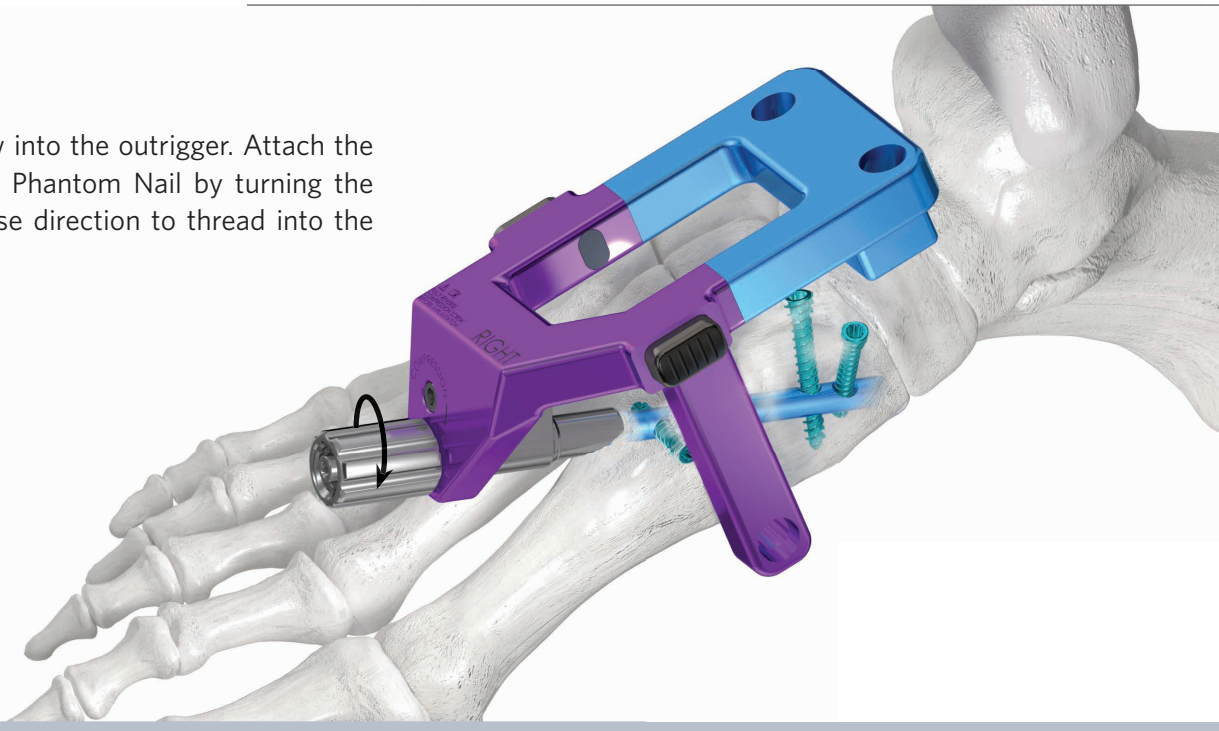
If removal of the Phantom Nail is necessary, the following steps should be followed:

1. Remove the locking screw at the distal aspect of the Phantom Nail using the provided solid driver. Turn the solid driver counterclockwise until the screw is removed.



2. Retrieve the outrigger for the Phantom Nail for the patient side. Retrieve the outrigger slider that corresponds to the color of the implanted Phantom Nail and patient side. If size is unknown and color is unable to be determined, use fluoroscopy to determine Phantom 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.

