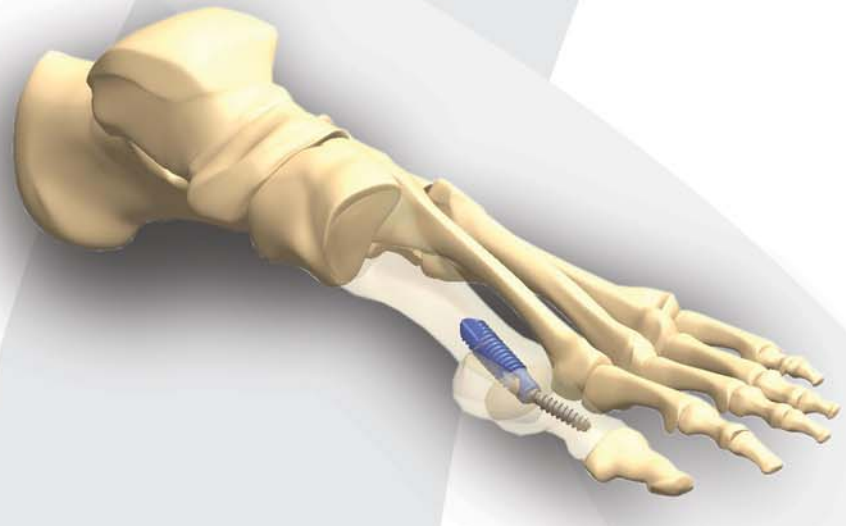
HALLUX™
INTRAMEDULLARY
FUSION DEVICE

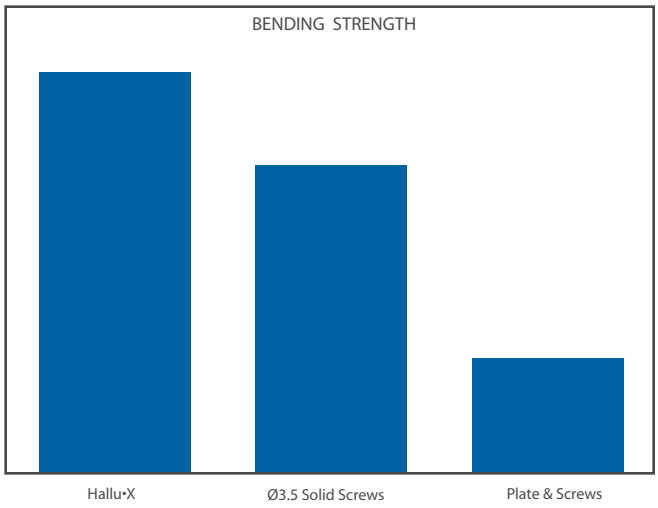
Surgical Technique



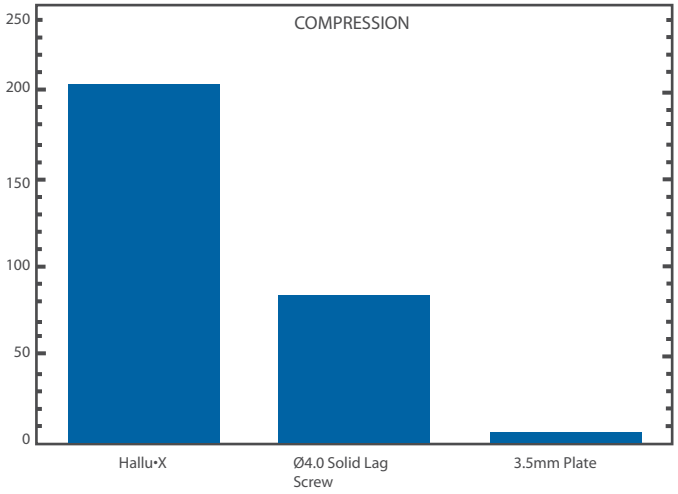
- Stable intramedullary fixation
- Implant compresses across joint
- Avoid hardware complications from tissue irritation caused by plates and screws
- Advanced instrumentation can reduce procedure time
- Avoids the need to bend plates or hardware
- Allows positioning of the phalanx to accommodate different 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 to Ø4.0 screw construct
45X more delivered compression than plate and screw construct

