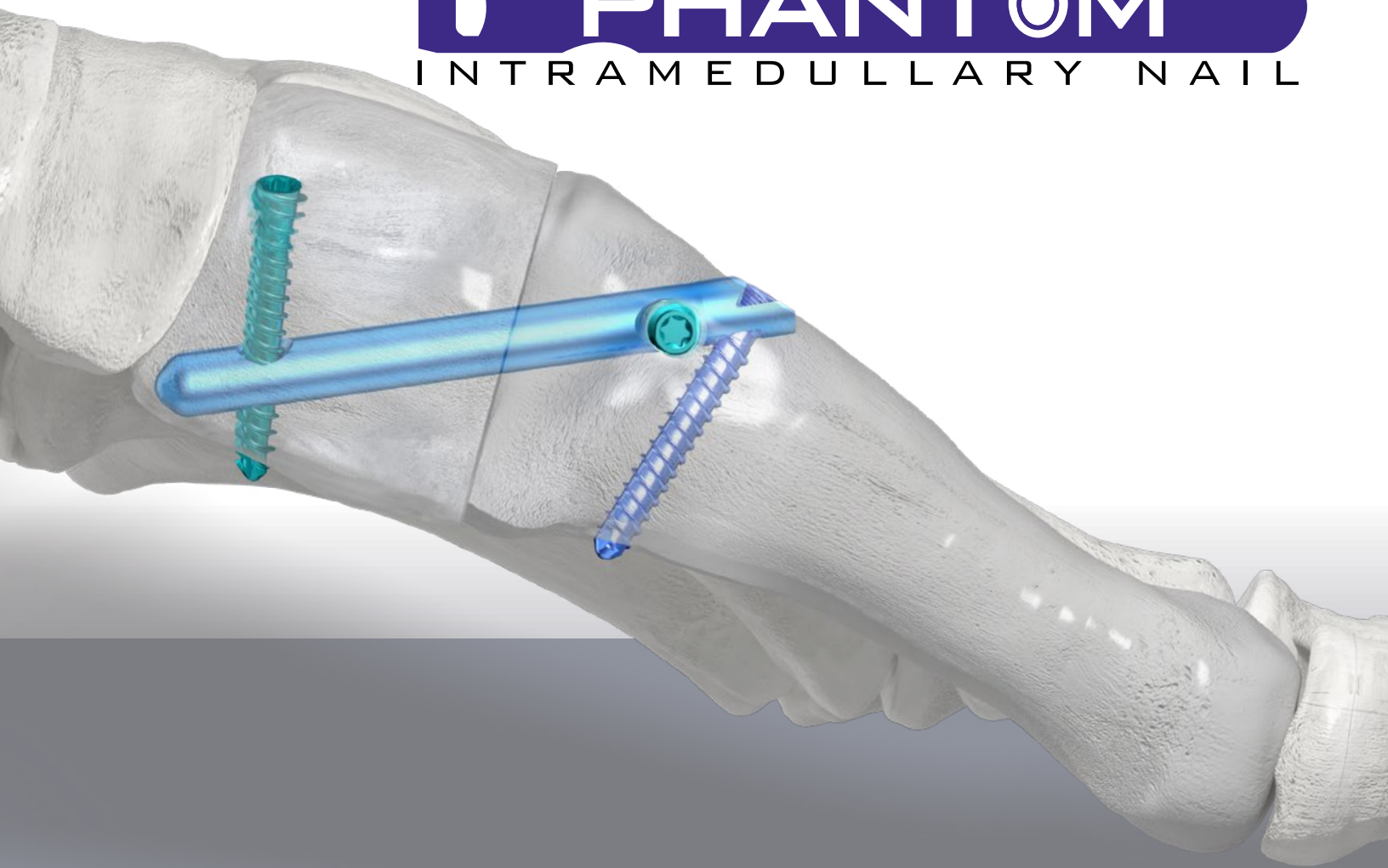


SURGICAL TECHNIQUE GUIDE:

LAPIDUS ARTHRODESIS USING THE PHANTOM® INTRAMEDULLARY NAIL

PHANTOM®
INTRAMEDULLARY NAIL



Exclusively foot & ankle **20**
Paragon®

SURGICAL TECHNIQUE GUIDE:

LAPIDUS ARTHRODESIS USING THE PHANTOM[®] INTRAMEDULLARY NAIL

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[®] Phantom[®] Small Bone 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.

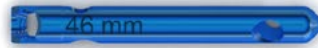
PRODUCT OFFERING

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

- Offered in 3 Hole (shown) and 4 Hole configurations



38 mm



46 mm



54 mm



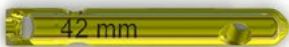
40 mm



48 mm



56 mm



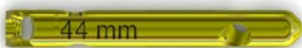
42 mm



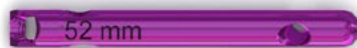
50 mm



58 mm



44 mm

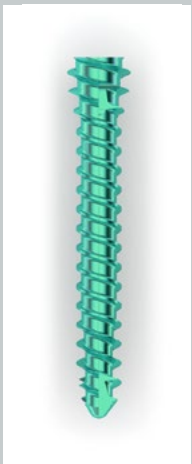


52 mm



60 mm

Phantom[®] Nail Threaded Pegs



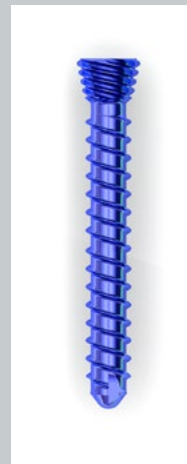
Size: 3.5 mm diameter

Length: 10-46 mm lengths,
2 mm increments

Color: Teal

- Two per 3 Hole Phantom[®] Nail
- Three per 4 Hole Phantom[®] Nail
- Inserted through the outrigger construct into the medial cuneiform and 1st metatarsal holes of the Phantom[®] Nail

Phantom[®] Nail Locking Screws



Size: 3.5 mm diameter

Length: 10-26 mm lengths,
2 mm increments

Color: Dark Blue

- One per Phantom[®] Nail
- Inserted at the most distal hole of the Phantom[®] Nail

SURGICAL TECHNIQUE GUIDE:

LAPIDUS ARTHRODESIS USING THE PHANTOM INTRAMEDULLARY 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

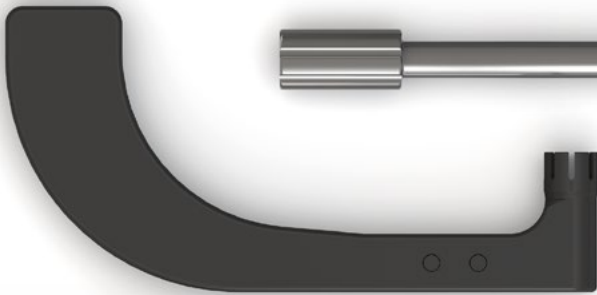
- Inserts into the outrigger and attaches to the Phantom Nail



