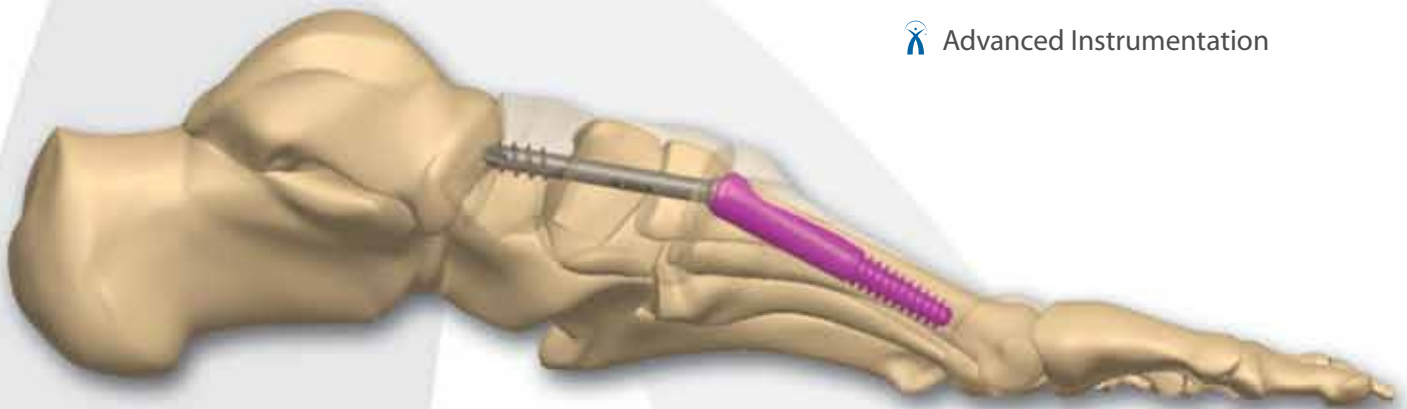


TARSTM
INTRAMEDULLARY
MIDFOOT FUSION DEVICE

Surgical Technique

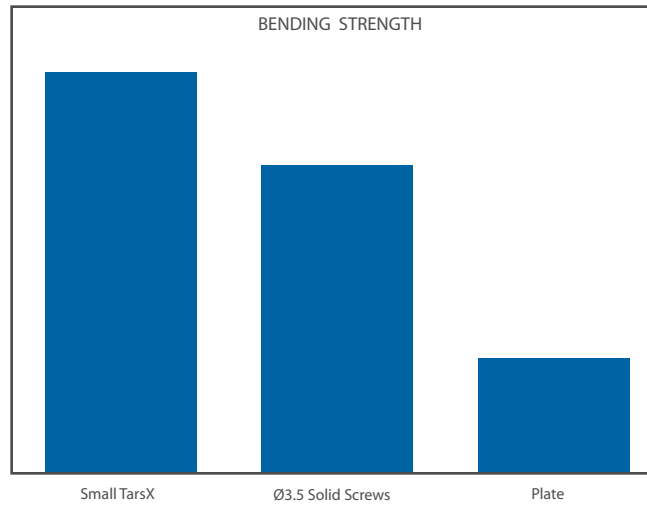
-  Rigid Midfoot Fusion
-  Total Intramedullary Fixation
-  Fuse Variable Levels
-  Restoration of Natural Arch
-  Advanced Instrumentation



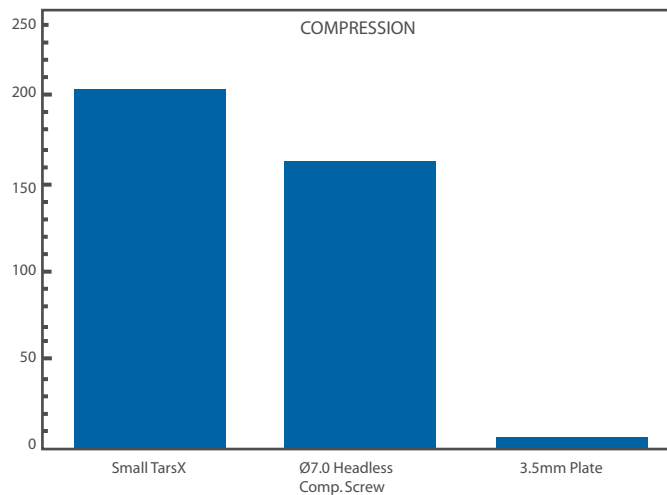
Patent Pending

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 joints.

