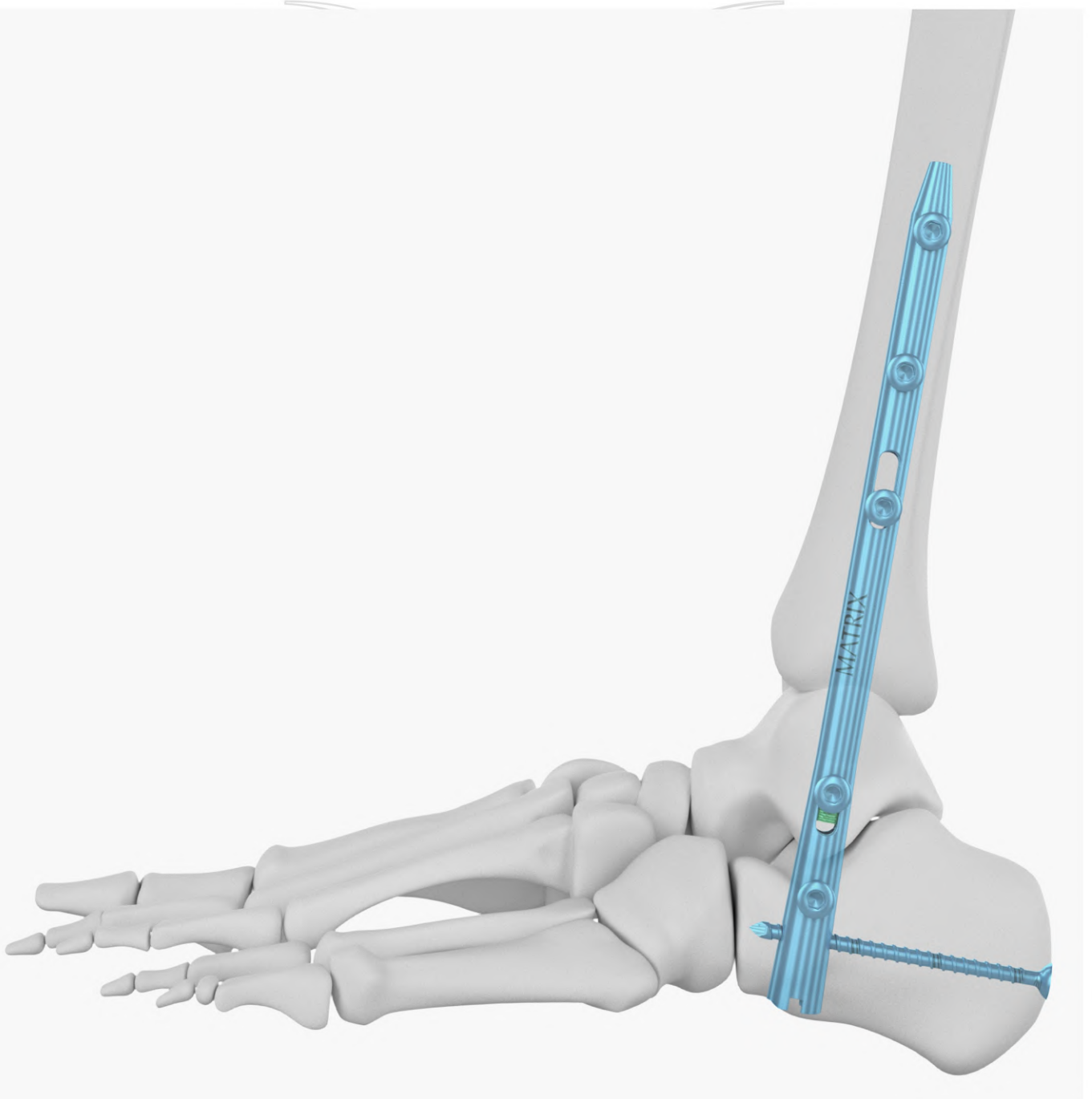


Surgical Technique

Viva Ankle Arthrodesis Nail System



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Introduction

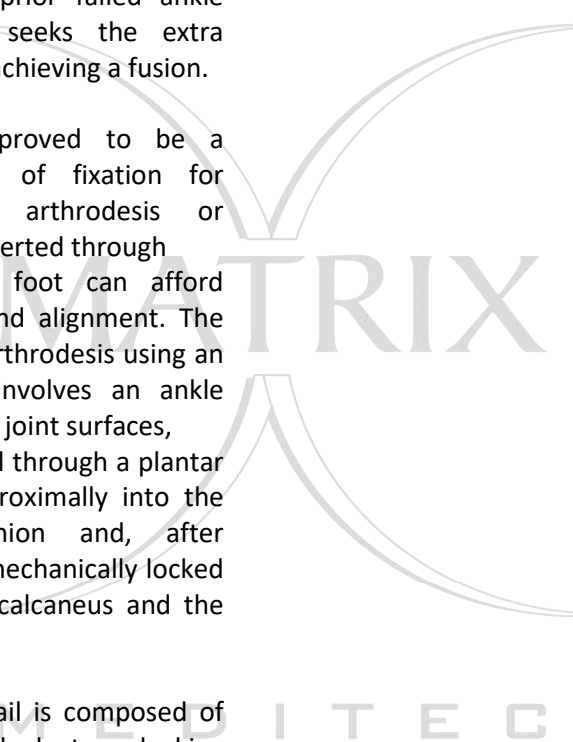
The goals of tibiotalocalcaneal arthrodesis are the relief of pain and deformity, and the development of a solid fusion. Numerous techniques exist for isolated tibiotalar arthrodesis, a procedure that leaves some motion at the subtalar joint. A number of clinical situations warrant inclusion of the subtalar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

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

The Viva Ankle Arthrodesis Nail is composed of titanium alloy. This unique dual stage locking mechanism is pre-assembled and embedded in each nail, and can provide internal tibiotalar compression, followed by independent locking of the calcaneal screws. In addition to a static screw site proximally, the nail offers dynamic compression slot, both of which accommodate cortical screws. Capable of treating varying patient anatomies, the Viva Ankle Arthrodesis Nail is universal and available in 9mm, 10mm, and 11mm diameters—all of which are available in lengths of 150 mm - 330mm.

