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Phoenix™ Ankle Arthrodesis Nail System
Featuring Dual Stage CoreLock™ Technology

To learn more about this product,
contact your local Biomet Sales Representative today.

For product information, including indications, contraindications, warnings, precautions and potential adverse effects, see the package insert and Biomet's website.

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Biomet, Inc.
P.O. Box 587
56 E. Bell Drive
Warsaw, Indiana 46581-0587
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Surgical Technique

Phoenix™ Ankle Arthrodesis Nail System

Featuring Dual Stage CoreLock™ Technology

- Capable of 7.0mm of inboard tibiotalar compression independent of mechanically locking calcaneal screws
- Radiolucent arm facilitates precise screw targeting in nails up to 210mm with added capabilities for templating tangential oblique screws for additional fusion site stability and rotational control

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Contents

Introduction

The goals of tibiotalocalcaneal 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 poor bone stock, such as severe osteoporosis, talar 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 tibiotalocalcaneal arthrodesis or tibiotalar arthrodesis. A nail inserted through the plantar aspect of the foot can afford excellent stability, position, and alignment. The process of tibiotalocalcaneal 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 patent-pending CoreLock™ technology. (Pub. No.: US2008/0294164A1), (Pub. Date: Nov. 27, 2008) This unique dual stage locking mechanism is pre-assembled and embedded in each nail, and can provide up to 7.0mm of internal tibiotalar compression, followed by independent locking of the calcaneal screws. In addition to a static screw site proximally, the nail offers a 10mm dynamic compression slot, both of which accommodate newly designed 5.0mm double lead cortical screws.

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

The system features a strong, lightweight radiolucent Targeting Arm that permits radiographic visualization in multiple planes, and can provide 30mm 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

Indications for tibiotalocalcaneal arthrodesis include:

- Charcot Foot
- Avascular Necrosis of the Talus
- Trauma (malunited tibial pilon fracture)
- Failed Total Ankle Replacement
- Severe deformity as a result of Talipes Equinovarus, Cerebral Vascular Accident, Paralysis or other neuromuscular disease
- Revision Ankle Arthrodesis
- Neuropathic Deformity
- Rheumatoid Arthritis
- Osteoarthritis
- Pseudarthrosis
- Post-traumatic arthrosis
- Previously infected arthrosis
- Severe endstage degenerative arthritis
- Severe defects after tumor resection
- Pantalar arthrodesis

Contraindications

Contraindications for tibiotalocalcaneal and plantar arthrodesis with nail fixation include:

- Dysvascular Limb
- Active Infection
- Severe Longitudinal Deformity
- Insufficient Plantar Heel Pad
- Where an isolated ankle or subtalar fusion can be performed
- Patient conditions including blood supply limitations and insufficient quantity or quality of bone
- Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions
- Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of the device.

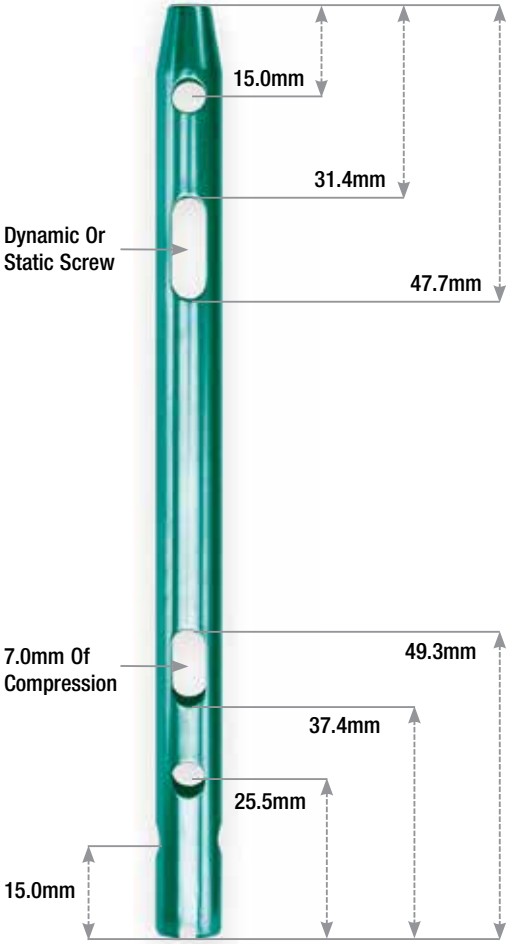
Implant Specifications

Nails

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

End Caps

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



Screws

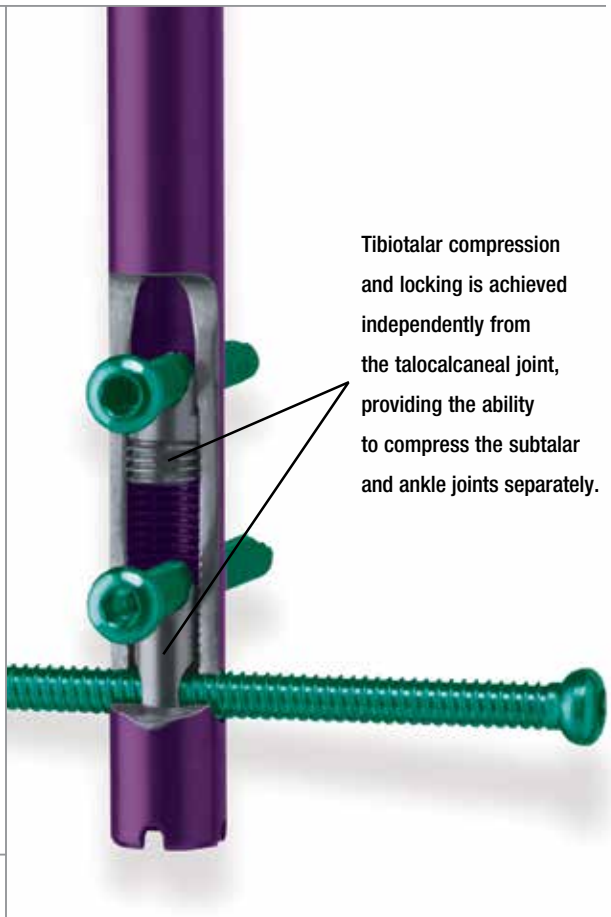
- 20mm – 60mm (Available in 2.0mm increments)
- 60mm – 110mm (Available in 5.0mm increments)
- 5.0mm Diameter

System Design Features

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

Pre-assembled/pre-embedded CoreLock™ mechanism is capable of 7.0mm 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 5.0mm 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 3.5mm 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 210mm in length
- Color-coded indicators for easy discernment
- In addition to the 7.0mm of inboard compression provided by the CoreLock™ mechanism, 30mm of compression across the tibotalar and subtalar joints can be achieved externally with the Targeting Arm's compression nut

