

Phoenix™ Ankle Arthrodesis Nail System

Featuring Dual Stage CoreLock™ Technology

Surgical Technique

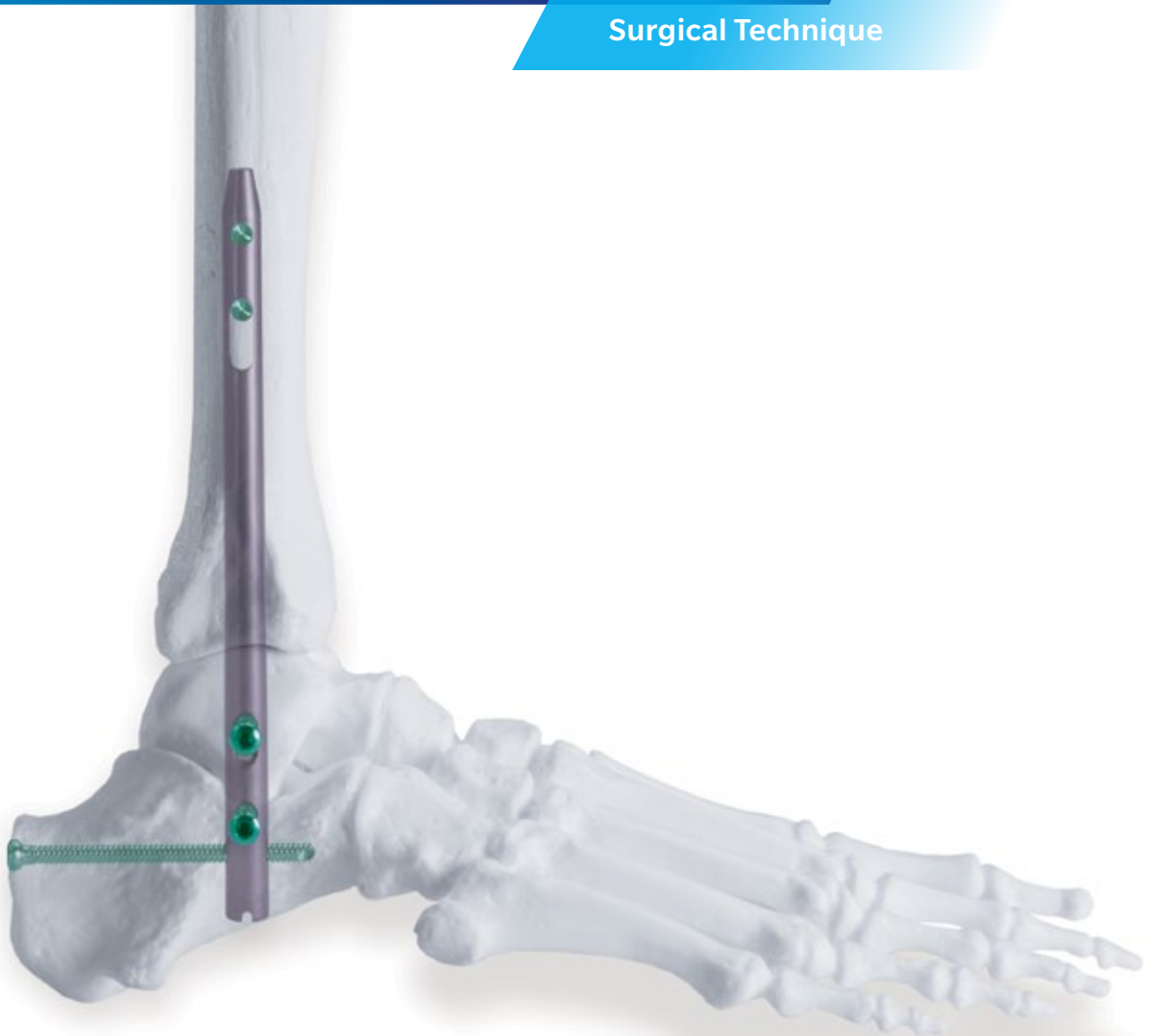


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Introduction



The goals of tibiototalcalcaneal arthrodesis are the relief of pain and deformity, and the development of a solid fusion. Numerous techniques exist for isolated tibiotalar arthrodesis, a procedure that leaves some motion at the subtalar joint. A number of clinical situations warrant inclusion of the subtalar joint as well. Disabling arthritis, subluxation or deformity of not only the tibiotalar, but also the talocalcaneal joint, are some of the indications for fusing the subtalar joint along with the ankle. In patients with AVN, or prior failed ankle fusion, the surgeon often seeks the extra purchase of calcaneal bone in achieving a fusion.

Intramedullary nailing has proved to be a generally accepted method of fixation for achieving tibiototalcalcaneal arthrodesis or tibiotalar arthrodesis. A nail inserted through the plantar aspect of the foot can afford excellent stability, position, and alignment. The process of tibiototalcalcaneal arthrodesis using an intramedullary nail, usually involves an ankle arthrotomy, preparation of the joint surfaces, and then placement of the nail through a plantar incision. Screws are placed proximally into the tibia in a standard fashion and, after compression, the nail can be mechanically locked distally with screws into the calcaneus and the talus.

The Phoenix Ankle Arthrodesis Nail is composed of titanium alloy and features proprietary CoreLock technology. This unique dual stage locking mechanism is pre-assembled and embedded in each nail, and can provide up to 7.0 mm of internal tibiotalar compression, followed by independent locking of the calcaneal screws. In addition to a static screw site proximally, the nail offers a 10 mm dynamic compression slot, both of which accommodate newly designed 5.0 mm double lead cortical screws.

Capable of treating varying patient anatomies, the Phoenix Ankle Arthrodesis Nail is universal and available in 10mm, 11mm, and 12 mm diameters—all of which are available in lengths of 150 mm - 300mm.

The system features a strong, lightweight radiolucent Targeting Arm that permits radiographic visualization in multiple planes, and can provide 30 mm of axial compression across both the ankle and sub-talar fusion sites. Variable templating of oblique screws tangential to the nail can also be accomplished when there is a need for additional fixation and control of rotation. With easy to use color-coded instrumentation conveniently contained in a single tray, the Phoenix Ankle Arthrodesis Nail System, addresses both patient and surgeon needs.

Indications and Contraindications

INDICATIONS

PHOENIX ANKLE ARTHRODESIS NAIL SYSTEM

The Phoenix Ankle Arthrodesis Nail System is indicated for tibiotalar calcaneal arthrodesis (fusion).

Specific indications include:

1. Avascular necrosis of the talus
2. Failed total ankle arthroplasty
3. Trauma (malunited tibial pilon fracture)
4. Severe deformity or instability as a result of talipes equinovarus, cerebral vascular accident, paralysis or other neuromuscular disease
5. Revision ankle arthrodesis
6. Neuroarthropathy
7. Rheumatoid arthritis
8. Osteoarthritis
9. Pseudoarthrosis
10. Post-traumatic arthrosis
11. Previously infected arthrosis
12. Charcot foot
13. Severe endstage degenerative arthritis
14. Severe defects after tumor resection
15. Pantalar arthrodesis

CONTRAINDICATIONS

1. Infection.
2. Patient conditions including blood supply limitations, and insufficient quantity or quality of bone.
3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
4. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of the device.

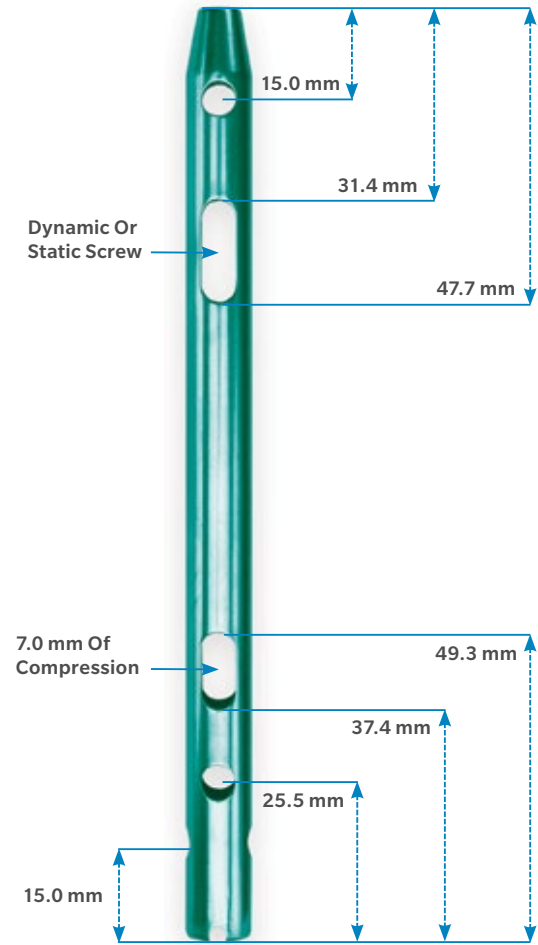
Additional contraindications for Phoenix Ankle Arthrodesis Nail System:

1. Dysvascular limb.
2. Severe longitudinal deformity.
3. Insufficient plantar heel pad.
4. Where an isolated ankle or subtalar fusion can be performed.

Implant Specifications

Nails

- Nail Lengths: 150 mm to 300 mm (30 mm increments)
- All nails are offered in 10 mm, 11 mm, and 12 mm diameters
 - Distal Diameter for 10 mm and 11 mm nails is 11 mm
 - Distal Diameter for 12 mm nail is 12 mm



End Caps

3.5 mm Inserter Connector retains head of End Cap to facilitate easier insertion



Screws

- 20 mm – 60 mm (Available in 2.0 mm increments)
- 60 mm – 110 mm (Available in 5.0 mm increments)
- 5.0 mm Diameter



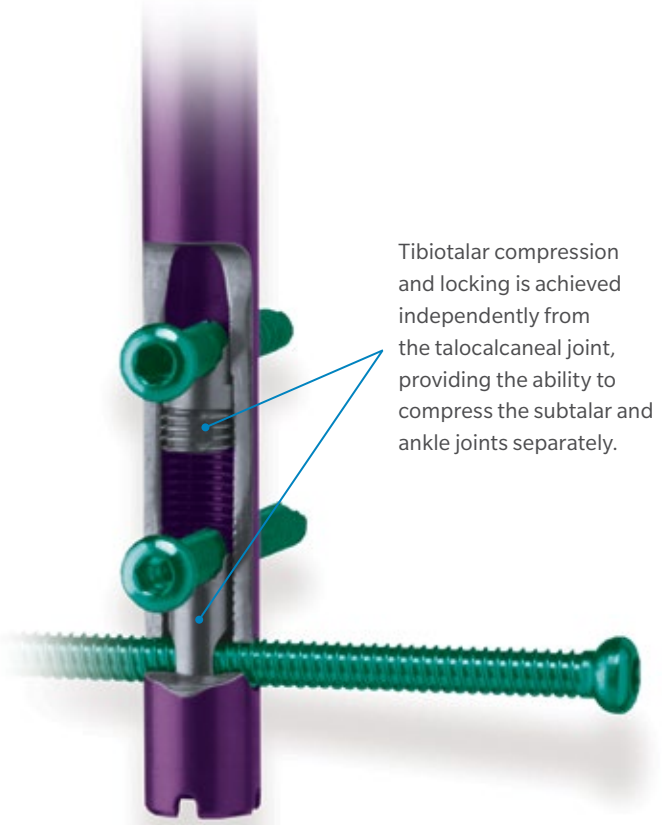
System Design Features

Following suit with the Phoenix Tibial and Femoral Nail offerings, this system features proprietary CoreLock technology which represents the only dual stage internal compression/locking mechanism currently available today.



Pre-assembled/pre-embedded CoreLock mechanism is capable of 7.0 mm of inboard tibiotalar compression.

Once the CoreLock mechanisms are engaged, the nail converts to a solid, fixed angle device.



Tibiotalar compression and locking is achieved independently from the talocalcaneal joint, providing the ability to compress the subtalar and ankle joints separately.

