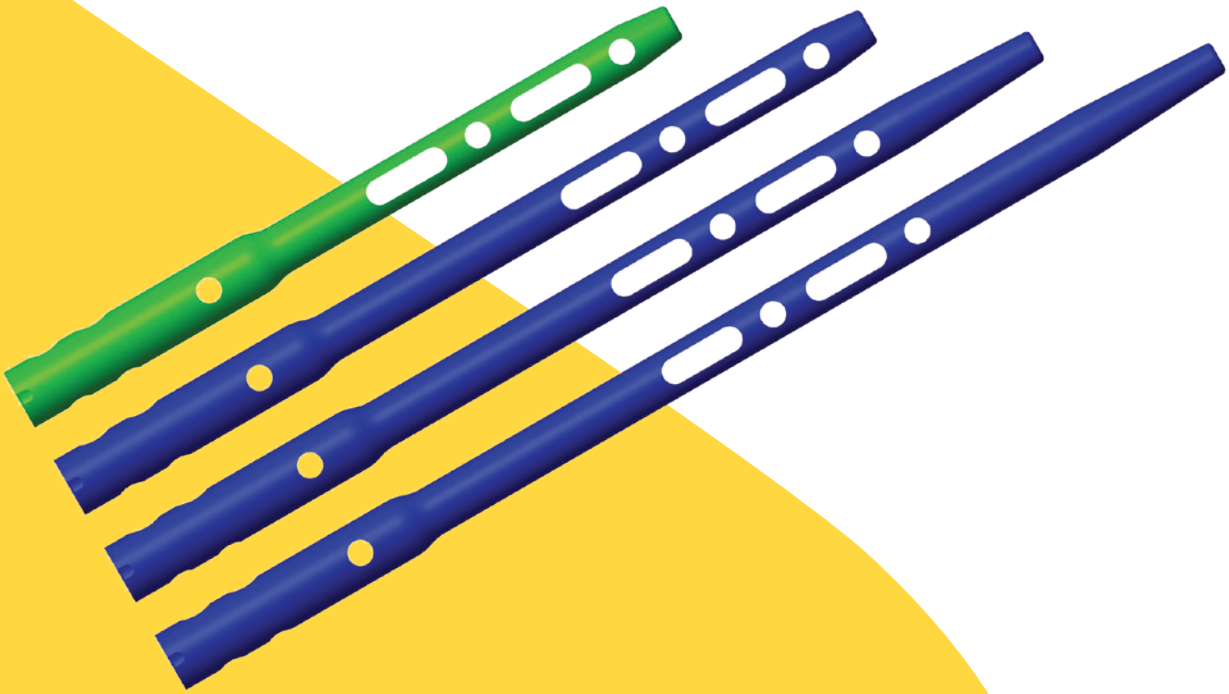
Smith+Nephew

PANTA◊ 2

Arthrodesis Nail System

Surgical Technique



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Design Rationale

The PANTA◊ 2 Arthrodesis Nail System offers an implant and instrumentation designed specifically for tibiotalocalcaneal (TTC) arthrodesis. The retrograde design of the PANTA 2 Nail allows:

- Re-alignment of the foot on the weight-bearing axis
- Correction of coronal and saggital plane deformities
- Rotational stability
- Axial compression

The PANTA 2 Nail System instrumentation has been designed to achieve TTC arthrodesis through:

- A Targeting Guide and Compression Device offering both visual and tactile verification of compression of up to 12mm
- Instrumentation designed for accurate placement of the Compression Rods, Calcaneal Screws, and Tibial Screws
- Radiolucent instrumentation offering visibility under fluoroscopy to facilitate PANTA 2 Nail implantation
- An instrumentation system offering multi-planar screw fixation in the tibia, the talus, and the calcaneus to optimize stability and alignment of the arthrodesis

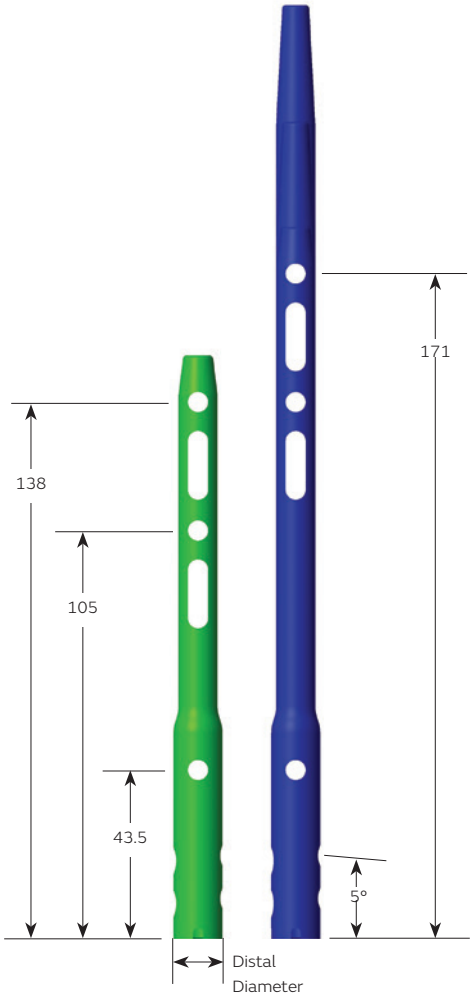
Magnetic Resonance (MR) statement

The PANTA◊ 2 Arthrodesis Nail System 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 PANTA 2 Arthrodesis Nail System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

The following technique is for informational and educational purposes only. It is not intended to serve as medical advice. It is the responsibility of treating physicians to determine and utilize the appropriate products and techniques according to their own clinical judgment for each of their patients. For more information on the product, including its indications for use, contraindications, and product safety information, please refer to the product's label and the Instructions for Use packaged with the product.

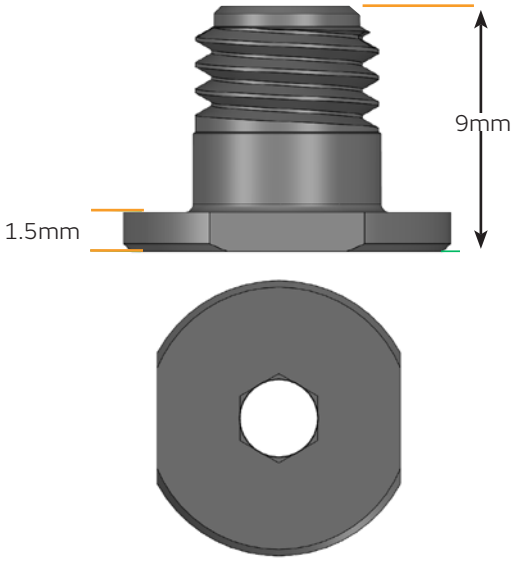
Prior to performing this technique, please consult the Instructions for Use documentation provided with each device for additional health and safety information, including indications, contraindications, warnings and precautions.

Implant description



The PANTA 2 Nail is available in 16 sizes. All nails are color-coded for easy size identification. Bony fixation is achieved using one IM nail, two tibial screws, two calcaneal screws and one (optional) talar screw.

Design Specifications	PANTA 2 Nail
Material	Titanium (Ti-6AL-4V ELI)
Diameter	10, 11, 12 and 13mm
Lengths	150, 180, 210 and 240mm
Distal Diameter	10mm, 11mm and 12mm Nails: 12.5mm 13mm Nail: 13mm
Cannulation	3.5mm
Slot Height	12.5mm



An optional End Cap may be inserted into the distal nail threads to prevent tissue ingrowth and facilitate future nail removal. The Hex Screwdriver can be used for insertion, and the End Cap is cannulated.

The nail, screws and end cap are manufactured from titanium alloy: Ti-6Al-4V ELI, per ASTM F136.

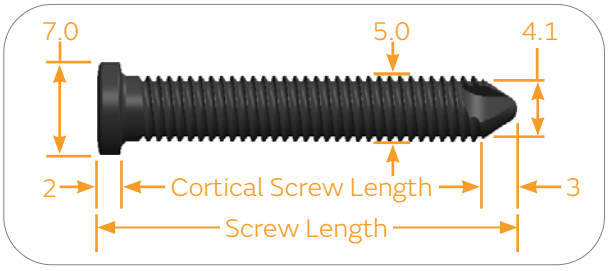
Design Specification	PANTA 2 End Cap
Total Height	9mm
Shoulder Height	1.5mm

The PANTA◊ 2 Screws are available in two designs, Partially Threaded (PT) and Fully Threaded (FT) screw designs.

Design Specification	PANTA 2 Screws
Material	Titanium (Ti-6Al-4v ELI)
Major Screw Diameter	Partially Threaded: 7.0mm Fully Threaded: 5.0mm
Minor Screw Diameter	Partially Threaded: 5.0mm Fully Threaded: 4.1mm
Screw Head	PT: Headless FT: Low-profile head (2mm height)
Driver Feature	3.5mm Hex
Screw Color	Black
Screw Lengths	PT: 45mm – 110mm, available in 5mm increments FT: 23 mm – 110mm Thread lengths of 18-60mm, available in 2mm increments; 65-105mm available in 5mm increments
Cortical Thread Length	PT: 45mm - 60mm: 15mm PT: 65mm - 110mm: 30mm FT: 18mm - 105mm
Indications of Use	PT: Calcaneus FT: Tibia, Talus and Calcaneus

Fully Threaded Screw

The PANTA 2 Fully Threaded Screw, is a self-tapping, dual-lead, cortically threaded screw with a low profile head to minimize tissue irritation. Proper placement of the screw in the Tibia and Talus will result in the Fully Threaded Screw threads having cortical bone fixation across the medial and lateral aspects of the bone **(Figure A)**.



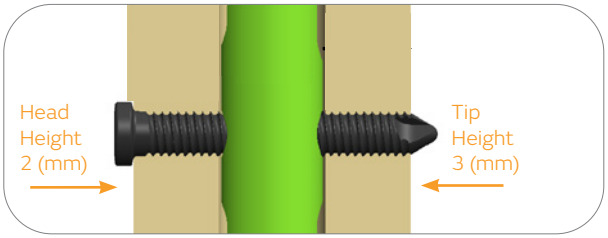
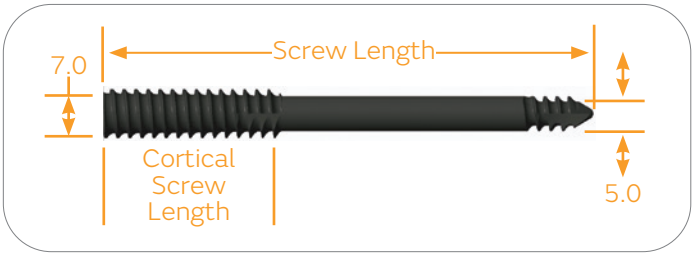


Figure A PANTA 2 Fully Thread Screw

Partially Threaded Screw

The PANTA 2 Partially Threaded Screws are self-tapping, headless screws. For use in the Calcaneus, the headless design allows the screw to be fully embedded in the bone minimizing soft tissue irritation **(Figure B)**.



PANTA 2 C-Screw

PANTA 2 The PANTA 2 Screws (Partially Threaded) are available by special order only.

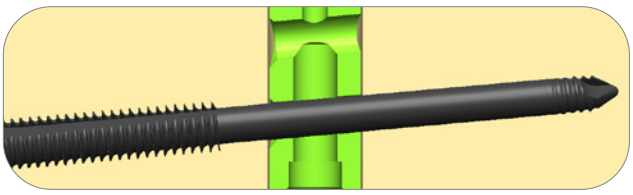


Figure B PANTA 2 Partially Threaded Screw

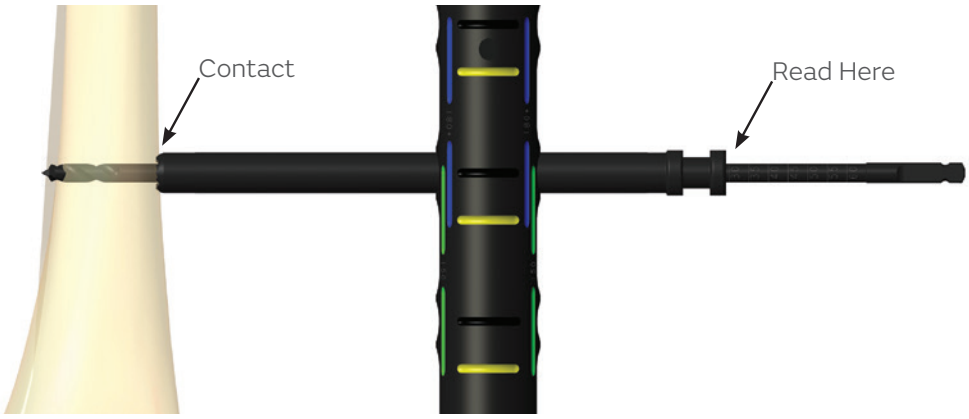
Screw measurement methods: Tibia and Calcaneus

Tibia Screw Measurement

Two depth measurement methods may be used to determine the correct screw length: using the Tibial Drill through the Soft Tissue Protector and Tibial Drill Guide assembly or using the Depth Gauge through the Tibial Soft Tissue Protector alone.

