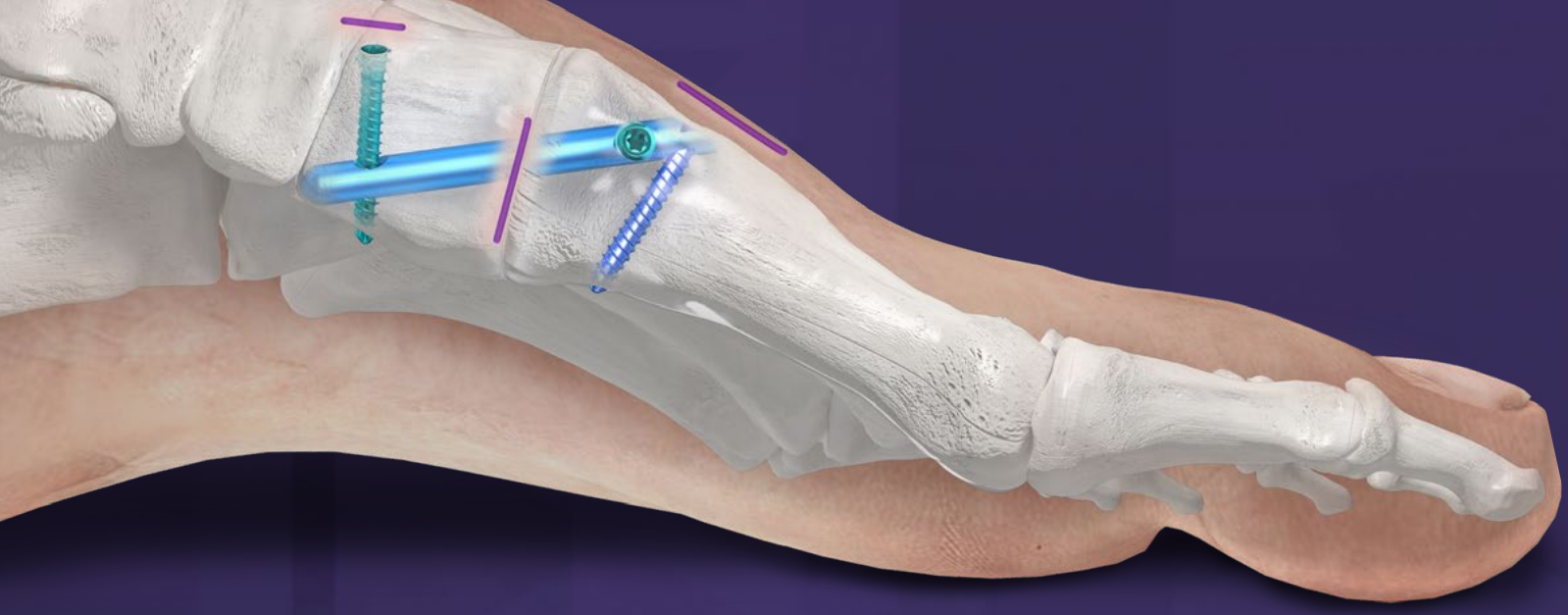
MIS LAPIDUS SYSTEM

SURGICAL TECHNIQUE GUIDE

Minimally Invasive Lapidus Arthodesis

Featuring the Small Bone
Phantom® Intramedullary Nail System

PHANTOM®
INTRAMEDULLARY NAIL



Exclusively foot & ankle
Paragon 28®

PRODUCT DESCRIPTION

The Paragon 28® Minimally Invasive Surgery (MIS) Lapidus System was designed for surgeons as a minimally invasive joint preparation option for a Lapidus Arthrodesis procedure. The MIS Lapidus System instrumentation allows the ability to access the 1st Tarsometatarsal (TMT) joint with minimal disruption to the soft tissue and overlying skin. Utilizing a percutaneously secured burr guide within a medial incision, a Shannon-Style Burr removes cartilage in a sweeping motion to prepare the fusion site for fixation.

INSTRUMENTATION OFFERING

Burr Cleaning Tool/Incision Marking Guide

Burr Guide

Shannon-Style Burr Ø3.0 mm

Burr Guide Paddle

6 mm Curved Osteotome

1.60 mm x 8 cm Olive Wire

Curette

1.60 mm x 10 cm K-Wire

The following technique demonstrates use of the MIS Lapidus System in a Lapidus Arthrodesis to implant a 3-Hole Phantom® Nail.

NECESSARY EQUIPMENT IN OPERATING SUITE

- Fluoroscopy in the room prior to starting the procedure (Mini or Large C-Arm)
- Power Equipment: Stryker TPS or Core U Drill (Start at 5000 rpm, max is 8000 rpm)

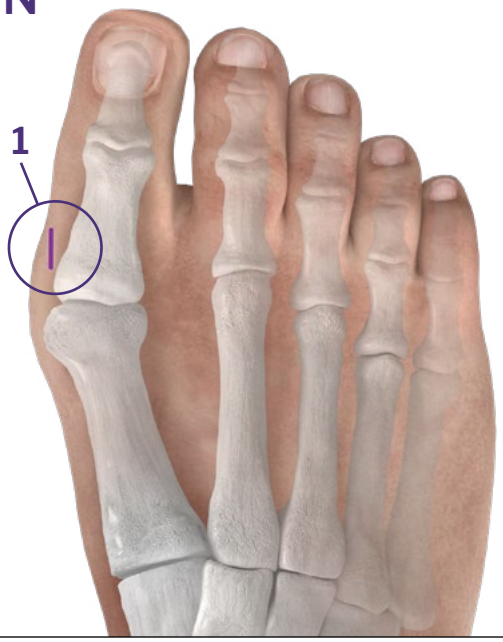
ACKNOWLEDGMENTS:
Paragon 28® would like to thank Gregory Guyton, MD for his contribution to the development of the surgical technique guide.

OPTIONAL MEDIAL EMINENCE RESECTION

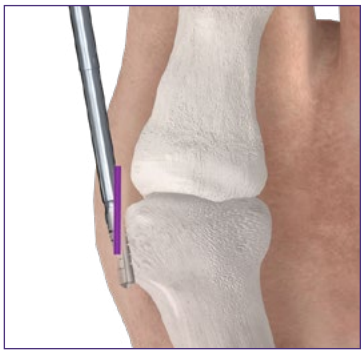
1 Incision for Medial Eminence Resection: 5-8 mm

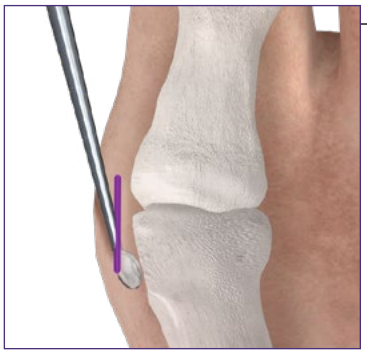
A medial midline incision is made centered over the distal aspect of the medial eminence of the 1st metatarsal head. Perform blunt dissection to deepen the incision to the capsular tissue in this area. Attach the burr to an approved power source.

Place the burr into the incision and through the joint capsule. Begin rotation of the burr prior to contacting bone. Use a sweeping motion of the burr to resect the medial eminence. Enough bone should be resected such that the cut is in-line with the shaft of the metatarsal.



NOTE: Per surgeon preference, an Akin osteotomy can be performed through this incision.





After checking the path of the burr on fluoroscopy, continue to sweep the burr over the medial eminence. Per surgeon preference, the curette can be used to further resect the medial eminence and remove bony debris. Fluoroscopy is recommended to ensure that the entire eminence is removed. Irrigation and digital manipulation is required to remove the bony debris.