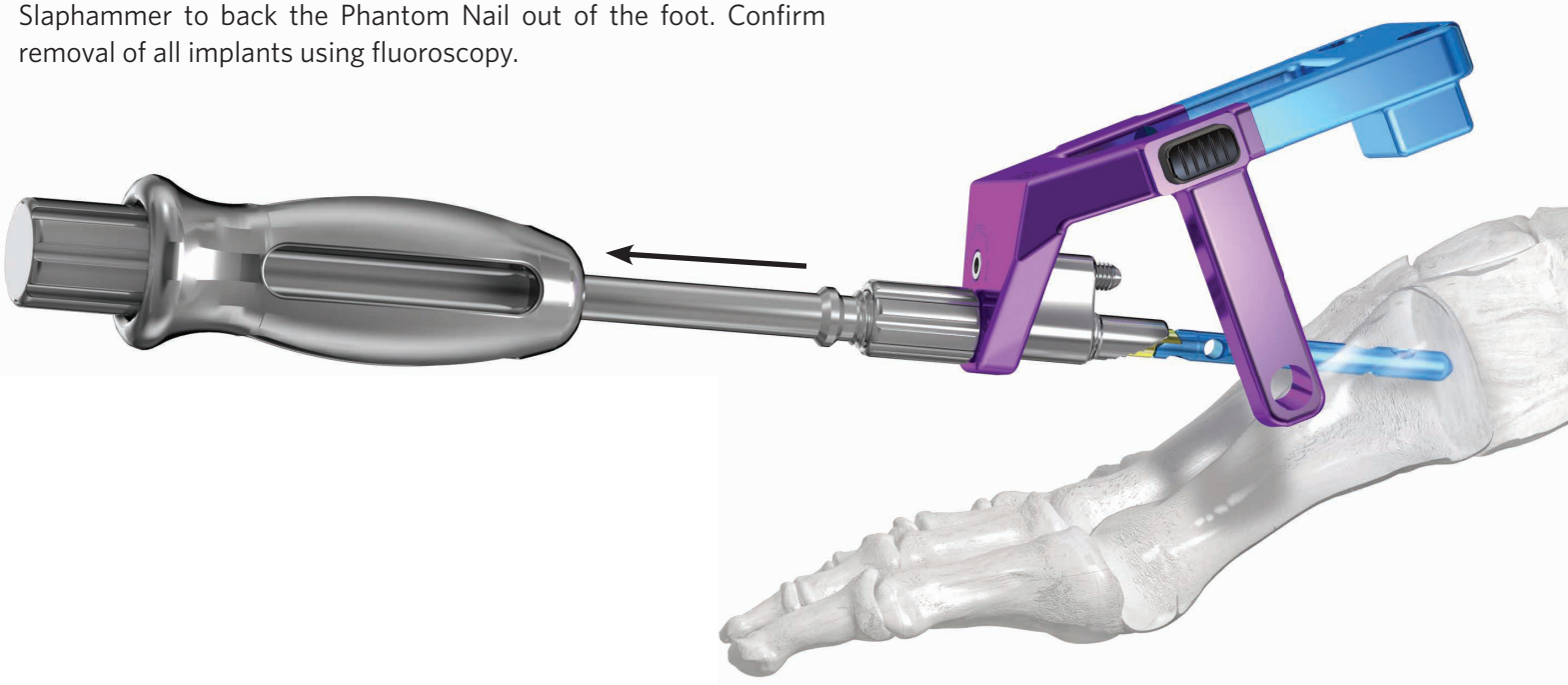
3. Insert the thumb screw into the outrigger. Attach the outrigger construct to the Phantom Nail by turning the thumb screw in a clockwise direction to thread into the inside of the Phantom Nail.



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. Remove the threaded peg. Repeat this for the remaining threaded pegs in the Phantom 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 Phantom Nail out of the foot. Confirm removal of all implants using fluoroscopy.

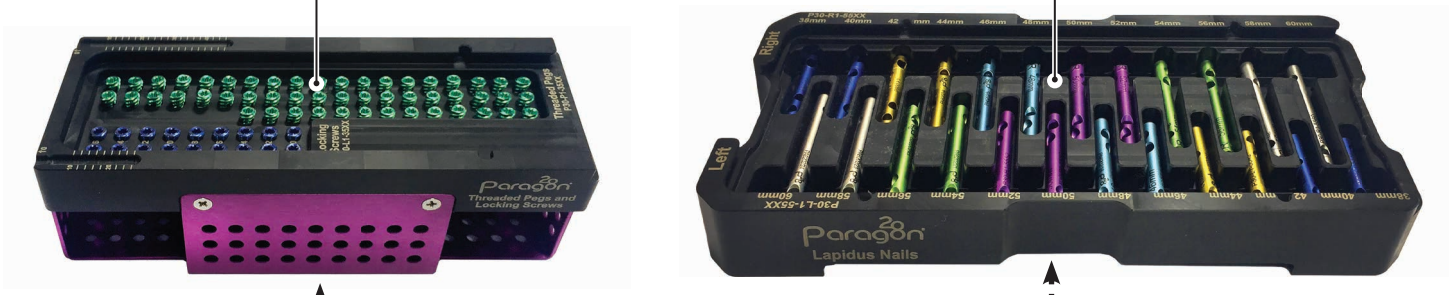


Threaded Peg and Locking Screw Caddy

Threaded Pegs are available in lengths 10–60 mm in 2 mm increments. 3.5 mm Locking Screws range from 10–30 mm in length in 2 mm increments.

