Nanoplasty™ 3D MIS Bunion Correction™ Key Steps

Inserter Preparation

Secure the Nanoplasty® implant by hand or use the Loading Block. If using the Loading Block, place the implant into the Loading Block, with the laser marking facing down. Slide the Inserter into the Loading Block. Slide the Connection Rod into the Inserter hole with the laser mark band and firmly tighten the Connection Rod to properly secure it to the implant.

Step 1: Surgical Approach

Use a K-wire under lateral and AP fluoroscopy to mark out the medial, longitudinal axis of the 1st metatarsal and the osteotomy site at the metadiaphyseal junction.

Insert a K-wire into the intersection of the skin markings. Use the Cut Guide to mark a longitudinal incision. Ensure that the "P" on the Cut Guide is proximal and the "D" is distal. Make a longitudinal incision over the skin marking, then slide the Cut Guide over the K-wire and align with the long axis of the metatarsal. Use a 1.6mm K-wire to pin proximally and a 2.2mm K-wire dorsally and make a complete transverse osteotomy with the sagittal saw.

Step 2: Implant Insertion

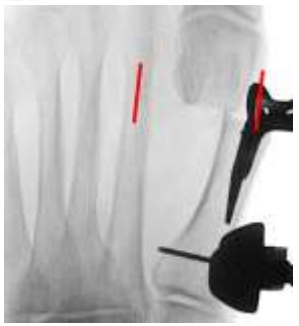
Use the Broach or tapered instrument to prepare the metatarsal shaft for implant placement. Insert the implant into the intramedullary canal, ensuring the Inserter is fully seated on the medial edge of the osteotomy and in line with the metatarsal shaft.

Tighten the Positioner Cup to stabilize the Inserter and align the implant. The distal portion should be parallel to the 2nd metatarsal shaft to ensure avoidance of hardware palpability.

Insert a K-wire through the Positioner Cup. Confirm positioning of the implant and Inserter utilizing AP and lateral fluoroscopy.

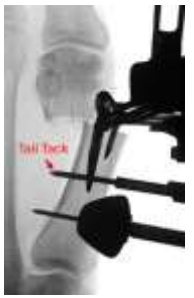
Caution: TMC intramedullary implants are not designed to be cut or bent.

Caution: Avoid excessive force or impaction when inserting the implant into the intramedullary canal.



Step 3: Translational Correction

Translate the capital fragment to the desired lateral position by turning the Gold Translation Screw using the T8 driver. Once in the desired position, insert the Tail Tack through the Inserter for further stabilization.



Step 4: Rotational Correction

Insert a K-wire into the capital fragment and rotate to gain correction. If using the Rotation Guide, attach it to the Inserter and engage the 2.2mm K-wire. Rotate the metatarsal head to the desired position. Utilize fluoroscopy, AP and lateral, to confirm sesamoid position and ensure alignment of the dorsal and plantar cortices. Once appropriate rotation is achieved, pin the capital fragment by placing two 1.6mm K-wires through the temporary fixation holes in the Inserter.

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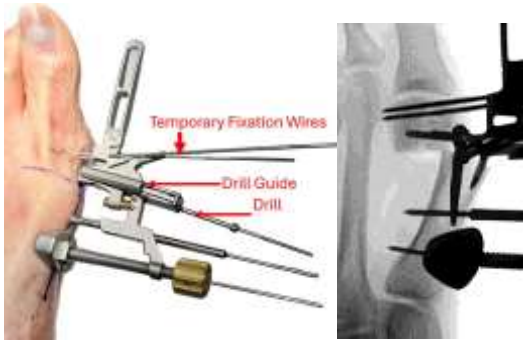
Step 5: Capital Fragment Fixation

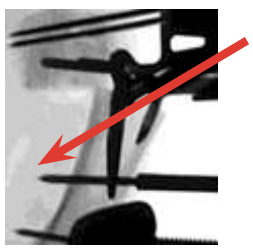
Slide the Drill Guide over the post of the Inserter. Drill the dorsal hole first, then the plantar hole leaving the drill inserted. Place an appropriate size locking screw (e.g. 10mm) in the dorsal hole. Remove drill from the plantar hole drill and place an appropriate size locking screw (e.g. 18mm). Confirm both screws are fully locked under fluoroscopy.