STEP 1 - Approach and Exposure

A standard longitudinal incision, length determined by exposure requirements, is first performed over the dorsal aspect of the medial midfoot. Adequate exposure to access the metatarsal canal is required. Careful capsular exposure is then performed through each window, with attention to crossing tendons and the adjacent neurovascular bundle.

Once adequate exposure has been obtained 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.

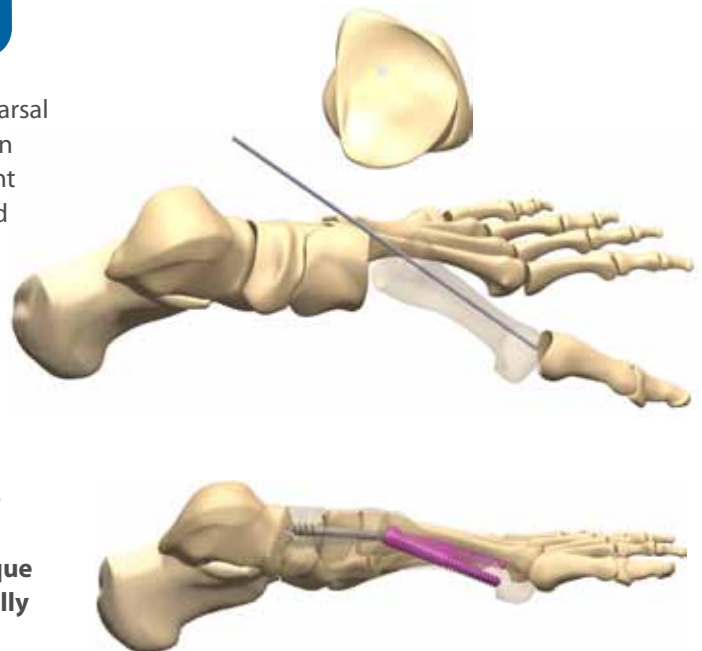


STEP 2 – Guidewire

Once satisfied with first ray position, plantarflex the 1st metatarsal to permit proximal insertion of a Ø1.6mm (6") guidewire down the dorsal aspect of the IM canal, as shown. 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.

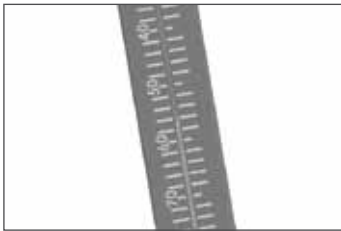
ACCEPTABLE ALTERNATIVE GUIDEWIRE PLACEMENT

Depending on the desired final placement of the lag screw component, the guidewire can be plantarly angled within the metatarsal canal to bring the lag crew trajectory more dorsal within the mid-foot. **Caution should be taken if this technique is utilized as the retrograde guidewire will exit more distally along the metatarsal.**



STEP 3 - Depth Measurement

Place the depth guide over the guidewire to the base of the metatarsal and measure the length.



STEP 4 - Pilot Hole

Select the Ø3.0mm pilot drill and place this cannulated drill over the guidewire. Drill to desired depth. Once drilling has been completed, remove both the drill and the guidewire.

