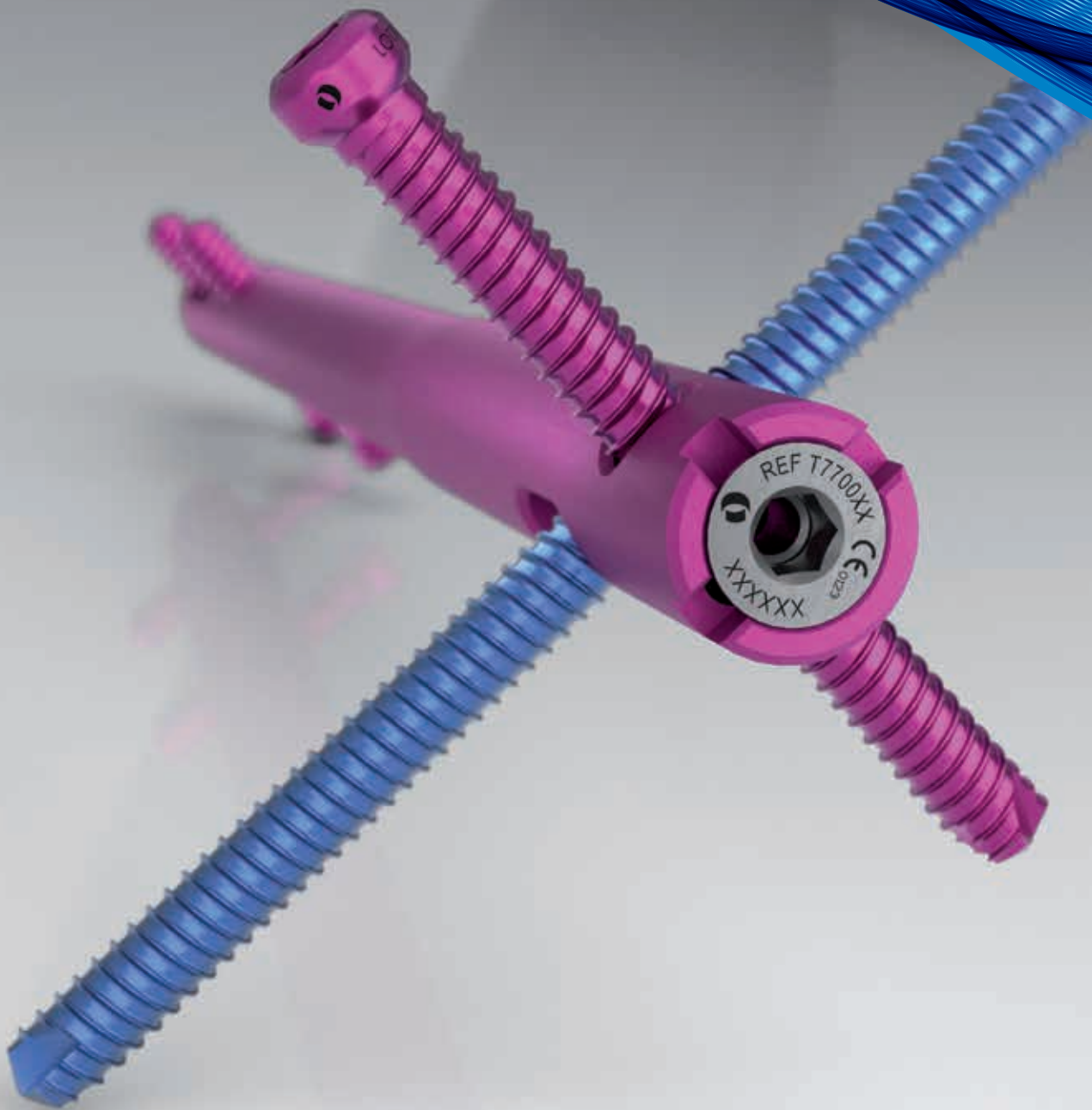


OPERATIVE TECHNIQUE

Ankle

Hindfoot Nailing System™



Ankle

Hindfoot Nailing System™

CONTENTS

1	General description
2	Features and benefits
5	Ordering information
6	Features and benefits
6	Preoperative planning
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The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please see the Instructions For Use for the complete list of indications, warnings, precautions, and other important medical information.

GENERAL DESCRIPTION

The AHN (Ankle Hindfoot Nailing System™) Revision Nail line extension is designed to address the specific demands of hindfoot arthrodesis with or without a viable talus bone.

The line extension consists of 2 different diameter nails in 3 different lengths for each diameter. The AHN Revision Nail implants are provided in single, sterile packaging only. All AHN Revision Nails must be accompanied by a specific targeting handle cover.

INTENDED USE

The Orthofix Ankle Hindfoot Nailing System™ is intended to facilitate tibiotalar 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 ankle
13. Severe endstage degenerative arthritis
14. Severe defects after tumor resection
15. Pantalar arthrodesis

CONTRAINDICATIONS

1. Active or latent infection in the affected area
2. General medical conditions including: impaired blood supply, pulmonary insufficiency (i.e. ARDS, fat embolism) and insufficient quantity or quality of bone
3. Patients who are unwilling or incapable of following post-operative care instructions
4. Suspected or documented metal allergy or intolerance
5. Severe longitudinal deformity
6. Insufficient plantar heel pad
7. Situations where an isolated ankle or subtalar fusion can be performed
8. Dysvascular limb

INSTRUCTIONS FOR USE (IFU)

See actual package insert for instructions for use.

MRI safety information

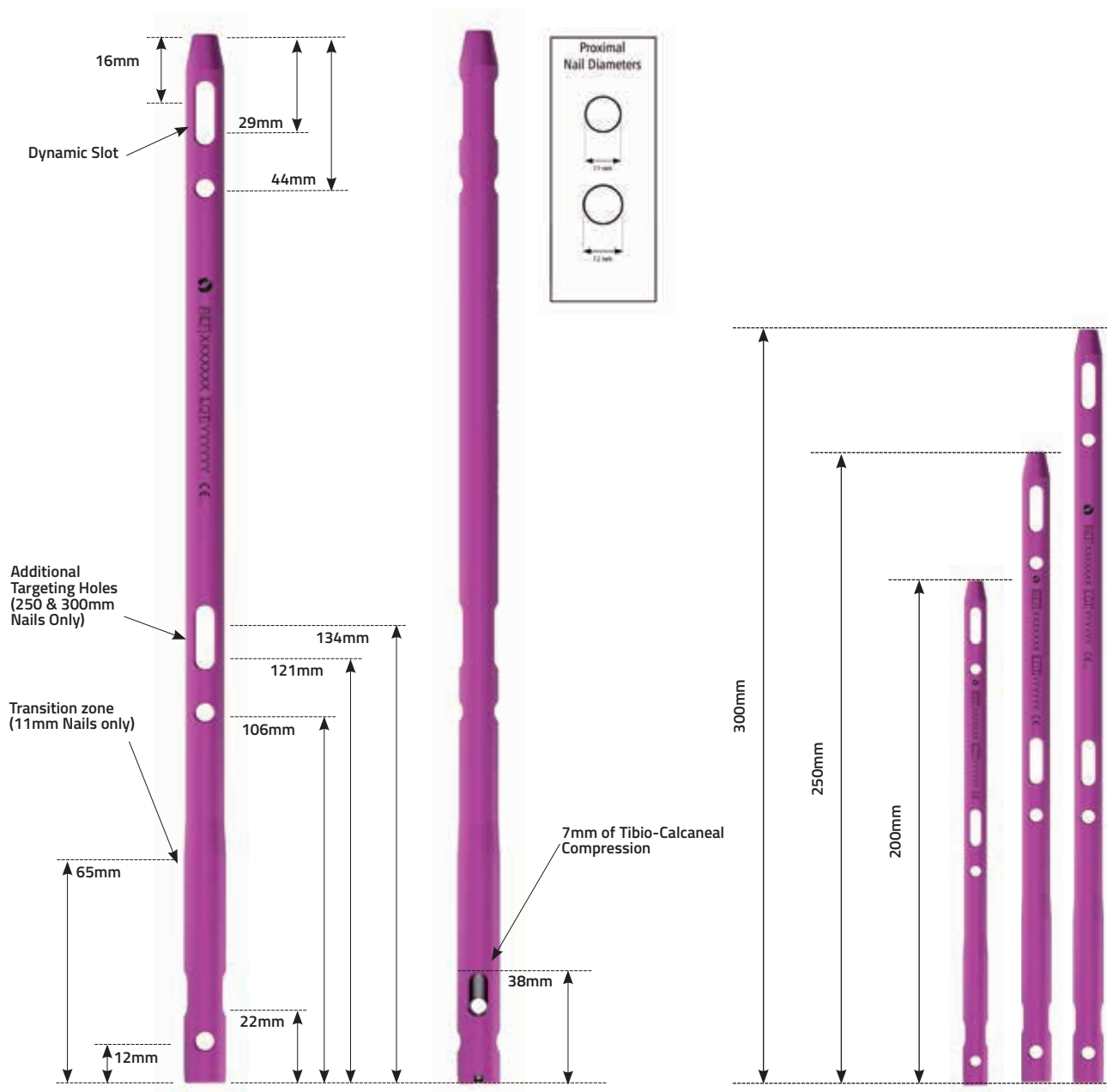
The AHN Revision Nail has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the AHN Revision Nail in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

FEATURES AND BENEFITS

- Pre-Assembled Internal Compression Mechanism
- Combination of Internal & External Compression Mechanisms
- Threaded calcaneal screw placement
- No prior assembly is needed. Designed to facilitate simple preparation and setup for surgery
- The two compression mechanisms are designed to provide stability to the implant construct
- Designed to reduce the number of surgical steps by eliminating the need for locking the calcaneal screw for internal compression

INSTRUCTIONS FOR USE (IFU)

See actual package insert for instructions for use.