Tip: Screw measurement accuracy is dependent on obtaining contact with the cortex of the bone. When using the Tibial Drill, the Tibial Drill Guide must be in contact with the cortex. If using the Depth Gauge, the sleeve of the Depth Gauge must be in contact with the cortex.

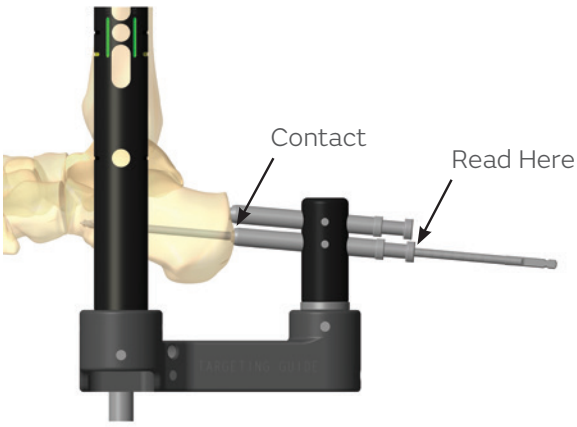
Example 1 ▪ Measuring with the Tibial Drill



Example 2 ▪ Measuring with the Depth Gauge

Calcaneal Screw Measurement

The Calcaneal Screw can only be measured using the Short or Long Calcaneal Drill. For screw measurement accuracy, the Calcaneal Drill Guide must be in contact with the cortex of the calcaneus.

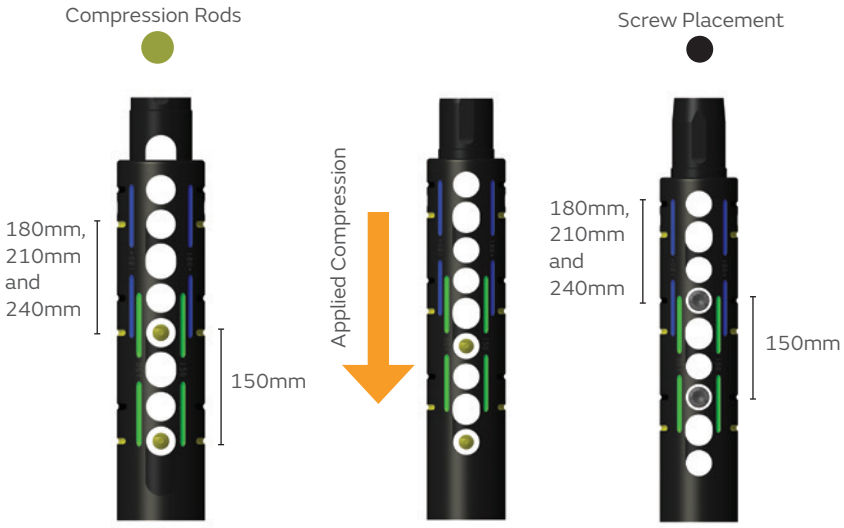


Instrument description

Instrument rationale

The PANTA◊ 2 Arthrodesis Nail System instrumentation is designed to achieve controlled compression across the ankle and subtalar joints. The Compression Guide and Targeting Device incorporate the following features:

- Fully cannulated system
- A dual armed Targeting Guide which applies a balanced application of compression across both tibiotalar and talocalcaneal joints
- The Targeting Guide is radiolucent allowing optimal visualization of the procedure
- A simple design which conforms to the anatomy of the hindfoot
- Controlled compression is applied through the Threaded Axis for a controlled compression is applied through the Threaded Axis, providing enhanced bony apposition



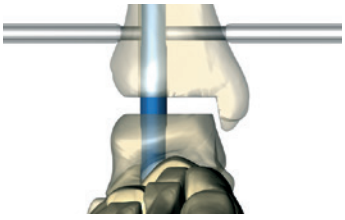
Compression and targeting system

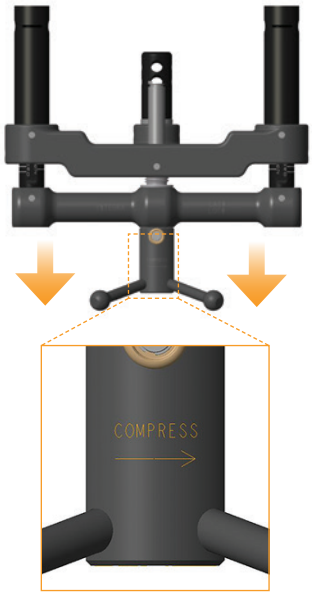
The Targeting Guide and Compression Device are designed to work as a compression system. Both are manufactured with carbon fiber arms that are radiolucent for visibility when using fluoroscopy, and with a titanium alloy base for support.

The PANTA 2 Arthrodesis Nail System has a dual function instrument that acts as a drill and compression rod which is used to stabilize the Targeting Guide and Compression Device construct to the bone and apply compression. When the compression wheel is turned clockwise, the carbon fiber arms of the Compression Device slide distally within the Targeting Guide which applies compression to the TTC joint. Up to 12mm of external, controlled compression may be applied to the arthrodesis site.

Applying compression

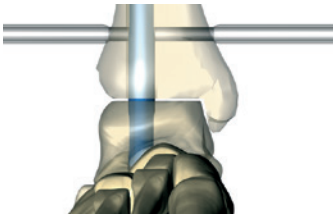
Compression wheel is zeroed out.





Compression wheel is turned clockwise.

Compression is applied



Surgical technique

Patient positioning

The patient is placed supine or prone with foot close to the end of the table to facilitate the procedure.
It is important to have an available support for the patient's leg throughout the procedure (i.e. foam bump and/or towel).

Preparation of the joint surfaces

A range of surgical approaches and incisions can be utilized including anterior, posterior, anterolateral or lateral approaches to the tibiotalar joint and subtalar joint. Single or separate incisions can be utilized depending upon the particular characteristics of the case. The essential prerequisite is to achieve satisfactory preparation of the bone surfaces for arthrodesis and satisfactory alignment of the limb through the arthrodesis sites prior to compression in order to achieve ultimate bone healing.

Incision

A plantar incision is made to prepare for insertion of the nail and support device assembly. This may be a longitudinal or transverse incision.

Care must be taken to protect the plantar neurovascular structures, both in the dissection and during the procedure, as these structures are at risk. General soft tissue retraction and protection instrumentation provided by the surgical facility may be used for this purpose.

Items Used:

Lg S+N Distraction Forceps 21cm Closed Arms (Distractor) - 119651ND

K-Wire, 2.5mm Diam x 150mm - PAN-1010-0210

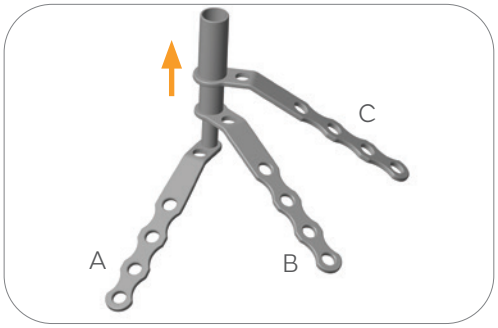


Figure 1-2

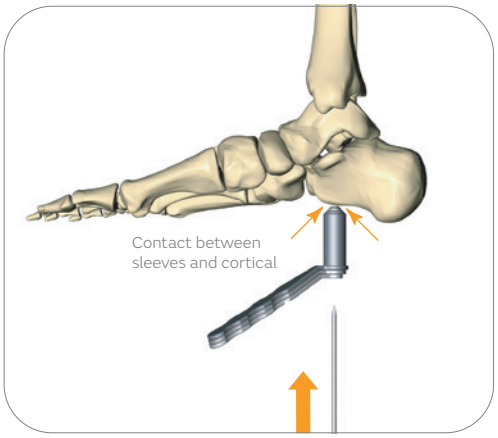


Figure 1-3

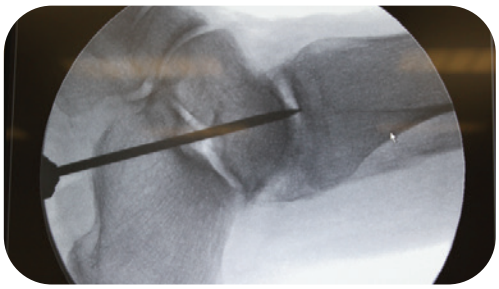


Figure 1-4a ▪ Mediolateral Views

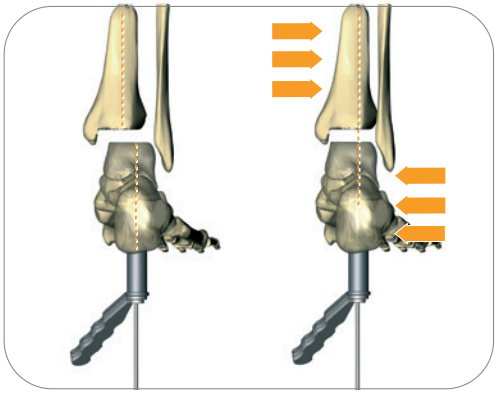


Figure 1-4b ▪ Posterior Views

PANTA◊ 2 Arthrodesis Nail Insertion
Step 1 ▪ Guide wire placement and initial drilling

1-1 Make the skin incision and guide wire insertion point slightly lateral to the midline to accommodate the lateral offset of the calcaneus relative to the medullary canal of the tibia.

1-2 Assemble the plantar protection sleeves **(Figure 1-2)**:

A – Internal Protection Sleeve

B – Central Protection Sleeve

C – External Protection Sleeve

1-3 Introduce the Guide Wire through the protection sleeves. **(Figure 1-3)**

1-4 Advance the Guide Wire through both the calcaneus and the talus using fluoroscopy to control the position in both the anteroposterior and mediolateral planes. **(Figure 1-4)**

Confirm the alignment of the calcaneus and talus and the anatomic axis of the tibia.

Advance the Guide Wire into the tibia. **(Figure 1-5)**

Note: The final nail length determination is made based on the final reamer depth described in the next step.

Items Used:

Internal Protection Sleeve Diameter 3.2mm - PAN-1010-0028

Central Protection Sleeve Diameter 9mm - PAN-1010-0029

External Protection Sleeve Diameter 3.5mm - PAN-1010-0030

Guide Wire 3.2mm x 600mm - PAN-1010-0034

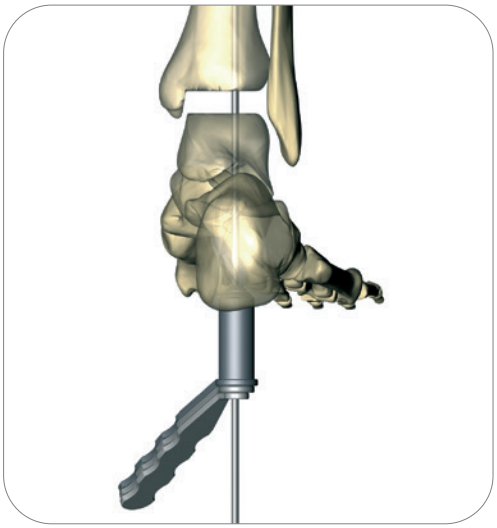


Figure 1-5

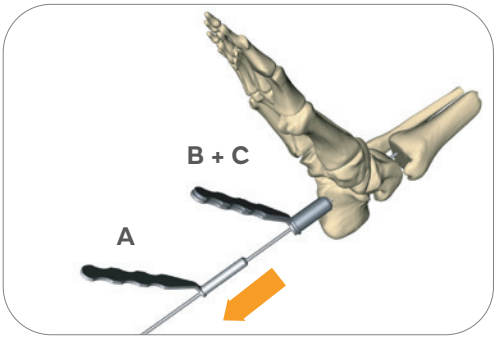


Figure 2-1

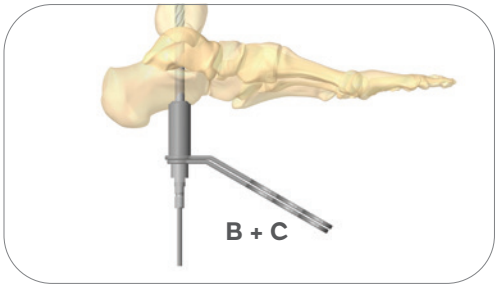


Figure 2-2

Step 2 ▪ Canal preparation

2-1 Remove the Internal Protection Sleeve **(A)**. **(Figure 2-1)**

2-2 The Central Protection Sleeve **(B)** has a built in stop for the 7mm and 9mm Drills. The nail insertion point is enlarged by inserting the 7mm Drill until it contacts the back (plantar) side of the sleeve. Next, insert the 9mm Drill until it hits the built in stop of the Central Protection Sleeve to further enlarge the opening.

