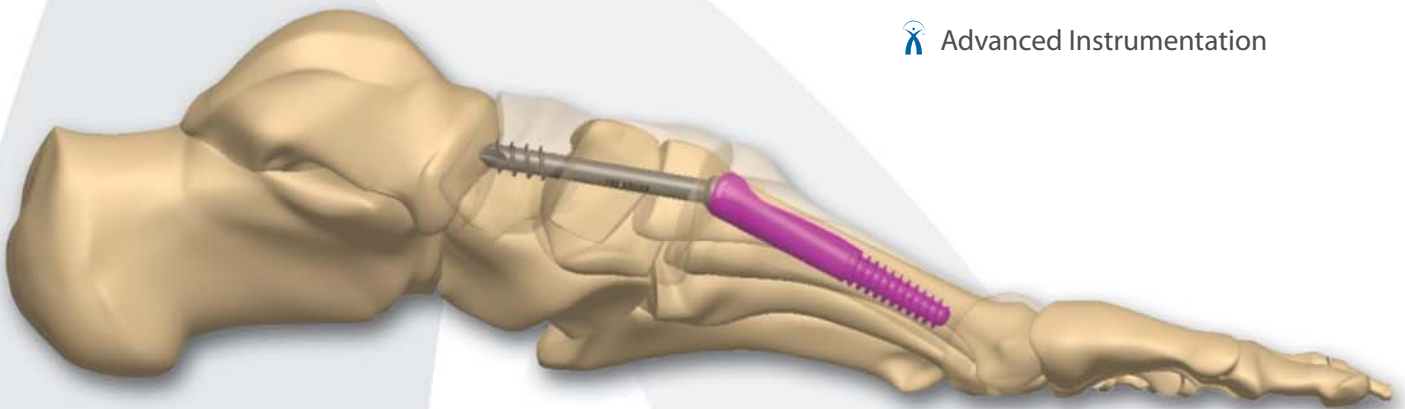


TARS[™]
INTRAMEDULLARY
MIDFOOT FUSION DEVICE

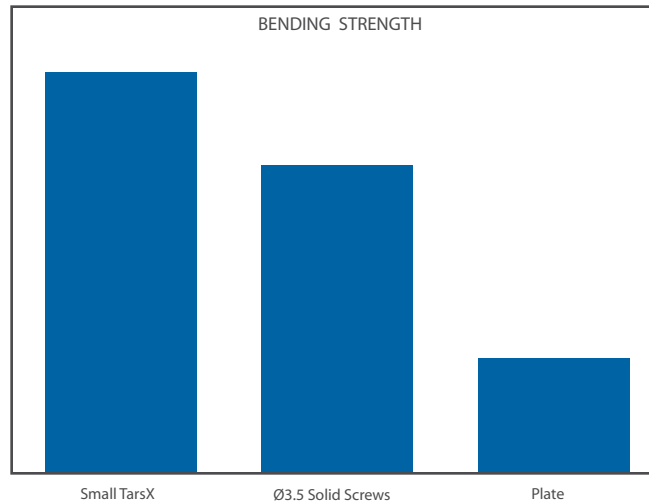
Surgical Technique

-  Rigid Midfoot Fusion
-  Total Intramedullary Fixation
-  Fuse Variable Levels
-  Restoration of Natural Arch
-  Advanced Instrumentation

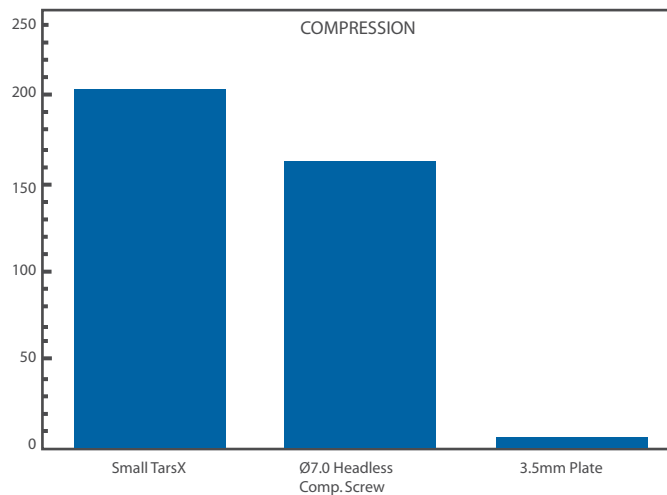


As described by Christopher DiGiovanni, MD

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



3.5X stronger than dorsal plate constructs



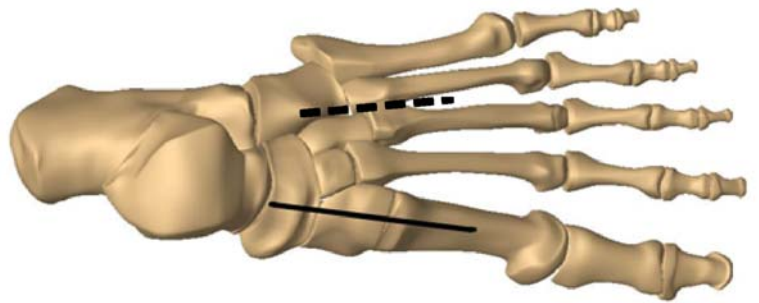
48x more delivered compression vs. plate construct

INDICATIONS FOR USE

The TarsX Intramedullary Midfoot Fusion Device is intended for fixation arthrodesis of the metatarsal-cuneiform, navicular-cuneiform, metatarsal-cuboid, talonavicular, and calcaneocuboid.