CoreLock mechanisms are designed with serrated surfaces that interdigitate with the screw threads for a secure, mechanical lock—not a friction lock.

This feature also allows for screws to be removed without having to disengage compression and/or locking mechanisms.



- Fully threaded 5.0 mm screws used for proximal and distal interlocking
- Aggressive double-lead thread design facilitates rapid insertion
- Threaded capture driver prevents screw disengagement during insertion



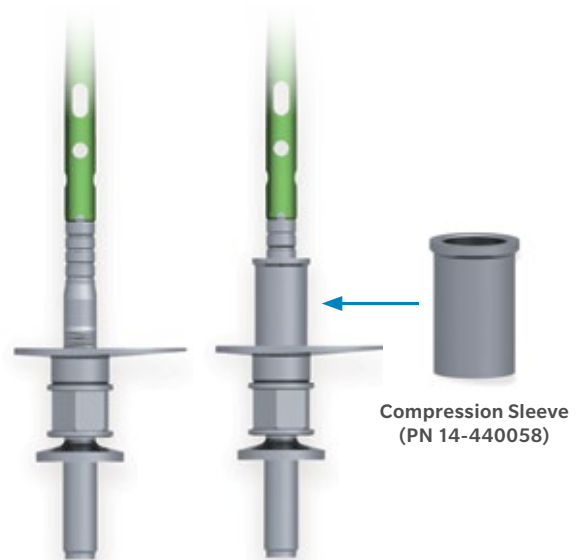
- Interior of screw head is threaded for retention to inserter
- Solid 3.5 mm Hex Inserter is also available

The Phoenix Ankle Arthrodesis Nail is inserted with a lightweight radiolucent Targeting Arm that permits radiographic visualization in multiple planes

- Capable of targeting nails up to 210 mm in length
- Color-coded indicators for easy discernment
- In addition to the 7.0 mm of inboard compression provided by the CoreLock mechanism, 30 mm of compression across the tibotalar and subtalar joints can be achieved externally with the Targeting Arm's compression nut



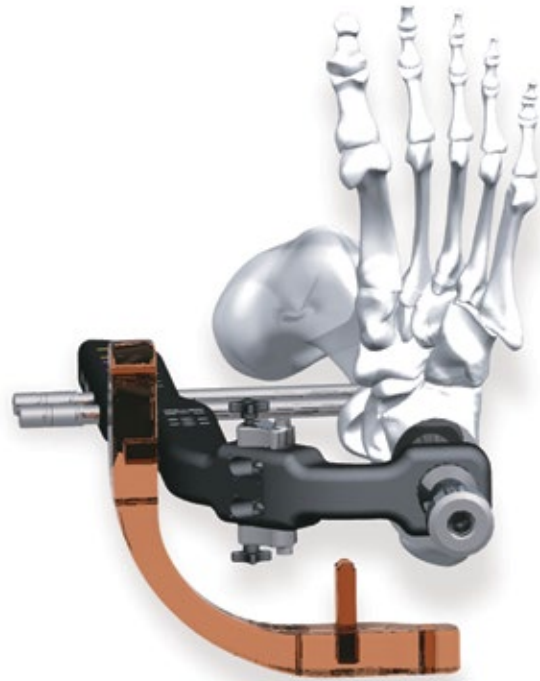
- A 3.2 mm Guide Wire or the Wire Pusher (PN 41027) can be inserted through the Targeting Arm to indicate the countersunk depth of the distal end of the nail
- Grooved countersinking indicators on the Targeting Jig Nose can be seen clearly in fluoroscopic views



- If the surgeon wishes to compress the calcaneus bone directly, the Compression Sleeve (PN 14-440058) can be stacked on top of the Compression Hat to exert force directly to the bone through the incision

PA Screw Alignment Guide Arm

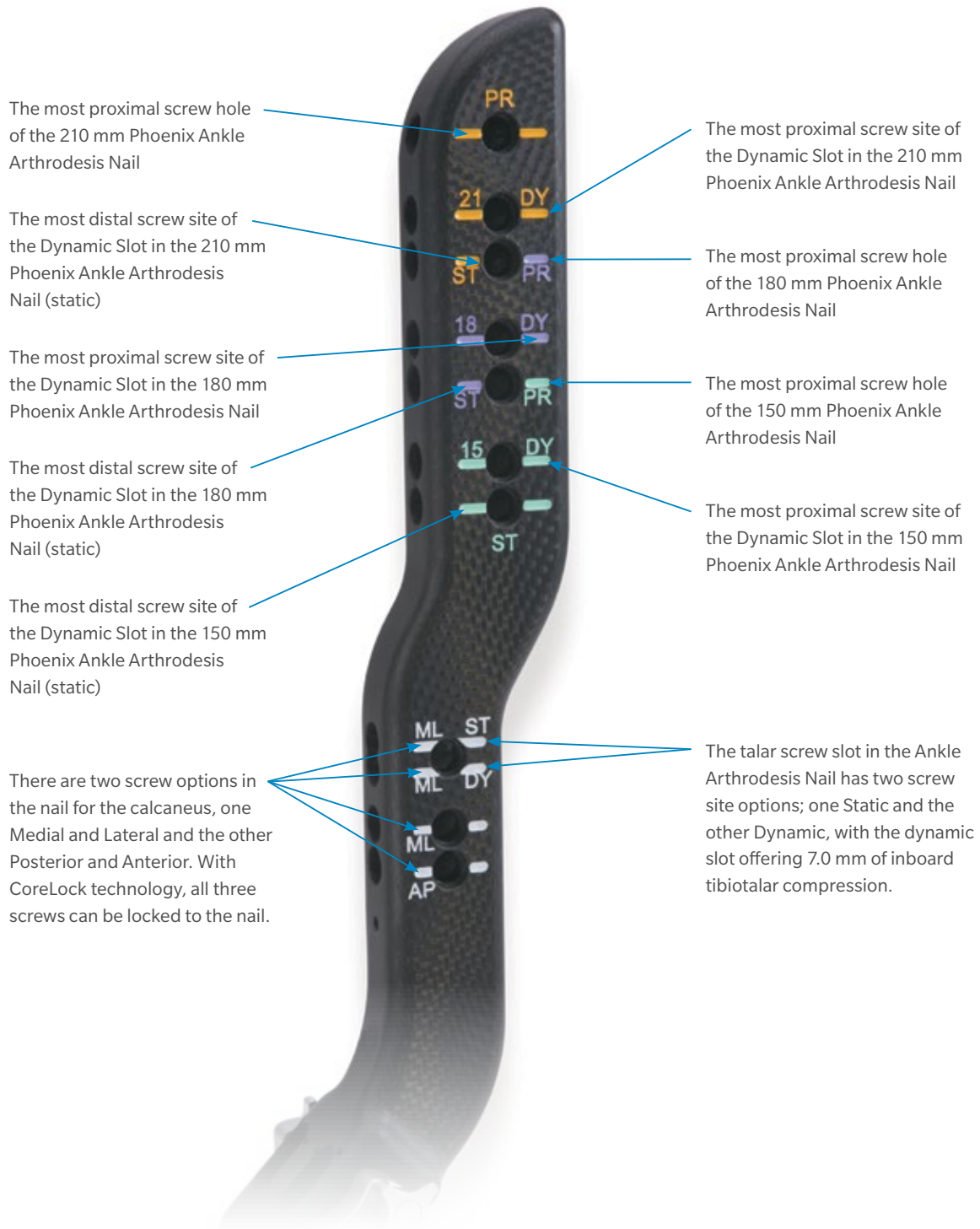
When the Targeting Arm is positioned to prepare the first tibial or talar screw, a radiolucent PA Alignment Guide Arm (14-440051) can be attached to indicate the location and trajectory of the calcaneal PA screw prior to initial insertion. This Guide will also indicate if the nail is rotated properly within the canal.



When additional fixation and/or control of rotation is desired, the Targeting Arm can accurately target an oblique screw on either side of the nail. Capable of 40° of variability, screw trajectories can be finely adjusted and then locked in place.



Targeting Arm Guides



The most proximal screw hole of the 210 mm Phoenix Ankle Arthrodesis Nail

The most distal screw site of the Dynamic Slot in the 210 mm Phoenix Ankle Arthrodesis Nail (static)

The most proximal screw site of the Dynamic Slot in the 180 mm Phoenix Ankle Arthrodesis Nail

The most distal screw site of the Dynamic Slot in the 180 mm Phoenix Ankle Arthrodesis Nail (static)

The most distal screw site of the Dynamic Slot in the 150 mm Phoenix Ankle Arthrodesis Nail (static)

There are two screw options in the nail for the calcaneus, one Medial and Lateral and the other Posterior and Anterior. With CoreLock technology, all three screws can be locked to the nail.

The most proximal screw site of the Dynamic Slot in the 210 mm Phoenix Ankle Arthrodesis Nail

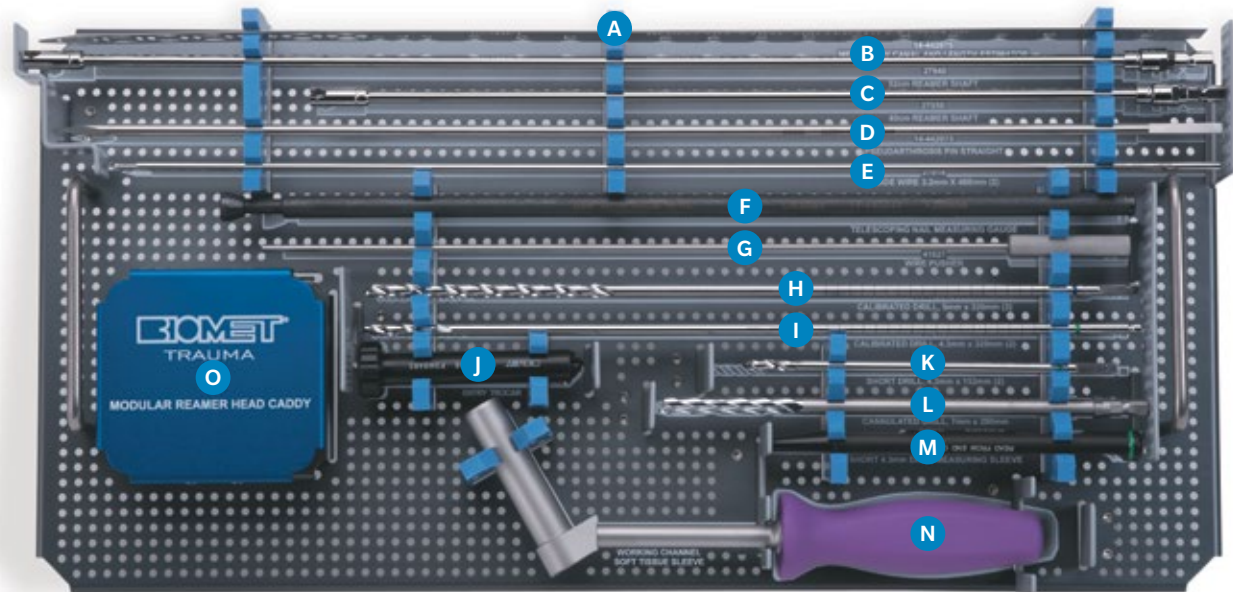
The most proximal screw hole of the 180 mm Phoenix Ankle Arthrodesis Nail

The most proximal screw hole of the 150 mm Phoenix Ankle Arthrodesis Nail

The most proximal screw site of the Dynamic Slot in the 150 mm Phoenix Ankle Arthrodesis Nail

The talar screw slot in the Ankle Arthrodesis Nail has two screw site options; one Static and the other Dynamic, with the dynamic slot offering 7.0 mm of inboard tibiotalar compression.