Warning: While reaming, the position of the foot may be lost due to plantar flexion at the ankle. Consider provisional K-Wire fixations to avoid plantar flexion to avoid loss of appropriate alignment.

Note: Take caution that the Guide Wire is not removed from the canal when completing the canal preparation.

Items Used:

Cannulated Drill 7mm Diam x 185mm - PAN-1010-0007

Cannulated Drill 9mm Diam x 185mm - PAN-1010-0009

Step 3 ▪ Reaming and nail choice

The size of the implanted nail is determined by reaming the canal. The chart on the next page can be used as a reference. The final reamer diameter should be at a minimum 0.5mm larger than the selected nail. Depth Markings along the reamer are read off of the External Protection Sleeve and are used to determine the appropriate nail length.

3-1 Remove the Central Protection Sleeve **(B)**

Note: Reamers should be used with a cannulated power drill.

3-2 Attach the reamers to power and place over the guide wire, and through the External Protection Sleeve **(C)**.

3-3 Continue sequential reaming over the Guide Wire through the External Protection Sleeve increasing the reamer diameter by 0.5mm until the appropriate size is achieved. The final diameter of the reamer should be at a minimum 0.5mm larger than the final implant.

Note: The reamer depth markings are designed to ream the canal an additional 21mm in depth; taking into account the plantar fascia tissue thickness and joint separation. If the plantar fascia tissue is thick and difficult to contact the cortex with the external protection sleeve, surgeon may need to account for this and ream deeper.

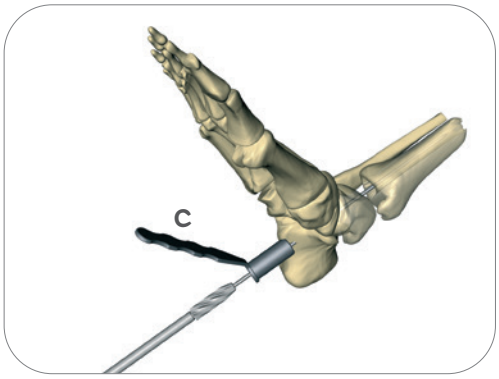


Figure 3-3

Nail Size	10mm	11mm	12mm	13mm
Final Reamer Diameter	10.5mm	11.5mm	12.5mm	13.5mm
Proximal Nail Diameter	10mm	11mm	12mm	13mm
Distal Nail Diameter	12.5mm	12.5mm	12.5mm	13mm
Distal Reaming	Yes	Yes	Yes	No

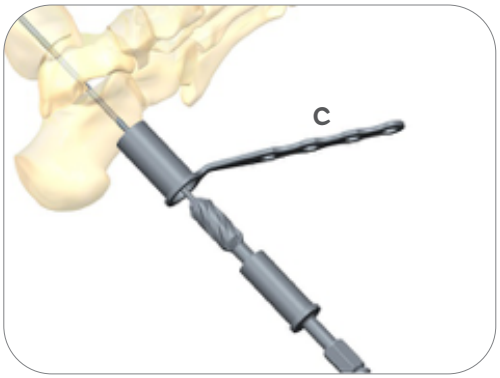


Figure 3-4

3-4 Use the Distal Reamer to prepare for the distal nail diameter. The Distal Reamer should be inserted until the stop contacts the back side of the External Protection Sleeve **(C)**. If the 13mm Nail is the selected size, the Distal Reamer will not be required.

Verify distal reamer depth using fluoroscopy.

Note: The final distal reamer depth must extend through the talus. If it is necessary to increase the distal reamer depth, remove the External Protection Sleeve and reinsert the Distal Reamer until the desired depth is reached under fluoroscopy.

3-5 Remove External Protection Sleeve **(C)**.

Note: Leave the Guide Wire in place as the Targeting Guide system is cannulated.

Items Used:

Reamer, Diameter 10mm - PAN-1010-0010

Reamer, Diameter 10.5mm - PAN-1010-0014

Reamer, Diameter 11mm - PAN-1010-0011

Reamer, Diameter 11.5mm - PAN-1010-0015

Reamer, Diameter 12mm - PAN-1010-0012

Reamer, Diameter 12.5mm - PAN-1010-0016

Reamer, Diameter 13mm - PAN-1010-0013

Reamer, Diameter 13.5mm - PAN-1010-0017

Distal Reamer, 13mm - PAN-1010-0019

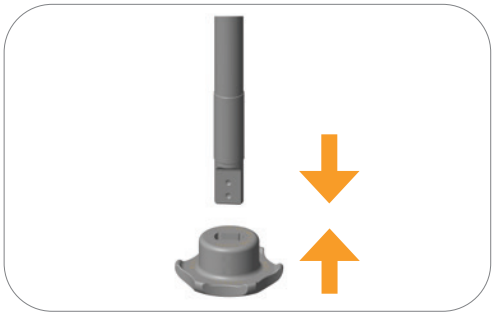


Figure 4-1

Figure 4-3

Figure 4-4a

Figure 4-4

Figure 4-5

Step 4 ▪ Nail assembly and targeting guide

The following step can be performed by the Scrub Tech on the back table

4-1 Assemble the Nail Fixation Bolt and Nail Fixation Bolt Handle **(Figure 4-1)**.

4-2 Remove the chosen nail size from the sterile package.

4-3 Orient the distal slot of the nail with the mating tab on the Targeting Guide prior to advancing the Nail Fixation Bolt construct.

Place the Nail Fixation Bolt construct through the Targeting Guide and into the distal thread of the selected nail **(Figure 4-3)**.

Warning: The Nail Fixation Bolt Handle is attached to the Nail Fixation Bolt with quick connect snap-on to allow easy disassembly. Care should be taken to prevent the accidental disassembly of the Nail Fixation Bolt Handle from the Nail Fixation Bolt. If the Nail Fixation Bolt construct is accidentally disassembled, the Nail Fixation Bolt Handle may fall out of the sterile field.

4-4 Turn the Nail Fixation Bolt Handle in the clockwise direction to assemble and tighten it to the distal nail thread **(Figure 4-4)**.

To avoid the nail toggling on the Targeting Guide/Nail Fixation Bolt assembly, it must be properly tightened with the Nail Fixation Bolt. Ensure that the Nail Fixation Bolt is tightened sufficiently throughout the procedure.

4-5 Thread the Lock Screw into the base of the Targeting Guide using the Driver Handle. Make sure to manually tighten sufficiently. Do not use power to tighten the Lock Screw.

Remove the Driver Handle.

Items Used:

Handle, Nail Fixation Bolt - PAN-1010-0121

Nail Fixation Bolt - PAN-1010-0120

Lock Screw - PAN-1010-0122

Targeting Guide - PAN-1010-0230

Driver Handle with Sm AO - G107992B

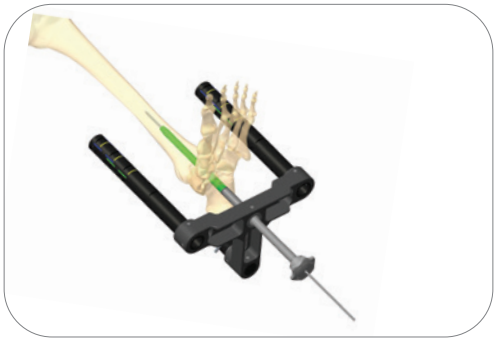


Figure 5-1

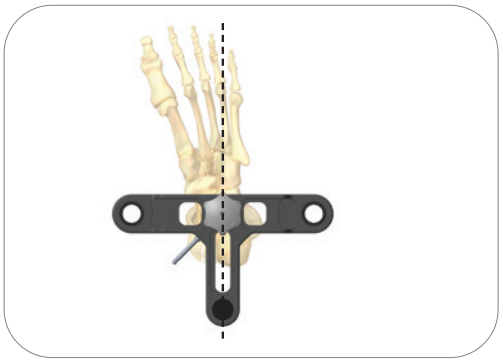


Figure 5-2

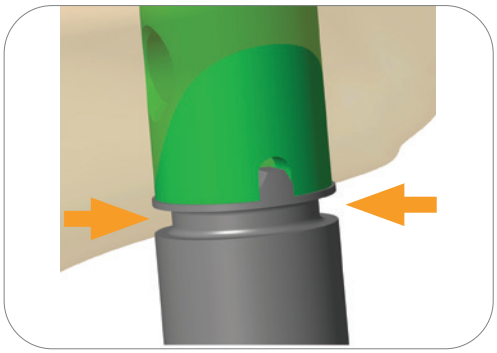


Figure 5-3a

Figure 5-3b

Step 5 ▪ Nail positioning

5-1 Align the proximal tip (cannula) of the nail with the distal end of the Guide Wire and introduce the Targeting Guide/Nail assembly into the prepared distal calcaneus. Holding the alignment of the arthrodesis, manually insert the nail assembly under fluoroscopic control **(Figure 5-1)**

Warning: For final nail positioning, do not hammer directly on the Targeting Guide. If necessary, gently mallet the Nail Fixation Bolt Handle.

5-2 Remove the Guide Wire.

Warning: If the Guide Wire is not visible after inserting the Targeting Guide/Nail assembly, remove the inserted product and the Guide Wire. Reinsert the Targeting Guide/Nail assembly per step 5-1 without the Guide Wire.

A final visual verification of the nail height is made under fluoroscopy.

The Targeting Guide/Nail assembly can be rotated into a position to optimize calcaneal screw placement. Final orientation is determined by patient anatomy.

Note: To maximize calcaneal bone purchase, use the calcaneal post of the Targeting Guide to orient the calcaneal screw toward the anterior process of the calcaneus for improved fixation.

5-3 Manually compress the arthrodesis site while using fluoroscopy to insert the nail to the final depth. The groove on the targeting guide located adjacent to the distal end of the nail should be flush with plantar cortex of the calcaneus.

Other unique identifiers for the final position of the nail, include:

- Anatomy of the arthrodesis
- Osseous structures
- Distal end of the nail relative to the plantar cortex of the calcaneus
- Proximal calcaneal screw hole relative to the subtalar joint
- Talar screw hole relative to the talus

Warning: The Targeting Guide should not be used to support the weight of the leg. The weight may cause the Targeting Guide to shift and increase the chance of mis-targeting the compression rod(s). If necessary, a bump or other means should be used to support the leg.

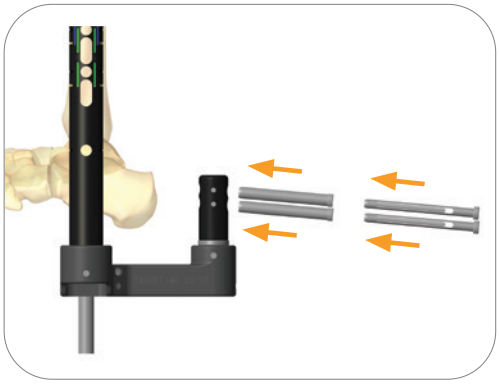


Figure 6-1

Step 6 ▪ Preparing for Calcaneal Drilling

Warning: Prior to drilling, ensure the nail is stable and sufficiently locked to the Targeting Guide.