The system features a strong, lightweight targeting Arm that permits visualization in multiple planes and can provide axial compression across both the ankle and sub-talar

fusion sites. Variable templating of oblique screws tangential to the nail can also be accomplished when there is a need for additional fixation and control of rotation. With easy to use instrumentation conveniently contained in a single tray, the Viva Ankle Arthrodesis Nail System addresses both patient and surgeon needs.



Indications and Contraindications

Indications

The Viva Ankle Arthrodesis Nail System is indicated for tibiotalocalcaneal arthrodesis (fusion).

Specific indications include:

1. Failed total ankle arthroplasty
2. Trauma
3. Revision ankle arthrodesis
4. Neuroarthroscopy
5. Rheumatoid arthritis
6. Osteoarthritis
7. Pseudoarthrosis
8. Post-traumatic arthrosis
9. Infected arthrosis
10. Charcot foot
11. Degenerative arthritis
12. Pantalar arthrodesis
13. Severe deformity or instability as a result of talipes quinovarus, cerebral vascular accident, paralysis or other neuromuscular disease

Contraindication

1. Infection
2. Conditions including blood supply limitations and insufficient quality of bone.
3. Foreign body sensitivity, testing is to be completed prior to implantation of the device.
4. Patients who are unwilling or incapable of following postoperative care instructions.



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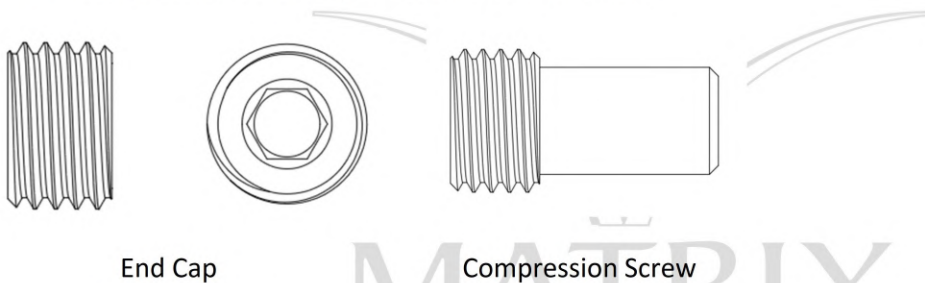
Implant Specifications

Nails

- Nail Lengths: 150mm to 330mm (30mm increments)
- All nails are offered in 9mm, 10mm and 11mm diameters
 - Distal Diameter for all nails are 12mm

End Caps

- 3.5mm Inserter Connector retains head of End Cap to facilitate easier insertion.
- Compression Screw is pre-assembled in the nail.



End Cap

Compression Screw

Screws

- 4.9mm Locking Bolt
 - 20mm – 60mm (In 2.0mm increments)
 - 60mm – 80mm (In 4.0mm increments)
- 3.9mm Locking Bolt
 - 22mm – 50mm (In 2.0mm increments)



3.9mm Locking Bolt



4.9mm Locking Bolt

Surgical Technique

Step 1: Patient positioning is based on surgeon preference and needs of each patient.

Lateral Patient Positioning:

The patient is positioned in the lateral position on operating table with the affected extremity up (Away from the operating table). The non-operated extremity is flexed at the hip and knee and placed very close to the anterior border of the operating table. If the surgeon wishes to address proximal locking screws from the lateral side, this is the ideal position.

Advantages of Lateral Approach:

- Screw insertion is easily accomplished as the leg does not have to be elevated off the operating table for Targeting Arm and drilling access
- If the surgeon wishes to implant all screws from lateral to medial, this position is ideal.

General Disadvantages of the Lateral Approach

- Not ideal for larger, heavier patients who may have difficulty breathing on their side.
- Difficult to access the medial gutter of the ankle.
- Difficult to compare rotation with the opposite foot

Supine Patient Positioning:

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

General Advantages of Supine Approach:

- Easy to position larger patients—may be preferable for patients who may experience breathing issues in the lateral decubitus position.
- Open access to medial and lateral sides of the ankle.
- Easy to check ankle rotation in relation to the opposite ankle.

General Disadvantages of the Supine Approach

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

Step 2: Surgical Exposure

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

Step 3: Fibular Resection

The distal 5 cm of the fibula is resected in a bevelled fashion at a level 2 cm proximal to the tibiotalar joint line. The distal portion of the fibula may be morsellized for use as an autogenous bone graft. Some prefer to skeletonize the distal fibula and lift off the lateral cortex to harvest the cancellous bone, while others prefer to remove the distal fibula. This local bone graft is utilized after nail placement. A standard technique for harvesting the fibula is to utilize an acetabular reamer which yields excellent graft material.

Note: Special care should be paid to the occasionally present lateral peroneal artery in the region of the syndesmosis, which may bleed excessively. The incision is extended distally to the sinus tarsi to allow subtalar joint visualization.

Step 4: Fusion Site Preparation

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

Flat Cut Resection

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

Step 5: Nail Entry Site and Incision

Following the preparation of the bony surfaces, a longitudinal plantar incision is made anterior to the subcalcaneal fat pad slightly lateral to the midline, especially in the patient with significant preoperative valgus deformity.

Blunt dissection is carried down to the plantar fascia, which is split longitudinally. The intrinsic muscles are swept medially or laterally and the neurovascular bundle on the sole of the foot is identified.

