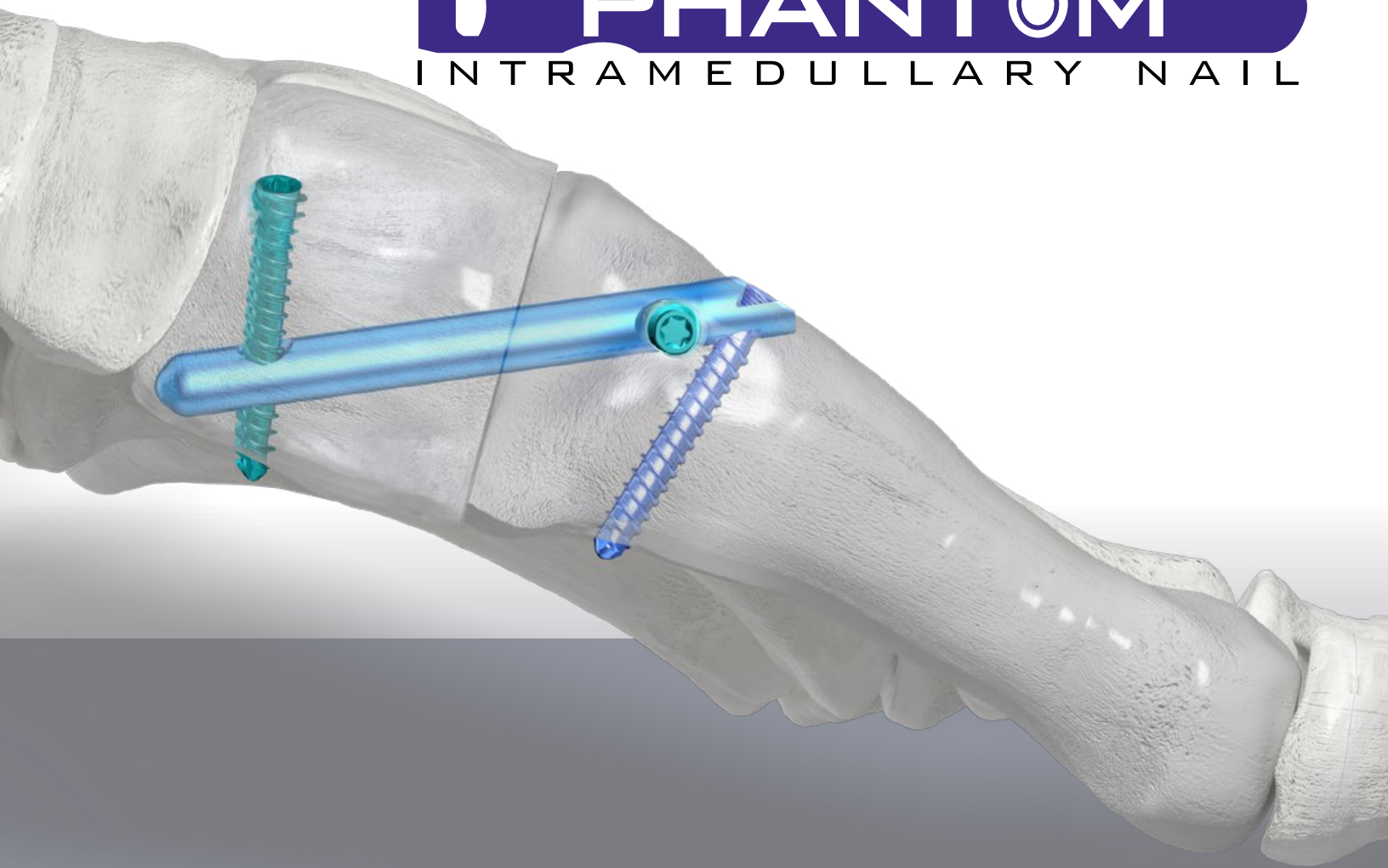


## SURGICAL TECHNIQUE GUIDE:

### 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.

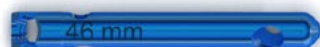
### PRODUCT OFFERING

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

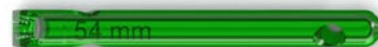
- Offered in 3 Hole (shown) and 4 Hole configurations



38 mm



46 mm



54 mm



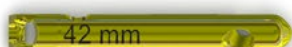
40 mm



48 mm



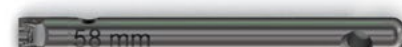
56 mm



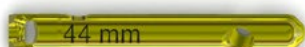
42 mm



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 1<sup>st</sup> 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

- 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

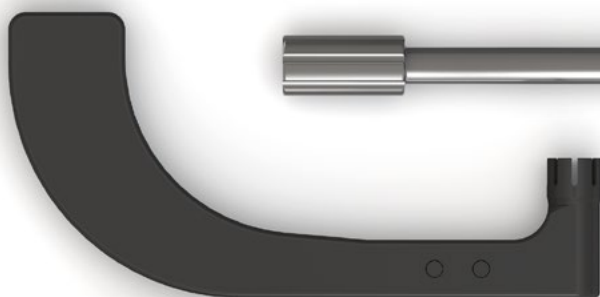
- Inserts into the outrigger and attaches to the Phantom Nail



Sphere Wire



Nail Positioning Guide



Polyaxial Targeting Guide



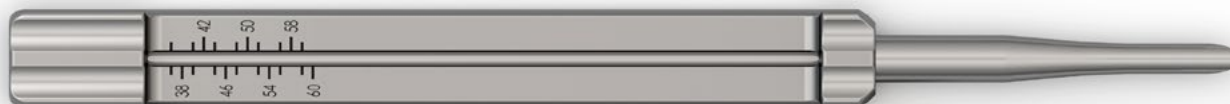
Polyaxial Targeting Guide - Sleeve Insert



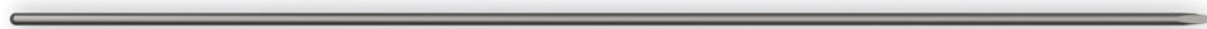
Ø2.75mm Drill Depth Gauge



Ø2.75mm Drill-Pin



Nail Depth Gauge



Ø2.3mm K-wire



Screw Guide



Drill-Pin Guide



Obturator

## SURGICAL TECHNIQUE GUIDE:

### LAPIDUS ARTHRODESIS USING THE PHANTOM INTRAMEDULLARY NAIL

#### INSTRUMENTS



Tissue Protector



Torque Indicating Driver



Solid Driver



Locking Guide



#### INCISION/EXPOSURE

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

Patient is positioned supine. Intraoperative fluoroscopy is highly recommended.

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



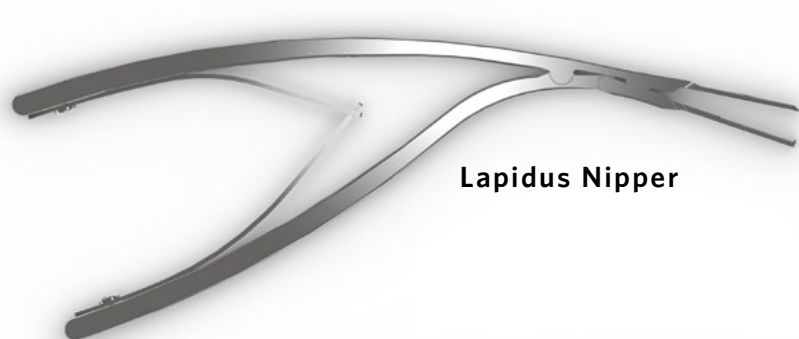


## SURGICAL TECHNIQUE GUIDE:

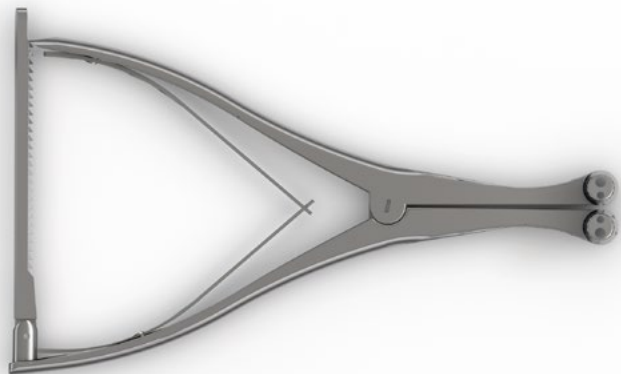
### LAPIDUS ARTHRODESIS USING THE PHANTOM INTRAMEDULLARY NAIL

#### JOINT PREPARATION

After exposure of the joint surfaces at the 1<sup>st</sup> 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**