6-1 The soft tissue protector instruments for the calcaneus are silver in color for easy identification **(Figure 6-1)**.

Note: The silver instruments also correspond to the appropriate insertion holes on the Targeting Guide.

Insert the Calcaneal Drill Guides into the Calcaneal Soft Tissue Protectors.

Place the Drill Guide/Soft Tissue Protector constructs on the skin to precisely determine the incision points. Make the incision(s) and push the Drill Guide/Soft Tissue Protector constructs against the posterior cortex of the calcaneus. Elevation of soft tissue and tendon from bone may be required for the guide to achieve bony contact.

To prepare the bone for drilling, insert the Trocar Awl through the Soft Tissue Protector construct and into the posterior cortex of the calcaneus. The Trocar Awl can attach to either the T-Handle or the Driver Handle.

Items Used:

Soft Tissue Protector, 7mm Diam, Calcaneal - PAN-1010-0183

Drill Guide, 4.1mm Diam, Calcaneal - PAN-1010-0185

4.1mm Trocar - PAN-1010-0188
T-Handle with AO Quick Connect - HTM0111-S01

Driver Handle w/ SM AO - G107992B

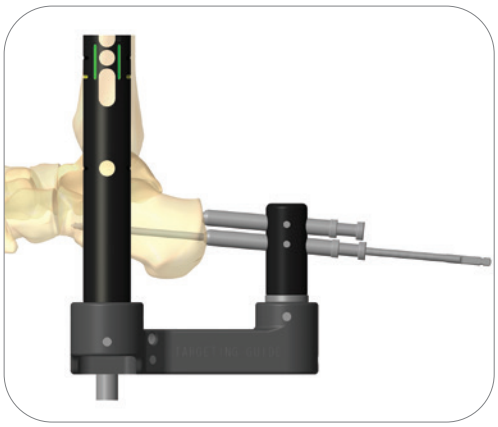


Figure 7-1

Step 7 ▪ Drilling for the Distal Calcaneal Screw

7-1 Prepare the distal hole using the Short Calcaneal Drill. **(Figure 7-1)**. Control the drill depth using fluoroscopy. The screw length is determined by the calibrated drill bit, read from back (posterior) side of the Calcaneal Soft Tissue Protector.

Warning: The Calcaneal Drill Guide must be in contact with the cortex. The calibrations on the Short Calcaneal Drill are used to determine the length of the calcaneal screw. See Page 16 for additional information.

7-2 To prevent loss of alignment, the Short Calcaneal Drill must be left in the distal hole while drilling the proximal hole and then inserting the proximal screw.

Reference image at the end of Step 8.

Item Used:

Short Calcaneal Drill, 4.1mm Diam - PAN-1010-0002

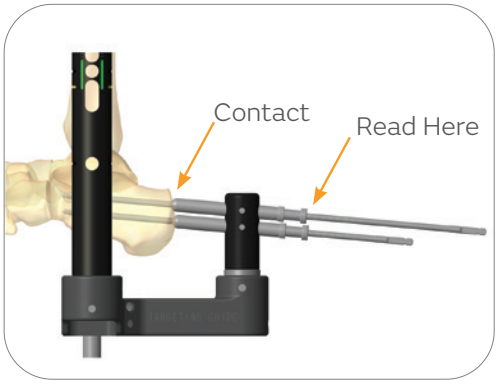


Figure 8-1

Step 8 ▪ Drilling for the Proximal Calcaneal Screw

8-1 Drill the proximal hole with the Long Calcaneal Drill.

Control the depth with fluoroscopy. The calibrations on the Long Calcaneal Drill are used to determine the length of the calcaneal screw **(Figure 8-1).**

After reading the depth, remove the Long Calcaneal Drill.

If there is difficulty reattaching to power for removal, the Tissue Protector Removal Tool's AO removal feature can be utilized for removal, as described on page 28.

Items Used:

Long Calcaneal Drill, 4.1mm Diam - PAN-1010-0003

Optional: Tissue Protector Removal Tool - PAN-1010-0187

Tip: The Long Calcaneal Drill and the Short Calcaneal Drill indicate the length of the appropriate calcaneal screw to be used. To get an accurate measurement from the drill, the inner sleeve must be in contact with the posterior calcaneal cortex.

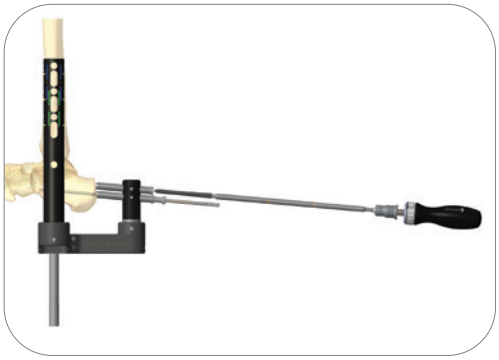


Figure 9-1

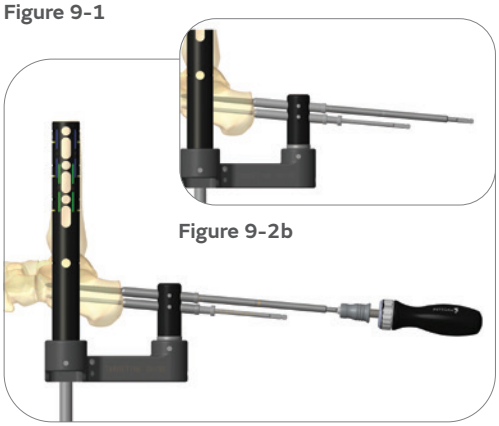


Figure 9-2b

Figure 9-2a

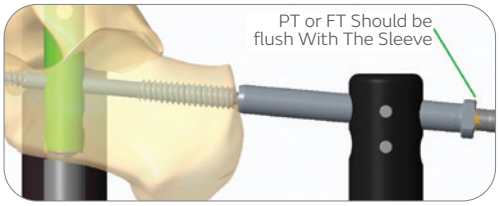


Figure 9-2c

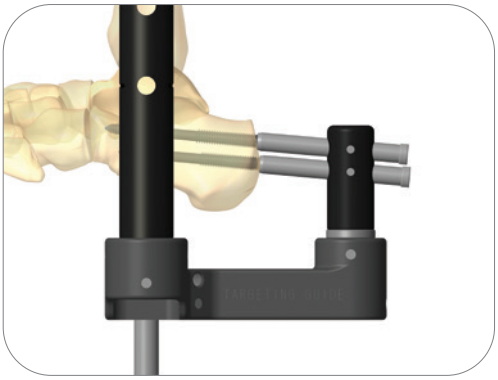


Figure 9-3

Step 9 ▪ Calcaneal screw insertion

9-1 Upon selection, screws are inserted by hand or under power using the Hex Screwdriver with axial force. Screw insertion is completed by hand using the Hex Screwdriver under fluoroscopic control.

Note: The distal Partially Threaded calcaneal screw is designed to work with the locking end cap as shown in Step 17.

9-2 Remove the proximal Calcaneal Drill Guide and insert the proximal screw. All screws should be inserted under fluoroscopic control, verifying insertion using perpendicular planes throughout the procedure.

The Hex Screwdriver has three laser mark depth lines that are read relative to the Calcaneal Soft Tissue Protector. The first two are labeled PT and FT and are used with the Calcaneal Soft Tissue Protectors. The line labeled PT is for the Partially Threaded screw and FT is for the Fully Threaded screw. The appropriate depth line indicates when the screw is fully seated.

9-3 For the distal screw, read depth directly on the drill bit as described in Step 8-1. Remove the Short Calcaneal Drill. The selected screw is inserted into the distal hole as described in Steps 9-1 and 9-2. Control the insertion depth and position using fluoroscopy. After fully seating the screw, remove the Calcaneal Soft Tissue Protectors.

Note: If the proximal Partially Threaded screw protrudes from the bone, consider using a shorter partially threaded screw to limit protrusion and potential soft tissue irritation.

Items Used:

AO Driver Shaft - 3.5mm Hex Screwdriver - PAN-1010-0190

Driver Handle with Sm AO - G107992B

T-Handle with AO connect - HTM1011-S01

Figure 10-2a

Figure 10-2b

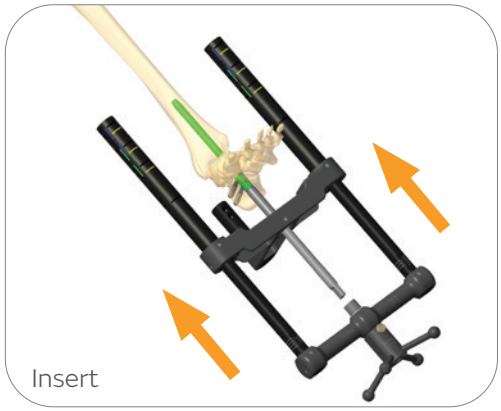


Figure 10-2c

Figure 10-3

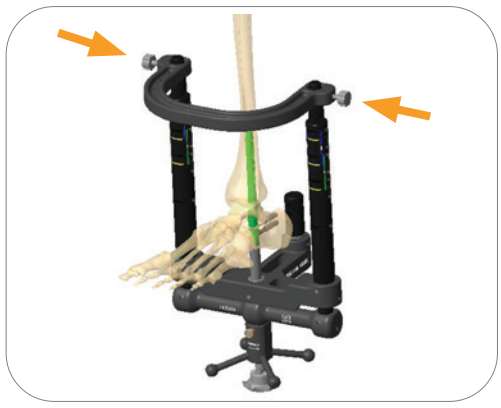


Figure 10-4

Step 10 ▪ Assembling the targeting guide for compression

10-1 Remove the Nail Fixation Bolt Handle from the Targeting Guide.

10-2 Insert the Threaded Axis into the Compression Device **(Figure 10-2a)**. Insert the Compression Wheel to the distal end of the Threaded Axis **(Figure 10-2b)**. Insert the Compression Device into the Targeting Guide **(Figure 10-2c)**.

10-3 Zero out the Compression Wheel by turning it counterclockwise, until the millimeter scale reads zero **(Figure 10-3)**.

10-4 The Targeting Guide Support is assembled to the proximal end of the Compression Device to provide extra support to the construct.

Assemble the Targeting Guide Support to the proximal ends of the Compression Device. The Targeting Guide will contact a positive stop. Ensure the thumb screws are not visible within the holes prior to introducing the Targeting Guide Support onto the Compression Device. Tighten the thumb screws on both sides of the Targeting Guide Support to lock it onto the Compression Device.

10-5 Re-attach the Nail Fixation Bolt Handle to the distal end of the Nail Fixation Bolt. Recheck nail position under fluoroscopy as needed.

Items Used:

Handle, Nail Fixation Bolt - PAN-1010-0121

Threaded Axis - PAN-1010-0113

Compression Device - PAN-1010-0231

Compression Wheel - PAN-1010-0135

Target Guide Support - PAN-1010-0201

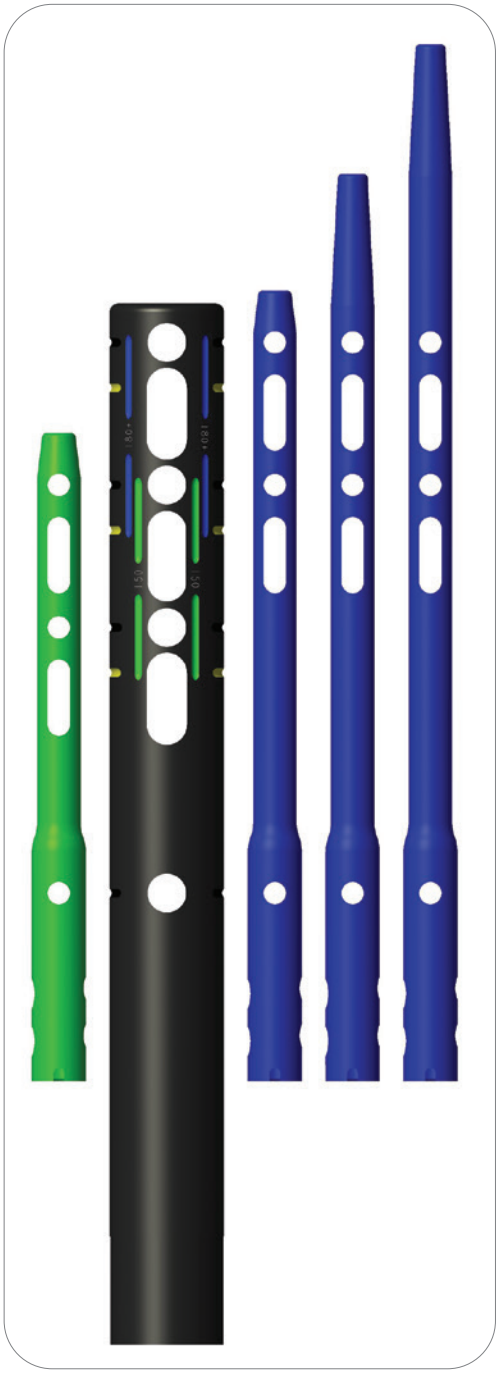


Figure 11-1

Step 11 ▪ Inserting compression rod drill guides and compression rods

11-1 The holes on the Targeting Guide are based on the chosen nail length. The middle and distal holes are used for the **150mm nails**, represented with a **green band**. The middle and proximal holes are used for the **180mm, 210mm**, and **240mm nails**, represented by a **blue band**. **Figure 11-1** illustrates the Targeting Guide hole configurations relative to the different length nails.