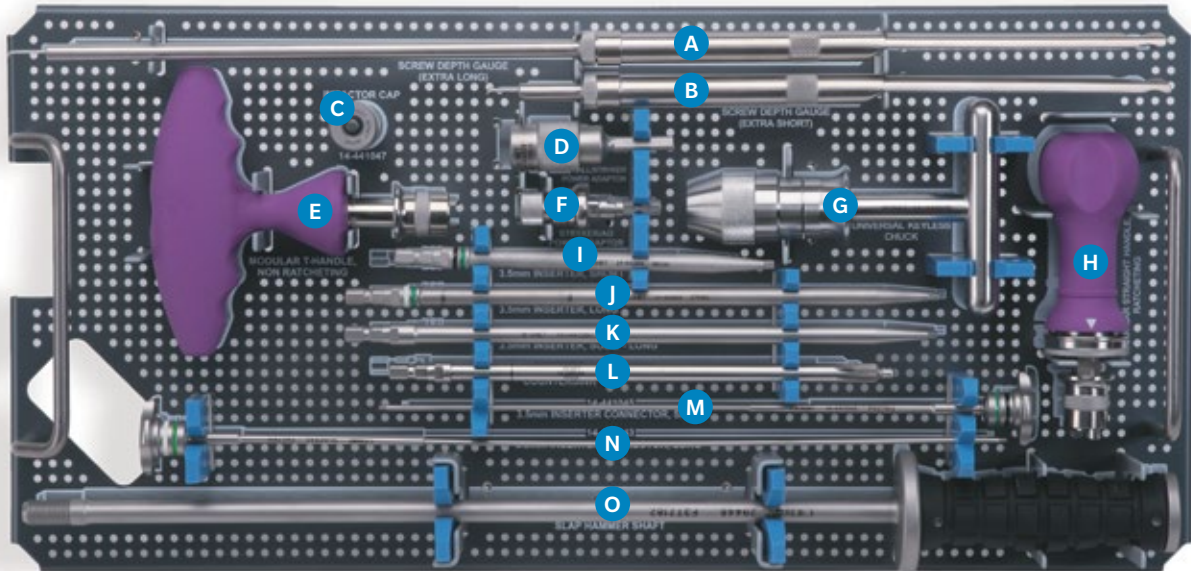
Phoenix Ankle Arthrodesis Nail System Tray Layout Top Tray



Label	Part Number	Description
A	14-442075	Medullary Canal and Length Estimator
B	27940	52 cm Reamer Shaft
C	27958	40 cm Reamer Shaft
D	14-442073	Pseudarthrosis Pin Straight
E	14-440052	3.2 mm x 320 mm Entry Guide Wire
F	14-440047	Telescoping Nail Measuring Gauge
G	41027	Wire Pusher
H	14-440043	5 mm x 320 mm Calibrated Drill Bit
I	41010	4.3 mm x 320 mm Calibrated Drill Bit

Label	Part Number	Description
J	14-440045	Wire Offset Guide/Trocar
K	27984	4.3 mm x 152 mm Calibrated Drill (Short)
L	14-440041	7 mm x 200 mm Cannulated Drill
M	14-442076	4.3 mm Short Drill Measuring Sleeve
N	41029	Working Channel/Soft Tissue Sleeve
O	467534– 467554	(34–54) Modular Reamer Heads, 8 mm–13 mm (0.5 mm increments)

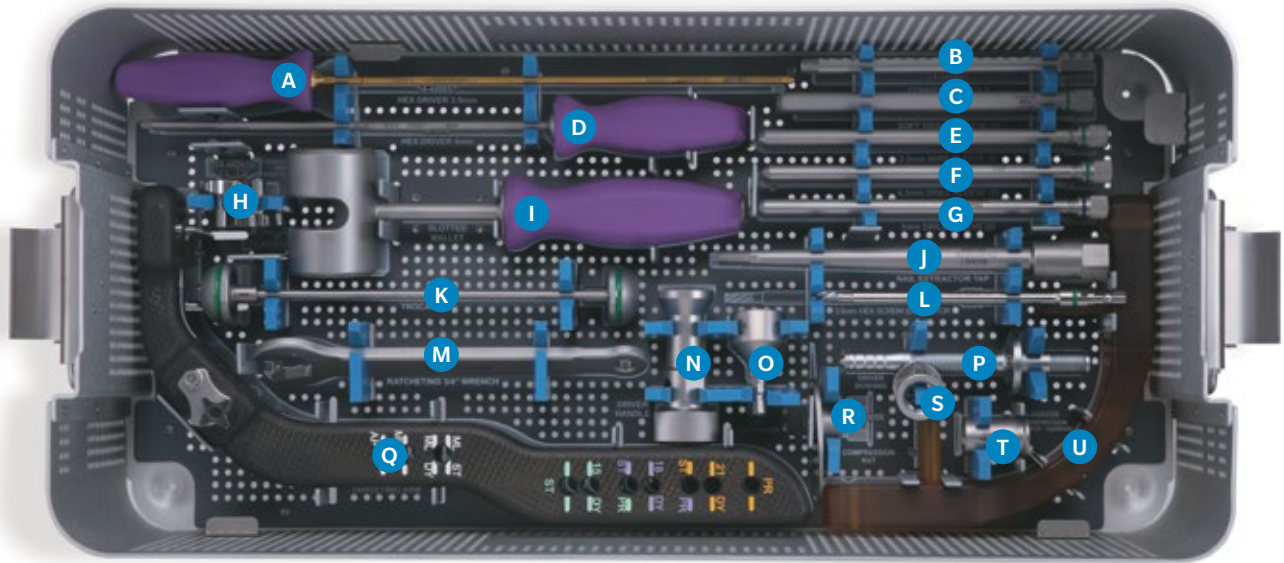
Phoenix Ankle Arthrodesis Nail System Tray Layout Middle Tray



Label	Part Number	Description
A	14-442081	Extra Long Screw Depth Gauge
B	14-442082	Extra Short Screw Depth Gauge
C	14-441047	Impactor Cap
D	14-442089	Hall/Stryker Power Adaptor
E	29407	Modular T-handle, Non-ratcheting
F	27977	Stryker/AO Power Adaptor
G	14-442078	Keyless Chuck T-handle
H	29408	Modular Straight Handle, Ratcheting
I	14-441046	3.5 mm Inserter, Short
J	14-441044	3.5 mm Inserter, Long
K	14-441051	3.5 mm Inserter, Solid – Long

Label	Part Number	Description
L	14-440049	Countersink
M	14-441045	3.5 mm Inserter Connector, Short
N	14-441043	3.5 mm Inserter Connector, Long
O	29448	Slap Hammer Shaft

Phoenix Ankle Arthrodesis Nail System Tray Layout Bottom Tray



Label	Part Number	Description
A	14-440057	3.5 mm Hex Driver (Gold)
B	14-440042	Connecting Bolt
C	41004	Soft Tissue Sleeve
D	41024	4.0 mm Hex Driver (Silver)
E	14-440046	3.2 mm Wire Bushing
F	41005	4.3 mm Drill Bushing
G	14-440044	5.0 mm Drill Sleeve
H	14-442056	Thumb Screw
I	14-442053	Slotted Mallet
J	14-441048	Nail Extractor Tap
K	14-440048	4.3 mm Trocar Interlock Ankle

Label	Part Number	Description
L	14-442084	3.5 mm Hex Screw Extractor
M	14-440040	¾ inch Ratcheting Wrench
N	14-440053	Driver Handle
O	14-442066	¾ inch Hex Driver
P	14-440054	Targeting Jig Nose/Driver Bushing
Q	14-440050	Carbon Target Arm, Ankle Nail
R	14-440055	Compression Hat
S	14-440056	Compression Nut
T	14-440058	Compression Sleeve, Narrow
U	14-440051	P/A Screw Alignment Guide Arm

Surgical Technique



Step 1: Determine Patient Positioning

Patient positioning is based on surgeon preference with consideration given to the case specific needs of each patient.

Lateral Patient Positioning

The patient is positioned in the lateral decubitus position on a radiolucent operating table with the affected extremity up (farthest away from the operating table). Great care must be taken to pad the patient's bony prominences and an axillary roll is used in the recumbent axilla. The non-operated extremity is flexed at the hip and knee and placed very close to the anterior border of the operating table. In this fashion, intraoperative fluoroscopy can be used as indicated to image the operated extremity in all planes. If the surgeon wishes to address proximal locking screws from the lateral side, this is the ideal position. General or spinal anesthesia is usually required and a thigh tourniquet facilitates the plantar dissection.

General Advantages of Lateral Approach

- PA Screw insertion is easily accomplished as the leg does not have to be elevated off the operating table for Targeting Arm and drilling access
- If the surgeon wishes to implant all screws (except the PA calcaneal screw) from lateral to medial, this position is ideal as there is no need to re-orient the Targeting Arm until the PA calcaneal screw is addressed

General Disadvantages of the Lateral Approach

- Not ideal for larger, heavier patients who may have difficulty breathing on their side
- Difficult to access the medial gutter of the ankle. Additional medial malleolous resection (if necessary) is more challenging. ML screw insertion may also be more difficult.
- Difficult to compare rotation with the opposite foot



Step 1: Determine Patient Positioning (cont.)

Supine Patient Positioning:

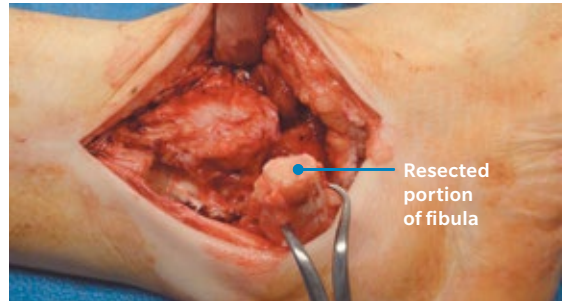
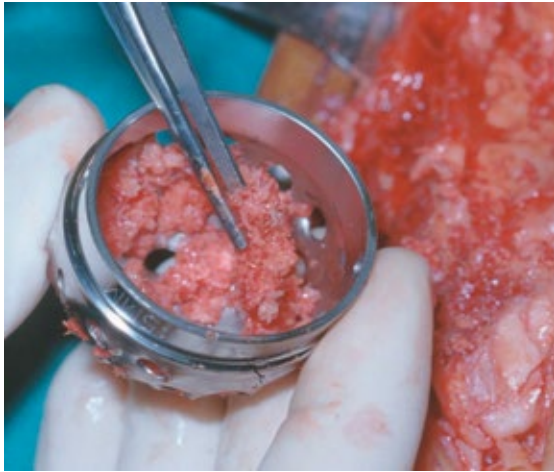
The patient is positioned supine on a radiolucent operating table with the affected extremity elevated in neutral alignment. If alignment and anatomy is normal, and the surgeon wishes to insert the proximal locking screws from medial to lateral, this is the preferred position. General or spinal anesthesia is usually required and a thigh tourniquet facilitates the plantar dissection.

General Advantages of Supine Approach:

- Easy to position larger patients—may be preferable for patients who may experience breathing issues in the lateral decubitus position
- Open access to medial and lateral sides of the ankle
 - Facilitates jig targeting for ML and LM approaches
 - Facilitates the resection of both the medial and lateral malleolus
- Easy to check ankle rotation in relation to the opposite ankle

General Disadvantages of the Supine Approach:

- Placement of the PA Screw is sometimes more difficult. In many cases, the leg needs to be lifted and held up off the table to allow for Targeting Arm and drilling access



Step 2: Surgical Exposure

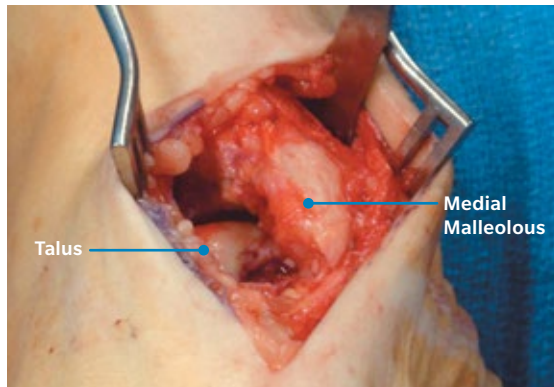
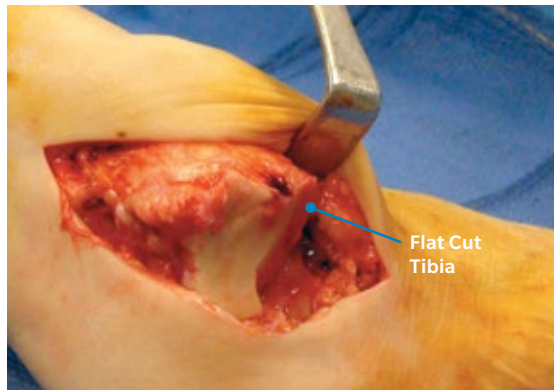
The transfibular approach affords excellent exposure for ankle fusion. A longitudinal incision is made over the posterior fibula, curving distally along the peroneus tendon. Great care should be taken to note the course of the existing neurovascular structures and tendons.