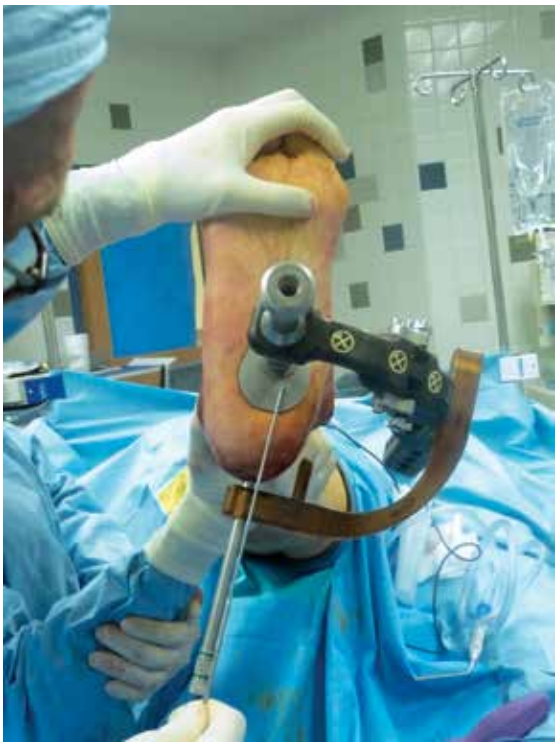
- A 3.2mm Guide Wire or the Wire Pusher (PN 41027) can be inserted through the Targeting Arm to indicate the countersunk depth of the distal end of the nail
- Grooved countersinking indicators on the Targeting Jig Nose can be seen clearly in fluoroscopic views

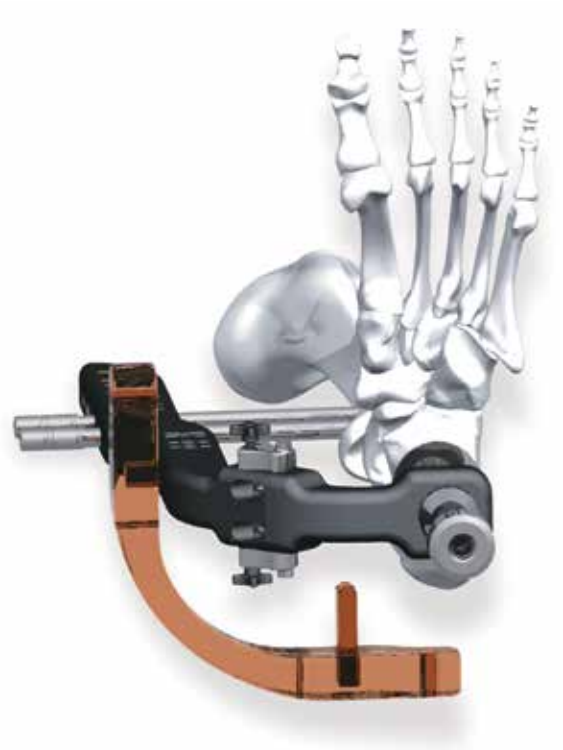
Compression Sleeve
(PN 14-440058)

- 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

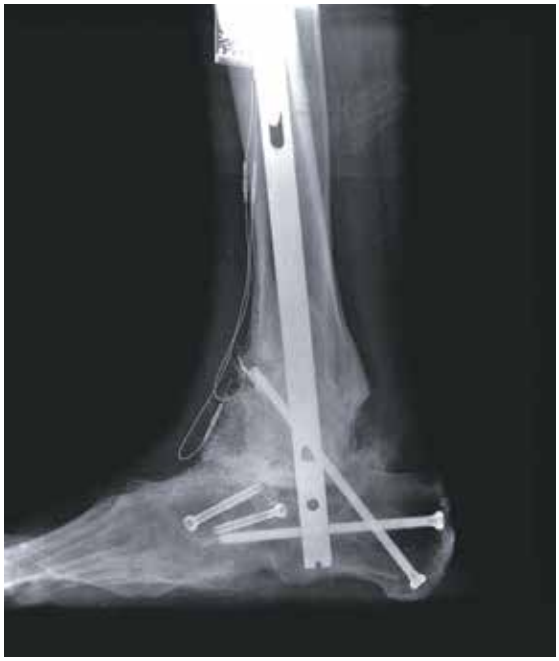
PA Screw Alignment Guide Arm

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 Guide

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

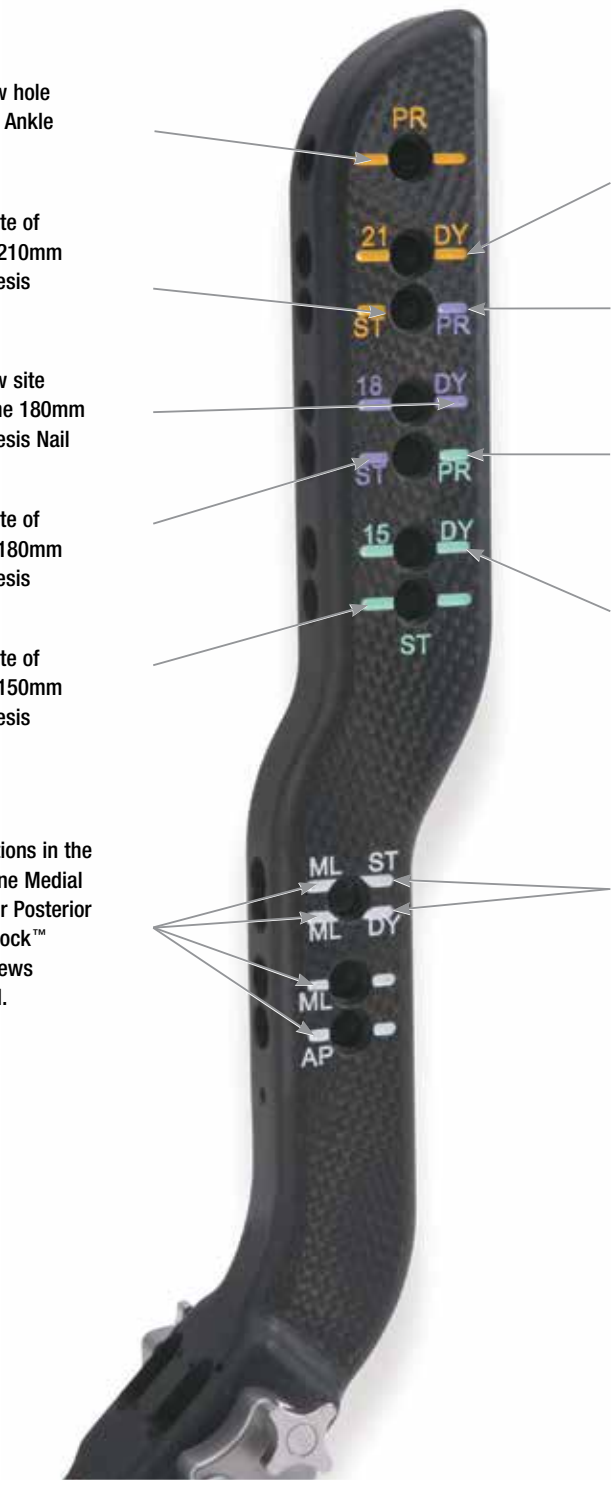
The most distal screw site of the Dynamic Slot in the 210mm Phoenix™ Ankle Arthrodesis Nail (static)