HALLU·X
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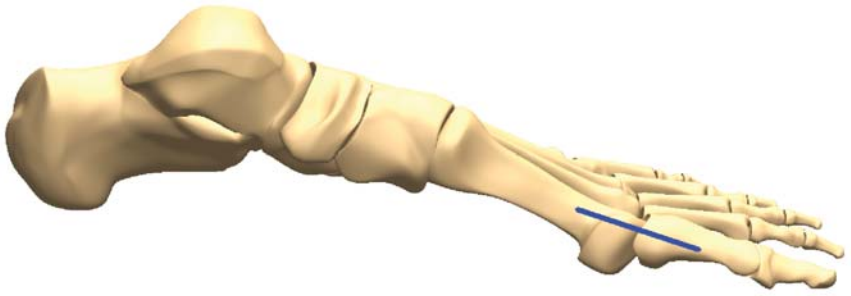
INDICATIONS FOR USE

The Extremity Medical Hallu•X Intramedullary Fusion Device is intended for fixation arthrodesis of the metatarsal-phalangeal joint.

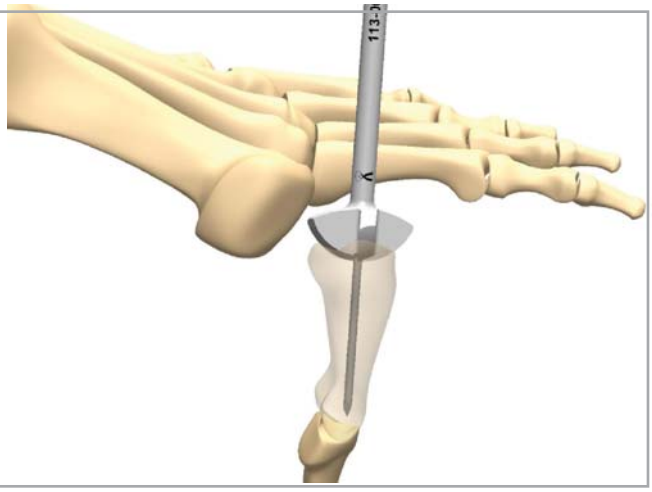
STEP 1 - Exposure

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



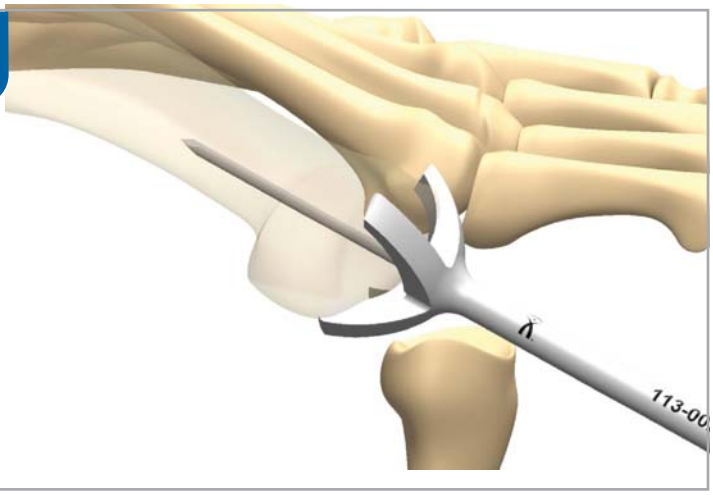
STEP 2a - Phalanx Preparation

Insert the Ø1.6mm guidewire in the center of a 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.

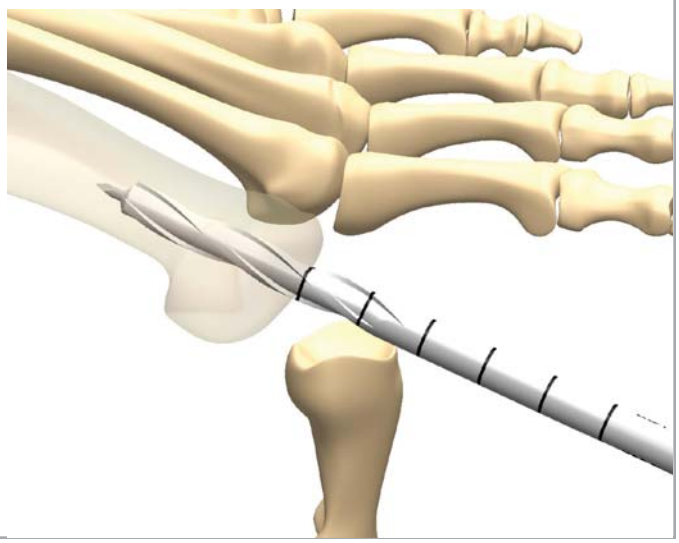


STEP 3 - Drill

Select the pilot drill diameter (Ø) 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.

