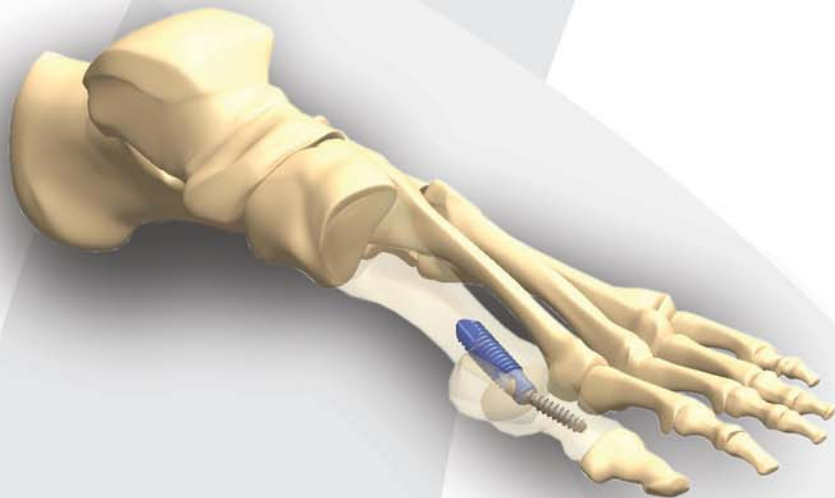











HALLU

INTRAMEDULLARY
FUSION DEVICE

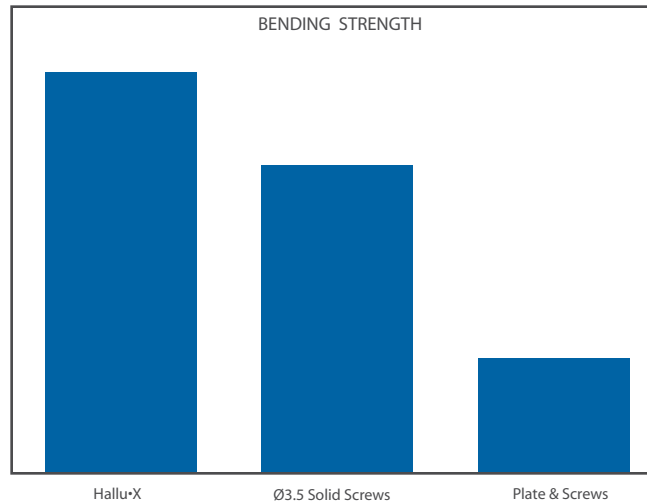
Surgical Technique



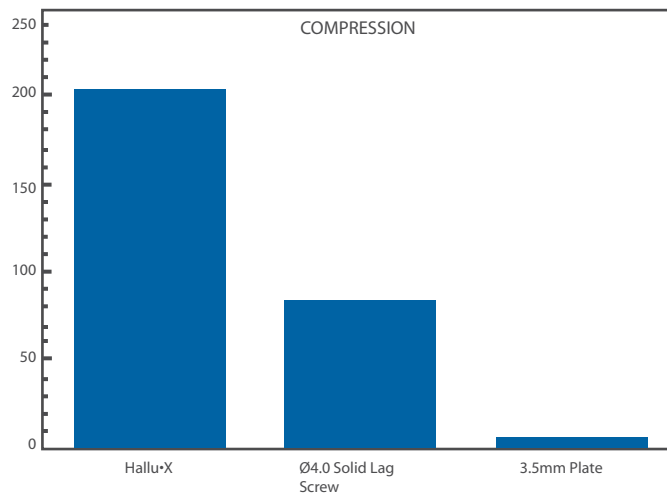
-  Stable intramedullary fixation
-  Implant compresses across joint
-  Avoid hardware complications from tissue irritation caused by plates and screws
-  Advanced instrumentation can reduce procedure time
-  Avoids the need to bend plates or hardware
-  Allows positioning of the phalanx to accommodate different clinical needs
-  Removable

Patent Pending

As described by Brian Donley, MD and Christopher DiGiovanni, MD
CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.