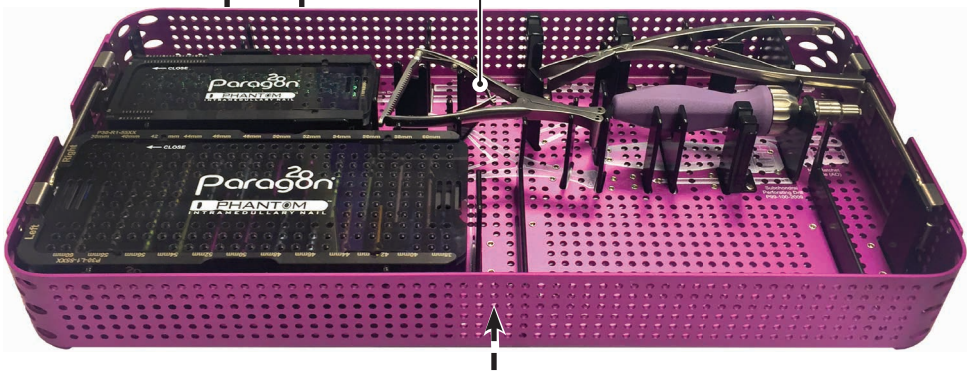
Phantom® Nail Caddy

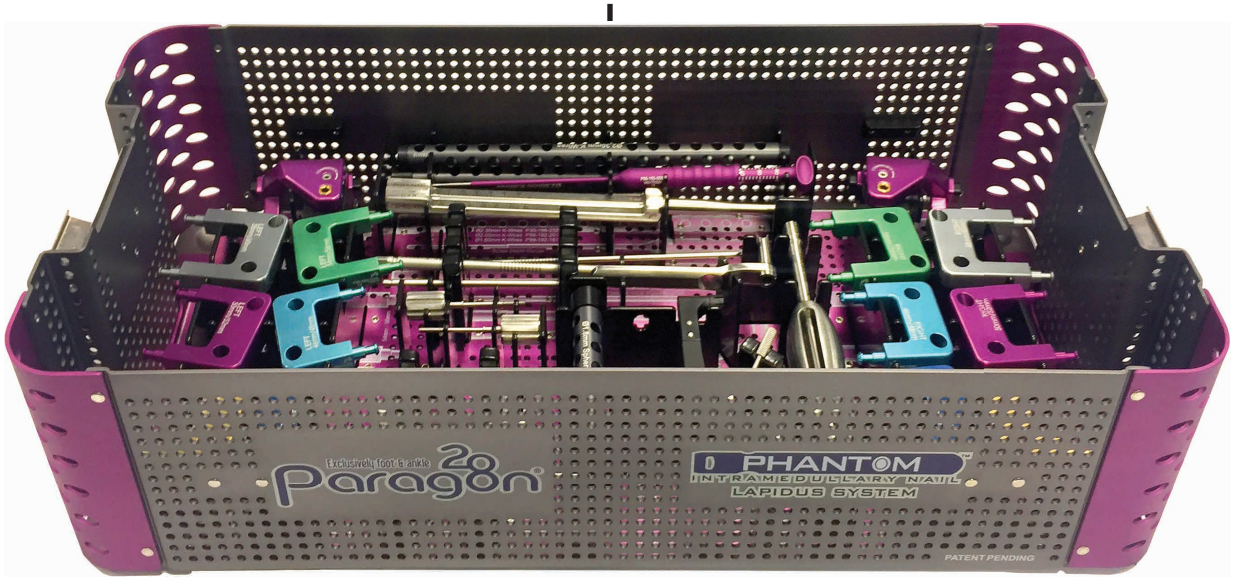
Two Phantom® Nails are available in each size, ranging from 38–60 mm in length by 2 mm increments. All nails are offered in right and left.



Phantom® Nail Tray:

A pin distractor, Lapidus nipper, handle, torque indicating handle, Phantom® Nail caddy and Threaded Peg and Locking Screw caddy are available in the top tray.





Phantom® Nail System Case:

All instrumentation needed to insert a Phantom® Nail is located at the bottom of the case including outriggers, outrigger sliders, K-wires, guides, and depth gauges.

INDICATIONS FOR USE

The Phantom™ Small Bone Intramedullary Nail System is indicated for use in stabilization and fixation of the first tarsometarsal joint for the treatment of 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

MR SAFETY INFORMATION

The Phantom™ System has not been evaluated for MR safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Phantom™ Small Bone Intramedullary System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

PHANTOM®
INTRAMEDULLARY NAIL

PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

Exclusively foot & ankle
Paragon 28®

www.PARAGON28.com

Endnotes:

1 Internal data on file, TR-17060501

P30-STG-2001 RevA

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DISCLAIMER

The purpose of the Phantom® Nail System Surgical Technique Guide is to demonstrate the optionality and functionality of the Phantom® Nail implants and instrumentation. Although variations in placement and use of the 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 Nail can be employed, appropriate for the size of the device.