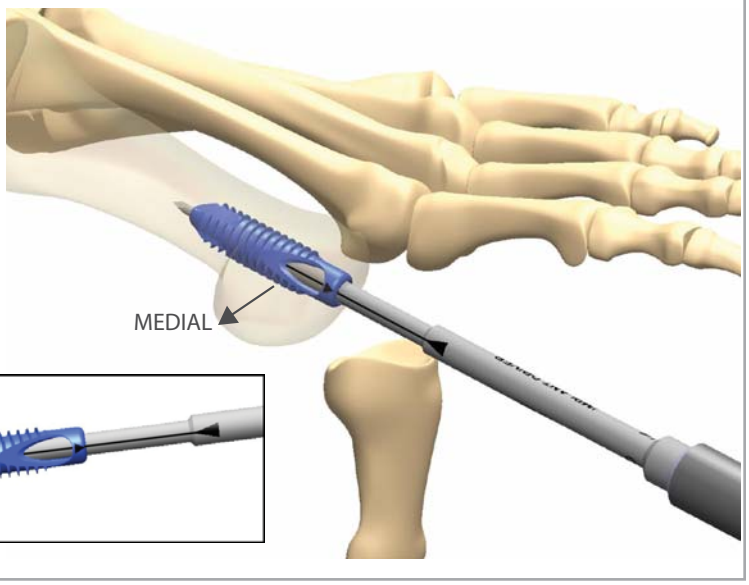
Metatarsal Implant	Pilot Drill Ø
Small	Ø4.5mm*
Medium	Ø6.0mm+
Large	Ø6.0mm+

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



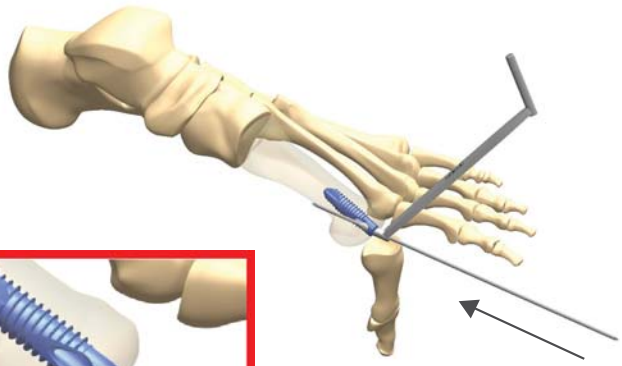
STEP 4 - Metatarsal Implant Alignment

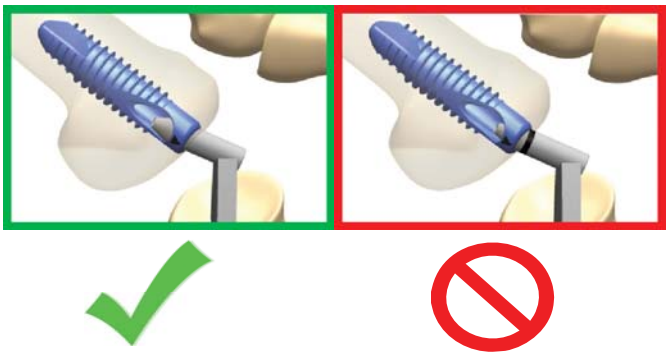
Select the appropriate metatarsal implant and align the implant to the screwdriver with the laser marked arrows aligning on both driver and implant. Insert the metatarsal implant until the entire implant is flush with or slightly recessed below the cut surface of the first metatarsal. Position the implant 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 visable when properly seated). Advance the double-ended guidewire through the guide and out through the cortex of the metatarsal.

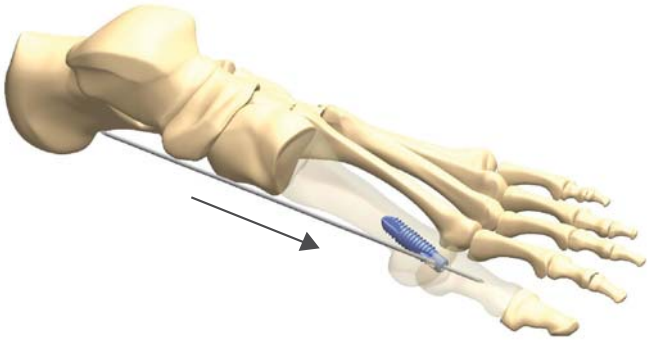




STEP 6 - Phalangeal Guidewire Placement

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 metatarsal-phalangeal joint into the lateral cortex of the phalanx. Fluoroscopy is recommended to verify accurate placement of the guidewire.