Sphere Wire



Nail Positioning Guide



Polyaxial Targeting Guide



Polyaxial Targeting Guide - Sleeve Insert



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

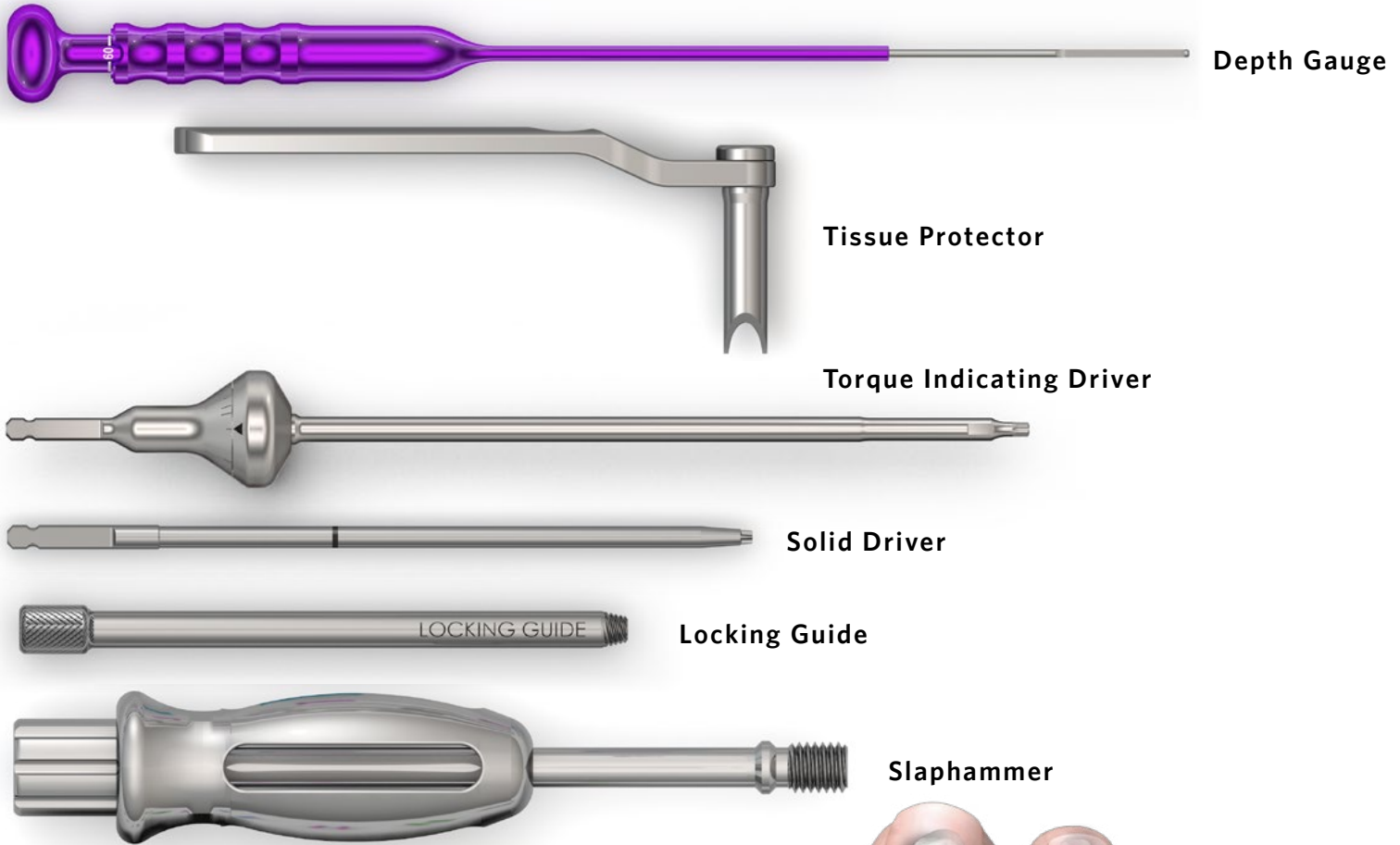


Obturator

SURGICAL TECHNIQUE GUIDE:

LAPIDUS ARTHRODESIS USING THE PHANTOM INTRAMEDULLARY NAIL

INSTRUMENTS



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.

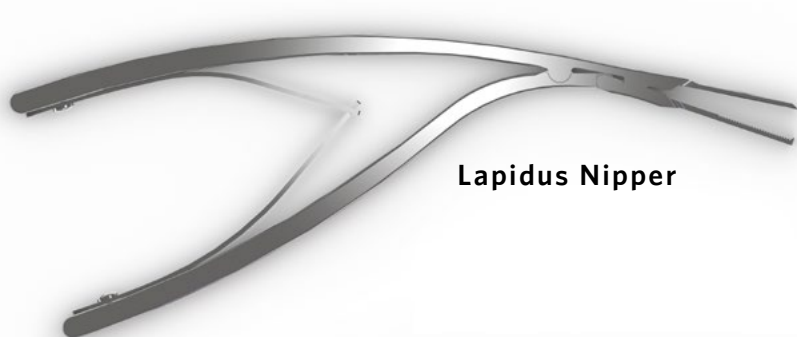


SURGICAL TECHNIQUE GUIDE:

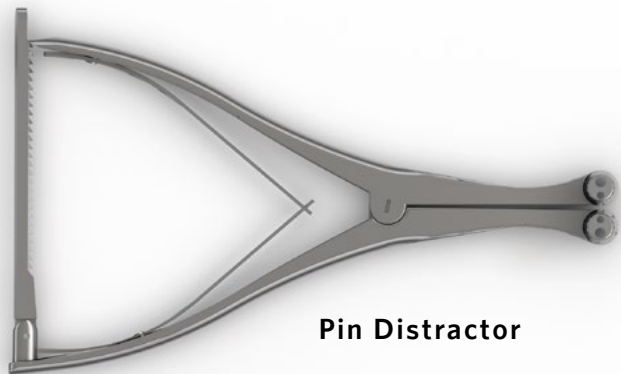
LAPIDUS ARTHRODESIS USING THE PHANTOM INTRAMEDULLARY NAIL

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.

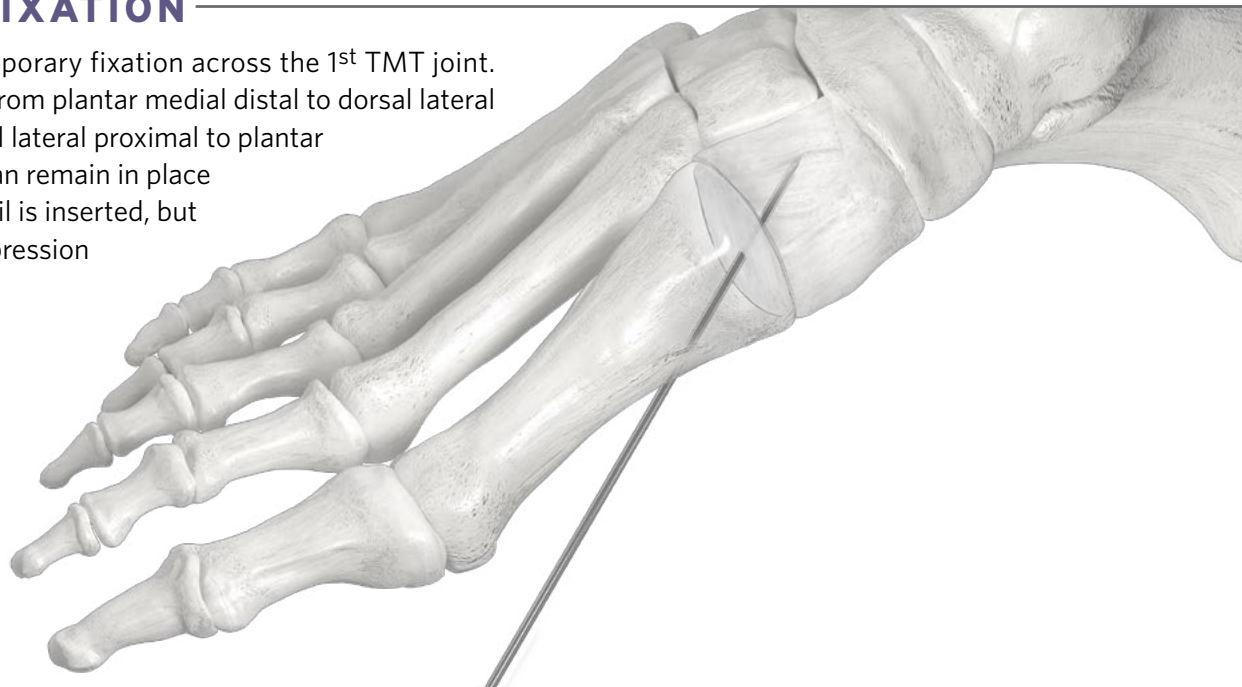
TIP: The PRESERVE™ Lapidus Angular Length Restoring Bone Graft can help restore length for a patient with a short 1st metatarsal, in a case with over-shortening or for revision procedures. This patented bone graft is anatomically shaped to the joint and features biplanar correction to plantarflex and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



Lapidus Graft

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.