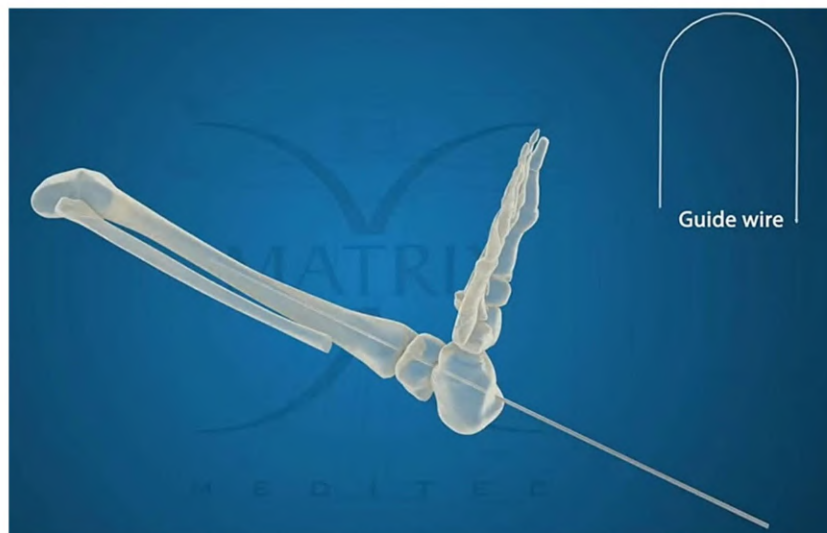


Step 6: Entry Guide Wire Insertion

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

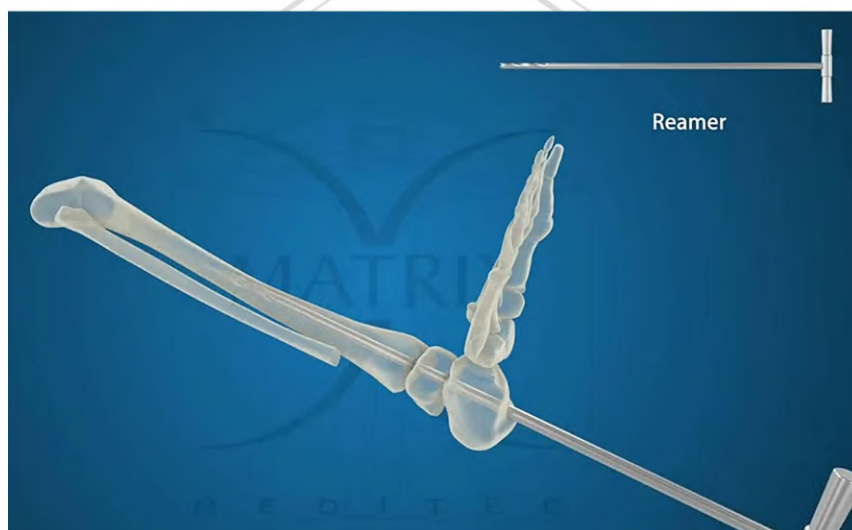
An awl is used to choose the guide wire insertion point.

An entry Guide Wire is inserted through the calcaneus, talus, and tibia. Confirm the position of the wire on the C-arm.



Step 7: Initial Reaming

Using the cannulated reamer, ream the subtalar and tibiotalar articular surfaces over the entry guide wire. It is helpful to have an assistant hold the foot in the appropriate alignment during the transmedullary reaming.



Step 8: Canal Reaming

Holding the foot in proper alignment, progressive reaming is performed over guide wire. This is achieved using the range of reamers. It is recommended to start with the 8.0mm reamer, and then follow sequentially in increments. Over-reaming by a full 1 mm may help reduce the need for excessive insertion force.

Step 9: Nail Length Determination

Length of the guide should be considered to choose the length. The exposed end of the Guide Wire may also be used to determine the proper nail length.

NOTE: Nails are available in lengths of 150mm, 180mm, 210mm, 240mm, 270 mm, 300 mm and 330mm and diameters of 9mm, 10 mm and 11mm.

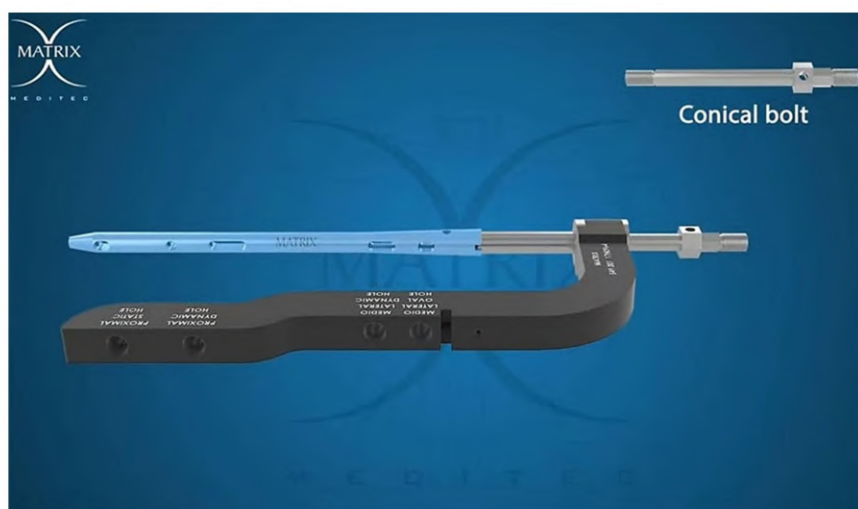
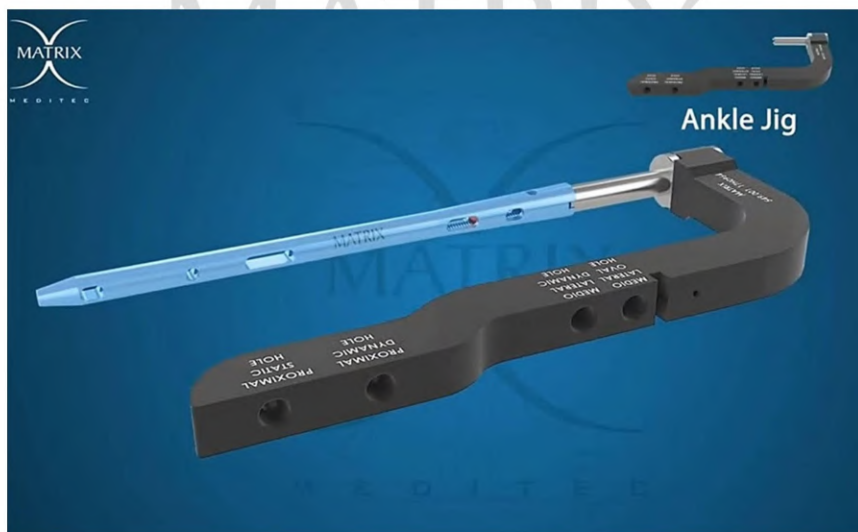
Step 10: Outrigger Assembly

Nail of selected diameter and length is assembled onto the jig using conical bolt. The conical bolt is passed through the jig Nose and threaded into the distal end of the nail. The two tangs on the bushing must engage the two slots on the distal end of the nail.

