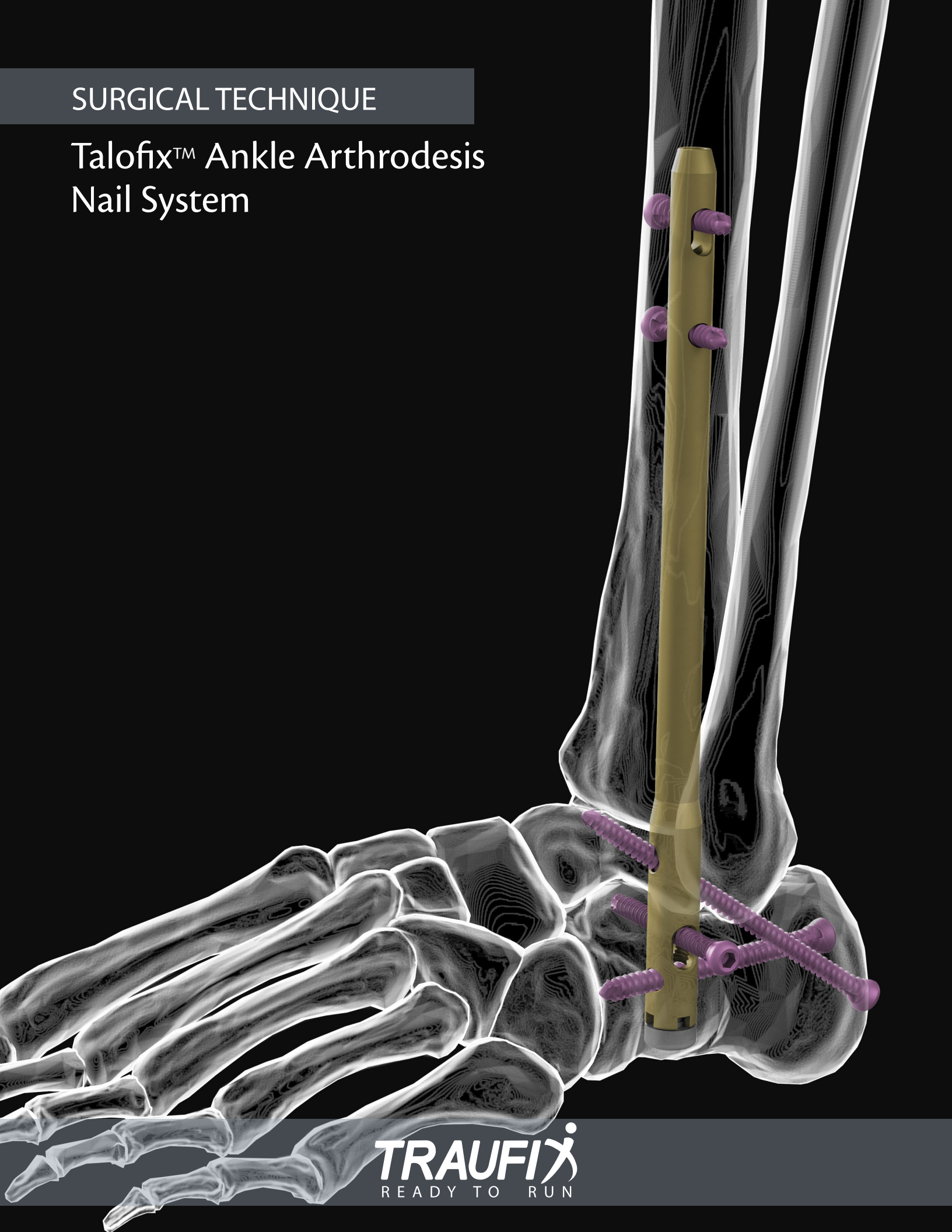
SURGICAL TECHNIQUE

Talofix™ Ankle Arthrodesis Nail System



TRAUFIX
READY TO RUN

CONTENTS

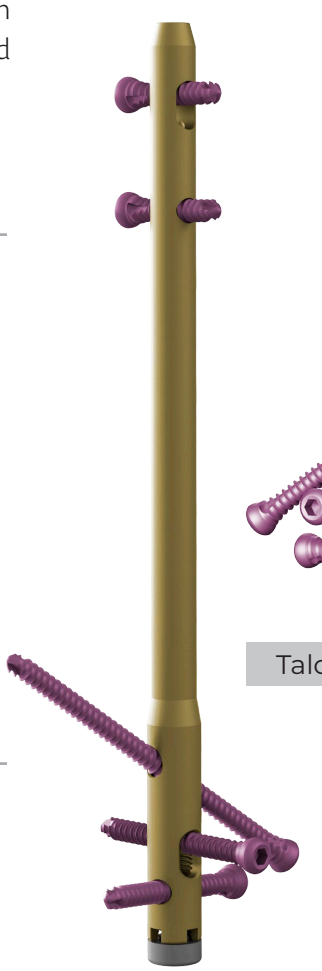
SURGICAL TECHNIQUE

System Description

The Talofix Nail System is an innovative development that provides the possibility of tibio-astragalus-calcaneal fusion with an intramedullary retrograde nail.

The main advantages of this technique are limited soft tissue damage in the ankle area, a high primary stability that allows EARLY support, and compression of the subtalar and tibiotalar joints.

Talofix Right



Talofix Left

Implant Options

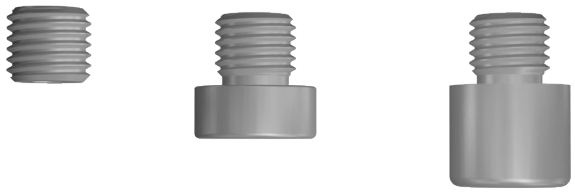
- **Diameter:** 10, 11 and 12 mm (left and right).
- **Sizes:** 160, 200 and 250mm.

Note: The distal diameter of all nails is 12 mm.

- **5mm self-tapping locking screws:** L=25mm-110mm.

Note: Screw length is measured from the top of the head to the tip.

- **Locking plugs** 0, 5 and 10mm.

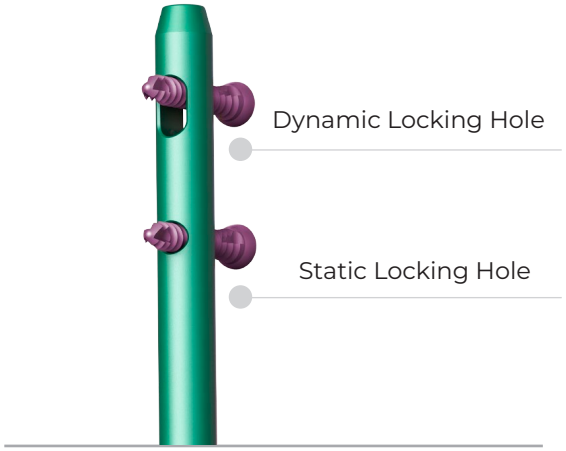


Innovative Design Features

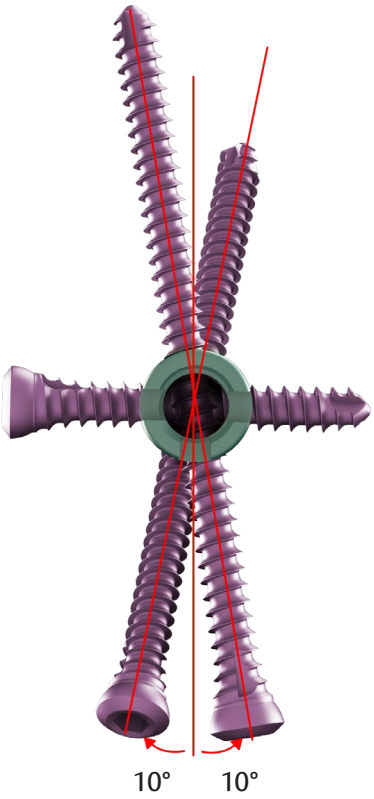
Nail: Provides different diameters and lengths for more clinical options, distal sliding hole allows a maximum compression distance of 5mm and provides static and dynamic locking holes proximally

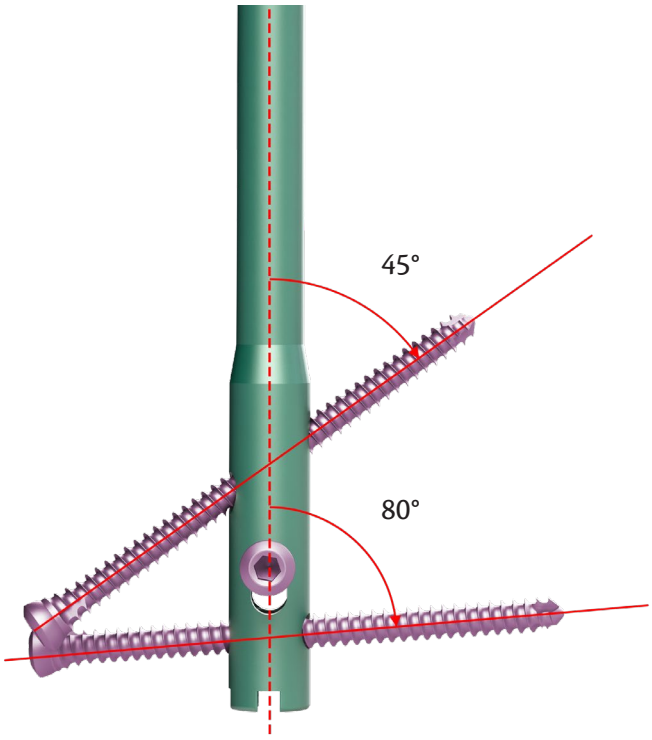
Dynamic and static holes: The static locking hole prevents the nail from rotating and moving axially in the medullary cavity, improving fixation stability. In case of osseous pseudarthrosis, only the dynamic sliding hole is used, to allow the nail to move axially in the medullary cavity and slide slightly between the bones, to promote consolidation.