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

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

The most distal screw site of the Dynamic Slot in the 150mm 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 210mm Phoenix™ Ankle Arthrodesis Nail

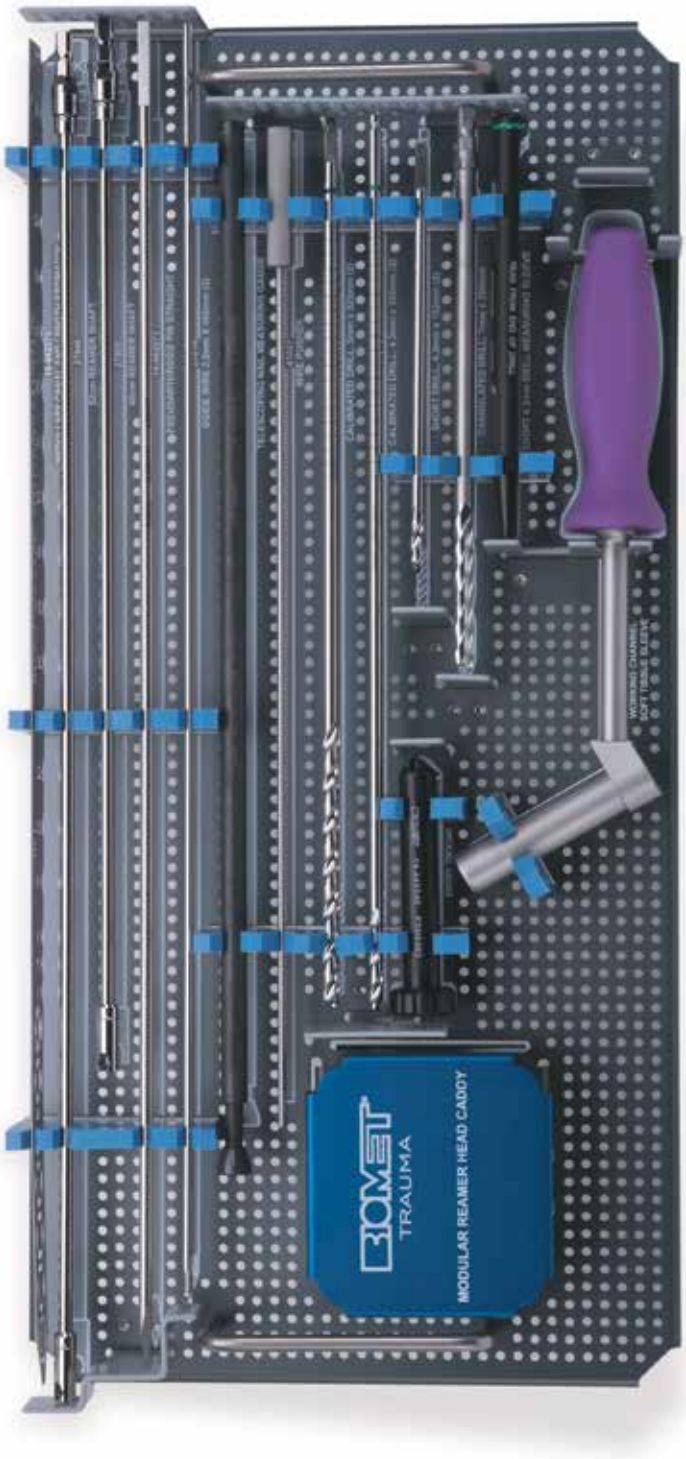
The most proximal screw hole of the 180mm Phoenix™ Ankle Arthrodesis Nail

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

The most proximal screw site of the Dynamic Slot in the 150mm 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 7.0mm of inboard tibiotalar compression.