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



**Subchondral Perforating Drill**



**Joint Preparation Chisel**

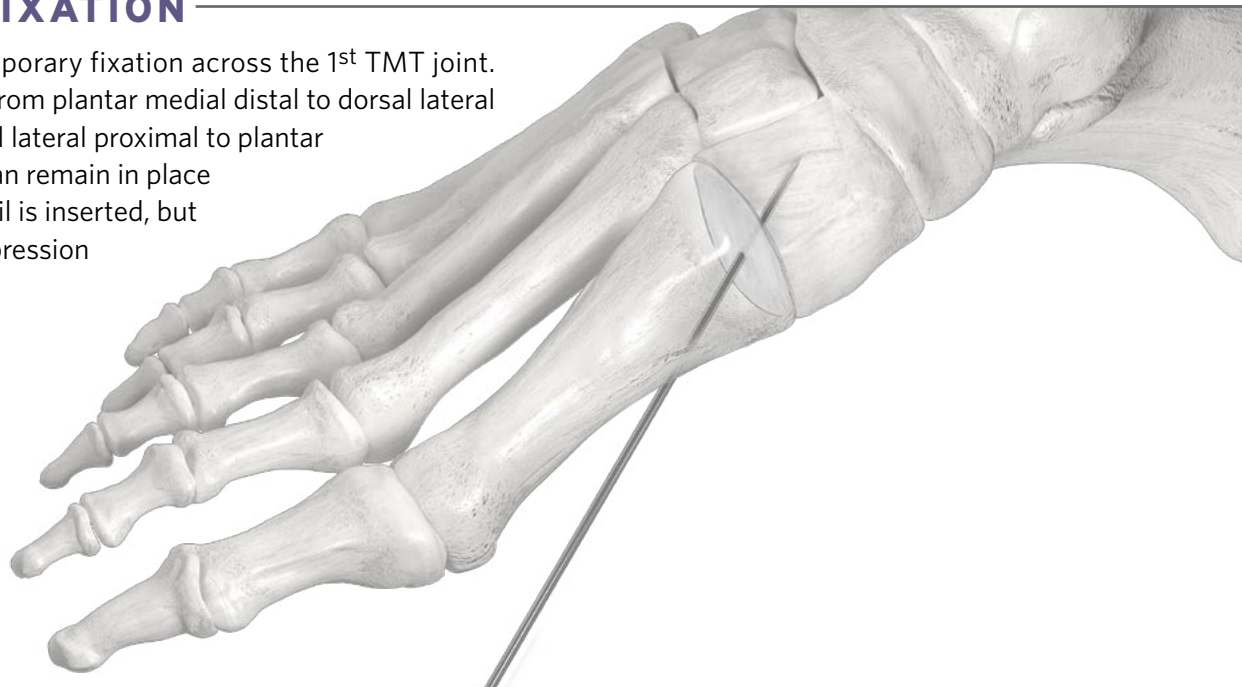
If necessary, bone grafting material can be inserted in the joint at this time.

**TIP:** The PRESERVE™ Lapidus Angular Length Restoring Bone Graft can help restore length for a patient with a short 1<sup>st</sup> 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 1<sup>st</sup> metatarsal. The Phantom Nail has sizes to accommodate a bone graft in the 1<sup>st</sup> TMT joint.



#### TEMPORARY FIXATION

A K-wire is placed for temporary fixation across the 1<sup>st</sup> 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 1<sup>st</sup> TMT joint.

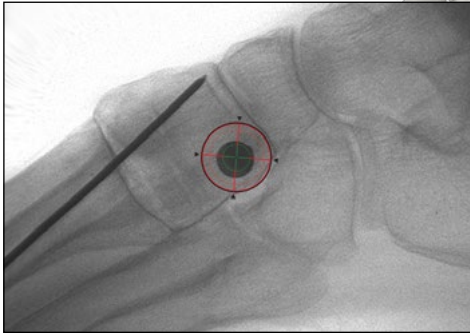


## SURGICAL TECHNIQUE GUIDE:

### LAPIDUS ARTHRODESIS USING THE PHANTOM INTRAMEDULLARY NAIL

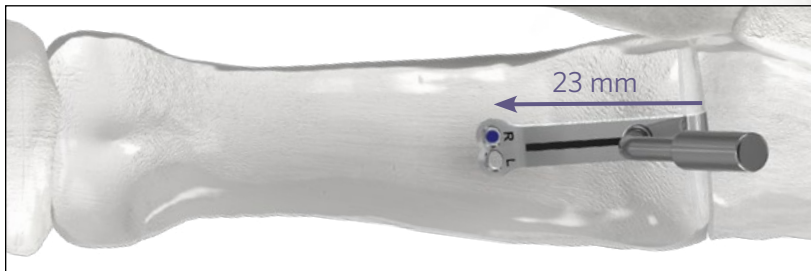
#### NAIL ALIGNMENT & POSITIONING

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.



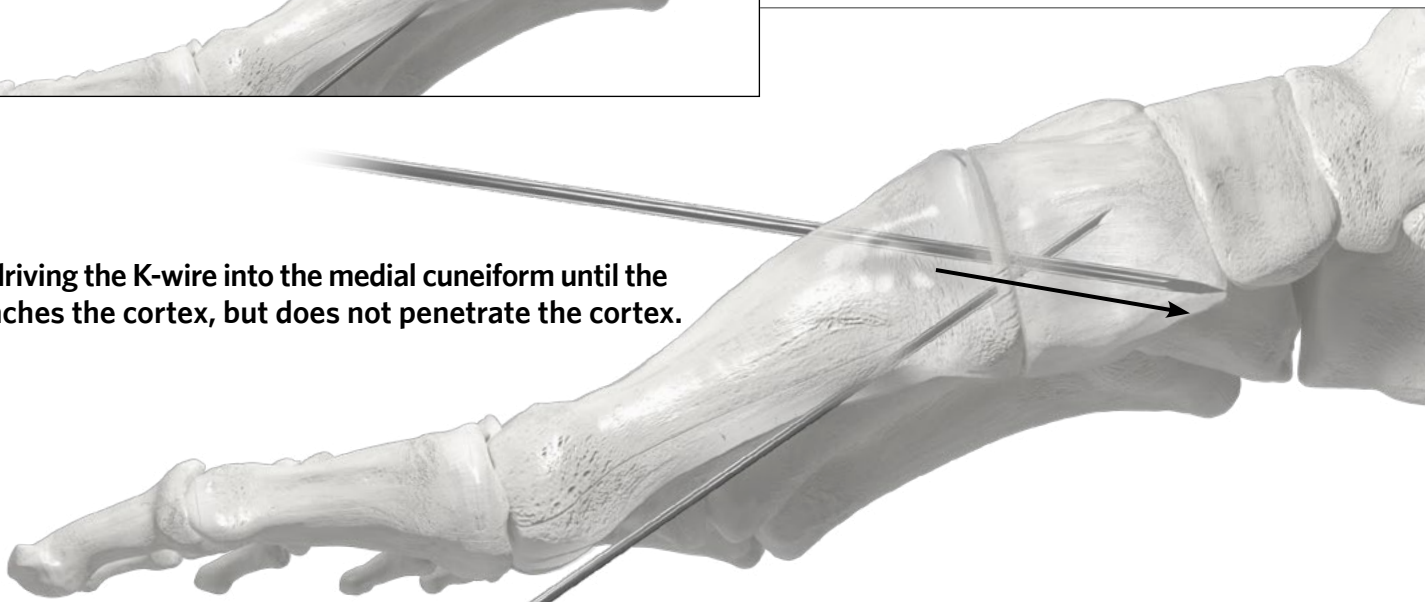
**NOTE:** Apply downward pressure to the sleeve insert claw guide as the K-wire enters the dorsal cortex of the 1<sup>st</sup> metatarsal to prevent skiving.

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.