Distal multi-planar screws crossing locking holes: Transverse fixation to improve fusion stability. The screw is inserted obliquely toward the anterior calcaneus or calcaneal neocuboid joint to improve pullout strength and stability.



Locking Screw
5.0 mm

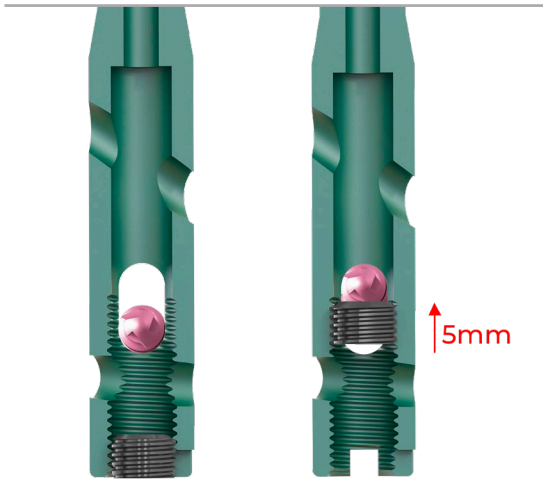




Locking plug for compression in distal sliding hole: Allows a maximum compression distance of 5 mm.

Self-tapping screw with anatomical design: The Fix 5.0 locking screw allows better bone locking and the head part has an anatomical design which allows the soft tissues to be unaffected reducing fatigue and/or possible damage.

Carbon Fiber Strut: Provides static and dynamic proxi- mal locking options for clinical choice and offers advanced precision and usability, as well as ergonomic positioning devices.



Indications and contraindications

Indications

The Talofix ankle arthrodesis nail for the management of:

- Severe foot and ankle deformity
- Arthritis
- Skeletal instability and defects, including, but not limited to, those following tumor resection and neuroosteoarthropathy (Charcot foot).
- Avascular necrosis of the talus
- Failed joint replacement or failed ankle fusion
- Fractures and pseudarthrosis of the distal tibia
- Osteoarthritis
- Rheumatoid arthritis and pseudoarthrosis

Contraindication

- Active infection
- Peripheral vascular neuropathy
- Young patients

Patient Positioning and Approach

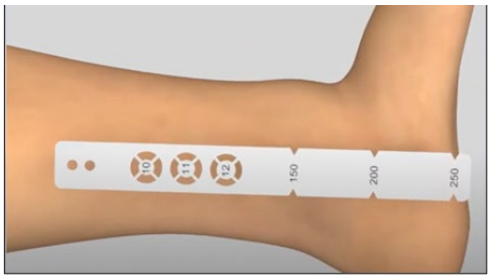
Patient Positioning

Place the patient supine on a radiolucent table. Care should be taken to ensure neutral alignment of the knee and ankle. Prepare the entire foot and ankle leaving the limb free from above the knee to allow intraoperative assessment of the lower limb alignment to avoid posterior deviation during the procedure, this position will allow:

•Comfortable exposure to the C-arm for radiological control.
•Proximal block from the medial side and distal block from the lateral side.
•Good access for posterior block.

Determining Nail Length

Adjust the ruler until the distal end is at the desired insertion depth of the nail. Mark the skin at this location on the lateral side. An image of the ruler can be used to choose the optimal nail length and diameter.



Ankle Positioning for Fusion

The position of the foot with neutral dorsiplantar flexion of the ankle, 5-10° of external rotation in relation to the tibial crest and 5° of valgus of the back of the foot, an assistant should maintain this position for a correct determination of the entry point

Surgical approach

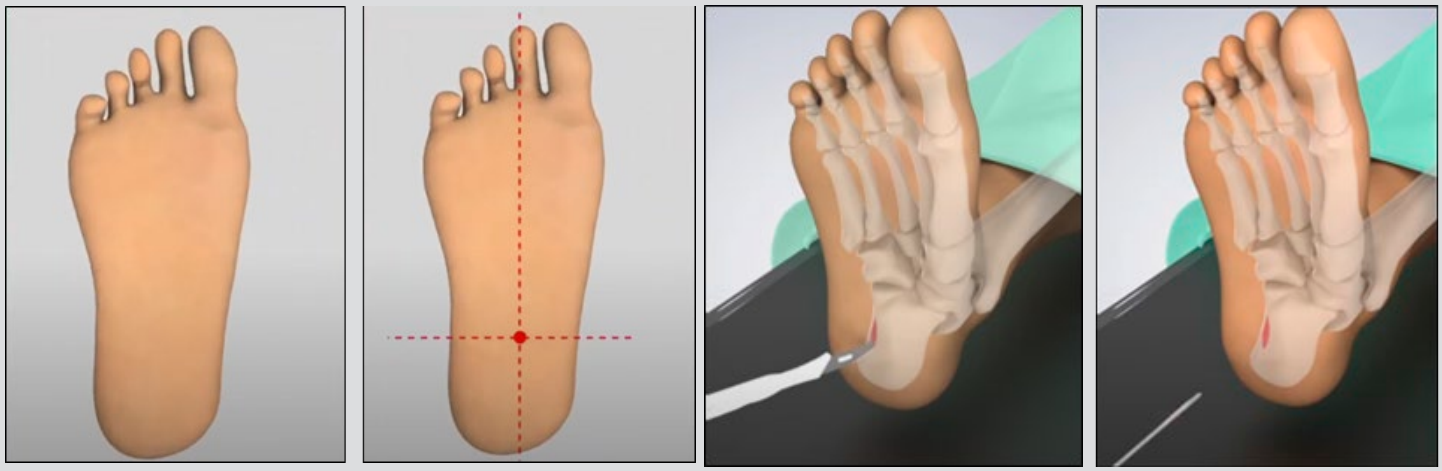
The entry site is in line with the tibial canal and the lateral column of the calcaneus. The entry point is at the intersection of these two lines.

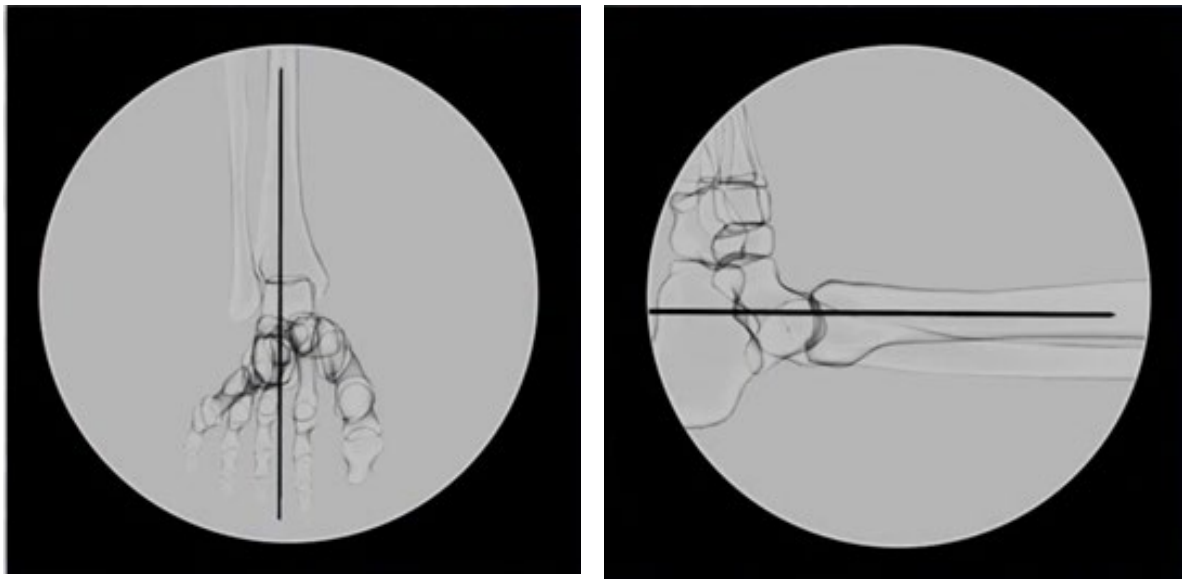
Incision

After preparation of the joint and X-ray evaluation to confirm the position of fusion and determination of the entry point, a longitudinal incision of approximately 2-3 cm is made. Careful dissection is then performed to access the plantar surface of the calcaneus

Entry point

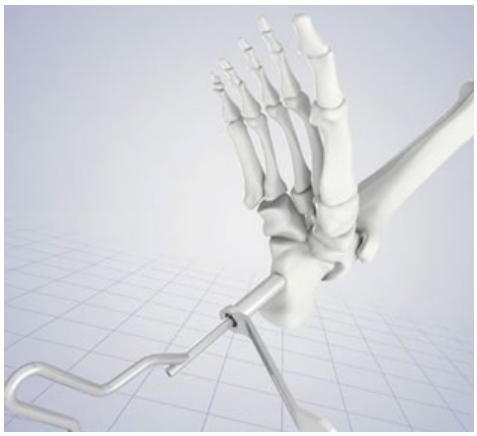
Insert the guide wire through the center of the lateral column of the calcaneus to the center of the dome of the talus. Direct the guide wire into the center of the tibial canal in the AP (supine) and ML (lateral) views.