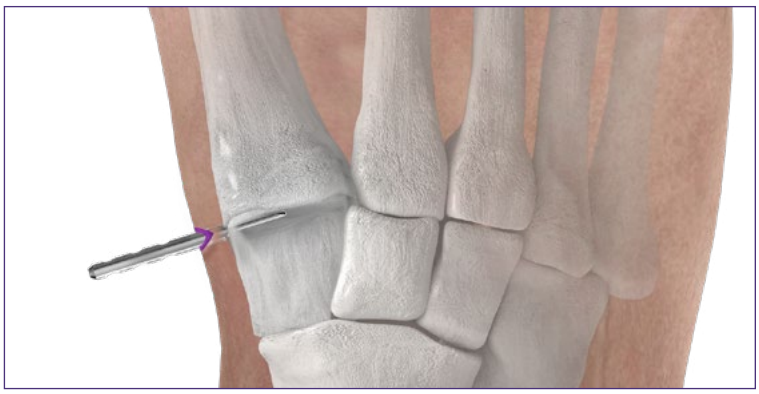
1ST TARSOMETATARSAL INCISION PLACEMENT

2 Incision for 1st Tarsometatarsal (TMT) Joint Resection: 8-10 mm

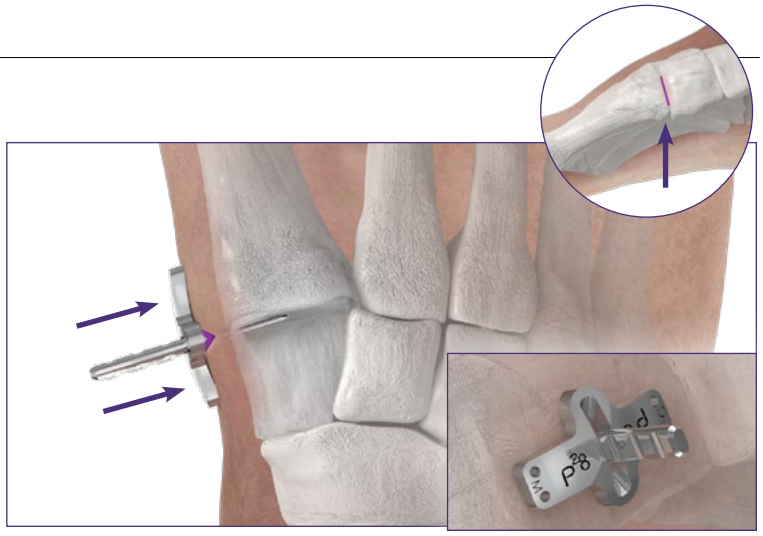
To allow for incision planning in this area, dorsiflex the foot under fluoroscopy to account for the angle of the joint from a dorsal to plantar view. Mark an 8 mm vertical incision location along the medial aspect of the foot. This incision may angle posteriorly from dorsal to plantar to follow the angle of the joint. Make a stab incision medially over the joint. Use blunt dissection to deepen the incision to the 1st TMT joint. Place the knife within the joint and confirm joint location using fluoroscopy. Release the joint capsule medially.

NOTE:
The Anterior Tibialis Tendon (ATT) is not at risk from this maneuver if the incision is properly placed. Insertion is primarily on the side of cuneiform.

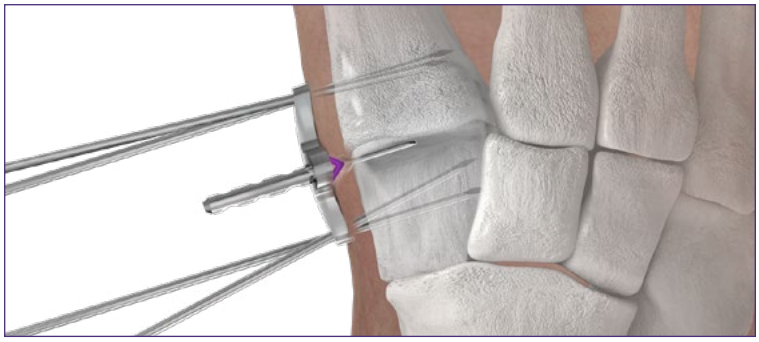
BURR GUIDE PLACEMENT



Retrieve the burr guide paddle. Insert the burr guide paddle into the 1st TMT joint through the vertical incision. Confirm burr guide paddle placement using fluoroscopy.

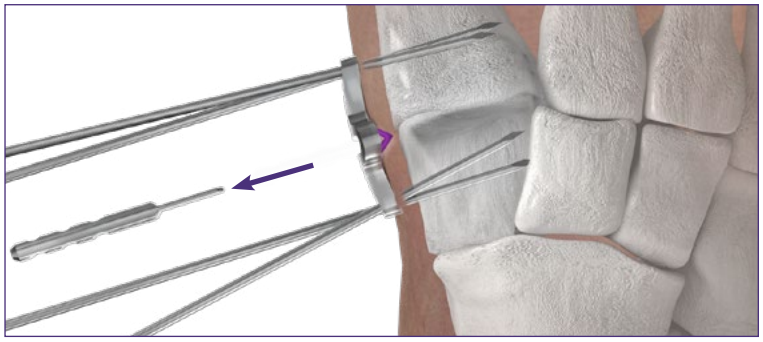


Slide the burr guide over the burr guide paddle with the "M" side of the burr guide oriented distally. Advance the burr guide over the burr guide paddle until the under-surface of the burr guide contacts the skin, ensuring that the burr guide paddle remains in the joint.



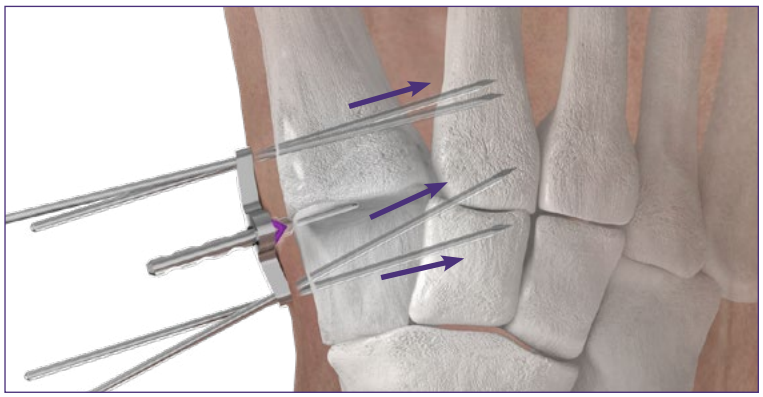
Place a 1.6 mm K-wire (or olive wire) into the laser marked hole of the cuneiform side of the burr guide marked "C". Place a second 1.6 mm K-wire (or olive wire) into the laser marked hole of the metatarsal side of the burr guide.

OPTIONAL: Place two additional 1.6 mm K-wires into the remaining unmarked holes of the burr guide for converging fixation, if desired.

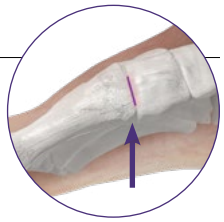


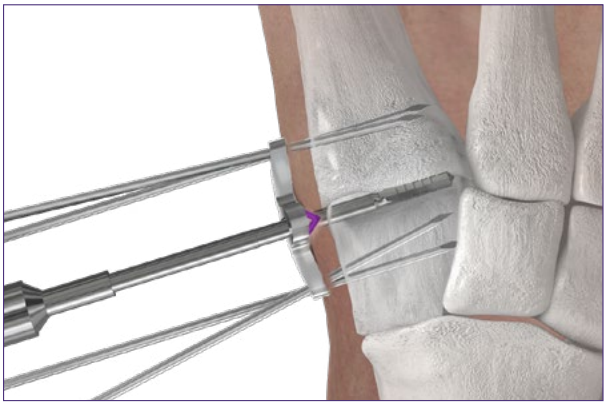
Remove the burr guide paddle when the burr guide is securely fastened to the 1st TMT joint.

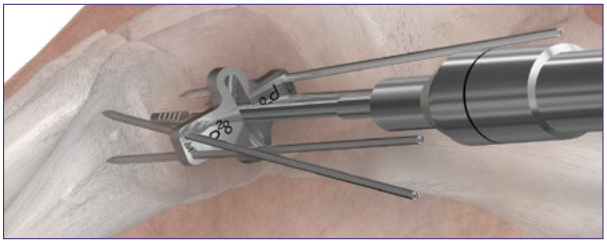
OPTIONAL: Modest correction of IM angle can be performed at this point prior to preparation of the joint by manipulating the first metatarsal and driving one or more guide pins into the second metatarsal base.



CARTILAGE RESECTION/JOINT PREPARATION





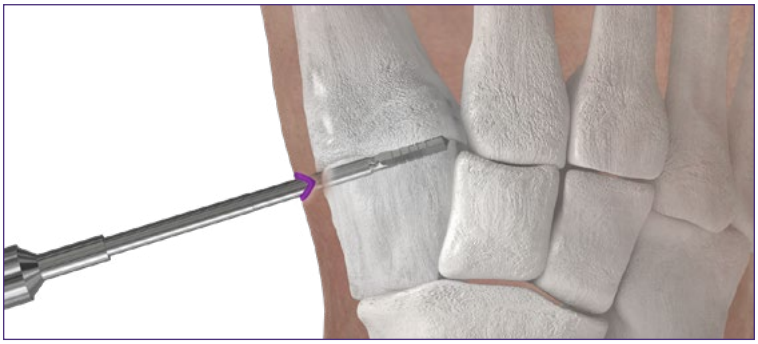


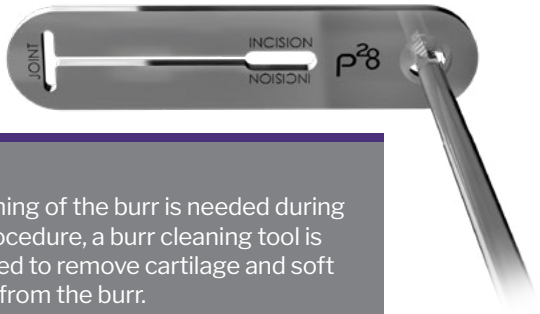
Retrieve the burr. Confirm that the burr is attached to an approved power source and that the power setting is at the lower end of the suggested range of speed.