The conical bolt is then tightened using the pin wrench. The assembly is then placed into the designated site of entry.

Alignment Check

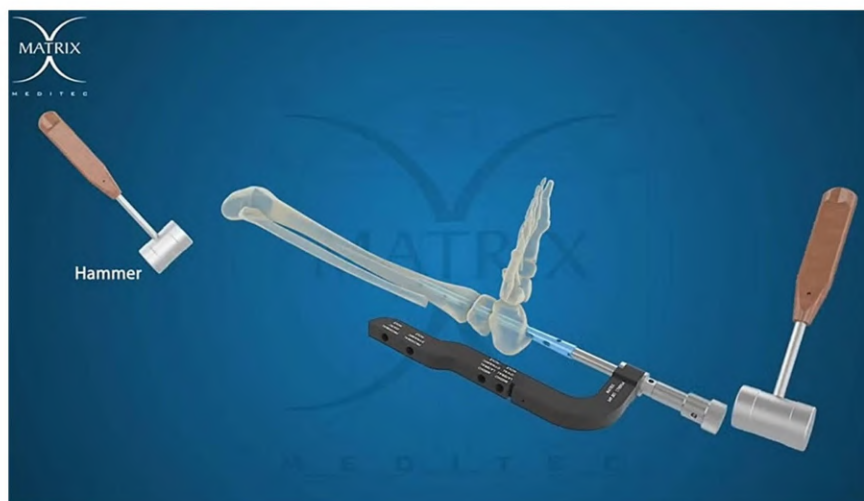
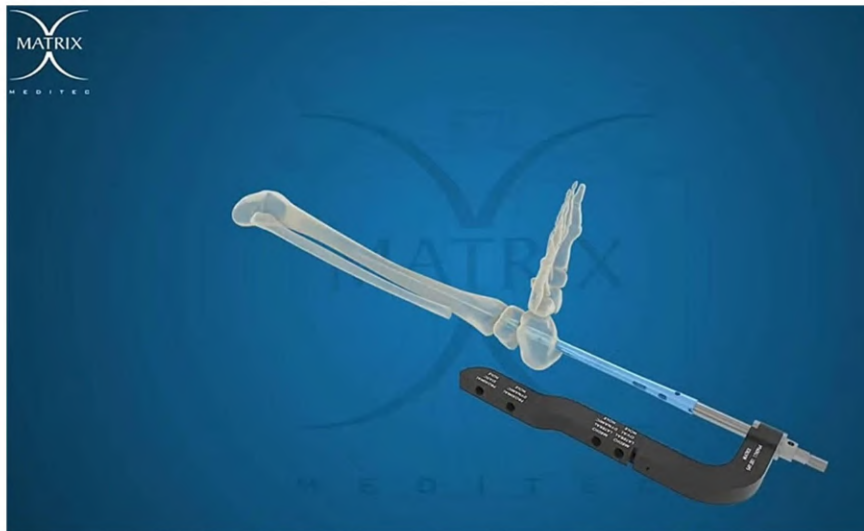
Before definitively tightening the nail to the assembly, it is good practice to perform an alignment check to ensure accurate screw targeting. Position the Targeting Arm so that the screw site can be accessed. Load the drill sleeve into the protection sleeve and then insert the stack into the appropriate Targeting Arm location. The drill bit is then be passed through the drill sleeve and nail holes (The drill bit should easily pass through both the static and dynamic holes of the nail). Once good alignment is confirmed, the conical bolt can then be tightened with confidence.



Step 11: Nail Insertion

After performing an alignment check, the Jig is positioned to address the tibial screws from medial to lateral. A lateral to medial approach may also be elected based on surgeon preference. If a lateral to medial approach is preferred, a slight internal rotation of the nail may help the surgeon avoid fibular interference when inserting the proximal locking screws into the tibia.

Driving head is attached on the threads of the distal part of conical bolt. Hammering is done by hammer to insert the nail to the desired length.



Step 12: Proximal Screw Placement

Remove the guide wire before inserting locking screws into the nail.

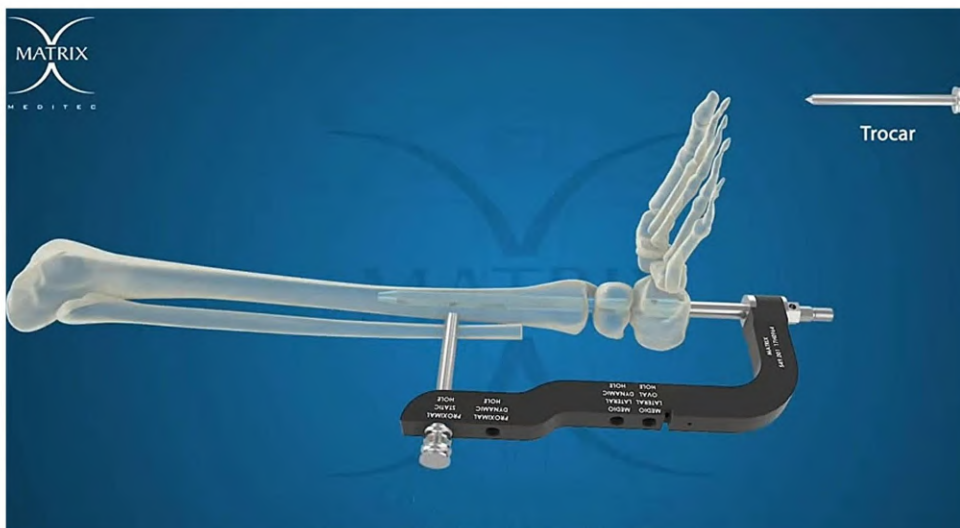
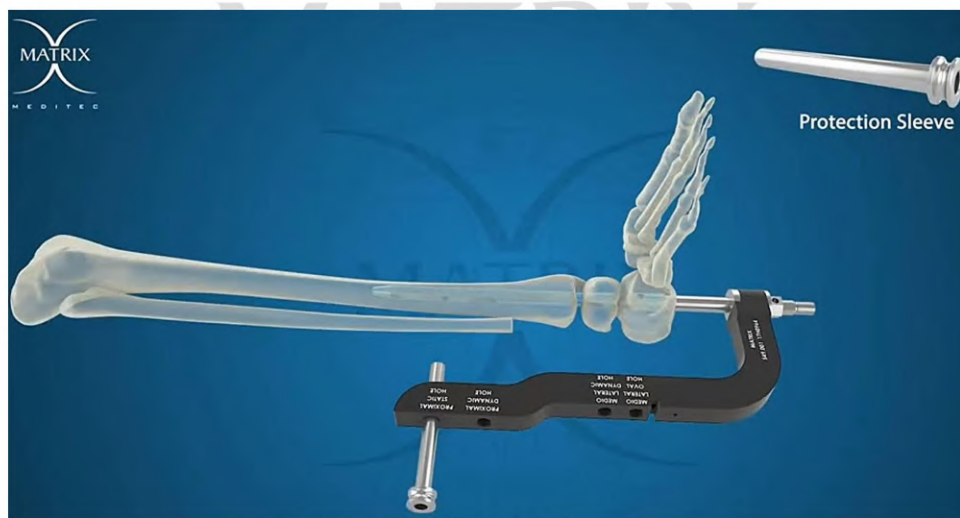
Identify the corresponding slot on jig and place the protection sleeve/drill sleeve stacks in the designated slots.