Opening the medullary canal

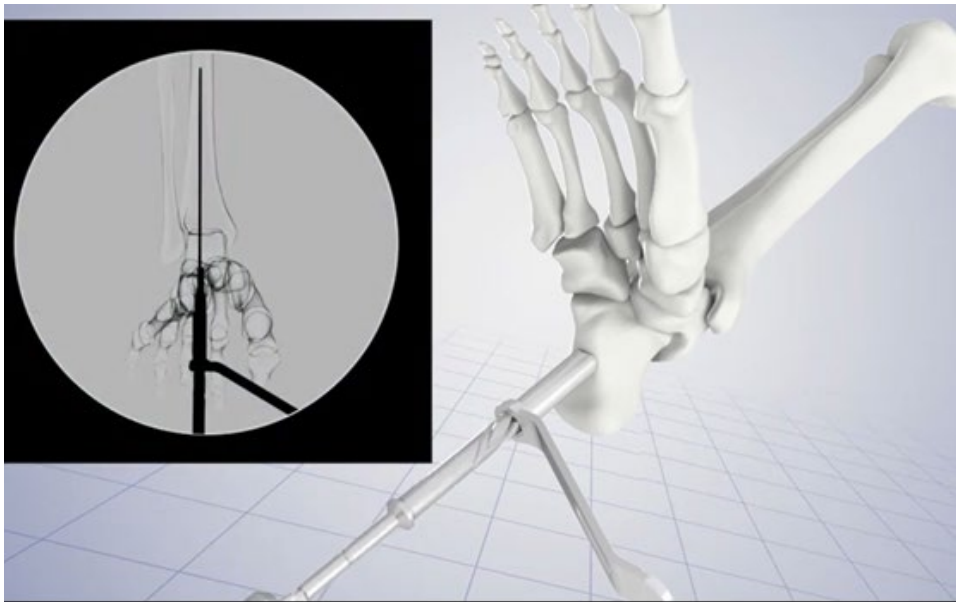
Open the canal, use a cannulated punch to open the canal on the plantar underside of the calcaneus through the protective sleeve.
Slide the cannulated punch into the guide wire, down to the bone. Using a smooth rotary motion, advance the punch deep into the medullary cavity, finishing by removing the punch and guide wire.



Milling

Place the cannulated drill over the guide wire with olive and through the protective tab to the bone. Drill through the calcaneus, talus and distal tibial canal, verify with the image intensifier that alignment is maintained. Then ream to a diameter at least 1.0 mm larger than the nail diameter. Continue reaming in 0.5mm increments and advancing, applying constant and moderate force, the olive at the end of the guide wire will stop the reamer.

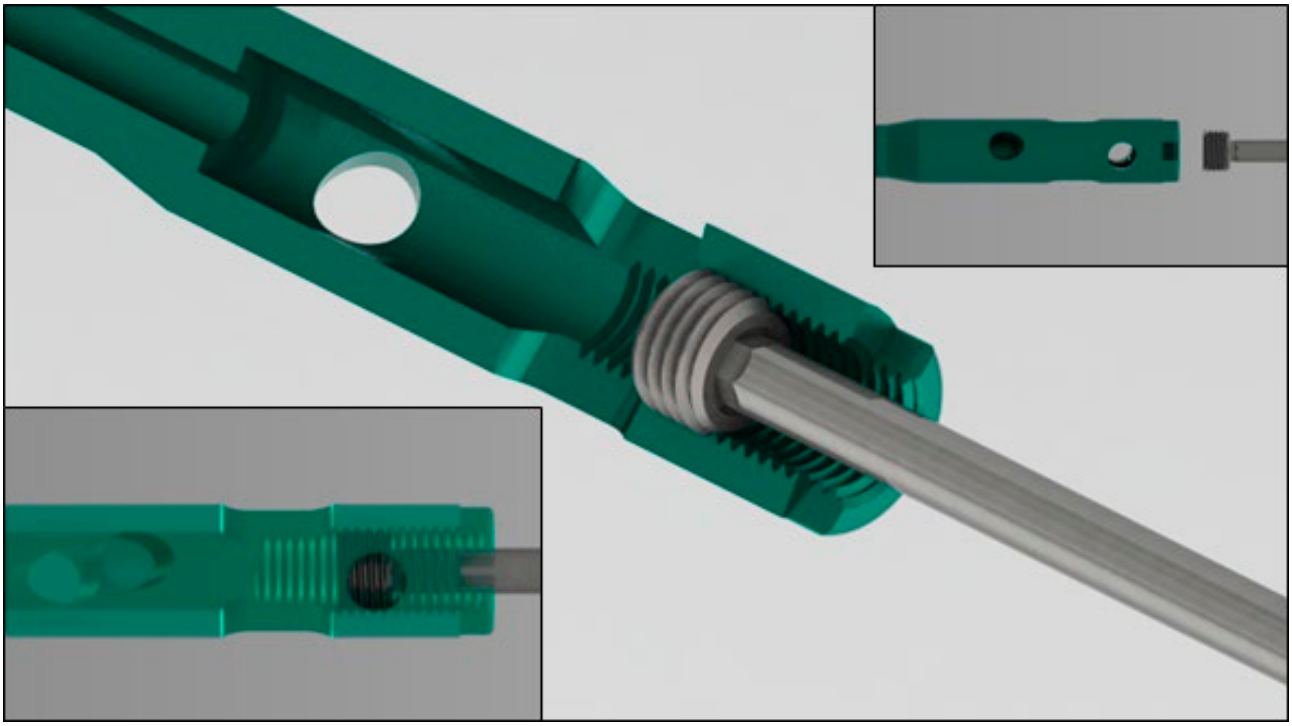
Note: Before reaming it is important to check the centered intramedullary position of the guide wire with an image intensifier.