DESCRIPTION OF PRODUCT COMPONENTS

Pre-Assembled Internal Compression Mechanism.
Combination of Internal & External Compression Mechanisms. Threaded calcaneal screw placement. No prior assembly is needed. Designed to facilitate simple preparation and setup for surgery. The two compression mechanisms are designed to provide excellent stability to the implant construct. Designed to reduce the number of surgical steps by eliminating the need for locking the calcaneal screw for internal compression.

Nails

- Cannulated
- Titanium
- Lengths: L200 - L250 - L300 mm
- Diameters: 11, 12mm
- Distal Diameter: 12mm
- Magenta: 200, 250, 300mm
- Calcaneal anterior to posterior slot allows for
 - 7mm of internal compression
 - screw can be locked within any position of the slot
- Tibial screws offer static and dynamic options
- Long Nails (250,300mm) include (2) sets of tibial screw holes. This provides the freedom to utilize the targeting assembly or free-hand per surgeon discretion.

Locking End Cap

- Lengths of 0, 5, 10mm
- Cannulated
- Functions to lock Calcaneal Screws



Locking Screws

Low Profile Screws (magenta)

(T774xxx)

- 5mm Diameter
- 4.3mm Core Diameter
- 20 - 120mm. See table on Page 5



Threaded Head Screws (dark blue)

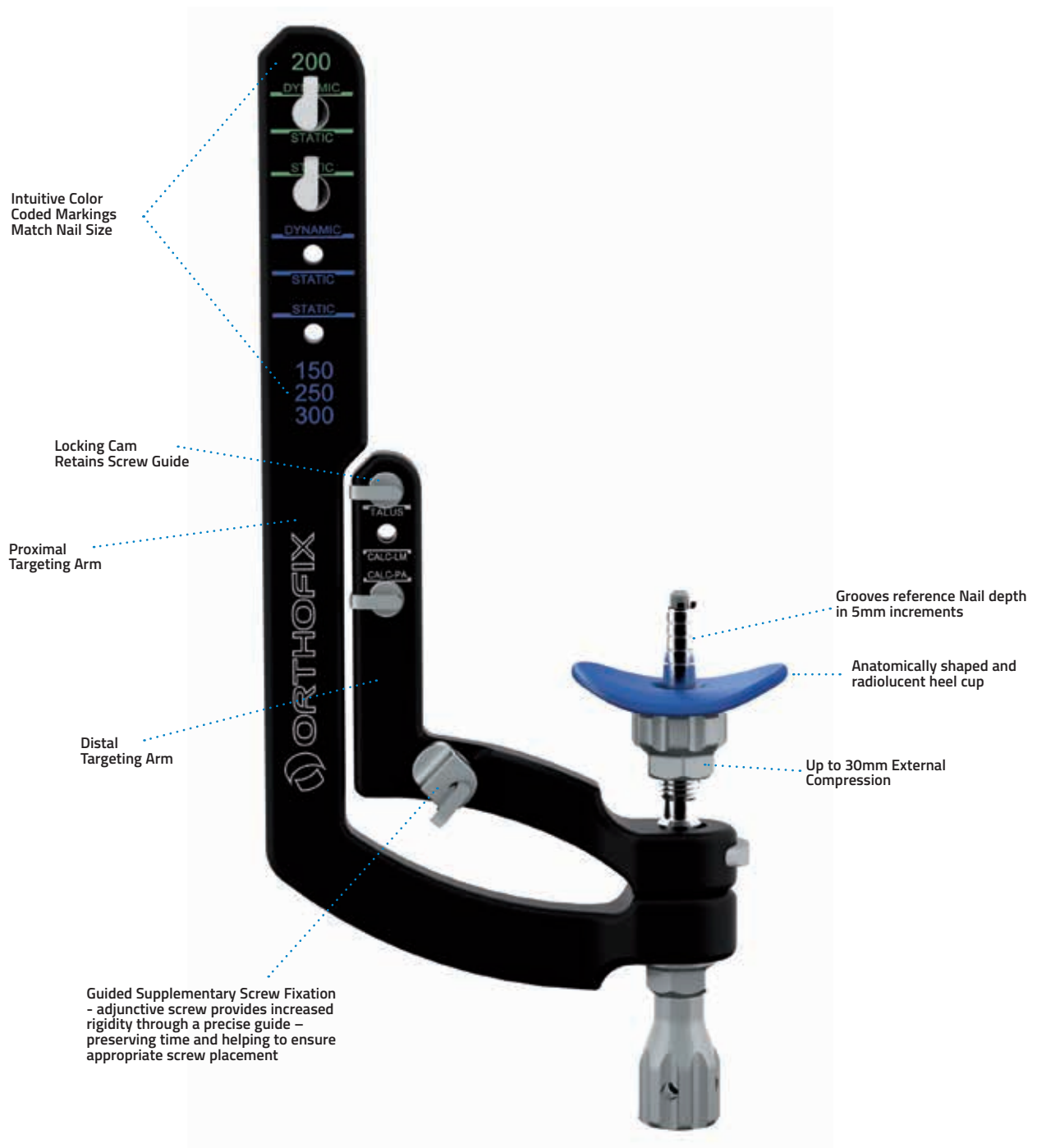
(T775xxx)

- 5mm Diameter
- 4.3mm Core Diameter
- 60 - 120mm; 5mm increments
- Designed for the calcaneus. The threaded head sinks into the bone, substantially reducing risk of posterior prominence



Targeting Assembly

- Precise targeting available for tibia in all lengths
- Radiolucent
- Proximal Targeting Arm is fixed; Distal Targeting Arm locks in 90 degree increments – helping to ensure a secure platform throughout the procedure



ORDERING INFORMATION

Titanium Ankle Hindfoot Nail	
Part #	Description
99-T771301	Ankle Hindfoot Revision Nail TI L300mm D11mm Sterile With Guide Jig
99-T772301	Ankle Hindfoot Revision Nail TI L300mm D12mm Sterile With Guide Jig
99-T771251	Ankle Hindfoot Revision Nail TI L250mm D11mm Sterile With Guide Jig
99-T772251	Ankle Hindfoot Revision Nail TI L250mm D12mm Sterile With Guide Jig
99-T771201	Ankle Hindfoot Revision Nail TI L200mm D11mm Sterile With Guide Jig
99-T772201	Ankle Hindfoot Revision Nail TI L200mm D12mm Sterile With Guide Jig

Threaded Head Screws D 5mm	
Part #	Description
99-T775060	L 60mm
99-T775065	L 65mm
99-T775070	L 70mm
99-T775075	L 75mm
99-T775080	L 80mm
99-T775085	L 85mm
99-T775090	L 90mm
99-T775095	L 95mm
99-T775100	L 100mm
99-T775105	L 105mm
99-T775110	L 110mm
99-T775115	L 115mm
99-T775120	L 120mm

Locking End Cap	
Part #	Description
99-T770000	L 0mm
99-T770005	L 5mm
99-T770010	L 10 mm

Sterile Packaged Instrumentation	
Part #	Description
99-177281	3.0mm x 800mm Ball Tip Guide Wire
99-177282	2.5mm x 800mm Guide Wire

Low Profile Screws D 5mm	
Part #	Description
99-T774020	L 20 mm
99-T774022	L 22.5mm
99-T774025	L 25mm
99-T774027	L 27.5mm
99-T774030	L 30mm
99-T774032	L 32.5mm
99-T774035	L 35mm
99-T774037	L 37.5mm
99-T774040	L 40mm
99-T774045	L 45mm
99-T774050	L 50mm
99-T774055	L 55mm
99-T774060	L 60mm
99-T774065	L 65mm
99-T774070	L 70mm
99-T774075	L 75mm
99-T774080	L 80mm
99-T774085	L 85mm
99-T774090	L 90mm
99-T774095	L 95mm
99-T774100	L 100mm
99-T774105	L 105mm
99-T774110	L 110mm
99-T774115	L 115mm
99-T774120	L 120mm

Flexible Reamer Set 172001C (US Market) 172001 (Intl Market) Consisting of:		
Part #	Description	Qty.
172991	Flexible Reamer System Box, empty	1
172090	Modular Reamer Head Ø 9mm	1
172095	Reamer Head Ø 9.5mm	1
172100	Reamer Head Ø 10mm	1
172105	Reamer Head Ø 10.5mm	1
172110	Reamer Head Ø 11mm	1
172115	Reamer Head Ø 11.5mm	1
172120	Reamer Head Ø 12mm	1
172125	Reamer Head Ø 12.5mm	1
172130	Reamer Head Ø 13mm	1
172135	Reamer Head Ø 13.5mm	1
172140	Reamer Head Ø 14mm	1
172145	Reamer Head Ø 14.5mm	1
172150	Reamer Head Ø 15mm	1
172155	Reamer Head Ø 15.5mm	1
172160	Reamer Head Ø 16mm	1
172165	Reamer Head Ø 16.5mm	1
172170	Reamer Head Ø 17mm	1
172200	Flexible Reamer Shafts	2
172080	Monobloc Flexible Reamer Ø 8mm	1
172085	Monobloc Flexible Reamer Ø 8.5mm	1
172210	Flexible Shaft Adapter	1
17955	Universal Chuck with T-Handle	1
172220	Soft Tissue Protector	1

