CarpalFix™

INTRAOSSEOUS
FUSION DEVICE

Surgical Technique
Carpal Fusion



Patent and Patent Pending

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

EXTREMITY MEDICAL™

Customer Service: 888.499.0079
www.extremitymedical.com

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INTRAOSSEOUS
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INDICATIONS FOR USE

The Extremity Medical Lag Screw and X-Post™ System is intended for the reduction and internal fixation of arthrodeses, osteotomies, intra-articular and extra-articular fractures and nonunions of the small bones of the hand and wrist.

NOTE: This technique describes the steps for hardware implantation as used in a Capito-Lunate fusion. Please follow the same steps as listed in this procedure for use with other carpal bone fusions.

Pre-Operative Planning - Templating

The Extremity Medical Lag Screw and X-Post™ System provides several X-Post™ options (45°, 60°, or 75°). Use the X-ray template to pre-operatively determine X-Post™ positioning and angle.

STEP 1 - Exposure & Joint Preparation

A standard longitudinal incision, which begins at Lister's tubercle and extends distally 6-8cm, is performed over the radiocarpal joint. Incise and elevate the capsule and expose the carpal bones. Removal of the scaphoid is at the discretion of the surgeon. Prepare the carpal bone surfaces for fusion by removing the remaining articular cartilage and subchondral bone. After removal of the cartilage and subchondral bone of the articulating surfaces, generous amounts of cancellous bone graft should be inserted between the bones.

STEP 2 - Provisional Fixation

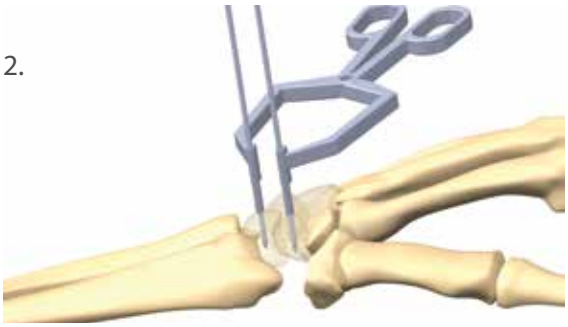
Align the carpals into the ideal orientation with your preferred method. Provisionally pin the bones. The provisional fixation may be left in throughout hardware implantation.

Note: When placing provisional pins, care must be taken to allow for adequate space to implant hardware.

1.



2.

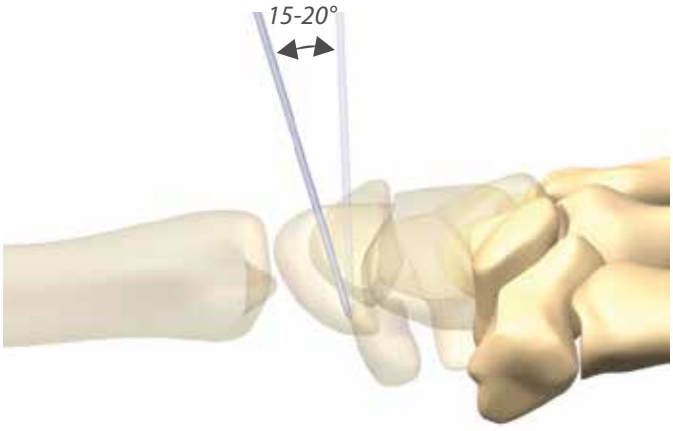


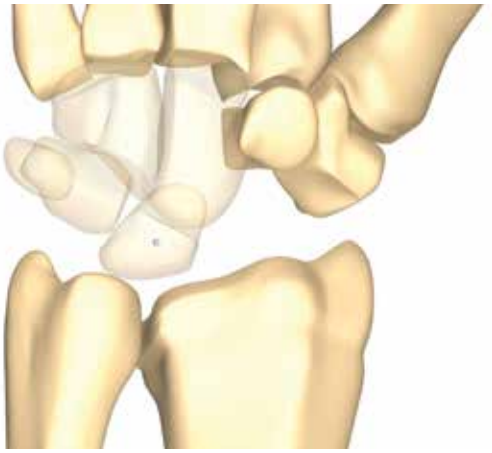
1) A provisional Ø1.6 Guidewire may be used to pin the Capito-Lunate joint.
2) A compression (Wolfe) clamp with parallel Ø1.6 Guidewires may be used to fixate the bones during hardware implantation.