Step 3: Fibular Resection

The distal 5 cm of the fibula is resected in a beveled fashion at a level 2 cm proximal to the tibiotalar joint line. The distal portion of the fibula may be morsellized for use as an autogenous bone graft.

Some prefer to skeletonize the distal fibula and lift off the lateral cortex to harvest the cancellous bone, while others prefer to remove the distal fibula. This local bone graft is utilized after nail placement. A standard technique for harvesting the fibula is to utilize a 36 mm acetabular reamer which yields excellent graft material.

Note: The peroneal tendons should be preserved. Special care should be paid to the occasionally present lateral peroneal artery in the region of the syndesmosis, which may bleed excessively. (Occasionally further fibular resection is needed to expose and tie off this vessel.) The incision is extended distally to the sinus tarsi to allow subtalar joint visualization.



Step 4: Fusion Site Preparation

The ankle joint preparation is crucial to successful fusion. Two techniques for preparation of the tibiotalar joint are described. Care should be taken to avoid excessive bony resection which may later result in limb shortening or loss of talar fixation.

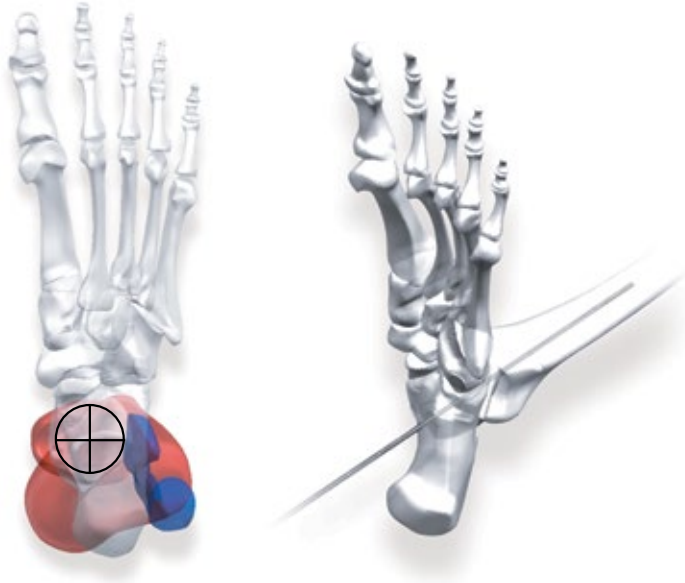
Flat Cut Resection (Shown)

A transverse saw cut is made across the distal tibia. This cut should include the medial malleolus. In this manner one is able to translate the distal tibia medially for a more direct alignment of the hindfoot relative to the tibia. At times it is easier to make a second incision medially and remove the medial malleolus with a saw. The ankle is then brought into neutral position and a matching talus cut is performed. The posterior and lateral talar surfaces should also be decorticated to allow greater fusion surface. The subtalar joint is prepared in a standard fashion with chisels or curettes.

Joint Congruent Resection

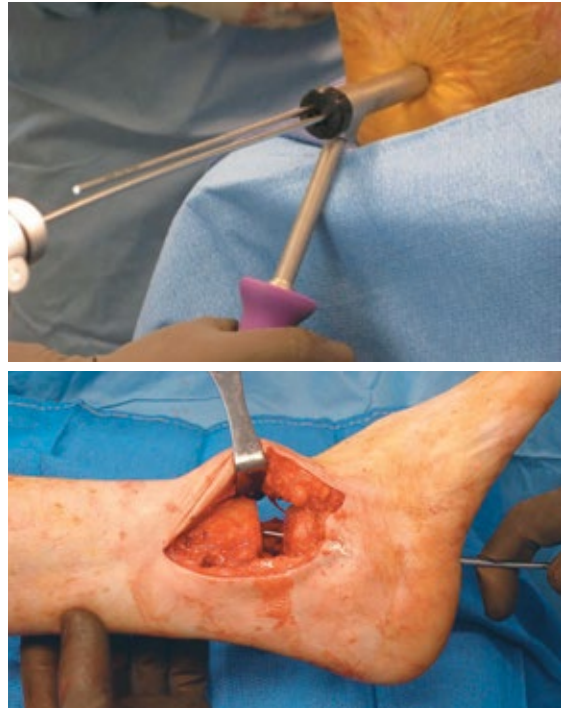
The tibiotalar joint is denuded of cartilage in a congruent fashion, removing anterior and posterior osteophytes with a chisel and rongeur. Diseased cartilage is removed down to bleeding subchondral cancellous bone, preserving (if possible) the natural concavity of the distal tibial articular surface and the dorsal concave surface of the talus. If necessary, when performing tibiotalocalcaneal arthrodesis, the tibiotalar joint may be provisionally fixed in place with thick, smooth K-wires, while both sides of the subtalar arthrodesis site are prepared with chisels, curettes, and rongeurs. An anterolateral ankle arthrotomy may be used and coupled with an anteromedial arthrotomy to correct any deformity present across the ankle joint. This technique effectively prepares the joint surface by removing what remains of the articular surface.

The ideal position of arthrodesis is in neutral dorsiflexion, three to five degrees of hind-foot valgus, and external rotation symmetric with the contralateral uninvolved extremity. Appropriate external rotation is achieved when the anteromedial crest of the tibia lies parallel with the second ray of the involved foot.



Step 5: Nail Entry Site and Incision

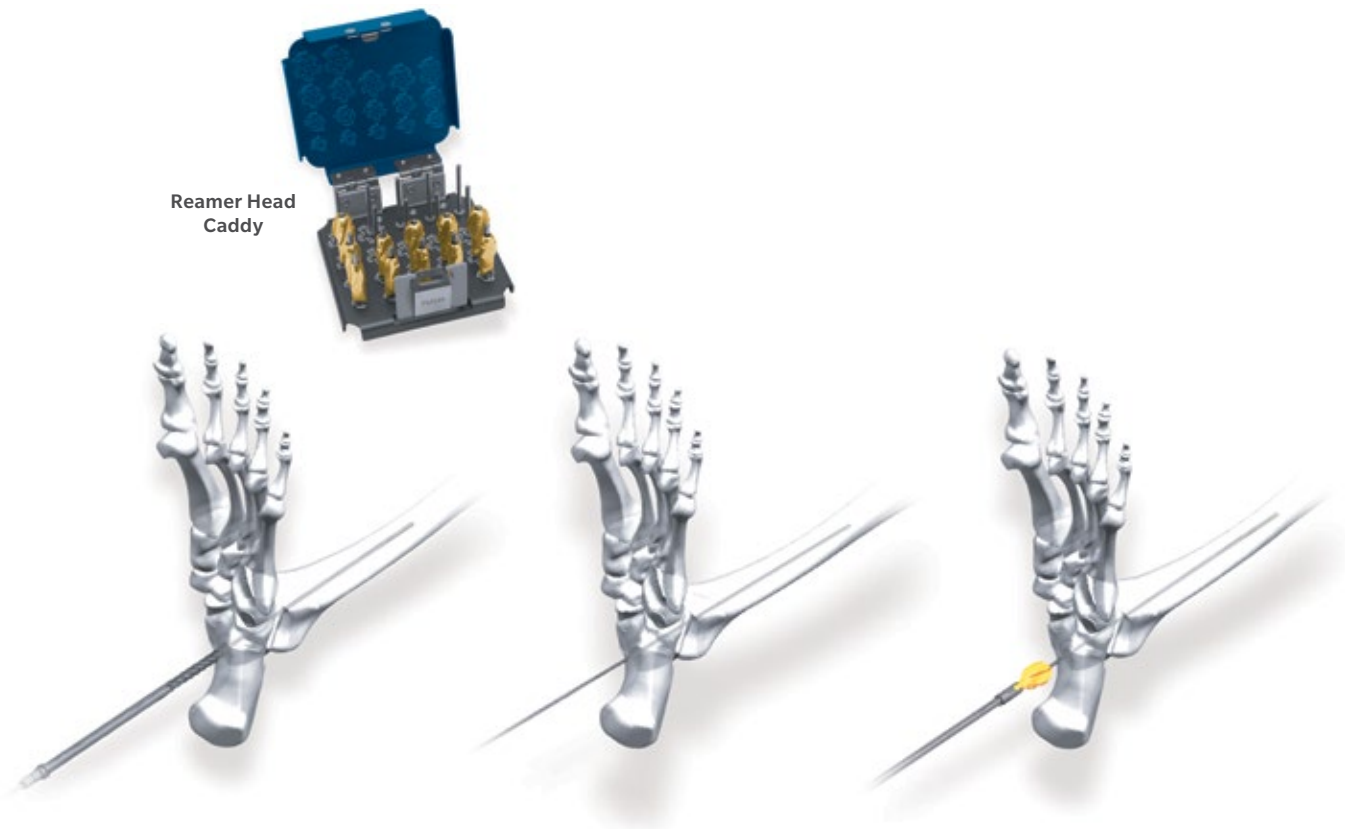
Following the preparation of the bony surfaces, a 3 cm longitudinal plantar incision is made anterior to the subcalcaneal fat pad slightly lateral to the midline, especially in the patient with significant preoperative valgus deformity. Blunt dissection is carried down to the plantar fascia, which is split longitudinally. The intrinsic muscles are swept medially or laterally and the neurovascular bundle on the sole of the foot is identified.



Step 6: Entry Guide Wire Insertion

The ideal position for the plantar calcaneal entry site is well anterior to the weight bearing surface of the calcaneal tuberosity and approximately 2 cm posterior to the articulation of the calcaneus with the transverse tarsal joints. In the coronal plane, the entry site should line up with the center of the tibial medullary canal.

A 3.2 mm x 320 mm Entry Guide Wire (PN 14-440052) is inserted through the calcaneus, talus, and tibia. Confirm the position of the wire on the C-arm. If the wire is not placed to satisfaction, the Wire Offset Guide (PN 14-440045) may be used to assist in proper placement.