FEATURES AND BENEFITS

- Patients with adequate soft tissue and vascular supply to allow for successful healing of wounds and fusion site
- Patients with incomplete pain relief or deformity recalcitrant to appropriate conservative measures

PREOPERATIVE PLANNING

- Note rotation of opposite side
- Standard and hindfoot alignment view weightbearing radiographs

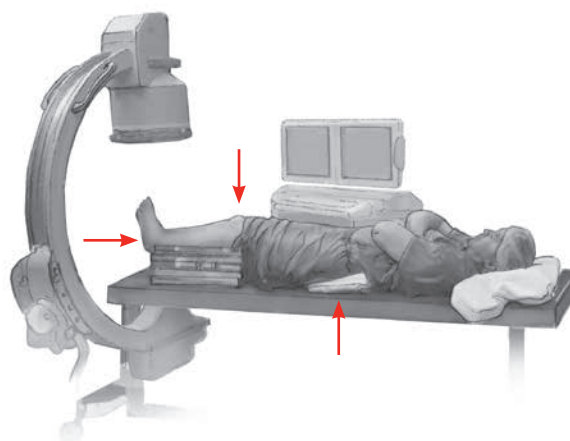
Ensure radiographic findings match patient's symptoms. When in doubt, perform differential intra-articular injection.



TIPS: 200mm nails are generally chosen for post-traumatic and talar deficient cases. Longer nails that extend proximal to the isthmus are generally chosen for Charcot/neuropathic conditions. This will decrease the probability of post-operative fracture due to stress riser at the tip of the nail.



NOTE: 250mm and 300mm nails require free-hand placement of the most proximal set of the tibial locking screws.



PATIENT POSITIONING

Examine the contralateral limb and check the rotation of foot relative to limb. In addition to a general anesthetic, a regional block (i.e. popliteal) performed PRIOR to the procedure provides optimal postoperative pain control. A thigh tourniquet should then be placed and elevated upon surgeon's preference. There are several options for patient positioning including supine, lateral decubitus, and prone. These are dependent on patient anatomy, previous incisions, bone defects, and surgeon's preference. Supine with a roll/bump under the ipsilateral hip on a radiolucent operating table with the leg elevated seems to offer the most advantages. This roll should be placed in such a manner that the leg is in neutral position (i.e. patella is straight up).

Supine Position Advantages:

- a) Permits the standard approach for ankle and subtalar arthrodesis.
- b) Facilitates ML/LM targeting.
- c) Easier to perform with larger patients.

Supine Position Disadvantage

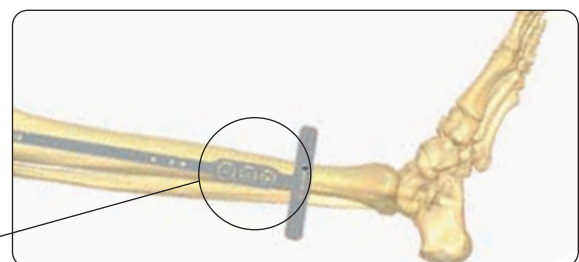
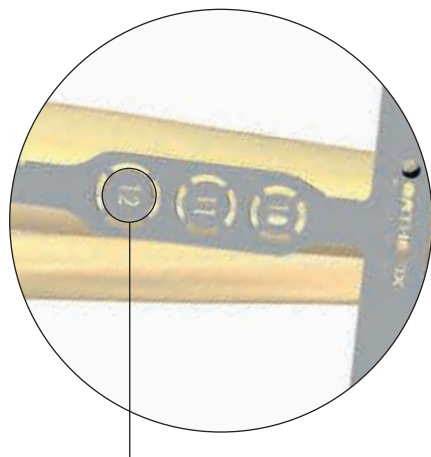
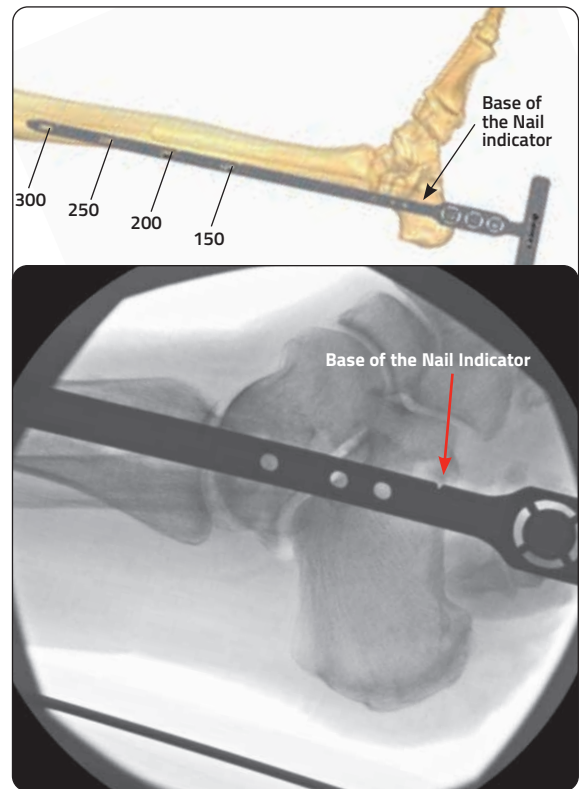
Placement of the posterior-anterior (P-A) screw can be more difficult.

C-Arm Positioning

The C-arm monitor should be positioned at 90 degrees to the table on the affected side, on the opposite side of the C-arm.

Measurement of Nail Length

The X-Ray Ruler (177275) can be used in combination with fluoroscopy to determine the appropriate nail length (and diameter). Ideal placement of the X-Ray Ruler would be on the side of the leg closest to the image intensifier where the base of the Nail Indicator will approximately locate the base of the Nail.



Inner circle represents the proximal diameter of the Nail

SURGICAL APPROACH

Part #	Description
177290	3.2mm x 400mm Entry Guide Wire

Multiple approaches have been well described for ankle arthrodesis. These include lateral, medial, anterior, combined medial and lateral, as well as posterior approach.

Joint Preparation

The joint preparation may be either a flat cut or joint congruent type of resection. Both options have their advantages. The choice of approach and type of resection are surgeon's preference. The subtalar joint is prepared in standard fashion with chisels or curettes to remove all remaining cartilage and fibrous tissue and achieve a bleeding bed of corticocancellous bone. Ideally during the resection of the distal tibia and proximal talus, no more than 6mm is removed from each side. In situations where the talar bone stock is limited secondary to avascular necrosis, charcot arthropathy, or revision total ankle to fusion, the distal tibia and calcaneal surface needs to be prepared. These surfaces are prepared to accommodate structural allograft or metal cage interposition. This can be done in a variety of ways including but not limited to chisel, osteotome, and/or saw. The medial wall or face of the talus should align with medial shaft of the tibia. It is often most successful to correct the deformities with the resection rather than rely on the implant to achieve reduction. The selection of the appropriate method is within the surgeon's discretion.

Ankle Positioning and Alignment

The ideal position of arthrodesis is neutral dorsiflexion (the foot is at a 90-degree angle to the long axis of the tibia) with 5-7 degrees of hindfoot valgus and external rotation symmetrical with the opposite side. (**Figure 1**)

If the opposite side does not have normal anatomy, then consider aligning the crest of the tibial shaft with the 2nd ray. The hindfoot position should be established and maintained prior to guide wire insertion, reaming, and nail insertion to ensure the nail does not change the foot position after it is inserted.

Entry Point Incision and Guide Wire Insertion

These steps are critical and have a great influence on both the rest of the case and the patient's clinical result. Time invested with these steps is well spent and makes the remaining steps and result ideal. (**Figure 2**)



TIPS:

- 1) The optimal insertion point for the Nail is immediately lateral to the plantar calcaneus' midpoint and in line with the longitudinal tibial axis.
- 2) To ease the use of fluoroscopy, many have found it helpful to have the operative side elevated to decrease fluoroscopic interference from the contralateral limb.
- 3) A longitudinal incision made prior to wire placement can allow for easier wire adjustment on the plantar aspect of the calcaneus.