It is recommended to perform portions of this step under fluoroscopy to occasionally check burr location. Insert the burr into the burr guide, allowing for rotation of the burr to start prior to contacting bone. Drive the burr into the joint until it impacts but does not penetrate the hard bone on the base of the second metatarsal. Confirm location fluoroscopically then sweep. Upon contacting the 1st TMT joint, sweep the joint dorsally and plantarly. An initial sweep is made to debride approximately 60% of the joint.

Confirm medial to lateral burr travel using fluoroscopy. Irrigation with saline through an angiocath tube is recommended to ensure all bony debris is removed.

The dorsal and plantar aspects of the joint will not be accessible through the guide. Remove the burr guide by removing the K-wires (or olive wires). Additional resection can be performed by re-inserting the burr into the 1st TMT joint without the burr guide and continuing burr movement along the path of the joint. Use fluoroscopy to check for adequate joint resection and to help prevent lateral over-resection. Irrigation should again be performed using saline through an angiocath tube to remove any remaining cartilage in the joint.





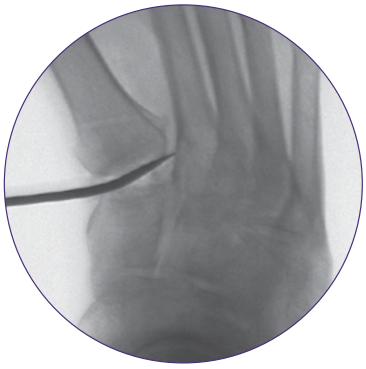
NOTE:
If cleaning of the burr is needed during the procedure, a burr cleaning tool is provided to remove cartilage and soft tissue from the burr.

If bone graft is desired, placement can be performed at this time.

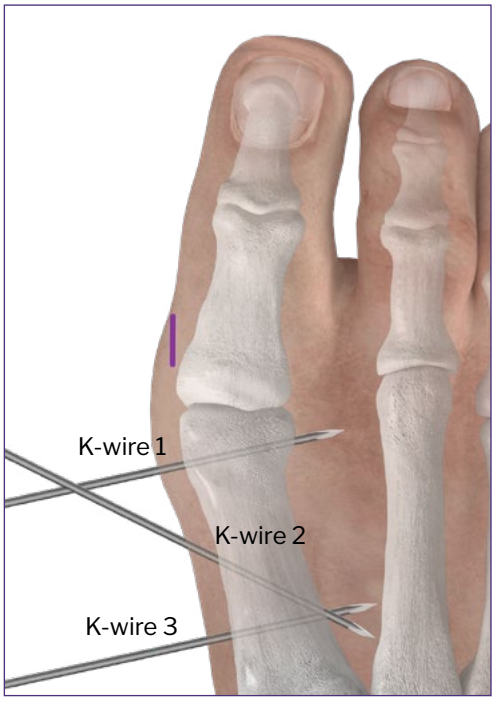
NOTE:
The provided curette and curved osteotome is available for additional joint preparation and fenestration following use of the burr. Excess debris should be removed with a curette.

DEFORMITY CORRECTION AND TEMPORARY FIXATION

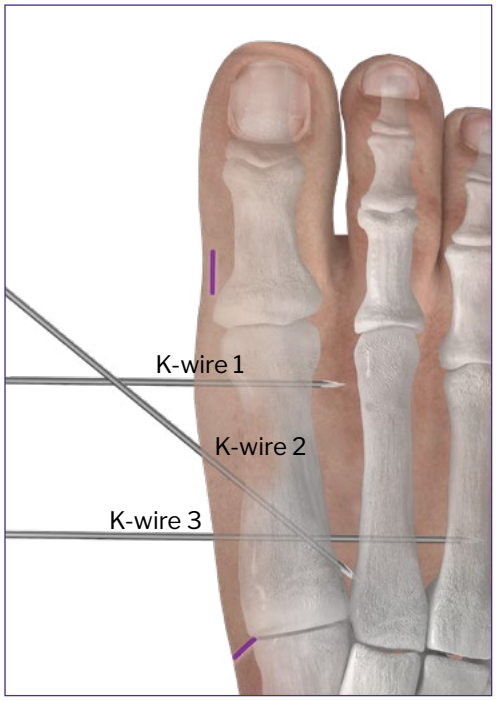
Reduction of the 1-2 intermetatarsal angle should be performed, per surgeon's preferred technique. Use the provided curved osteotome through the medial incision to break up ligamentous attachments between the 1st and 2nd metatarsals until free. Additional joint preparation using the burr may be necessary.



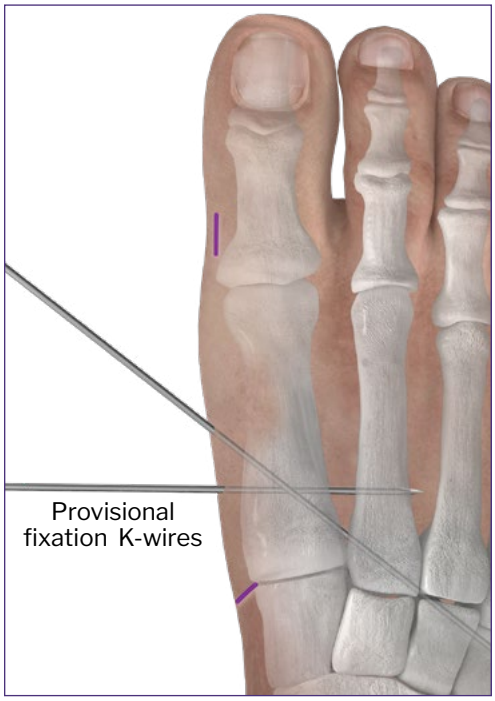
Curved Osteotome Use for Intermetatarsal Ligament Release



Rotation and angulation should both be assessed and corrected. The toe should be controlled while the surgeon's thumb is used to displace the metatarsal head laterally (K-wire 1). If a significant pronation deformity is present, a K-wire can be placed 2 cm proximal to the metatarsophalangeal joint at a 45° angle to the shaft (K-wire 2). This wire is then used as a joystick to concurrently supinate the metatarsal while it is displaced laterally.



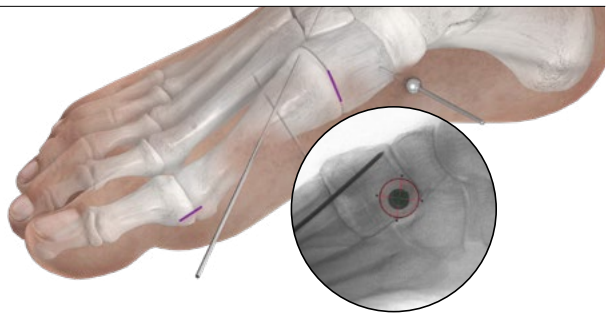
To achieve an angular correction, the base of the metatarsal should be stabilized to prevent it from displacing laterally as well (K-wire 3). The curved ostetotome may be used through the incision to lever the metatarsal base medially or, alternatively, an additional wire may be placed into the lateral aspect of the metatarsal base and used to push it medially.



While the deformity correction is being held, provisional fixation should be applied. Two K-wires are typically used and are placed approximately 1.5 – 3 cm distal to the tarsometatarsal joint. Both are kept in the plantar half of the bone to avoid the lateral nail placement. One wire is placed between the first and second metatarsal bases, while another is placed more obliquely toward the cuneiforms.

NAIL ALIGNMENT AND POSITIONING

Obtain the sphere wire and place 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 the sphere wire into the medial cuneiform once the correct start point is verified. Insert until the thicker portion contacts bone, as shown above. ***Do not over insert.***

PHANTOM NAIL INCISION PLACEMENT

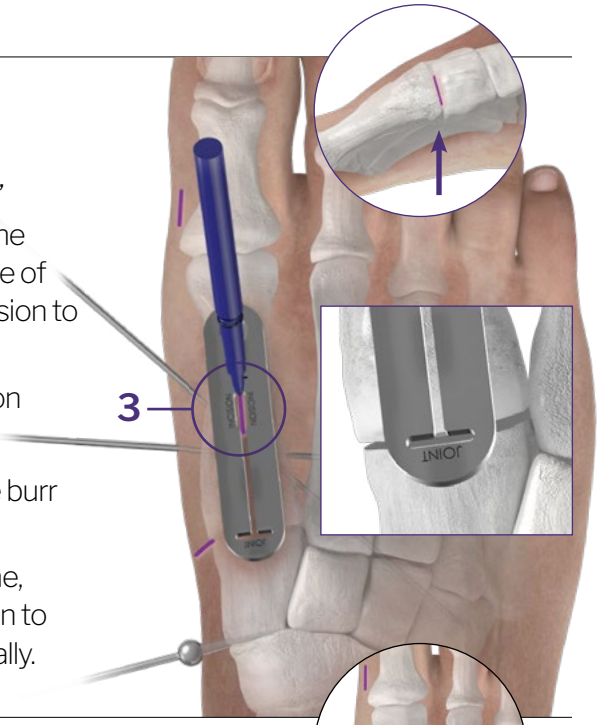
3 Phantom Nail Incision 8 mm

Retrieve the burr cleaning tool/incision marking guide, and point the "INCISION" marking distally over the metatarsal. Under fluoroscopy, align the 1st TMT joint line with the horizontal "JOINT" line of the template, while aligning the vertical midline of the template with the long axis of the 1st metatarsal. The guide will allow the incision to be placed with a starting point 23 mm distal to the joint.