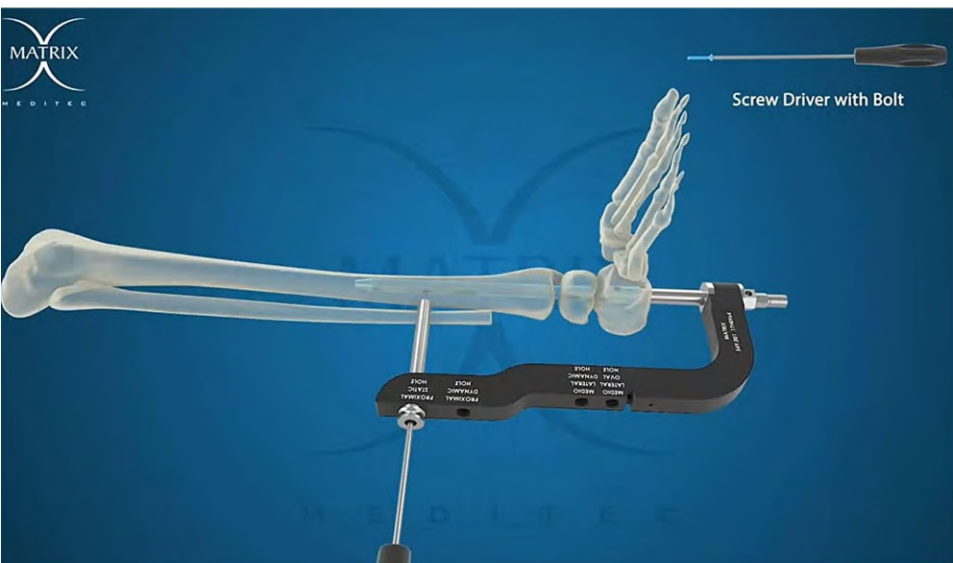
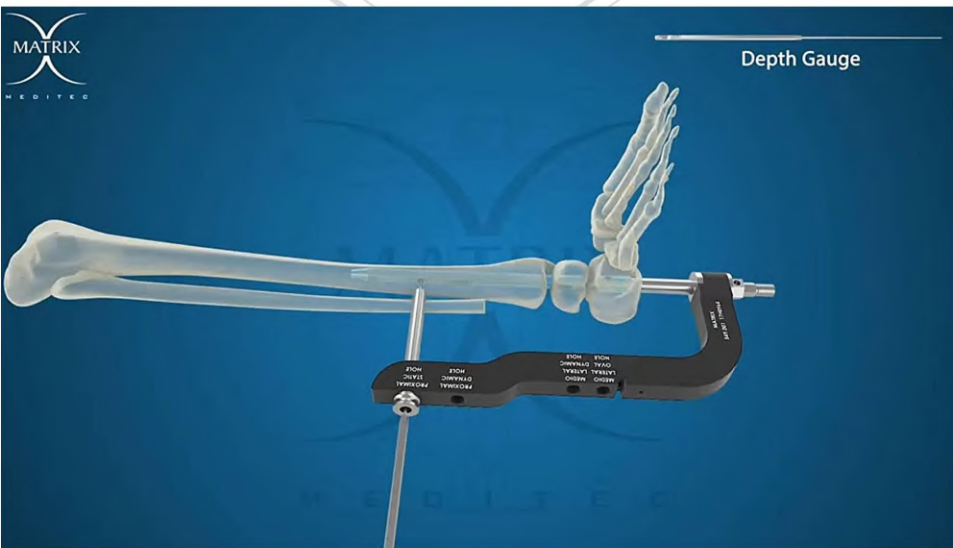
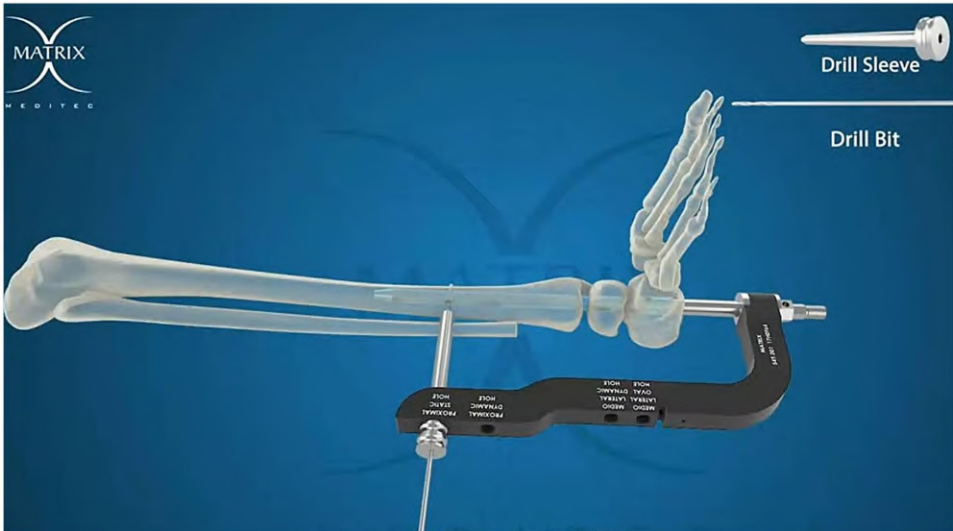
NOTE: It is recommended that the Dynamic Slot in the proximal end of the nail be addressed first as it is closer to the jig's nail locking assembly. Targeting accuracy diminishes as you move farther away from the locking assembly.