1.5X stronger than multiple screw construct
3.5X stronger than dorsal plate constructs



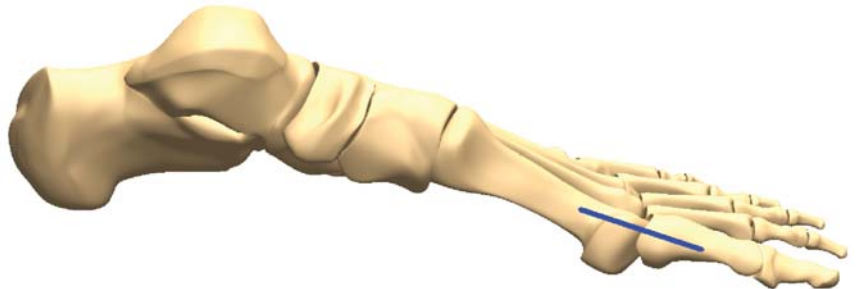
2.5X more delivered compression than Ø4.0 screw construct
45X more delivered compression than plate construct

INDICATIONS FOR USE

The Extremity Medical Hallu·X Intramedullary Fusion Device is intended for fixation arthrodesis of the metatarsophalangeal joint.

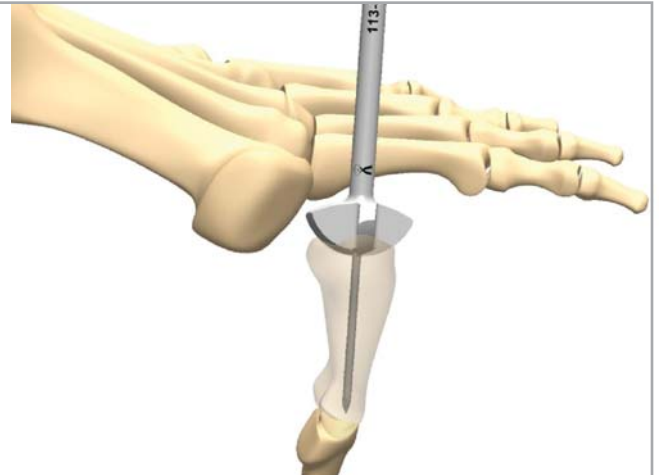
STEP 1 - Exposure

A longitudinal incision is made on the medial side across the first metatarsophalangeal joint. Use appropriate dissection to expose the metatarsophalangeal joint.



STEP 2a - Phalanx Preparation

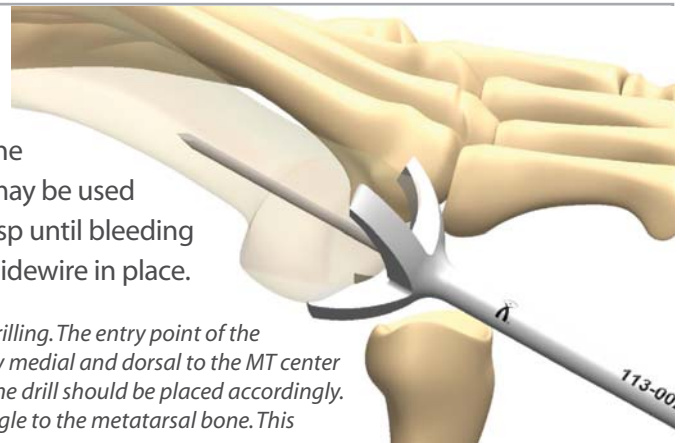
Insert the Ø1.6mm guidewire in the center of the phalanx and locate the cone rasp over the wire. Gradually remove the articulating cartilage until bleeding bone is observed. Remove the guidewire.



STEP 2b - Metatarsal Preparation

Insert the guidewire into the center of the medullary canal of the metatarsal and place the cup rasp over the wire. Fluoroscopy may be used to confirm proper placement of the guidewire. Advance the rasp until bleeding subchondral bone is observed. Remove the rasp leaving the guidewire in place.