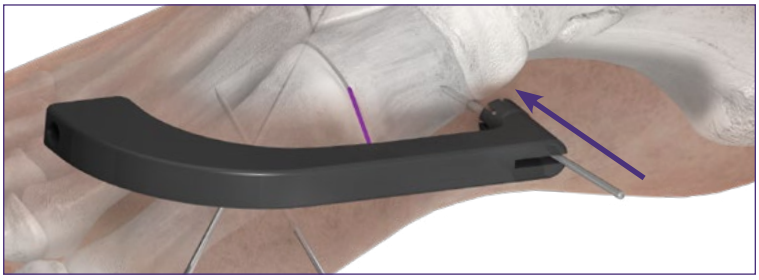
OPTIONAL: A 0.045" K-wire may be placed in the joint space to confirm incision marking guide placement.

Incise through the guide an incision line the length of the "INCISION" slot on the burr cleaning tool/incision marking guide.

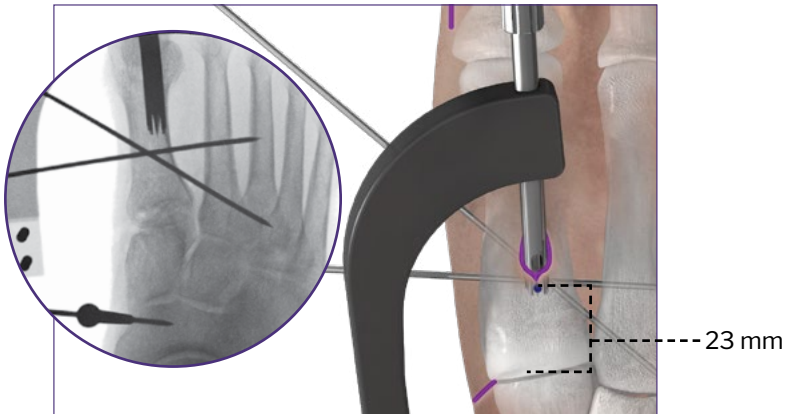
Make an 8 mm longitudinal incision at the lateral aspect of the drawn incision line, just lateral to the extensor hallucis longus (EHL) tendon. Perform blunt dissection to access the dorsal surface of the 1st metatarsal, retracting the EHL tendon medially.

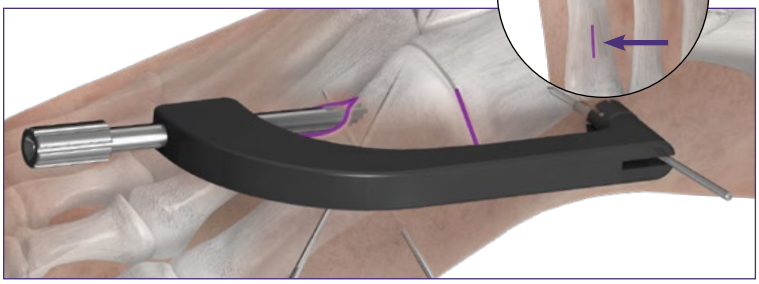


PHANTOM NAIL PREPARATION



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.

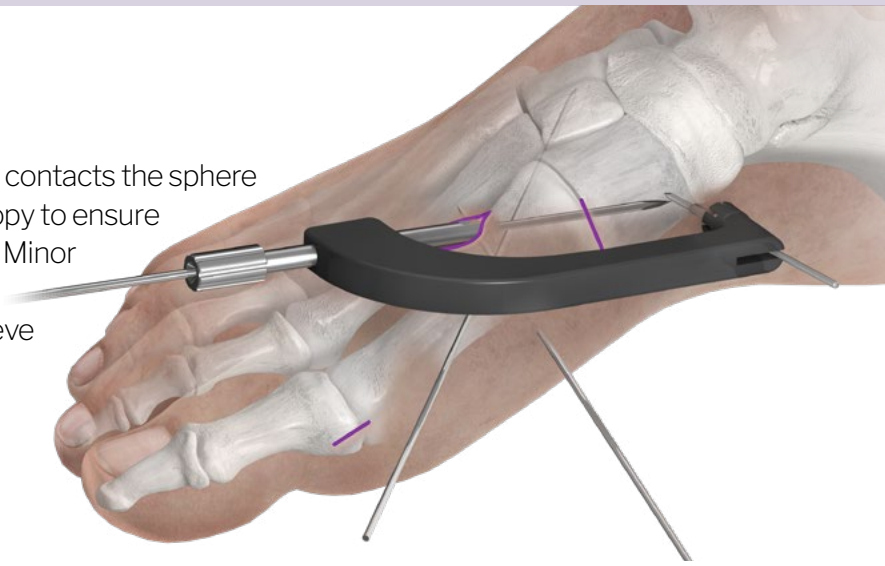




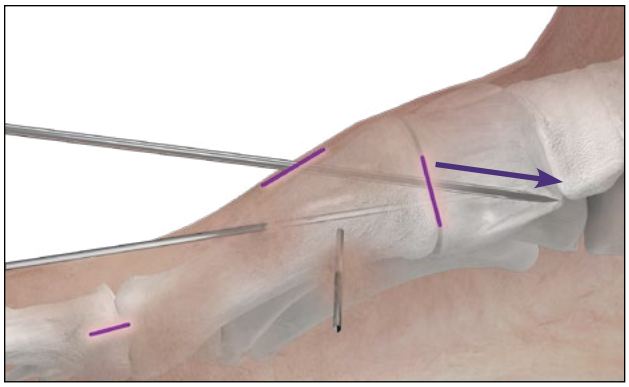
Insert the sleeve insert into the distal end of the polyaxial targeting guide. Allow the sleeve insert to be inserted into the incision to achieve the desired start position. Check the sleeve insert position on fluoroscopy to ensure that it is in contact with the first metatarsal. The wire should be driven in 1-2 mm initially while the position is checked. This allows the position to be easily adjusted if necessary.

Confirm the start point of the 2.3 mm K-wire is an adequate distance from the 1st TMT joint (approximately 23 mm) **and slightly lateral to the midline** of the metatarsal.

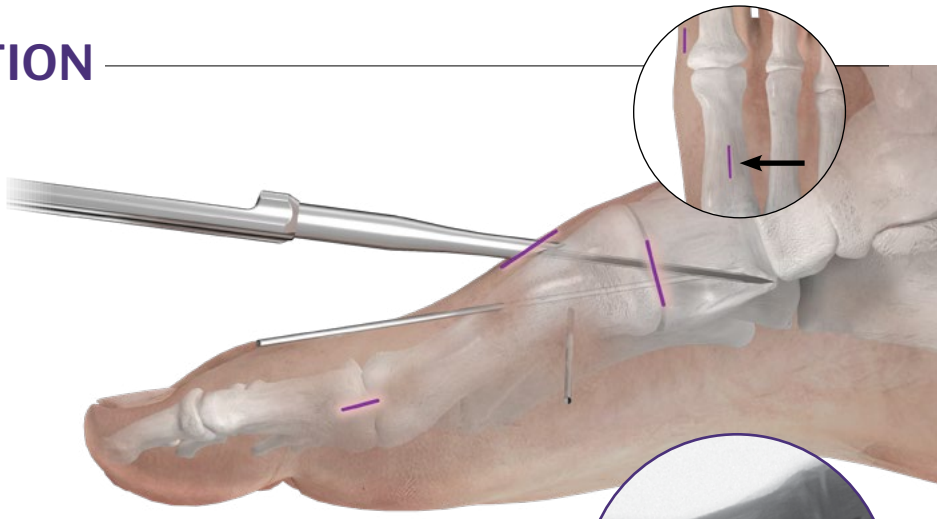
Drive the 2.3 mm K-wire through the sleeve insert until it contacts the sphere wire. If the sphere wire is not contacted, check fluoroscopy to ensure that re-pinning is not necessary due to major deflection. Minor deflection may occur due to the length of the K-wire. Confirm K-wire position using fluoroscopy.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