Nail insertion and fixation

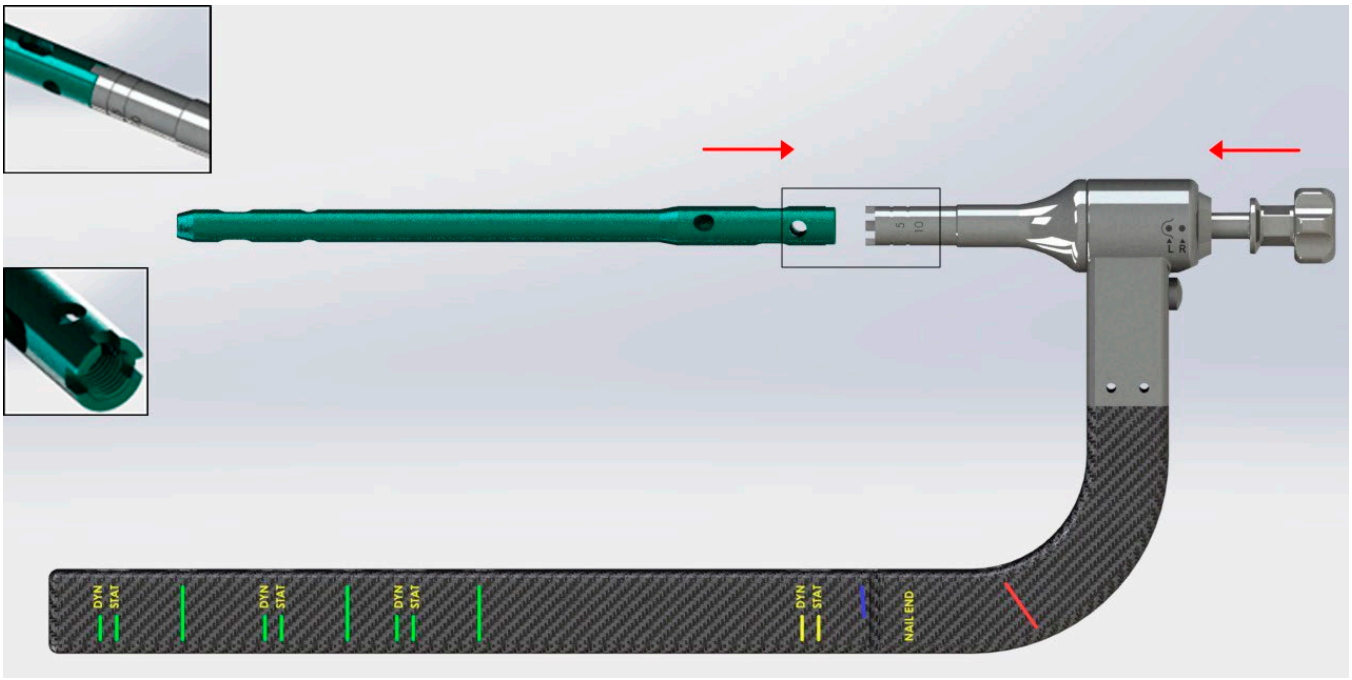
Plug loading 0mm for dynamizing

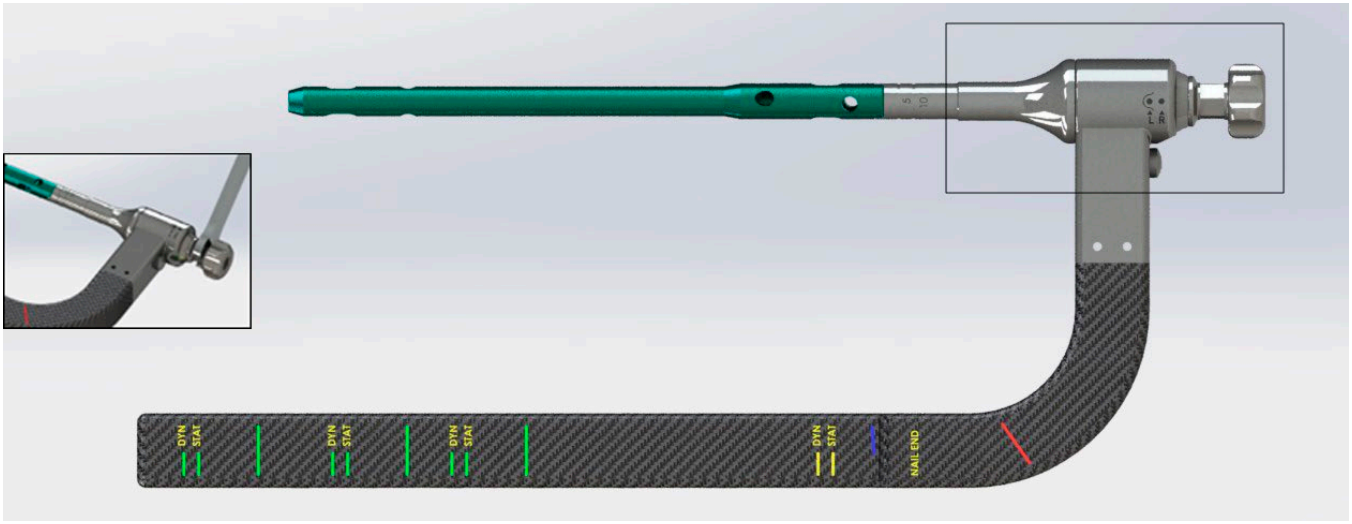
In case of using the dynamizing, pre-load the 0mm plug before fixing the nail to the clamp, the insertion of the plug should be before the dynamizing slot and between the hole for locking the calcaneus.



Nail Attachment to the nail clamp

Connect the selected nail into the adapter until its three connecting teeth engage in the corresponding grooves of the nail. The guide shaft is placed through the nail adapter and tightened firmly with a wrench, to avoid loosening during nail insertion. The colors on the adapter will indicate the positions of each hole either static or dynamic.



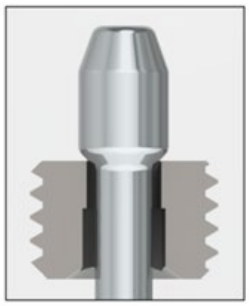


Nail insertion:

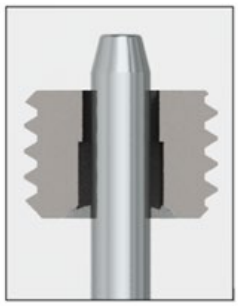
Insert the nail over the guide wire with olive tip (if used) and advance it into the medullary canal with twisting movements, if necessary, use gentle and controlled hammer blows to place the nail, verify the correct position of the nail by checking that the depth and rotation are correct.

Note: In case of difficulties inserting the nail, select a smaller diameter nail or proceed to ream the medullary cavity to enlarge its diameter.

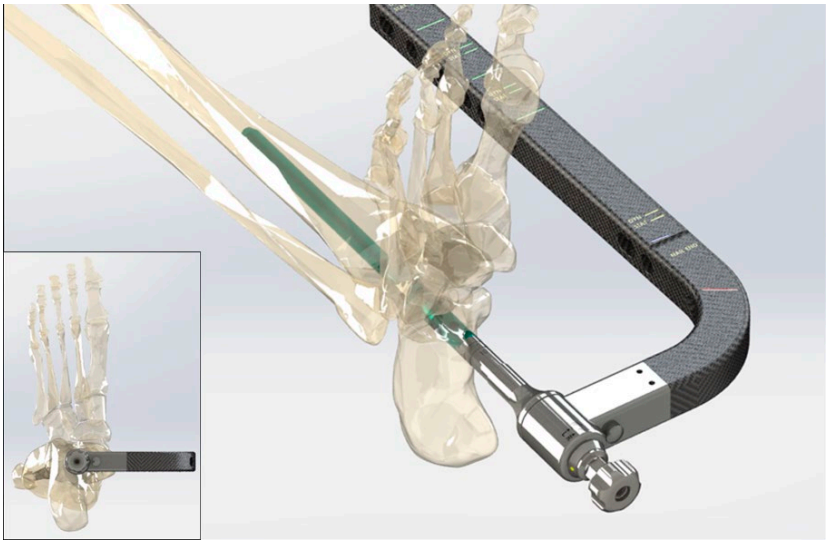
Note: If dynamizing is to be used, replace the olive-tipped guide with a nonolive guide before inserting the nail, as the plugs do not have a bore diameter for the olive-tipped guide to pass through.



guide with olive

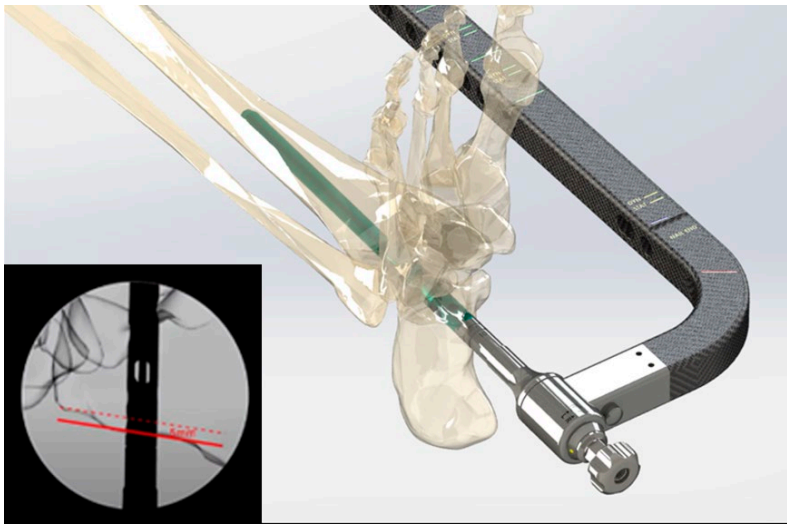


guide without olive



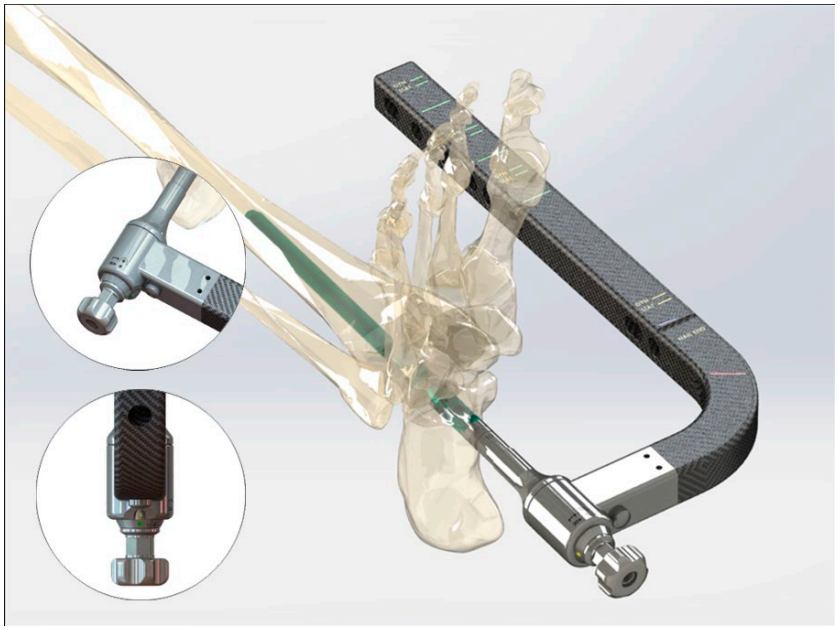
Depth verification

Verify the depth of nail insertion by fluoroscopy. It is suggested that the end of the nail be inserted approximately 5 mm deep into the calcaneus.



Strip Shaft

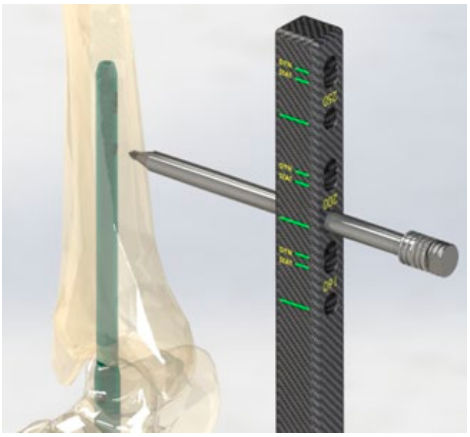
It is color-coded the upper circle represents left and the lower circle on the right. Adjust the axis of the slider in the distal medial area by pressing the button (the slot that aligns with the upper circle, the green icon, on the left).