STEP 3 - X-Post™ Guidewire

Insert a Ø0.9mm Guidewire in the Lunate parallel to the Capito-Lunate joint. This Guidewire will serve as an alignment wire for the X-Post™ orientation. Verify proper positioning with fluoroscopy.

Note: To allow for more orthogonal placement of the Lag Screw, the initial X-Post™ Guidewire wire may be canted up to 20° from proximal-dorsal to distal-volar.





STEP 4 - X-Post™ Depth Measurement

Place the depth gauge over the X-Post™ Guidewire and down to bone to determine the length of the X-Post™.

Note: The Depth Gauge is a two-sided gauge. Read this measurement from the side labeled X-Post™ Depth.

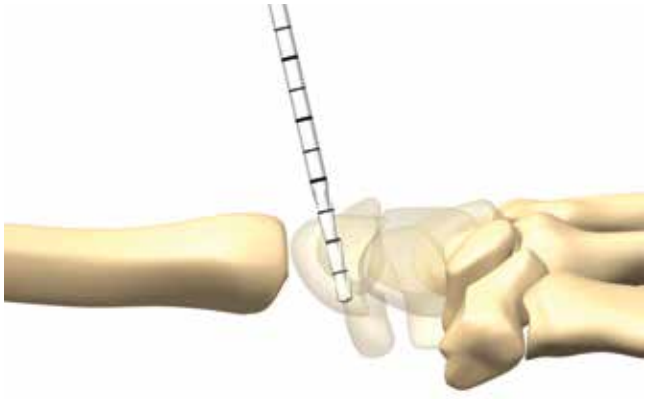
It is recommended that the X-Post™ be countersunk 1-2mm below the cortical surface. This difference can be factored into the final implant selection by selecting an X-Post™ 1-2mm shorter than the measured length.





STEP 5 – Preparation for X-Post™: Pilot Drill

Drill to the measured depth utilizing the Ø2.7mm Cannulated Drill. Either the Short or Long Tapered Guide may be used to prevent soft tissue impingement.





STEP 6 - Preparation for X-Post™ : Countersink

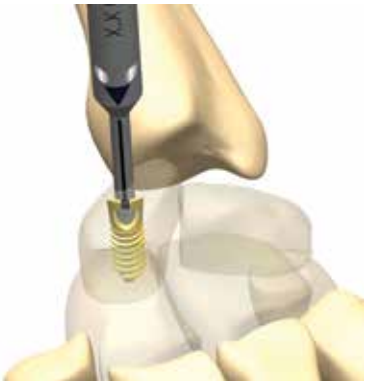
Place the cannulated X-Post™ Countersink over the Guidewire and advance by hand until the depth line is no longer visible.

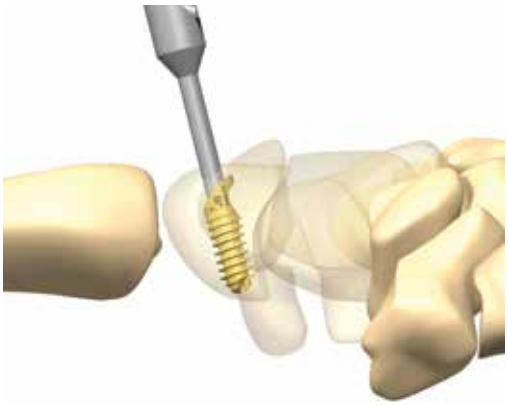


STEP 7 - X-Post™ Insertion

Select the appropriate X-Post™ (length based on the Step 4 measurement and the angle determined from the pre-operative templating). Align the laser marked arrows of the Ø2.0 mm Hex Driver to markings on the implant. When the implant and Hex Driver are aligned in this fashion, the laser marked arrows will indicate the direction of the Lag Screw.

Insert the X-Post™ until countersunk 1-2mm below the cortical rim. The laser marked arrow should be facing the intended fusion area.