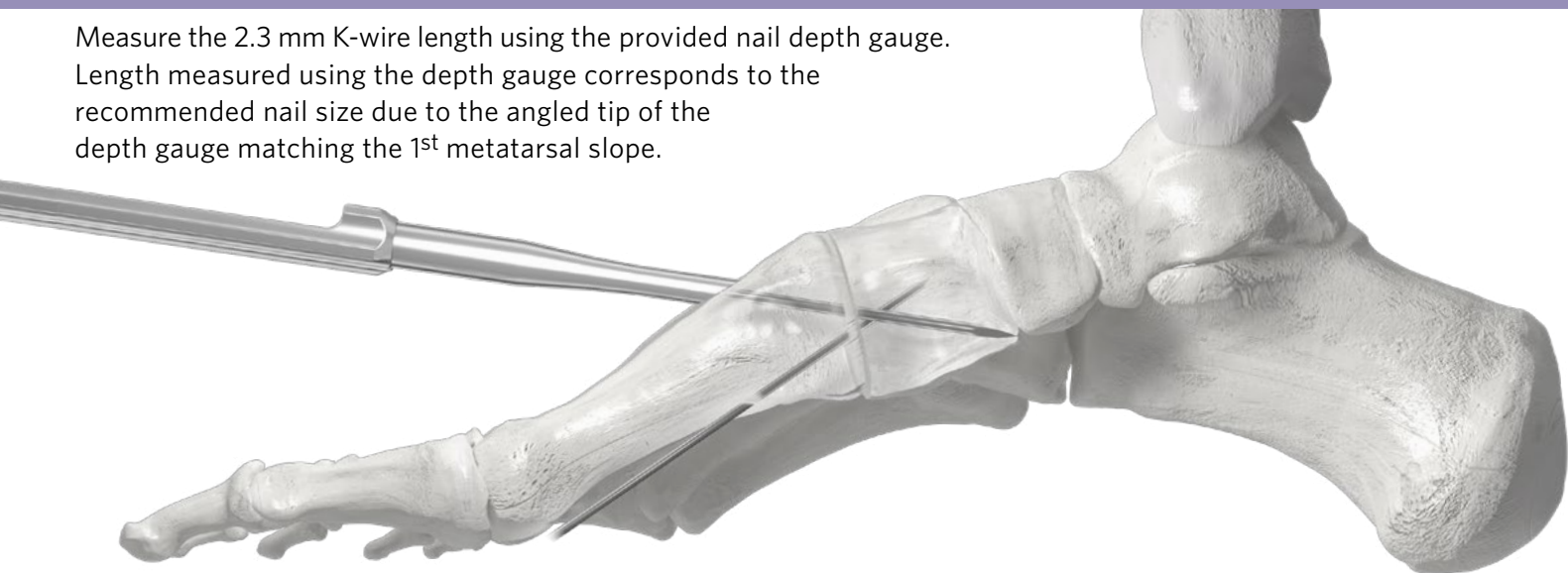




## SURGICAL TECHNIQUE GUIDE:

### 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 1<sup>st</sup> metatarsal slope.

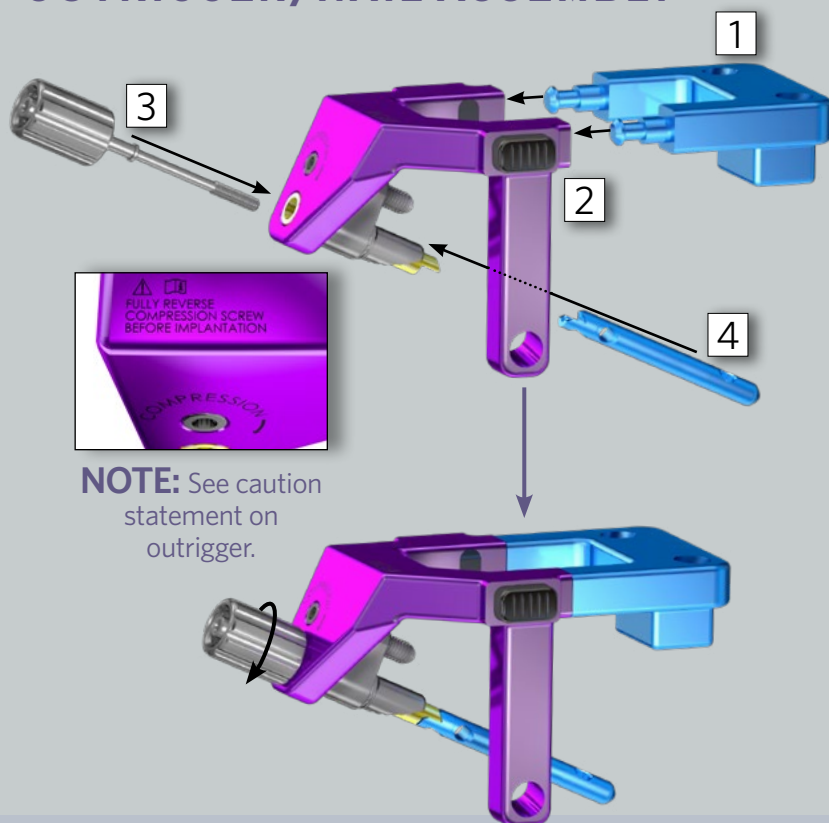


### NAIL PREPARATION & DRILLING

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 1<sup>st</sup> 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.



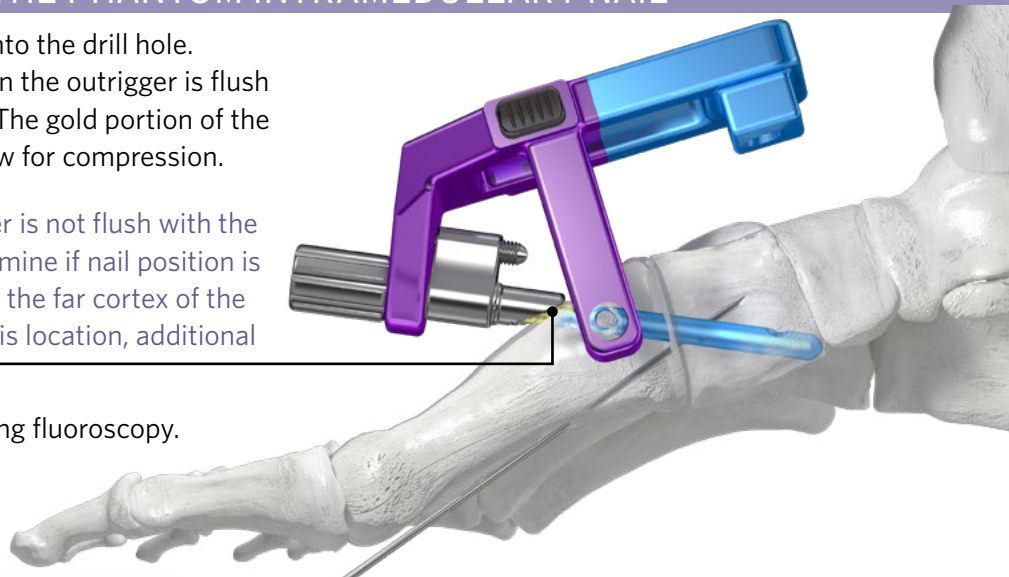
## SURGICAL TECHNIQUE GUIDE:

### 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 1<sup>st</sup> metatarsal to allow for compression.

**NOTE:** If the contoured piece of the outrigger is not flush with the dorsal 1<sup>st</sup> 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.

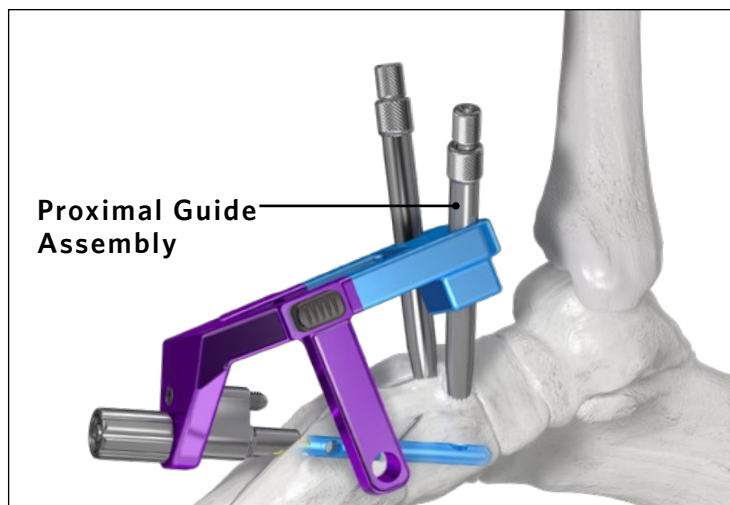
Confirm Phantom Nail size and placement using fluoroscopy.