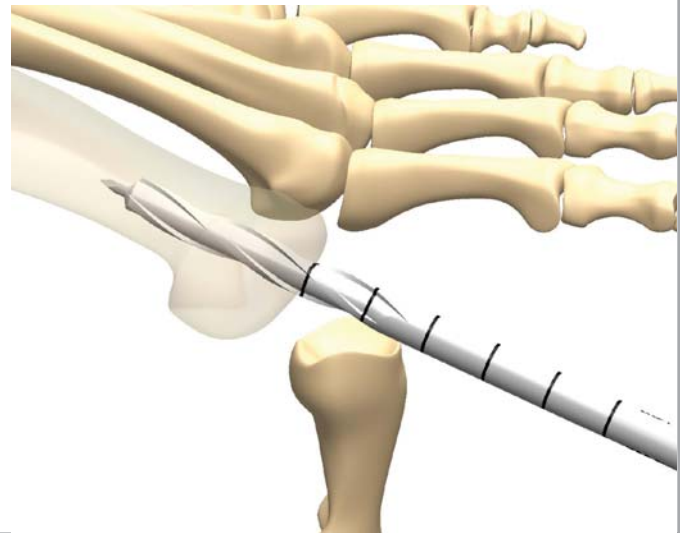
NOTE: Removal and re-positioning of the guidewire is recommended before drilling. The entry point of the guidewire for the drill is different from the reamer. The drill should start slightly medial and dorsal to the MT center point, and the drilled hole should be aimed slightly lateral. The guidewire for the drill should be placed accordingly. It is common and acceptable to position the Metatarsal implant at a slight angle to the metatarsal bone. This avoids a lag screw which is too short.



STEP 3 - Drill

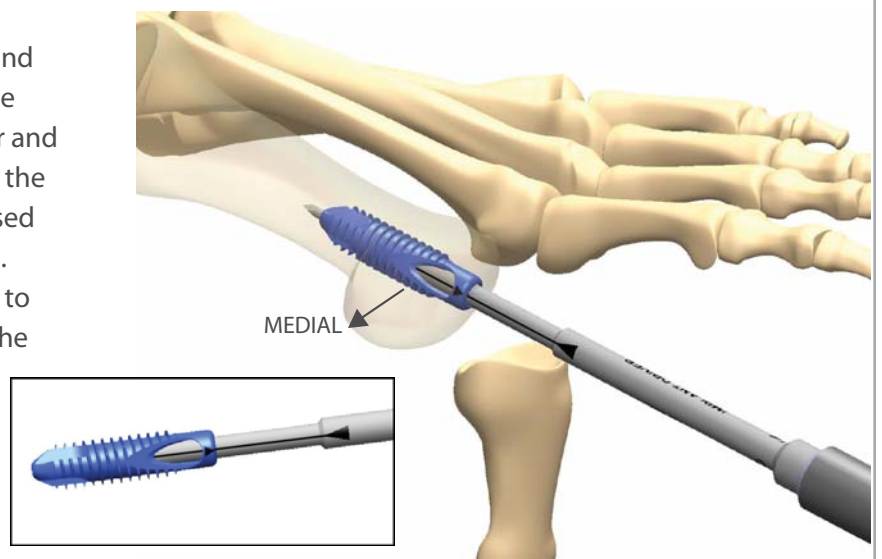
Select the pilot drill diameter (\varnothing) based on the metatarsal implant size selected (pre-operative x-ray templates are available to size implants) and place the cannulated drill over the guidewire. Advance the drill to the appropriate depth (laser marks on the drill indicate depth in 10mm increments) and remove the drill leaving the guidewire in place. The metatarsal implants are offered in lengths of 30mm and 45mm.

Metatarsal Implant	Pilot Drill \varnothing
Small	\varnothing 4.5mm
Medium	\varnothing 6.0mm
Large	\varnothing 6.0mm



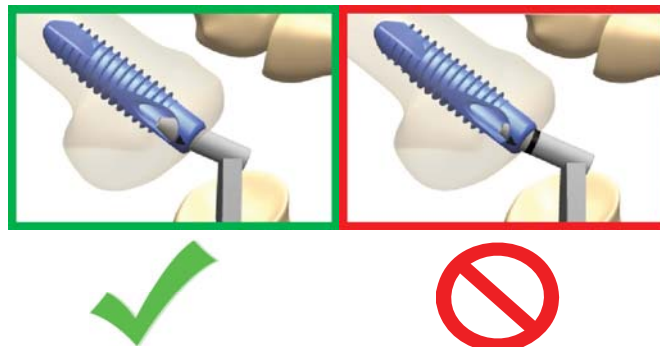
STEP 4 - Metatarsal Implant Alignment

Select the appropriate metatarsal implant and align the implant to the screwdriver with the laser marked arrows aligning on both driver and implant. Insert the metatarsal implant until the entire implant is flush with or slightly recessed below the cut surface of the first metatarsal. Position the implant so the indicator points to the medial side of the metatarsal. Remove the driver and wire.