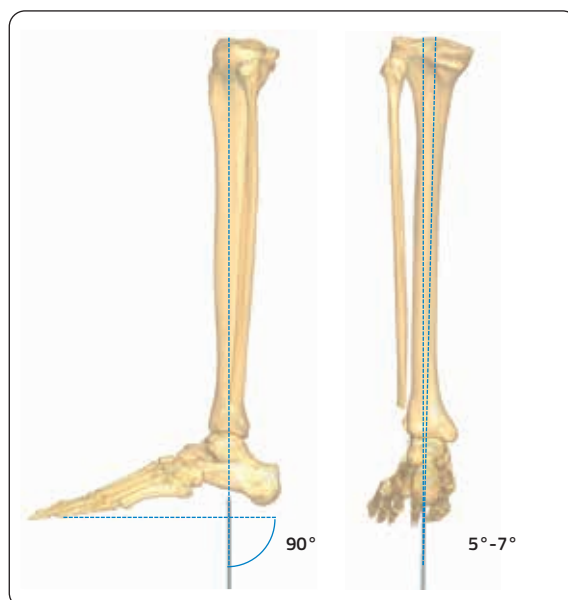


Fig. 1

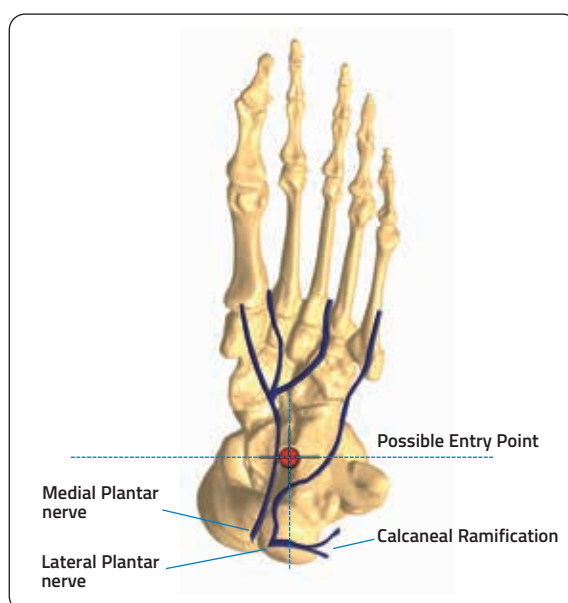


Fig. 2

After the ankle and subtalar joints have been prepared for arthrodesis, the 3.2mm x 400mm Entry Guide Wire is placed.

With the C-arm in the AP view, use the guide wire as a guide to mark the center of the tibia with a marking pen to help align the guide wire. Perform an axial view of the calcaneus and mark the axis of the calcaneus with a marking pen.

Next, insert the 3.2mm x 400mm Entry Guide Wire while viewing alignment via fluoroscopy in the lateral view. With the hindfoot aligned as previously described, the Entry Guide Wire is placed starting just anterior to the heel fat pad and in line with the center of the calcaneal axis.

Place the wire under power and confirm placement in all 3 views. Foot and ankle should be 90 degrees to tibial shaft. **(Figure 3a)**

- a) AP view - Medial wall of talus aligns with medial tibial diaphysis.
- b) Axial view - Guide wire centered on calcaneus axis.
- c) Lateral view - Foot and ankle 90 degrees to tibial shaft. Control forward foot shift. This can result in awkward gait if foot is translated anterior relative to the tibia. **(Figure 3b)**



NOTE:

- 1) Maintain proper hindfoot position prior to and during guide wire insertion to ensure the Nail does not change foot position.
- 2) Failing to control forward foot shift can result in awkward gait if foot is translated anterior relative to tibia.

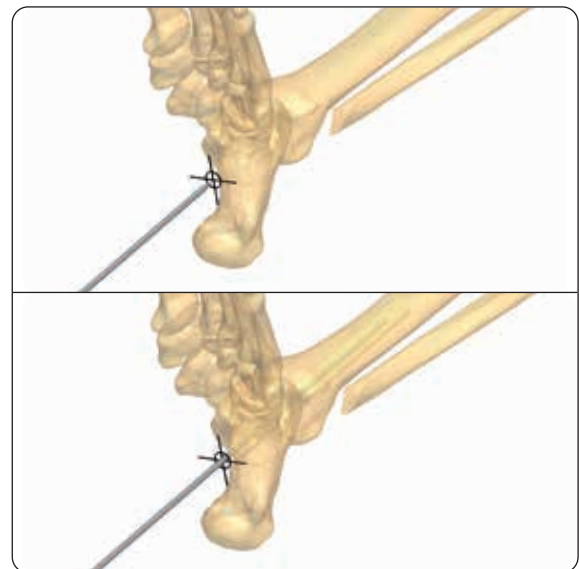


Fig. 3a

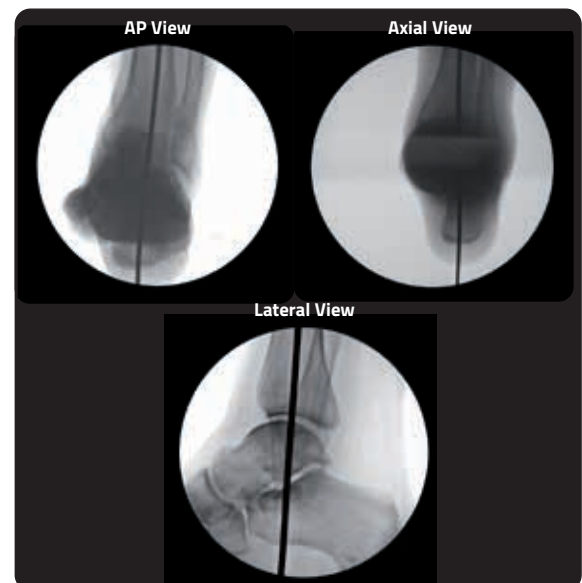


Fig. 3b

Part #	Description
177290	3.2mm x 400mm entry Guide Wire
177302	Entry Tissue Sleeve
177215	7mm Bushing
177287	7mm Entry Drill
177216	9mm Bushing
177288	9mm Entry Drill

A 3cm longitudinal incision is performed for the Entry Tissue Sleeve. Bluntly dissect to the plantar fascia and divide it longitudinally. Continue dissection with an elevator to the plantar aspect of the calcaneus. Retract the neurovascular (NV) bundle (lateral plantar nerve) to the medial side using a blunt right angle retractor. Insert the Entry Tissue Sleeve to the plantar calcaneal bone surface and remove the retractor. **(Figure 4a)**

Thread the 7mm Bushing into the Entry Tissue Sleeve. Insert the 7mm Entry Drill over the Entry Guide Wire and drill through calcaneus, talus, and up to the tibial plafond. **(Figure 4b)**



NOTE:

- 1) Entry Drills and Bushings are color-coded for ease of identification.
 - 2) The 7mm and 9mm drills bottom out on their respective bushings.
- Replace the 7mm Bushing with the 9mm Bushing and insert the 9mm Entry Drill over the Entry Guide Wire, drilling up to the tibial plafond.



Fig. 4a



Fig. 4b

Part #	Description
177289	13mm Entry Reamer
99-177281	3.0mm x 800mm Ball Tip Guide Wire
177291	Reaming Wire Pusher

Remove the 9mm Bushing and insert the 13mm Entry Reamer over the Entry Guide Wire and ream through the calcaneus, talus and up to the tibial plafond. **(Figure 5a)**



NOTE: The 13mm reamer bottoms out on the entry Tissue Sleeve.

Replace the 3.2mm x 400mm Entry Guide Wire with the 3.0mm x 800mm Ball Tip Guide Wire and insert it to desired depth.

Attach the 9mm Flexible Reamer Head on to the Flexible Reamer Shaft. Slide the Flexible Reaming assembly onto the Ball Tip Guide Wire. Continue to ream the medullary canal of the tibia sequentially in 0.5mm increments until the desired depth and diameter is reached. Confirm successful reaming with fluoroscopy in both AP and ML planes. A Reaming Wire Pusher is provided to keep the guide wire in place while performing these reaming steps. **(Figure 5b)**



TIPS:

- 1) Nail diameter is dictated by the size of the native tibia. In most cases, a 11 and 12mm diameter nail provides satisfactory stability to allow progression toward fusion.
- 2) In order to ensure Nail is inserted without excessive resistance:
 - a) Ream 0.5 to 1.0mm greater than the selected diameter with 200mm Nails.
 - b) Ream 1.0-1.5mm greater than the selected diameter with 250/300mm Nails.



NOTE:

- 1) Aggressive over-reaming of the cortex to place a larger-diameter nail may compromise the cortex, leading to a stress fracture.
- 2) Nails should extend past stress risers in the tibial shaft such as previous screw holes from removed hardware or severely osteopenic bone.



Fig. 5a

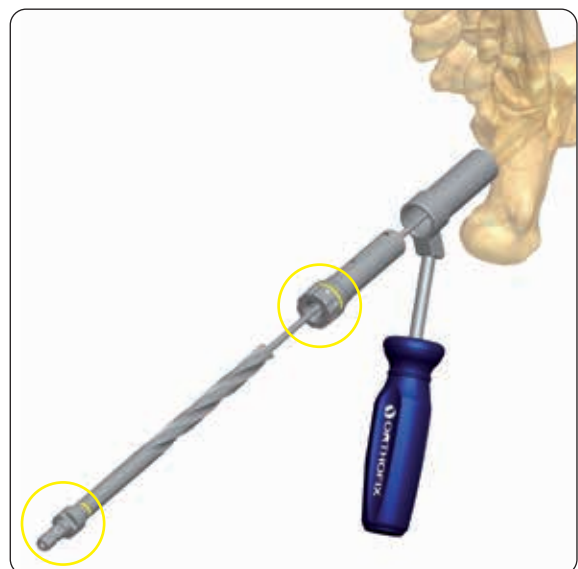


Fig. 5b

Part #	Description
177120	Distal Targeting Arm
177100	Proximal Targeting Arm
177110	Nail Attachment Rod
177125	Heel Cup
177071	Impactor
177301	Locking Driver
177305	Compression Driver
177010	Guide Jig
177011	

Nail Selection

Select Nail of appropriate length and diameter. Confirm internal locking and compression mechanisms are in the most distal (south) position of the slot(s). If not, adjust accordingly using the Locking Driver (two black bands).