At this point, the rotation of the foot relative to the tibia should be controlled and aligned at its final position.

Verify that the Nail Fixation Bolt and nail are securely tightened by turning the Nail Fixation Bolt Handle clockwise. It may be necessary to tighten the Lock Screw if the Nail Fixation Bolt is loose.

Warning: The Targeting Guide should not be used to support the weight of the leg. The weight may cause the Targeting Guide to shift and increase the chance of mis-targeting. If necessary, a bump or other means should be used to support the leg.

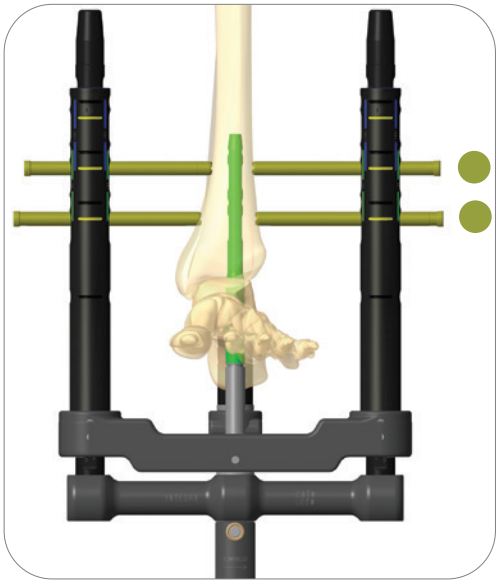


Figure 11-2

Compression Rod Drill Guides & Compression Rods

Determine the number of Compression Rods that will be used for compressing the tibiotalocalcaneal (TTC) arthrodesis site. Two Compression Rods are recommended for achieving greater compression. For easy identification, instruments used for compression will be color coded gold.

11-2 Two Compression Rods:

Insert a total of four Compression Rod Drill Guides, two each on both the medial and lateral sides, in the appropriate proximal and distal gold color coded holes of the Targeting Guide.

One Compression Rod:

Insert a total of two Compression Rod Drill Guides, one each on both the medial and lateral side, in the appropriate proximal or distal gold color coded holes of the Targeting Guide.

11-3 After confirming the appropriate location and prior to inserting the Compression Rod, create an incision on the entry side to ensure that the Compression Rod Drill Guide contacts bone. There are two options for creating an incision on the exit side:

(1) A matching incision and placement of the Compression Rod Drill Guide with bone.

(2) The incision is made only after the Compression Rod passes through the entry point which creates a skin tent on the exit side used to identify the incision area. The exit side Compression Rod Drill Guide is placed to the bone after making the incision.

Items Used:

Compression Rod Drill Guide, 5mm Diam - PAN-1010-0181

Compression Rod, 5mm Diam - PAN-1010-0175

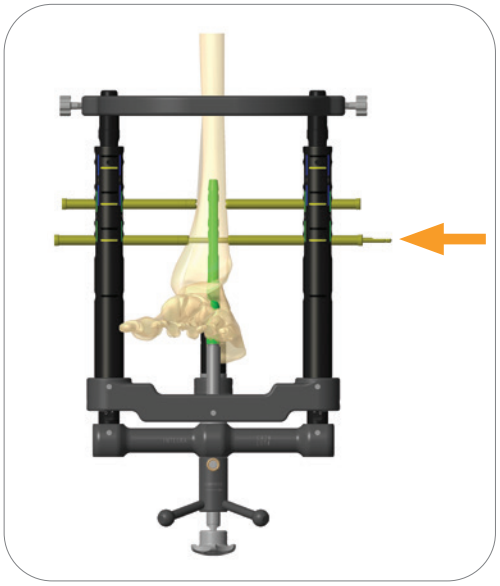


Figure 11-4

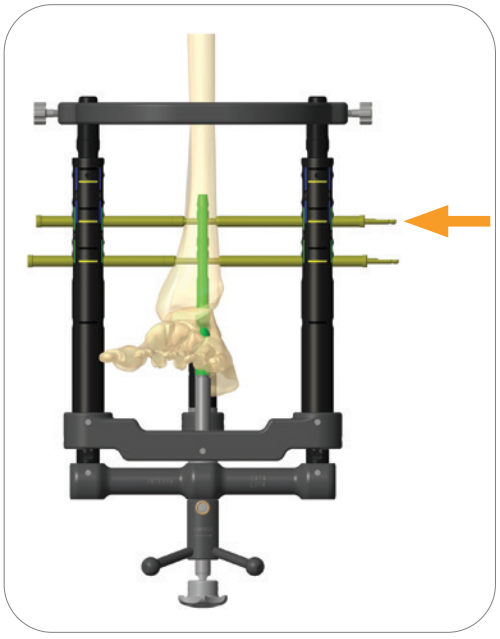


Figure 11-5

Inserting the Compression Rods

11-4 Insert the first gold color coded Compression Rod in the distal hole and advance the Compression Rod using power. **(Figure 11-4)**

Warning: If a metal-on-metal sound is audible, stop advancing the Compression Rod. Remove the Compression Rod Drill Guide and check under fluoroscopy to ensure that the Compression Rod is passing through the nail. Disassemble the Compression Rod Drill Guides for true lateral view. If the Compression Rod Drill Guides are removed for fluoro, replace prior to compression.

Note: To verify that the Compression Rod is passing through the Targeting Guide, do not place the far Compression Rod Drill Guide against the skin. Pass the Compression Rod through the close Compression Rod Drill Guide until the skin tents on the far side of the patient's leg and make an incision to allow the Compression Rod to pass. Advance the Compression Rod Drill Guide on the far side until it comes in contact with the patient.

Leave the Compression Rod in place (Figure 11-4).

Warning: Do not use the Targeting Guide as leverage when placing the Compression Rods. If additional leverage is needed to advance the Compression Rod, use the patient's leg.

Ensure the Compression Rods only pass through the gold color coded holes. Passing Compression Rods through any other hole can result in the inability to adequately compress the TTC joint and/or loss of implant fixation.

11-5 Insert a second gold color coded Compression Rod in the proximal hole as described in Step 11-4.

Leave the Compression Rod(s) in place.

Items Used:

Compression Rod, 5mm - PAN-1010-0175

Compression Rod Drill Guide, 5mm Diam - PAN-1010-0181

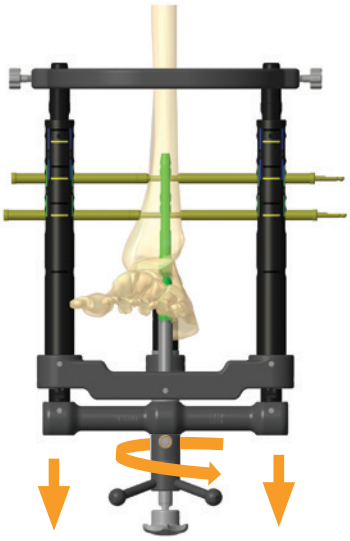
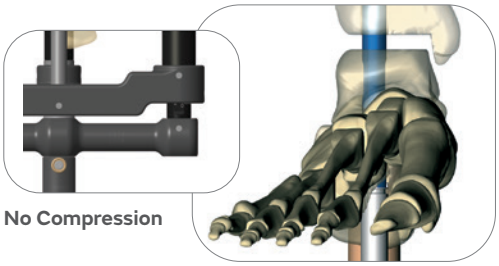
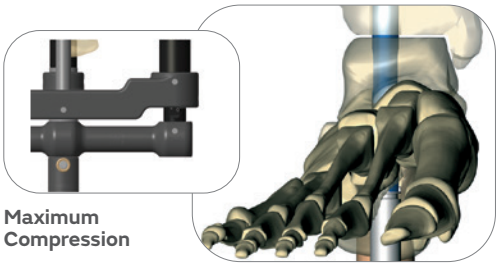


Figure 12-1

Figure 12-2





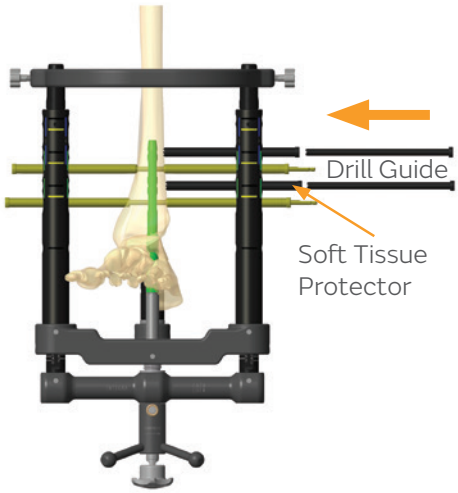
Step 12 ▪ Compression

12-1 On both arms of the Compression Device, calibrated compression markings are available to gauge the amount of compression applied. The markings are to be read relative to the distal edge of the Targeting Guide base **(Figure 12-1)**

12-2 Gently apply compression by turning the Compression Wheel clockwise. Up to 12mm of compression can be applied.

The compression can be visualized at any point using fluoroscopy. Stop when the desired compression is reached.

Warning: Avoid overcompressing the arthrodesis site. Applying too much compression can have adverse effects and impede the removal of the Compression Rod(s). If the Rod(s) are visually bending, maximum compression has been achieved. Applying additional compression will only further bend the Compression Rod(s) while not applying additional compression to the arthrodesis site.



Screw Placement

Figure 13-1

Step 13 ▪ Preparing the Tibia for screw insertion

13-1 For easy identification, the instruments used for the tibial and talus screws are color coded black. They also correspond to the appropriate black insertion lines on the Targeting Guide.

Position the Tibial Soft Tissue Protector in the appropriate black, color-coded holes in the Compression Device/Targeting Guide assembly. Insert the Tibial Drill Guide into the Tibial Soft Tissue Protector.

As indicated, the distal and middle holes are used for all **150mm nails (green band)**. The middle and proximal holes are used for the **180mm, 210mm, and 240mm nails (blue band)** (Refer to page 18).

The screws may be placed from medial-to-lateral or lateral-to-medial into the tibia. The advantage of medial-to-lateral is that the insertion process passes through less soft tissue and avoids intrusion of the fibula. The advantage of lateral-to-medial screw placement is greater soft tissue protection over the screw head.

13-2 Create incisions corresponding to the location of the Soft Tissue Protectors.

Advance the Tibial Soft Tissue Protector and Tibial Drill Guide until they touch the tibial cortex. The Tibial Drill Guide must contact the cortex to provide an accurate measurement for the tibial screw length.

Fluoroscopy is used to assess that the Tibial Drill Guide is in contact with the bone.