Proximal drill guided locking

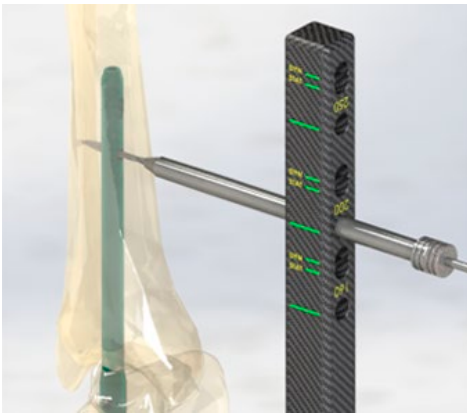
Insert the protective sleeve, drill guide and trocar. Use a 4.3 mm drill bit to drill a hole, guided locking of the proximal screws should be performed with the guide in the appropriate hole to lock the proximal static nail hole (160 mm, 200 mm and 250 mm nail lengths are marked on the locking guide), make a small incision in the skin in front of the trocar and push the con-joint until the tissue protection sleeve is in contact with the medial cortex of the tibia

Note: Before starting to drill for the first proximal locking screw, check for correct rotational position for fusion.



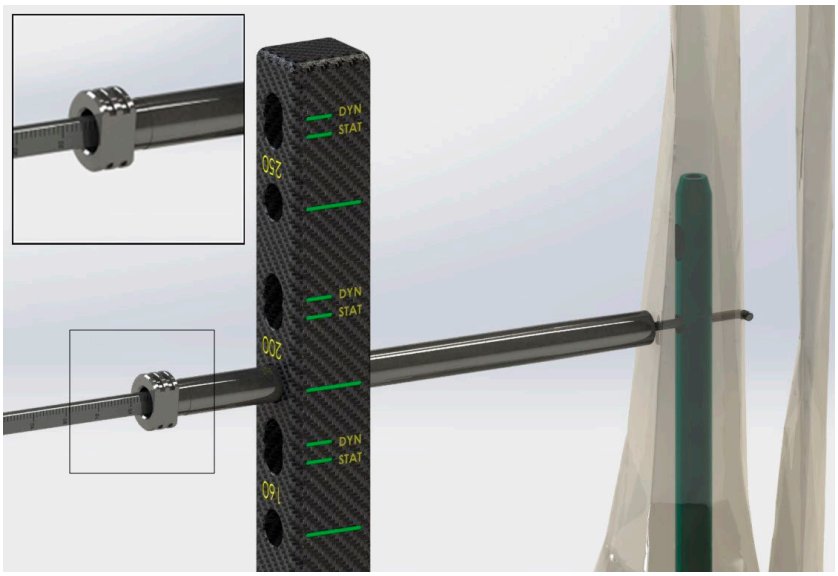
Proximal Screw Drilling

The trocar is removed, keeping the tissue protection sleeve and drill guide in position, to ensure accurate drilling, it is recommended to use the 4.3 mm drill bit to open the first cortex.



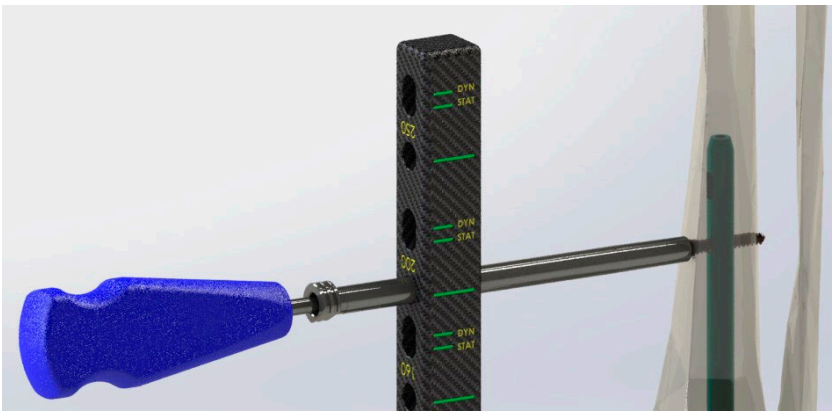
Determine the length with Depth Gauge

Measure the depth and choose a suitable 5.0 mm locking screw, place the depth gauge with its outer sleeve. Insert the depth gauge through the outer sleeve and advance until the resistance of the second cortex is felt. Perform a check with the image intensifier. Apply firm pressure on the outer sheath of the depth gauge against the cortex to ensure an accurate measurement. The screw length can be read directly on the back of the outer sheath of the depth gauge. Insert the screw with a SW 3.5" screwdriver.



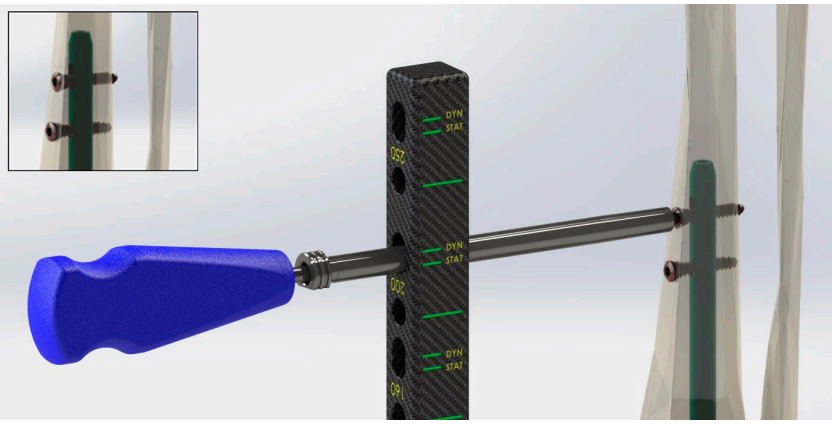
Screw insertion 5.0mm

After removing the drill diameter reducer, the fully threaded locking screw of correct length is inserted through the tissue protection cannula using the screwdriver SW 3.5, the screw is advanced through both cortices.



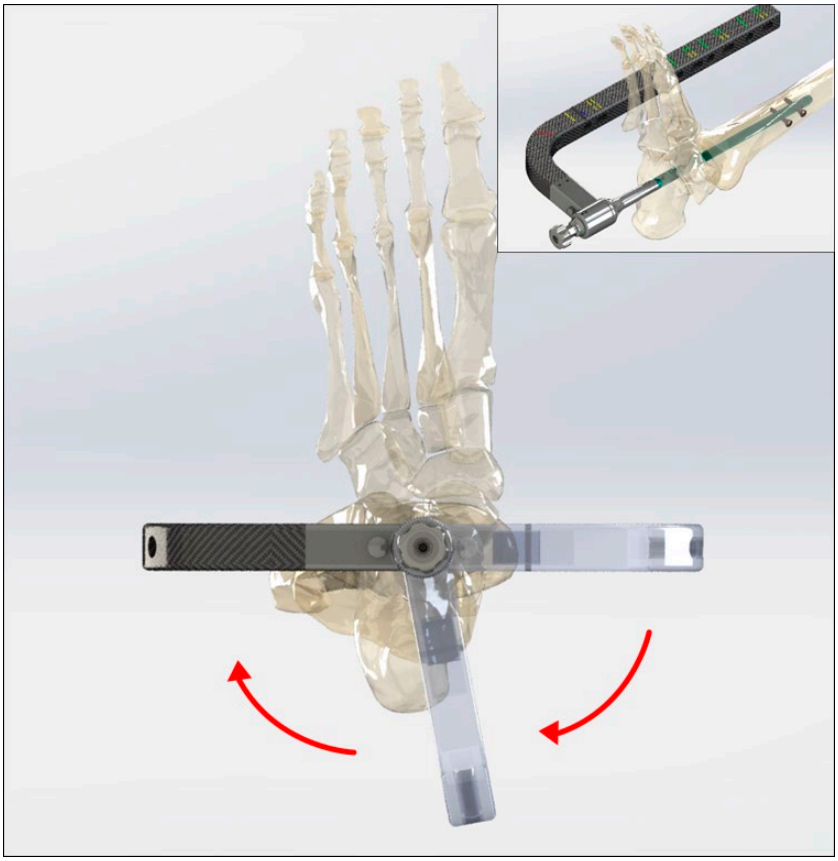
Insertion of the 5.0mm screw into dynamic hole

Repeat the above operating steps to insert a 5.0mm locking screw for the second locking screw, this can only be placed in the dynamic position of the proximal oval hole.



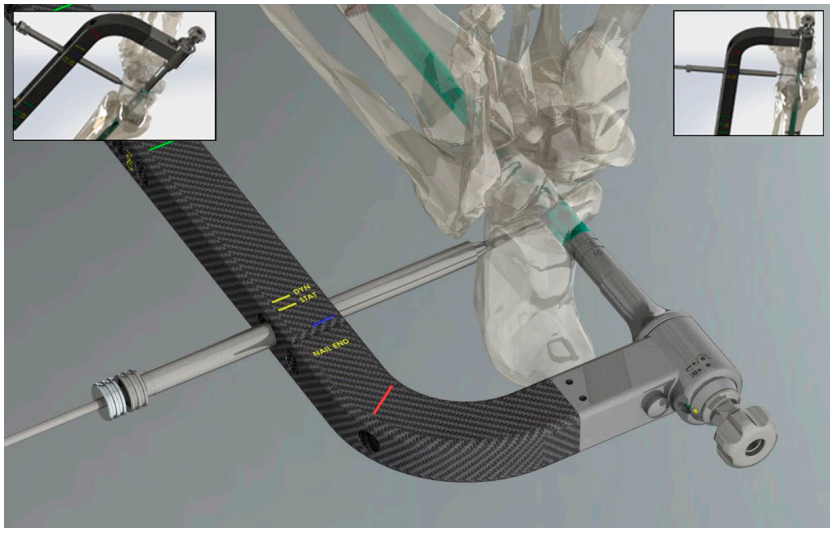
Position adjustment for compression hole

Adjust the target axis to the lateral ankle (the slot coincides with the upper circle: the yellow icon), so that the slider moves to the lateral side of the foot.