Targeting Arm Assembly

Press button on Distal Targeting Arm and assemble to shaft of the Proximal Targeting Arm. Align the WHITE dot of the Distal Targeting Arm with the BLACK dot on the shaft of the Proximal Targeting Arm. Next, slide and seat the Distal Targeting Arm onto the base of the Proximal Targeting Arm until each are flush with the other. When flush, rotate Distal Targeting Arm until the Targeting Assembly locks in place. Last, thread the Heel Cup onto the Proximal Targeting Arm.

(Figure 6b)



NOTE: Engaging the button and rotating the Distal Targeting Arm at the same time can cause the Targeting Assembly to disengage.

Nail Assembly

Thread the Nail Attachment Rod into the base of the Proximal Targeting Arm.

Align three tabs of Nail (female end) with tabs on Nail Stand (male end) and fully seat. Thread Nail Attachment Rod into Nail by hand. Use Impactor to fully tighten. (Figure 6c)

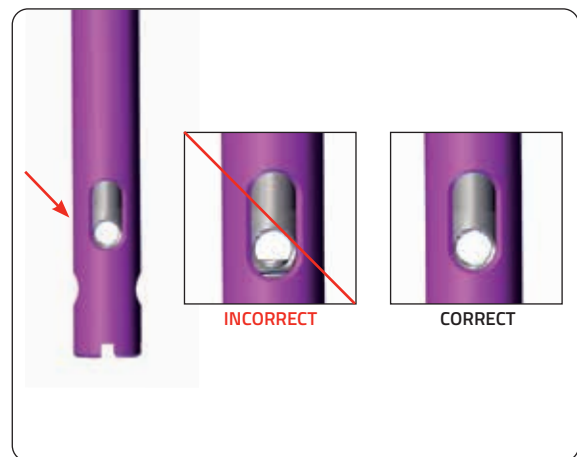


Figure 6a Internal compression mechanism



Fig. 6b

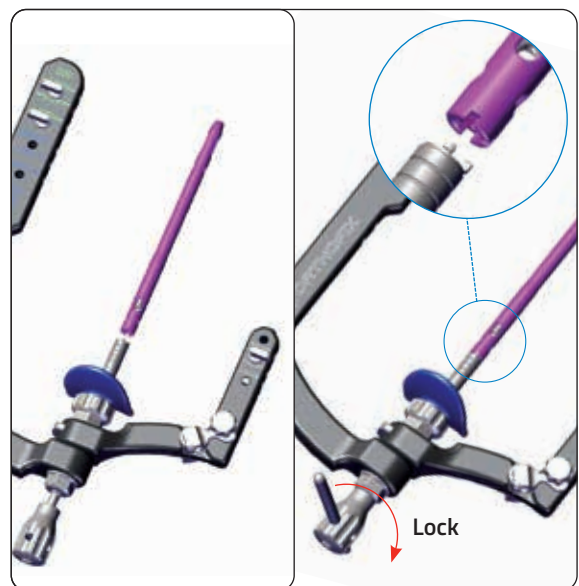


Fig. 6c

Assembling the Guide Jig

The first component of the Jig Guide to be mounted (177010) has a pin that fits into the talar hole of the proximal targeting arm. Assemble the Jig Guide by sliding the corresponding mask from top to bottom until they match and fix with Prt. (Figure 7)

Part #	Description
177211	Screw Guide
177213	4.3mm Drill Guide
177286	4.3mm Calibrated Drill
177100	Proximal Targeting Arm
177120	Distal Targeting Arm
177125	Heel Cup

Alignment Check

Prior to inserting the Nail, perform an alignment check between the Nail and Targeting Assembly on the back table. Verify using the Screw Guide, 4.3mm Drill Guide, and 4.3mm Calibrated Drill in each applicable hole.



NOTE: Verify that the drill smoothly enters and exits the PA calcaneal hole. Adjust the internal compression mechanisms if necessary prior to inserting the Nail. The position of the internal mechanism must be flush with the bottom of the compression slot. If not, adjust accordingly using the Compression Driver. Refer to page 12, Figure 6a, Internal Compression Mechanism.

Targeting Arm Orientation

The Proximal Targeting Arm should be positioned in the lateral orientation for which the tibial screws will be inserted. The Distal Targeting Arm should be aligned in the orientation (Posterior) for which the PA calcaneal screw will be inserted. (Figure 8)



NOTE: If positioned medial (so that it is “pack” with the distal handle), the Guide Jig must be removed.



TIP:

- 1) Proximal screws placed medial to lateral (M-L) provide easier access to drilling and measuring for the appropriate screw. Disadvantage: Proximal screws placed M-L can lead to screw head prominence, especially in very thin patients. If such scenario presents itself, consider placing proximal screws in the L-M orientation.
- 2) The Distal Outrigger Assembly allows the surgeon to choose the position of the screws in the calcaneus. Remember the calcaneus is slightly externally rotated relative to the talus and the Targeting Assembly can be slightly externally rotated to achieve a central position of the posterior to anterior calcaneal screw in the calcaneus.



Fig. 7

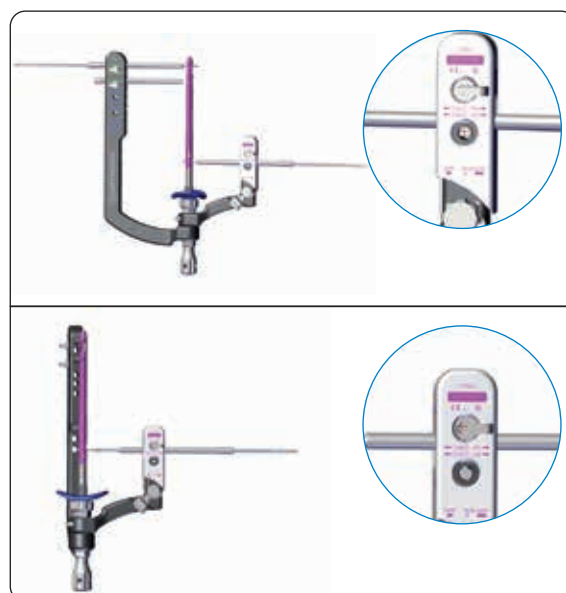


Fig. 8

Part #	Description
177110	Nail Attachment Rod
177380	Slotted Mallet
177385	Slotted Mallet Adaptor
99-177282	2.5mm x 800mm Guide Wire
17353	Guide Wire Exchange Tube
99-177281	3.0mm x 800mm Ball Tip Guide Wire

Nail Insertion

Remove the Ball Tip Wire before inserting Nail. The Ball Tip Wire will not pass through the Nail due to the internal compression mechanism. Insert Nail. The Nail Attachment Rod and the Slotted Mallet can be used in conjunction with the Slotted Mallet Adaptor. **(Figure 9)**



PRECAUTIONS: Do not strike any other area of the Targeting Assembly as this can cause damage and compromise accuracy.



NOTE: If passing the Nail over a guide wire is desired, use the 2.5mm x 800mm Guide Wire. An Exchange Tube is available to facilitate the replacing of the 3.0mm x 800mm Ball Tip Guide Wire.

Part #	Description
177290	3.2mm x 400mm Entry Guide Wire

Nail Positioning/Countersinking

Insert the Nail and countersink a minimum of 5mm. Verify that there is no calcaneal prominence in more than 1 plane. With the base of the Nail identified, align the posterior and the lateral to medial screw holes to allow for adequate fixation in the calcaneus. Confirm the Nail position using fluoroscopy; adjusting the Nail placement as necessary. This step is critical for optimal results. Time invested will determine the overall success of the case. **(Figure 10)**



PRECAUTIONS: Prominent nails are poorly tolerated.

- 1) The Nail should be countersunk a minimum of 5mm into the plantar aspect of the calcaneus.
- 2) Manual compression of the arthrodesis site is essential in order to account for the soft tissue (fat pad) of the heel.
- 3) Remain cognizant of the calcaneal anatomy.



Fig. 9



Fig. 10

Nail Base Identification

The base of the Nail can be determined by:

1. Using fluoroscopy, locate the first groove on the Barrel, which is the interface between the Nail and the Nail Stand. The remaining grooves are 5mm apart and can be used as an aid for countersinking. **(Figure 11a)**
2. Insert the 3.2mm x 400mm Entry Guide Wire in the most distal K-wire hole of the Proximal or Distal Targeting Arms. **(Figure 11b, c)**



TIP: Positioning the Distal Targeting Arm in the posterior position can improve the fluoroscopy imaging.

