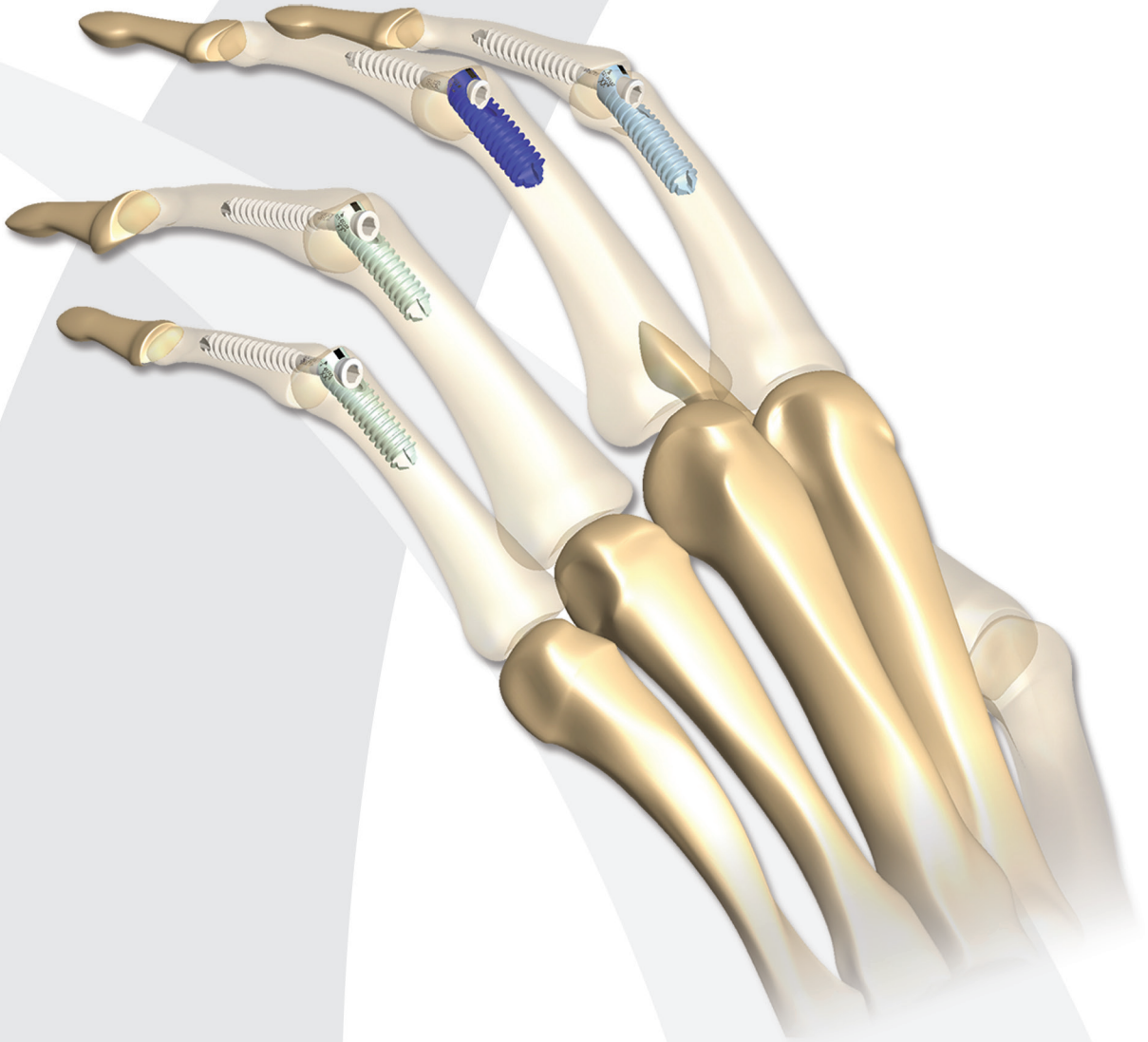
APEX™

IP FUSION DEVICE

Surgical Technique



Patent and Patent Pending

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

EXTREMITY MEDICAL™

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IP FUSION DEVICE
Surgical Technique

INDICATIONS FOR USE

The APEX IP Fusion Device is intended for reduction and internal fixation of arthrodesis of the interphalangeal joints of the hand.