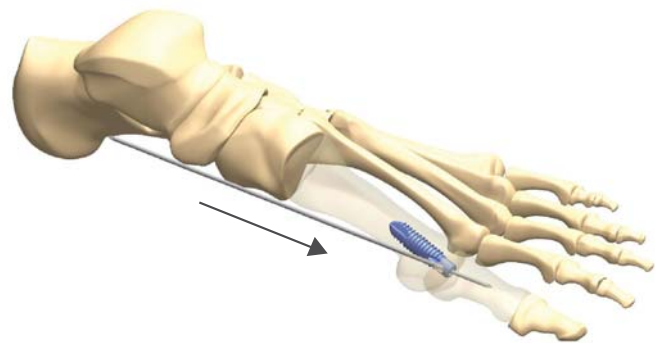
STEP 5 – Alignment Guide Placement

Seat the metatarsal alignment guide into the metatarsal implant (the depth marking should not be visible when properly seated). Advance the double-ended guidewire through the guide and out through the cortex of the metatarsal.



STEP 6 - Phalangeal Guidewire Placement

Place the guidewire completely through the guide and medial cortex. Remove the guide and advance the guidewire until the joint can be reduced. Select the desired position of the phalanx and advance the guidewire across the metatarsophalangeal joint into the lateral cortex of the phalanx. Fluoroscopy is recommended to verify accurate placement of the guidewire in both AP and Lateral views.

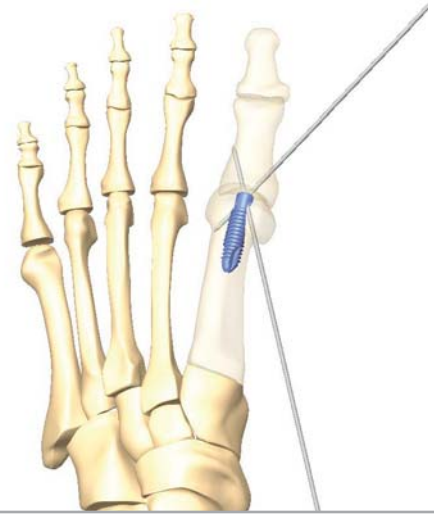


Note: To reposition the screw trajectory, remove the guidewire and rotate the metatarsal implant. At this time, you may also adjust the positioning of the phalanx to modify the final resting position of the guidewire. Repeat the above steps to reposition the guidewire.

NOTE: Angling the Metatarsal Implant in the metatarsal affects the trajectory of the lag screw. Consideration of the Metatarsal Implant to metatarsal angle should be given to ensure optimal lag screw length. It is desired to have longer lag screw reach into the phalanx.

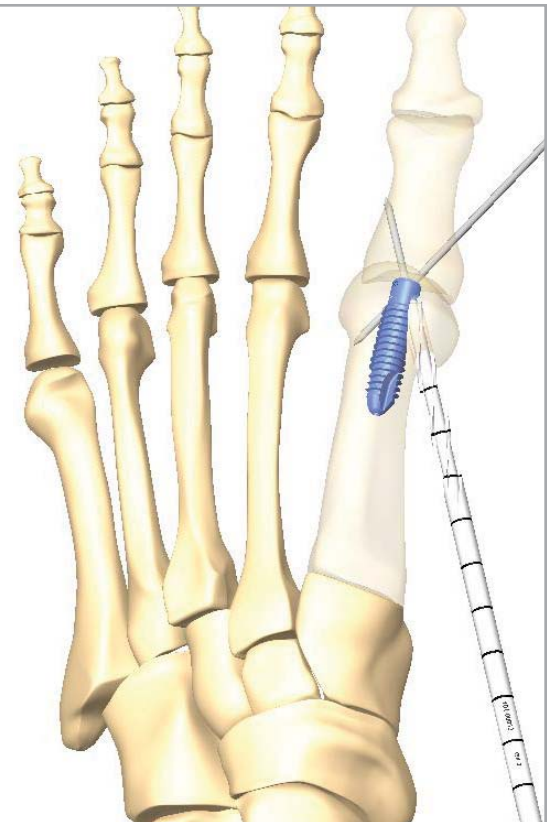
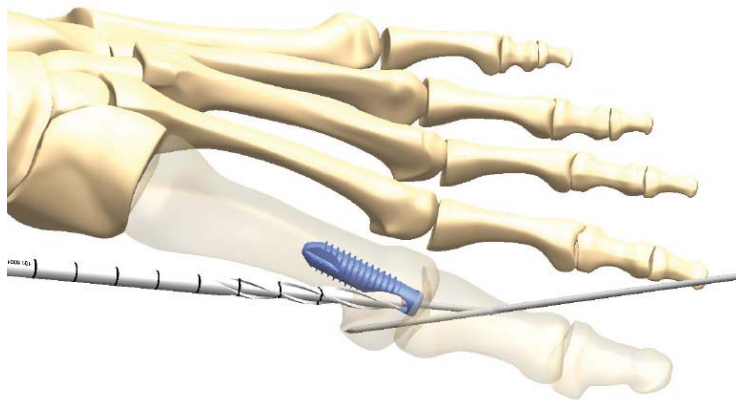
STEP 7 – Provisional Pin