Step 7: Initial Reaming

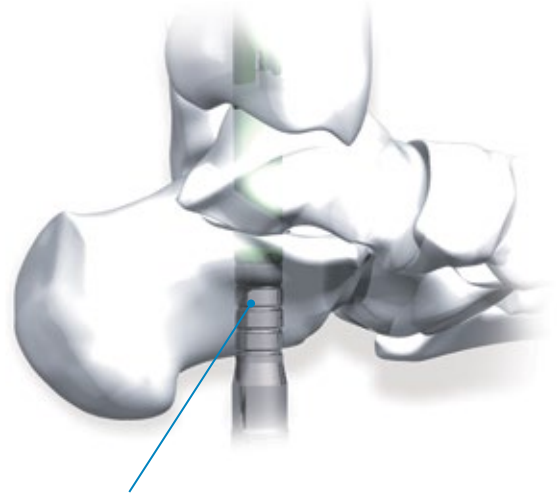
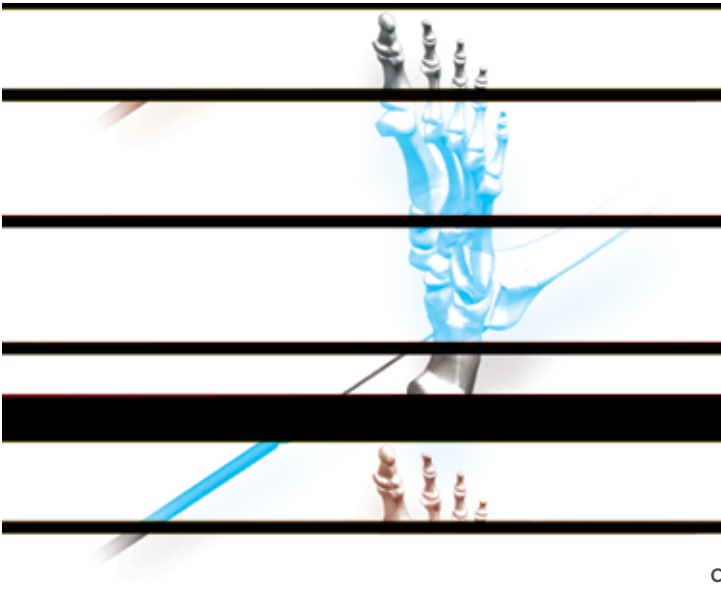
Using the 7.0 mm x 200 mm Cannulated Drill (PN 14-440041), ream the subtalar and tibiotalar articular surfaces over the 3.2 mm Entry Guide Wire. It is helpful to have an assistant hold the foot in the appropriate alignment during the transmedullary reaming.

Step 8: Bead Tip Guide Wire Placement and Canal Reaming

Holding the foot in proper alignment, remove the 3.2 mm Entry Guide Wire. A 2.6 mm x 80 cm Bead Tip Guide Wire (PN 14-410002) is inserted transcaneally through the talus into the medullary canal of the tibia using image intensification. Progressive reaming is performed over the Bead Tip Guide Wire. This is achieved using the Modular Reamer Heads (PN 467534 - 467554) and the flexible Ni-Ti Reamer Shaft (PN 27940 or 27958). It is recommended to start with the 8.0 mm end-cutting reamer, and then follow sequentially in 0.5 mm increments. Ream to 0.5 mm to 1.0 mm larger than the diameter of the nail to be implanted.

ⓘ **Note:** Over-reaming by a full 1 mm may help reduce the need for excessive insertion force.

The depth to which the surgeon reams is also influenced by the patient's specific needs. If bone quality is poor in the distal tibia, it is recommended that a longer nail be used achieve proximal locking farther away from the poor bone stock. In this case, canal reaming may progress through the isthmus.



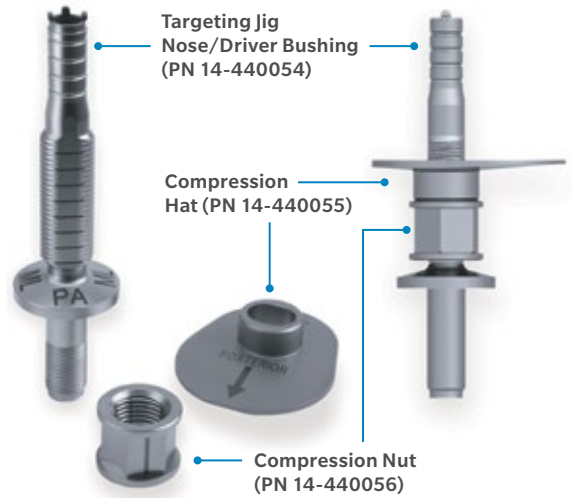
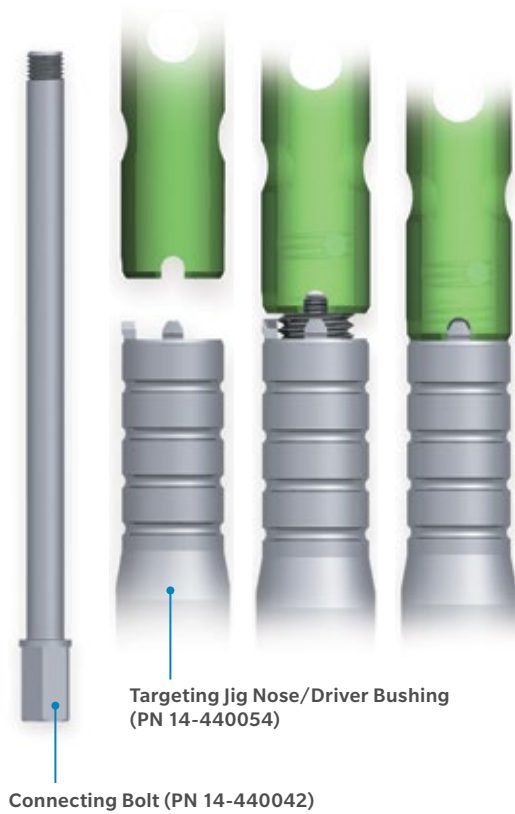
Countersinking grooves are in 5.0 mm increments and can be seen clearly in fluoroscopic views

Step 9: Nail Length Determination

A Telescoping Nail Measuring Gauge (PN 14-440047) may be used to determine the proper nail length by passing it over the exposed end of the Guide Wire. Alternatively, a second 2.6 mm x 80 cm Bead Tip Guide Wire can be used to estimate length of the nail. The set also includes a Medullary Canal and Length Estimator (PN 14-442075) to assist in sizing nails appropriately.

ⓘ **Note:** Nails are available in lengths of 150 mm, 180 mm, 210 mm, 240 mm, 270 mm and 300 mm and diameters of 10 mm, 11 mm and 12 mm. Targeting Arm will only target nails up to 210 mm in length.

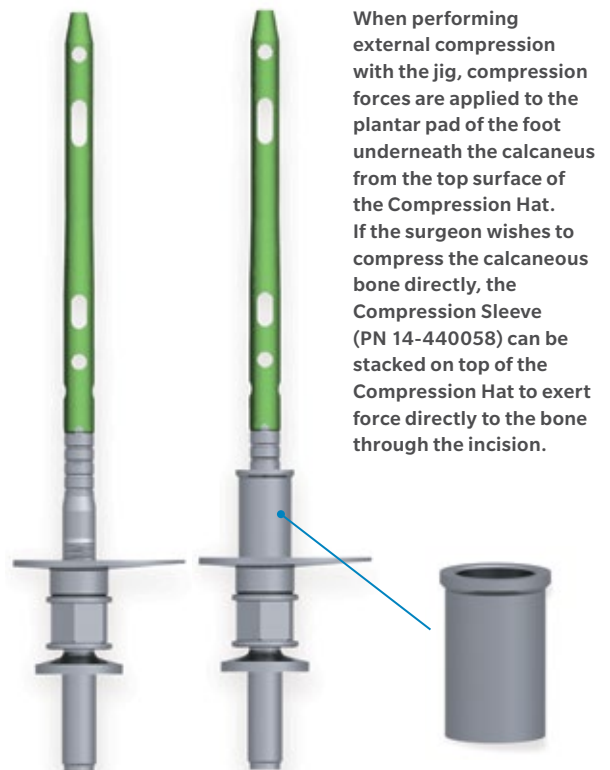
The proximal end of the nail should extend at least 5 cm above any potential cortical stress risers. This would include non-union sites, tibial fractures, osteotomy sites, or cortical holes that may exist after previous hardware removal. Ideally, the nail should be countersunk 5.0 mm-10 mm in the plantar cortex of the calcaneus. The nail may be countersunk more if warranted by the patient anatomy.



Step 10: Outrigger Assembly

The Compression Nut (PN 14-440056) and Compression Hat (PN 14-440055) are assembled on the Targeting Jig Nose/Driver Bushing (PN 14-440054).

The Connecting Bolt (PN 14-440042) is then passed through the Targeting Jig Nose and threaded into the distal end of the nail. The three tangs on the bushing must engage the three slots on the distal end of the nail.





Step 10: Outrigger Assembly (cont.)

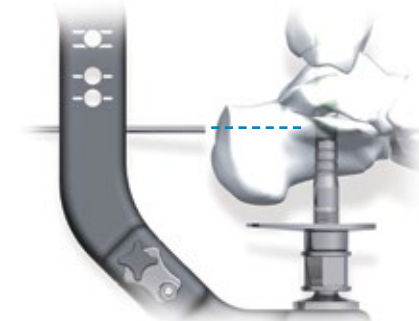
The Connecting Bolt is then tightened using the 9.5 mm hex portion on the Ratcheting $\frac{3}{4}$ " Wrench (PN 14-440040). The assembly is then placed into the designated site of the Targeting Arm (PN 14-440050).

Alignment Check

Before definitively tightening the nail to the assembly, it is good practice to perform an alignment check to ensure accurate screw targeting. Position the Targeting Arm so that the ML can be accessed.

Load the 4.3 mm Drill Sleeve (PN 41005) into the Soft Tissue Sleeve (PN 41004) and then insert the stack into the appropriate Targeting Arm location. The 4.3 mm Drill Bit (PN 41010 or PN 27984) is then be passed through the Drill Sleeve and nail holes (The drill bit should easily pass through both the static and dynamic holes of the nail). Once good alignment is confirmed, the Connecting Bolt can then be tightened with confidence.

Once the Connecting Bolt is definitively tightened, the Driver Handle (PN 14-440053) is threaded over the distal portion of the Targeting Jig Nose/Driver Bushing to securely lock the outrigger assembly.



Step 11: Nail Insertion

After performing an alignment check, the Targeting Arm is positioned to address the tibial screws from medial to lateral (shown).

A lateral to medial approach may also be elected based on surgeon preference. If a lateral to medial approach is preferred, a slight internal rotation of the nail may help the surgeon avoid fibular interference when inserting the proximal locking screws into the tibia.

Countersink the nail 5.0 mm-10 mm to allow for desired compression. This also prevents painful prominence in plantar soft tissue.

When countersinking the nail, a 3.2 mm Entry Guide Wire or the Wire Pusher (PN 41027) can be passed through the Targeting Arm to indicate the depth of the distal end of the nail. This feature can be utilized regardless of the plane the Targeting Arm is positioned.

The PA Screw Alignment Guide may be used to estimate the location and trajectory of the PA calcaneal screw prior to initial screw preparation.



Step 12: Proximal Screw Placement

ⓘ **Note 1:** The nail's depth and orientation is established once the first proximal locking screw is introduced. In addition to utilizing the PA Alignment Guide to estimate the location and trajectory of the PA calcaneal screw, it is recommended that the surgeon check the alignment of the talar compression screw prior to implanting the first proximal locking screw.

Place a Soft Tissue Sleeve/Drill Guide stack in the appropriate Targeting Arm slot to ensure that the screw is on target for good purchase within the talus.

In cases where the talus is severely compromised and there is limited bone to work with, targeting this screw site first is sometimes preferred. If the surgeon prefers to target the talar screw first, an abbreviated alternative technique is illustrated on pages 30-33.

ⓘ **Note 2:** If a mallet is used to insert the nail, it is recommended that the Driver Handle be removed to allow the Connecting Bolt to be re-tightened. This will help ensure that good alignment is maintained in the event loosening occurs during insertion.

ⓘ **Note 3:** Manually impact arthrodesis prior to initial screw insertion.

ⓘ **Note 4:** Proximal screw placement can be approached from both the medial and lateral sides of the tibia. The medial to lateral approach has been depicted.

Remove the 2.6 mm x 80 cm Bead Tip Wire Guide before inserting locking screws into the nail.

Identify the corresponding color coded indicators on the proximal portion of the Targeting Arm and place soft tissue sleeve/drill sleeve stacks in the designated slots.

ⓘ **Note 5:** It is recommended that the Dynamic Slot in the proximal end of the nail be addressed first as it is closer to the Targeting Arm's nail locking assembly. Targeting accuracy diminishes as you move farther away from the locking assembly.

