



Patent and Patent Pending CAUTION:

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

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INDICATION FOR USE

The TRIO Calcaneal Osteotomy Device is intended for fi xation of osteotomies of the calcaneus.

EXPOSURE

Perform a linear oblique incision along the lateral aspect of the calcaneus, approximately 4cm long, posterior to the peroneal tendons and sural nerve. Once the appropriate level of dissection has been performed, expose the lateral calcaneal wall using retractors as necessary for the osteotomy.



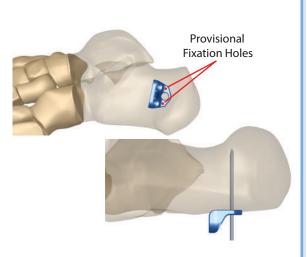
PLATE SELECTION

The TRIO plates are available in 6+ and 10+ sizes. The design of the TRIO plate allows for fl exibility in the amount of displacement one can achieve. The 6+ plate can be utilized for displacements of 6mm or more. The 10mm plate allows for displacements of 10mm or more. Select the plate that best meets the needs for the amount of correction desired.



Plate Placement

Mark the approximate location of the osteotomy on the lateral calcaneal wall. Place the implant on the lateral calcaneal wall at the approximate osteotomy position. Provisionally pin the plate with a 1.6mm Guidewire through one of TRIO's provisional fi xation holes. TRIO's cutting surface should correspond with the osteotomy location. Rotate and align the implant's cutting surface with the intended osteotomy plane, and verify this orientation via fl uoroscopy. Insert the second 1.6mm Guidewire through the second provisional fi xation hole to maintain the device's orientation.

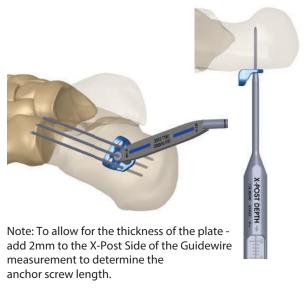


State 2

Anchor Screw Placement

Note: IO FiX™ Screws have self-drilling and self-tapping features. Pre-drilling for screws with a 3.4mm drill is left up to the surgeon's discretion.

Insert the blue Tapered Drill Guide (8.0mm) into TRIO's posterior screw hole. Advance a 1.6mm Guidewire through the wire side of the guide stopping just before reaching the far cortex. This Guidewire should be placed perpendicular to the lateral wall of the calcaneus. Verify the position and orientation of the Guidewire via fl uoroscopy, and measure the Guidewire depth with the Depth Gauge (X-Post side) by placing the Depth Gauge over the Guidewire and down to bone.



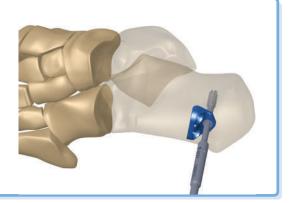




State 2

Anchor Screw Placement (Continued)

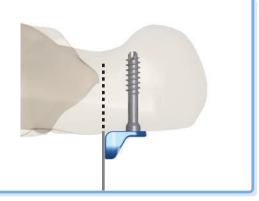
Select the appropriate Ø5.0mm Tapered Lag Screw length and insert the screw over the Guidewire with the 3.0mm Hex Driver. Advance the Tapered Lag Screw through the plate until it is fully seated.



State 3

Create Osteotomy

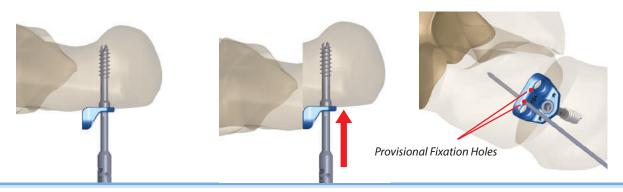
Utilizing TRIO's cutting surface as vertical saw guide, create the osteotomy perpendicular to lateral calcaneal wall with a sagittal saw (+30mm long blade). A straight osteotome may be utilized to complete the osteotomy if the cut is stopped just short of the far cortex.



State 4

Medial Displacement

By utilizing the 3.0 Hex Driver as a pushing device, displace the posterior calcaneal fragment medially. For a precise 6mm or 10mm shift, advance the plate until the top surface aligns with the edge of the lateral calcaneal wall. Provisionally pin through the plate holes. If additional fi xation is required, provisionally pin a 1.6mm Guidewire from the posterior to anterior calcaneous outside of the plate taking care to avoid the Anchor Screw. The design of TRIO allows for fl exibility in the amount of displacement achieved. The 6+ plate can be utilized for displacements of 6mm or more. The 10+ plate allows for 10mm or more.



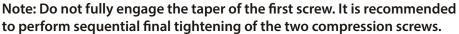




Compression Screw Insertion (Tapered or Polyaxial Screw)

Advance a 1.6mm Guidewire through the Guidewire side of the blue Tapered Drill Guide (8.0mm) into the anterior calcaneal fragment. Verify the Guidewire's trajectory via fluoroscopy. To determine the appropriate screw length, measure the Guidewire depth by placing the Depth Gauge (Lag Screw side) over the guidewire and down to bone. This length represents the actual length of the screw.

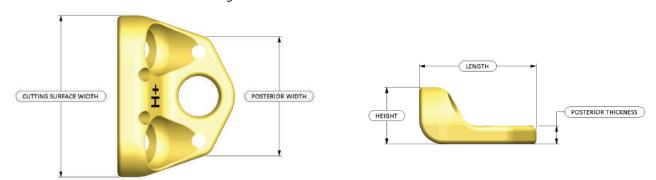
Insert the appropriate Ø5.0mm Tapered Lag Screw over the Guidewire with the 3.0mm Hex Driver.



Remove the provisional fixation and insert the second Lag Screw in the same manner as the initial compression screw. Final tightening of both Lag Screws should be executed with two-finger pressure, taking care not to over torque the Driver.

IMPLANT REMOVAL

Clear any tissue ingrowth from the screw heads. Insert the removal tool into the removal driver. Thread the removal driver/tool into the screw to allow for rigid attachment. Rotate counterclockwise to remove.



TRIO Plate Specifications								
Part #		TRIO Plate	Height	Length	Cutting Surface Width	Posterior Width	Posterior Thickness	Angle, Compression Screw
118-	20006	6+ (Gold)	6mm	14.5mm	20mm	14.8mm	2.25mm	60°
118-	20010	10+ (Blue)	10mm	14.511111				

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