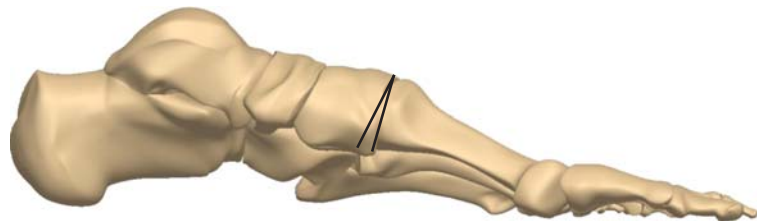
STEP 1 - Medial Column Incision

A standard longitudinal incision, length determined by exposure requirements, is first performed over the dorsal aspect of the medial midfoot. In the event that fusion is necessary across medial column articulations more proximal to the 1st and/or 2nd TMT joints, a separate standard medial utility incision can also be performed more proximally along the midaxillary line for further access. Alternatively, if multiple TMTs are being fused, an additional dorsal longitudinal incision can be made between the 3rd and 4th metatarsals with proximal extension as necessary. In all cases, careful capsular exposure is then performed through each window, with attention paid to crossing tendons and the adjacent neurovascular bundle.



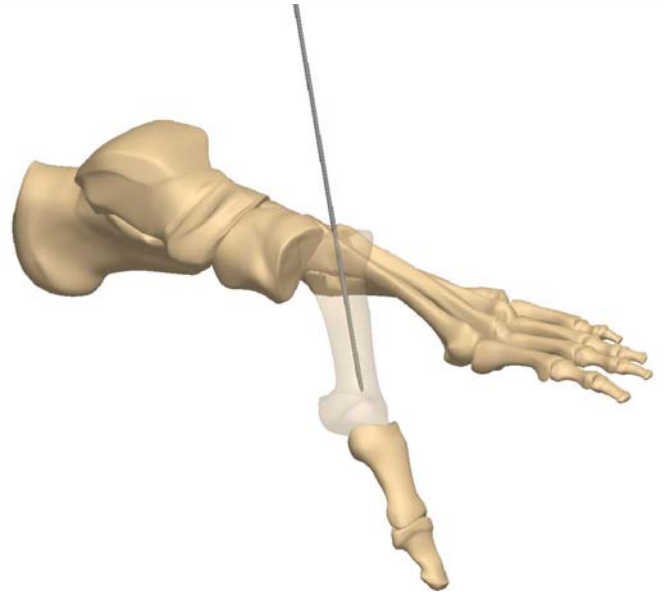
STEP 2 – Metatarsal Osteotomy

Once adequate subperiosteal dissection has been performed to enable satisfactory visualization of the joint to be fused (in this example, the 1st TMT joint), the articulation can be subsequently denuded of cartilage and anatomically aligned. In preparation for fixation and fusion of the 1st TMT joint, it is recommended that a sagittal saw be utilized to make cuts on both sides of the joint. The articular surface of the base of the 1st metatarsal should be the first cut. This should be performed in an orthogonal fashion at the subchondral level to expose a healthy, bleeding subchondral surface amenable to fusion. This will also improve exposure of the more proximal side and ease access to and visualization of the medial cuneiform cut. A neutral to 5°, proximally angled osteotomy should be performed on the medial cuneiform side, such that subsequent reduction permits neutral or slight plantarflexion of the 1st ray.



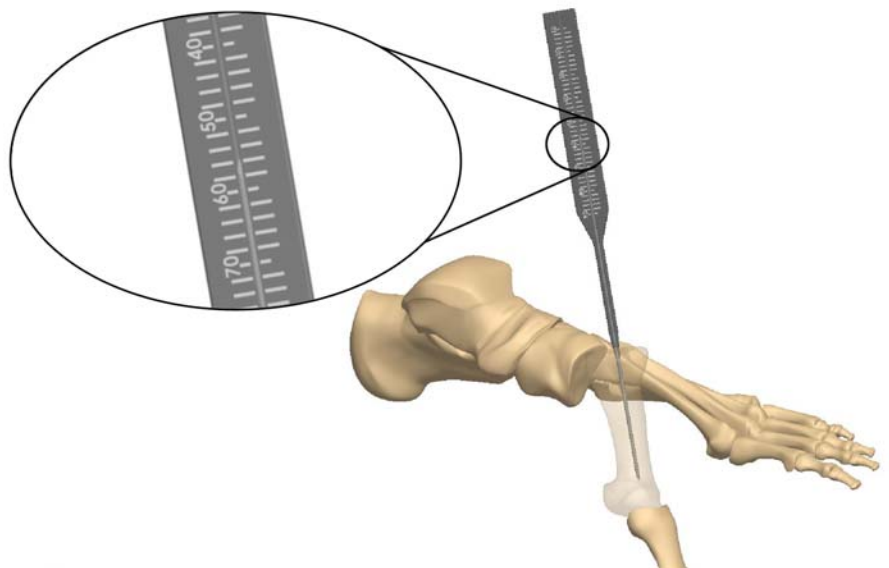
STEP 3 - Guidewire Insertion

Once satisfied with first ray position based on manual reduction and perhaps image intensification, plantarflex the 1st metatarsal to permit proximal to distal intramedullary placement of a 1.6mm guidewire down the center of the 1st metatarsal canal. Confirm placement with fluoroscopy on at least 2 views (AP and lateral), and avoid penetration of the metatarsal head with the guidewire. Stopping at the metadiaphyseal head/neck junction should provide sufficient purchase and placement.



STEP 4 - Depth Measurement

Place the depth guide over the guidewire and measure the length. The measurement guide should be advanced until just flush with the cut surface of the metatarsal before a reading is taken, to ensure its accuracy.