## PROXIMAL FIXATION

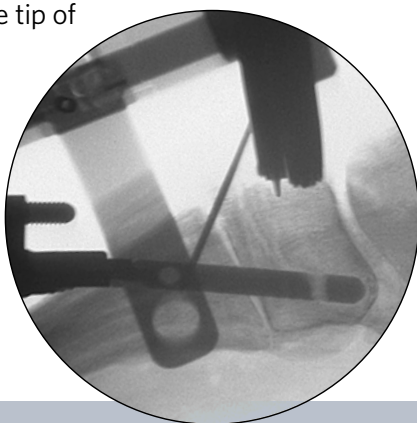


Assemble two drill-pin guides and screw guides.



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 1<sup>st</sup> 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.

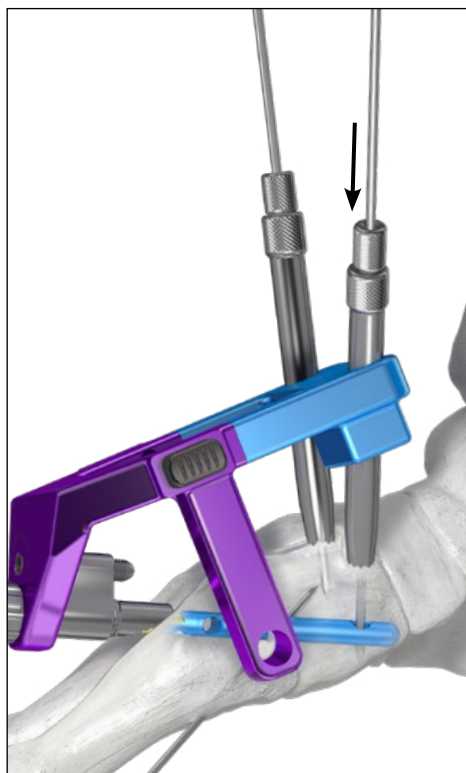
#### **NOTE: 4 HOLE PHANTOM NAIL**

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

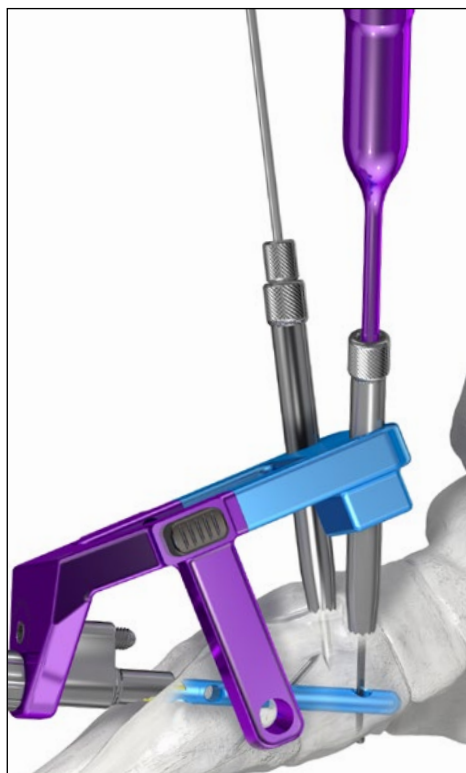
## SURGICAL TECHNIQUE GUIDE:

### 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.



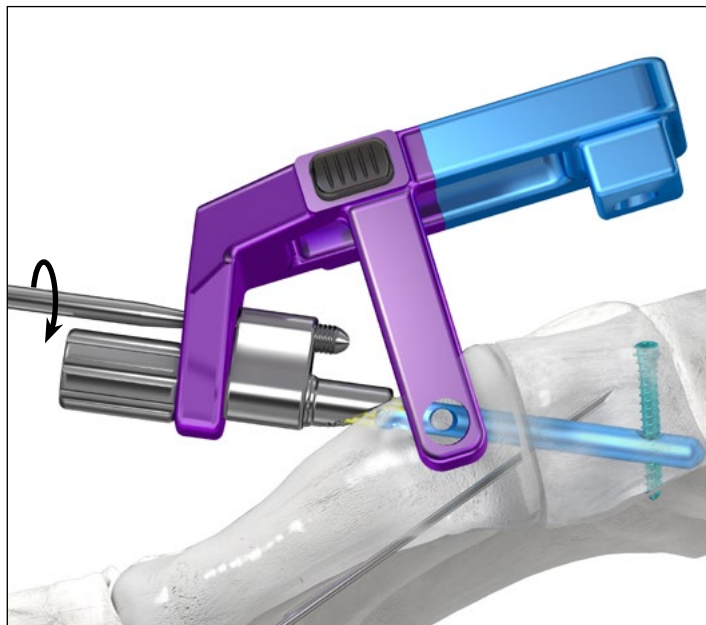
**NOTE: 4 HOLE PHANTOM NAIL**

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

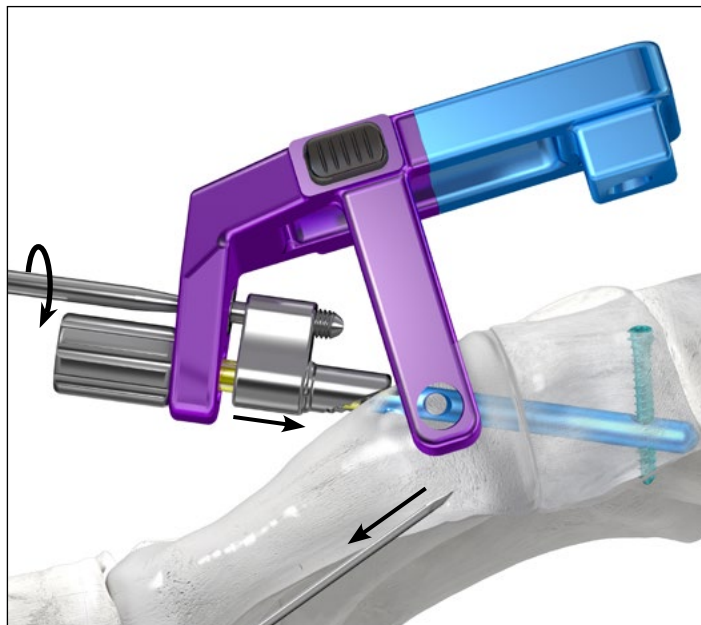
#### COMPRESSION



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.

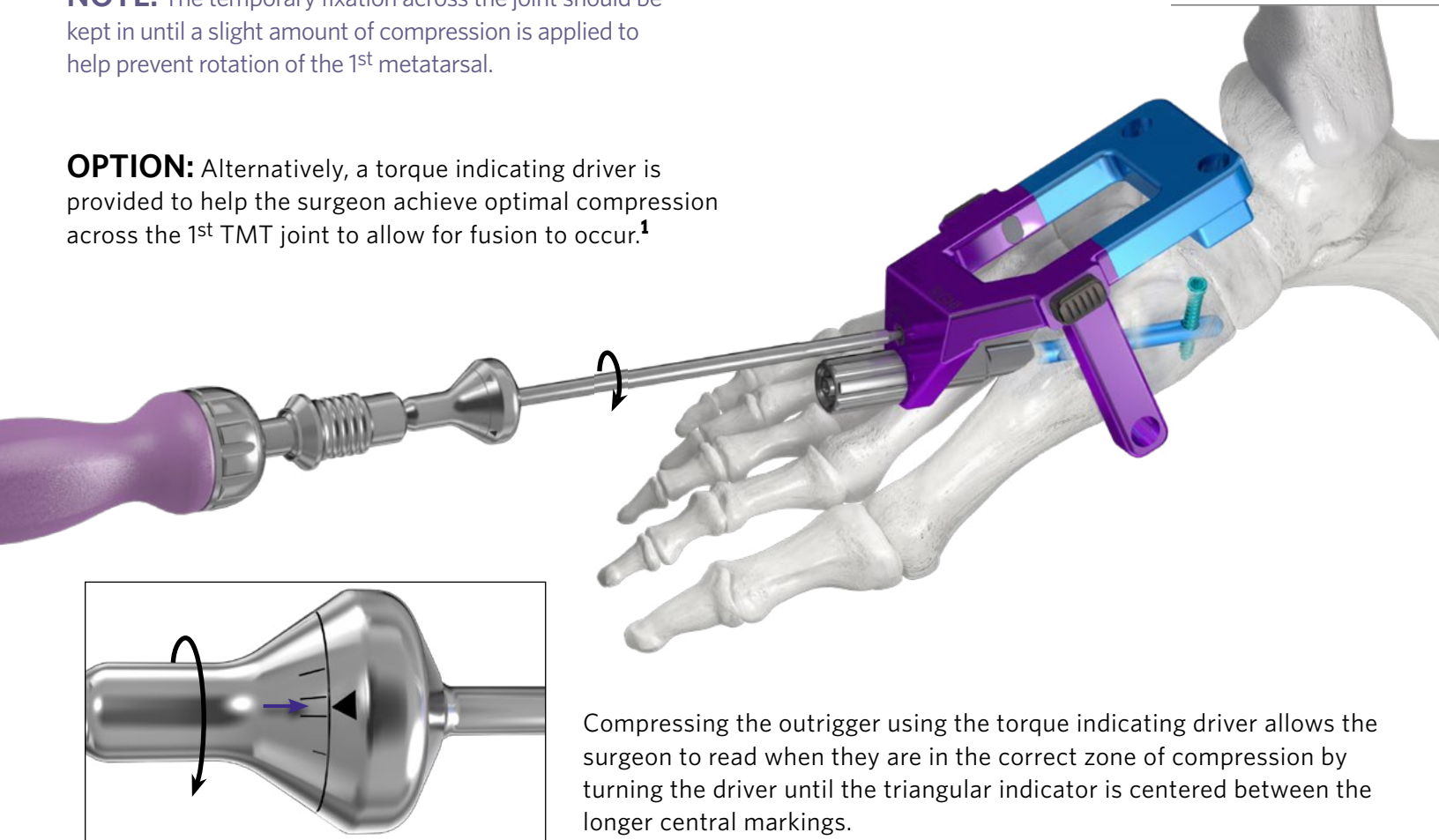
**NOTE:** The temporary fixation across the joint should be kept in until a slight amount of compression is applied to help prevent rotation of the 1<sup>st</sup> metatarsal.