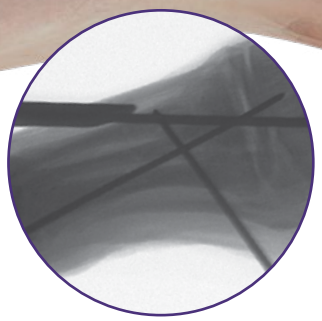


PHANTOM NAIL PREPARATION



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



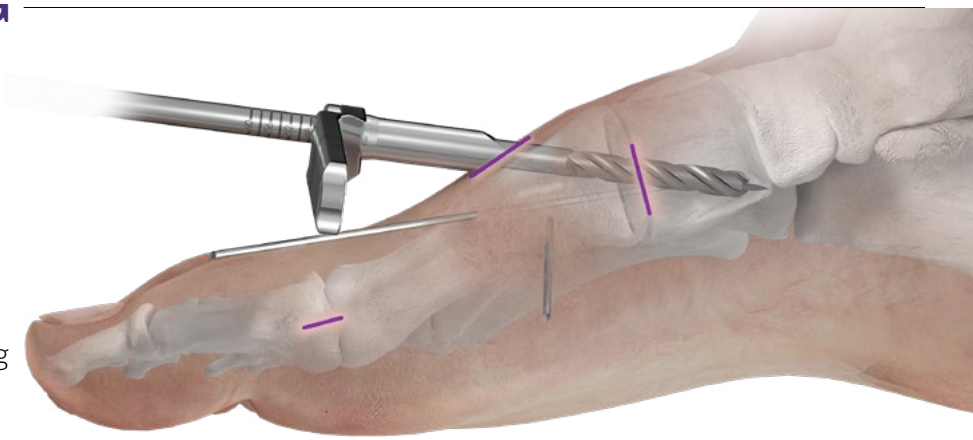


Confirm the 2.3 mm K-wire position under fluoroscopy. Measure the 2.3 mm K-wire length using the provided Phantom Nail depth gauge. Confirm that the depth gauge is contacting the bone using fluoroscopy.

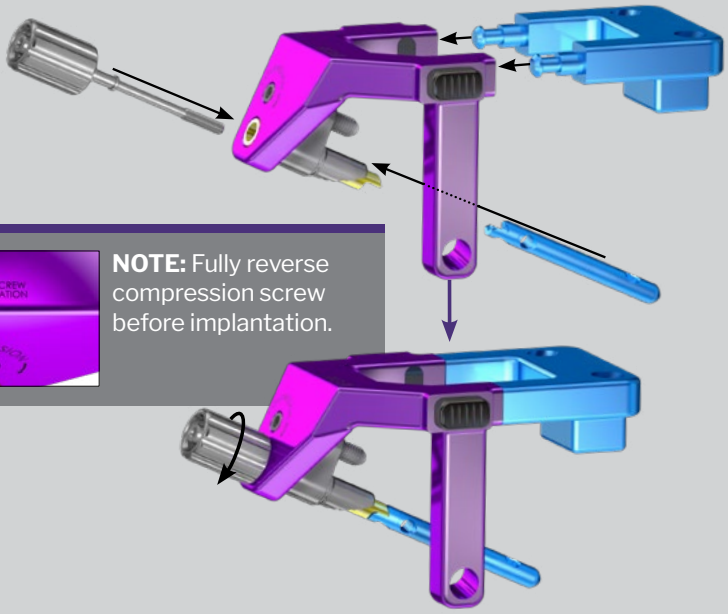
PHANTOM NAIL DRILLING

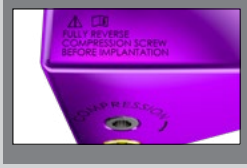
Drill over the 2.3 mm K-wire using the cannulated nail drill and tissue protector. The tissue protector is designed such that the sloped surface matches the slope of the 1st metatarsal and the handle will point either medial or lateral.

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 the 2.3 mm K-wire.



OUTRIGGER/NAIL ASSEMBLY





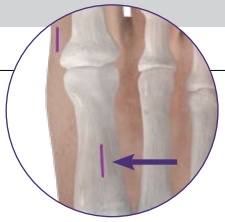
NOTE: Fully reverse compression screw before implantation.

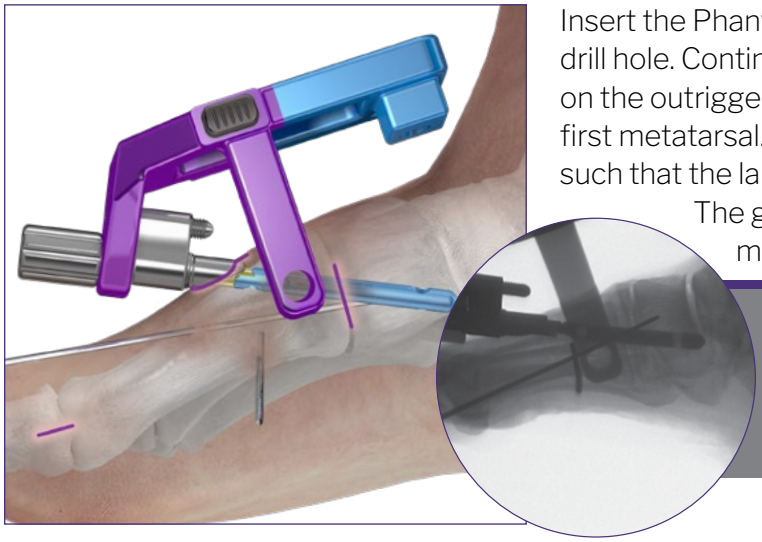
PERFORM ON BACK TABLE:

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.

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.

PHANTOM NAIL INCISION PLACEMENT





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. Check complete entry of the nail using fluoroscopy such that the larger diameter silver contoured piece is flush to the bone. The gold portion of the outrigger's should be 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 under fluoroscopy, additional drilling may be necessary. The tip of the nail should be at the far cortex of the medial cuneiform.

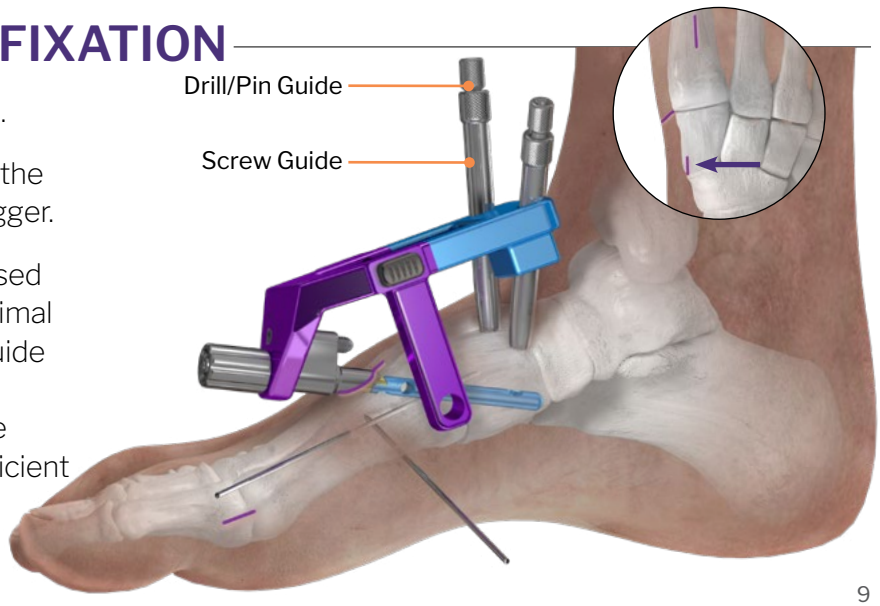
Confirm Phantom Nail size and placement using fluoroscopy.

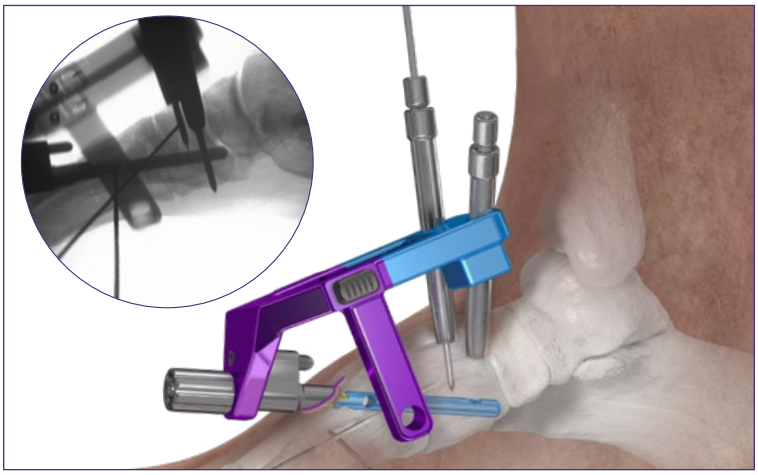
PHANTOM NAIL PROXIMAL FIXATION

Insert the two drill-pin guides into the screw guides.