Pre-Operative Planning - Templating

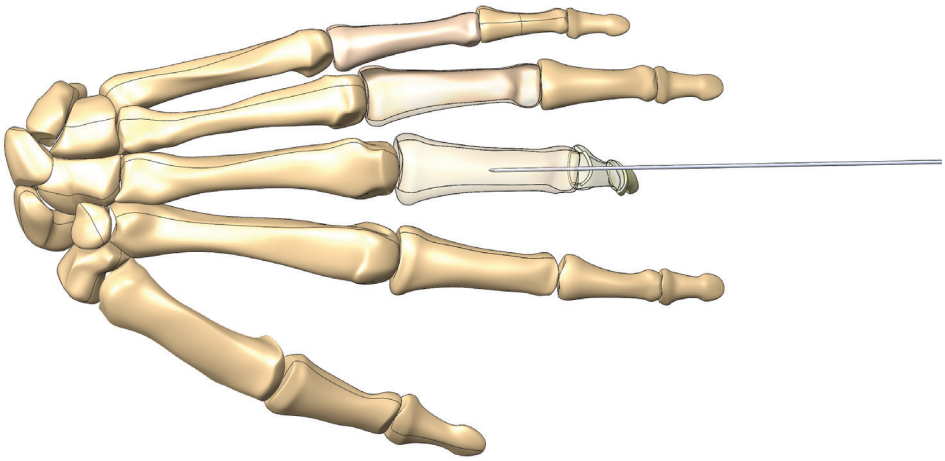
The APEX IP Fusion Device System provides several Post sizes and angles. Use the X-ray template to determine the optimal size, angle, and position of the construct for the intended application.

STEP 1 - Exposure & Joint Preparation

A dorsal longitudinal incision is made over the PIP joint, extending from the mid-proximal phalanx to the mid middle phalanx. The extensor tendon is incised longitudinally in its midline over the entire length of the skin incision. Each half of the tendon is reflected laterally during which its insertion on the middle phalanx is released. Flex the PIP joint to expose the joint surfaces of the proximal and middle phalanges.

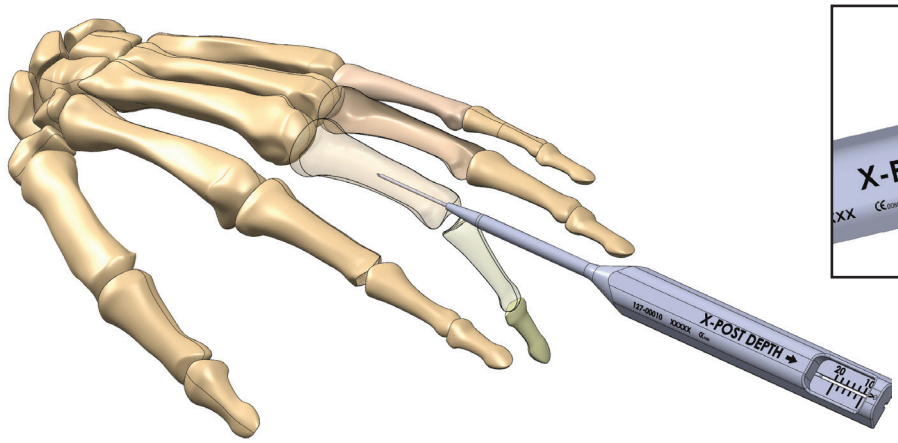
STEP 2 - Initial Guidewire

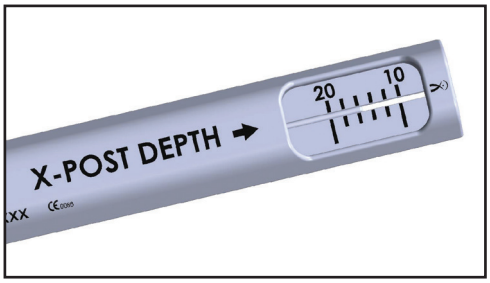
Insert a Ø0.9mm Guidewire into the canal of the proximal phalanx and confirm its central location in the canal using fluoroscopy.



STEP 3 - Post Depth Measurement

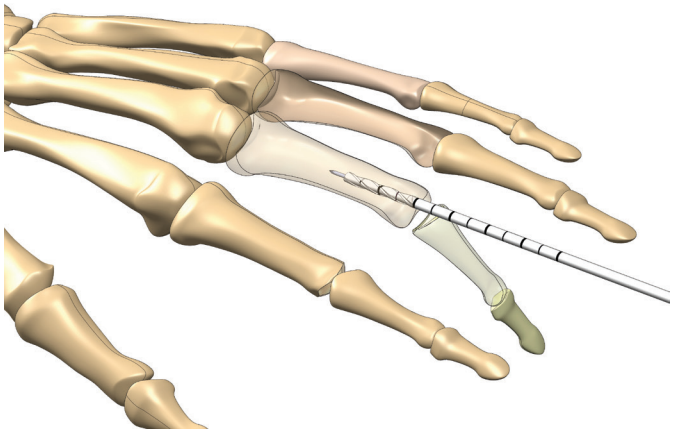
Slide the depth gauge over the Post guidewire until flush with the joint surface to measure the length of the Post. Ensure the reading is made from the side of the guide labeled "X-Post™ Depth."