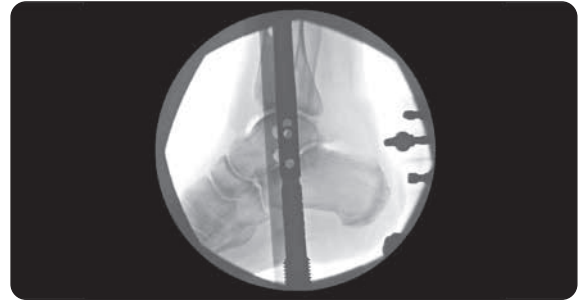


Fig. 11a



Fig. 11b



Fig. 11c

Tibial Screw Placement

After drilling and measuring as previously described, insert the first Low Profile Screw (magenta) (static hole first) into the appropriate hole labeled on the Proximal Targeting Arm for each Nail (200, 250, 300mm). Next, insert the second Low Profile Screw (magenta) into the oval slot; either the static or dynamic position. The dynamic position is marked on the Proximal Targeting Arm and corresponds with the top portion of the slot. **(Figure 12a)**



NOTE: Do not lean on Targeting Assembly as Nail flexion might occur and targeting could be compromised.

There are 2 options for proximal screw placement in the 250 and 300mm Nails. **(Figure 12b)**

1. Proximal Targeting Arm - This option allows the surgeon to target the distal set of the tibial holes. This targeting option is available with all nail diameters and lengths.
2. Freehand - This option allows the surgeon to “free-hand” the proximal set of the Tibial holes using the 4.3mm Freehand Drill (177284) and Short Depth Gouge (177304).

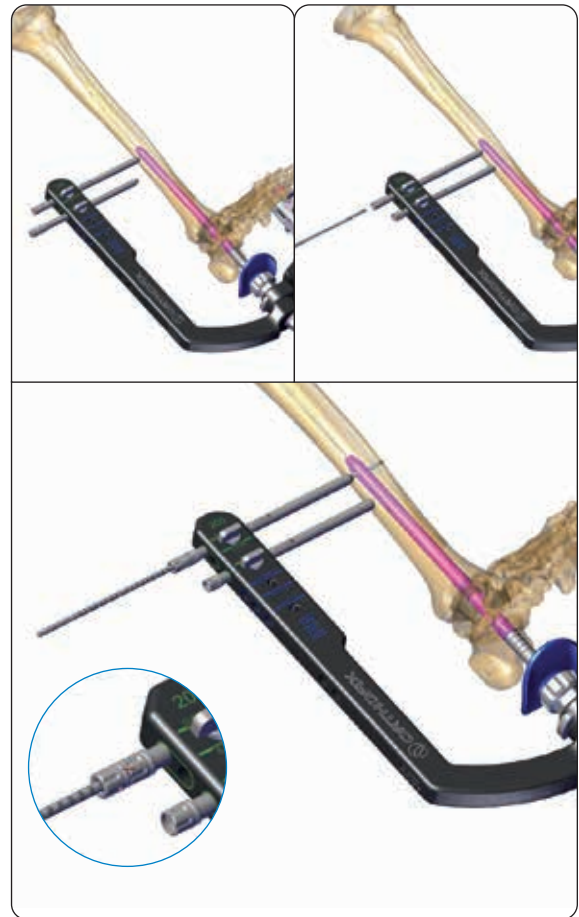


Fig. 12a

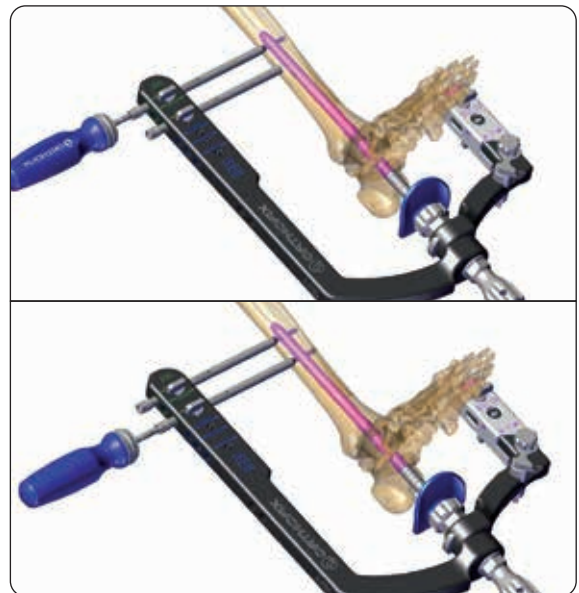


Fig. 12b

Part #	Description
177072	24mm Wrench
177125	Heel Cup

External Compression

To compress the subtalar and the tibio-talar joints, the 24mm Wrench should be used to turn the Heel Cup in a clockwise fashion. Advance the Heel Cup until the desired compression is achieved. **(Figure 13)**



PRECAUTIONS:

- 1) Prior to compressing, take care to estimate how much compression will be needed to avoid unwanted soft tissue impingement, irritation and nail protrusion.
- 2) Avoid over-compressing the arthrodesis sites! External compression should be monitored via fluoroscopy.

Part #	Description
177292	Countersink (optional)
177283	6.1mm Drill (optional)
177286	4.3mm Calibrated Drill

Placement of posterior anterior (PA) "CALC-PA" Screw

Position the Distal Targeting Arm on the posterior side of the ankle. Insert the Screw and Drill Guide in the "CALC-PA" hole. **(Figure 14a)**

After having drilled and measured the correct screw length, insert a Low Profile Screw (magenta) or Threaded Head Screw (dark blue). If using the Low Profile Screws (magenta) in the calcaneus, the Countersink can be used to reduce screw head prominence in the heel. Insert the Countersink through the Screw Guide. Be sure to account for any countersinking when selecting the appropriate screw length. **(Figure 14b)**



NOTE:

- 1) The Threaded Head Screw (dark blue) is designed to minimize soft tissue irritation.
- 2) A 6.1mm Drill can be used to drill the near cortex (only). This drill should be used in conjunction with the 4.3mm Calibrated Drill (177286). Use of the 6.1mm Drill is recommended with hard (sclerotic) bone.



Fig. 13



Fig. 14a

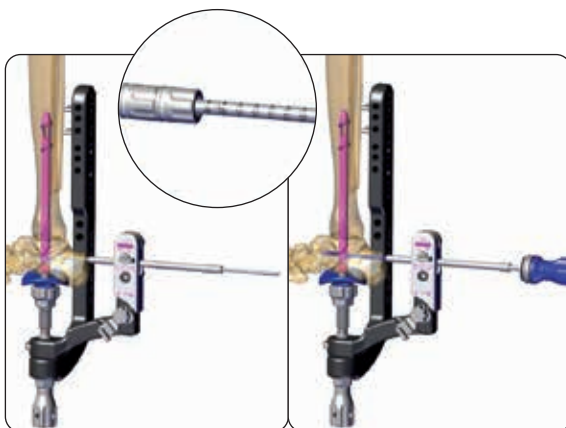


Fig. 14b

Part #	Description
177340	Ratcheting Straight Handle
177305	Compression Driver

Internal Compression (Calcaneal to Tibia)

To internally compress the subtalar & tibio-talar joints, attach the Compression Driver (two black bands) marked "2" to a Ratcheting Straight Handle and insert through the Nail Attachment Rod. Engage Compression Driver with internal mechanism and rotate clockwise to compress the subtalar & tibio-talar joints. **(Figure 15)**



NOTE:

- 1) Do not over-torque locking and internal compression mechanism.
- 2) Internal compression should be monitored via Fluoroscopy in order to avoid over-compressing the arthrodesis site.
- 3) Up to 7mm of mechanical compression can be achieved through the internal compression mechanism.
- 4) The compression driver serves as a tool in determining the amount of internal subtalar & tibio-talar joints. The amount of compression is observed via markings on the side of the compression driver. Each mark equals (=) 2mm compression.



Fig. 15

Calcaneal Screw LM Placement

Lateral-Medial (L-M) "CALC LM" Screw

After internal and external compression, position the Distal Targeting Arm on the lateral side of the ankle (recommended as shown). **(Figure 16a)**

Insert the Screw Guide and Drill Guide in the "CALC-LM" hole. After having drilled and measured the correct screw length, insert a Low Profile Screw (magenta) using previously described technique. **(Figure 16b)**

Oblique Supplementary Screw Fixation (Optional)

The oblique supplementary screw is useful to obtain increased rigidity of the construct and to maintain compression before release of the external heel compression. The oblique aiming guide allows for quick and

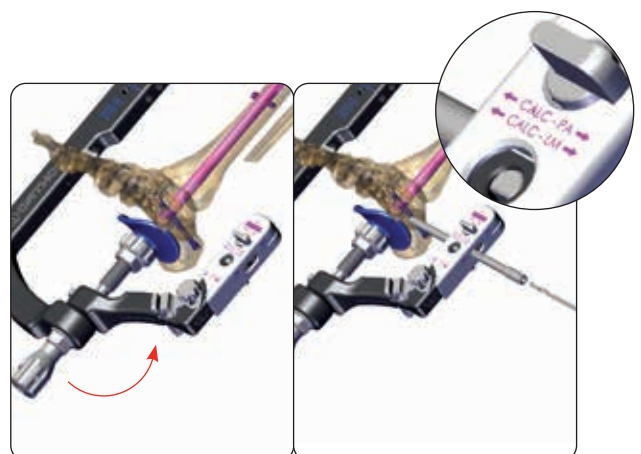


Fig. 16a

precise screw placement by providing the surgeon with a visual reference that ensures the screw is inserted within the "safe zone", which will minimize interference with the distal fixation. **(Figure 17a)** After final external compression has been applied, place the Screw Guide through the Oblique Guide lateral to Nail (recommended). Loosen the Oblique Guide Knob and adjust (click) the Oblique Guide (adjust the angle range of the additional screw) so that the white arrow on the Distal Targeting Arm is pointing to the black marking on the Oblique Guide Knob, corresponding to the magenta marking indicated as SAFE on the Guide Jig. Magenta markings correspond to the black ones on the Guide Knob, and indicate the SAFE and UNSAFE marked zones. Securely tighten the knob to lock the position. Drill and measure the correct screw length using the Drill Guide and 4.3mm Calibrated Drill. The C-arm should be in the lateral position. View the drill via fluoroscopy to ensure appropriate length and placement. If warranted, use the 6.1mm Drill through the near cortex (only). Insert appropriate length Low Profile or Threaded Head Screw. If using Low Profile Screws in the calcaneus, the Countersink can be used to reduce screw head prominence in heel. **(Figure 17b)** Be sure to account for any countersinking when selecting the appropriate screw length.