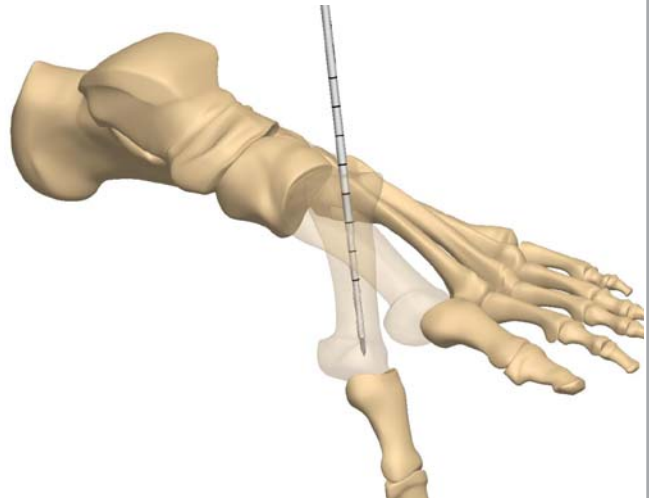


STEP 5 – Pilot Hole

Select a pilot drill diameter (\emptyset) based on perceived metatarsal implant size, as determined by pre-operative templating and confirmed by intra-operative inspection. Place this cannulated drill over the guidewire, and advance drill until it progresses beyond the diaphyseal isthmus (bottleneck) of the metatarsal, much like the reaming distance of a femoral or tibial nailing. Once drilling has been completed, remove both the drill and the guidewire.

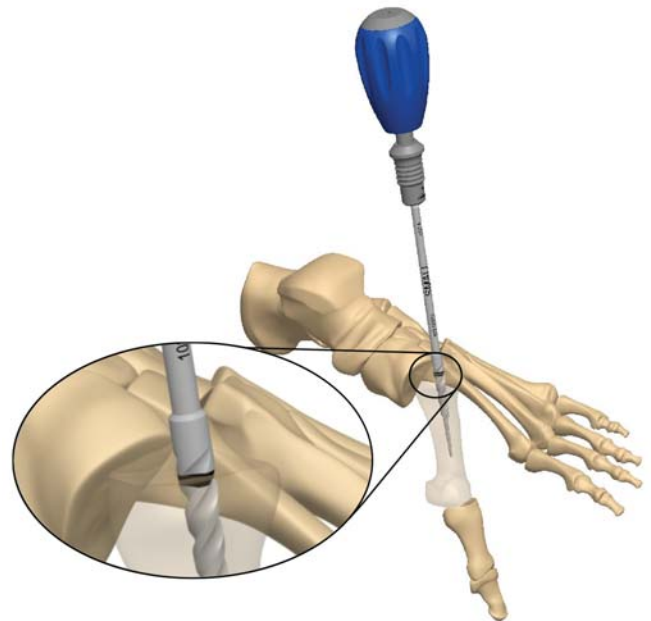
Metatarsal Implant	Pilot Drill \emptyset
Small	\emptyset 3.0mm*
Medium	\emptyset 3.4mm*
Large	\emptyset 4.5mm*

(*)Depth markings start at 20mm and progress in 10mm increments



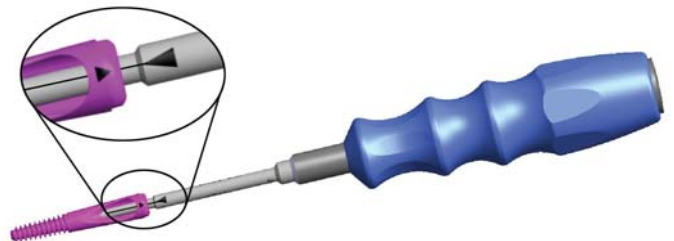
STEP 6 - Reaming

The exposed medullary canal should then be successively reamed with the supplied reamers, up to the corresponding implant size intended for insertion. Always begin with the smallest reamer, ensuring it seats completely within the canal before using the next one. All reamers should be inserted until their respective laser mark is flush with the cut base of the metatarsal. Progressively ream up with sequential reamers until the desired size has been seated. In the event this is perceived not to be an adequate fit, start again at STEP 5 with the upsized corresponding drill, and proceed then to STEP 6 accordingly. In the event introduction of the final reamer becomes too difficult, do not force its advancement. Instead, stop at that point, and consider either re-drilling with the original drill bit if it is felt that it was not advanced as far as it initially should have been (and continue again with STEP 6 from the beginning), or, if satisfied with progress to this point, then simply remove this reamer and prepare to utilize a metatarsal implant that is one size down from the one originally templated.



STEP 7 – Metatarsal Implant Selection and Alignment

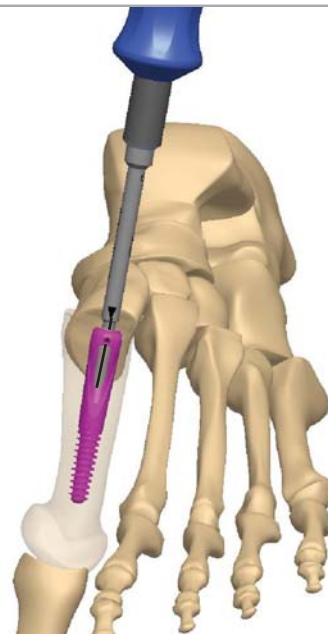
Select the appropriate sized implant based on the depth of one's reaming and, especially, the size of the final reamer used. Align the arrow indicator on the metatarsal implant to exactly match the corresponding arrow indicator on the screwdriver. When directly opposed (as they always should be), these indicators mark the location of the implant's window through which the subsequent lag screw will pass and seat. This also assists in enabling the surgeon to gauge angulation of the lag screw, to facilitate certain cases whereby the direction of the proximally directed implant may wish to be changed by small degrees in both the sagittal and transverse planes. Since final seating of the metatarsal implant should result in excellent intramedullary purchase and further manipulation could result in decreased purchase or the need for insertion of a longer or larger metatarsal implant, it is desirable to decide beforehand where this window should rest (typically directly dorsal) so that further insertion or removal (bony stripping) is avoided.