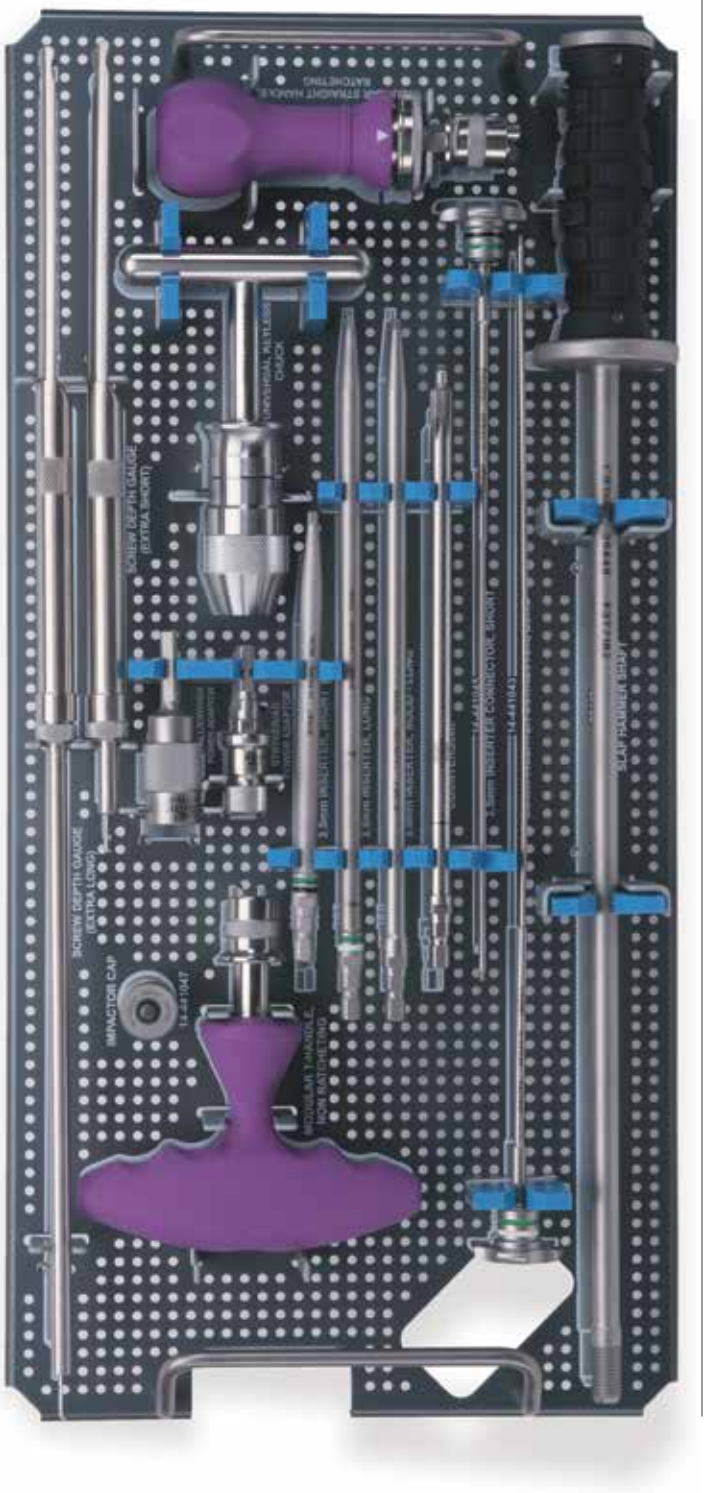
Tray Layout



Top Level

Catalog #	Description
27958	40cm Reamer Shaft
27940	52cm Reamer Shaft
467534	8.0mm Reamer Head
467536	8.5mm Reamer Head
467538	9.0mm Reamer Head
467540	9.5mm Reamer Head
467542	10mm Reamer Head
467544	10.5mm Reamer Head
467546	11mm Reamer Head
467548	11.5mm Reamer Head
467550	12mm Reamer Head
467552	12.5mm Reamer Head
467554	13mm Reamer Head
41027	Wire Pusher (Longer)
14-442073	Pseudarthrosis Pin Straight
14-442075	Medullary Canal and Length Estimator
14-442076	Short 4.3mm Drill Bit Measuring Sleeve
41029	Working Channel/Soft Tissue Sleeve
14-440045	Wire Offset Guide/Trocar
14-440047	Telescoping Nail Measuring Gauge
14-440041	7.0mm x 200mm Cannulated Drill
14-440052	3.2mm x 320mm Guide Wire
41010	Calibrated Drill 4.3mm
27984	Calibrated Drill 4.3mm (Short)
14-440043	5.0mm x 320mm Calibrated Drill Bit

Tray Layout (Continued)



Middle Level

Catalog #	Description
29448	Slap Hammer
14-441043	3.5mm Inserter Connector, Long
14-441044	3.5mm Inserter, Long
14-441045	3.5mm Inserter Connector, Short
14-441046	3.5mm Inserter, Short
14-441047	Impactor Cap
14-442081	Screw Depth Gauge (Extra Long)
14-442082	Screw Depth Gauge (Extra Short)
14-442089	Hall/Stryker† Power Adaptor
27977	Styker†/AO Power Adaptor
29407	T-Handle With Stryker† Quick Connect
29408	Straight Ratcheting Handle
14-442078	Keyless Chuck T-Handle
14-440049	Countersink
14-441051	3.5mm Inserter, Solid-Long

Bottom Level

Catalog #	Description
41004	Soft Tissue Sleeve
41005	4.3mm Drill Sleeve
14-441048	Nail Extractor Tap
41024	4.0mm Hex Driver (Silver)
14-442053	Slotted Mallet
14-442056	Sleeve Locking Set Screw
14-442066	3/4" Hex Driver
14-442084	3.5mm Hex Screw Extractor
14-440050	Targeting Arm
14-440054	Targeting Jig Nose/Driver Bushing
14-440040	Ratcheting 3/4" wrench
14-440055	Compression Hat
14-440042	Connecting Bolt
14-440044	5.0mm Drill Sleeve
14-440046	3.2mm Wire Sleeve
14-440051	P/A Screw Alignment Guide Arm
14-440048	4.3mm Trocar Interlock Ankle
14-440057	3.5mm Hex Driver (Gold)
14-440053	Driver Handle
14-440058	Compression Sleeve - Narrow
14-440056	Compression Nut
14-440060	Instrument Sterilization Tray

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:

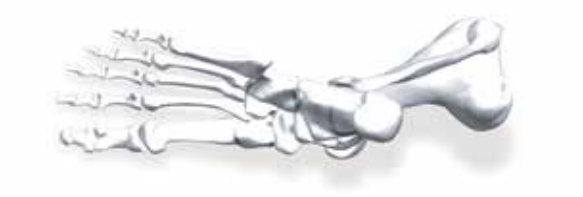
The patient is positioned in the lateral decubitus position on a radiolucent operating table with the affected extremity up (farthest away from the operating table). Great care must be taken to pad the patient's bony prominences and an axillary roll is used in the recumbent axilla. The non-operated extremity 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



Supine Patient Positioning:

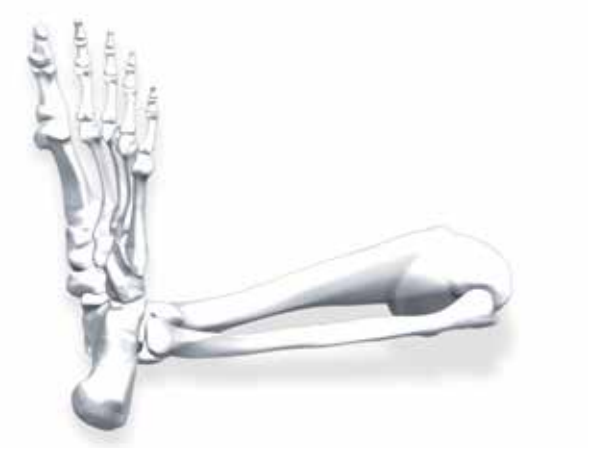
The patient is positioned supine on a radiolucent operating table with the affected extremity elevated in neutral alignment. If alignment and anatomy is normal, and the surgeon wishes to insert the proximal locking screws from medial to lateral, this is the preferred position. General or spinal anesthesia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



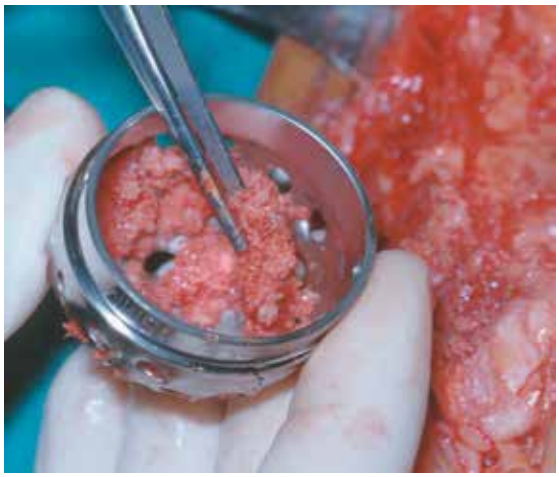
Step 2: Surgical Exposure

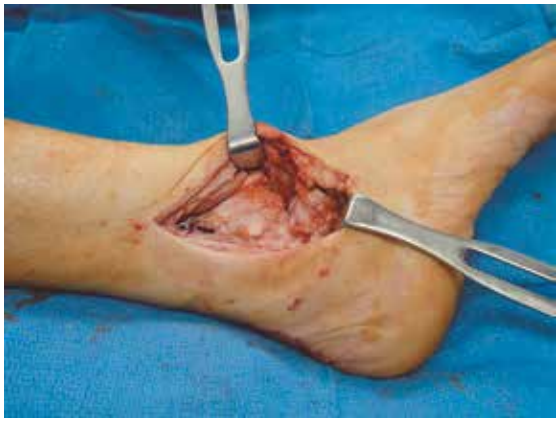
The transfibular approach affords excellent exposure for ankle fusion. A longitudinal incision is made over the posterior fibula, curving distally along the peroneus tendon. Great care should be taken to note the course of the existing neurovascular structures and tendons.