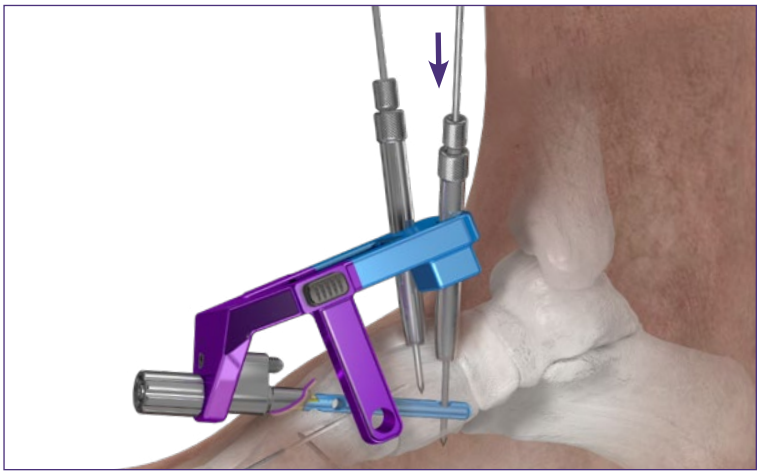
Place a screw guide/drill-pin assembly into each of the proximal holes in the medial cuneiform of the outrigger.

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



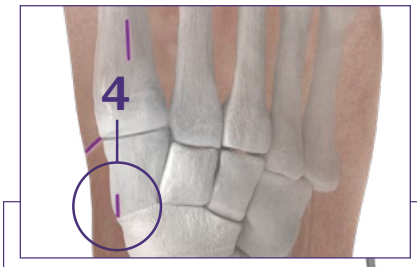


Insert a 2.75 mm drill-pin approximately 5 mm through the cortex into the lateral drill-pin guide, aligning the guide and drill-pin with the tibial shaft. This pin does not penetrate the nail.



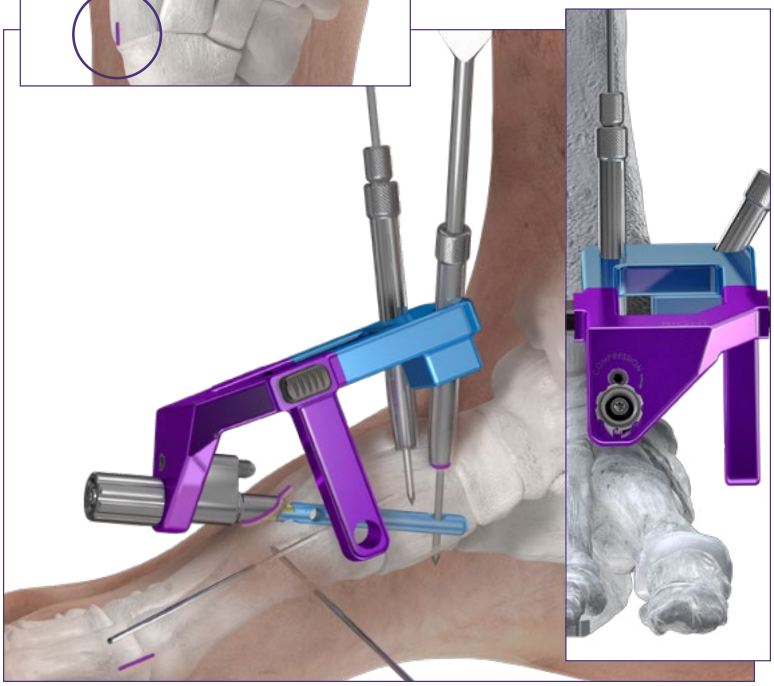
Using a second 2.75 mm drill-pin, drill bicortically through the medial drill-pin, penetrating the nail and retaining the drill-pin in the medial cuneiform.

PHANTOM NAIL PROXIMAL INSERTION

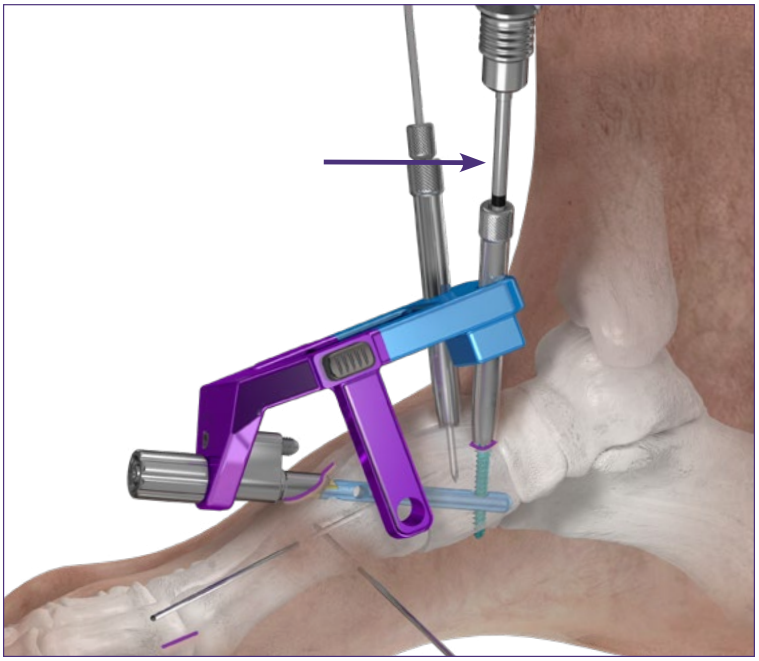


4 Medial Cuneiform Incision for Threaded Peg Placement

Make an approximately 5-8 mm incision around the medial drill pin.
Use blunt dissection to spread the tissue below the incision until bone is reached.

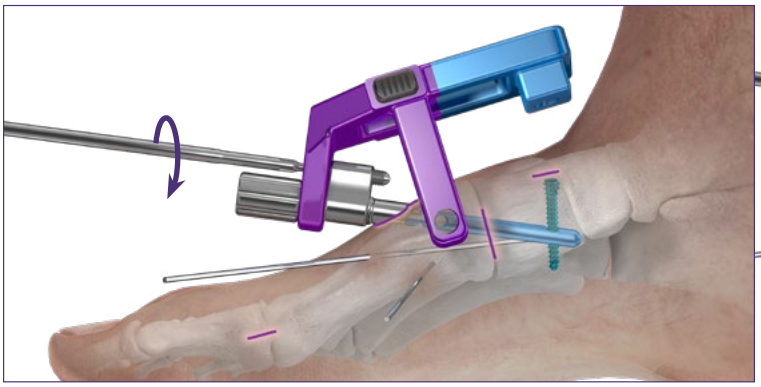


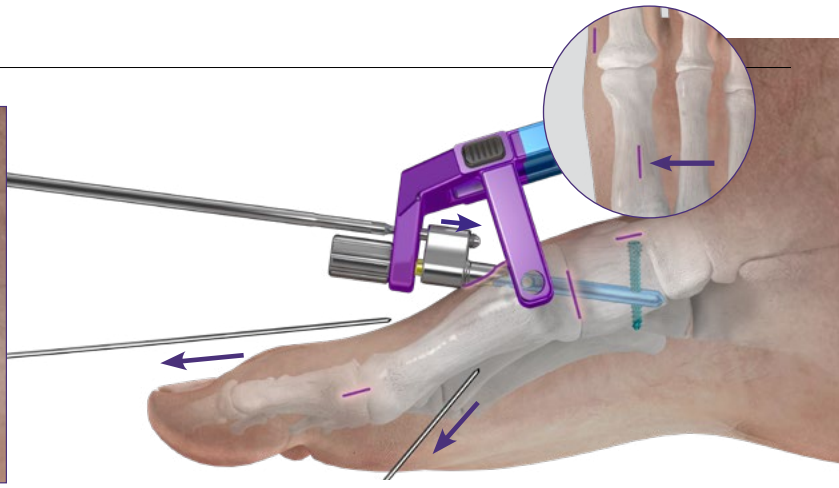
Remove the medial drill-pin guide. Use fluoroscopy to check the depth of the medial drill-pin, ensuring that it is bicortical. When depth is correct, measure for threaded peg length using the cannulated (shown) or standard depth gauge through the screw guide.



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 fixed bicortically. Confirm threaded peg length and position using fluoroscopy. Remove the drill pin in the distal lateral hole.

COMPRESSION

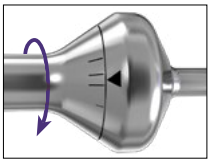




Tighten the top screw on the outrigger to create a slight amount of compression.

NOTE:
Tighten the top screw in the outrigger to create enough compression to allow the bones to contact one another. The temporary fixation K-wires can now be removed without losing the rotational correction.

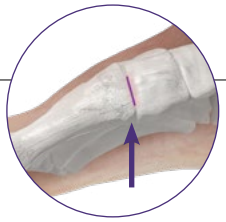
Remove the temporary fixation K-wires. Continue tightening with the torque indicating driver until two-finger tightness is achieved.