* Black marking on the Oblique Guide Knob corresponding to the magenta marking indicated as SAFE on the Guide Jig = "Safe Zone" For precise targeting through the calcaneus, talus and mid-foot.



NOTE:

- 1) ***"Safe zone"** - defined as a trajectory for the oblique supplementary screw placement that avoids the implanted hardware - nail and screws (talar and both calcaneal screws). Outside the black marking corresponding to the magenta marking indicated as SAFE on the Guide Jig = "non-safe" zone; interference with existing hardware will occur (nail-talar-calcaneal screws x 2).
- 2) The supplementary screw should be placed after the internal compression at the tibiotalar joint and after use of the external compression heel cup, but ideally before releasing the compression gained from the external compression heel cup. This will provide for rigidity to the subtalar fusion.
- 3) The optimal position for the supplementary screw is lateral to the Nail. The lateral position allows for an increased amount of bony purchase from the calcaneus to the tibia. A medially placed screw will achieve less bony purchase in the calcaneus than a laterally placed screw.



NOTE: If more calcaneal bone is medial to the Nail, the hindfoot is likely malpositioned in varus. However, an exception to this rule may occur when a patient has had a previous ankle fusion with lateralization of the hindfoot. A laterally based supplementary screw may pass lateral to the talus and tibia providing very little bony purchase proximally.

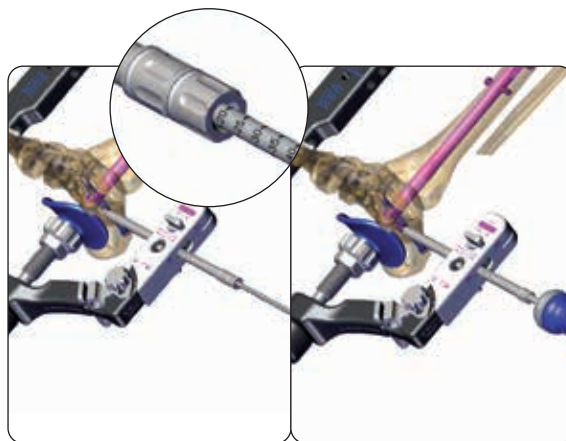


Fig. 16b



Fig. 17a

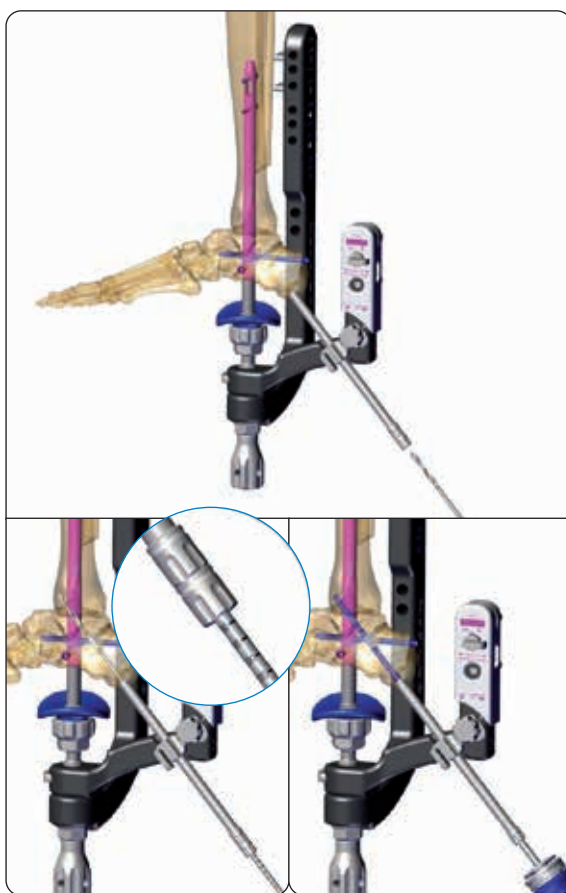


Fig. 17b

Part #	Description
177110	Nail Attachment Rod GP510 3.5mm Cannulated Hex Driver
177387	1.8mm x 350mm Guide Wire

Targeting Assembly Removal

Loosen the Nail Attachment Rod from the Nail by rotating counter-clockwise. Carefully pull and remove the Targeting Assembly from the Nail. Locking End Cap Insertion: Select the appropriate Locking End Cap (0, 5, 10mm). Utilizing the 3.5mm Cannulated Hex Driver (GP510) and the 1.8mm x 350mm Guide Wire, insert the Locking End Cap in a cannulated fashion. Confirm placement with fluoroscopy.

(Figure 18b)



NOTE: The Locking End Cap is required to lock the LM calcaneal screw. Tighten the End Cap until secure in place.



PRECAUTIONS: Refrain from leaving the Nail, in combination with the selected Locking End Cap, prominent on the plantar aspect of the foot.

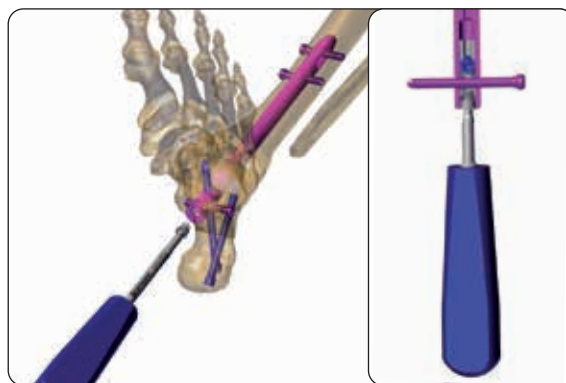


Fig. 18a

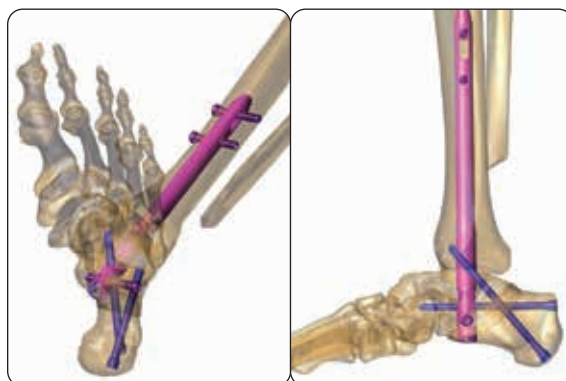
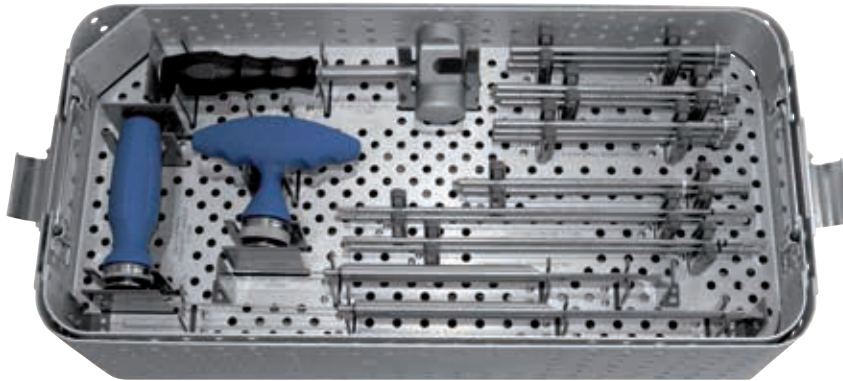


Fig. 18b

TRAYS

Insertion Instruments Tray empty 177991

Insertion Instruments Tray full (450437C for US Market)