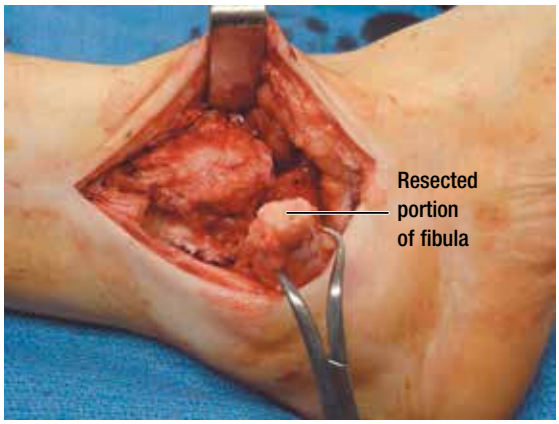
Step 3: Fibular Resection

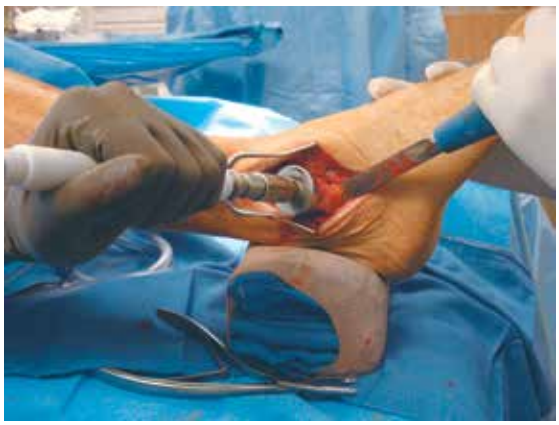
The distal 5cm of the fibula is resected in a beveled fashion at a level 2cm proximal to the tibiotalar joint line. The distal portion of the fibula may be morsellized for use as an autogenous bone graft.

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 36mm acetabular reamer which yields excellent graft material.









Images provided by Mark Myerson, M.D.

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

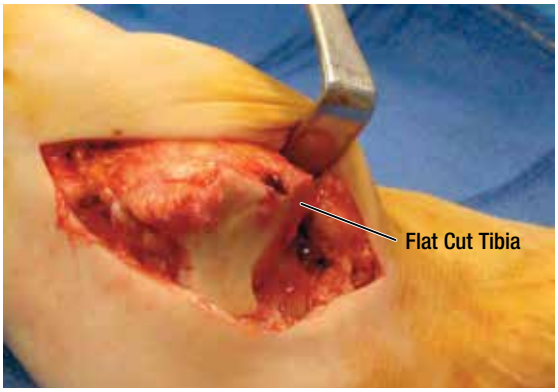
The ankle joint preparation is crucial to successful fusion. Two techniques for preparation of the tibiotalar joint are described. Care should be taken to avoid excessive bony resection which may later result in limb shortening or loss of talar fixation.

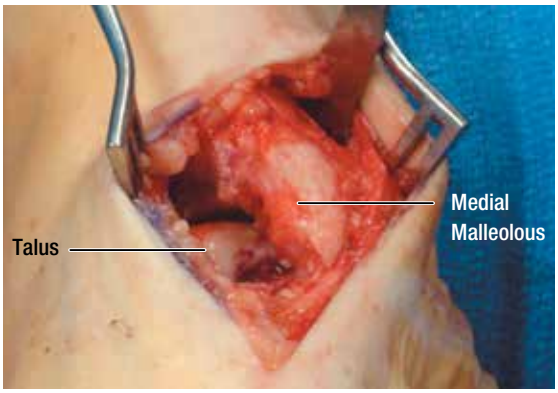
Flat Cut Resection (Shown)

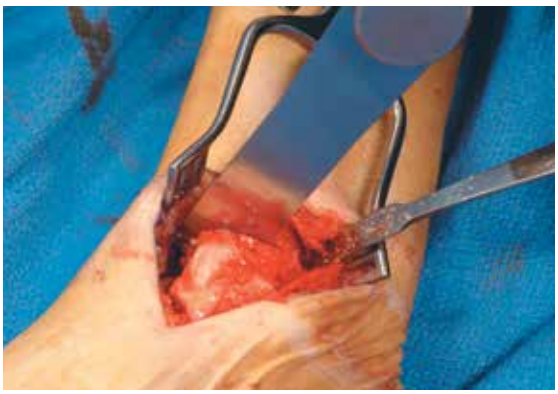
A transverse saw cut is made across the distal tibia.
This cut should include the medial malleolus. In this manner one is able to translate the distal tibia medially for a more direct alignment of the hindfoot relative to the tibia. At times it is easier to make a second incision medially and remove 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.

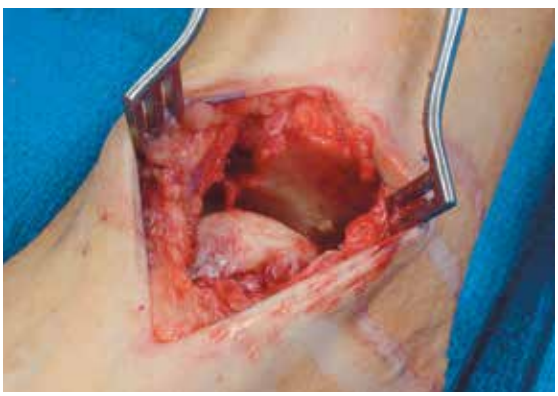
Joint Congruent Resection

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.