Using the C-arm, a small stab incision is made on the medial side of the leg. The 4.3 mm Drill Sleeve is passed down to the medial cortex of the tibia. A 4.3 mm Calibrated Drill Bit (PN 41010 or PN 27984) is utilized to penetrate both the medial and lateral cortices.

Having successfully drilled the first hole, leave the drill bit in place while drilling the second hole to minimize blood loss. With the Drill Sleeve firmly against the medial cortex, the appropriate locking screw length can be read directly from the calibrations on the Drill Bit.

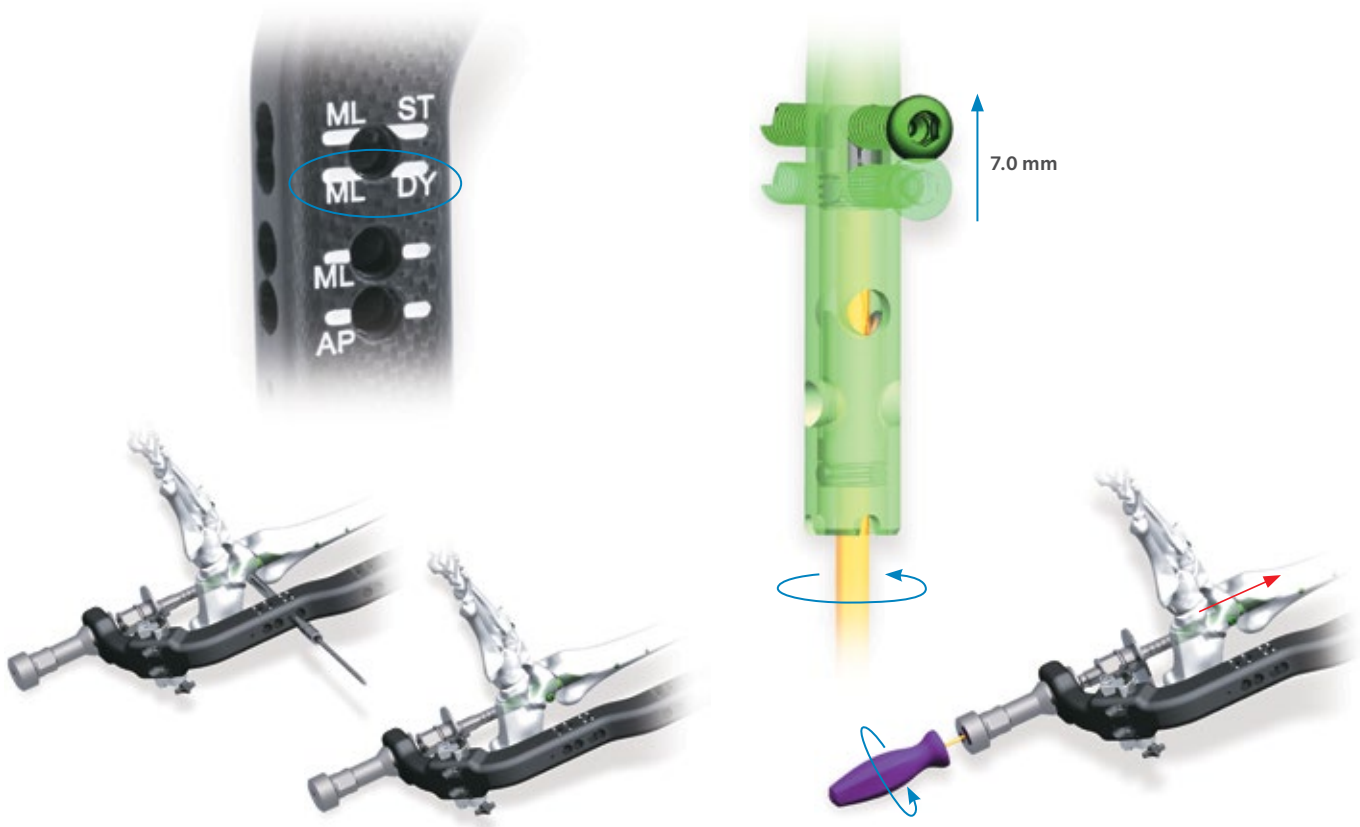
When utilizing the Depth Gauges (14-442081—Screw Depth Gauge, Extra Long) or (14-442082—Screw Depth Gauge Extra Short), the Drill Sleeves must be removed from the Soft Tissue Sleeve.



Step 12: Proximal Screw Placement (cont.)

After removing the Drill Sleeve, insert the appropriate 5.0 mm screw using the 3.5 mm Inserter (PN14-441044) and 3.5 mm Inserter Connector (PN 14-441043). A solid 3.5 mm Hex Driver (PN 14-440057) is also included in the set.

The second proximal locking screw is inserted in a similar fashion.



Step 13: Talar Screw Insertion and Internal Compression

The talar screw is inserted lateral to medial. To re-orient the jig, loosen the Driver Handle (3 turns is sufficient) and rotate the Targeting Arm 180° to the lateral side. Once in position, re-tighten the Driver Handle to lock down the Targeting Arm.

To achieve internal compression with the CoreLock mechanism, the talar screw must be inserted through the appropriate Dynamic Slot of the Targeting Arm. The lateral articular surface of the talus is directly visualized and the Drill Sleeve is passed down to the lateral cortex. Using the 4.3 mm Drill Bit, prepare and implant a 5.0 mm screw through the talus in the same manner described previously.

Once the tibial and talar screws are addressed, internal compression can ensue.

Using the 3.5 mm Hex Driver - (PN 14-440057) (gold shaft), advance the internal compression mechanism with clockwise revolutions to achieve up to 7.0 mm of tibiotalar compression.



Travel Indicators are calibrated in 5.0 mm increments



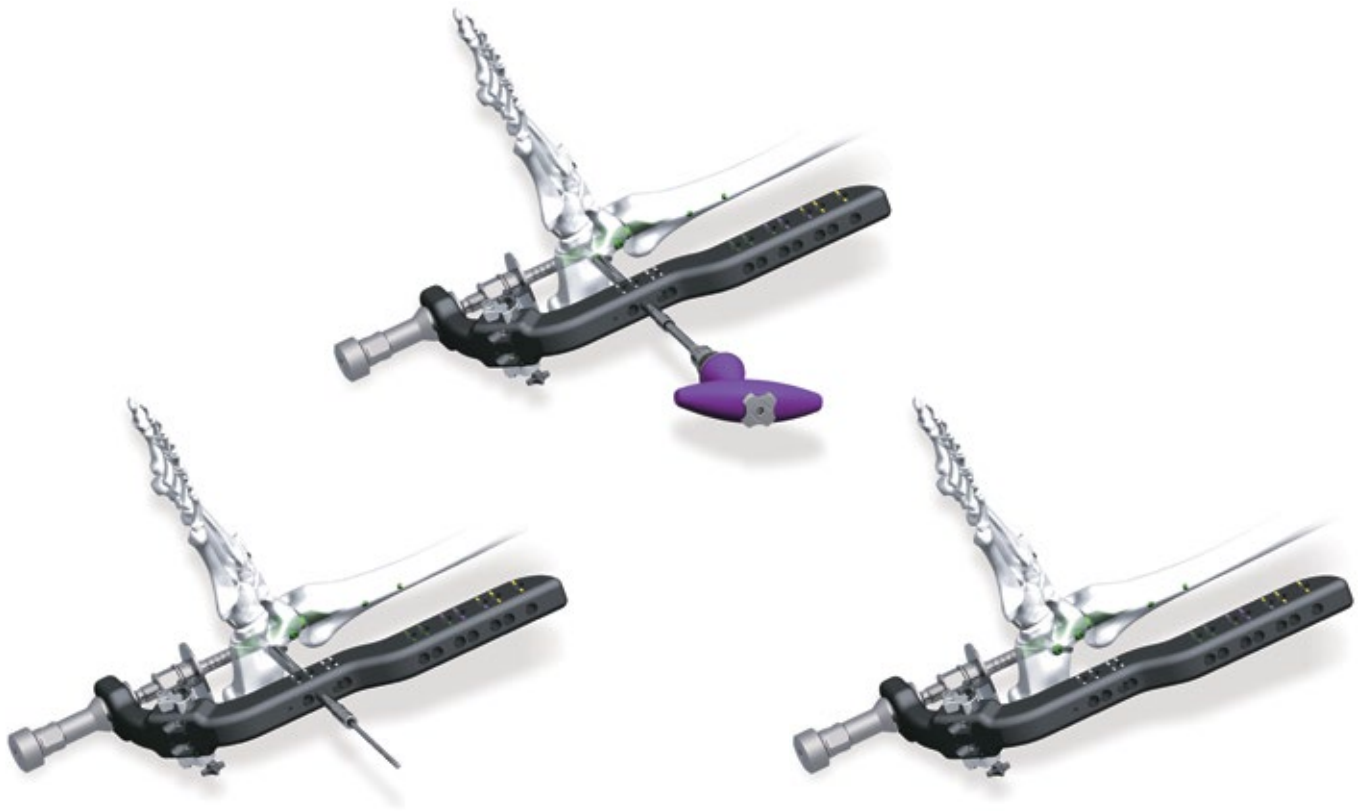
Step 14: External Compression

Prior to compression, it is important to be mindful of the depth to which the nail is countersunk in the calcaneal plantar surface. When countersinking the nail, carefully estimate the amount of compression desired to avoid unwanted nail protrusion in the planter surface.

The Compression Nut is advanced with clockwise revolutions using the $\frac{3}{4}$ " Ratcheting Wrench (PN 14-440040). The Compression Nut will drive the Compression Hat proximally to compress the tibiotalar and subtalar joints.

Perform each turn slowly and be careful not to overtighten the Compression Nut. Excessive compression forces may compromise the plantar cortex of the calcaneus and may also leave the distal portion of the nail prominent.

Care must also be taken to avoid soft tissue impingement between the Compression Hat and calcaneus. Once the fusion site is compressed to surgeon satisfaction, final locking can ensue distally.

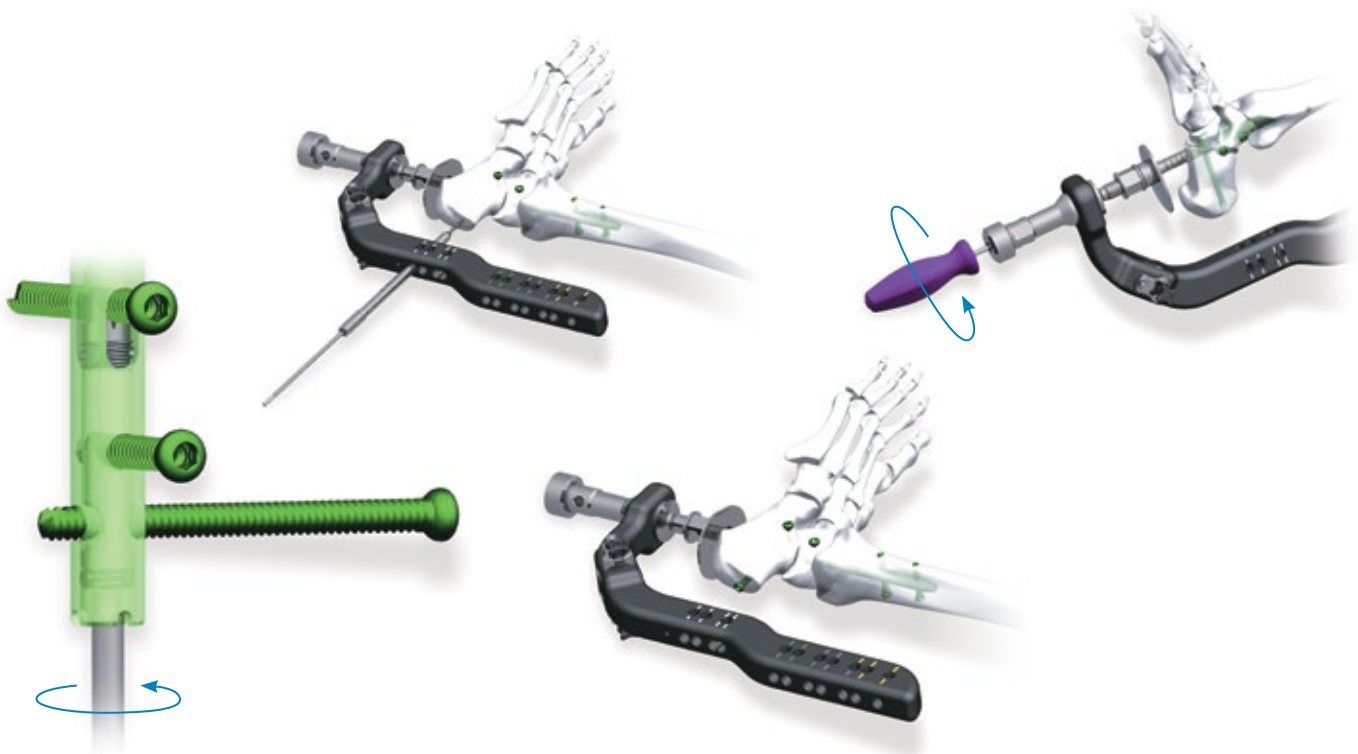


Step 15: Distal Screw Placement

After internal and external compression, a 4.3 mm Drill Guide/Soft Tissue Sleeve stack is placed in the appropriate Targeting Arm slot to address the distal locking screw.