Advance a Ø1.6mm guidewire across the metatarsophalangeal joint from the medial side of the proximal phalanx to the lateral side of the metatarsal taking care to position the guidewire so that the wire will not impede the drill and implant.



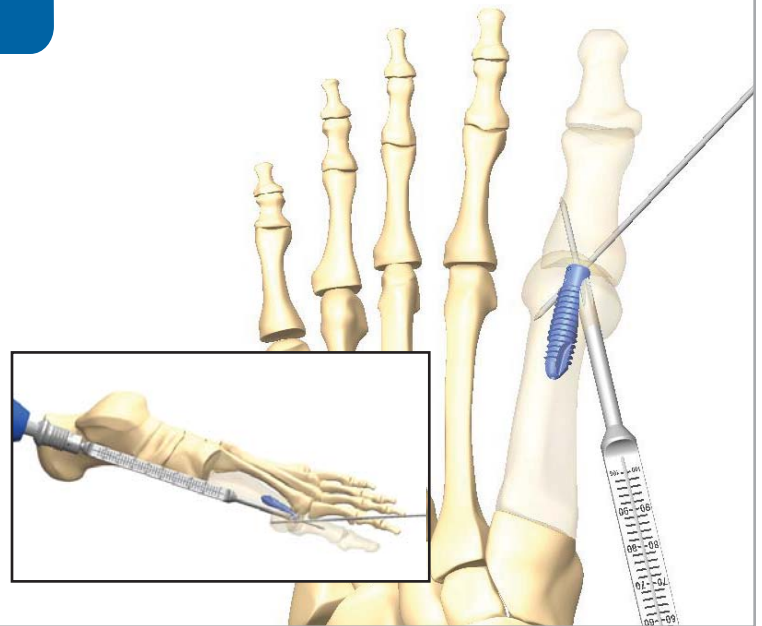
STEP 8 - Medial Window

Create a medial window in the metatarsal cortex. The drill should be advanced through the cortical shell which may be felt by a release in pressure as the drill passes through the cortex. Care should be taken to follow the exact trajectory of the guidewire.



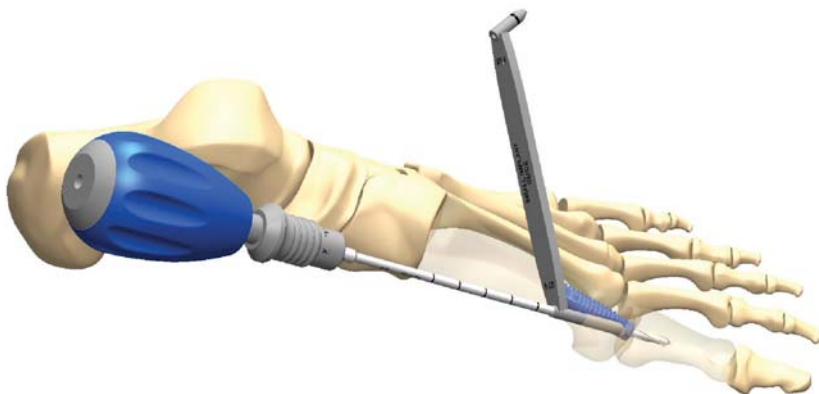
STEP 9 – Depth Measurement

Advance the lag screw depth gauge over the guidewire and into the metatarsal implant. The gauge must be fully seated in the metatarsal implant in order to read accurately. Fluoroscopy is required to verify correct seating of the depth gauge. In the event the depth gauge is not fully seated, remove the depth gauge and advance the $\text{\O}4.5$ drill further. After measuring, advance the guidewire through the lateral cortex and grip with a clamp to prevent premature removal. In the event that a solid screw is selected remove the guide wire and advance the appropriate sized screw.