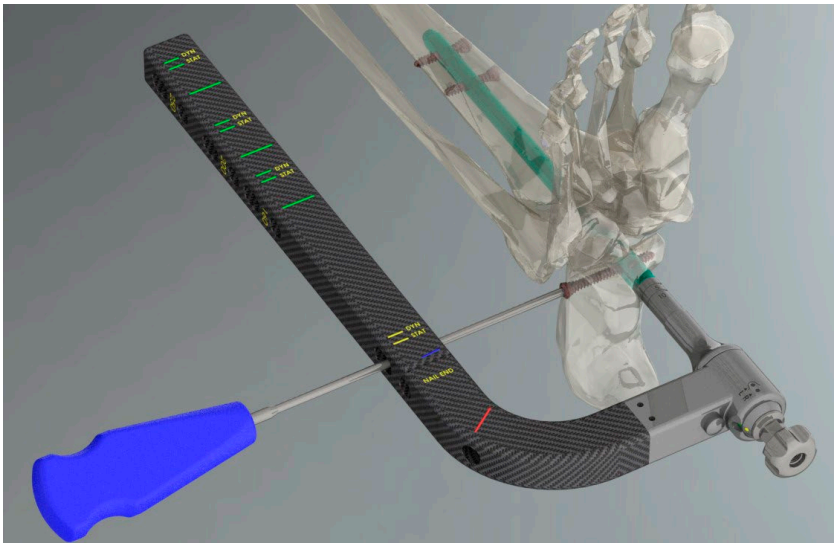
Tibio-calcaneal compression hole

Insert the distal compression locking device: use a 4.3 mm drill bit, use the tissue protection sleeve and the drill guide in position to drill a hole, measure the depth.



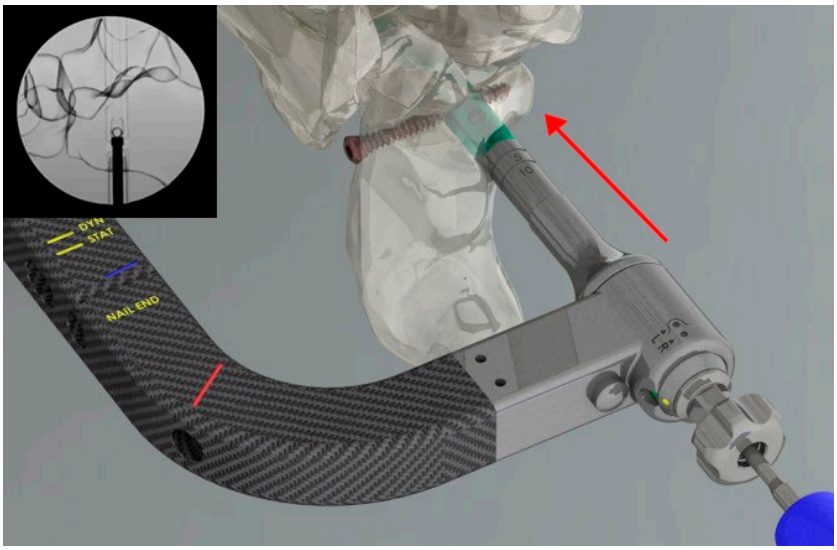
Tibiocalcaneal Compression Screw Insertion

Choose a suitable 5.0 mm locking screw, remove the drill diameter reducer, insert the fully threaded locking screw of correct length through the tissue protection cannula using the SW 3.5 screwdriver.



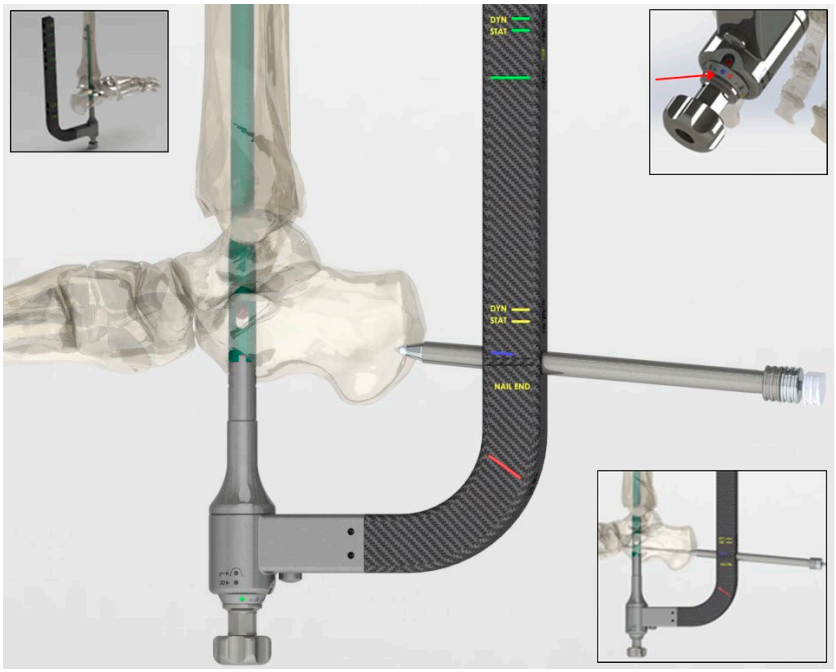
Compression with 0mm locking plug

Perform compression for the articular surface by turning the compression nut using the screwdriver SW 3.5.



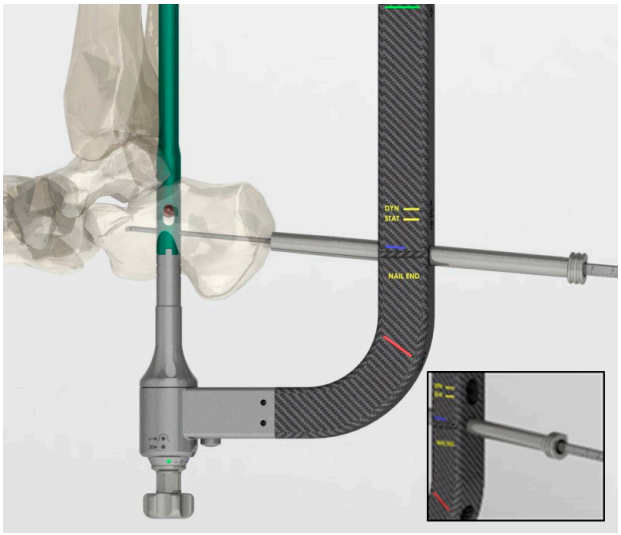
Insertion of the calcaneal locking screw

Adjust the steering shaft to the posterior medial aspect of the ankle (slot aligns with the lower circle, blue icon) and repeat the above operating steps.



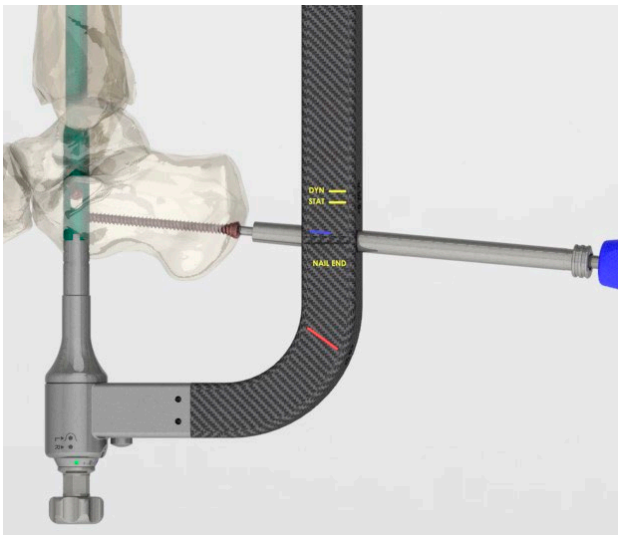
Determining Length with Calcaneal Depth Gauge

Measure the depth and choose a suitable 5.0 mm locking screw, the depth gauge is placed with its outer sleeve. Insert the depth gauge through the outer sleeve and advance until the resistance of the subchondral area is felt



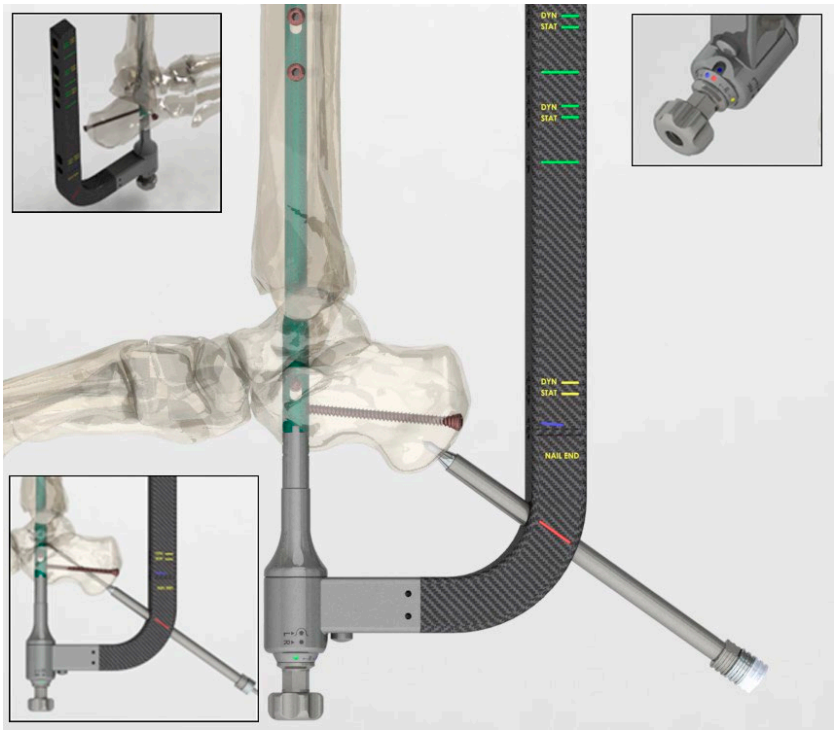
5.0mm Screw Insertion

Choose a suitable 5.0mm locking screw, remove the drill diameter reducer, insert the fully threaded locking screw of correct length through the tissue protection sleeve using the SW 3.5 screwdriver.