**OPTION:** Alternatively, a torque indicating driver is provided to help the surgeon achieve optimal compression across the 1<sup>st</sup> TMT joint to allow for fusion to occur.<sup>1</sup>



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.



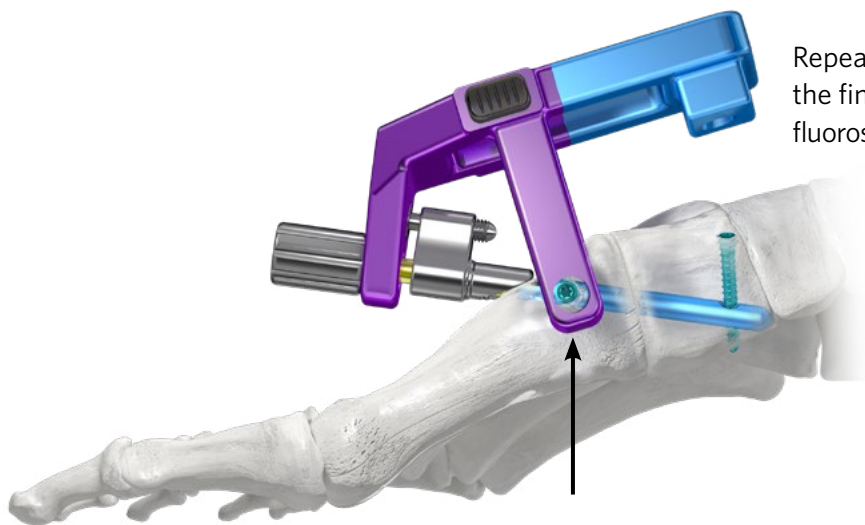
Compressing the outrigger using the torque indicating driver allows the surgeon to read when they are in the correct zone of compression by turning the driver until the triangular indicator is centered between the longer central markings.



## SURGICAL TECHNIQUE GUIDE:

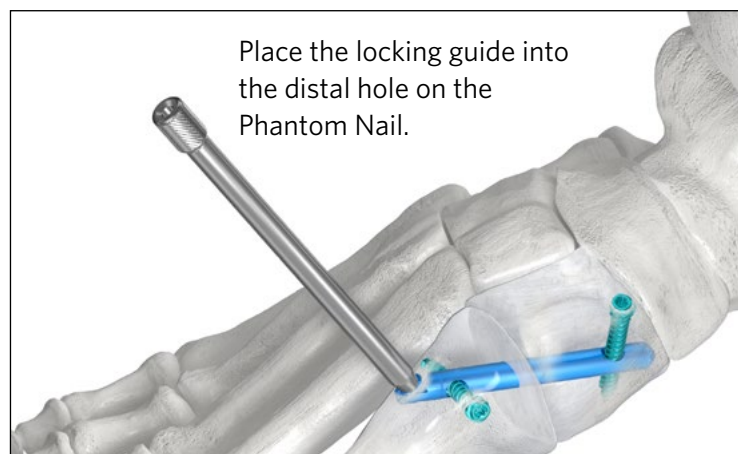
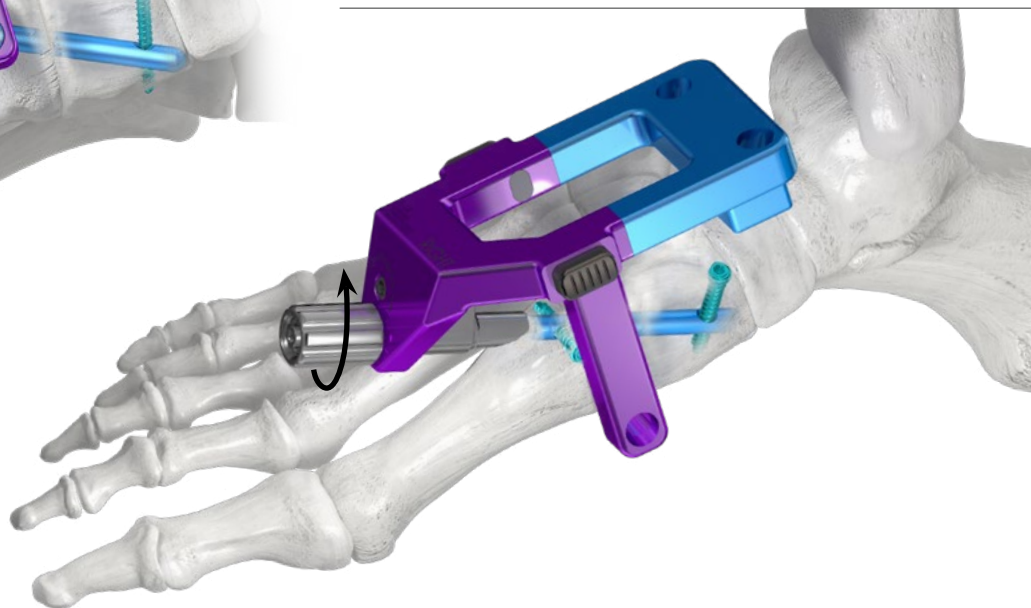
### LAPIDUS ARTHRODESIS USING THE PHANTOM INTRAMEDULLARY NAIL

#### DISTAL FIXATION

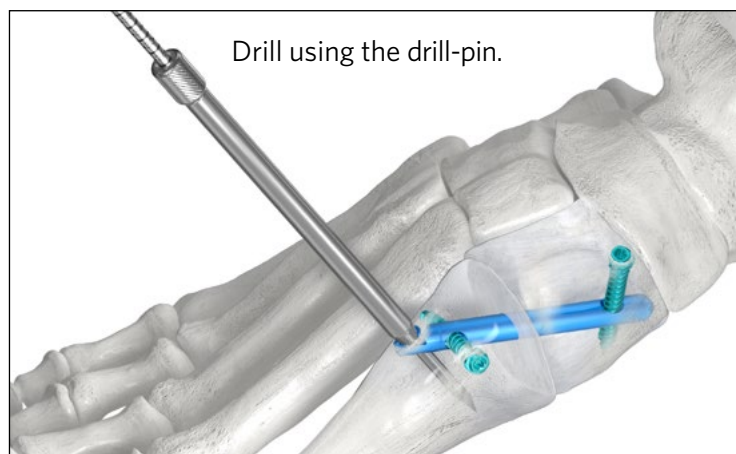


Repeat the steps of placing a threaded peg into the final outrigger hole. Confirm placement using fluoroscopy.