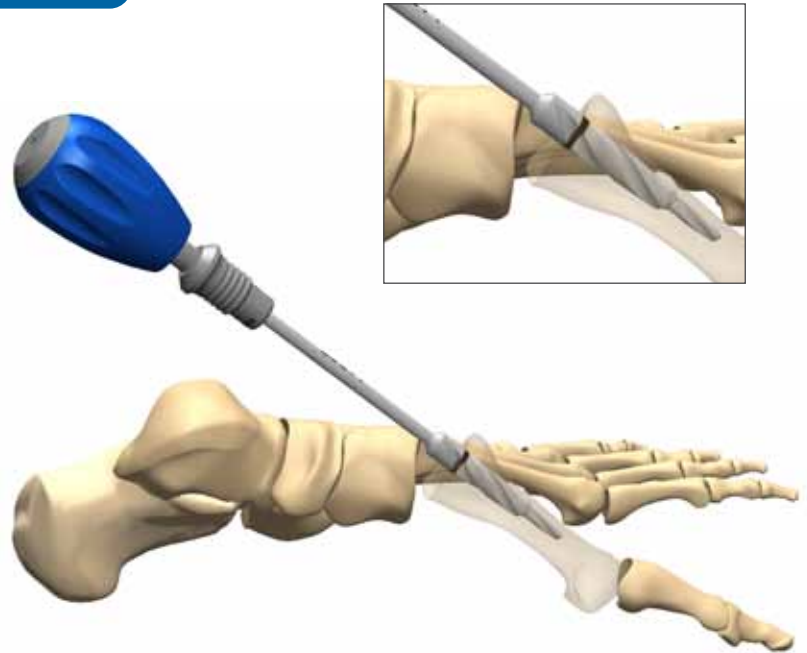
Metatarsal Implant	Pilot Drill Ø
All	Ø3.0mm

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



STEP 5 – Reaming

The exposed medullary canal should then be successively reamed, with the supplied reamers, to the corresponding implant size. Always begin with the smallest reamer, ensuring it seats completely within the canal. All reamers should be inserted until their respective black line is flush with the cut base of the metatarsal. Progressively ream with sequentially larger sized reamers until the desired size has been determined.



STEP 6 - Metatarsal Implant Selection and Alignment

Select the appropriate sized implant based on the size of the final reamer used and the depth measurement. Align the arrow indicator on the metatarsal implant to match the corresponding arrow indicator on the implant driver. When the arrows are directly opposed, these indicators mark the location of the implant's dorsal window through which the lag screw will pass.



STEP 7 – 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. Using the arrow indicator on the implant driver as a reference to the dorsal window, adjust the metatarsal implant for the intended screw trajectory.

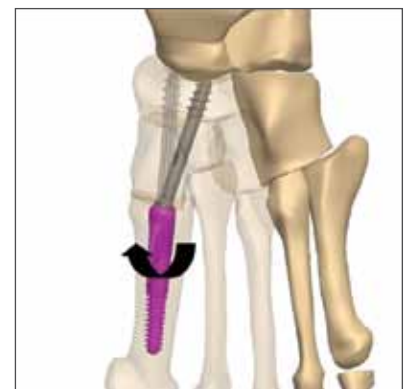
In order to counteract any increase of torque that may occur during implantation, a clamp can be secured to the metatarsal and used as a counter-torque handle.



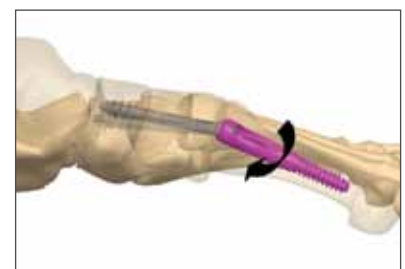
A/P

Important: The illustrations at right depict an example of how final position of the implant can affect the resultant trajectory angle in both the sagittal and transverse planes

Note: In the event the lag screw is intended to fuse up to the talus a more medial approach may be advised.