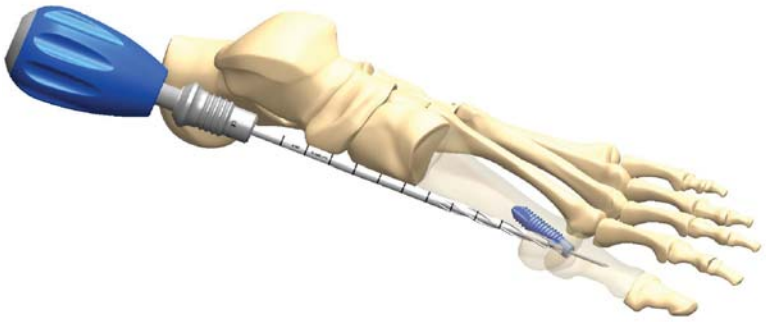
Note: To reposition the screw trajectory, remove the guidewire and rotate the metatarsal implant. At this time, you may also adjust the positioning of the phalanx to modify the final resting position of the guidewire. Repeat the above steps to reposition the guidewire.



STEP 7a – Medial Window

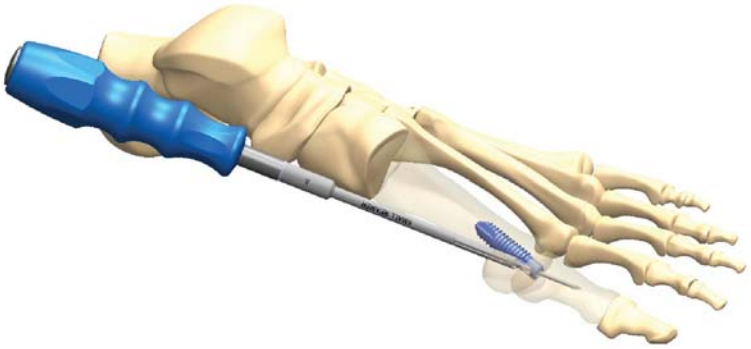
Create a medial window in the metatarsal cortex by manually drilling using the Ø4.5 cannulated drill or the dorsal reamer. The drill or reamer should be advanced far enough to remove the cortical shell, but not contact the metatarsal implant.

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.



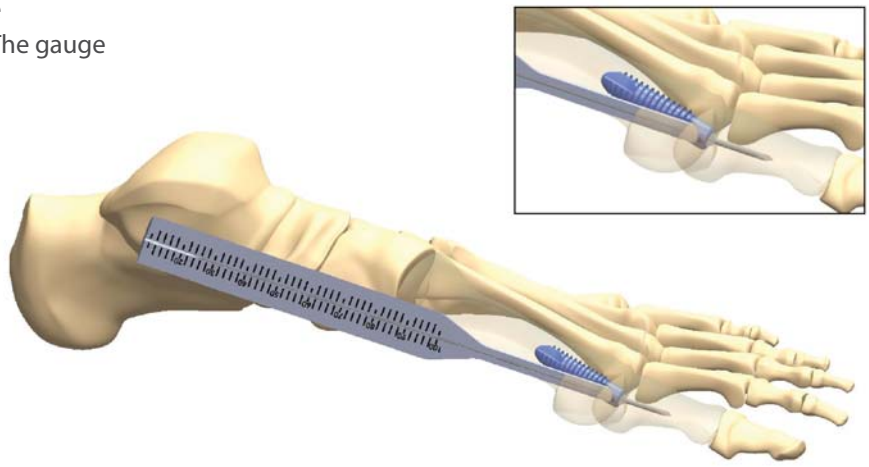
STEP 7b - Medial Window (Dorsal Reamer) - Optional

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 medial 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.