STEP 8 – Metatarsal Implant

Insert the metatarsal implant using the screwdriver provided, until the base of the implant is flush with or slightly recessed below the cut surface of the 1st metatarsal. In approaching this point, care should be taken to ensure the matching indicator arrows end up where desired (as discussed above). This will generally be along the mid-line of the dorsal aspect of the metatarsal.

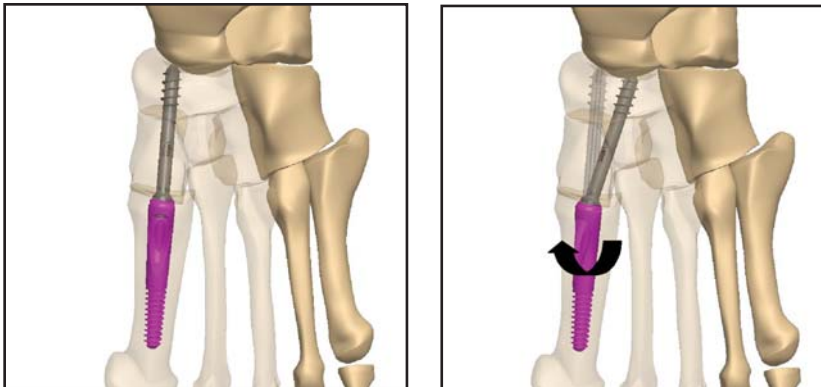
continued



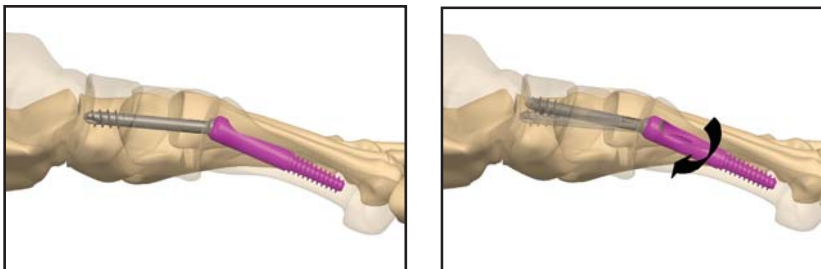
STEP 8 – Metatarsal Implant (cont'd)

Important: The lag screw's ultimate trajectory can be controlled by under or over-rotating the metatarsal implant alignment arrow to either side of direct midline (direct dorsal). The illustrations below depict an example of how these fine adjustments can affect the resultant trajectory angle in both the sagittal and transverse planes

A/P



LATERAL

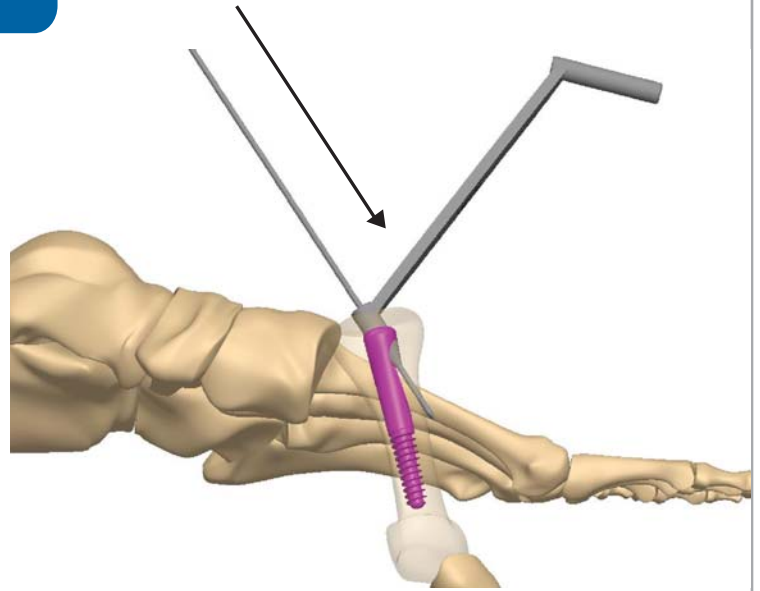


Metatarsal Implant Rotation Angle (°)	Lag Screw Resultant Angle (°)
0.0	0.0
10.0	3.6
20.0	7.1
30.0	10.3
40.0	13.2
50.0	15.6
60.0	17.5
70.0	18.9
80.0	19.7
90.0	20.0

NOTE: If multiple rays are going to be fused in the midfoot (TMTs), the other rays should be prepared at this time in identical fashion, by repeating steps 1-8. This should be done prior to insertion of any lag screw, which will prevent access and exposure to other TMT joints.