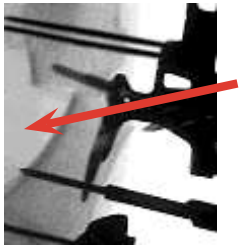
Step 6: Angled Screw Hole Selection

Choose the appropriate angled hole for locking screw insertion that will provide adequate bone bridges on the lateral cortex.

The proximal hole is anticipated to be the common selection, while the distal hole may be used for patients with large width metatarsals who require minimal translation.



Proximal Angled Screw Hole

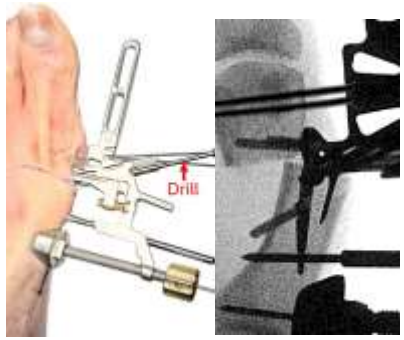


Distal Angled Screw Hole

Caution: To ensure adequate bone bridge, avoid drilling and inserting a locking screw in both angled locking screw holes.

Step 7a: Proximal Screw Hole Fixation (if selected)

Drill through the proximal angled drill hole on the Inserter. Under fluoroscopy, confirm the drill depth and then determine the screw length using the laser marks on the drill. Remove the drill and insert the locking screw according to the length measured.

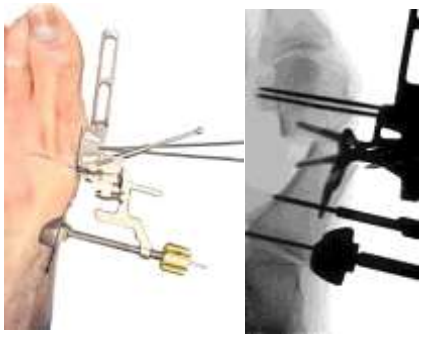


Caution: Use care to not cross threads while inserting the screw head into the plate.

Caution: Use care to not overtighten once the screw head locks into the plate, as this can result in stripping of the screw head or deforming the driver tip.

Step 7b: Distal Screw Hole Fixation (if selected)

Unthread and remove the Connection Rod using the T8 driver. Drill through the Connection Rod drill hole on the Inserter. Under fluoroscopy, confirm the drill depth and then determine the screw length using the laser marks on the drill. Remove the drill and insert the locking screw according to the length measured.



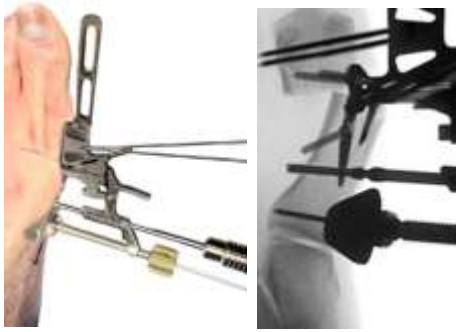
Caution: Use care to not cross threads while inserting the screw head into the plate.

Caution: Use care to not overtighten once the screw head locks into the plate, as this can result in stripping of the screw head or deforming the driver tip.

Step 8: Bicortical Screw Fixation

Under fluoroscopy, determine the desired length of the screw. Remove the Tail Tack. Then insert a fully threaded cannulated screw through the most proximal hole of the implant until the head is fully seated in the medial cortex.

Confirm that all screws are fully seated. Turn the Gold Translation Screw counterclockwise to back off the translation. Remove the K-wire and back off the Positioner Cup before removing the Inserter.



Step 9: Medial Spike Removal

The medial spike of the metatarsal shaft can be removed with a wedge burr, rongeur, or the TMC medial spike removal instrument.

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