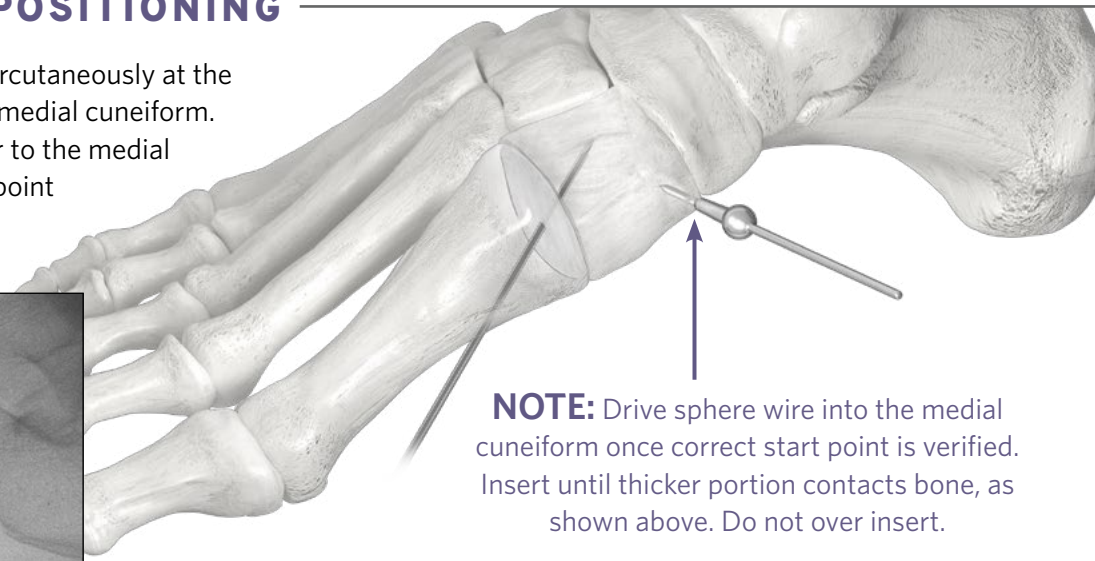
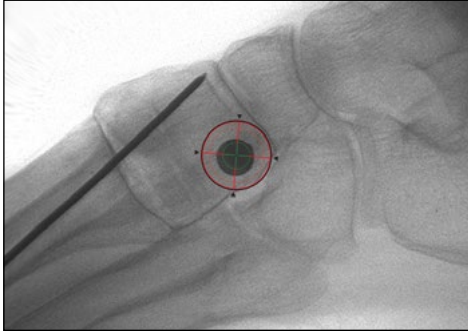


SURGICAL TECHNIQUE GUIDE:

LAPIDUS ARTHRODESIS USING THE PHANTOM INTRAMEDULLARY NAIL

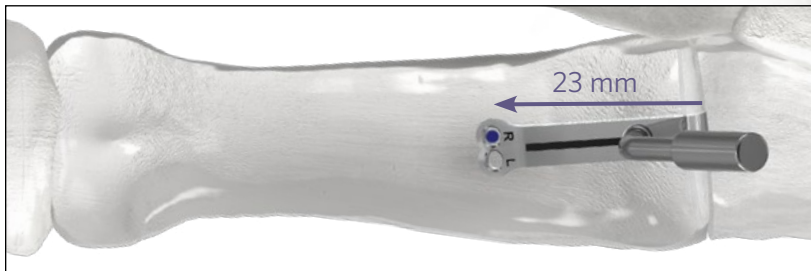
NAIL ALIGNMENT & POSITIONING

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. A pen mark is made at either the "R" or "L" mark for the patient side, allowing for a slightly lateral to midline start point.



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.

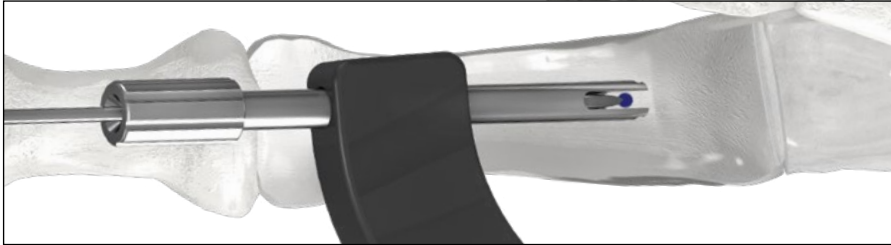


SURGICAL TECHNIQUE GUIDE:

LAPIDUS ARTHRODESIS USING THE PHANTOM INTRAMEDULLARY NAIL

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.



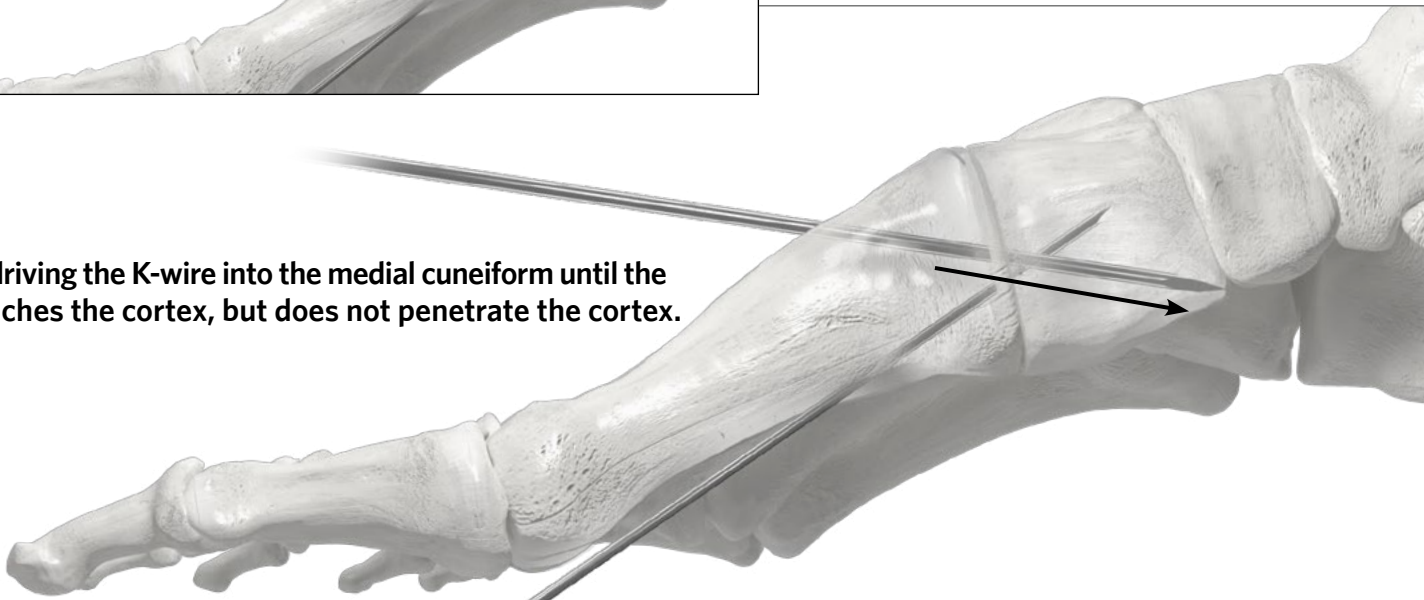
NOTE: Apply downward pressure to the sleeve insert claw guide as the K-wire enters the dorsal cortex of the 1st metatarsal to prevent skiving.

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.



SURGICAL TECHNIQUE GUIDE:

LAPIDUS ARTHRODESIS USING THE PHANTOM INTRAMEDULLARY NAIL

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.

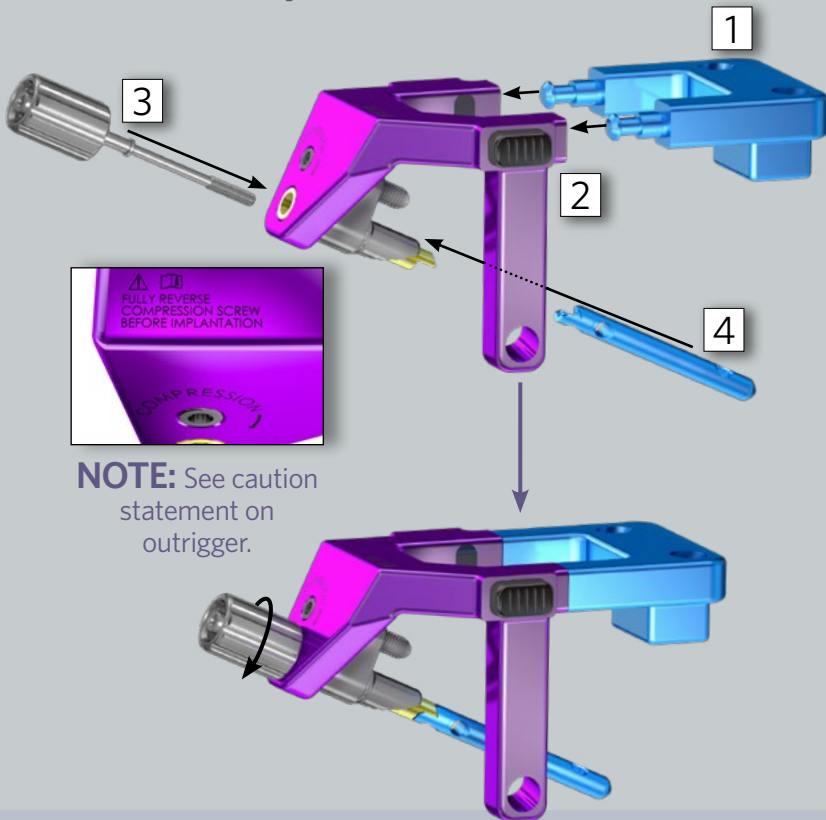


NAIL PREPARATION & DRILLING

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



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.