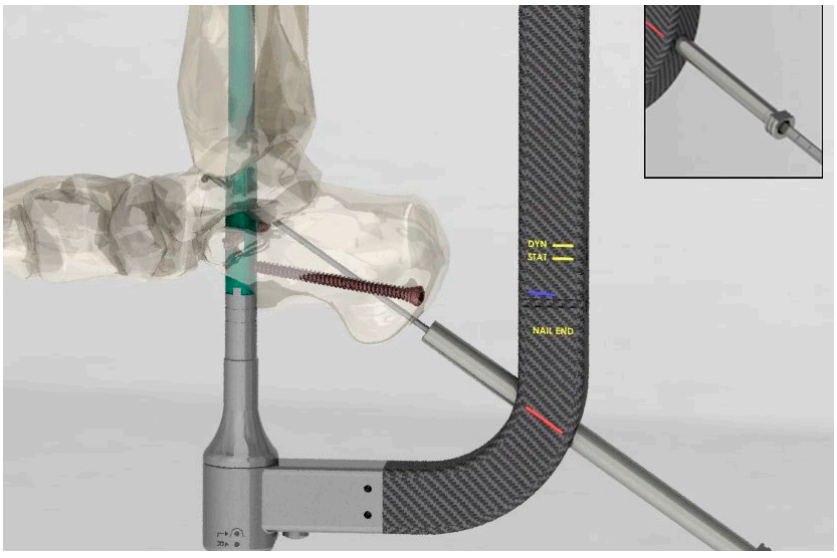
Insert the talus/calcaneal locking screw

Adjust the orientation axis on the posterior lateral side of the ankle (the slot aligns with the lower circle: the red icon) and repeat the above operating steps.



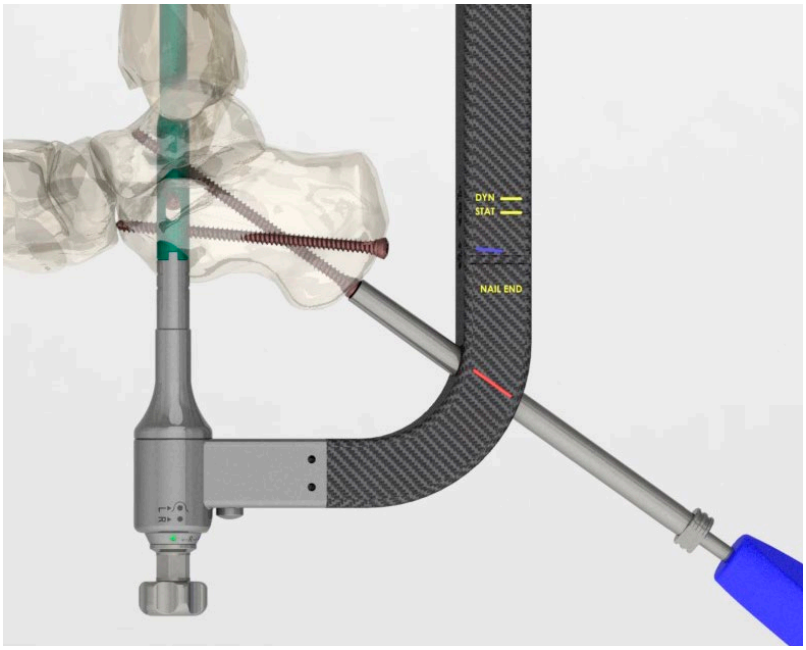
Determining Length with Talus Depth Gauge

Measure the depth and choose a suitable 5.0 mm locking screw, the depth gauge is placed with its outer sleeve. Insert the depth gauge through the outer sheath and advance until the resistance of the subchondral area is felt.



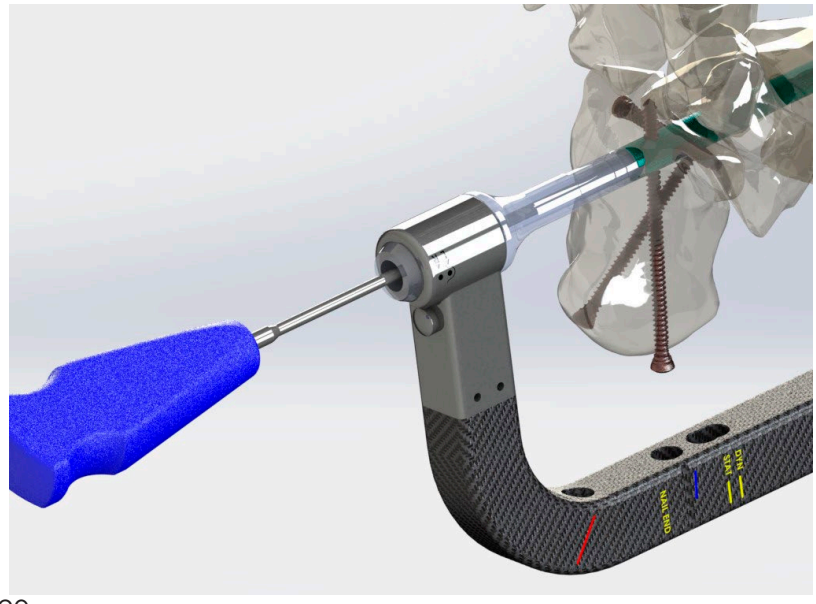
Insertion of the 5.00mm screw for talus/calcaneal locking

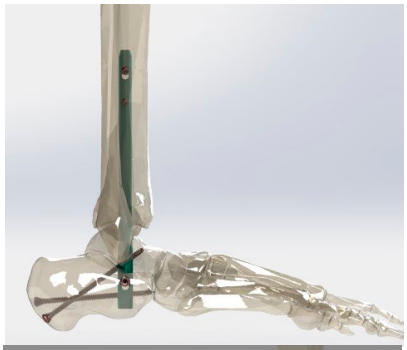
Choose a suitable 5.0 mm locking screw, remove the drill diameter reducer, insert the fully threaded locking screw of correct length through the tissue protection sleeve using the Screwdriver SW 3.5.

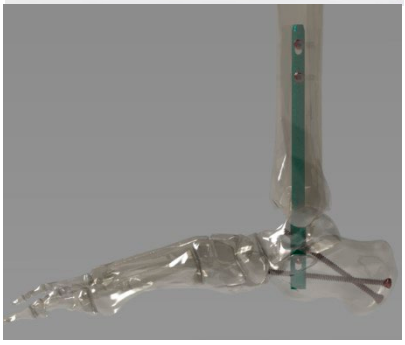


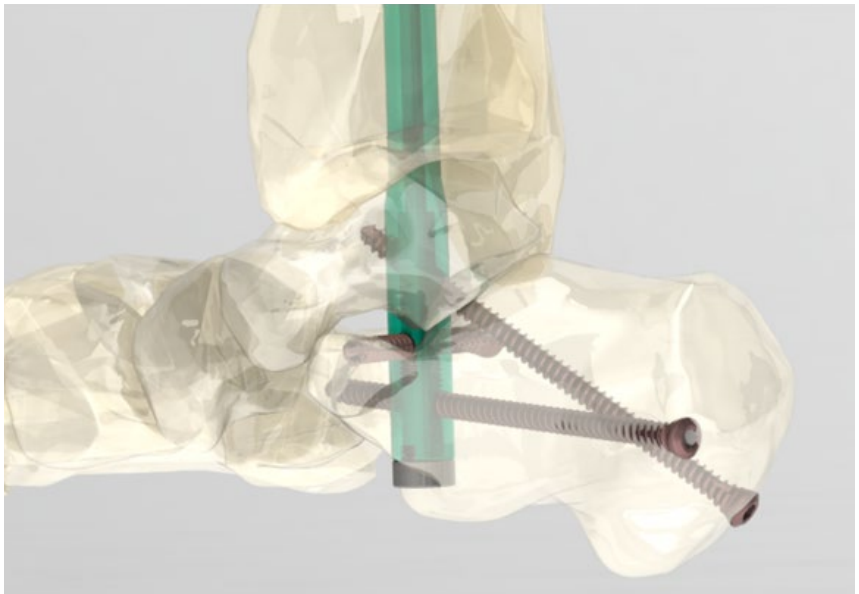
Inserting the locking plug

Through the channel of the nail adaptor the locking plug (0mm) is inserted with the help of the screwdriver SW 3.5, extension plugs +5 and +10 mm are also available, to adjust the length of the nail, these plugs cannot be inserted through the channel of the adaptor due to the larger diameter of their head.