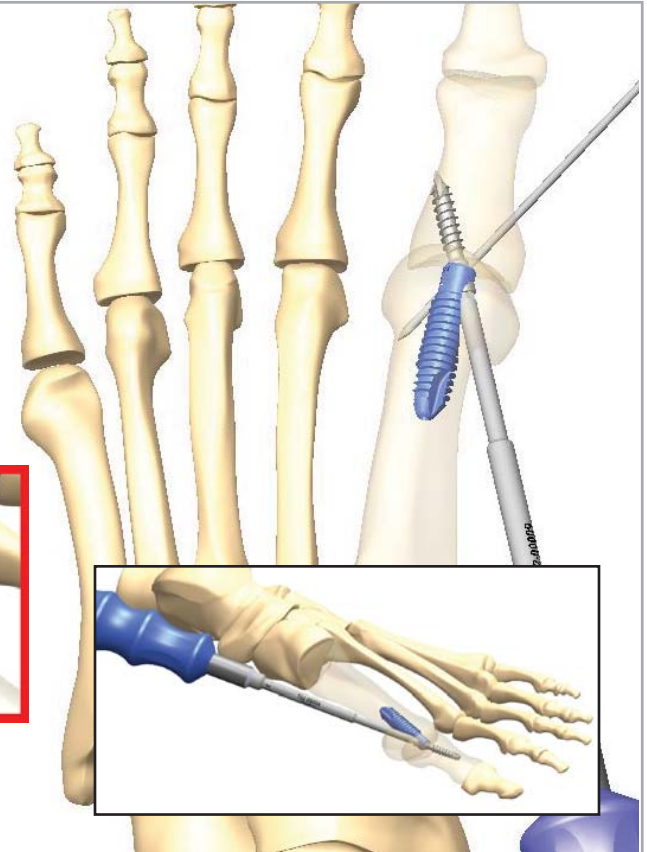
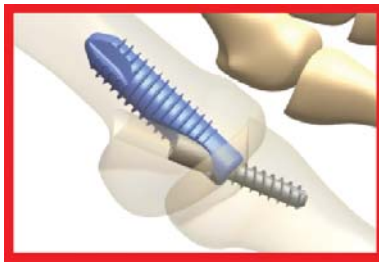
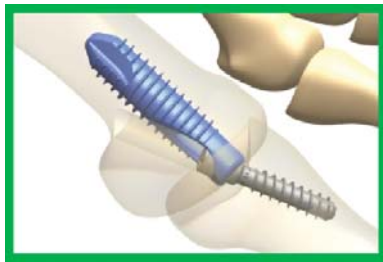
STEP 10 – Pilot Drill

Place the drill guide through the dorsal window and metatarsal implant. Select the $\text{\O}3.0$ cannulated drill and drill to the lateral cortex of the phalanx.



STEP 11 – Lag Screw

Place the correctly sized lag screw over the guidewire and advance the lag screw until fully seated in the metatarsal implant. An increase in torque and a hard stop will indicate successful locking of the implants. Fluoroscopy is advised to confirm proper alignment and seating of the implants. In the event that initial screw placement is unsatisfactory, consider repositioning the metatarsal implant, re-drilling, and inserting the distal implant so that it exits in a different direction. Remove the provisional pin.

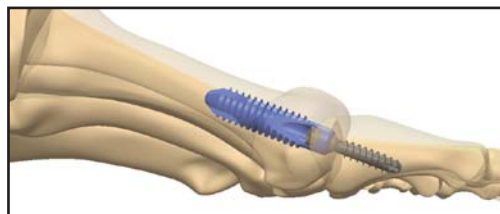


STEP 12 - Closure

Surgical closure is then performed in a normal fashion.