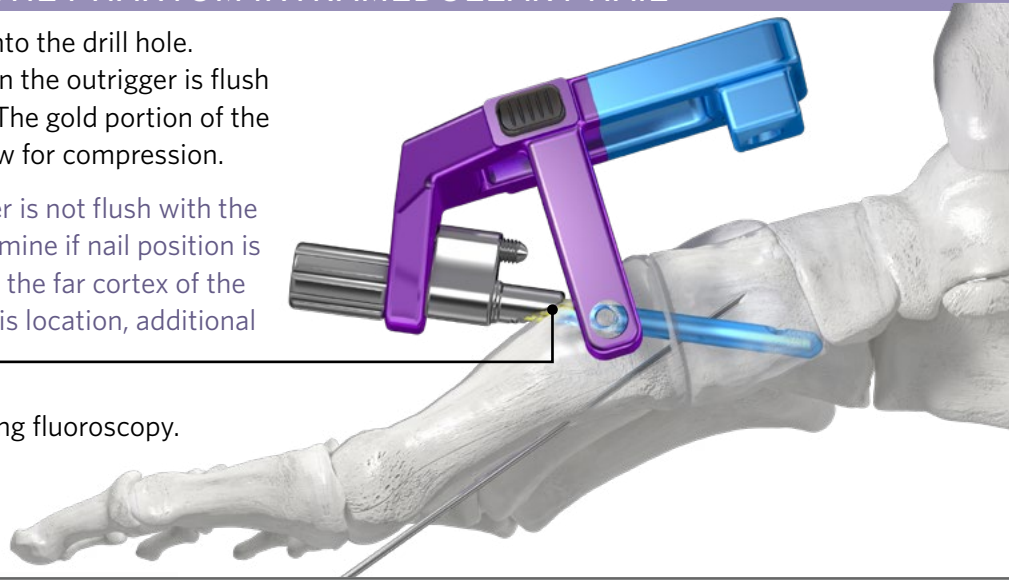
SURGICAL TECHNIQUE GUIDE:

LAPIDUS ARTHRODESIS USING THE PHANTOM INTRAMEDULLARY NAIL

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.

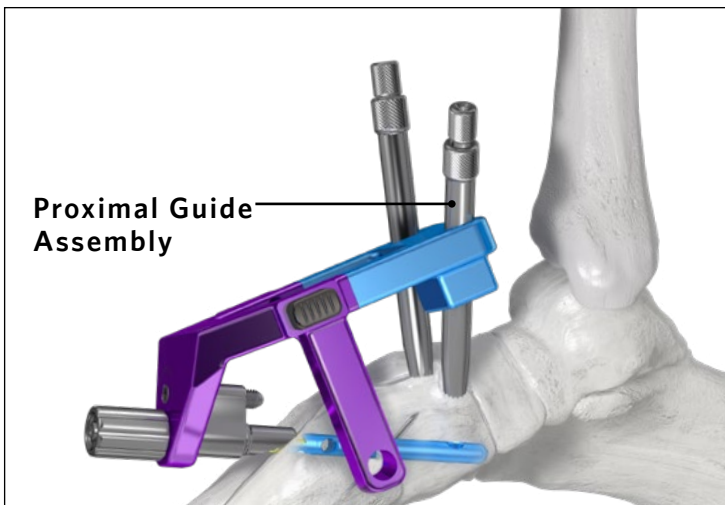
Confirm Phantom Nail size and placement using fluoroscopy.



PROXIMAL FIXATION

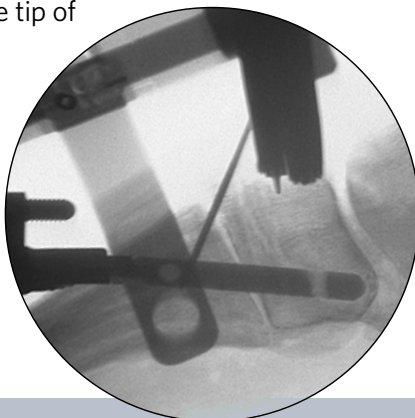


Assemble two drill-pin guides and screw guides.



Place a screw guide/drill-pin guide into each of the holes in the outrigger slider.

As an additional sizing check, fluoroscopy can be used to determine appropriate position of the medial cuneiform 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.



Insert a 2.75 mm drill-pin approximately 5 mm through the cortex into the lateral drill-pin guide, aligning the guide and drill-pin with the tibial crest.

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.

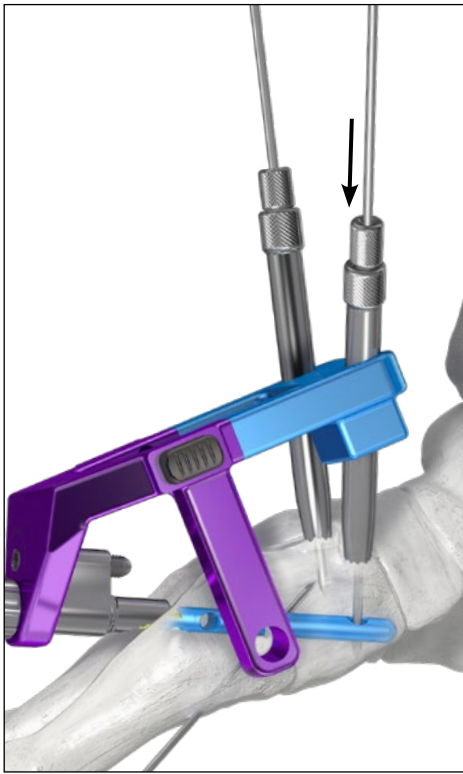
NOTE: 4 HOLE PHANTOM NAIL

If using a 4 Hole Phantom Nail, insert the 2.75 mm drill-pin bicortically in the drill-pin guide.

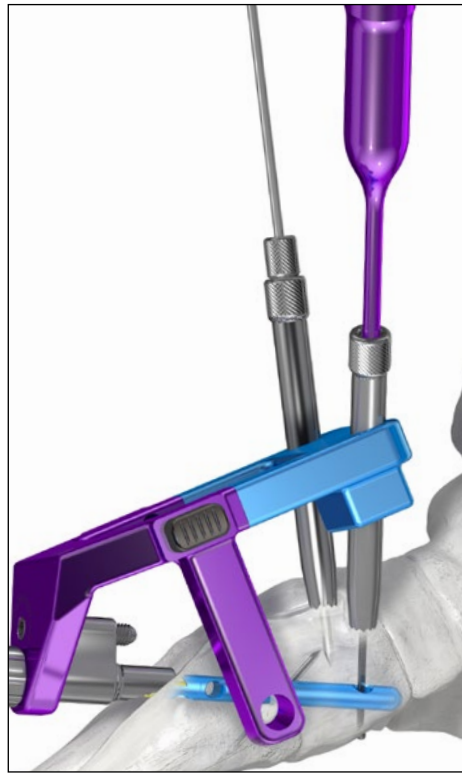
SURGICAL TECHNIQUE GUIDE:

LAPIDUS ARTHRODESIS USING THE PHANTOM INTRAMEDULLARY NAIL

PROXIMAL FIXATION



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 medial drill-pin guide. Measure for threaded peg length using the depth gauge through the screw guide, ensuring correct length for bicortical fixation. 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 medial 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 and bicortically fixed. Remove the drill-pin in the distal lateral hole.

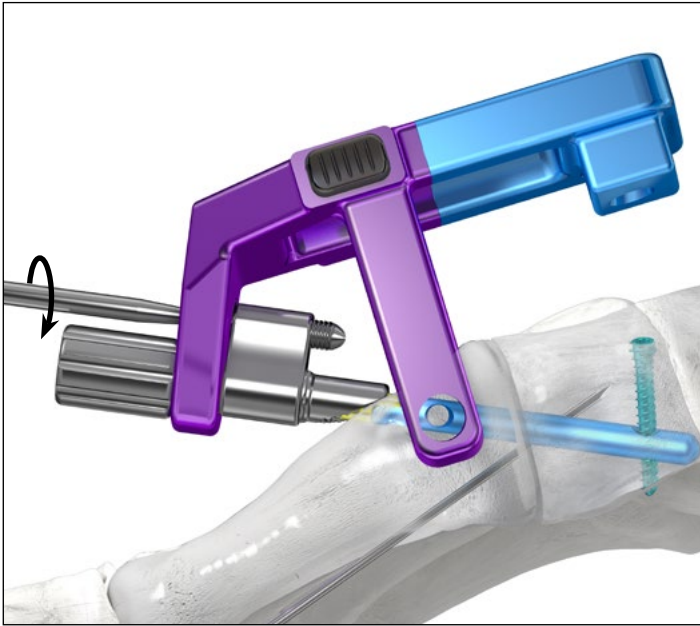


When using a 4 Hole Phantom Nail, remove the drill-pin and drill-pin guide from the lateral hole in the outrigger slider first. Repeat the steps above for threaded peg insertion into the distal lateral hole and confirm bicortical peg placement under fluoroscopy. Repeat the steps as shown above for placement of a threaded peg into the proximal medial hole.