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

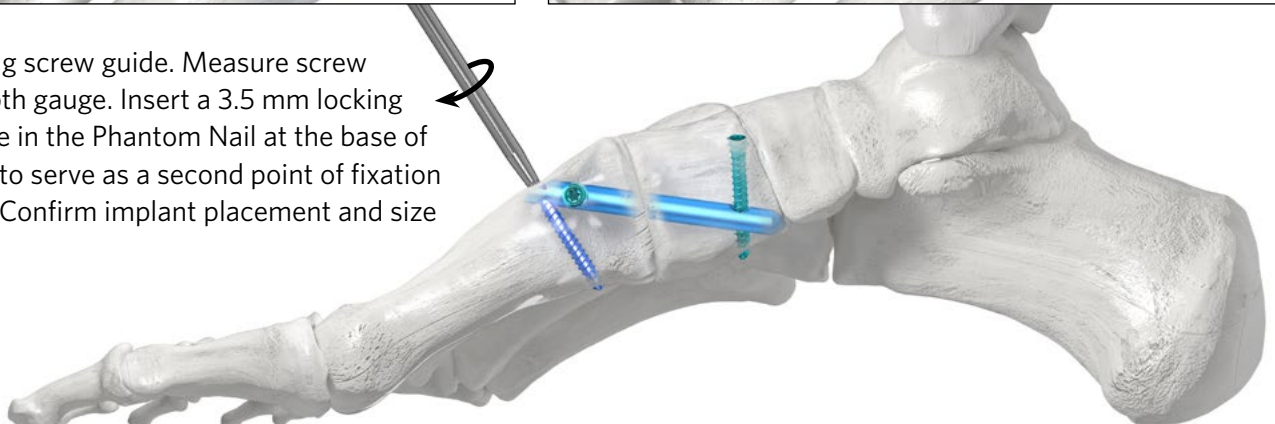


Place the locking guide into the distal hole on the Phantom Nail.



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 1<sup>st</sup> 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.

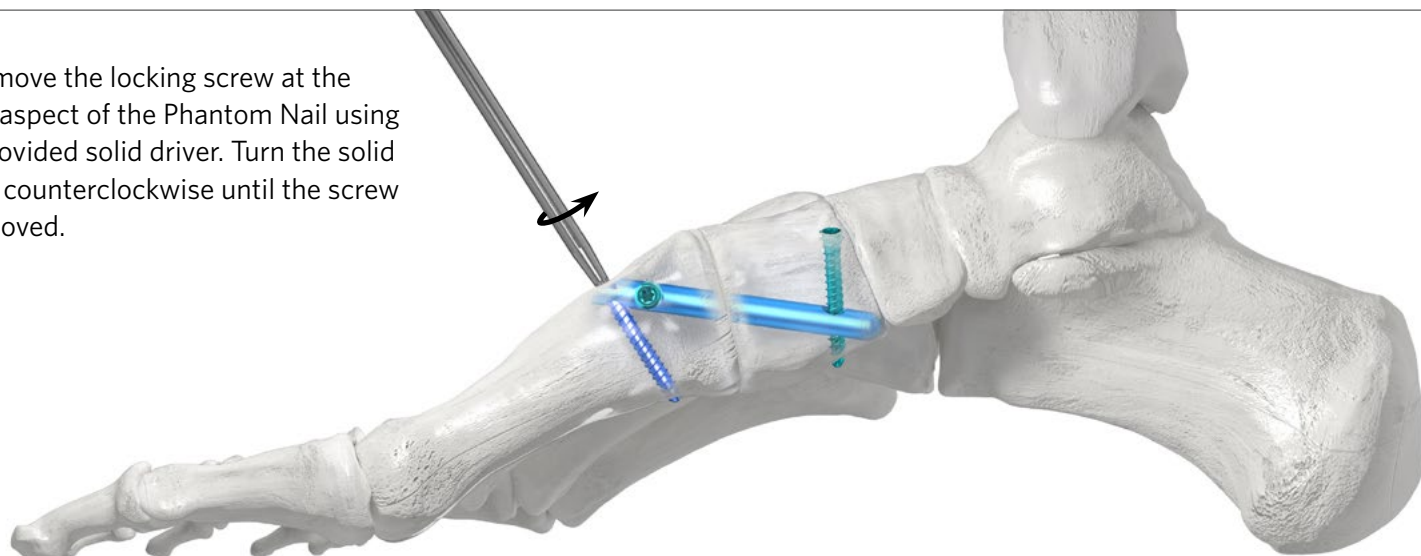
## SURGICAL TECHNIQUE GUIDE:

### LAPIDUS ARTHRODESIS USING THE PHANTOM INTRAMEDULLARY NAIL

#### REMOVAL/REVISION

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

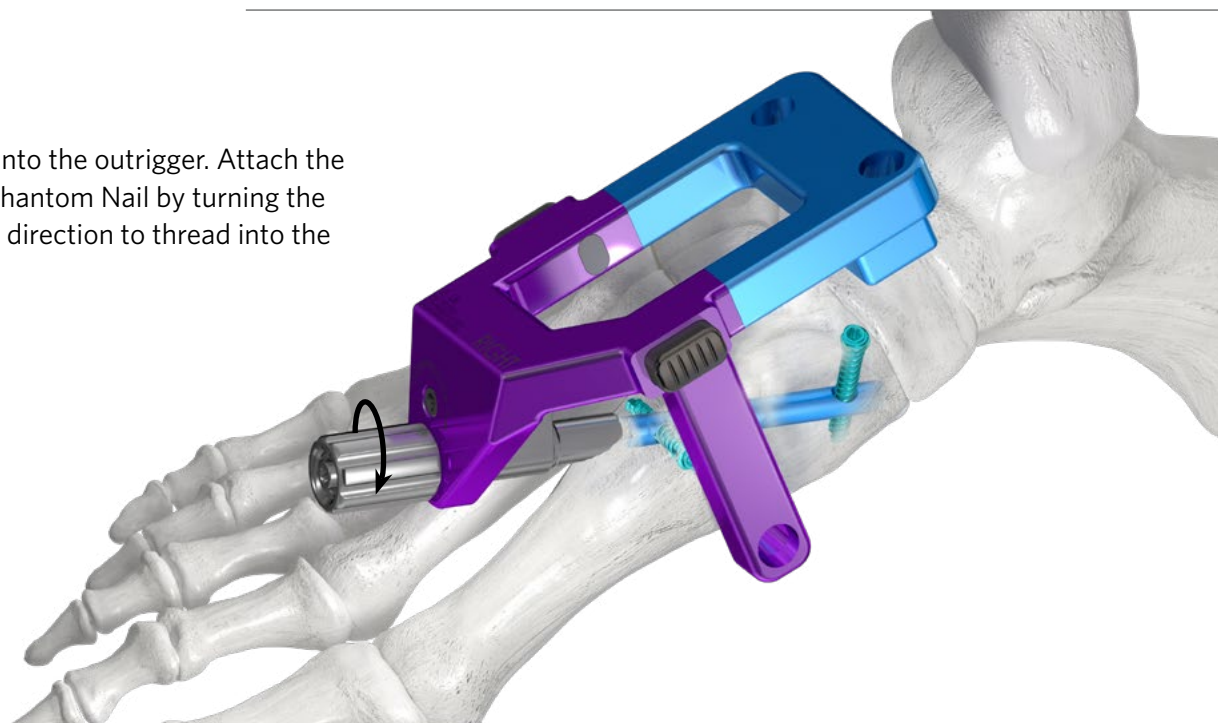
1. Remove the locking screw at the distal aspect of the Phantom Nail using the provided solid driver. Turn the solid driver counterclockwise until the screw is removed.