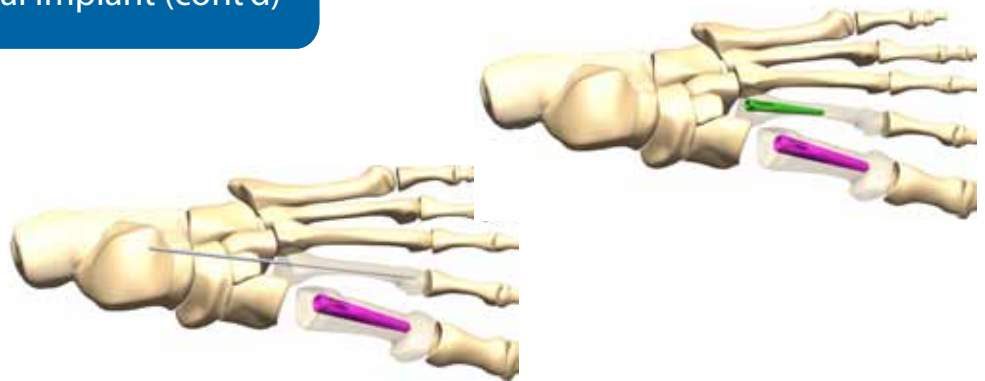
LATERAL



STEP 7 – Metatarsal Implant (cont'd)

MULTIPLE-RAY INDICATION

For indications requiring multiple instrumented rays, the lesser metatarsals should be prepared at this point following Steps 2 thru 7 for each ray.



STEP 8 – Guide Alignment

Seat the size specific implant guide into the base of the metatarsal implant. The guide is fully seated when the black ring is no longer visible. Once confirmed, place the Ø1.6mm guidewire through this implant guide proximally, and advance it until it exits the distal dorsal cortex of the metatarsal. Attention should be paid to the skin incision at this point to ensure adequate exposure and exit of the wire.

Important: In the event the guidewire fails to break through the metatarsal cortex, a peck drilling motion or a Ø1.5mm drill can be used to aid in the exit.



STEP 9 – Guidewire Retraction

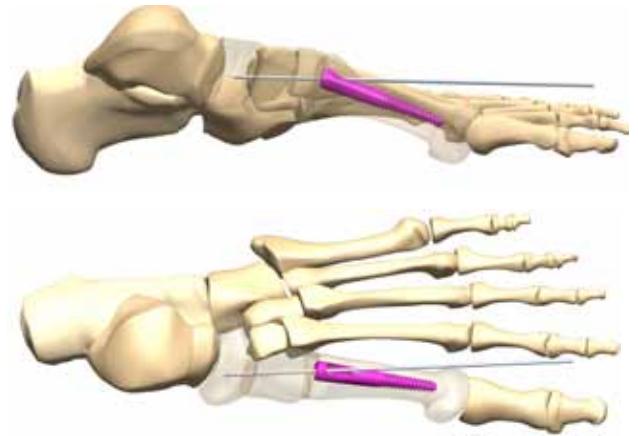
Remove the guide, and then pull the guidewire as shown until its proximal end is flush with the metatarsal base.



STEP 10 – Midfoot Alignment

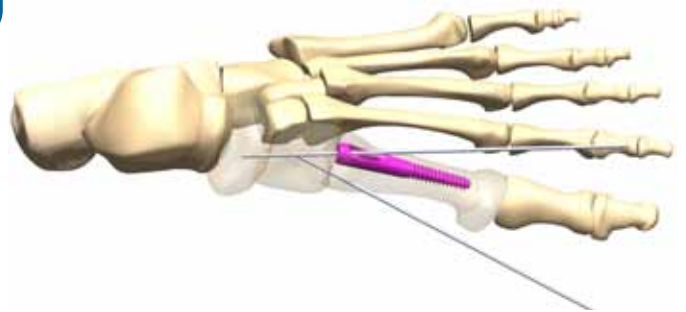
Reduce the joint and advance the guidewire across the TMT joint to its desired position. Confirm the location of the guidewire using fluoroscopy, and recheck that reduction is maintained in both the AP and LATERAL views.

If the final guidewire placement is not ideal, remove the guidewire completely from the metatarsal. Engage the Metatarsal Implant with the Implant Driver and adjust the implant to modify the guidewire trajectory. Repeat steps 8 thru 11 until a desired placement is obtained.



STEP 10a – Provisional Pin (Optional)

For added stability across the joint, a guidewire is inserted medially at an oblique angle to the existing guidewire trajectory. This guidewire can also act as a placement for an interfragmentary screw that can be placed for additional stability across the joint. Care must be taken not to place the two guidewires too close to each other to ensure the screws do not impinge on each other.