Items Used:

Soft Tissue Protector, 7mm Diam., Tibial - PAN-1010-0184

Drill Guide, 4.1mm Diam., Tibial - PAN-1010-0186

Figure 14-1

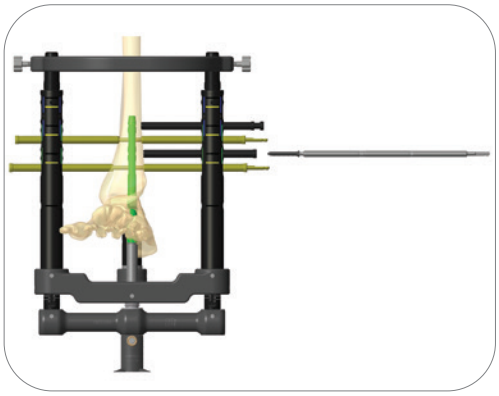


Figure 14-2

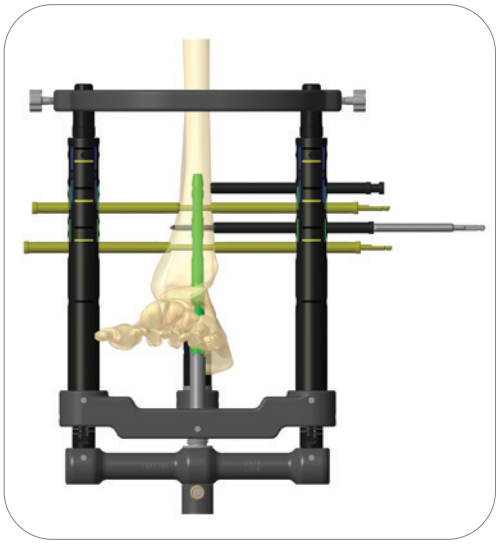


Figure 14-3

Step 14 ▪ Distal and Proximal Tibial drill and screw insertion

14-1 To prepare the bone for drilling, insert the Trocar Awl through the Tibial Drill Guide/Soft Tissue Protector construct into the cortex of the tibia. The Trocar Awl can attach to either the T-Handle or the Driver Handle. Use the Tibial Drill to pre-drill for the distal tibia screw.

Two measuring options are available to determine the screw length: the calibrated drill bit or the depth gauge (refer to Tibial Screw Measurement step page 25).

Verify the depth under fluoroscopy.

14-2 Remove the Tibial Drill and Tibial Drill Guides from the Tibial Soft Tissue Protectors.

The screws can be inserted under power using the Hex Screwdriver until the Tibial line is flush with back of the Tibial Soft Tissue Protector. Complete Screw insertion by hand using the Hex Screwdriver with the Driver Handle.

14-3 Check each step of the screw insertion as noted above using fluoroscopy in perpendicular AP and lateral planes.

Verify the screw is fully seated by pulling the Tibial Soft Tissue Protector away from the cortex, leaving the Hex Screwdriver engaged with the screw.

It is recommended that only the fully threaded screws are used, due to the range of screw sizes offered.

14-4 Introduce the proximal screw as described for the distal screw.

Manually confirm that the screws are fully seated using the Hex Screwdriver with the Driver Handle.

Tip: The head of the screw is seated against the bone when the tibial laser mark on the Hex Screwdriver is flush with the Tibial Soft Tissue Protector.

Items Used:

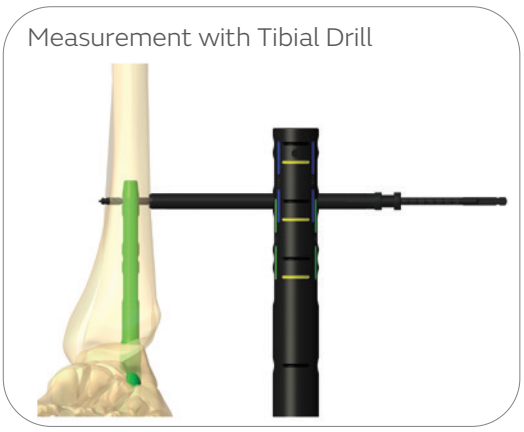
Tibial Drill, 4.1mm Diam- PAN-1010-0004

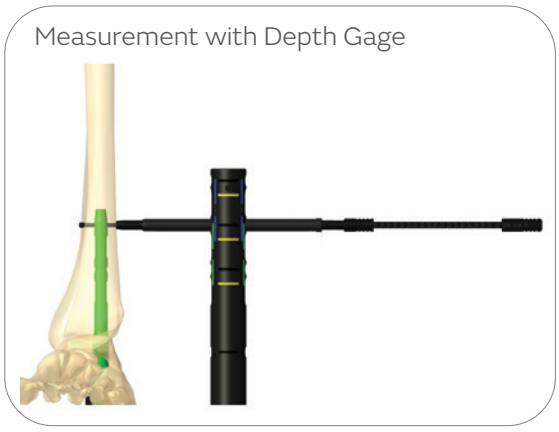
AO Driver Shaft - 3.5mm Hex Screwdriver - PAN-1010-0190

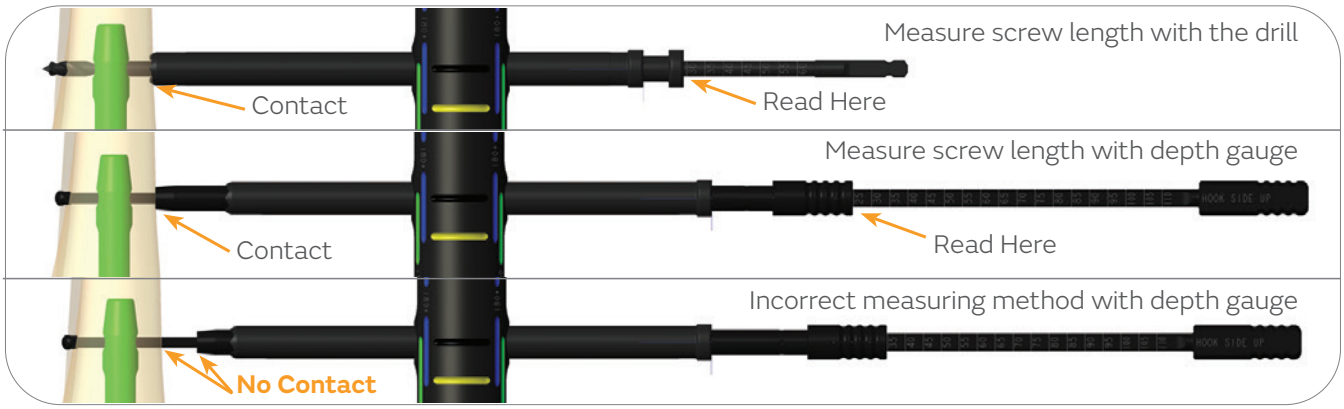
Driver Handle w/ Sm AO - G107992B

Tibial Screw Measurement Methods

There are two methods available to determine the appropriate size for the Tibial Screw: using the Depth Gauge or the Tibial Drill Guide. If using the Depth Gauge, remove the Tibial Drill Guide from the Tibial Soft Tissue Protector, insert the Depth Gauge until the Depth Gauge sleeve contacts the cortex. Measure off the back of the Depth Gauge as shown in the images below. If using the Tibial Drill Guide, confirm that the Tibial Drill Guide is in contact with the cortex. Measure off the back of the Tibial Drill Guide using the calibrations on the Tibial Drill as shown in images below.







Measurement with Tibial Drill

Measurement with Depth Gauge

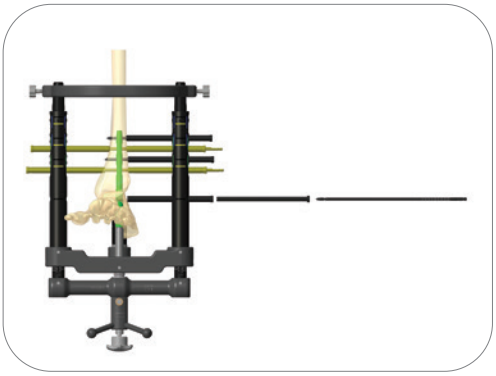


Figure 15-1

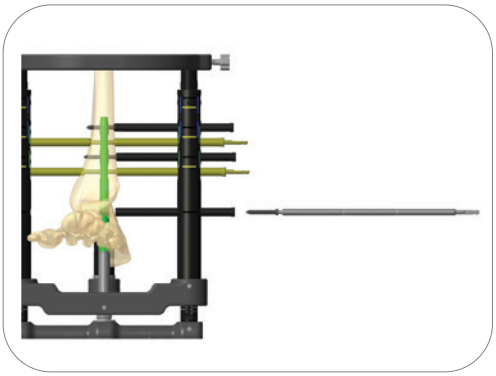


Figure 15-3

Step 15 ▪ Talar Screw (Optional)

15-1 To prepare the bone for drilling, insert the Trocar Awl through the Tibial Drill Guide/Soft Tissue Protector construct and into the cortex of the talus. The Trocar Awl can attach to either the T-Handle or the Driver Handle.

Assemble the black color coded Tibial Soft Tissue Protector with the Tibial Drill Guide. Position the Tibial Soft Tissue Protector and the Tibial Drill Guide construct in the appropriate black color coded hole in the Targeting Guide. Make a skin incision. The position of the talar screw is the same for all nail sizes and is indicated with a black color code line on the Targeting Guide. Use the Tibial Drill to prepare the screw hole. A medial-lateral or lateral-medial approach can be used introducing the screw.

Note: Check the drill position using fluoroscopy. The talar screw is designed to obtain bicortical fixation.

15-2 Read the screw length either from the calibrations on the Tibial Drill or with the Depth Gauge (See instruction on page 24).

15-3 The screw can be inserted by hand or under power using the Hex Screwdriver and insert to the Talar laser line. Complete by hand using the Driver Handle.

Check each step of the screw insertion as noted above using fluoroscopy in perpendicular AP and lateral planes.

Note: Reference Steps 13 and 14 for drilling, measuring and screw placement.

Items Used:

Soft Tissue Protector, 7mm Diam, Tibial - PAN-1010-0184

Tibial Drill, 4.1mm Diam- PAN-1010-0004

Depth Gauge - PAN-1010-0160

AO Driver Shaft - 3.5mm Hex Screwdriver - PAN-1010-0190

Driver Handle w/ SM AO - G107992B

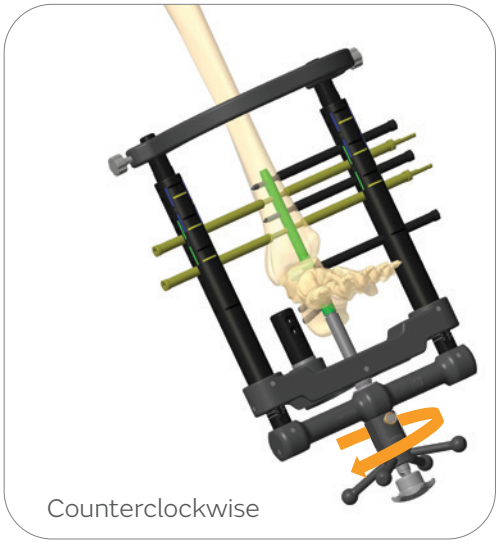


Figure 16-1

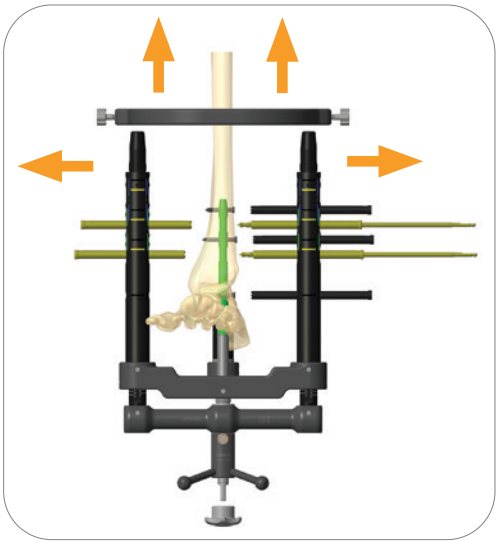


Figure 16-2

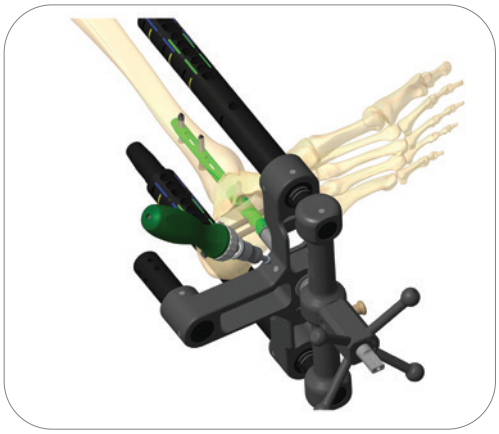


Figure 16-3a

Step 16 ▪ Compression Device Removal

16-1 Release the Compression Device by turning the Compression Wheel counterclockwise until the wheel turns freely to reduce the force on the Compression Rods.