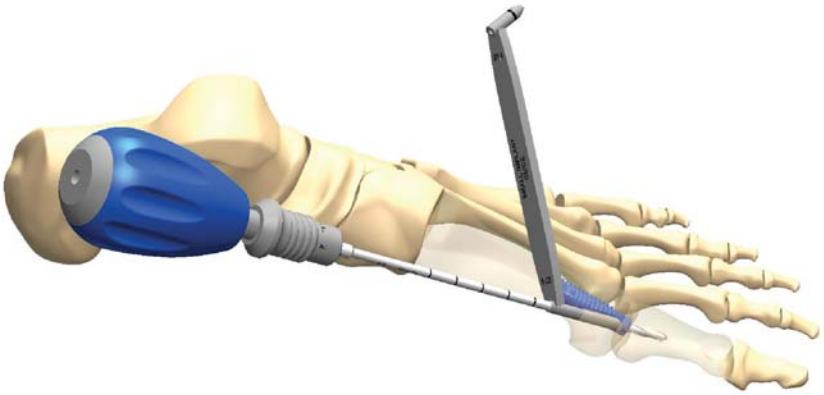
STEP 8 – Depth Measurement

Advance the lag screw depth gauge over the guidewire and into the metatarsal implant. The gauge must be fully seated to read accurately.



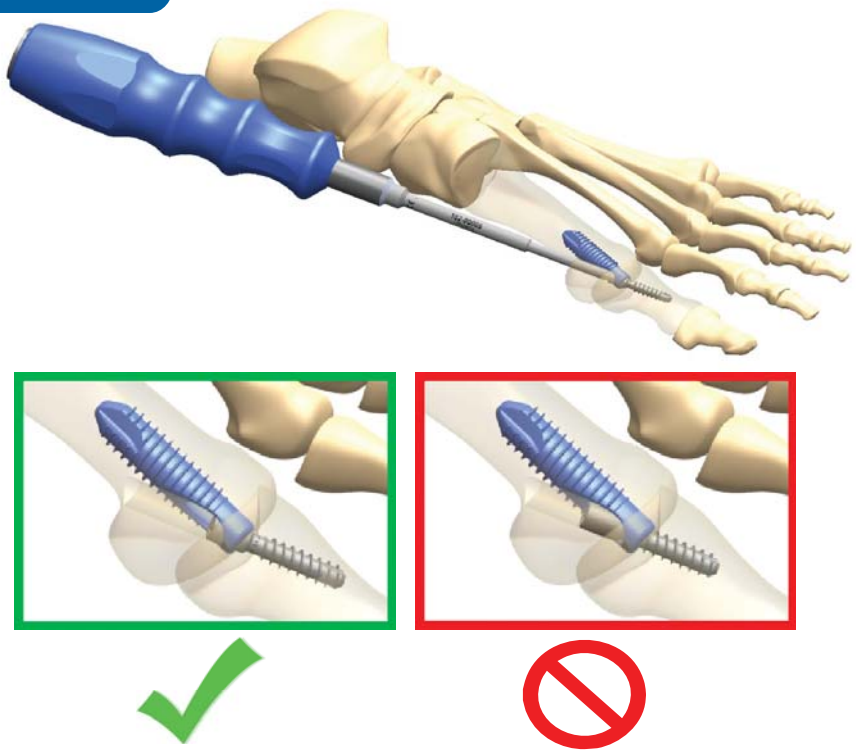
STEP 9 –Drill

Place the drill guide through the dorsal window and metatarsal implant. Select the Ø3.0 cannulated drill and drill to the lateral cortex of the phalanx.



STEP 10 – 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.



STEP 11 - Closure

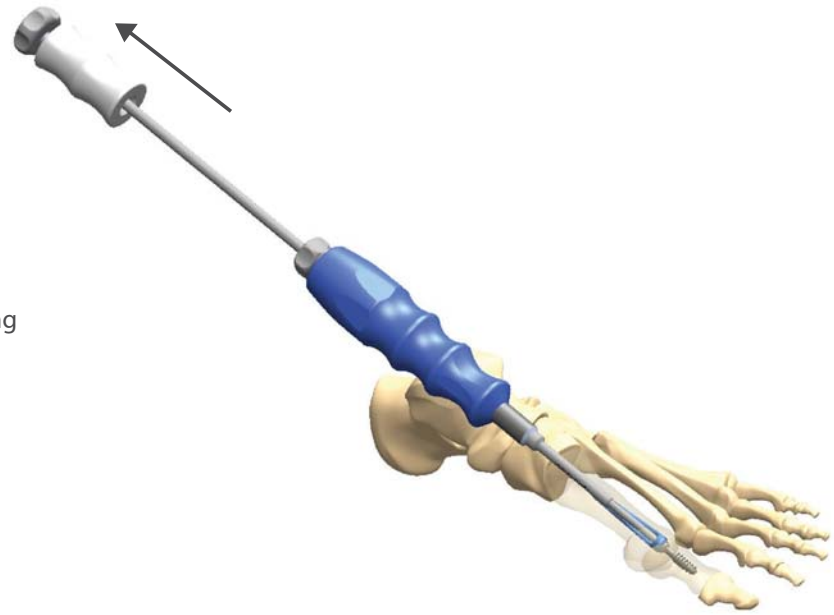
Surgical closure is then performed in a normal fashion.