The most appropriate position for the LM distal locking screw varies on a per case basis. In instances where the talus is severely compromised, this screw may end up in the joint space or calcaneus (shown).

With the Targeting Arm positioned on the lateral side of the ankle, pass the 4.3 mm Drill Bit bi-cortically. Measure and insert the appropriately sized 5.0 mm screw.



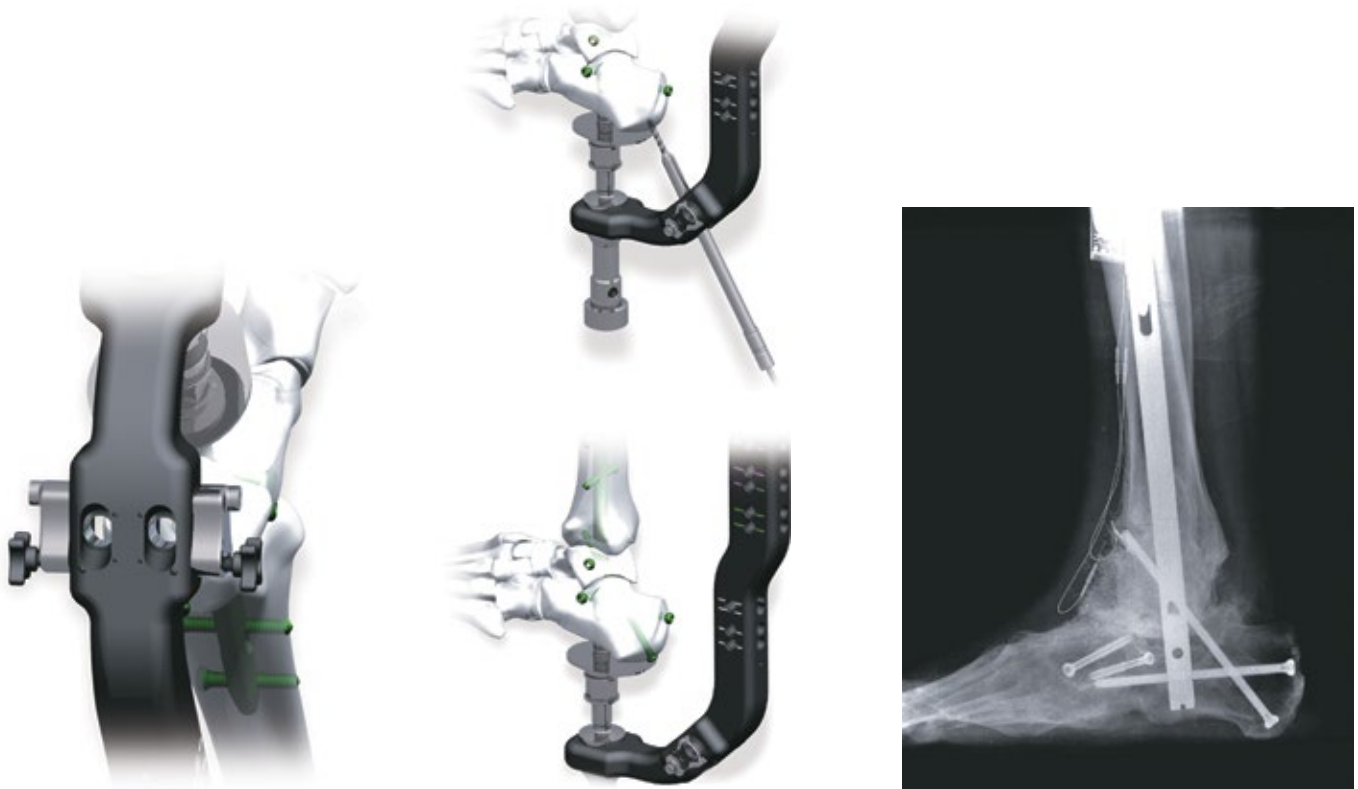
Step 16: PA Screw Placement

Rotate the Targeting Arm 90° to allow for a posterior to anterior approach. Insert a 4.3 mm Drill Guide and Soft Tissue Sleeve into the target site marked “PA”. The appropriate position is marked on the skin and a small stab incision is made. Pass the Drill Sleeve/Soft Tissue Sleeve stack down the cortex through the incision.

Using fluoroscopy, pass the 4.3 mm Calibrated Drill Bit to the desired depth in the calcaneus. Determine the appropriate screw length from the calibrations on the Drill Bit or by using the depth gauge. For true pantalar arthrodesis, this screw may be passed through the calcaneus into the cuboid or navicular.

To reduce screw head prominence in heel, a Countersink (PN 14-440049) can be used through the Soft Tissue Sleeve. Be sure to account for any countersinking when selecting the appropriate screw size.

With the distal locking screws in place, utilize the 4.0 mm Hex Driver (PN 41024) (silver shaft) to advance the second CoreLock mechanism with clockwise revolutions. Once all screws are locked, the nail is effectively a ridged, fixed angle construct.



Additional Oblique Screw Option

When additional fixation or control of rotation is desired, the Targeting Arm can accurately target an oblique screw on either side of the nail. Capable of 40° of variability, screw trajectories can be finely adjusted and then locked in place. Placement of a calcaneotalotibial screw is shown.



Step 17: End Cap Insertion

An End Cap may help protect the threads in the distal end of the nail by inhibiting fibrous and bony in-growth. This is important to consider if the nail needs to be removed at a later time.

End Cap sizes range from a fully recessed 0 mm end cap to a +20 mm cap (5.0 mm increments).

Note: The 0 mm End Cap is the only size that can be inserted through the Targeting Jig Nose/Driver Bushing.

To insert the 0 mm End Cap through in this manner, apply pressure on the Targeting Jig Nose/Driver Bushing while carefully removing the Connecting Bolt. Once the Connecting Bolt is removed, the nail is no longer locked to the Targeting Jig Nose/Driver Bushing. Steadily hold the Targeting Jig Nose/Driver Bushing in place with the tangs manually engaged in the nail.

Insert End Cap through the Targeting Jig Nose/Driver Bushing with the 3.5 mm Hex Driver. Advance the End Cap until securely in place.

All other End Caps (5.0 mm, 10 mm, 15 mm, and 20 mm) are inserted with the outrigger removed as they will not fit through the Targeting Jig Nose/Driver Bushing.



Step 18: Fibular Bone Graft and Wound Closure

The fibular bone graft may be placed anteriorly and especially posteriorly to facilitate fusion. The posterior surface of the tibia and calcaneus should be decorticated to provide a raw cancellous bone surface for apposition for cancellous bone graft.

Obtain confirmatory AP and lateral X-rays before wound closure. Because of the large bleeding cancellous surfaces at the arthrodesis sites and the large amount of bone graft applied in this procedure, it is often advisable to apply a closed suction drainage tube. The wound is closed in layers and the patient is treated with additional external fixation if deemed appropriate.



Nail Removal

When a nail is to be removed, the proximal locking screws should be left in place until the Nail Extractor Tap (PN 14-441048) is attached to the nail.

Locking screw removal may be indicated after fusion if local irritation is experienced. Although the screws are locked to the nail, they can still be removed without having to disengage the CoreLock mechanism(s). This voids the need to re-enter the plantar pad to disengage locking in the event that screws need to be removed.

The End Cap is removed and the Nail Extractor Tap is threaded into the distal end of the nail. The screws are removed with the 3.5 mm Inserter (PN 14-441046) or (PN 14-441044). In the presence of bony ingrowth, you can utilize the Hex Screw Extractor (PN 14-442084) which has cutting threads to pass through fibrous or bony matter. The Slap Hammer (PN 29448) is threaded into the Nail Extractor Tap to assist in nail removal.

Postoperative Care

It is advised that the patient be non-weight bearing on the operated extremity until clinical and radiographic union is apparent. Often a period of cast immobilization anywhere from 6–12 weeks is necessary to achieve this goal. Further protection with a walking boot or brace may help ease the transition to weight bearing.

Talar Screw First Approach



The first interlocking screw dictates the nail's orientation within the ankle. In cases where the talus is severely compromised and there is limited bone to work with, targeting this screw site first is sometimes preferred.

The following is an abbreviated alternative technique for this approach starting after Nail Insertion.

Talar Screw Insertion

Position the Targeting Arm to address the talar screw from lateral to medial.

- ⓘ **Note 1:** If a mallet is used to insert the nail, it is recommended that the Driver Handle be removed to allow the Connecting Bolt to be re-tightened. This will help ensure that good alignment is maintained in the event loosening occurs during insertion.
- ⓘ **Note 2:** Manually impact arthrodesis prior to initial screw insertion.

Remove the 2.6 mm x 80 cm Bead Tip Wire Guide before inserting locking screws into the nail.

To achieve internal compression with the CoreLock mechanism, the talar locking screw must be inserted through the appropriate Dynamic Slot of the Targeting Arm. Identify the Dynamic Slot indicator on the Targeting Arm and place the 4.3 mm Drill Sleeve/Soft Tissue Sleeve stack in the designated site.

PA Screw Alignment Guide should be used to estimate the location and trajectory of the PA calcaneal screw before the talar screw is prepared and introduced.