Note: Removing the Compression Rod Drill Guides will further release tension and facilitate removal of the Compression Rods.

If the Compression Rod Drill Guides become bound within the Targeting Guide or Compression Device, the Tissue Protector Removal Tool may used to facilitate removal (See instructions on page 28).

16-2 Remove all the Compression Rods, Drill Guides, Target Guide Support and Soft Tissue Protectors.

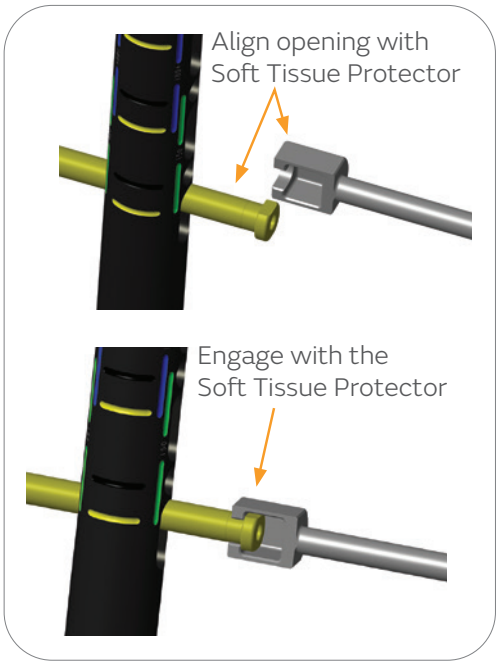
16-3 Reattach the Driver Handle to the Lock Screw (Fig.16-3a). Turn one revolution counterclockwise to disengage from the Nail Fixation Bolt.

Remove the Driver Handle.

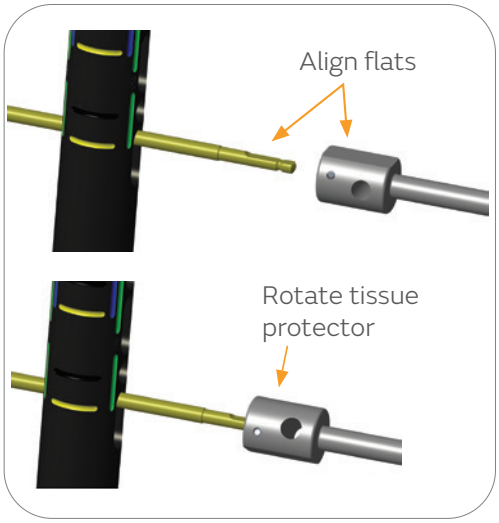
Unscrew the Nail Fixation Bolt by turning the Nail Fixation Bolt Handle counterclockwise to remove the Compression/Targeting Device Assembly from the nail.

Figure 16-3b

Tissue Protector Removal Tool



Soft Tissue Protector Removal Feature



Drill Guide / Compression Rod Removal Feature

Tissue Protector Removal Tool

The Tissue Protector Removal Tool is a double sided instrument that can be used to remove the PANTA◊ 2 soft tissue protectors (Tibial and Calcaneal) from the Targeting Guide. The other side is equipped with an AO removal feature, which can attach to the PANTA 2 drills if power cannot be easily attached to the AO feature.

Soft Tissue Protector Removal Feature

To remove a soft tissue protector using the AO Removal Feature of the Tissue Protector Removal Tool, align the appropriate end of the Tissue Protector Removal Tool with the soft tissue protector **(Figure A)**. Insert the Tissue Protector Removal Tool around the soft tissue protector. Pull axially on the Tissue Protector Removal Tool to remove the Soft Tissue Protector **(Figure B)**.

Drill Guide / Compression Rod Removal Feature

To remove a drill or Compression Rod using the AO Removal Feature of the Tissue Protector Removal Tool, align the flat of the appropriate end of the Tissue Protector Removal Tool with the flat on the AO connection of the drill.

Insert Tissue Protector Removal Tool to hard stop. Once inserted to the hard stop, rotate the Tissue Protector Removal Tool (either direction) a minimum of 90 degrees to engage the AO removal feature.

Pull axially on the Tissue Protector Removal Tool to remove the drill or Compression Rod.

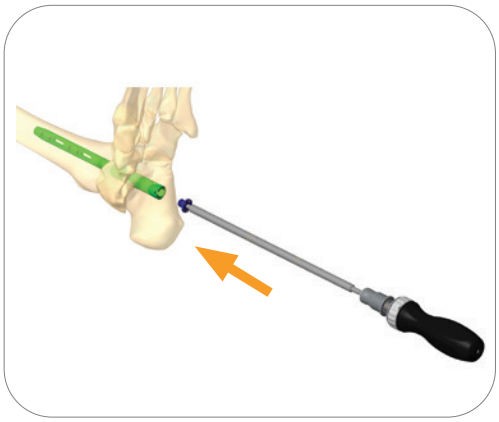


Figure 17-1

Step 17 ▪ End Cap Insertion (Optional)

17-1 The End Cap is manually screwed into the distal (plantar) threaded hole in the PANTA 2 Nail using the Hex Screwdriver with the Driver Handle.

Note: Specific to the partially threaded screws used in the calcaneus; the distal screw is locked by the End Cap.

Warning: Use caution when inserting the End Cap into the Nail. It is done through a blind hole and can be difficult to engage. The External Protection Sleeve can be used to guide End Cap insertion and will prevent loss of the End Cap in the wound if it becomes disassembled from the Hex Screwdriver.

Items Used:
End Cap - PAN-1010-1802
External Protection Sleeve Diameter 13.5mm - PAN-1010-0030
AO Driver Shaft - 3.5mm Hex Screwdriver - PAN-1010-0190
Driver Handle w/ SM AO - G107992B

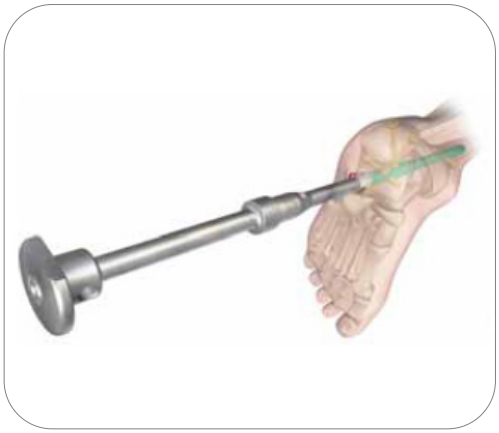


Figure 18-1

Figure 18-2

Step 18 ▪ Closure

A final check is performed using fluoroscopy. The wound is closed in layers using suture. A drain may be used if deemed necessary by the surgeon.

Postoperative Care

The patient should be placed in a boot or cast and should remain non-weight bearing for 8 weeks post-op. The patient should resume partial weight bearing between post-op weeks 8 through 14 and full weight bearing after week 14.

Arthrodesis Nail Removal

Use general instruments (ie, osteotomes, rongeurs) around implanted components to loosen the bone-implant interface and/or to facilitate removal.

Remove the End Cap using the Hex Screwdriver with the Driver Handle. Fluoroscopy can be useful during this step.

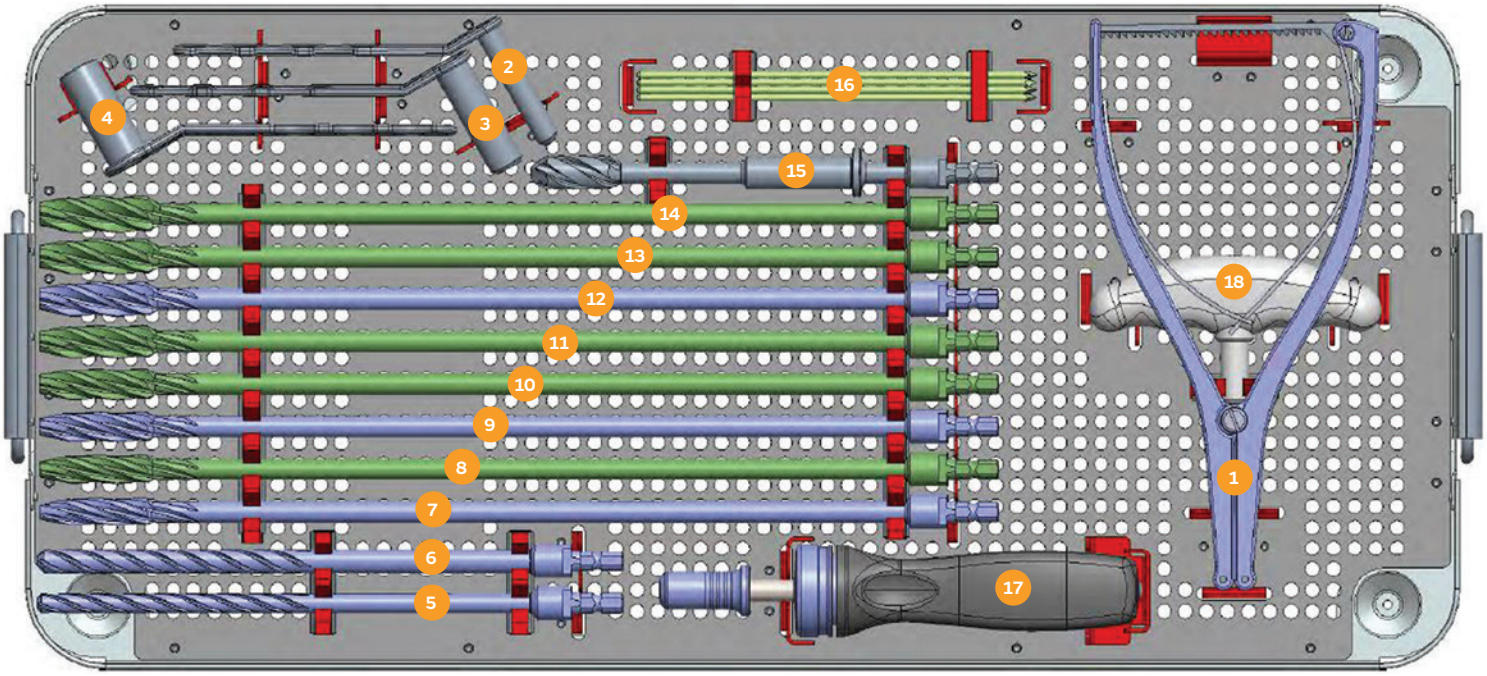
The calcaneal screws will need to be removed first. The Hex Screwdriver can be used to remove the calcaneal screws. In case of talar screw presence, remove it.

Next, remove the tibial screws with the Hex Screwdriver. Once all the screws have been removed from the nail, thread the Impactor into the back of the Extractor. Thread the assembly into the top of the nail. Use the Slotted Hammer with a back-slapping motion to extract the nail.

Items Used:
Impactor, 7175-1133
Extractor, 7175-1142
Slotted Hammer, 7175-1135

Note: Leave one screw within the Tibia, Talus, or Calcaneus engaged until the nail removal system is applied. This will prevent the nail from rotating.