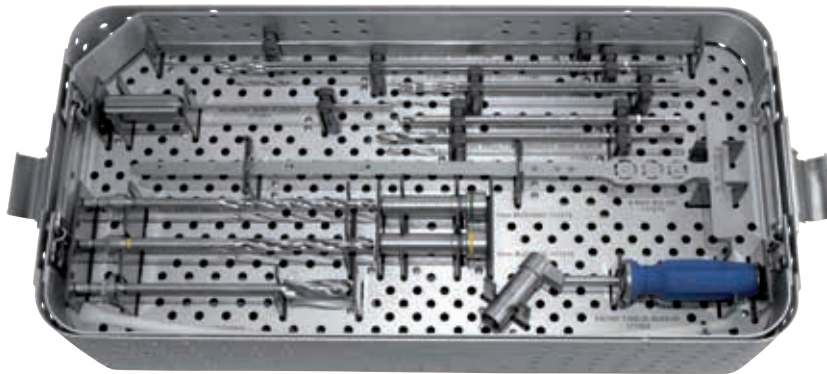
Top Tray



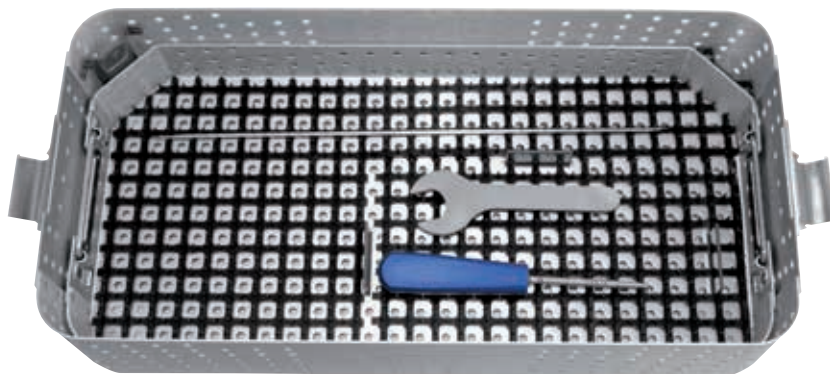
Bottom Tray

Drills and Reamers Tray empty 177992

Drills and Reamers Tray full (450438C for US Market)






















Top Tray




















Bottom Tray

Insertion Instruments Tray empty 177991
Insertion Instruments Tray full (450437C for US Market)

Instruments		
	Part #	Description
	177380	Slotted Mallet
	177340	Ratcheting Straight Handle
	177350	Ratcheting T-Handle
	177301	Locking Driver
	177305	Compression Driver
	177304	Short Depth Gouge
	177300	Long Depth Gouge
	177211	Screw Guide
	177212	Trocac
	177213	4.3mm Drill Guide
	177320	3.5mm Hex Screw Driver
	177100	Proximal Targeting Arm
	177120	Distal Targeting Arm
	177026	Locking Cam
	177125	Heel Cup
	177385	Slotted Mallet Adaptor
	177071	Impactor
	177110	Nail Attachment Rod
	177072	24mm Wrench

Drills and Reamers Tray empty 177992
Drills and Reamers Tray full (450438C for US Market)

Drills and Reamers		
	Part #	Description
	177291	Reaming Wire Pusher
	177287	7mm Entry Drill
	177288	9mm Entry Drill
	177289	13mm Entry Reamer
	17353	Guide Wire Exchange Tube
	177286	4.3mm Calibrated Drill
	177275	X-Ray Ruler
	177215	7mm Bushing
	177216	9mm Bushing
	177290	3.2mm x 400mm Entry Guide Wire
	177284	4.3mm Freehand Drill
	177292	Countersink
	177283	6.1mm Drill for Threaded Head Screw
	177302	Entry Tissue Sleeve
	177387	1.8 x 350mm Guide Wire
	177072	24mm Wrench
	GP510CE	3.5mm Cannulated Hex Driver

NAIL REMOVAL

Part #	Description
177996	Extraction Tray empty
450439C	Extraction Tray full
for US Market	
177392	Screw Extractor Size 4
177395	Needle Nose Vise Grips
177394	Screw Head Gouge
177393	Screw Extractor Size 5
177340	Ratcheting Straight Handle
177320	3.5mm Hex Screw Driver

1. Clear ingrowth at the base of the Nail, including hexagonal recess, to gain access to the Locking End Cap
2. Remove the Locking End Cap

Remove the Locking End Cap using the 3.5mm Hex Screw Driver and the Ratcheting Straight Handle. **(Figure 19)**



NOTE: The following instruments can be utilized to gain access and remove the locking end cap and the screws:

Screw Head Gouge: Use to expose screw head.
Screw Extractor, size 4: Reverse threaded design.
Screw Extractor, size 5: Reverse threaded design, more aggressive option compared to 177392.
Needle Nose Vise Grips: Use when head of screw, or the Locking End Cap's hex, are completely compromised.

3. Remove the Following Screws as Applicable:

Posterior-anterior (PA), lateral-medial (LM), and oblique supplementary screw. Use the 3.5mm Hex Screw Driver. **(Figure 20a, 20b)**



NOTE:

- 1) If there is bone growth blocking access to the head of the screw, use the screw head gouge and vise grips to clear away any bone that may prevent removal. Repeat the same operation for each screw.
- 2) If the screw hex feature is damaged, the Screw Extractors 177392 and 177393 can be used. The screw extractor must be driven in reverse (counter clockwise), at low speed, in order to bite into the screw hex for removal.

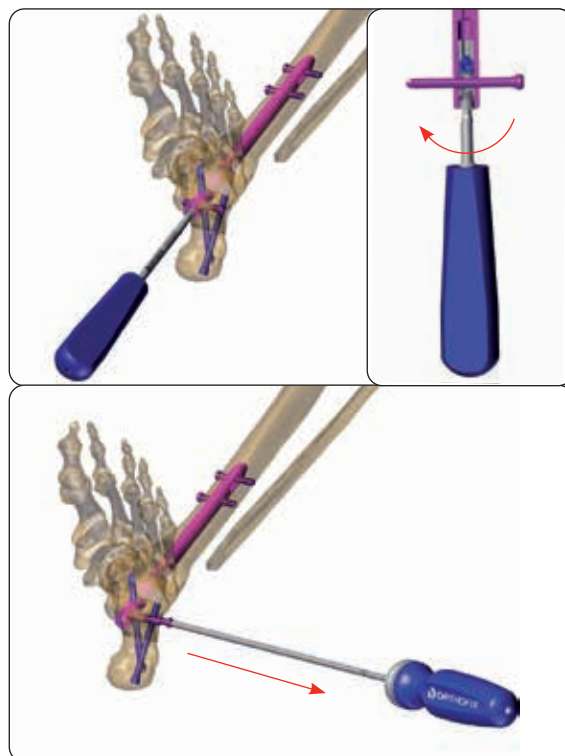


Fig. 19



Fig. 20a

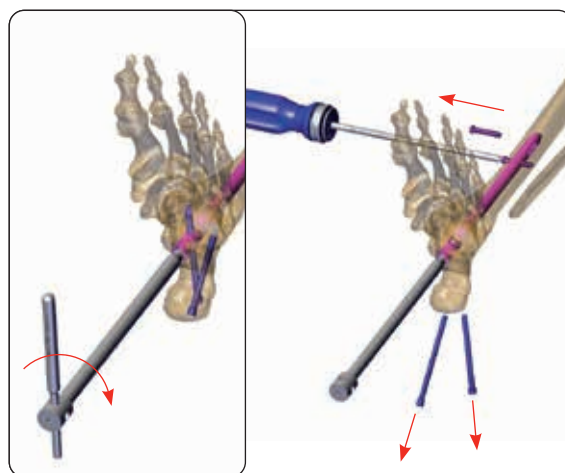


Fig. 20b

Part #	Description
177385	Slotted Mallet Adaptor
177071	Impactor SMN177370 SMN Slap Hammer
177380	Slotted Mallet
177391	Cross-Threading Adaptor

4. Thread the Nail Removal Tool Thread into the Slotted Mallet Adaptor into the base of Nail. The Impactor should be used to appropriately tighten the Slotted Mallet Adaptor into the Nail. **(Figure 21)**



NOTE:

- 1) **Additional options for nail removal:**
Slotted Mallet: Use in conjunction with the Slot Hammer.
- 2) **Cross-Threading Adaptor:** Use when threads of Nail's base are compromised. Use in conjunction with the Slotted Mallet.

Part #	Description
177340	Ratcheting Straight Handle
177380	Slotted Mallet
177320	3.5mm Hex Screw Driver

5. Tibia Screw

Remove the Tibial Screw(s) using the 3.5mm Hex Screw Driver.



NOTE: Ensure step 4 has been completed prior to attempting to remove Tibial Screws in order to prevent the Nail from migrating superiorly prior to removal.

6. Remove Nail **(Figure 21)**

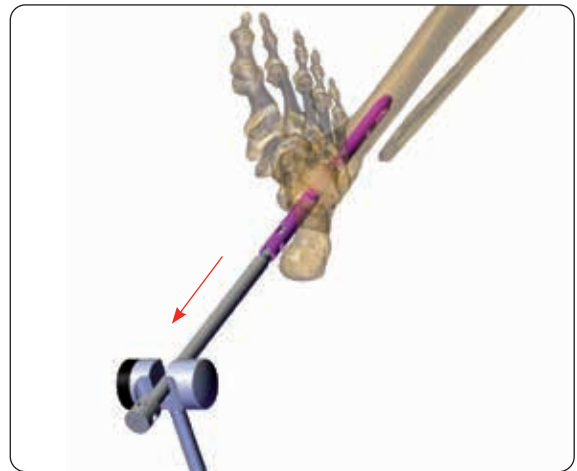


Fig. 21

Please refer to the "Instructions for Use" supplied with the product for specific information on indications for use, contraindications, warnings, precautions, possible adverse events, MRI (Magnetic Resonance Imaging) safety information and sterilization.

Electronic Instructions for use available at the website <http://ifu.orthofix.it>

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