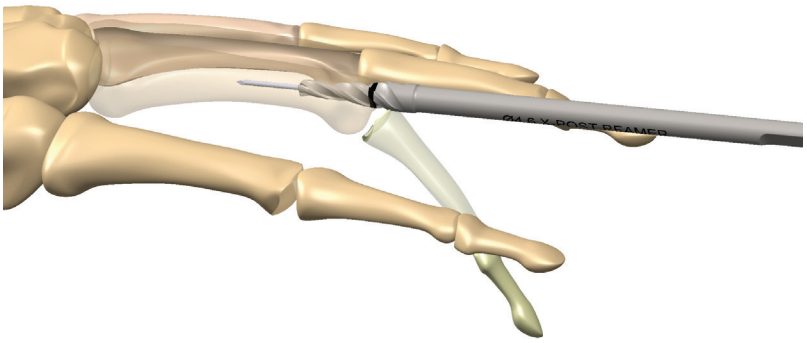
STEP 4 - Preparation for Post: Pilot Drill

Drill utilizing the 2.7mm cannulated drill to the measured depth. The 2.7 drill side of the Short Tapered Guide may be used to protect the adjacent soft tissues.



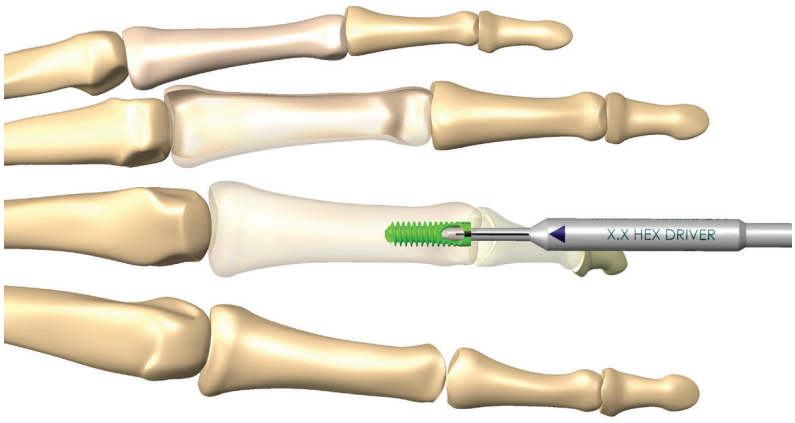
STEP 5 – Preparation for Post: Reaming

Place the cannulated X-Post™ Reamer over the Guidewire and advance by hand until the depth line (bold laser mark) is buried approximately 1-2 mm beneath the joint surface.



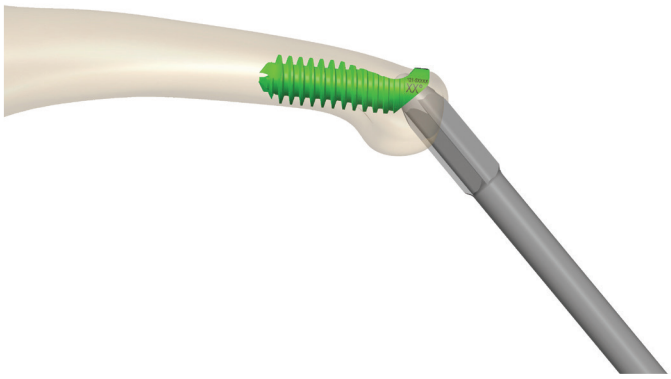
STEP 6 - Post Insertion

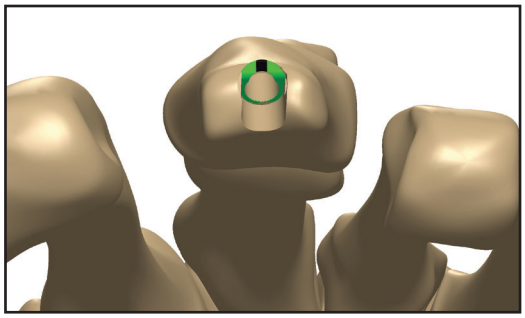
Select the proper Post and align the bold laser mark on the implant with the laser line and arrow on the 2.0 mm Hex Driver. Using the Hex Driver, insert the Post until its dorsal rim is sunk 1-2mm below the dorsal cortical rim of the phalanx, and align the laser line and arrow with the dorsal aspect of the finger to ensure proper rotation for the arthrodesis.