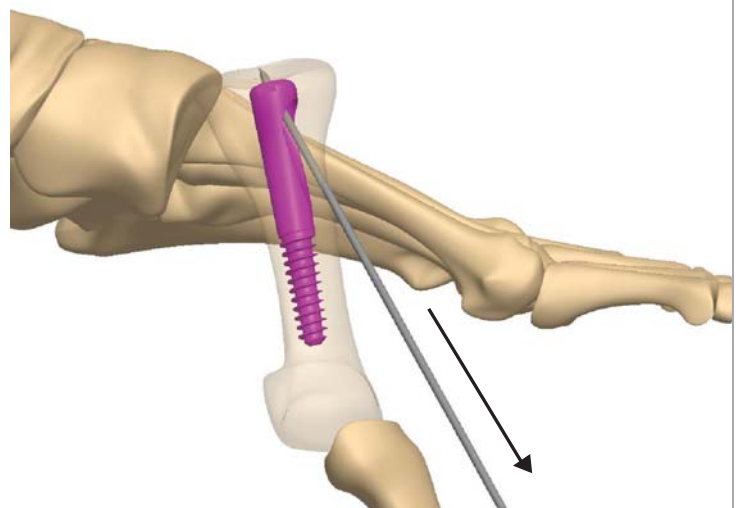
STEP 9 – Guide Alignment

In preparation for insertion of the lag screw, expose the base of the 1st metatarsal again and seat the appropriately sized guide into the base of the metatarsal implant. The guide is fully seated when the laser-marked ring is no longer visible, and the guide should sit flush, stably, and without step-off. Once confirmed, place the appropriate double-ended guidewire through this implant guide proximally, and advance it until it exits the more distal dorsal cortex of the metatarsal. Attention should be paid to the skin incision at this point so as to ensure adequate exposure and exodus of the wire.



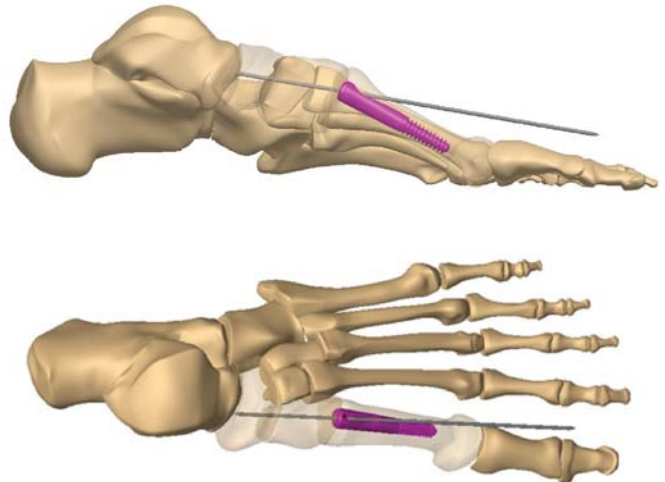
STEP 10 – Guidewire Retraction

Remove the guide, and then back out any residual wire in retrograde fashion until its proximal end is flush with the metatarsal base.



STEP 11 – Midfoot Alignment

Holding the 1st TMT joint carefully reduced at this point advance the guidewire in antegrade fashion across the TMT joint to its desired position. For isolated 1st TMT fusion, this is ideally just short of the articular surface of the NC joint, but in cases where the NC and/or TN joints have also been taken down and prepared for fusion, this wire can be advanced further as would be appropriate. Confirm the location of the guidewire using fluoroscopy, and recheck that reduction is maintained in both the AP and LATERAL views. If repositioning is required, back up the guidewire to the level of the TMT joint again, and repeat steps 8 and 10 until the desired position is obtained.



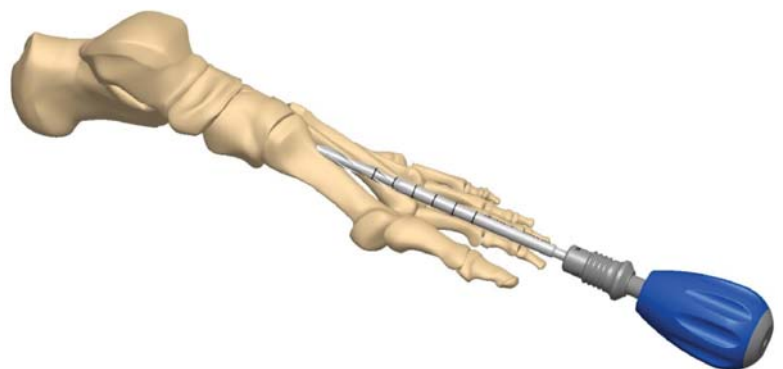
STEP 12a – Dorsal Window (Drill)

Select the proximal (window) drill diameter to now be used, based on the size of the already inserted metatarsal implant. Place this cannulated drill over the positioned guidewire, and advance the drill until the dorsal cortex of the 1st metatarsal has been removed.

Important: The drill should never be advanced into, or through, the metatarsal implant. Implant-drill (metal-metal) contact could ultimately impair the interface stability of the two seated components.

Metatarsal Implant	Window Drill Ø
Small	Ø3.4mm*
Medium	Ø4.5mm*
Large	Ø6.0mm ⁺

Depth markings start at (*) 20mm and (+) 30mm and progress in 10mm increments



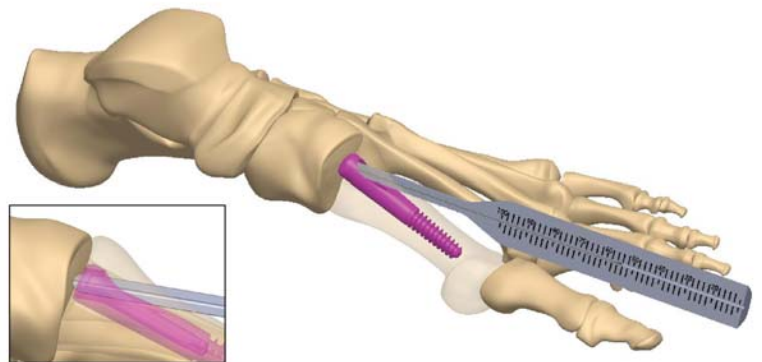
STEP 12b – Dorsal Window (Dorsal Reamer) – Optional

If any concern exists with regard to control or advancement of the drill over the guidewire, an alternative technique for creating this entry portal for the lag screw is depicted below. Instead of using the drill to create this dorsal bony window, use the special trephine reamer provided in the set, which can be controlled and advanced by hand. This is also designed to be advanced over the guidewire to ensure accurate portal placement for subsequent lag screw insertion.