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

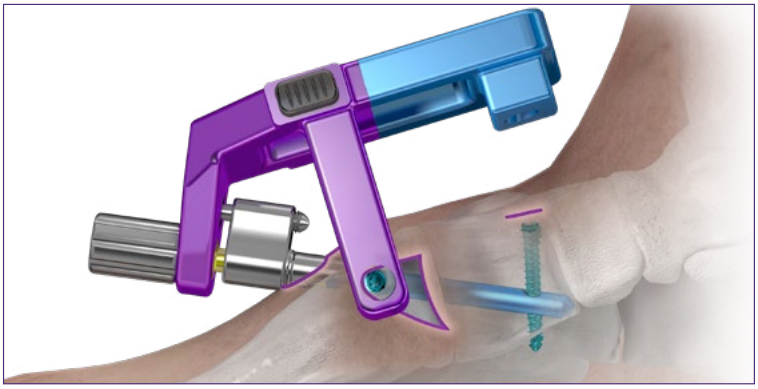
Compressing the outrigger using the torque indicating driver allows the surgeon to read when they are in the correct zone of compression by turning the driver until the triangular indicator is centered between the longer central markings.

PHANTOM NAIL DISTAL FIXATION

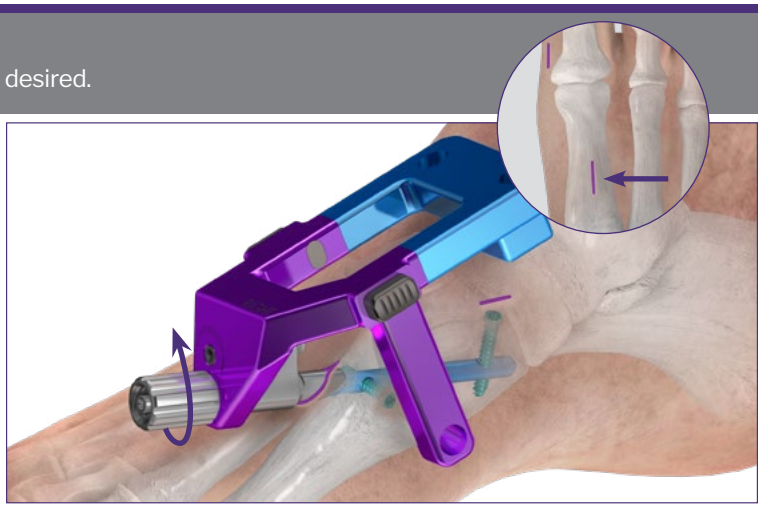


Insert the screw guide and drill-pin guide into the medial hole of the outrigger assembly through the incision for joint preparation, if skin tension allows. Insert a drill-pin bicortically into the drill-pin guide.

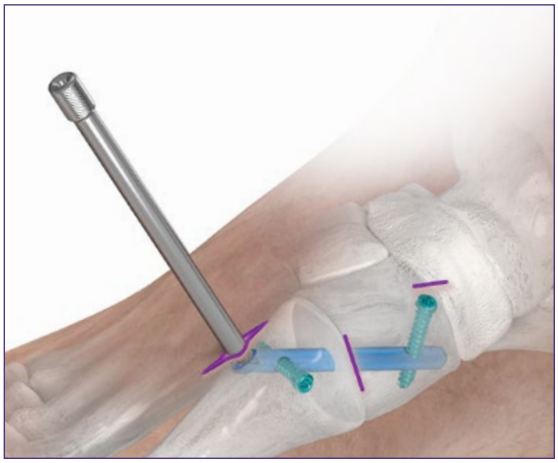
NOTE:
An additional incision can be made for medial peg insertion, if desired.



Measure for screw length using the cannulated depth gauge. Insert a threaded peg into the Phantom Nail through the incision. Confirm bicortical threaded peg placement using fluoroscopy.

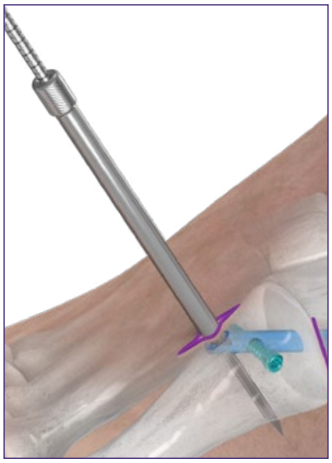


Remove the outrigger from the Phantom Nail by turning the thumb screw on the outrigger counter-clockwise until it is released from the Nail. As an alternative option, a driver may be inserted to remove the outrigger.

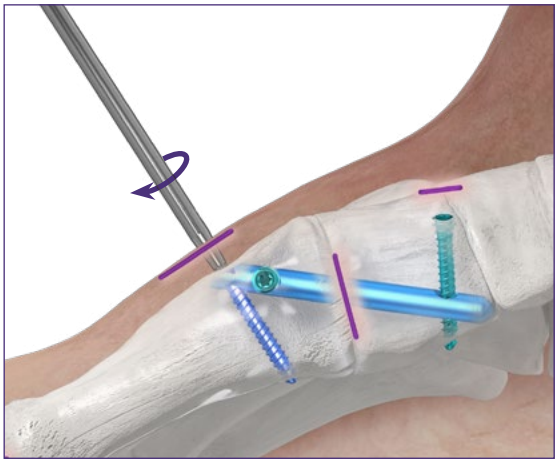


Thread the locking guide into the distal hole on the Phantom Nail, at an angle of 45° from the long axis of the Nail.

TIP: Insert the drill-pin into the hole in the nail by hand first, followed by the locking guide.



Drill bicortically using the drill-pin.



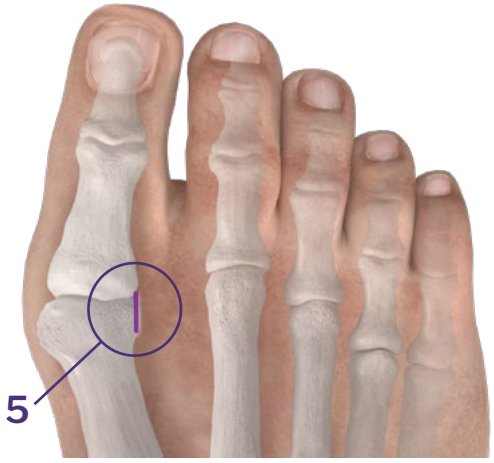
Remove the locking screw guide. Measure screw length using the standard hook depth gauge. Insert a 3.5 mm locking screw bicortically into the distal hole of the Phantom Nail to serve as a second point of fixation in the metatarsal. Confirm implant placement and size using fluoroscopy.

OPTIONAL DISTAL LATERAL RELEASE

NOTE:
Distal soft tissue release is optional and may be performed at different stages of the procedure, per surgeon's preference.

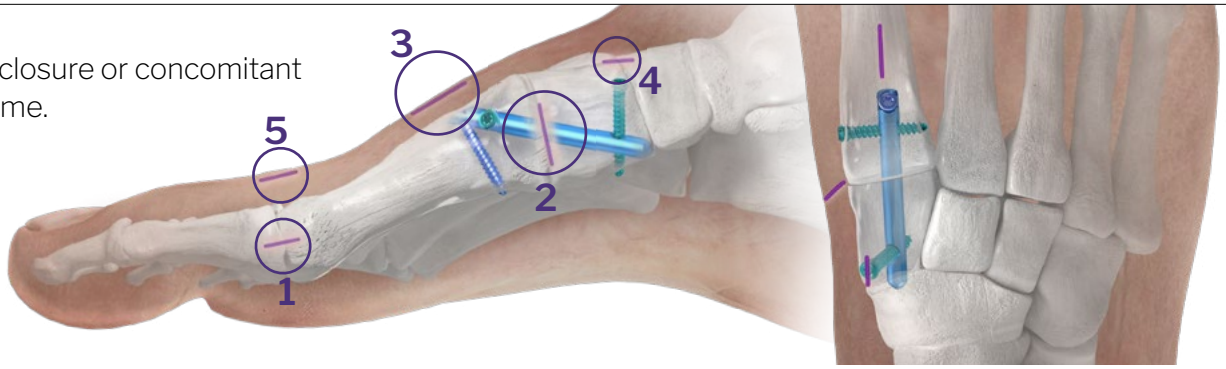
5 Incision for Lateral Release: 5 – 8 mm

Incision location is determined by palpating the 1st metatarsophalangeal (MTP) joint. Make a longitudinal stab incision lateral to the extensor hallucis longus (EHL) tendon at the head of the 1st MTP joint. Perform blunt soft tissue dissection to access the MTP joint capsule. Penetrate the MTP joint capsule, and with the knife in the capsule, make a lateral sweeping motion to cut the capsule and release the adductor tendon.



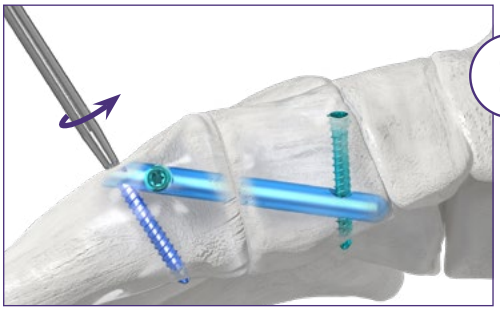
CLOSURE

Proceed to incision closure or concomitant procedures at this time.