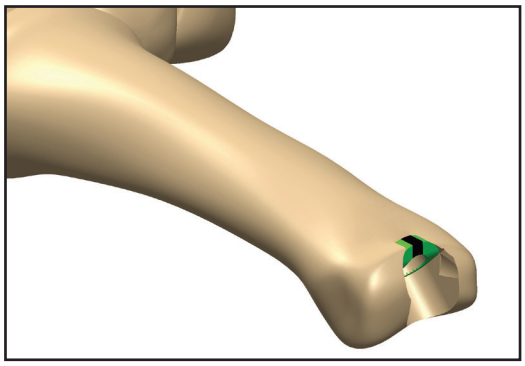


STEP 7 - Clear the Volar Aspect of the Proximal Phalanx Using the Clearing Tool

Remove the bone from the volar aspect of the proximal phalanx to allow for the X-Post™ Clearing Tool to seat properly. This step can be completed with the Clearing Tool as depicted below, or alternatively with a Rongeur.



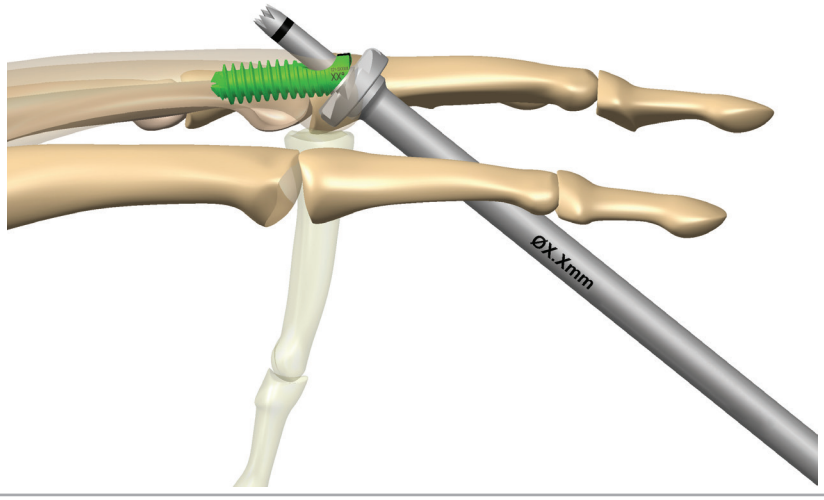




STEP 8a - Joint Preparation & Dorsal Window Creation

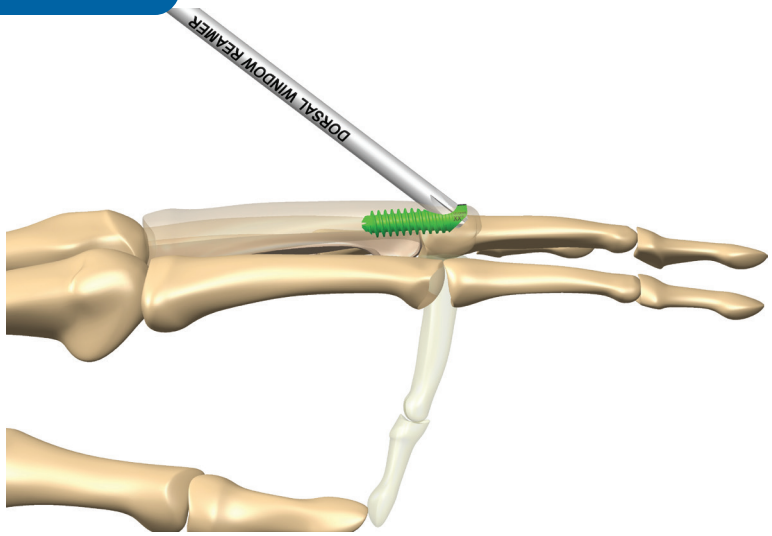
Insert the Proximal Rasp into the eyelet of the Post at the angle matching the selected Post (30 or 45 degrees) and rotate by hand until the stop on the rasp contacts the implant surface. Protect the dorsal soft tissues as the rasp exits the bone dorsally.

Note: Due to the geometry of the implant, the rasp will not appear visually flush with the adjacent surface on the dorsal side of the implant.