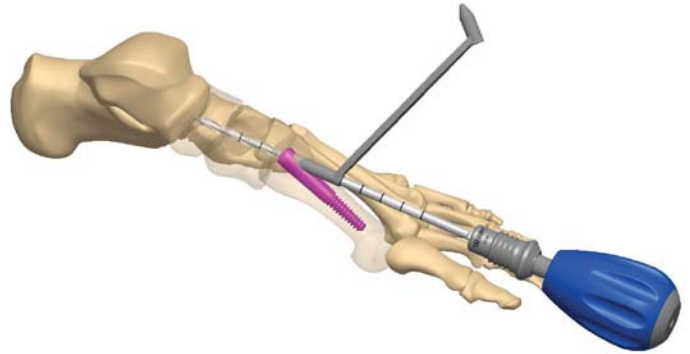
STEP 13 – Lag Screw Depth Measurement

Next, place the lag screw depth gauge over this guidewire and through the dorsal cortex. The gauge should traverse through the metatarsal implant and seat fully so that its proximal most end is flush with the reduced cuneiform. Record the desired lag screw length so this can be obtained and readied for insertion.



STEP 14 – Drill

Select the appropriate lag screw drill diameter based, again, on the previously placed metatarsal implant. Place its drill guide through the dorsal cortical window and seat it into the metatarsal implant so it is stable and flush. This will prevent the drill from contacting the metatarsal implant. Then, drill across the TMT joint and to the desired level in the midfoot using the appropriately size drill bit. It is recommended to stop just short of the guidewire so as to avoid concomitant guidewire removal upon removal of the drill bit, and also to maximize lag screw purchase during its later insertion.

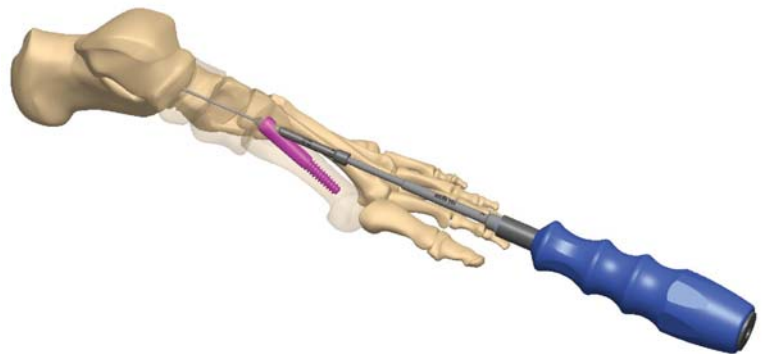


Metatarsal Implant	Lag Screw Drill Ø
Small	Ø3.0mm*
Medium	Ø3.4mm*
Large	Ø4.5mm*

(*)Depth markings start at 20mm and progress in 10mm increments

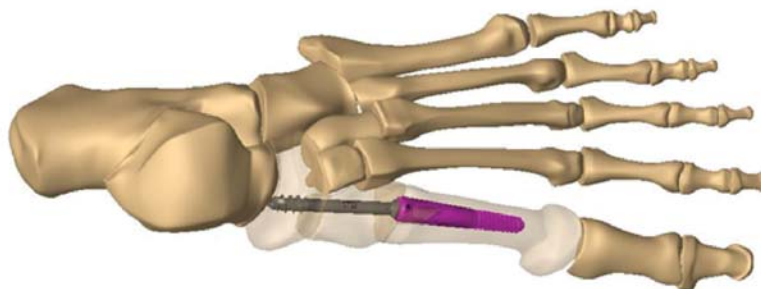
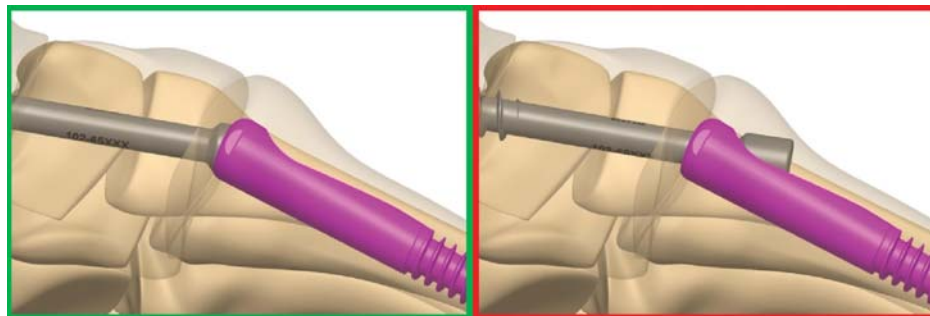
STEP 15 – Lag Screw

Introduce the requested lag screw over the guidewire and through the metatarsal implant from distal to proximal using the supplied screwdriver. Avoid excessive torque during insertion and expect a smooth and fluid advancement of the screw. In the event this is not the case, recheck alignment and co-linearity, prior to further forced advancement, which could result in premature binding or incarceration of the implant. Continue rotating the lag screw until its head is fully seated within the metatarsal implant, which should lead to a subtle but noticeable sudden increase in torque appreciated. A definitive 'stop' or 'seating' indicates that the Morse Taper between the implants has successfully engaged.



STEP 16 – Verification

Fluoroscopy in several planes is recommended at this time to confirm the two implants have seated properly and enacted the desired midfoot alignment. The lag screw should be noted to be fully seated within the metatarsal implant, and appropriate lengths should be assessed at this time as well. Once these things are confirmed, these later steps can be repeated for adjacent rays if they have also been prepared for similar fusion.