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:

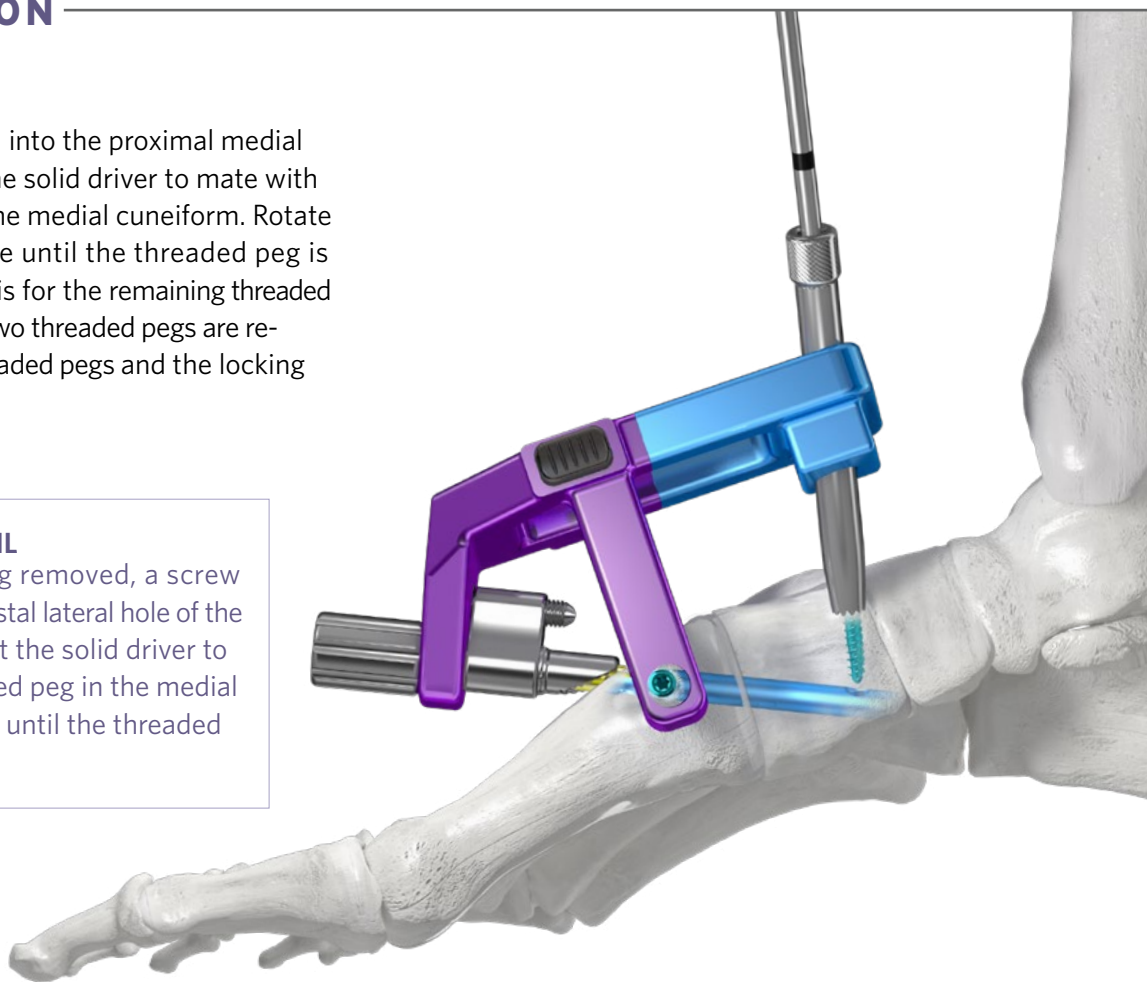
### LAPIDUS ARTHRODESIS USING THE PHANTOM INTRAMEDULLARY NAIL

#### REMOVAL/REVISION

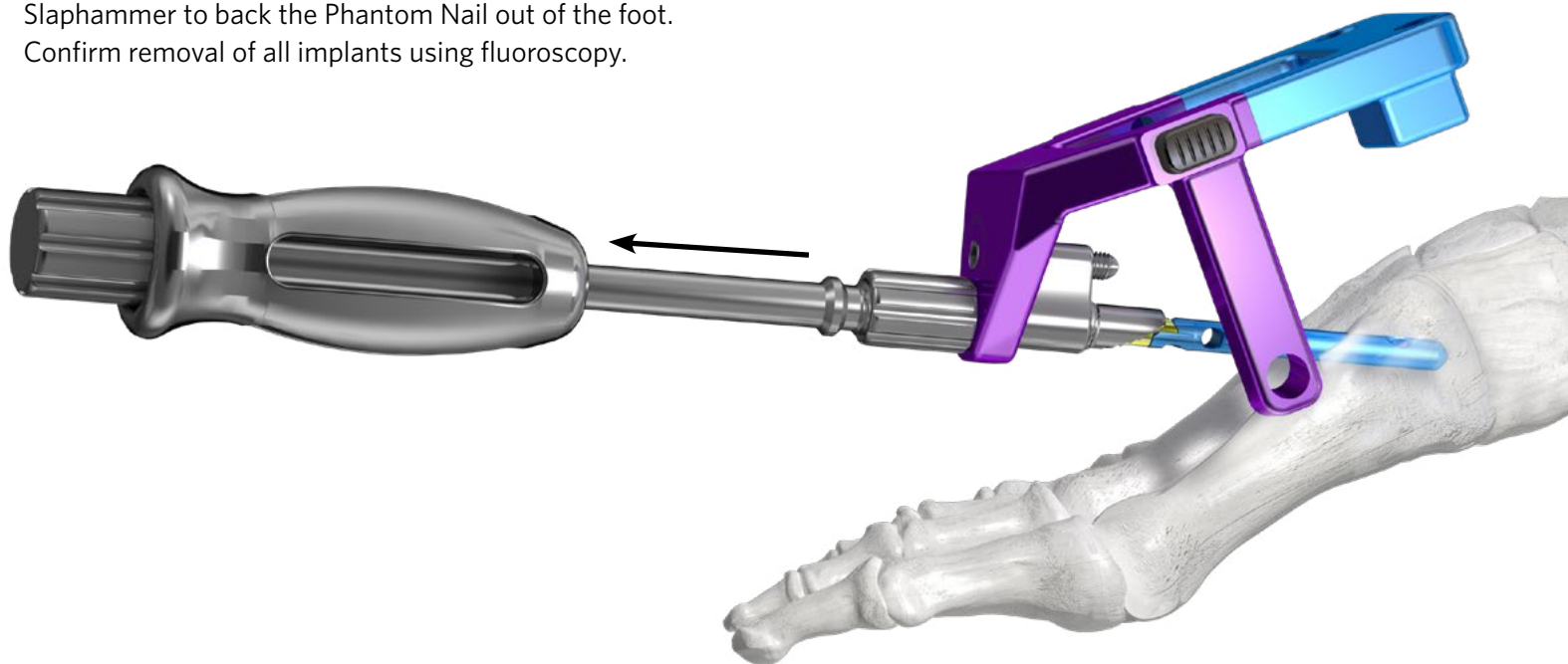
**4.** Insert the screw guide portion into the proximal medial hole of the outrigger and insert the solid driver to mate with the head of the threaded peg in the medial cuneiform. Rotate the solid driver counterclockwise until the threaded peg is removed from the bone. Repeat this for the remaining threaded 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.