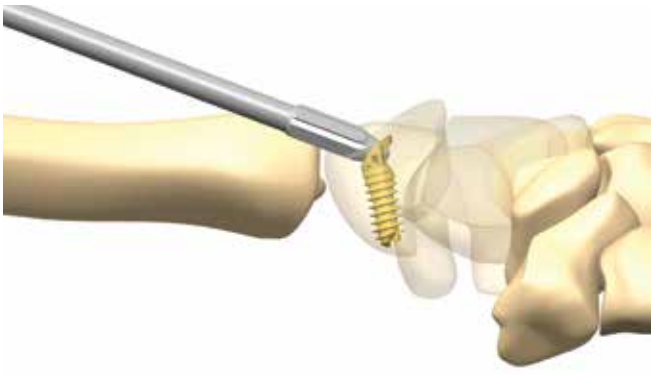




STEP 8 - Clear Additional Bone

In order to gain access to the implant eyelet, remove any obstructing bone by hand using the X-Post™ Clearing Tool. This will allow the guide to seat properly. Alternatively, a rongeur can be used to remove any impinging bone.

NOTE: Any difficulty seating the Drill Guide in Step 9 could be due to bony interference at the implant eyelet.

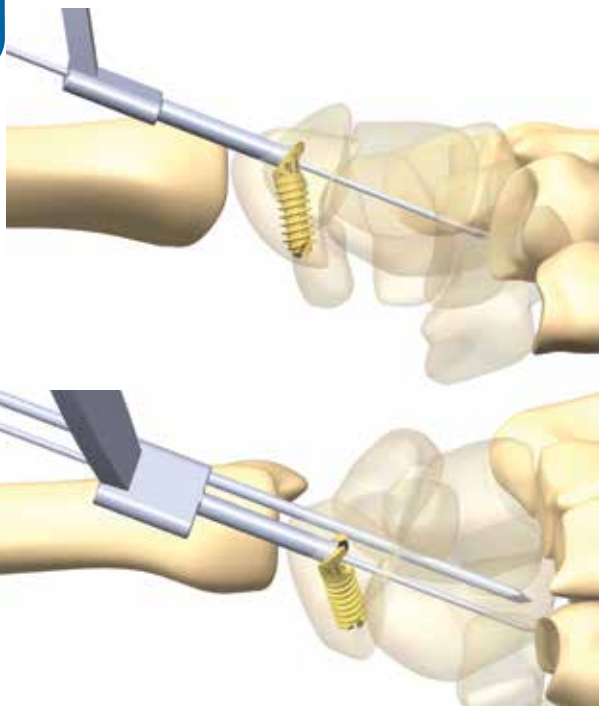


STEP 9 – Lag Screw Guidewire Insertion

Insert the Long Tapered Guide into the eyelet of the X-Post™. Ensure that the guide is seated into the taper of the implant to the level where the head of the guide is no longer visible. This will keep the Guidewire concentric with the eyelet, and allows for optimal locking of the Lag Screw and X-Post™ construct.

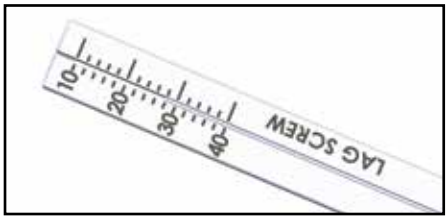
Once the Long Tapered Guide is seated, drive a Ø0.9mm Guidewire through the hole of the guide to the appropriate level. Verify the positioning of the Guidewire under fluoroscopy.

Optional: If provisional fixation has not already been applied, the supplemental holes on the guide may be utilized for temporary fixation.