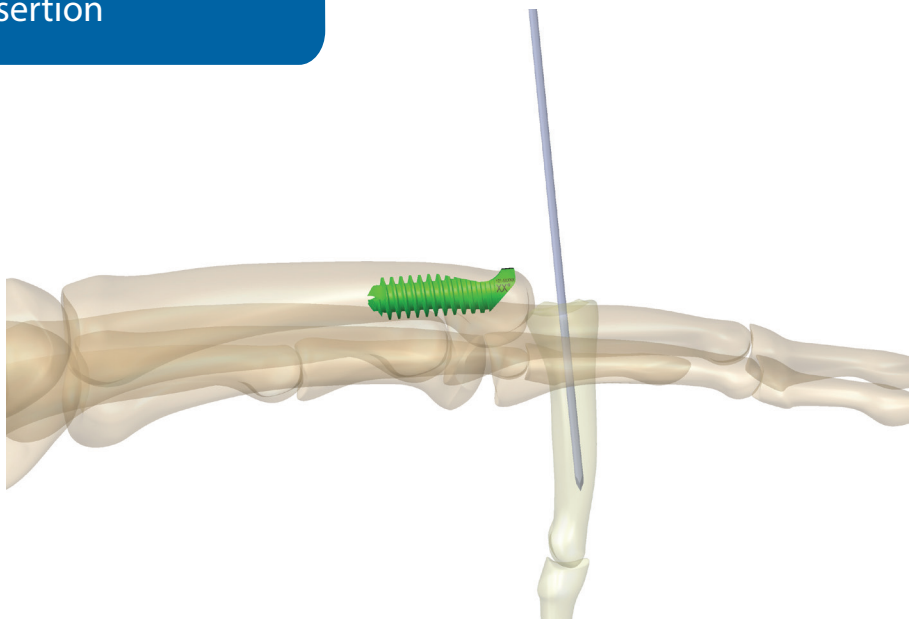
STEP 8b – Dorsal Window Clearing

Insert the Dorsal Window Reamer through the implant. Rotate this reamer manually and advance until the tip comes out of the front side of the implant. This creates space for the head of the screw.



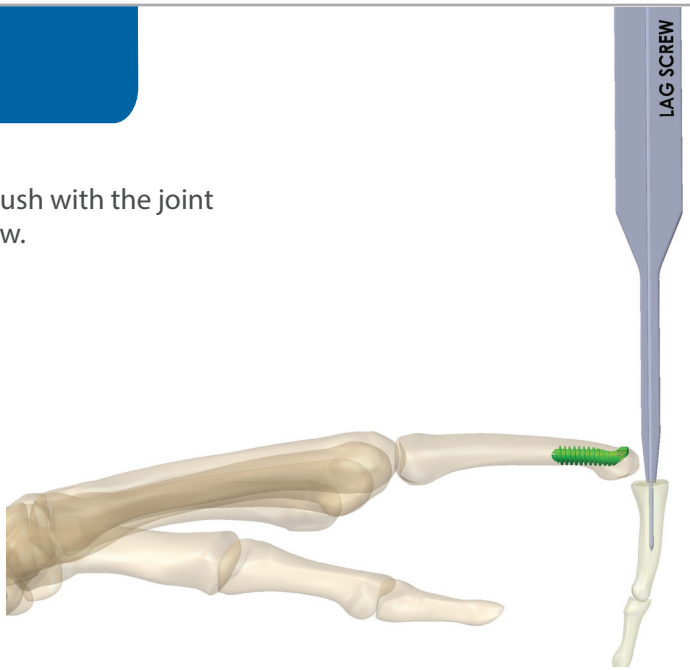
STEP 9 – Guidewire Insertion

Insert another Ø0.9mm Guidewire into the canal of the middle phalanx and verify its central position in the canal with flouroscopy.