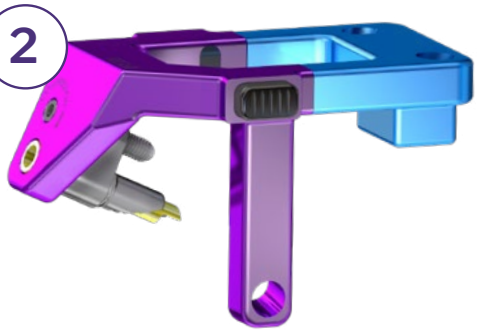
REMOVAL/REVISION

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

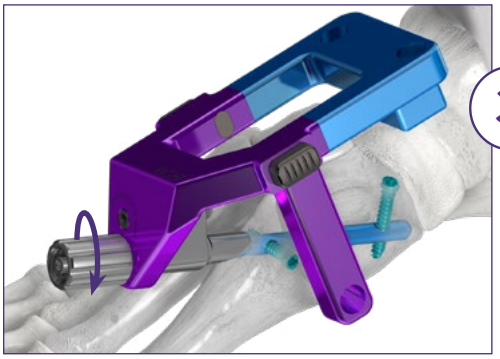


1 Remove the locking screw at the distal aspect of the Phantom Nail using the provided solid driver. Turn the solid driver counterclockwise until the screw is removed.

2

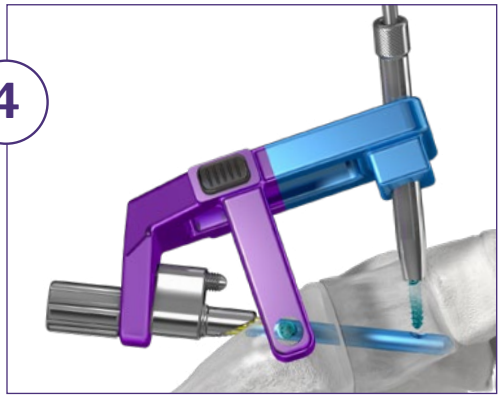


Retrieve the outrigger for the Phantom Nail for the patient side. Retrieve the outrigger slider that corresponds to the color of the implanted Phantom Nail and patient side. If size is unknown and color is unable to be determined, use fluoroscopy to determine Phantom Nail length using a measuring device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

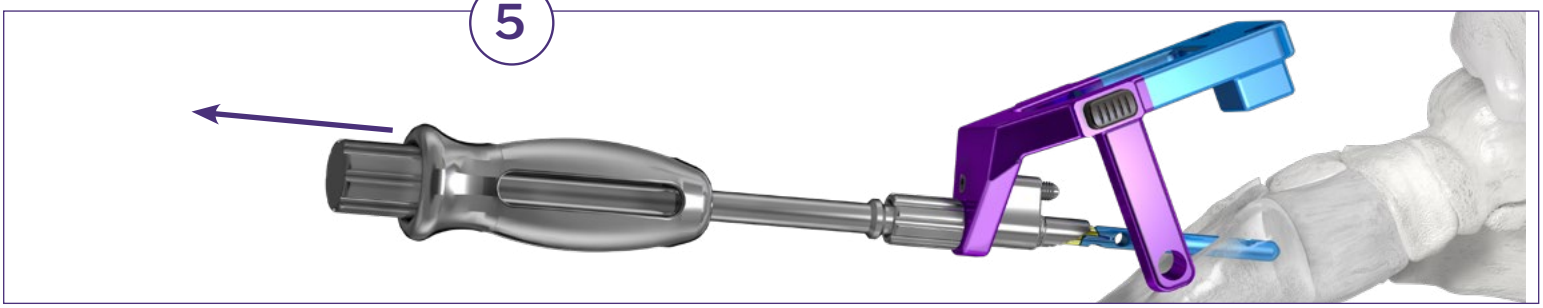
4



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 counter-clockwise 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.

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.

5



THREADED PEG AND LOCKING SCREW CADDY

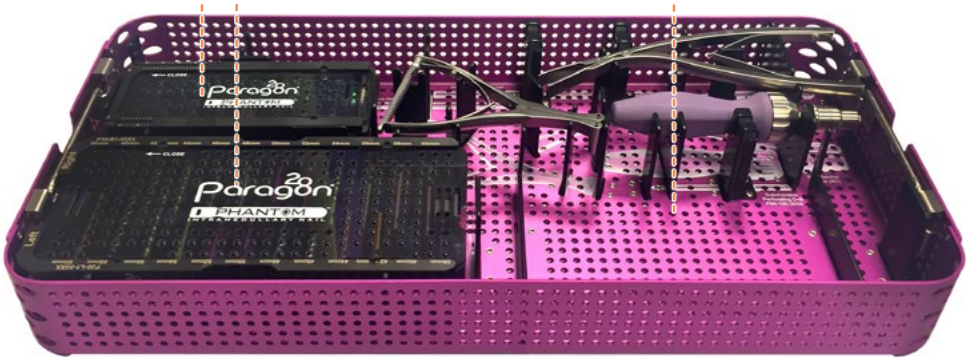
Threaded Pegs are available in lengths 10–46 mm in 2 mm increments. 3.5 mm Locking Screws range from 10–26 mm in length in 2 mm increments.

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.

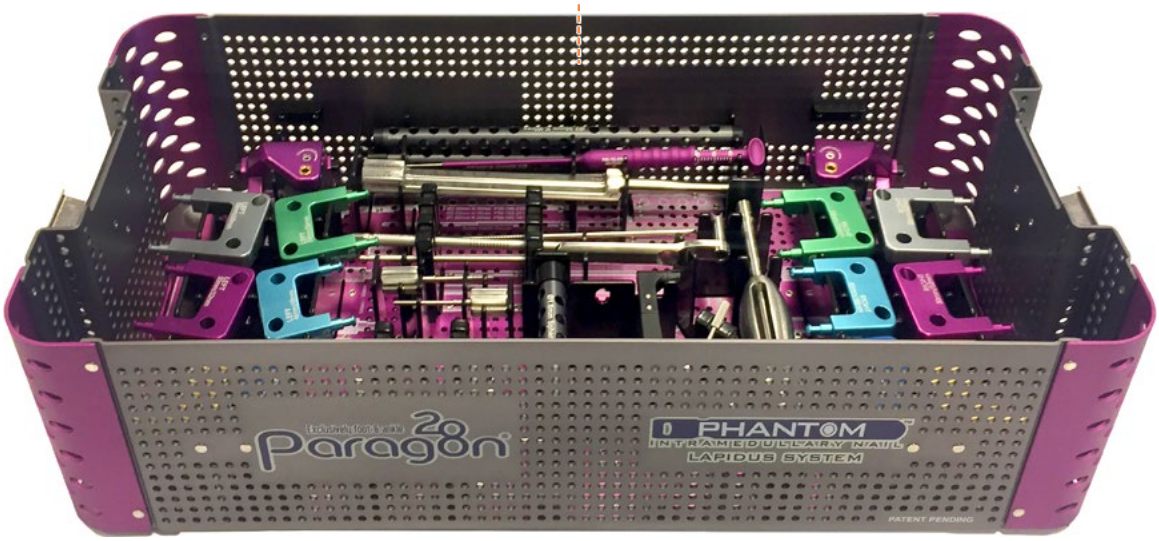
MIS LAPIDUS CADDY

The Shannon-Style Burrs, Burr Guide, Burr Guide Paddle, Burr Cleaning Tool/Incision Marking Guide, 6 mm Curved Osteotome, Currette, olive wires and K-wires are all located within the MIS Lapidus Caddy.



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.

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

INDICATIONS FOR USE

The Small Bone Phantom® 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, nonunions, pseudarthroses and malunions by revision, joint fusion or reconstruction procedures.

CONTRAINDICATIONS

The Paragon 28® Small Bone Phantom® Intramedullary Nail System implants are not designed or sold for any use except as indicated. Use of the Small Bone Phantom® 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.

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, guide wires, and screws are to be treated as sharps.
- **Do not use other manufacturer's instruments or implants in conjunction with the Small Bone Phantom® Intramedullary Nail System.**

MR SAFETY INFORMATION

The Small Bone 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 Small Bone Phantom® Intramedullary System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

MIS LAPIDUS SYSTEM

PHANTOM®

INTRAMEDULLARY NAIL

PATENTED, DESIGNED & EXCLUSIVELY DISTRIBUTED BY

Exclusively foot & ankle Paragon 28®

P30-STG-0003 RevC [2021-06-30]

Paragon 28, Inc.
14445 Grasslands Dr.
Englewood, CO 80112
(855) 786-2828

ENDNOTES:

1 Internal data on file, TR-17060501

DISCLAIMER

The purpose of the MIS Lapidus System Surgical Technique Guide is to demonstrate the optionality and functionality of the MIS Lapidus instrumentation. Although variations in placement and use of the Small Bone Phantom® Intramedullary Nail can be performed, the fixation options demonstrated in this technique were chosen to demonstrate the functionality of the system and for simplicity of explanation. Other uses for the Small Bone Phantom® Intramedullary Nail can be employed, appropriate for the size of the device. CAUTION: Federal Law (USA) restricts this device to sale and use by, or on the order of, a physician