STEP 11 – Dorsal Window (Drill)

Select the proximal (window) drill, based on the size of the metatarsal implant. Place this cannulated drill over the guidewire, and advance the drill until the dorsal cortex of the 1st metatarsal has been removed.

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

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.

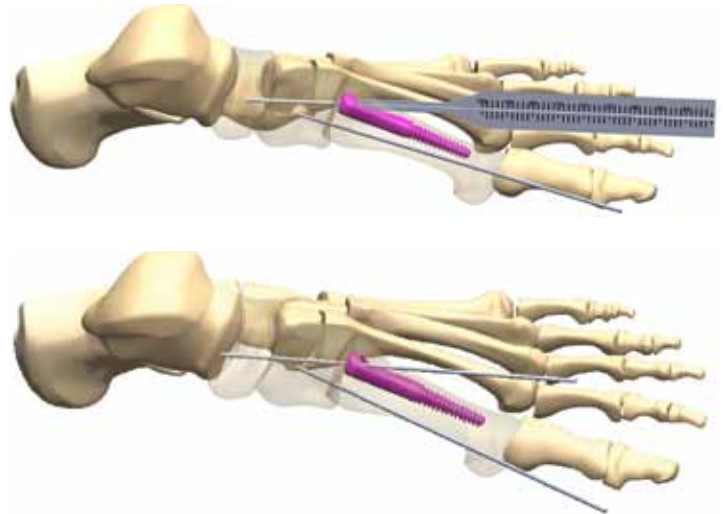


STEP 12 – Lag Screw Depth Measurement

Place the lag screw depth gauge over the guidewire and through the dorsal cortex. The gauge should seat fully so that its proximal most end is flush with the reduced cuneiform. Record the desired lag screw length.

Note: If difficulty arises while trying to retrograde the guidewire through the metatarsal implant, an alternative guidewire placement technique can be found at the end of this surgical guide. This alternative technique is recommended for the 1st Ray only.

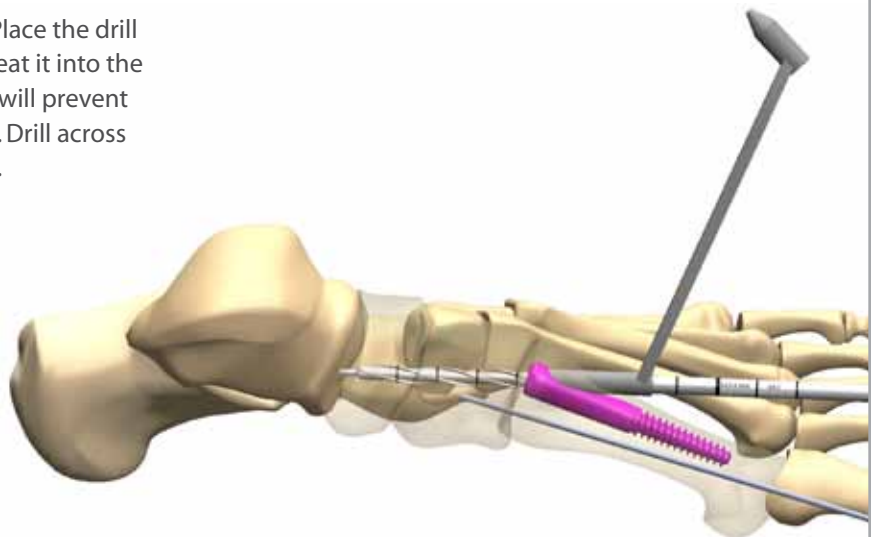
Important: Once the depth measurement is taken, advance the guidewire to ensure the wire remains intact during subsequent steps.



STEP 13 – Drill

Select the appropriate lag screw drill diameter. Place the 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. Drill across the TMT joint to the desired level in the midfoot.