SURGICAL TECHNIQUE GUIDE:

LAPIDUS ARTHRODESIS USING THE PHANTOM INTRAMEDULLARY NAIL

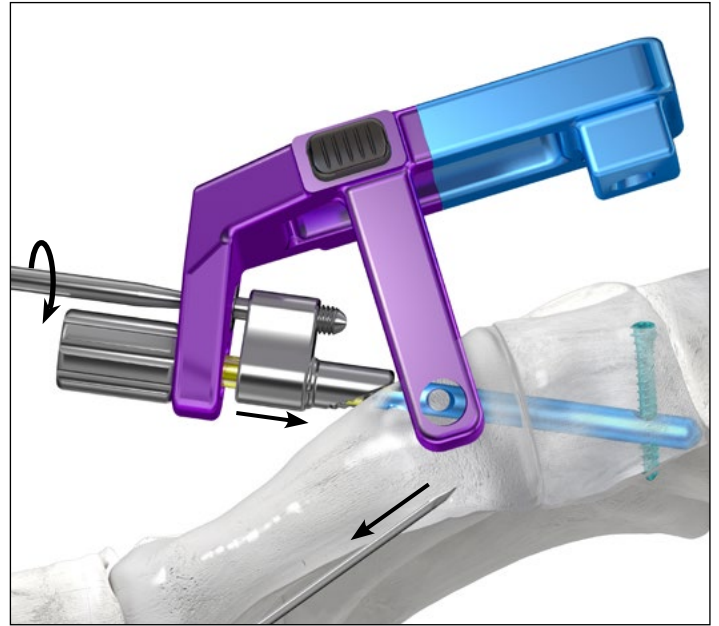
COMPRESSION



Remove the screw guides from the medial and lateral holes in the outrigger slider. Use a driver to tighten the top screw on the outrigger to create a slight amount of compression.

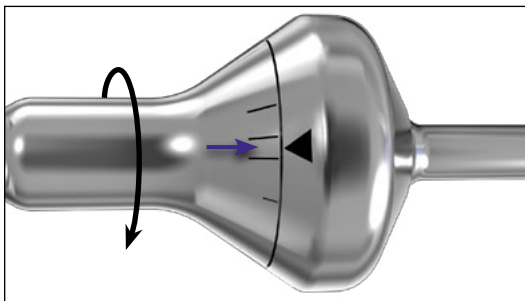
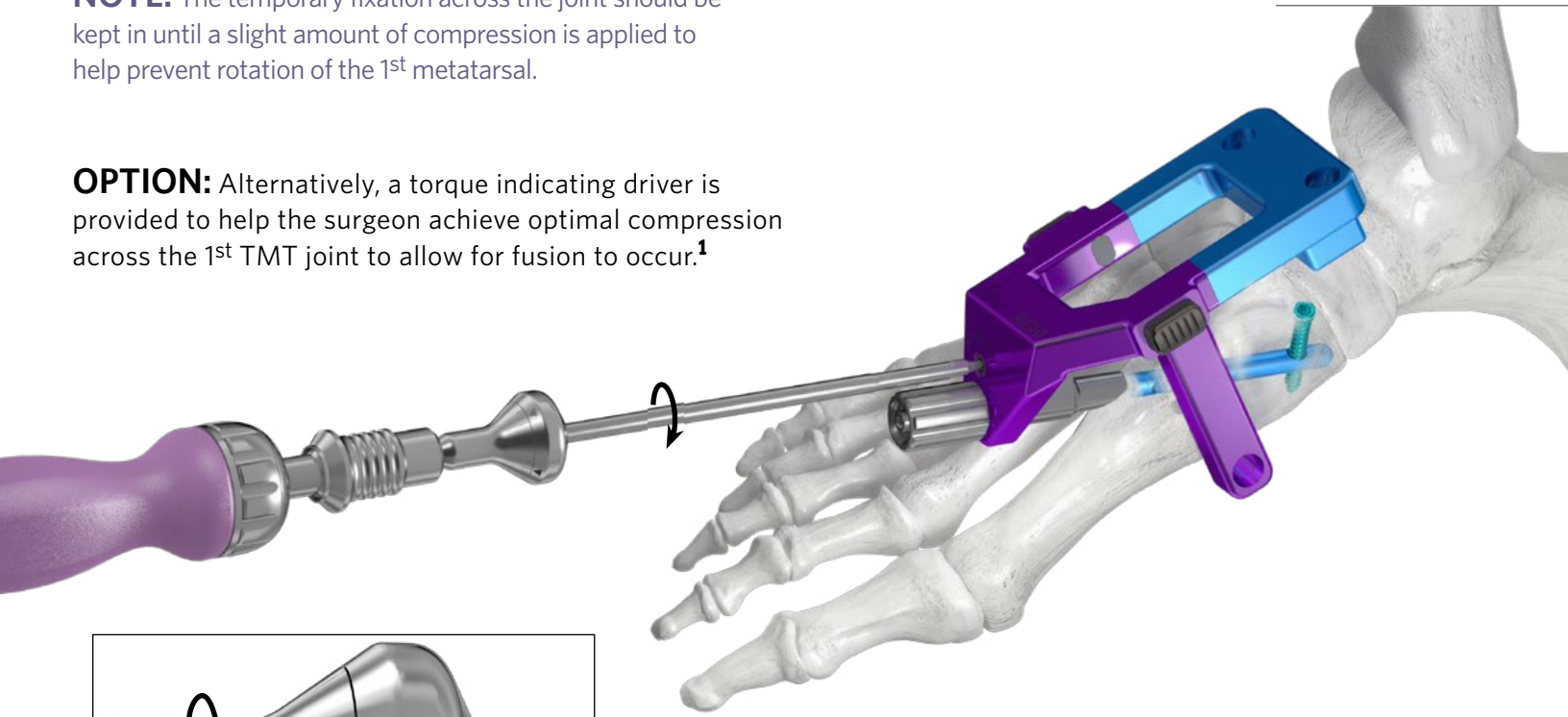
NOTE: The temporary fixation across the joint should be kept in until a slight amount of compression is applied to help prevent rotation of the 1st metatarsal.

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



Remove any temporary fixation across the joint. Continue tightening until two-finger tightness is achieved.