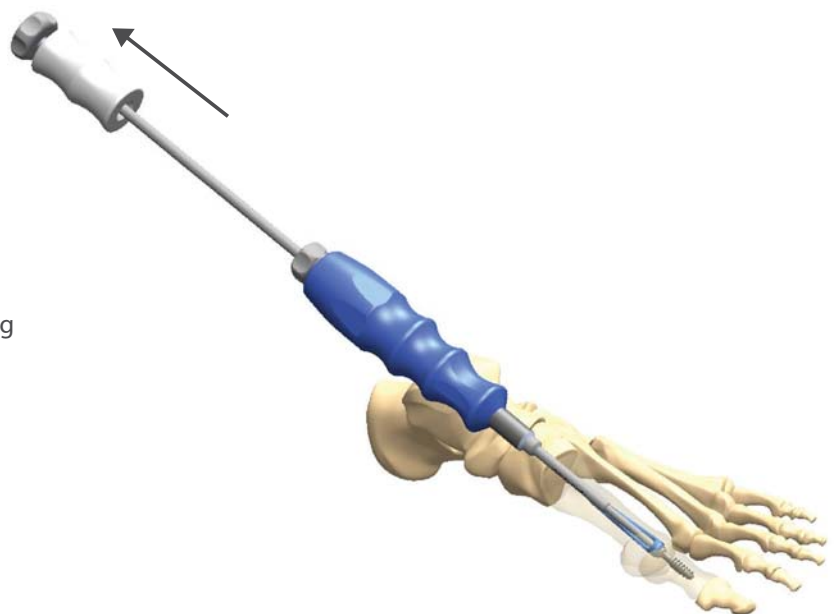
Postoperative Treatment

A standard postoperative protocol should be followed including limited initial load bearing.

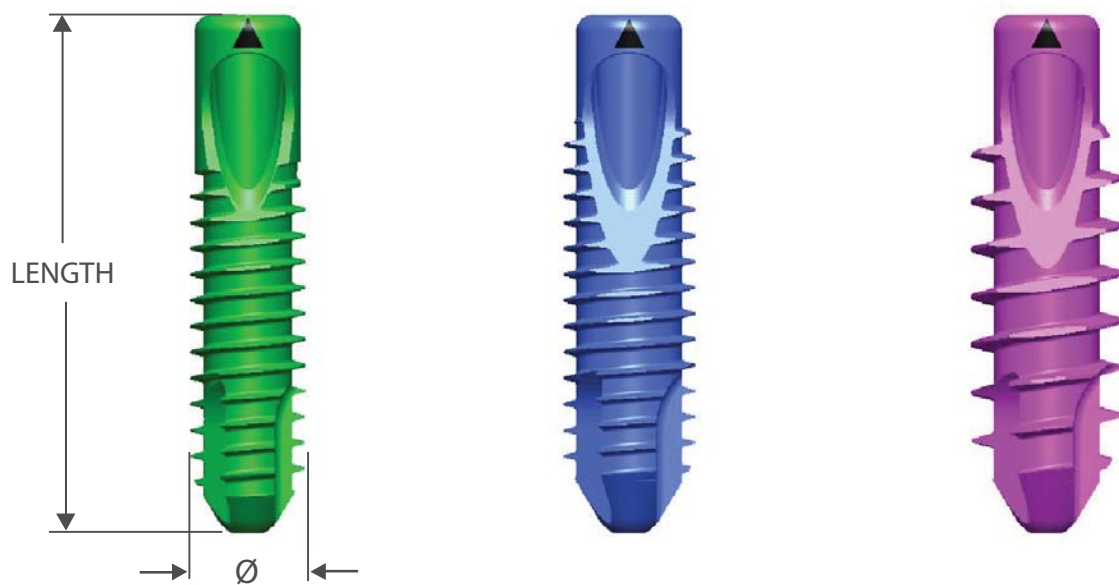


Screw Removal

Remove tissue in-growth from the medial cortex and proximal implant hex recess. Attach the screwdriver to the phalangeal Implant and engage the screw removal tool with both the implant and screwdriver. Unscrew the distal screw counterclockwise a half turn and attach the built in slap hammer and apply slight pressure to disengage the locking mechanism. Continue turning the screwdriver counterclockwise until the entire lag screw is removed. The metatarsal implant can be removed by exposing the MTP joint and clearing all tissue in-growth from the hex recess. Use the the implant driver to remove the metatarsal implant