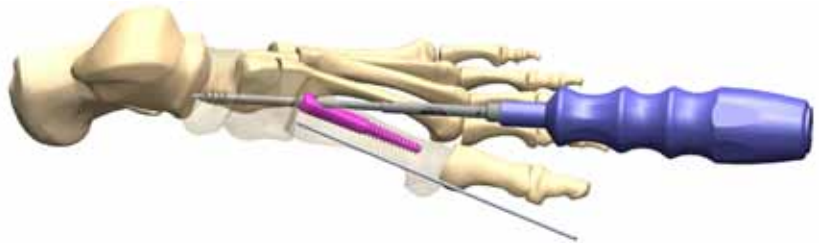
Metatarsal Implant	Lag Screw Drill Ø
Small	Ø3.0mm
Medium	Ø3.4mm
Large	Ø4.5mm



STEP 14 – Lag Screw

Note: Prior to final seating of the lag screw retract the provisional pin back beyond the TMT joint to ensure proper compression takes place.

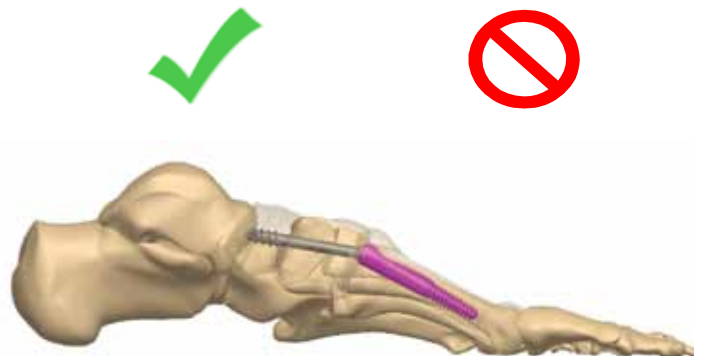
Note: Select a lag screw length shorter (~5mm) than measured to compensate for compression.



Introduce the 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. Continue rotating the lag screw until its head is fully seated within the metatarsal implant, indicated by a subtle but noticeable increase in torque. A definitive 'stop' or 'seating' indicates that the Morse Taper between the implants has successfully engaged.

STEP 15 – Verification

Fluoroscopy in several planes is recommended at this time to confirm the two implants have seated properly. The lag screw should be noted to be fully seated within the metatarsal implant.



ALTERNATIVE STEP 8 – C-Guide Alignment and Guidewire Bushing

Seat the appropriately sized C-Guide into the base of the metatarsal implant. The guide should sit in the implant window flush with the base of the metatarsal implant. Insert the Ø1.6mm Guidewire Bushing through the barrel of the C-Guide until it contacts the dorsal aspect of the metatarsal. A small stab incision is recommended should a percutaneous approach be used.



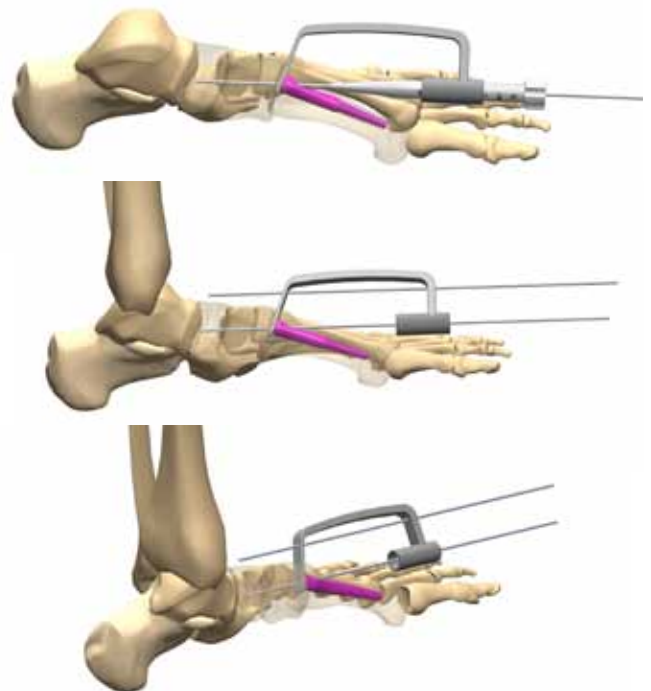
ALTERNATIVE STEP 9 – Advance 9" Guidewire

Insert the 9" guidewire through the guidewire bushing and across the intended joints. Confirm the location of the guidewire using fluoroscopy, and recheck that reduction is maintained in both the AP and LATERAL views.