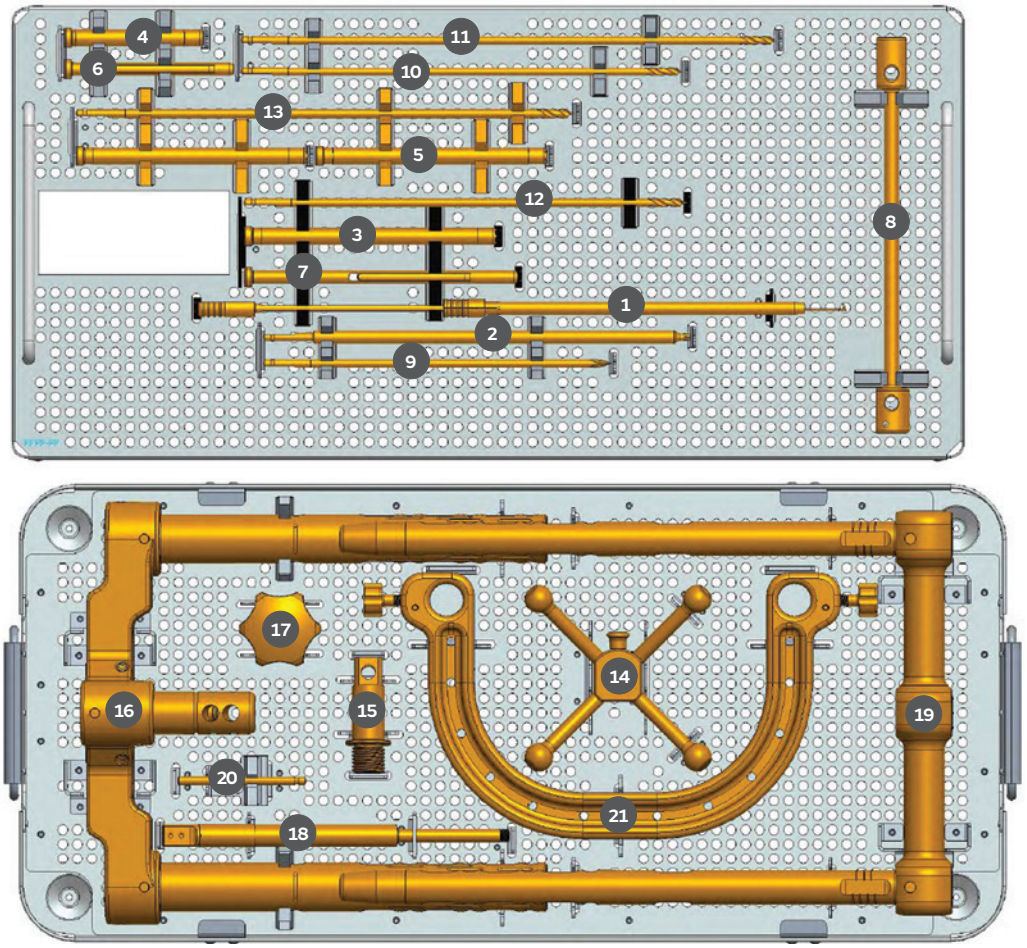
Instrumentation



Nail preparation case

Tray location number	Reference	Description
1	119651ND	Distractor
2	PAN-1010-0028	Internal Protection Sleeve Diameter 3.2mm
3	PAN-1010-0029	Central Protection Sleeve Diameter 9mm
4	PAN-1010-0030	External Protection Sleeve Diameter 13.5mm
5	PAN-1010-0007	Cannulated Drill 7mm Diam x 185mm
6	PAN-1010-0009	Cannulated Drill 9mm Diam x 185mm
7	PAN-1010-0010	Reamer, Diameter 10mm
8	PAN-1010-0011	Reamer, Diameter 11mm
9	PAN-1010-0012	Reamer, Diameter 12 mm
10	PAN-1010-0013	Reamer, Diameter 13 mm
11	PAN-1010-0014	Reamer, Diameter 10.5mm
12	PAN-1010-0015	Reamer, Diameter 11.5mm
13	PAN-1010-0016	Reamer, Diameter 12.5mm
14	PAN-1010-0017	Reamer, Diameter 13.5mm
15	PAN-1010-0019	Distal Reamer, 13mm
16	PAN-1010-0210	K-Wire, 2.5mm Diam x 150mm
17	G107992B	Driver Handle w/ Sm AO
18	HTM0111-S01	T-Handle with AO Quick Connect

Instrumentation



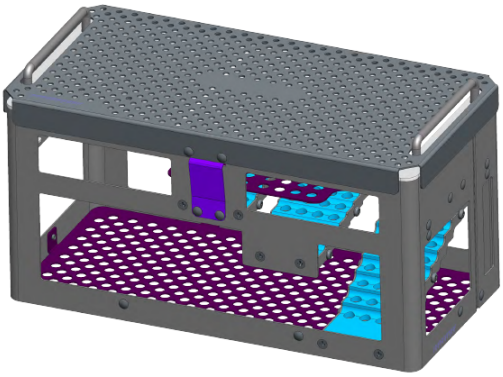
Targeting and compression tray

Top Tray

Tray Location Number	Reference	Description
1	PAN-1010-0160	Depth gauge
2	PAN-1010-0190	AO Driver Shaft - 3.5mm Hex Screwdriver
3	PAN-1010-0184	Soft Tissue Protector, 7mm Diam, Tibial
4	PAN-1010-0183	Soft Tissue Protector, 7mm Diam, Calcaneal
5	PAN-1010-0181	Compression Rod Drill Guide, 5mm Diam
6	PAN-1010-0185	Drill Guide, 4.1mm Diam, Calcaneal
7	PAN-1010-0186	Drill Guide, 4.1mm Diam, Tibial
8	PAN-1010-0187	Tissue Protector Removal Tool
9	PAN-1010-0188	4.1mm Trocar
10	PAN-1010-0002	Short Calcaneal Drilll, 4.1mm Diam
11	PAN-1010-0003	Long Calcaneal Drill, 4.1mm Diam
12	PAN-1010-0004	Tibial Drill, 4.1mm Diam
13	PAN-1010-0175	Compression Rod, 5mm Diam.

Bottom Tray

Tray Location Number	Reference	Description
14	PAN-1010-0135	Compression Wheel
15	PAN-1010-0113	Threaded Axis
16	PAN-1010-0230	Targeting Guide
17	PAN-1010-0121	Handle, Nail Fixation Bolt
18	PAN-1010-0120	Nail Fixation Bolt
19	PAN-1010-0231	Compression Device
20	PAN-1010-0122	Lock Screw
21	PAN-1010-0201	Target Guide Support



P2SCREWCASE2

Category	Reference	Description
Implant-Screw	PAN-1010-1418NS	PANTA° 5.0mm Fully Threaded size 18
Implant-Screw	PAN-1010-1420NS	PANTA 5.0mm Fully Threaded size 20
Implant-Screw	PAN-1010-1422NS	PANTA 5.0mm Fully Threaded size 22
Implant-Screw	PAN-1010-1424NS	PANTA 5.0mm Fully Threaded size 24
Implant-Screw	PAN-1010-1426NS	PANTA 5.0mm Fully Threaded size 26
Implant-Screw	PAN-1010-1428NS	PANTA 5.0mm Fully Threaded size 28
Implant-Screw	PAN-1010-1430NS	PANTA 5.0mm Fully Threaded size 30
Implant-Screw	PAN-1010-1432NS	PANTA 5.0mm Fully Threaded size 32
Implant-Screw	PAN-1010-1434NS	PANTA 5.0mm Fully Threaded size 34
Implant-Screw	PAN-1010-1436NS	PANTA 5.0mm Fully Threaded size 36
Implant-Screw	PAN-1010-1438NS	PANTA 5.0mm Fully Threaded size 38
Implant-Screw	PAN-1010-1440NS	PANTA 5.0mm Fully Threaded size 40
Implant-Screw	PAN-1010-1442NS	PANTA 5.0mm Fully Threaded size 42
Implant-Screw	PAN-1010-1444NS	PANTA 5.0mm Fully Threaded size 44
Implant-Screw	PAN-1010-1446NS	PANTA 5.0mm Fully Threaded size 46
Implant-Screw	PAN-1010-1448NS	PANTA 5.0mm Fully Threaded size 48
Implant-Screw	PAN-1010-1450NS	PANTA 5.0mm Fully Threaded size 50
Implant-Screw	PAN-1010-1452NS	PANTA 5.0mm Fully Threaded size 52
Implant-Screw	PAN-1010-1454NS	PANTA 5.0mm Fully Threaded size 54
Implant-Screw	PAN-1010-1456NS	PANTA 5.0mm Fully Threaded size 56
Implant-Screw	PAN-1010-1458NS	PANTA 5.0mm Fully Threaded size 58
Implant-Screw	PAN-1010-1460NS	PANTA 5.0mm Fully Threaded size 60
Implant-Screw	PAN-1010-1465NS	PANTA 5.0mm Fully Threaded size 65
Implant-Screw	PAN-1010-1470NS	PANTA 5.0mm Fully Threaded size 70
Implant-Screw	PAN-1010-1475NS	PANTA 5.0mm Fully Threaded size 75

P2SCREWCASE2 *(continued)*

Category	Reference	Description
Implant-Screw	PAN-1010-1480NS	PANTA 5.0mm Fully Threaded size 80
Implant-Screw	PAN-1010-1485NS	PANTA 5.0mm Fully Threaded size 85
Implant-Screw	PAN-1010-1490NS	PANTA 5.0mm Fully Threaded size 90
Implant-Screw	PAN-1010-1495NS	PANTA 5.0mm Fully Threaded size 95
Implant-Screw	PAN-1010-1500NS	PANTA 5.0mm Fully Threaded size 100
Implant-Screw	PAN-1010-1505NS	PANTA 5.0mm Fully Threaded size 105
Implant-Cap	PAN-1010-1802NS	End Cap
Implant-Screw	PAN-1010-2645NS	PANTA 5.0mm Partially Threaded C-Screw size 45
Implant-Screw	PAN-1010-2650NS	PANTA 5.0mm Partially Threaded C-Screw size 50
Implant-Screw	PAN-1010-2655NS	PANTA 5.0mm Partially Threaded C-Screw size 55
Implant-Screw	PAN-1010-2660NS	PANTA 5.0mm Partially Threaded C-Screw size 60
Implant-Screw	PAN-1010-2665NS	PANTA 5.0mm Partially Threaded C-Screw size 65
Implant-Screw	PAN-1010-2670NS	PANTA 5.0mm Partially Threaded C-Screw size 70
Implant-Screw	PAN-1010-2675NS	PANTA 5.0mm Partially Threaded C-Screw size 75
Implant-Screw	PAN-1010-2680NS	PANTA 5.0mm Partially Threaded C-Screw size 80
Implant-Screw	PAN-1010-2685NS	PANTA 5.0mm Partially Threaded C-Screw size 85
Implant-Screw	PAN-1010-2690NS	PANTA 5.0mm Partially Threaded C-Screw size 90
Implant-Screw	PAN-1010-2695NS	PANTA 5.0mm Partially Threaded C-Screw size 95
Implant-Screw	PAN-1010-2700NS	PANTA 5.0mm Partially Threaded C-Screw size 100
Implant-Screw	PAN-1010-2705NS	PANTA 5.0mm Partially Threaded C-Screw size 105
Implant-Screw	PAN-1010-2710NS	PANTA 5.0mm Partially Threaded C-Screw size 110

Sterile implants and guide wire

Category	Reference	Description
Implant-Nail	PAN-1010-10150	PANTA Nail, 10mm Dia. X 150mm
Implant-Nail	PAN-1010-10180	PANTA Nail, 10mm Dia. X 180mm
Implant-Nail	PAN-1010-10210	PANTA Nail, 10mm Dia. X 210mm
Implant-Nail	PAN-1010-10240	PANTA Nail, 10mm Dia. X 240mm
Implant-Nail	PAN-1010-11150	PANTA Nail, 11mm Dia. X 150mm
Implant-Nail	PAN-1010-11180	PANTA Nail, 11mm Dia. X 180mm
Implant-Nail	PAN-1010-11210	PANTA Nail, 11mm Dia. X 210mm
Implant-Nail	PAN-1010-11240	PANTA Nail, 11mm Dia. X 240mm
Implant-Nail	PAN-1010-12150	PANTA Nail, 12mm Dia. X 150mm
Implant-Nail	PAN-1010-12180	PANTA Nail, 12mm Dia. X 180mm
Implant-Nail	PAN-1010-12210	PANTA Nail, 12mm Dia. X 210mm
Implant-Nail	PAN-1010-12240	PANTA Nail, 12mm Dia. X 240mm
Implant-Nail	PAN-1010-13150	PANTA Nail, 13mm Dia. X 150mm
Implant-Nail	PAN-1010-13180	PANTA Nail, 13mm Dia. X 180mm
Implant-Nail	PAN-1010-13210	PANTA Nail, 13mm Dia. X 210mm
Implant-Nail	PAN-1010-13240	PANTA Nail, 13mm Dia. X 240mm
Consumable	PAN-1010-0034	Guide Wire 3.2mm Diam x 600mm

Removal instruments

Reference	Description
7175-1142	Humeral Nail Extractor
7175-1133	Impactor
7175-1135	Slotted Hammer

Surgical technique

Smith+Nephew does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.

Notes

Notes

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