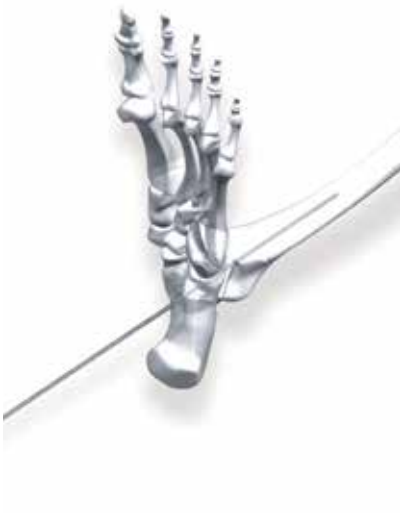
Step 5: Nail Entry Site and Incision

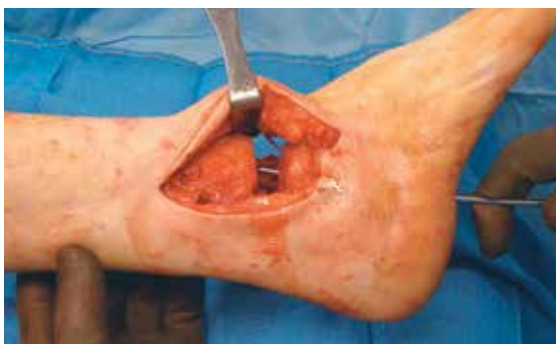
Following the preparation of the bony surfaces, a 3cm longitudinal plantar incision is made anterior to the subcalcaneal fat pad slightly lateral to the midline, especially in the patient with significant preoperative valgus deformity. Blunt dissection is carried down to the plantar fascia, which is 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 2cm 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 3.2mm x 320mm 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 7.0mm x 200mm Cannulated Drill (PN 14-440041), ream the subtalar and tibiotalar articular surfaces over the 3.2mm Entry Guide Wire. It is helpful to have an assistant hold the foot in the appropriate alignment during the transmedullary reaming.

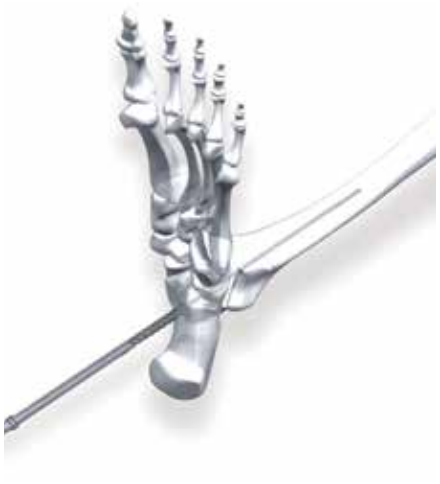
Step 8: Bead Tip Guide Wire Placement and Canal Reaming

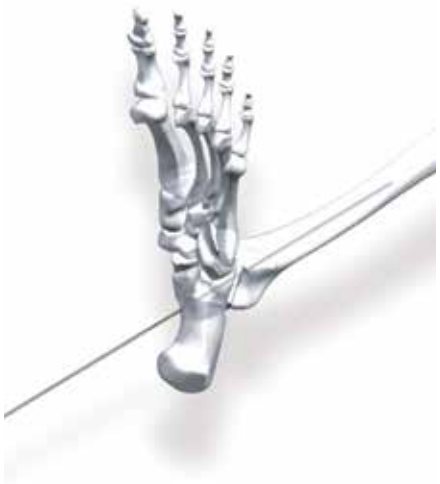
Holding the foot in proper alignment, remove the 3.2mm Entry Guide Wire. A 2.6mm x 80cm Bead Tip Guide Wire (PN 14-410002) is inserted trans-calcaneally through the talus into the medullary canal of the tibia using image intensification. Progressive reaming is performed over the Bead Tip Guide Wire. 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 8.0mm end-cutting reamer, and then follow sequentially in 0.5mm increments. Ream to 0.5mm to 1.0mm larger than the diameter of the nail to be implanted.

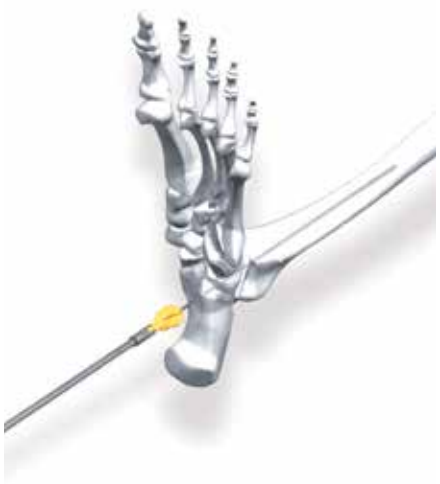
NOTE: Over-reaming by a full 1mm may help reduce the need for excessive insertion force.

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.

Reamer Head Caddy





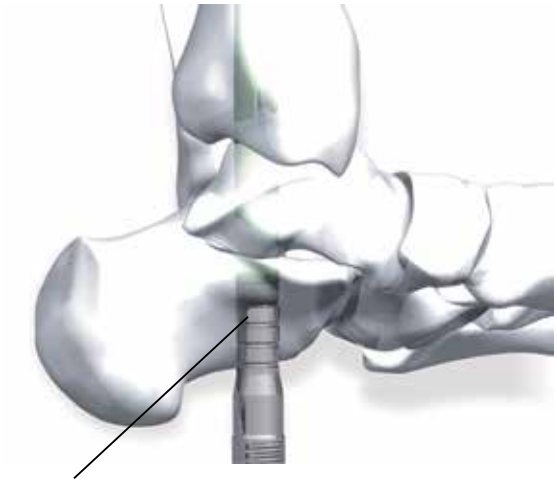


Step 9: Nail Length Determination

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 2.6mm x 80cm 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 150mm, 180mm, 210mm, 240mm, 270mm and 300mm and diameters of 10mm, 11mm and 12mm. ***Targeting Arm will only target nails up to 210mm in length.***

The proximal end of the nail should extend at least 5cm 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 5.0mm-10mm in the plantar cortex of the calcaneus. The nail may be countersunk more if warranted by the patient anatomy.



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

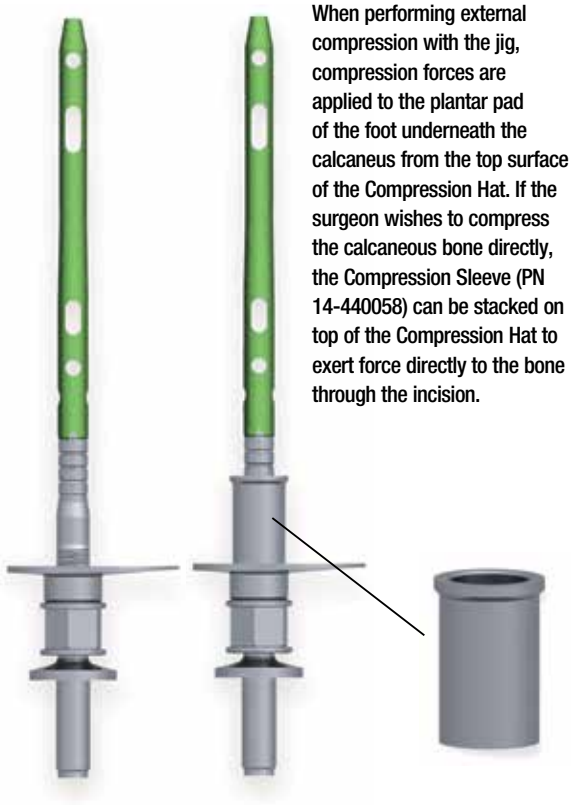
Step 10: Outrigger Assembly

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.