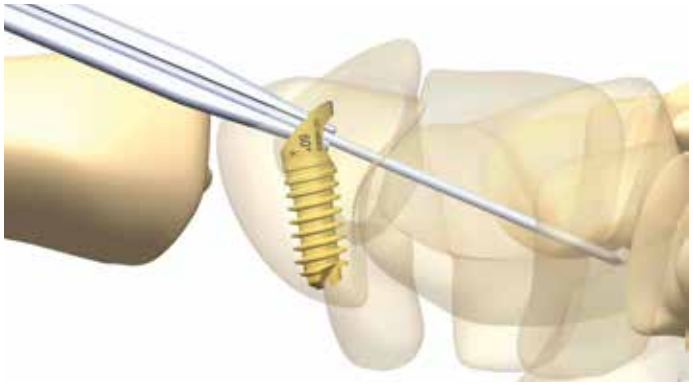


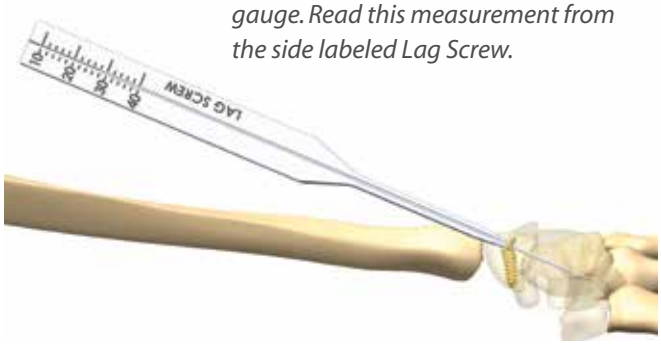
STEP 10 - Lag Screw Depth Measurement

Measure the length of the Lag Screw by placing the Depth Gauge over the Guidewire and down to the bone.



Note: The Depth Gauge is a two-sided gauge. Read this measurement from the side labeled Lag Screw.

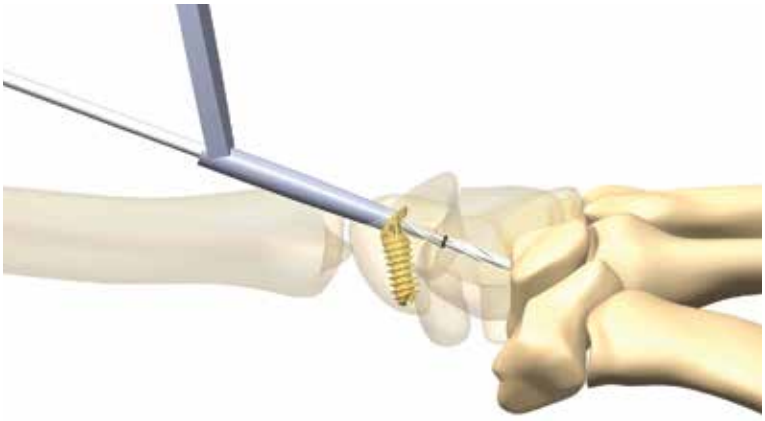




STEP 11 - Pilot Drill for Lag Screw

Drill utilizing the Ø2.0mm Cannulated Drill. Align the first depth marking to the top of the Tapered Guide. Based on this zero reference, drill to the depth measurement previously recorded.

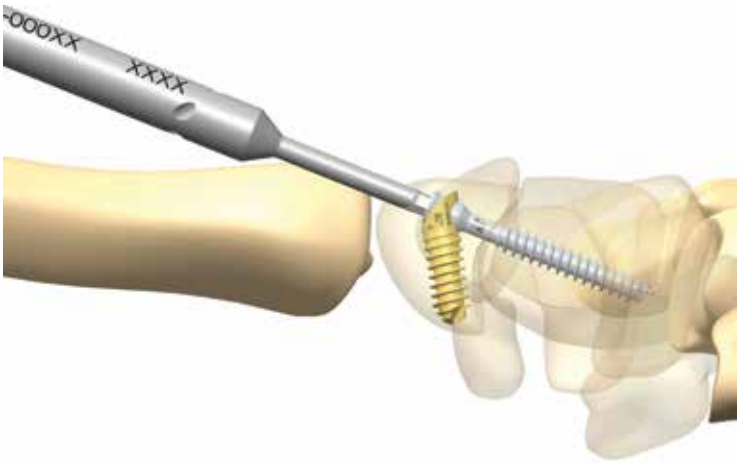
Graduations on drill are in 10mm increments.