Using the C-arm, a small stab incision is made on the medial side of the leg. The drill sleeve is passed down to the medial cortex of the tibia. A drill bit is utilized to penetrate both the medial and lateral cortices. Having successfully drilled the first hole, leave the drill bit in place while drilling the second hole to minimize blood loss. With the Drill Sleeve firmly against the medial cortex, the appropriate locking screw length can be read directly from the calibrations on the Drill Bit.

When utilizing the depth gauge the drill sleeves must be removed from the protection sleeve. After removing the Drill Sleeve, insert the appropriate screw using the screw driver with 3.5mm hex.

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

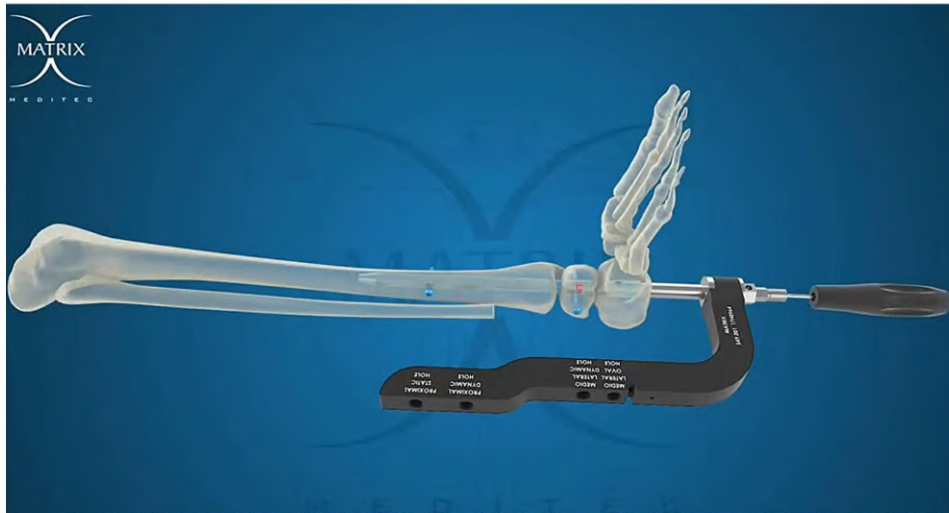




Step 13: Talar screw Insertion and Internal Compression

The talar screw is inserted lateral to medial. To achieve internal compression, the talar screw must be inserted through the appropriate Dynamic Slot of the jig. The lateral articular surface of the talus is directly visualized and the drill sleeve is passed down to the lateral cortex. Using the drill bit, prepare and implant a screw through the talus in the same manner described previously.

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



Using the screw driver with 3.5mm Hex advance the internal compression mechanism with clockwise revolutions to achieve up to 7.0 mm of tibiotalar compression.

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

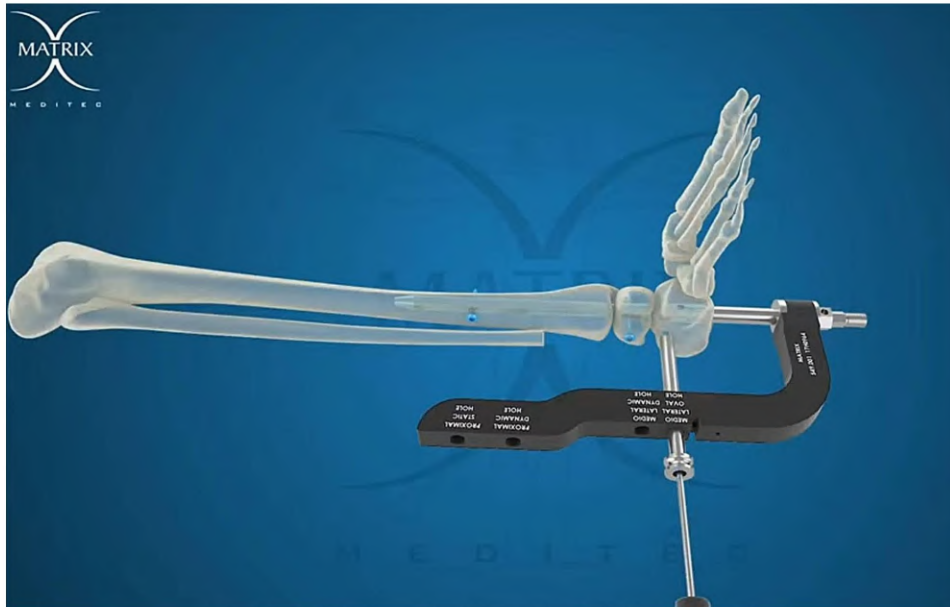
The compression nut is pre introduced in the nail. The Compression Nut will drive the compression site proximally to compress the tibiotalar and subtalar joints. Perform each turn slowly and be careful not to over-tighten the Compression Nut. Excessive compression forces may compromise the plantar cortex of the calcaneus and may also leave the distal portion of the nail prominent.

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

Step 14: Distal Screw Placement

After compression, a protection sleeve/drill sleeve stack is placed in the appropriate jig slot to address the distal locking screw.