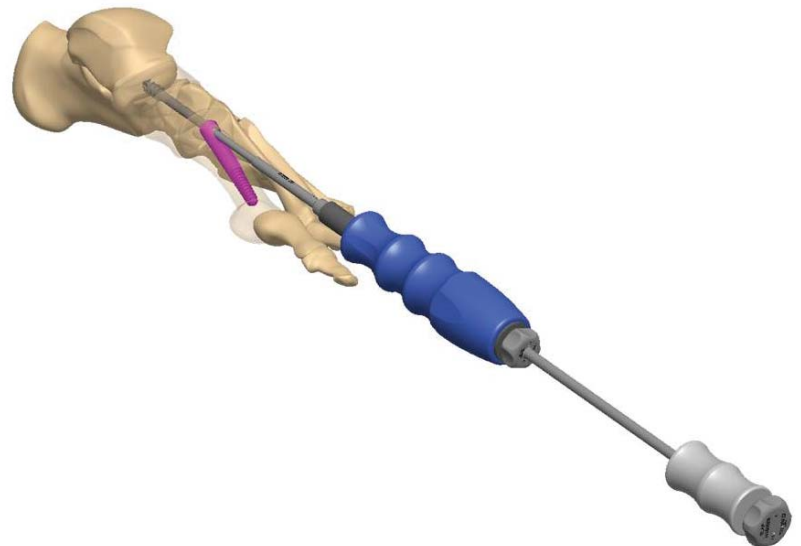


POST OPERATIVE TREATMENT

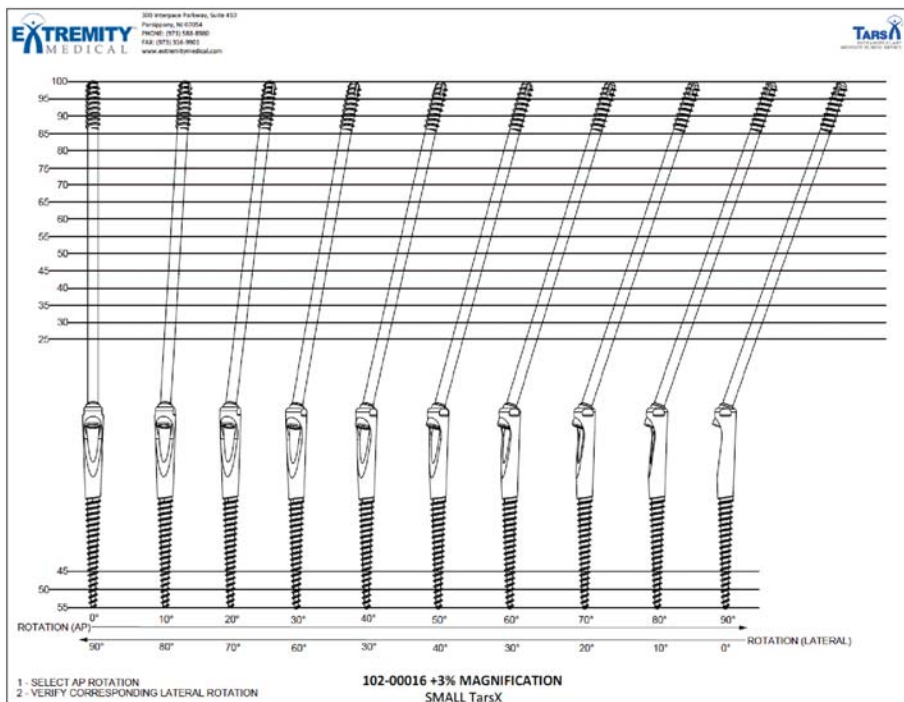
Subsequent to incision closure, patients should initially be immobilized non-weight bearing in a well padded splint for the first two weeks post-operatively. Following repeat incision assessment and suture removal, standard post-operative protocols for midfoot fusion, as preferred by the surgeon, should be followed. Progression to full weight-bearing and transition out of cast immobilization should be based on bone quality and healing rates, and will likely be individualized on a case by case basis.

IMPLANT REMOVAL

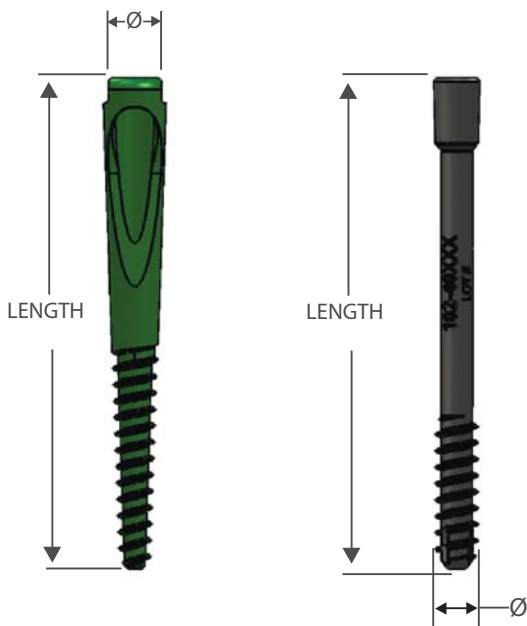
Repeat exposure and remove any tissue ingrowth surrounding the dorsal cortex of the associated metatarsal and lag screw hex recess. Once this can be visualized, attach the appropriate screwdriver to the lag screw head and engage the screw removal tool and slap hammer. Unscrew the lag screw counterclockwise one half-turn, and apply gentle pressure with the slap hammer to release the Morse taper (locking mechanism). As gentle manual pressure is then continually applied, keep turning the screwdriver counterclockwise until the entire lag screw has been removed. The metatarsal implant can then be removed by plantar-flexing the TMT joint, exposing the base of the metatarsal, and clearing all tissue ingrowth from the hex recess. Attach the removal driver, turning counterclockwise until the entire metatarsal implant is removed.