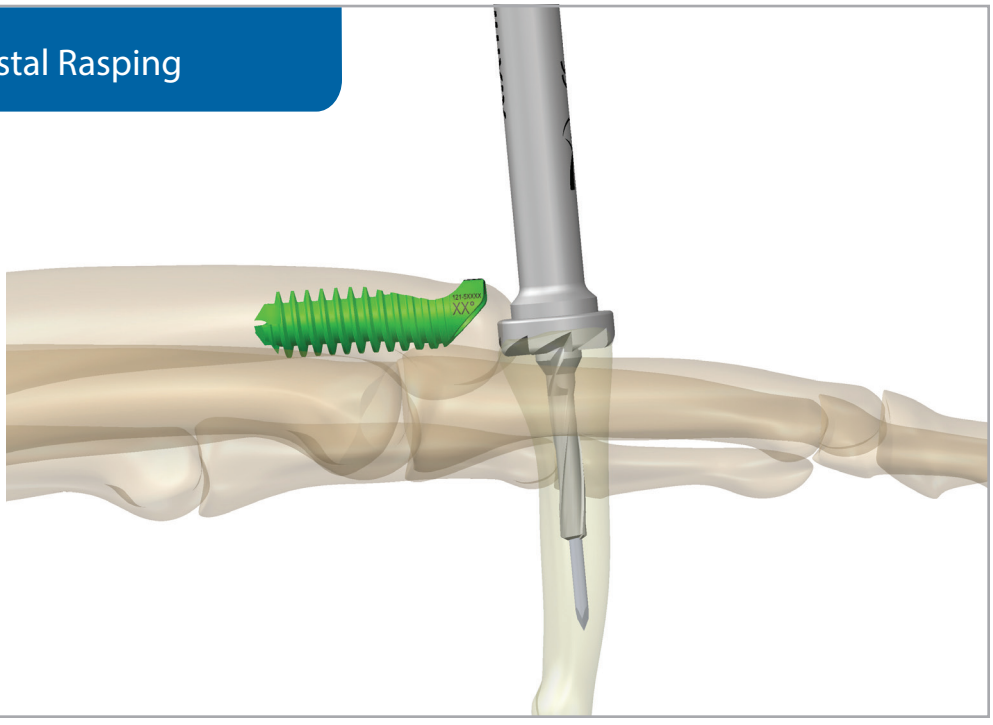
STEP 10 - Lag Screw Depth Measurement

Slide the depth gage over the guidewire until flush with the joint surface to determine the length of the Lag Screw.



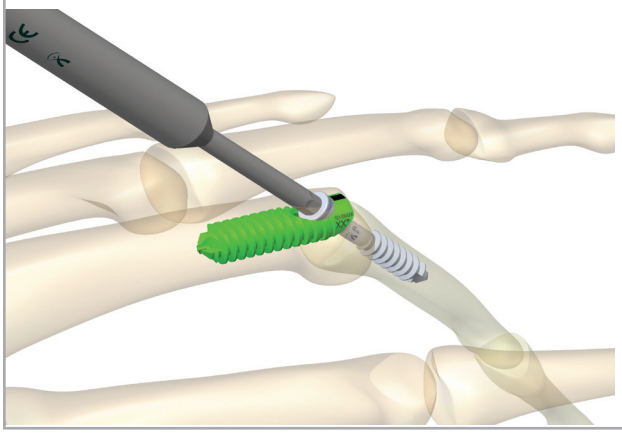
STEP 11 - Pilot & Distal Rasping

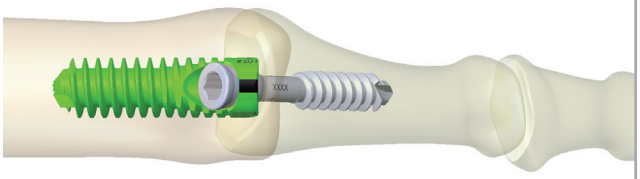
Advance the Distal Rasp over the guidewire and rasp the joint surface until it is flat and metaphyseal bone is exposed.

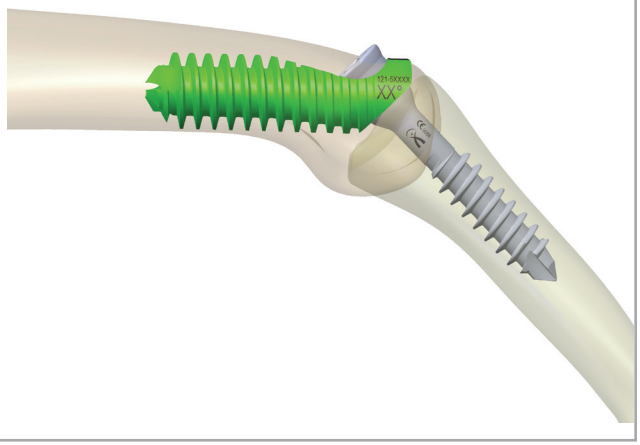


STEP 12 - Insert Lag Screw

Manually compress the joint until the joint surfaces are fully opposed. Maintain this manual compression and provide counter rotation as the lag screw is inserted. Insert the Lag Screw using TWO finger pressure until compression is felt and visualization confirms the Lag Screw is flush against the Post. The Morse Taper engagement should be felt as the Lag Screw becomes engaged in the Post.







POSTOPERATIVE TREATMENT

Subsequent to tendon and skin closure, the finger is immobilized in a padded splint for two weeks postoperatively. Further care follows the standard postoperative protocols for arthrodesis as preferred by the surgeon. Progression of movement and transition out of cast immobilization is individually based depending on bone quality and expected healing rate.