Important: In the event of hard bone or guidewire deflection, consider either burring or partially drilling a wire start point using the larger drill bushing and drill.

ADDITIONAL ALIGNMENT ASSISTANCE

A second guidewire can be inserted through the C-Guide arm to aid the surgeon with predicting the trajectory of the guidewire through the intended joints.



ALTERNATIVE STEP 10 – Lag Screw Length Measurement

Remove the guidewire bushing and place the C-Guide depth gauge over the guidewire and seat the depth gauge against the distal end of the C-Guide, as shown. Advance the guide wire an additional 5-10mm after the measurement is taken to prevent inadvertent removal during drilling.



ALTERNATIVE STEP 11 – Dorsal Window (Drill)

Remove the depth gauge and place the matching sized drill bushing into the C-Guide. Advance the dorsal window drill until the drill contacts the distal tip of the C-Guide.

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

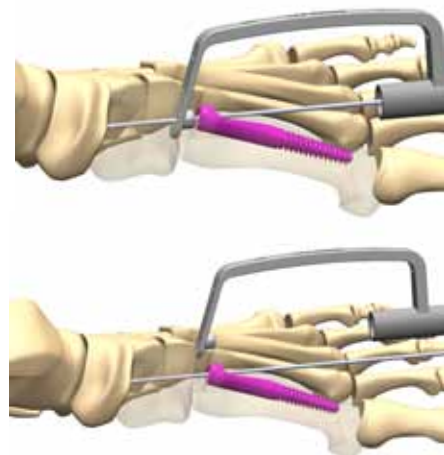
Important: In the event the window is not fully cleared remove the drill bushing and continue to advance the drill.



ALTERNATIVE STEP 12 – Removal of C-Guide

Remove the drill bushing. The C-Guide has a slot allowing removal from the guide while leaving the guidewire in place. Disengage the C-Guide from the metatarsal implant by sliding the guide retrograde, gently expose the joint and slide the C-Guide over the guidewire.

With the guidewire in place, follow the remaining procedural steps to complete the implant construct.



POST OPERATIVE TREATMENT

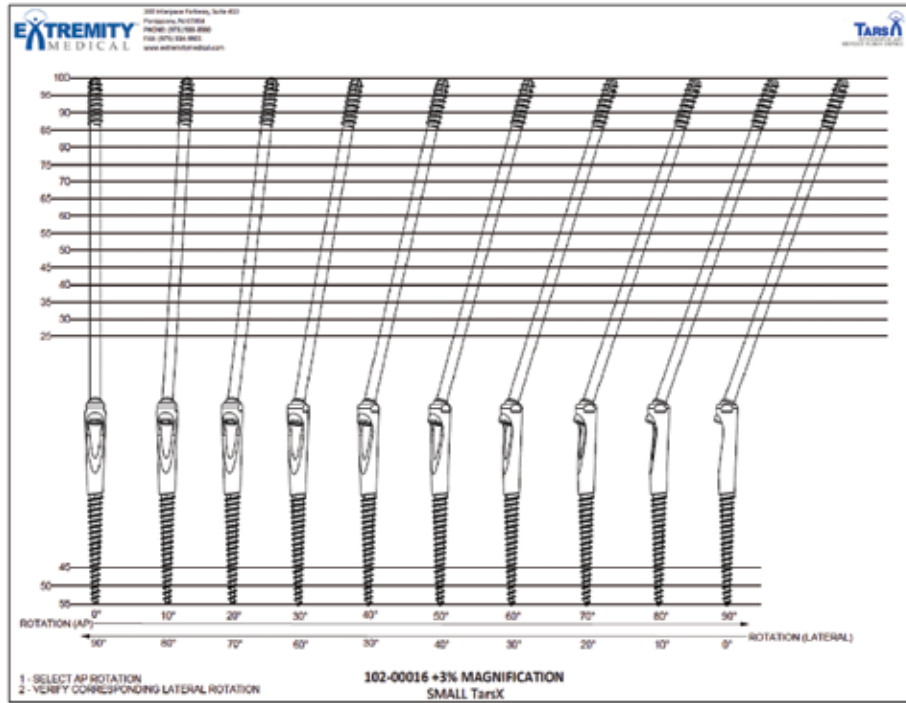
Patients should initially be immobilized non-weight bearing in a well padded splint. Following repeat incision assessment and suture removal, standard post-operative protocols for midfoot fusion, as preferred by the surgeon, should be followed. Progression to full weight-bearing and transition out of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