Targeting Jig Nose/Driver Bushing (PN 14-440054)

Connecting Bolt (PN 14-440042)



When performing external compression with the jig, compression forces are applied to the plantar pad of the foot underneath the calcaneus from the top surface of the Compression Hat. If the surgeon wishes to compress the calcaneous 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.

The Connecting Bolt is then tightened using the 9.5mm hex portion on the Ratcheting 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 4.3mm Drill Sleeve (PN 41005) into the Soft Tissue Sleeve (PN 41004) and then insert the stack into the appropriate Targeting Arm location. The 4.3mm 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

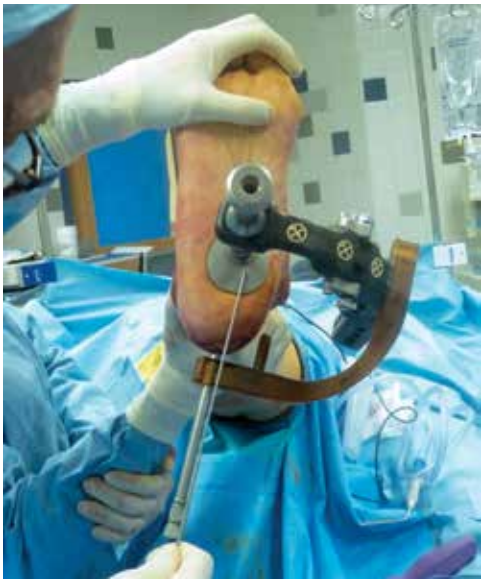
After performing an alignment check, the Targeting Arm is positioned to address the tibial screws from medial to lateral (shown).

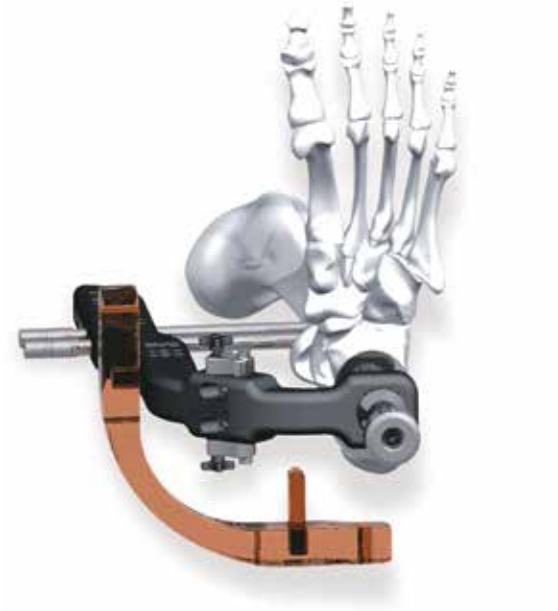
A lateral to medial approach may also be elected based on surgeon preference. If a lateral to medial approach is preferred, a slight internal rotation of the nail may help the surgeon avoid fibular interference when inserting the proximal locking screws into the tibia.

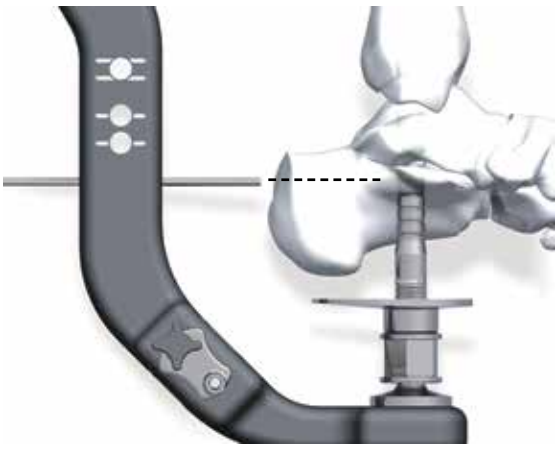
Countersink the nail 5.0mm-10mm to allow for desired compression. This also prevents painful prominence in plantar soft tissue.

When countersinking the nail, a 3.2mm 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 2.6mm x 80cm 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 4.3mm Drill Sleeve is passed down to the medial cortex of the tibia. A 4.3mm 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.

After removing the Drill Sleeve, insert the appropriate 5.0mm screw using the 3.5mm Inserter (PN14-441044) and 3.5mm Inserter Connector (PN 14-441043). A solid 3.5mm 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

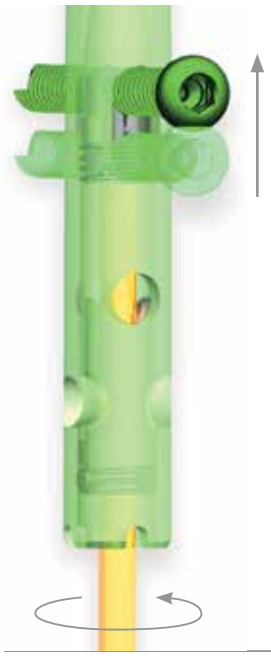
The talar screw is inserted lateral to medial. To re-orient the jig, loosen the Driver Handle (3 turns is sufficient) and rotate the Targeting Arm 180° to the lateral side. Once in position, re-tighten the Driver Handle to lock down the Targeting Arm.

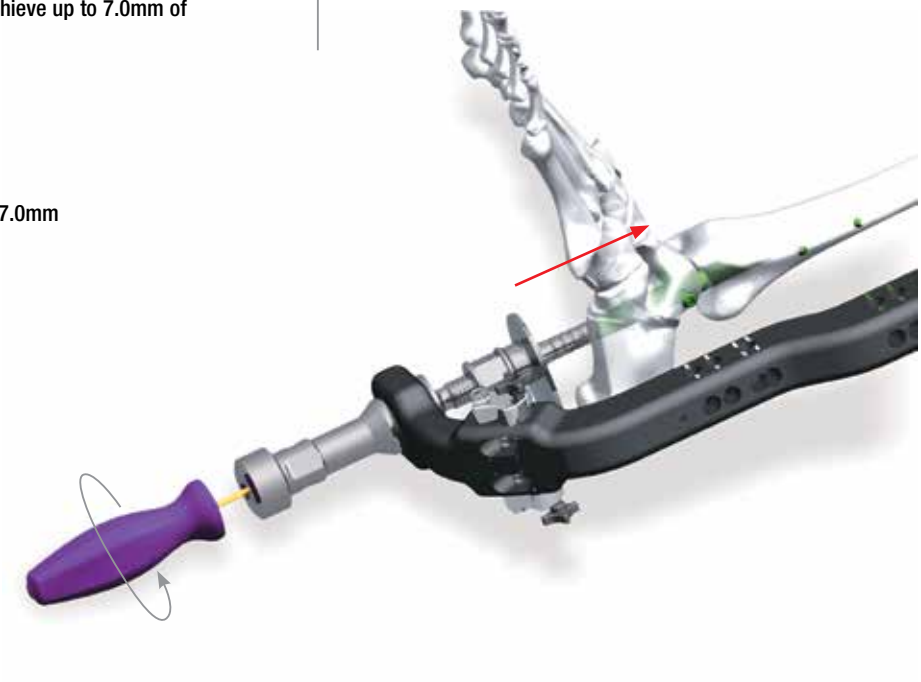
To achieve internal compression with the CoreLock™ mechanism, the talar screw must be inserted through the appropriate Dynamic Slot of the Targeting Arm. The lateral articular surface of the talus is directly visualized and the Drill Sleeve is passed down to the lateral cortex.