ARTHRODESIS OF THE THUMB INTERPHALANGEAL JOINT

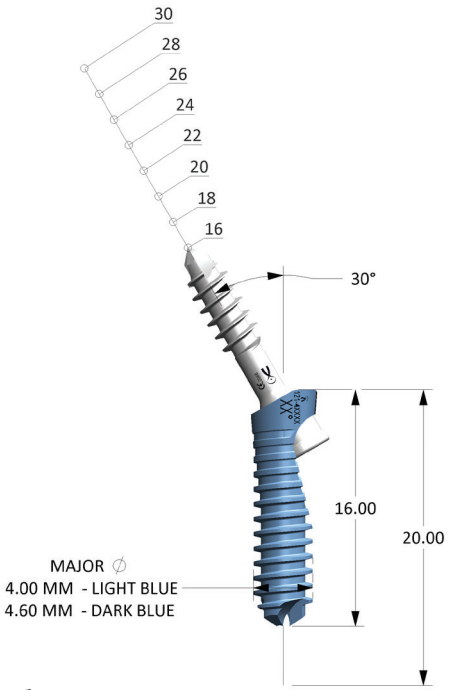
The same basic technique is used when performing an arthrodesis of the thumb IP joint however the distal phalanx of the thumb is often more curved than the middle phalanx of the finger and thus Lag Screw placement must be adjusted accordingly.

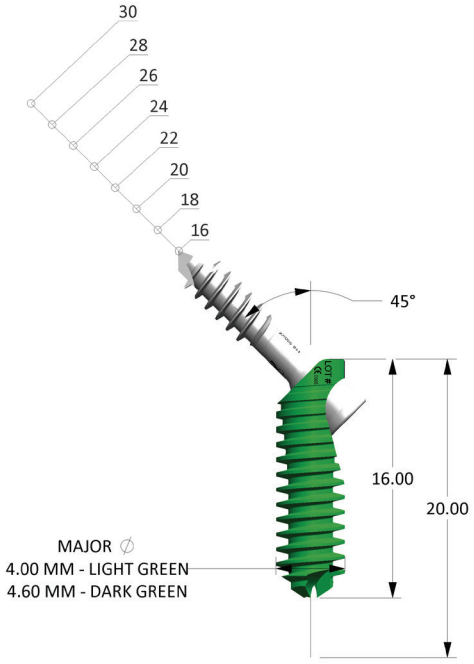
IMPLANT REMOVAL

Remove any tissue ingrowth from the Lag Screw. Insert the driver into Lag Screw and completely remove it. Insert the driver into the Post and remove it by turning counterclockwise.

NOTES:

IMPLANT SPECIFICATIONS



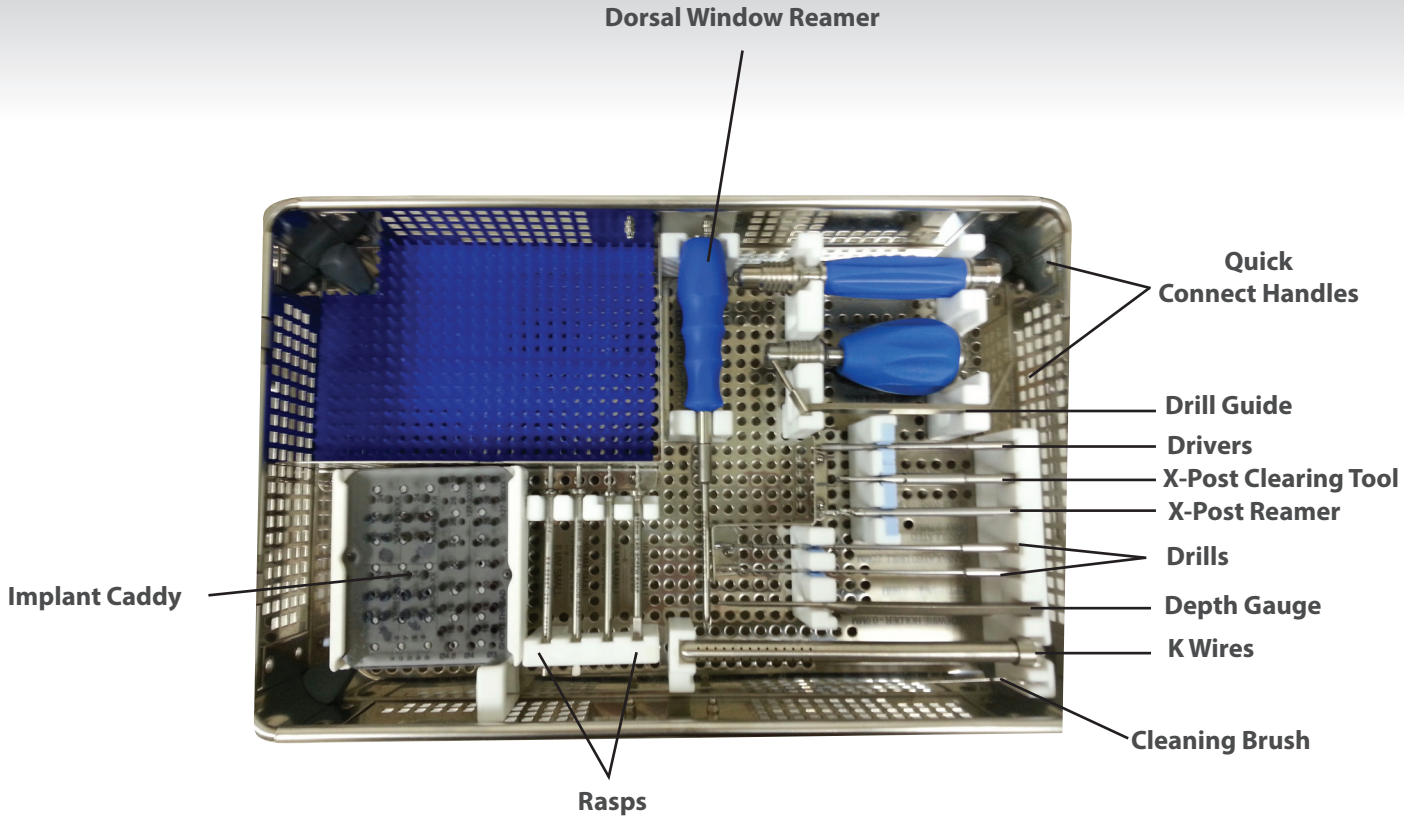


Posts

Green Posts - 45°		
Reference #	Description	Qty
121-44516	Medium PIP Post - 4.0 x 16mm (45 deg)	2
121-44520	Medium PIP Post - 4.0 x 20mm (45 deg)	2
121-54516	Large PIP Post - 4.6 x 16mm (45 deg)	2
121-54520	Large PIP Post - 4.6 x 20mm (45 deg)	2
Blue Posts - 30°		
121-40316	Medium PIP Post - 4.0 x 16mm (30 deg)	2
121-40320	Medium PIP Post - 4.0 x 20mm (30 deg)	2
121-50316	Large PIP Post - 4.6 x 16mm (30 deg)	2
121-50320	Large PIP Post - 4.6 x 20mm (30 deg)	2

Screws

Reference #	Description	Qty
121-30016	Lag Screw (Solid Tapered) 3.0 x 16mm	2
121-30018	Lag Screw (Solid Tapered) 3.0 x 18mm	2
121-30020	Lag Screw (Solid Tapered) 3.0 x 20mm	2
121-30022	Lag Screw (Solid Tapered) 3.0 x 22mm	2
121-30024	Lag Screw (Solid Tapered) 3.0 x 24mm	2
121-30026	Lag Screw (Solid Tapered) 3.0 x 26mm	2
121-30028	Lag Screw (Solid Tapered) 3.0 x 28mm	2
121-30030	Lag Screw (Solid Tapered) 3.0 x 30mm	2
127-30216	Lag Screw (Cannulated Tapered) 3.0 x 16mm	2
127-30218	Lag Screw (Cannulated Tapered) 3.0 x 18mm	2
127-30220	Lag Screw (Cannulated Tapered) 3.0 x 20mm	2
127-30222	Lag Screw (Cannulated Tapered) 3.0 x 22mm	2
127-30224	Lag Screw (Cannulated Tapered) 3.0 x 24mm	2
127-30226	Lag Screw (Cannulated Tapered) 3.0 x 26mm	2
127-30228	Lag Screw (Cannulated Tapered) 3.0 x 28mm	2
127-30230	Lag Screw (Cannulated Tapered) 3.0 x 30mm	2



Instruments

Reference #	Description	Qty
Disposable Instruments		
101-00004	Guidewire - 0.9mm	10
101-00011	Cannulated Drill – 2.0mm	2
101-00022	Cleaning Brush - 0.9mm	1
118-00004	4.6 X-Post Reamer	1
121-00108	8mm Proximal Rasp	1
121-00110	10mm Proximal Rasp	1
121-00208	8mm Distal Rasp	1
121-00210	10mm Distal Rasp	1
121-00007	APEX X-Ray Template	1
127-00027	Cannulated Drill – 2.7mm	2
Re-Usable Instruments		
101-00008	Guidewire Holder - 0.9mm	1
102-00017	AO Quick Connect Handle	1
118-00020	2.0 Hex Driver	2
121-00000	APEX Instrument Tray	1
121-00001	APEX Implant Caddy	1
121-00002	Dorsal Window Reamer	1
127-00003	Short Tapered Guide – 4.6mm	1
127-00005	X-Post Clearing Tool	1
127-00006	Small AO Handle	1
127-00010	Depth Gauge – 0.9mm	1