With the jig positioned on the lateral side of the ankle, pass the drill bit bi-cortically. Measure and insert the appropriately sized screw.



Step 15: Secondary Compression

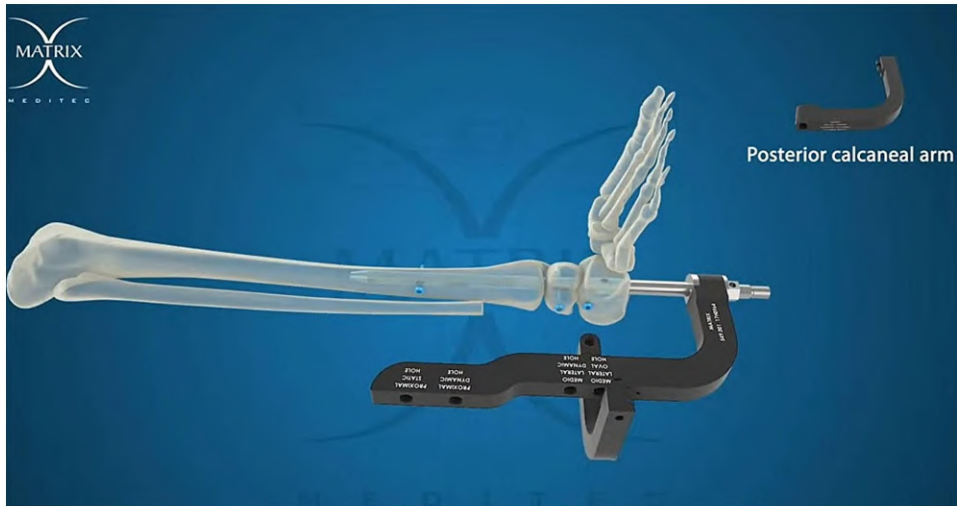
The compression nut is introduced after removing the conical bolt through jig and tightened using screw driver with 3.5mm hex.

The Compression Nut will drive the compression site proximally to compress the calcaneal/talar joints. Conical bolt is reattached after the satisfactory compression is done.



Step 16: PA Screw Placement

Attach the posterior calcaneal arm to allow for a posterior to anterior approach. Insert a conical bolt and drill sleeve into the arm. The appropriate position is marked. Pass the conical sleeve/drill sleeve stack down the cortex through the incision.



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

Once all screws are locked, the nail is effectively a ridged, fixed angle construct.



Step 18: Fibular Bone Graft and Wound Closure

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

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



Ordering Information

Implants

Nails:

Code	Description
926.09.150	MP Viva TTC Nail 9.0mm 150mm TIT
926.09.180	MP Viva TTC Nail 9.0mm 180mm TIT
926.09.210	MP Viva TTC Nail 9.0mm 210mm TIT
926.09.240	MP Viva TTC Nail 9.0mm 240mm TIT
926.09.270	MP Viva TTC Nail 9.0mm 270mm TIT
926.09.300	MP Viva TTC Nail 9.0mm 300mm TIT
926.09.330	MP Viva TTC Nail 9.0mm 330mm TIT
926.10.150	MP Viva TTC Nail 10.0mm 150mm TIT
926.10.180	MP Viva TTC Nail 10.0mm 180mm TIT
926.10.210	MP Viva TTC Nail 10.0mm 210mm TIT
926.10.240	MP Viva TTC Nail 10.0mm 240mm TIT
926.10.270	MP Viva TTC Nail 10.0mm 270mm TIT
926.10.300	MP Viva TTC Nail 10.0mm 300mm TIT
926.10.330	MP Viva TTC Nail 10.0mm 330mm TIT
926.11.150	MP Viva TTC Nail 11.0mm 150mm TIT
926.11.180	MP Viva TTC Nail 11.0mm 180mm TIT
926.11.210	MP Viva TTC Nail 11.0mm 210mm TIT
926.11.240	MP Viva TTC Nail 11.0mm 240mm TIT
926.11.270	MP Viva TTC Nail 11.0mm 270mm TIT
926.11.300	MP Viva TTC Nail 11.0mm 300mm TIT
926.11.330	MP Viva TTC Nail 11.0mm 330mm TIT

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Screws:

Locking Bolt 4.9mm

Code	Description
004.022	Locking Bolt 4.9mm, Trocar Tip 22mm
004.024	Locking Bolt 4.9mm, Trocar Tip 24mm
004.026	Locking Bolt 4.9mm, Trocar Tip 26mm
004.028	Locking Bolt 4.9mm, Trocar Tip 28mm
004.030	Locking Bolt 4.9mm, Trocar Tip 30mm
004.032	Locking Bolt 4.9mm, Trocar Tip 32mm
004.034	Locking Bolt 4.9mm, Trocar Tip 34mm
004.036	Locking Bolt 4.9mm, Trocar Tip 36mm
004.038	Locking Bolt 4.9mm, Trocar Tip 38mm
004.040	Locking Bolt 4.9mm, Trocar Tip 40mm
004.042	Locking Bolt 4.9mm, Trocar Tip 42mm
004.044	Locking Bolt 4.9mm, Trocar Tip 44mm
004.046	Locking Bolt 4.9mm, Trocar Tip 46mm
004.048	Locking Bolt 4.9mm, Trocar Tip 48mm
004.050	Locking Bolt 4.9mm, Trocar Tip 50mm
004.052	Locking Bolt 4.9mm, Trocar Tip 52mm
004.054	Locking Bolt 4.9mm, Trocar Tip 54mm
004.056	Locking Bolt 4.9mm, Trocar Tip 56mm
004.058	Locking Bolt 4.9mm, Trocar Tip 58mm
004.060	Locking Bolt 4.9mm, Trocar Tip 60mm
004.064	Locking Bolt 4.9mm, Trocar Tip 64mm
004.068	Locking Bolt 4.9mm, Trocar Tip 68mm
004.072	Locking Bolt 4.9mm, Trocar Tip 72mm
004.076	Locking Bolt 4.9mm, Trocar Tip 76mm
004.080	Locking Bolt 4.9mm, Trocar Tip 80mm