Using the 4.3mm Drill Bit, prepare and implant a 5.0mm screw through the talus in the same manner described previously.

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

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





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 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 over-tighten the Compression Nut. Excessive compression forces my 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.

- Travel Indicators are calibrated in 5.0mm increments

Step 15: Distal Screw Placement

After internal and external compression, a 4.3mm 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 4.3mm Drill Bit bi-cortically. Measure and insert the appropriately sized 5.0mm screw.

Step 16: PA Screw Placement

Rotate the Targeting Arm 90° to allow for a posterior to anterior approach. Insert a 4.3mm 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.

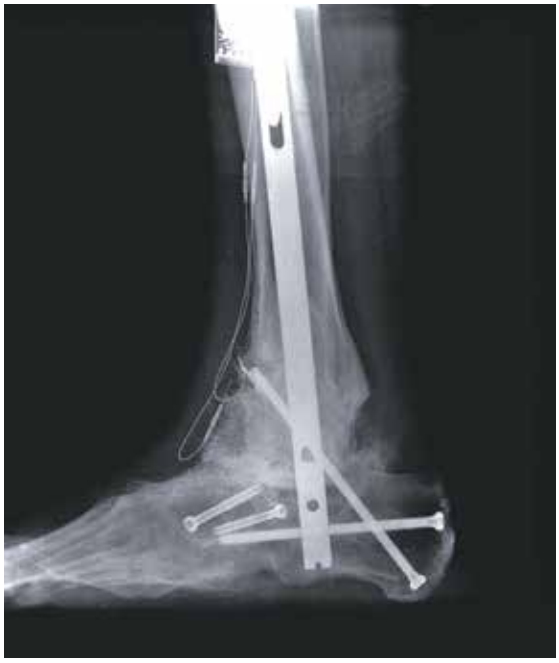
Using fluoroscopy, pass the 4.3mm Calibrated Drill Bit to the desired depth in the calcaneus. Determine the appropriate screw length from the calibrations on the Drill Bit or by using the depth gauge. For true pantalar arthrodesis, this screw may be passed through the calcaneus into the cuboid or navicular.

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 4.0mm 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 0mm end cap to a +20mm cap (5.0mm 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 0mm 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 3.5mm Hex Driver. Advance the End Cap until securely in place.

All other End Caps (5.0mm, 10mm, 15mm, and 20mm) 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 3.5mm 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.

Integrity® Fracture Walker

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 2.6mm x 80cm 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 4.3mm 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 4.3mm 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.

After removing the Drill Sleeve, insert the appropriate 5.0mm screw through the Soft Tissue Sleeve using the 3.5mm Inserter (PN 14-441044) and 3.5mm Inserter Connector (PN 14-441043). A solid 3.5mm 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 4.3mm 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.

After removing the Drill Sleeve, insert the appropriate 5.0mm screw using the 3.5mm Inserter (PN 14-441044) and 3.5mm Inserter Connector (PN 14-441043). A solid 3.5mm 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 3.5mm Hex Driver - (PN 14-440057) (gold shaft), advance the internal compression mechanism with clockwise revolutions to achieve up to 7.0mm 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	4.3mm Drill Sleeve	2
29448	Slap Hammer	1
14-441046	3.5mm Inserter, Short	1
14-441047	Impactor Cap	1
14-441048	Nail Extractor Tap	1
27940	52cm Reamer Shaft	1
27958	40cm Reamer Shaft	1
41024	4.0mm Hex Driver (Silver)	1
467534	8.0mm Reamer Head	1
467536	8.5mm Reamer Head	1
467538	9.0mm Reamer Head	1
467540	9.5mm Reamer Head	1
467542	10mm Reamer Head	1
467544	10.5mm Reamer Head	1
467546	11mm Reamer Head	1
467548	11.5mm Reamer Head	1
467550	12mm Reamer Head	1
467552	12.5mm Reamer Head	1
467554	13mm 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	Targeting Arm Wing Nut	2
14-442066	3/4" Hex Driver	1
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	3.5mm 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 3/4" Wrench	1
14-440055	Compression Hat	1
14-440056	Compression Nut	1
14-440042	Connecting Bolt	1
14-440044	5.0mm Drill Sleeve	2
14-440046	3.2mm Wire Sleeve	2
14-440051	PA Screw Alignment Guide Arm	1
14-440045	Wire Offset Guide/Trocar	1
14-440048	Trocar	2
14-440057	3.5mm Hex Driver (Gold)	1
14-440053	Driver Handle	1
14-440047	Telescoping Nail Measuring Gauge	1
14-440058	Compression Sleeve - Narrow	1
14-441043	3.5mm Inserter Connector, Long	1
14-441044	3.5mm Inserter, Long	1
14-441045	3.5mm Inserter Connector, Short	1
14-441051	3.5mm Inserter, Solid-Long	1
14-442078	Keyless Chuck T-Handle	1
14-440065	Instrument Loaner Kit	1
14-440060	Sterilization Tray	1

Disposables

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

Ordering Information

Nails

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

End Caps

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

Screws

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

Sterilization

Unless supplied sterile, metallic internal fixation devices must be sterilized prior to surgical use. Product provided sterile is sterilized by exposure to a minimum dose of 2.5 Megarads (25kGy) gamma radiation. Where specified, do not use implants after expiration date. These guidelines also apply to devices provided sterile where the integrity of the packaging has been compromised and re-sterilization is required prior to initial use. Do not resterilize components that have been previously implanted, exposed to biological contamination, or appear to have compromised mechanical integrity.

Pre-Vacuum Steam Sterilization:
Temperature: 270°F (132°C)
Time: Eight (8) Minutes
NOTE: Allow for cooling

Since Biomet is not familiar with individual hospital handling methods, cleaning methods and bioburden, Biomet cannot assume responsibility for sterility of products provided as non-sterile even though the recommended guideline is followed.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Further Information

See the package insert for warnings, precautions, possible adverse effects and additional product information.

This brochure describes a surgical technique used by George Quill, M.D., Mark Myerson, M.D. and Stuart Miller, M.D. Biomet Trauma as the manufacturer of this device, does not practice medicine and does not recommend this product or any specific surgical technique for use on any individual patient. The surgeon who performs any implant procedure is responsible for determining the appropriate product(s) and utilizing the appropriate technique(s) for said implantation in each individual patient.

For further information, please contact the Customer Service Department at:

Biomet Trauma
100 Interpace Parkway
Parsippany, NJ 07054
(973) 299-9300 - (800) 526-2579
www.biomettrauma.com

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