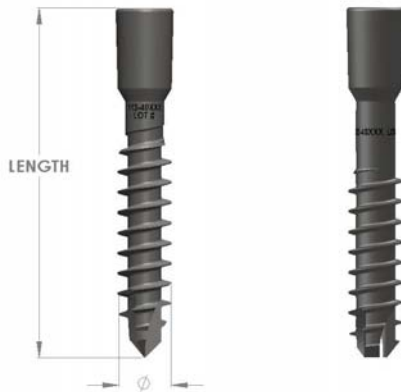


METATARSAL IMPLANTS



Catalog Number	Description
113-12530	Small Metatarsal Implant - 6.5mm x 30 mm
113-12545	Small Metatarsal Implant - 6.5mm x 45 mm
113-22530	Medium Metatarsal Implant - 7.5mm x 30 mm
113-22545	Medium Metatarsal Implant - 7.5mm x 45 mm
113-32530	Large Metatarsal Implant - 8.5mm x 30 mm
113-32545	Large Metatarsal Implant - 8.5mm x 45 mm

LAG SCREWS



Catalog#	Description
102-40016	Small Lag Screw - 4.0mm x 16 mm
102-40018	Small Lag Screw - 4.0mm x 18 mm
102-40020	Small Lag Screw - 4.0mm x 20 mm
102-40022	Small Lag Screw - 4.0mm x 22 mm
102-40024	Small Lag Screw - 4.0mm x 24 mm
102-40026	Small Lag Screw - 4.0mm x 26 mm
102-40028	Small Lag Screw - 4.0mm x 28 mm
102-40030	Small Lag Screw - 4.0mm x 30 mm
102-40032	Small Lag Screw - 4.0mm x 32 mm
102-40034	Small Lag Screw - 4.0mm x 34 mm
102-40036	Small Lag Screw - 4.0mm x 36 mm
113-40016	Small Lag Screw (Solid) 4.0mm x 16mm
113-40018	Small Lag Screw (Solid) 4.0mm x 18mm
113-40020	Small Lag Screw (Solid) 4.0mm x 20mm
113-40022	Small Lag Screw (Solid) 4.0mm x 22mm
113-40024	Small Lag Screw (Solid) 4.0mm x 24mm
113-40026	Small Lag Screw (Solid) 4.0mm x 26mm
113-40028	Small Lag Screw (Solid) 4.0mm x 28mm
113-40030	Small Lag Screw (Solid) 4.0mm x 30mm
113-40032	Small Lag Screw (Solid) 4.0mm x 32mm
113-40034	Small Lag Screw (Solid) 4.0mm x 34mm
113-40036	Small Lag Screw (Solid) 4.0mm x 36mm

DISPOSABLE INSTRUMENT CATALOG NUMBERS

Catalog #	Description
101-00013	Cannulated Drill - 4.5 mm
101-00023	Cleaning Brush - 1.6 mm
102-00002	Cannulated Drill - 3.0 mm
102-00018	Cannulated Drill - 6.0 mm
102-00023	Double-Ended Guidewire - 1.6 mm
113-00002	Hallu.X X-Ray Template

RE-USABLE INSTRUMENT CATALOG NUMBERS

Catalog#	Description
101-00009	Guidewire Holder - 1.6 mm
102-00003	Small Implant Guide
102-00009	Screwdriver
102-00017	AO Quick Connect Handle
102-00020	Removal Screwdriver
102-00021	Removal Tool
102-00022	Slap Hammer
102-00038	4.5/6.5mm Tissue Protector
113-00000	Hallu.X Instrument Tray
113-00001	Hallu.X Implant Caddie
113-00004	Lag Screw Depth Gauge
113-00114	Cone Spherical Rasp - 14 mm
113-00116	Cone Spherical Rasp - 16 mm
113-00118	Cone Spherical Rasp - 18 mm
113-00120	Cone Spherical Rasp - 20 mm
113-00214	Cup Spherical Rasp - 14 mm
113-00216	Cup Spherical Rasp - 16 mm
113-00218	Cup Spherical Rasp - 18 mm
113-00220	Cup Spherical Rasp - 20 mm