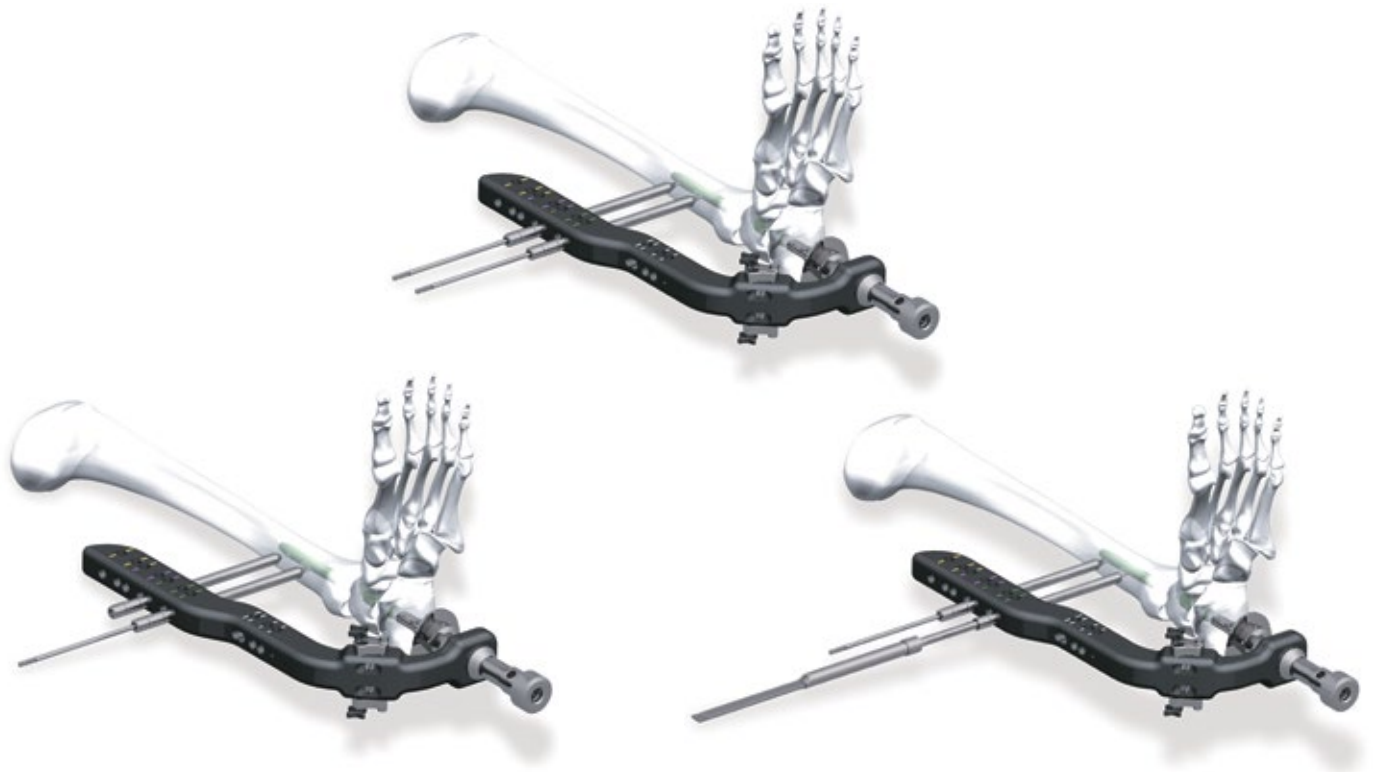
The lateral articular surface of the talus is directly visualized and the Drill Guide is passed down to the cortex through the incision.

A 4.3 mm Calibrated Drill Bit (PN 41010 or PN 27984) is utilized to penetrate both the lateral and medial cortices. With the Drill Sleeve firmly against the lateral cortex, the appropriate length of locking screw can be read directly from the calibrations on the Drill Bit. When utilizing the Depth Gauges (14-442081—Screw Depth Gauge, Extra Long) or (14-442082—Screw Depth Gauge Extra Short), the Drill Sleeves must be removed from the Soft Tissue Sleeve.



Talar Screw Insertion (cont.)

After removing the Drill Sleeve, insert the appropriate 5.0 mm screw through the Soft Tissue Sleeve using the 3.5 mm Inserter (PN 14-441044) and 3.5 mm Inserter Connector (PN 14-441043). A solid 3.5 mm Hex Driver (PN 14-440057) is also included in the set.



Tibial Screw Insertion

- ⓘ **Note:** Proximal screw placement can be approached from both the medial and lateral sides of the tibia. The medial to lateral approach has been depicted.

Re-position the Targeting Arm to address the proximal tibial screws from medial to lateral. If a lateral to medial approach is desired, the Targeting Arm can stay in its current position.

Identify the corresponding color coded indicators on the proximal portion of the Targeting Arm and place Drill Sleeve/Soft Tissue Sleeve stacks in the designated slots.

- ⓘ **Note:** It is recommended that the dynamic slot in the proximal end of the nail be addressed first as it is closer to the Targeting Arm's nail locking assembly. Targeting accuracy diminishes as you move farther away from the locking assembly.

Using the C-arm, a small stab incision is made on the medial side of the leg. The drill guide is passed down to the medial cortex of the tibia. A 4.3 mm Calibrated Drill Bit (PN 41010 or PN 27984) is utilized to penetrate both the medial and lateral cortices.

Having successfully drilled the first hole, leave the drill bit in place while drilling the second hole to minimize blood loss. With the Drill Sleeve firmly against the medial cortex, the appropriate length of locking screw can be read directly from the calibrations on the Drill Bit. When utilizing the Depth Gauges (14-442081—Screw Depth Gauge, Extra Long) or (14-442082—Screw Depth Gauge Extra Short), the Drill Sleeves must be removed from the Soft Tissue Sleeve.



Tibial Screw Insertion (cont.)

After removing the Drill Sleeve, insert the appropriate 5.0 mm screw using the 3.5 mm Inserter (PN 14-441044) and 3.5 mm Inserter Connector (PN 14-441043). A solid 3.5 mm Hex Driver (PN 14-440057) is also included in the set.

The second proximal locking screw is inserted in the same fashion.

Once the tibial and talar screws are addressed, internal compression can ensue.

Using the 3.5 mm Hex Driver - (PN 14-440057) (gold shaft), advance the internal compression mechanism with clockwise revolutions to achieve up to 7.0 mm of tibiotalar compression. (Resume surgical sequence at Step 13: Talar Screw Insertion and Internal Compression).

Ordering Information

Instruments

Catalog #	Description	Qty
41004	Soft Tissue Sleeve	2
41005	4.3 mm Drill Sleeve	2
29448	Slap Hammer	1
14-441046	3.5 mm Inserter, Short	1
14-441047	Impactor Cap	1
14-441048	Nail Extractor Tap	1
27940	52 cm Reamer Shaft	1
27958	40 cm Reamer Shaft	1
41024	4.0 mm Hex Driver (Silver)	1
467534	8.0 mm Reamer Head	1
467536	8.5 mm Reamer Head	1
467538	9.0 mm Reamer Head	1
467540	9.5 mm Reamer Head	1
467542	10 mm Reamer Head	1
467544	10.5 mm Reamer Head	1
467546	11 mm Reamer Head	1
467548	11.5 mm Reamer Head	1
467550	12 mm Reamer Head	1
467552	12.5 mm Reamer Head	1
467554	13 mm Reamer Head	1
41027	Wire Pusher (Longer)	1
14-442081	Screw Depth Gauge (Extra Long)	1
14-442082	Screw Depth Gauge (Extra Short)	1
14-442089	Hall/Stryker [†] Power Adaptor	1
27977	Stryker [†] /AO Power Adaptor	1
29407	T-Handle With Stryker [†] Quick Connect	1
29408	Straight Ratcheting Handle	1
14-442053	Slotted Mallet	1
14-442056	Sleeve Locking Set Screw	2
14-442066	¾" Hex Driver	1

Catalog #	Description	Qty
14-442073	Pseudarthrosis Pin Straight	1
14-442075	Medullary Canal and Length Estimator	1
14-442076	Short 4.3 Drill Bit Measuring Sleeve	1
14-442078	Keyless Chuck T-Handle	1
14-442084	3.5 mm Hex Screw Extractor	1
41029	Working Channel/Soft Tissue Sleeve	1
14-440050	Targeting Arm	1
14-440054	Targeting Jig Nose/Driver Bushing	1
14-440049	Countersink	1
14-440040	Ratcheting ¾" Wrench	1
14-440055	Compression Hat	1
14-440056	Compression Nut	1
14-440042	Connecting Bolt	1
14-440044	5.0 mm Drill Sleeve	2
14-440046	3.2 mm Wire Sleeve	2
14-440051	PA Screw Alignment Guide Arm	1
14-440045	Wire Offset Guide/Trocar	1
14-440048	Trocar	2
14-440057	3.5 mm Hex Driver (Gold)	1
14-440053	Driver Handle	1
14-440047	Telescoping Nail Measuring Gauge	1
14-440058	Compression Sleeve - Narrow	1
14-441043	3.5 mm Inserter Connector, Long	1
14-441044	3.5 mm Inserter, Long	1
14-441045	3.5 mm Inserter Connector, Short	1
14-441051	3.5 mm Inserter, Solid-Long	1
14-442078	Keyless Chuck T-Handle	1
14-440065	Instrument Loaner Kit	1
14-440060	Sterilization Tray	1

[†]Hall is a trademark of Conmed Corporation. Stryker is a trademark of Stryker Corporation.

Disposables

Catalog #	Description	Qty
14-410002	2.6 mm x 80 cm Bead Tip Guide Wire	1
41010	Calibrated Drill 4.3 mm	2
27984	Calibrated Drill 4.3 mm (Short)	2
14-440043	5.0 mm x 320 mm Calibrated Drill Bit	2
14-440041	7.0 mm x 200 mm Cannulated Drill	1
14-440052	3.2 mm x 320 mm Entry Guide Wire	2

Nails

Catalog #	Description
14-440115	10 mm x 150 mm
14-440118	10 mm x 180 mm
14-440121	10 mm x 210 mm
14-440124	10 mm x 240 mm
14-440127	10 mm x 270 mm
14-440130	10 mm x 300 mm
14-440215	11 mm x 150 mm
14-440218	11 mm x 180 mm
14-440221	11 mm x 210 mm
14-440224	11 mm x 240 mm
14-440227	11 mm x 270 mm
14-440230	11 mm x 300 mm
14-440315	12 mm x 150 mm
14-440318	12 mm x 180 mm
14-440321	12 mm x 210 mm
14-440324	12 mm x 240 mm
14-440327	12 mm x 270 mm
14-440330	12 mm x 300 mm

End Caps

Catalog #	Description
14-444180	0 mm End Cap
14-440071	+5.0 mm End Cap
14-440072	+10 mm End Cap
14-440073	+15 mm End Cap
14-440074	+20 mm End Cap

Screws

Catalog #	Description
14-405020	5.0 mm x 20 mm Cortical Screw
14-405022	5.0 mm x 22 mm Cortical Screw
14-405024	5.0 mm x 24 mm Cortical Screw
14-405026	5.0 mm x 26 mm Cortical Screw
14-405028	5.0 mm x 28 mm Cortical Screw
14-405030	5.0 mm x 30 mm Cortical Screw
14-405032	5.0 mm x 32 mm Cortical Screw
14-405034	5.0 mm x 34 mm Cortical Screw
14-405036	5.0 mm x 36 mm Cortical Screw
14-405038	5.0 mm x 38 mm Cortical Screw
14-405040	5.0 mm x 40 mm Cortical Screw
14-405042	5.0 mm x 42 mm Cortical Screw
14-405044	5.0 mm x 44 mm Cortical Screw
14-405046	5.0 mm x 46 mm Cortical Screw
14-405048	5.0 mm x 48 mm Cortical Screw
14-405050	5.0 mm x 50 mm Cortical Screw
14-405052	5.0 mm x 52 mm Cortical Screw
14-405054	5.0 mm x 54 mm Cortical Screw
14-405056	5.0 mm x 56 mm Cortical Screw
14-405058	5.0 mm x 58 mm Cortical Screw
14-405060	5.0 mm x 60 mm Cortical Screw
14-405065	5.0 mm x 65 mm Cortical Screw
14-405070	5.0 mm x 70 mm Cortical Screw
14-405075	5.0 mm x 75 mm Cortical Screw
14-405080	5.0 mm x 80 mm Cortical Screw
14-405085	5.0 mm x 85 mm Cortical Screw
14-405090	5.0 mm x 90 mm Cortical Screw
14-405095	5.0 mm x 95 mm Cortical Screw
14-405100	5.0 mm x 100 mm Cortical Screw
14-405105	5.0 mm x 105 mm Cortical Screw
14-405110	5.0 mm x 110 mm Cortical Screw

Sterilization

Biomet Intramedullary Nail implants are provided sterile and clearly marked "STERILE" on the packaging. These implants have been sterilized using a minimum dosage of 2.5 megaRad (25 kGy) of gamma radiation. Where specified, do not use implants after expiration date.


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 **Legal Manufacturer**
Biomet Trauma
56 East Bell Drive
Warsaw, Indiana 46581
USA

www.zimmerbiomet.com

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