STEP 12 – Insert Lag Screw

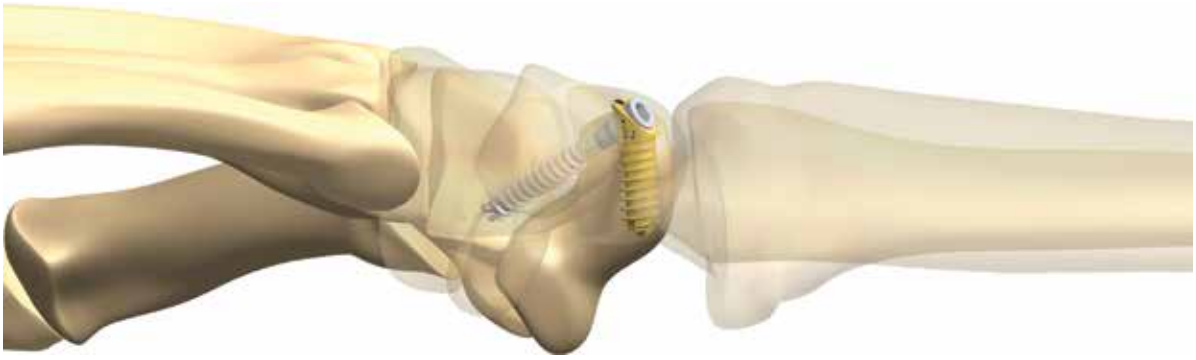
Insert the Lag Screw under TWO finger pressure until tactile compression is felt, and the visualization shows the Lag Screw flush against the X-Post™ . With the tapered Lag Screw, the Morse Taper engagement should be felt as the tapers engage.

Note: Remove any provisional wires prior to final tightening, this will ensure maximum compression is applied.



FINAL POSITIONING

If additional fixation is determined necessary, an additional headed or headless screw may be implanted per standard techniques.

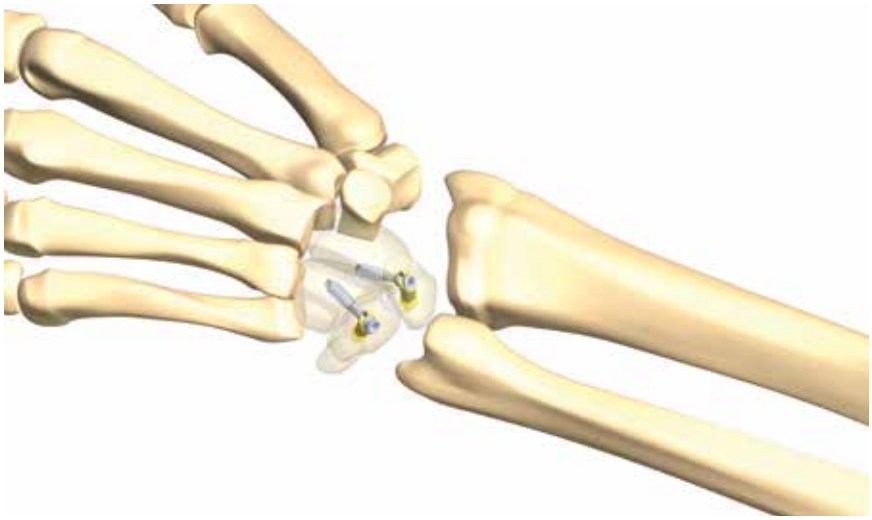


FOUR-CORNER FUSION

When performing a four-corner fusion, it is critical that the Triquetrum-Hamate joint surface be prepared before the Capito-Lunate joint is fixated.

It is recommended to follow these steps in performing a four-corner fusion:

1. Prepare the surfaces fully
2. Harvest and insert bone graft
3. Implant both X-Posts™
4. Implant the Lag Screws sequentially



POSTOPERATIVE TREATMENT

Subsequent to incision closure, patients should initially be immobilized in a well-padded splint for the first two weeks postoperatively. Following repeat incision assessment and suture removal, standard post-operative protocols for arthrodesis, as preferred by the surgeon, should be followed. Progression of movement 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

Remove any tissue ingrowth from the Lag Screw. Insert the 2.0 Hex Driver into the Lag Screw and completely remove it by turning counterclockwise. Insert the 2.0 Hex Driver into the Post and remove it by turning counterclockwise.