IMPLANT REMOVAL

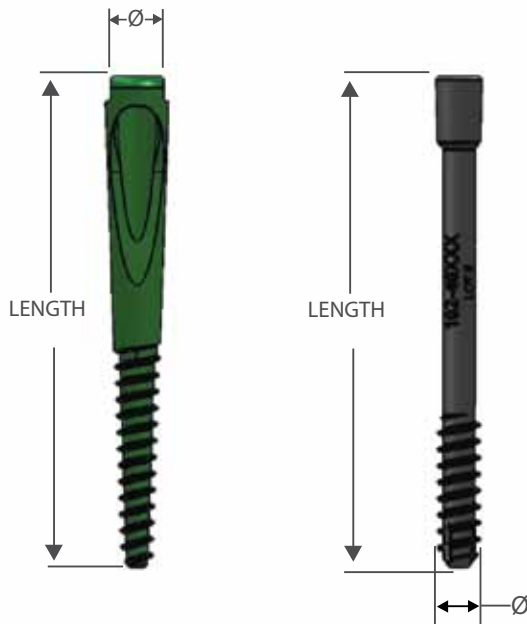
Repeat exposure and removal any tissue ingrowth surrounding the dorsal cortex of the associated metatarsal and lag screw hex recess. Once this can be visualized, attach the appropriate screwdriver to the lag screw head and engage the screw removal tool and slap hammer. Unscrew the lag screw counterclockwise 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 (102-00016)



IMPLANT DIMENSION



Mating Components and Drill Ø Selection

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

FULLY THREADED LAG SCREWS

Fully Threaded Lag Screws can be special ordered if the indication permits.



IMPLANT CATALOG NUMBERS

Catalog #	Description
102-12045	Small Metatarsal Implant - Ø 6.0mm x 45mm
102-12050	Small Metatarsal Implant - Ø 6.0mm x 50mm
102-12055	Small Metatarsal Implant - Ø 6.0mm x 55mm
102-22050	Medium Metatarsal Implant - Ø 8.0mm x 50mm
102-22055	Medium Metatarsal Implant - Ø 8.0mm x 55mm
102-22060	Medium Metatarsal Implant - Ø 8.0mm x 60mm
102-32045	Large Metatarsal Implant - Ø 9.0mm x 45mm
102-32050	Large Metatarsal Implant - Ø 9.0mm x 50mm
102-32055	Large Metatarsal Implant - Ø 9.0mm x 55mm
102-40020	Small Lag screw 4.0mm x 20mm
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
102-50020	Medium Lag screw 5.0mm x 20mm
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
102-65020	Large Lag screw 6.5mm x 20mm
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	3.0 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
102-00024	Small C-Guide
102-00025	Medium C-Guide
102-00026	Large C-Guide
102-00027	Ø3.4mm Drill Bushing
102-00028	Ø4.5mm Drill Bushing
102-00029	Ø6.0mm Drill Bushing
102-00030	C-Guide Depth Gauge
102-00032	9" Double-Ended Guidewire - Ø1.6 mm
102-00034	9" Guidewire Holder - Ø 1.6mm
102-00040	Ø1.6mm Wire Bushing
113-00003	Depth Gauge