XRAY TEMPLATE



IMPLANT DIMENSION



Mating Components and Drill Ø Selection

Implant Size	Lag Screw Ø	Metatarsal Pilot Ø	Window Drill Ø	Lag Screw Drill Ø
Small 6.0mm	Ø4.0	Ø3.0	Ø3.4	Ø3.0
Medium 8.0mm	Ø5.0	Ø3.4	Ø4.5	Ø3.4
Large 9.0mm	Ø6.5	Ø4.5	Ø6.0	Ø4.5

IMPLANT CATALOG NUMBERS

Catalog #	Description
102-12045	Small Metatarsal Implant - 6.0mm x 45mm
102-12050	Small Metatarsal Implant - 6.0mm x 50mm
102-12055	Small Metatarsal Implant - 6.0mm x 55mm
102-22050	Medium Metatarsal Implant - 8.0mm x 50mm
102-22055	Medium Metatarsal Implant - 8.0mm x 55mm
102-22060	Medium Metatarsal Implant - 8.0mm x 60mm
102-32045	Large Metatarsal Implant - 9.0mm x 45mm
102-32050	Large Metatarsal Implant - 9.0mm x 50mm
102-32055	Large Metatarsal Implant - 9.0mm x 55mm
102-40025	Small Lag Screw 4.0mm x 25mm
102-40030	Small Lag Screw 4.0mm x 30mm
102-40035	Small Lag Screw 4.0mm x 35mm
102-40040	Small Lag Screw 4.0mm x 40mm
102-40045	Small Lag Screw 4.0mm x 45mm
102-40050	Small Lag Screw 4.0mm x 50mm
102-40055	Small Lag Screw 4.0mm x 55mm
102-40060	Small Lag Screw 4.0mm x 60mm
102-40065	Small Lag Screw 4.0mm x 65mm
102-40070	Small Lag Screw 4.0mm x 70mm
102-40075	Small Lag Screw 4.0mm x 75mm
102-40080	Small Lag Screw 4.0mm x 80mm
102-40085	Small Lag Screw 4.0mm x 85mm
102-40090	Small Lag Screw 4.0mm x 90mm
102-40095	Small Lag Screw 4.0mm x 95mm
102-40100	Small Lag Screw 4.0mm x 100mm
102-50025	Medium Lag Screw 5.0mm x 25mm
102-50030	Medium Lag Screw 5.0mm x 30mm
102-50035	Medium Lag Screw 5.0mm x 35mm
102-50040	Medium Lag Screw 5.0mm x 40mm
102-50045	Medium Lag Screw 5.0mm x 45mm
102-50050	Medium Lag Screw 5.0mm x 50mm
102-50055	Medium Lag Screw 5.0mm x 55mm
102-50060	Medium Lag Screw 5.0mm x 60mm
102-50065	Medium Lag Screw 5.0mm x 65mm
102-50070	Medium Lag Screw 5.0mm x 70mm
102-50075	Medium Lag Screw 5.0mm x 75mm
102-50080	Medium Lag Screw 5.0mm x 80mm
102-50085	Medium Lag Screw 5.0mm x 85mm
102-50090	Medium Lag Screw 5.0mm x 90mm
102-50095	Medium Lag Screw 5.0mm x 95mm
102-50100	Medium Lag Screw 5.0mm x 100mm
102-65025	Large Lag Screw 6.5mm x 25mm
102-65030	Large Lag Screw 6.5mm x 30mm
102-65035	Large Lag Screw 6.5mm x 35mm

Catalog #	Description
102-65040	Large Lag Screw 6.5mm x 40mm
102-65045	Large Lag Screw 6.5mm x 45mm
102-65050	Large Lag Screw 6.5mm x 50mm
102-65055	Large Lag Screw 6.5mm x 55mm
102-65060	Large Lag Screw 6.5mm x 60mm
102-65065	Large Lag Screw 6.5mm x 65mm
102-65070	Large Lag Screw 6.5mm x 70mm
102-65075	Large Lag Screw 6.5mm x 75mm
102-65080	Large Lag Screw 6.5mm x 80mm
102-65085	Large Lag Screw 6.5mm x 85mm
102-65090	Large Lag Screw 6.5mm x 90mm
102-65095	Large Lag Screw 6.5mm x 95mm
102-65100	Large Lag Screw 6.5mm x 100mm

INSTRUMENT CATALOG NUMBERS

Catalog#	Description
101-00009	Guidewire Holder - Ø1.6 mm
101-00012	Cannulated Drill - Ø3.4 mm
101-00013	Cannulated Drill - Ø4.5 mm
101-00023	Cleaning Brush - Ø1.6 mm
102-00000	TarsX Instrument Tray
102-00001	TarsX Implant Caddie
102-00002	Cannulated Drill - Ø3.0 mm
102-00003	Small Implant Guide
102-00004	Medium Implant Guide
102-00005	Large Implant Guide
102-00006	Small Dorsal Reamer
102-00007	Medium Dorsal Reamer
102-00008	Large Dorsal Reamer
102-00009	Screwdriver
102-00010	Small Metatarsal Reamer
102-00011	Medium Metatarsal Reamer
102-00012	Large Metatarsal Reamer
102-00016	TarsX X-Ray Template
102-00017	AO Quick Connect Handle
102-00018	Cannulated Drill - Ø6.0 mm
102-00020	Removal Screwdriver
102-00021	Removal Tool
102-00022	Slap Hammer
102-00023	Double-Ended Guidewire - Ø1.6 mm
113-00003	Depth Gauge