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

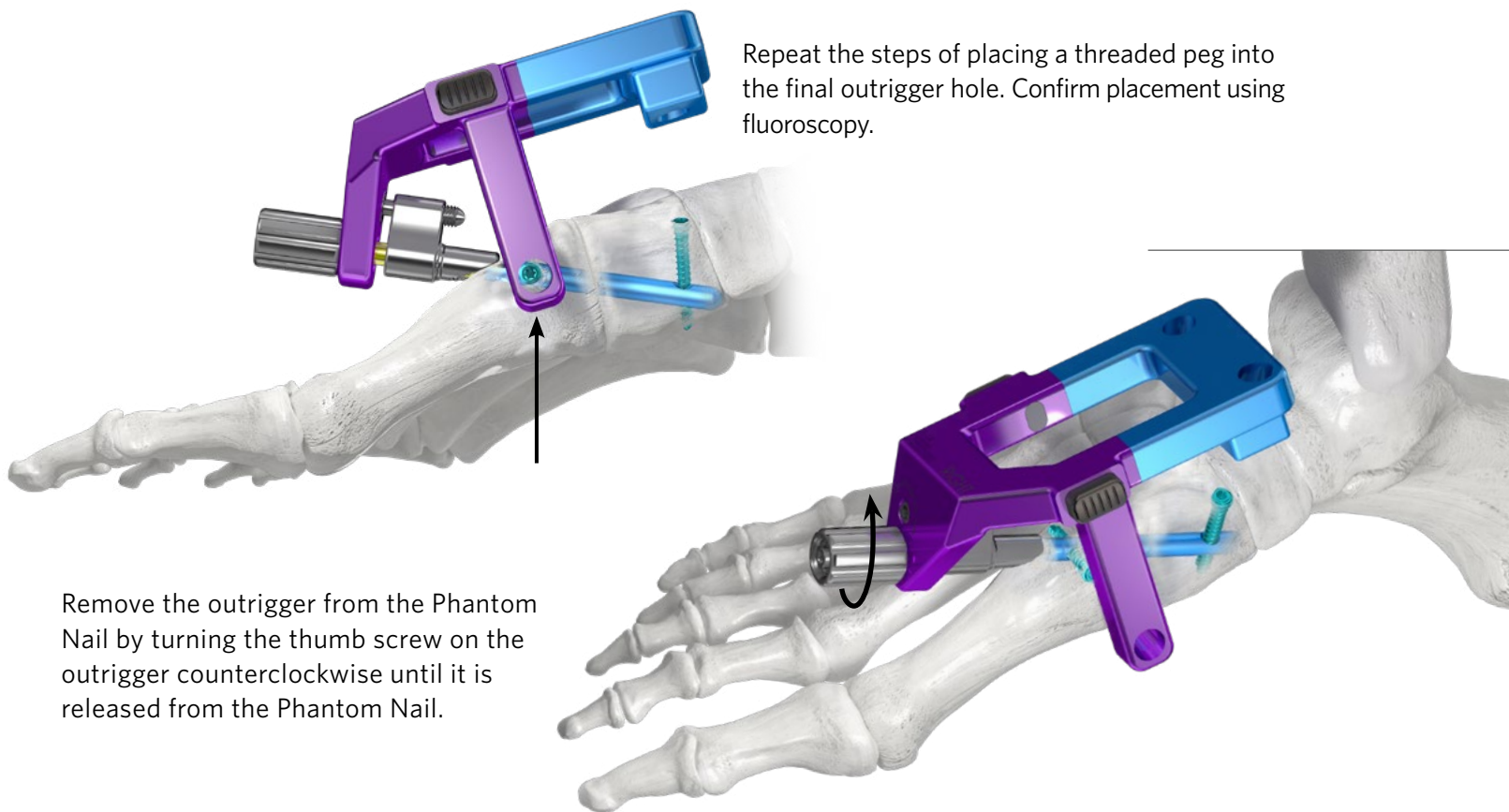


Compressing the outrigger using the torque indicating driver allows the surgeon to read when they are in the correct zone of compression by turning the driver until the triangular indicator is centered between the longer central markings.

SURGICAL TECHNIQUE GUIDE:

LAPIDUS ARTHRODESIS USING THE PHANTOM INTRAMEDULLARY NAIL

DISTAL FIXATION

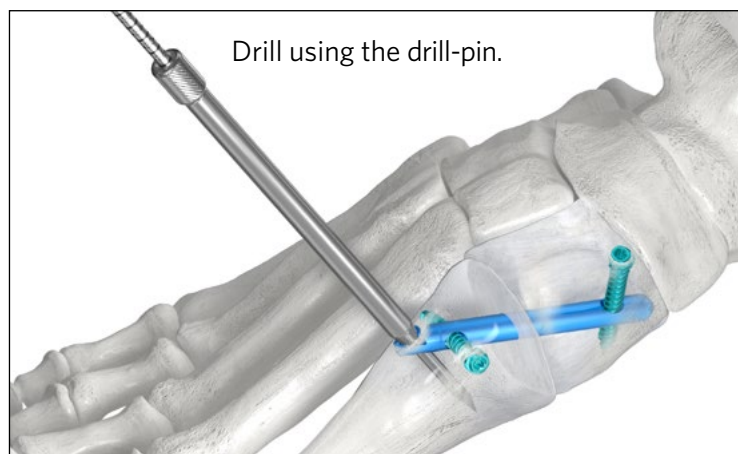


Repeat the steps of placing a threaded peg into the final outrigger hole. Confirm placement using fluoroscopy.

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

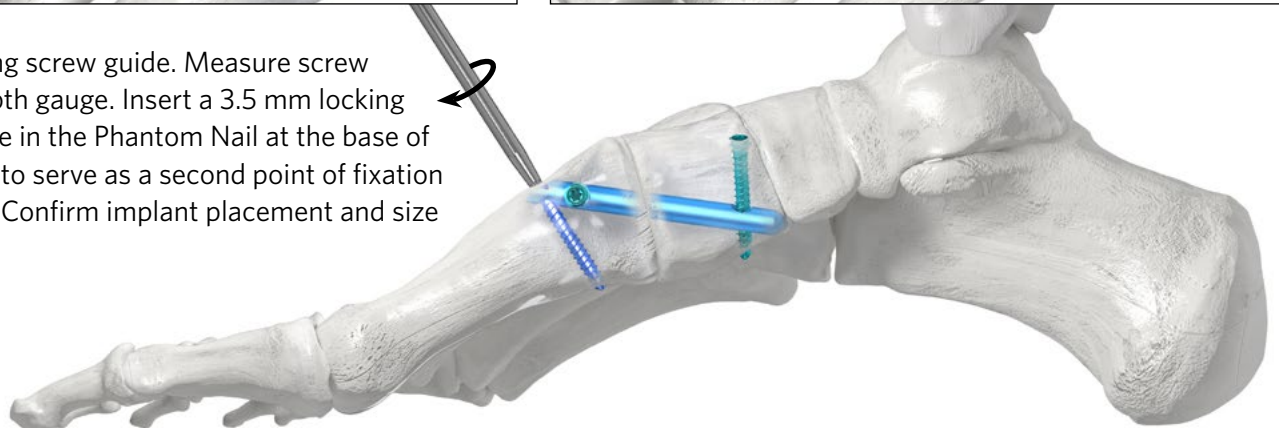


Place the locking guide into the distal hole on the Phantom Nail.



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.

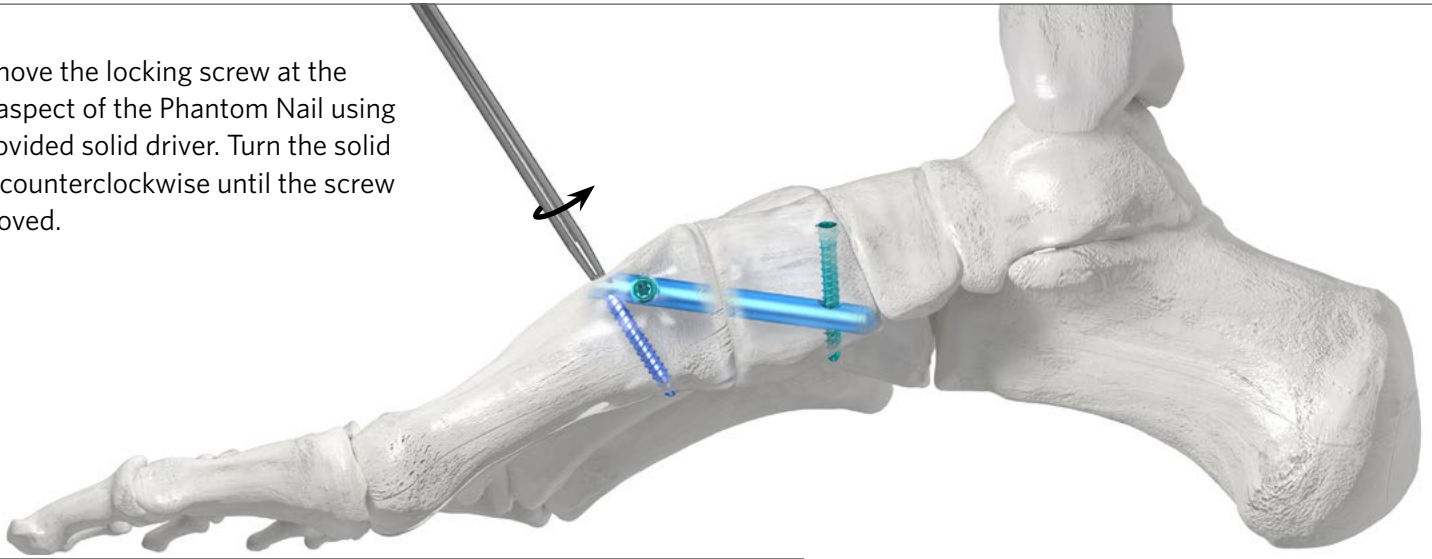
SURGICAL TECHNIQUE GUIDE:

LAPIDUS ARTHRODESIS USING THE PHANTOM INTRAMEDULLARY NAIL

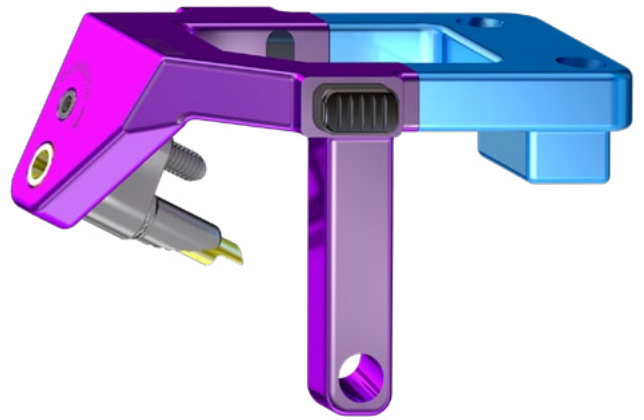
REMOVAL/REVISION

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

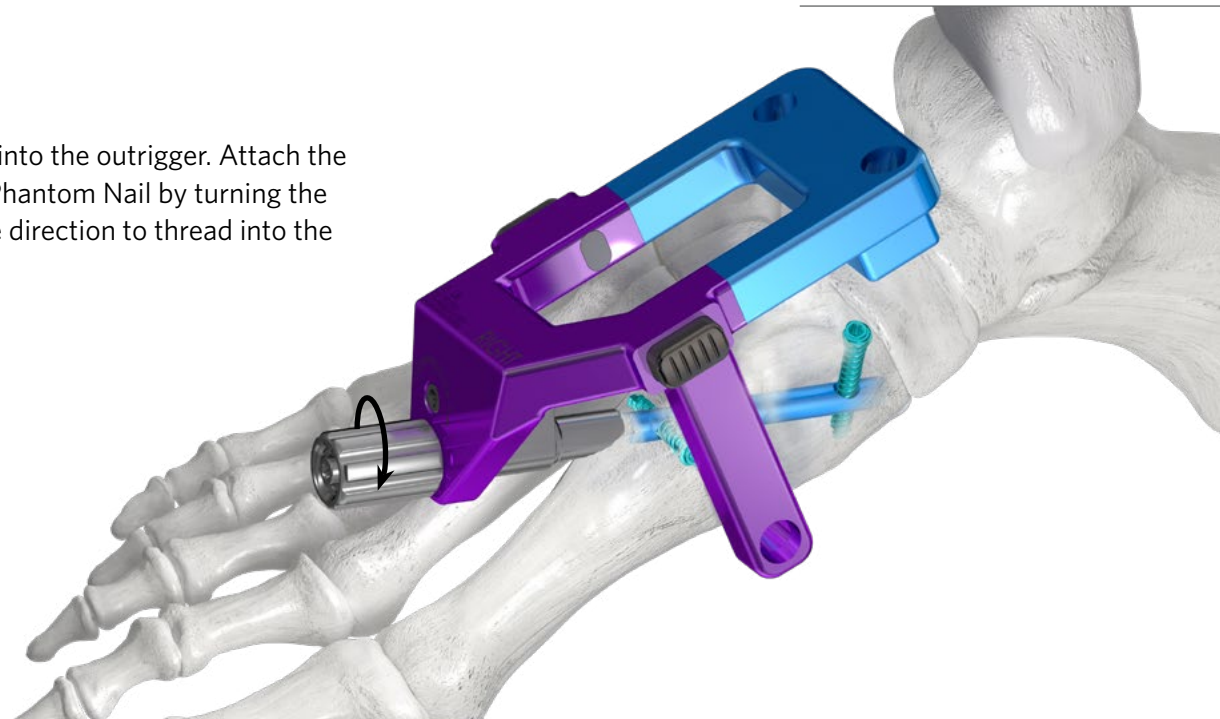
1. Remove the locking screw at the distal aspect of the Phantom Nail using the provided solid driver. Turn the solid driver counterclockwise until the screw is removed.



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.



SURGICAL TECHNIQUE GUIDE:

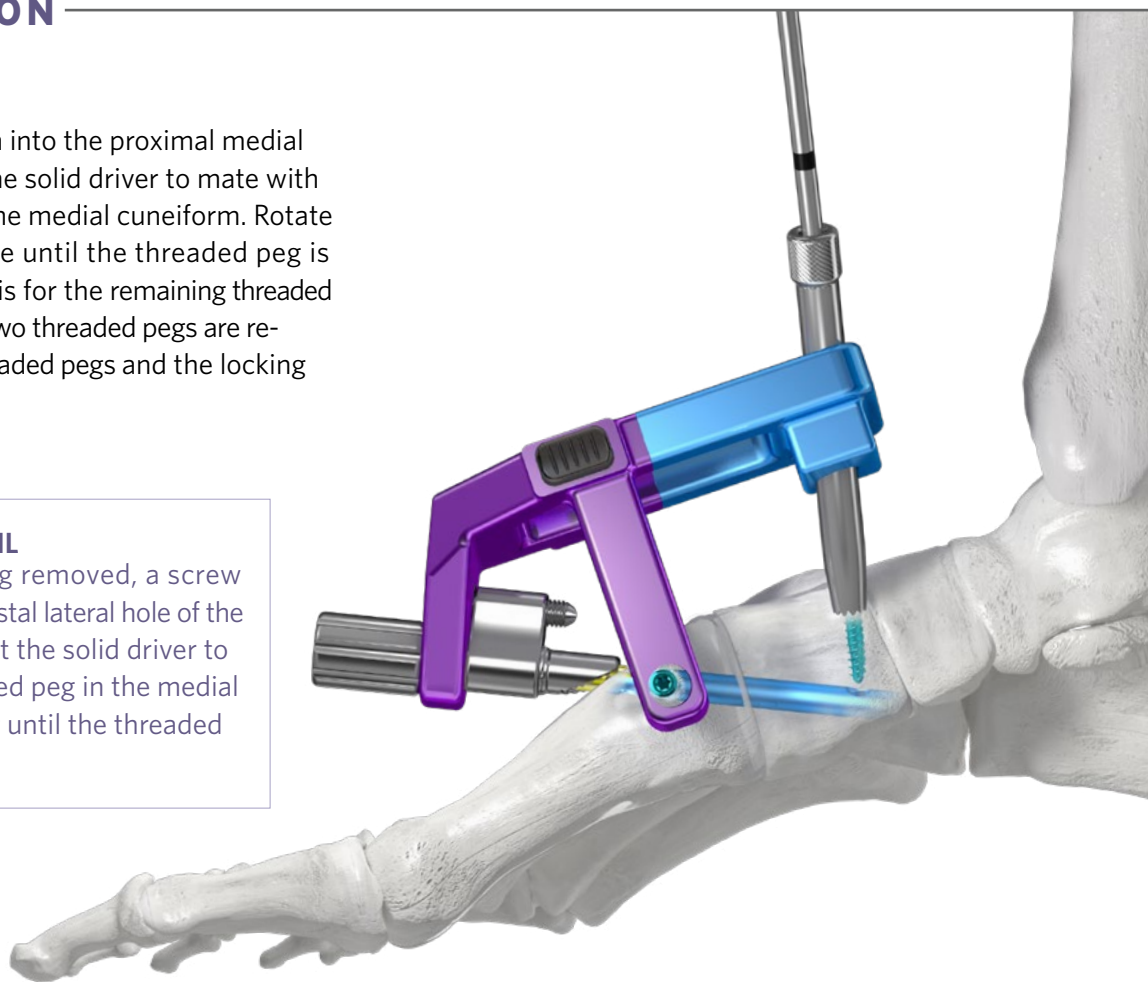
LAPIDUS ARTHRODESIS USING THE PHANTOM INTRAMEDULLARY NAIL

REMOVAL/REVISION

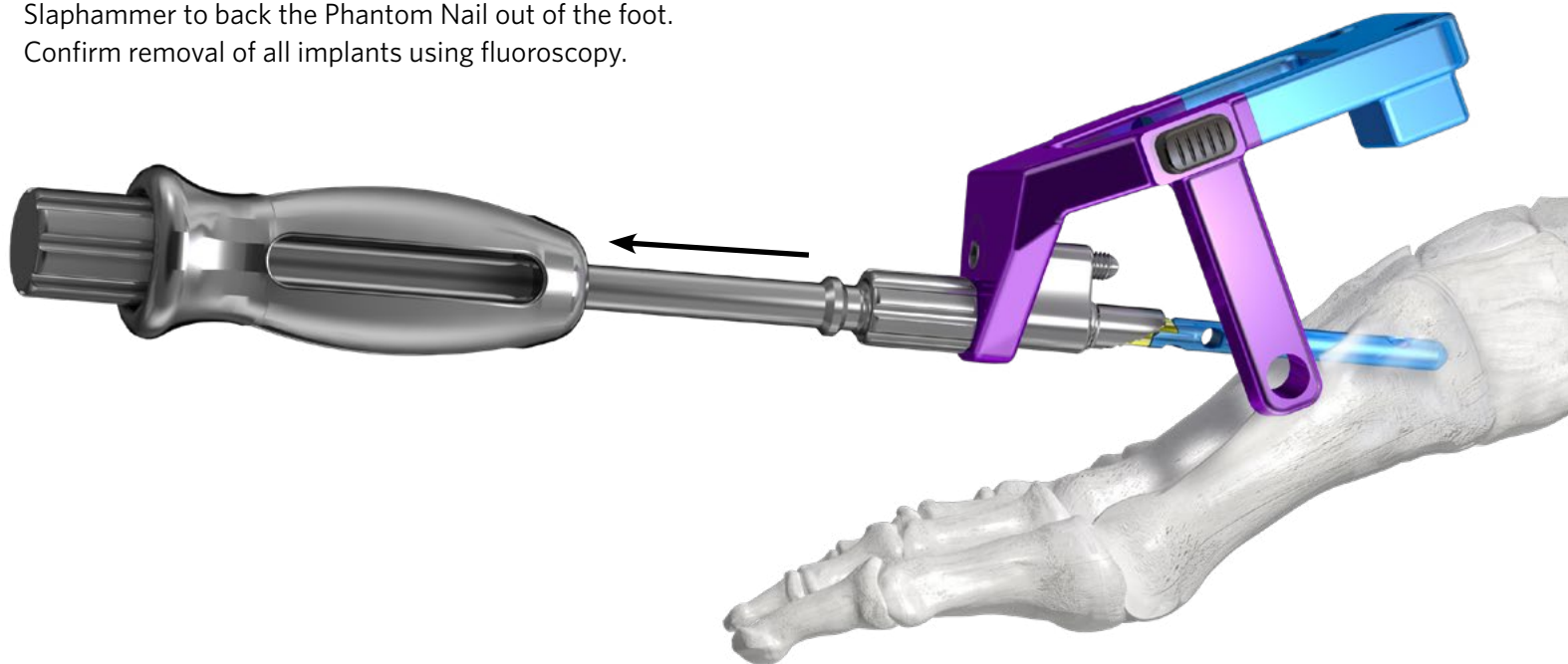
4. Insert the screw guide portion into the proximal medial hole of the outrigger and insert the solid driver to mate with the head of the threaded peg in the medial cuneiform. Rotate the solid driver counterclockwise until the threaded peg is removed from the bone. Repeat this for the remaining threaded peg in the Phantom Nail until the two threaded pegs are removed. Confirm removal of all threaded pegs and the locking screw using fluoroscopy.

NOTE: 4 HOLE PHANTOM NAIL

If a 4 Hole Phantom Nail is being removed, a screw guide should be placed in the distal lateral hole of the outrigger over the cuneiform. Insert the solid driver to mate with the head of the threaded peg in the medial cuneiform. Rotate the solid driver until the threaded peg is removed from bone.



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.

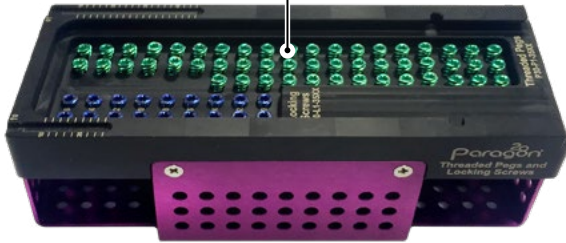


SURGICAL TECHNIQUE GUIDE:

THE PHANTOM® INTRAMEDULLARY NAIL CADDY SYSTEM

Threaded Peg and Locking Screw Caddy

Threaded Pegs are available in lengths 10–46 mm in 2 mm increments. 3.5 mm Locking Screws range from 10–26 mm in length in 2 mm increments.



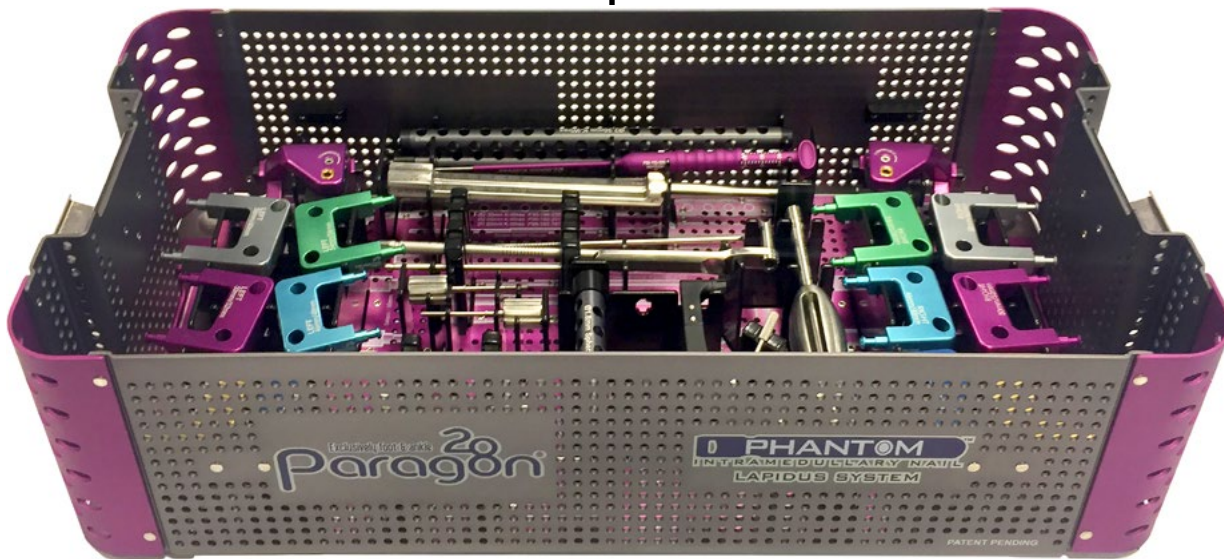
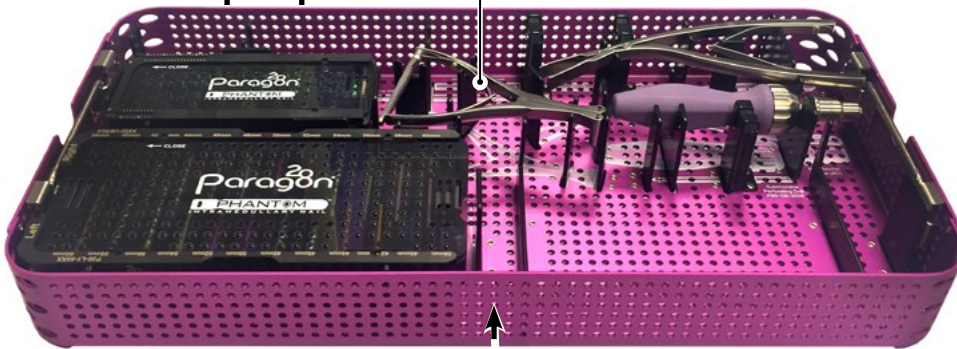
Phantom® Nail Caddy

One 3 Hole and one 4 Hole Phantom Nail 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.

SURGICAL TECHNIQUE GUIDE:

INDICATIONS, CONTRAINDICATIONS, AND WARNINGS

Refer to www.paragon28.com/ifus for the complete and most current instructions for use document.

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.

Saw blades are flat surgical cutting instruments with a serrated edge designed for cutting bone/tissue during orthopaedic surgery in the foot and ankle.

A drill is an orthopedic drill surgical instrument consisting in a shaft of metal with a cutting edge designed to be rotated to bore into bone to create a hole.

Wires are intended for the temporary fixation of bone fractures, positioning of implants, and guiding of instruments.

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
- Corpulence; an overweight or corpulent patient can strain the implant to such a degree that stabilization or implant failure can occur
- 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**

The logo features a dark blue horizontal bar with rounded ends. On the left side of the bar is a white circle with a vertical line through its center. To the right of this symbol, the word "PHANTOM" is written in white, uppercase, sans-serif font. A registered trademark symbol (®) is located at the top right of the bar. Below the bar, the words "INTRAMEDULLARY NAIL" are written in a smaller, dark blue, uppercase, sans-serif font.

PHANTOM[®]
INTRAMEDULLARY NAIL

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Endnotes:

¹ Internal data on file, TR-17060501

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DISCLAIMER

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