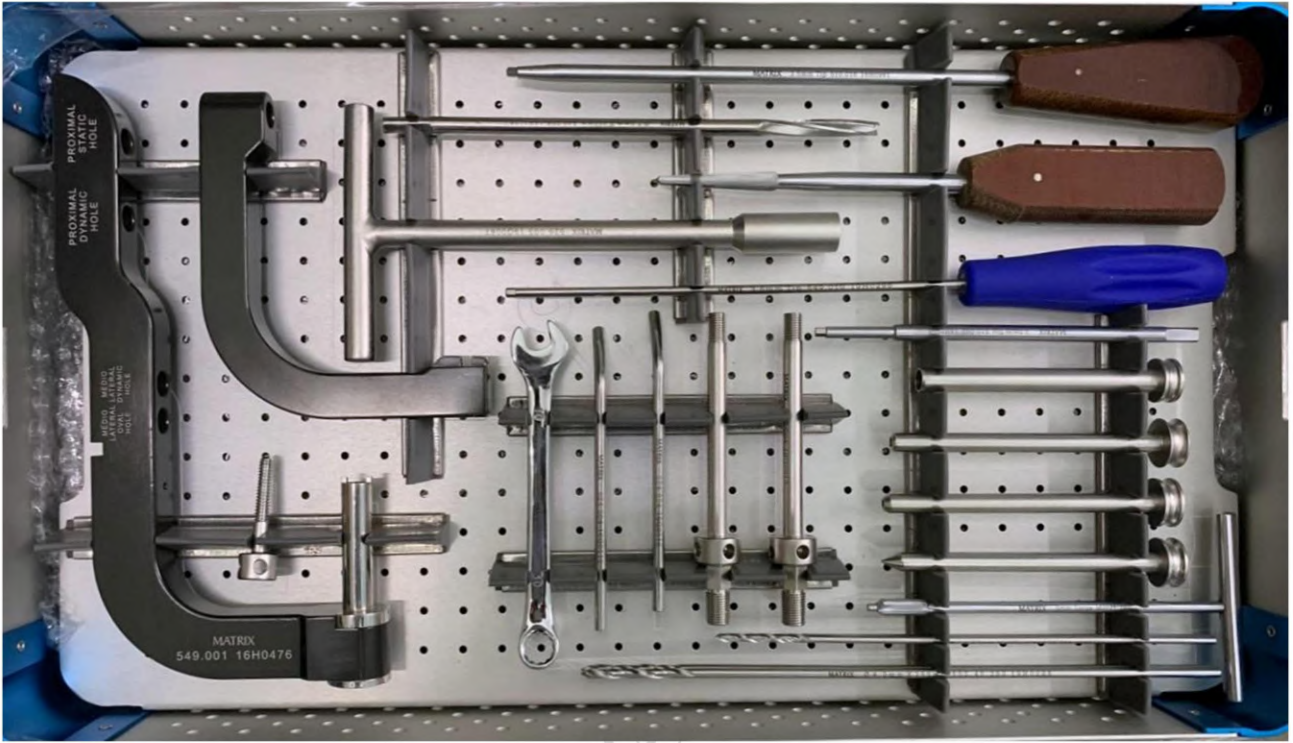
Locking Bolt 3.9mm

Code	Description
022.022	Locking Bolt 3.9mm, Trocar Tip 22mm
022.024	Locking Bolt 3.9mm, Trocar Tip 24mm
022.026	Locking Bolt 3.9mm, Trocar Tip 26mm
022.028	Locking Bolt 3.9mm, Trocar Tip 28mm
022.030	Locking Bolt 3.9mm, Trocar Tip 30mm
022.032	Locking Bolt 3.9mm, Trocar Tip 32mm
022.034	Locking Bolt 3.9mm, Trocar Tip 34mm
022.036	Locking Bolt 3.9mm, Trocar Tip 36mm
022.038	Locking Bolt 3.9mm, Trocar Tip 38mm
022.040	Locking Bolt 3.9mm, Trocar Tip 40mm
022.042	Locking Bolt 3.9mm, Trocar Tip 42mm
022.044	Locking Bolt 3.9mm, Trocar Tip 44mm
022.046	Locking Bolt 3.9mm, Trocar Tip 46mm
022.048	Locking Bolt 3.9mm, Trocar Tip 48mm
022.050	Locking Bolt 3.9mm, Trocar Tip 50mm

Instruments:

Sr No.	Code	Name	QTY
1	549.001	Insertion Jig For TTC Nail	1
2	549.002	Posterior Calcaneal Locking Arm	1
3	549.003	Connecting Bolt For Posterior Calcaneal Locking Arm	1
4	549.004	Conical Bolt For TTC Nail	2
5	549.005	Protection Sleeve 10.0mm	1
6	549.006	Cannulated Drill 7.0mm 200mm For 2.8mm Guide Pin	1
7	549.007	Impactor/Extractor 250mm For TTC Nail	1
8	549.008	Spanner 10.0mm	1
9	530.007	Slotted Hammer 270mm	1
10	526.003	T-Wrench For Bolt 10mm	1
11	526.004	Driving Head	1
12	540.003	Awl	1
13	524.004	Pin Wrench	1
14	524.011	Drill Sleeve 4.0mm	1
15	524.013	Drill Sleeve 3.2mm	1
16	524.014	Trocar	1
17	524.015	Depth Gauge For locking Bolt 100mm	1
18	510.016	Screw Driver 3.5 mm Tip Long With Fiber Handle	1
19	510.002	Screw Driver with T-Handle 3.5mm	1
20	M2090	Steinmann Pin Introducer With SS Chuck & Key	1
21	M2021	Countersink 8.0mm	1
22	502.40.250	Drill Bit 4.2mm 250mm	2
23	502.32.200	Drill Bit 3.2mm 200mm	2
24	MS1.792	T-Reamer Cannulated 8.0mm	1
25	MS1.793	T-Reamer Cannulated 9.0mm	1
26	MS1.794	T-Reamer Cannulated 10.0mm	1
27	MS1.795	T-Reamer Cannulated 11.0mm	1
28	MS1.796	T-Reamer Cannulated 12.0mm	1
29	512.28.510	Guide Wire 2.8mm 510mm	2

M E D I T E C



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