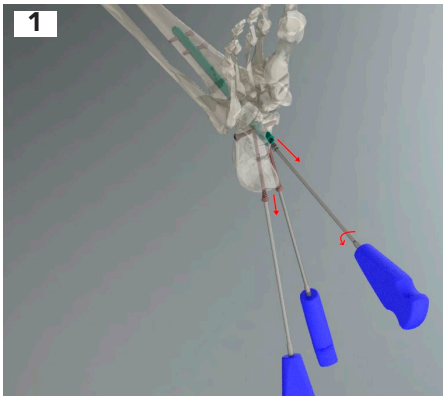


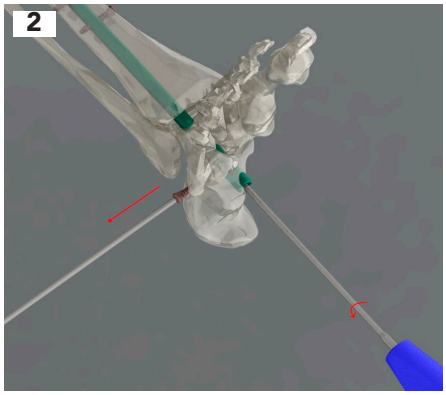
COMPLETE ARTHRODESIS

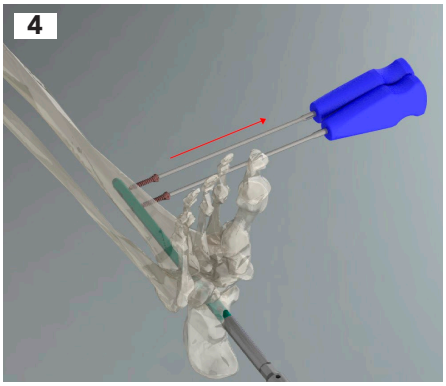
Nail Removal

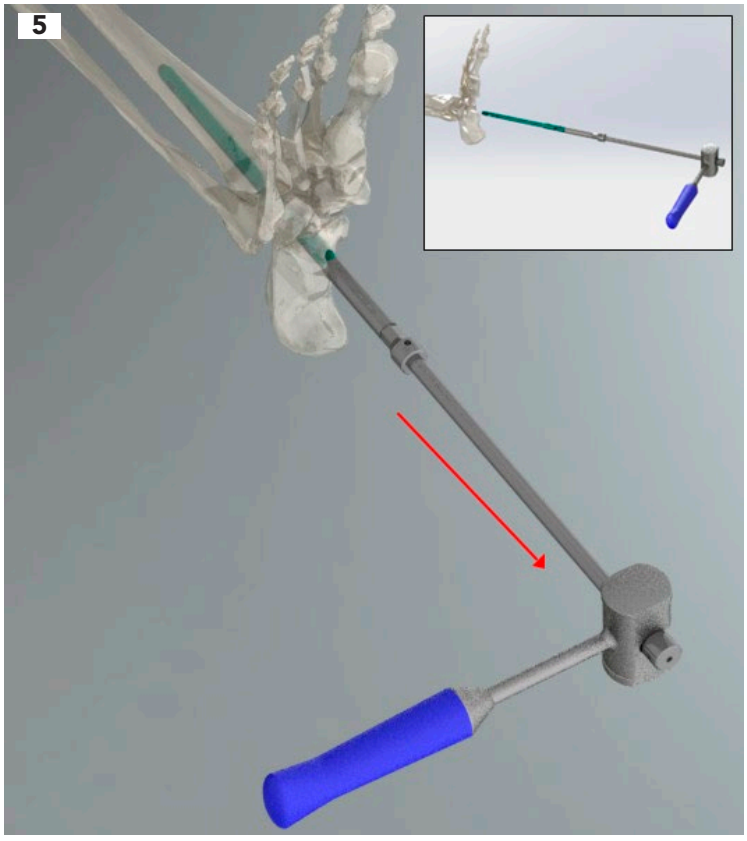
It is recommended that the nail not be removed unless there is infection or the patient is symptomatic. However, if removal is required, then the tissue of the sole of the foot is dissected to expose the distal part of the nail, cleaned of tissue or bone that may have grown into the internal thread of the distal part of the nail.

1. The plug and the calcaneal angular screws are removed first, as are the talus screws.
2. Loosen the compression plug to allow removal of the lateral calcaneal screw.
3. Insert the removal guide into the nail.
4. Remove the remaining screws.
5. Use the slide hammer to remove the nail in a controlled manner.



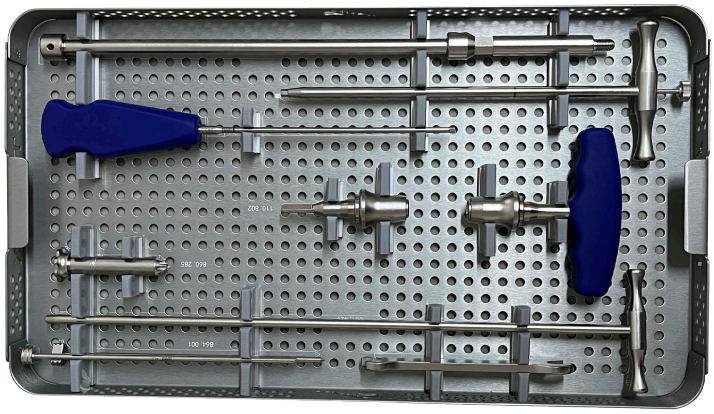


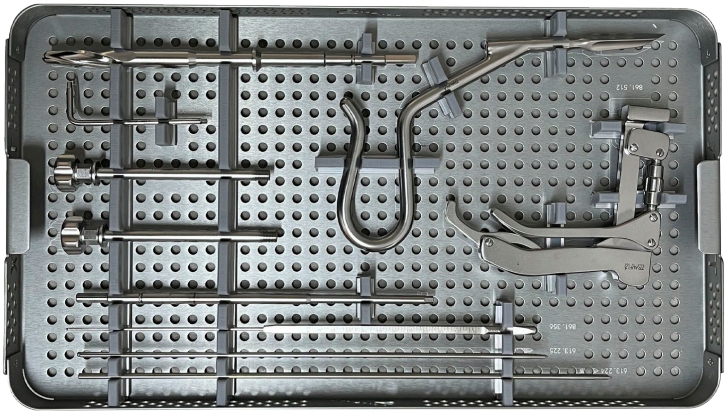


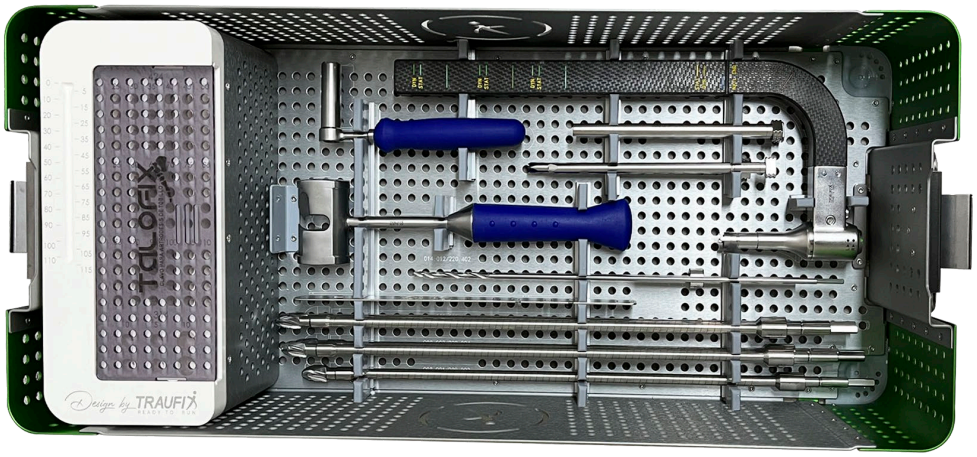


INSTRUMENTATIONS

QTY.	EQUIPMENT
2	Guide wire with threaded tip Ø 3.2 x 343
2	Guide wire with threaded tip Ø3.2 x 300
1	Depth gauge 0 – 110 mm
1	Hexagonal screwdriver tip SW 4.5 mm
2	Connection screw M8x1 / SW11
1	Allen wrench SW3.0 mm
1	Graduated proximal drill Ø12.5 / Ø3.2
1	Cannulated punch
1	Guide wire clamping handle
2	Guide wire with olive tip Ø 2.5/ Ø4.0/680
1	Spanish key SW11
2	Punch Ø4.0
1	Cannulated reduction rod with T-handle
1	Guide wire guide Ø3.2 / Ø12.5
1	Quick coupling T-handle
1	Adapter
1	Screwdriver with hexagonal tip SW3.5
1	Locking screwdriver with T-handle SW4.5/M3.0
1	Nail extraction guide M8x1 / Ø10 / Ø4.0
1	Carbon fiber handle
1	Sleeve protector with handle Ø12.5
2	Outer sleeve Ø10/Ø8.1 x 155
2	Inner sleeve Ø4.0
1	Sliding Hammer
2	Drill bit Ø4.0x300
1	Drill bit with stop Ø4.0/SW3.0
1	Template
1	Flexible shaft for rhyme tip Ø 9mm, Ø 10mm, Ø 11mm, Ø 12mm, Ø 13mm.







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