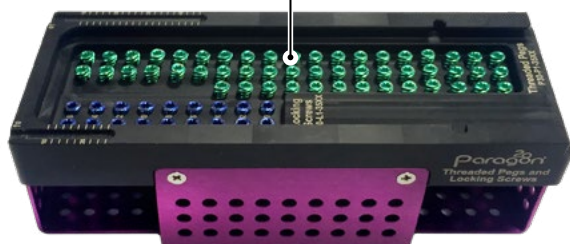


## SURGICAL TECHNIQUE GUIDE:

### 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.



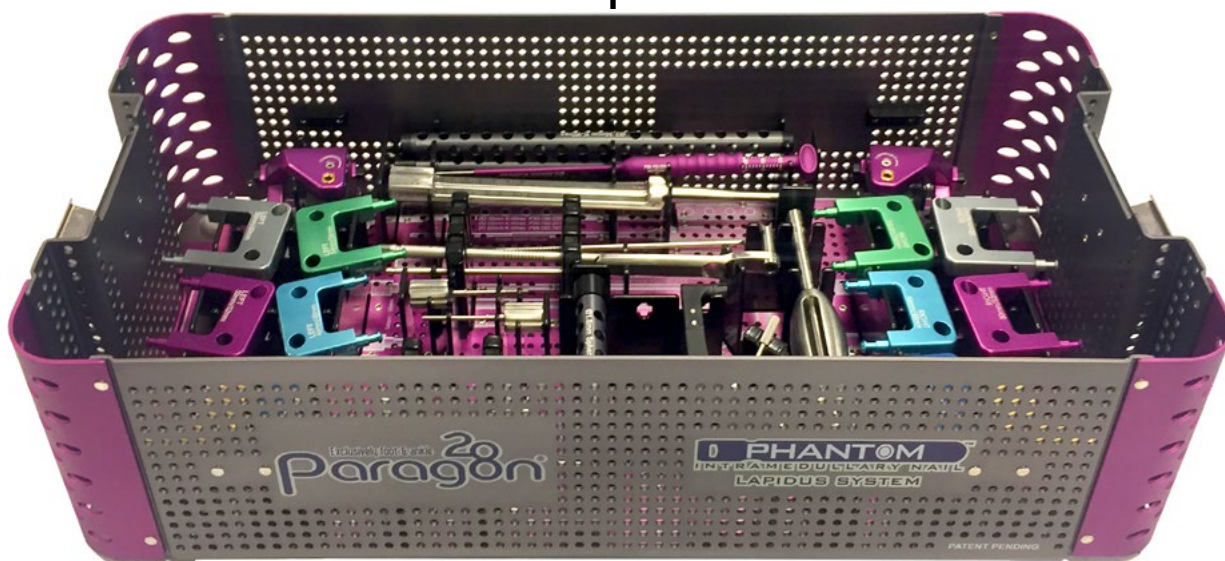
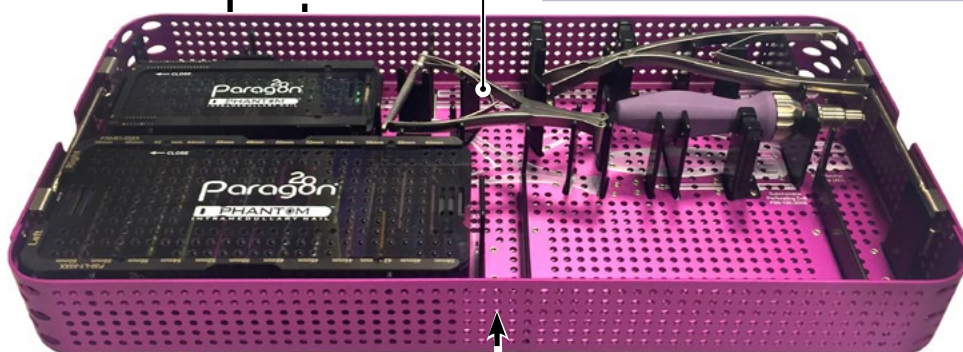
#### Phantom® Nail Caddy

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.

## PHANTOM INTRAMEDULLARY NAIL LAPIDUS SYSTEM CASE:

PART #	DESCRIPTION	USE
P30-900-100R	Lapidus Nail, Outtrigger, Assembly, Right	Reusable
P30-900-100L	Lapidus Nail, Outtrigger, Assembly, Left	Reusable
P30-900-027R	Lapidus Nail, Outtrigger Slider, Right, 38mm/40mm	Reusable
P30-900-031R	Lapidus Nail, Outtrigger Slider, Right, 42mm/44mm	Reusable
P30-900-035R	Lapidus Nail, Outtrigger Slider, Right, 46mm/48mm	Reusable
P30-900-040R	Lapidus Nail, Outtrigger Slider, Right, 50mm/52mm	Reusable
P30-900-043R	Lapidus Nail, Outtrigger Slider, Right, 54mm/56mm	Reusable
P30-900-047R	Lapidus Nail, Outtrigger Slider, Right, 58mm/60mm	Reusable
P30-900-027L	Lapidus Nail, Outtrigger Slider, Left, 38mm/40mm	Reusable
P30-900-031L	Lapidus Nail, Outtrigger Slider, Left, 42mm/44mm	Reusable
P30-900-035L	Lapidus Nail, Outtrigger Slider, Left, 46mm/48mm	Reusable
P30-900-040L	Lapidus Nail, Outtrigger Slider, Left, 50mm/52mm	Reusable
P30-900-043L	Lapidus Nail, Outtrigger Slider, Left, 54mm/56mm	Reusable
P30-900-047L	Lapidus Nail, Outtrigger Slider, Left, 58mm/60mm	Reusable
P30-900-5002	Lapidus Nail, Thumbscrew, Assembly	Reusable
P30-900-5001	Lapidus Nail, Slaphammer, Assembly	Reusable
P30-901-5175	Lapidus Nail, Screw Guide	Reusable
P30-902-2987	Lapidus Nail, Drill/Pin Guide	Reusable
P30-903-2812	Lapidus Nail, Obturator	Reusable
P30-905-2300	Lapidus Nail, Nail Positioning Guide	Reusable
P30-906-2989	Lapidus Nail, Locking Guide	Reusable
P30-100-5309	Lapidus Nail, Tissue Protector	Reusable
P30-100-6810	Lapidus Nail, Claw Guide, Assembly	Reusable
P30-100-5493	Lapidus Nail, Claw Guide Sleeve Insert	Reusable
P30-196-2323	Lapidus Nail, K-wire, Long Trocar Tip, Ø2.3mm x 230mm	Single-use
P30-196-2720	Lapidus Nail, K-Wire, Ø2.75mm x 200mm	Single-use
P30-110-5517	Lapidus Nail, Cannulated Drill, Ø5.5mm x 170mm	Reusable
P30-952-2720	Lapidus Nail, Ø2.75mm K-Wire Depth Gauge	Reusable
P30-952-3000	Lapidus Nail, Nail Depth Gauge	Reusable
P99-150-0086	Depth Gauge, 60mm	Reusable
P99-251-1607	K-wire, Olive, Threaded, Ø1.8mm x 72mm	Single-use
P99-191-LT10	HX10 x 138mm Solid Driver	Reusable

## PHANTOM INTRAMEDULLARY NAIL LAPIDUS SYSTEM INSTRUMENT TRAY:

PART #	DESCRIPTION	USE
P99-192-1615	Ø1.60mm x 15cm Kirschner Wire, 316 LVM	Single-use
P99-192-2015	Ø2.00mm x 15cm Kirschner Wire, 316 LVM	Single-use
P99-000-AOMN	Mini Axial Ratchet Handle, AO Pull Adapter, Cannulated	Reusable
P30-100-TORQ	Torque Indicating Driver, T10	Reusable
P99-150-0019	Lapidus Nipper	Reusable
P99-100-2009	Refresh Drill, Ø2.0mm x 85mm	Reusable

## PHANTOM INTRAMEDULLARY NAIL LAPIDUS SYSTEM INSTRUMENT TRAY: \_\_\_\_\_

PART #	DESCRIPTION	USE
P99-150-0035	Bone Fenestration Chisel	Reusable
P99-150-0015	Medium Hintermann Distractor	Reusable

## PHANTOM INTRAMEDULLARY NAIL LAPIDUS SYSTEM NAIL CADDY: \_\_\_\_\_

PART #	DESCRIPTION	USE
P30-R2-55[38-60]	Lapidus Nail, Ø5.5mm x 38-60mm, Right, 3 Hole	Single-use
P30-R1-55[38-60]	Lapidus Nail, Ø5.5mm x 38-60mm, Right	Single-use
P30-L2-55[38-60]	Lapidus Nail, Ø5.5mm x 38-60mm, Left, 3 Hole	Single-use
P30-L1-55[38-60]	Lapidus Nail, Ø5.5mm x 38-60mm, Left	Single-use

## PHANTOM INTRAMEDULLARY NAIL LAPIDUS SYSTEM THREADED PEG AND LOCKING SCREW CADDY \_\_\_\_\_

PART #	DESCRIPTION	USE
P30-P1-35[10-46]	Lapidus Nail, Threaded Peg, Ø3.5mm x 10-46mm	Single-use
P30-S1-35[10-26]	Lapidus Nail, Locking Screw, Ø3.5mm x 10-26mm	Single-use



# SURGICAL TECHNIQUE GUIDE:

## INDICATIONS, CONTRAINDICATIONS, AND WARNINGS

Refer to [www.paragon28.com/ifus](http://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.

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

Refer to [www.paragon28.com/ifus](http://www.paragon28.com/ifus) for the complete and most current instructions for use document.

## 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**

## MRI SAFETY INFORMATION

MRI Safety Information



A patient with the Paragon 28® Phantom® Small Bone Intermedullary Nail System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Name/Identification of device	Paragon 28® Phantom® Small Bone Intramedullary Nail System
Nominal value(s) of Static Magnetic Field [T]	1.5 T or 3 T
Maximum Spatial Field Gradient [T/m and gauss/cm]	30 T/m (3000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF transmit-receive coil
Maximum Whole Body SAW [W/kg]	2.0 W/kg (Normal Operating Mode)
Limits on Scan Duration	2.0 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
If information about a specific parameter is not included, there are no conditions associated with that parameter.	



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#### Endnotes:

<sup>1</sup> Internal data on file, TR-17060501

P30-STG-0001 RevF [2024-12-02]

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#### DISCLAIMER

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