Postoperative Treatment

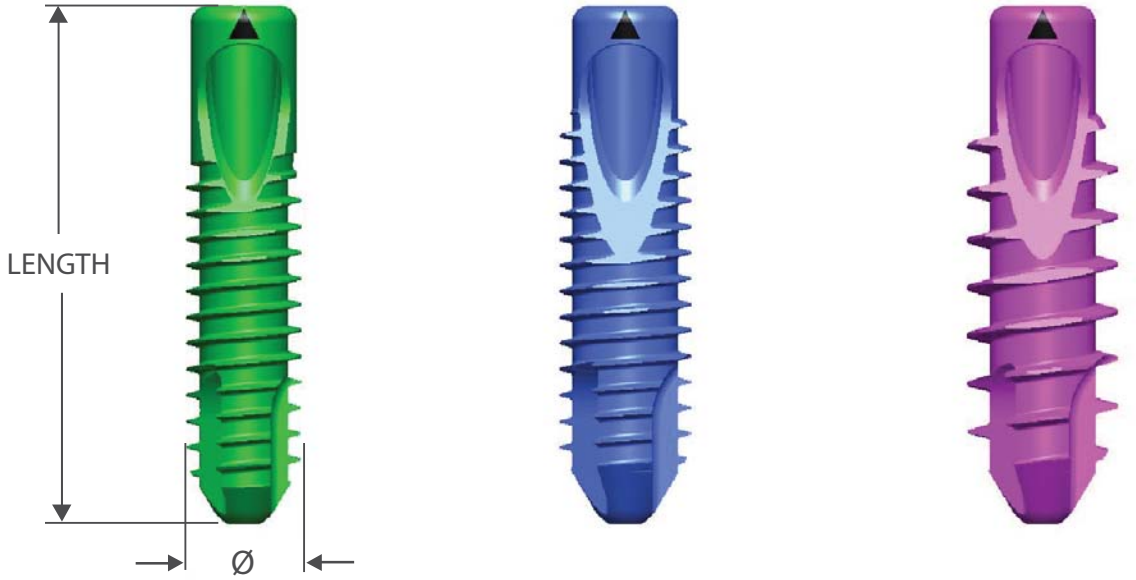
A standard postoperative protocol should be followed including limited initial load bearing.

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 proximal screw is removed. The proximal implant can be removed by exposing the MTP joint and clearing all tissue in-growth from the hex recess. Attach the removal driver and removal tool and turn counterclockwise until the entire proximal implant is removed.

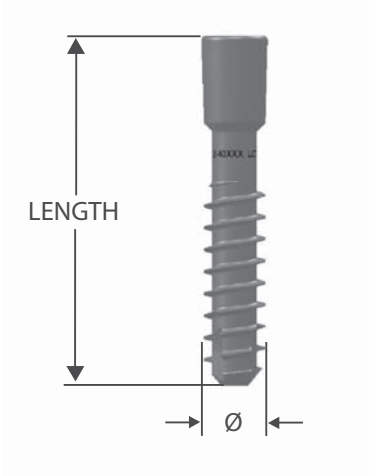


METATARSAL IMPLANTS



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	Lag Screw - 4.0mm x 16 mm
102-40018	Lag Screw - 4.0mm x 18 mm
102-40020	Lag Screw - 4.0mm x 20 mm
102-40022	Lag Screw - 4.0mm x 22 mm
102-40024	Lag Screw - 4.0mm x 24 mm
102-40026	Lag Screw - 4.0mm x 26 mm
102-40028	Lag Screw - 4.0mm x 28 mm
102-40030	Lag Screw - 4.0mm x 30 mm
102-40032	Lag Screw - 4.0mm x 32 mm
102-40034	Lag Screw - 4.0mm x 34 mm
102-40036	Lag Screw - 4.0mm x 36 mm

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
102-00006	Small Dorsal Reamer
102-00009	Screwdriver
102-00017	AO Quick Connect Handle
102-00020	Removal Screwdriver
102-00021	Removal Tool
102-00022	Slap Hammer
113-00000	Hallu•X Instrument Tray
113-00001	Hallu•X Implant Caddie
113-00003	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