SUPPLEMENTAL INDICATION INFORMATION

Placement of the Lag Screw and X-Post™ construct is based on surgeon preference and access.

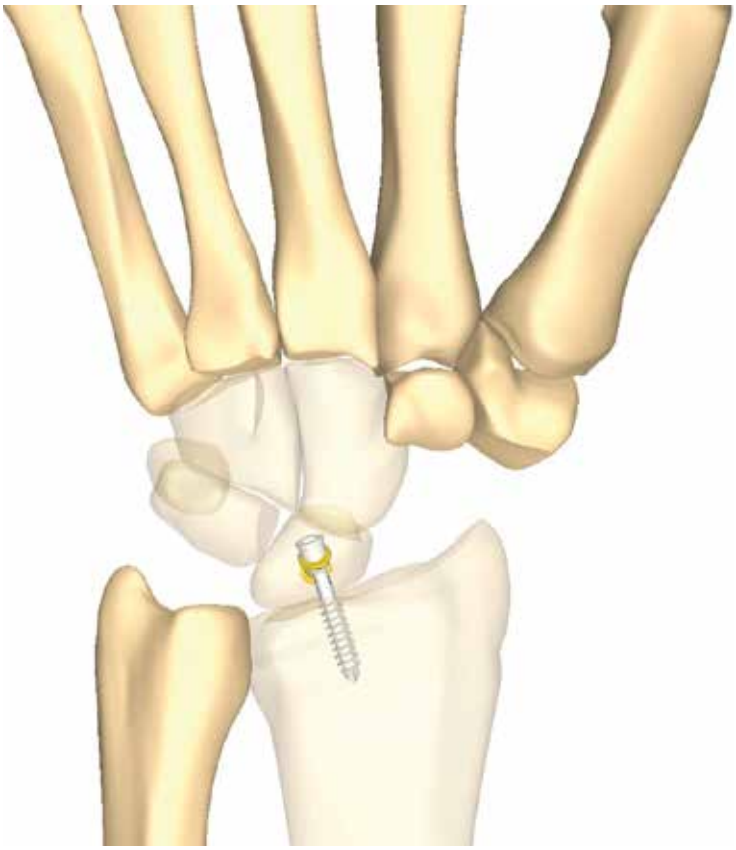
1. Radiolunate Fusion

Approach and Exposure

A dorsal longitudinal or transverse incision centered over the radiocarpal joint is performed. A transverse or longitudinal capsulotomy Is performed at the discretion of the surgeon. The articulating surfaces should be debrided down to bleeding subchondral or cancellous bone.

X-Post™ Placement

Typically, the X-Post™ is placed centered between the radiolunate joint surfaces and tangent to the distal articulating surface of the lunate. This Guidewire must be centered between the radiolunate and Capito-Lunate joint surfaces to allow sufficient room for the threads of the implant. Verify proper positioning with fluoroscopy.



SUPPLEMENTAL INDICATION INFORMATION

Placement of the Lag Screw and X-Post™ construct is based on surgeon preference and access.

2. Thumb Basal Joint Fusion

Approach and Exposure

An L-shaped Wagner incision is typically utilized for this procedure. Care must be taken to identify and protect sensory nerve branches in the subcutaneous tissues. The thenar muscles are reflected from the metacarpal to expose the basal joint while carefully protecting the insertion of the APL. The capsule is incised on the radial and dorsal aspect of the trapeziometacarpal joint to fully expose the articulating surface. A Ø0.9mm Guidewire Is inserted from radial to ulnar in the trapezium midway between the articular surfaces, and parallel to the TM joint surface. Verify positioning of the Guidewire via fluoroscopy.

At this point, the position of the fusion is selected, and a Ø1.6mm Guidewire is inserted between the thumb and index metacarpals to provisionally fix the position of fusion. Fluoroscopy is used to confirm the selected position. Ideally, the tip of the thumb should flex to pinch the middle phalanx of the partially flexed index finger.

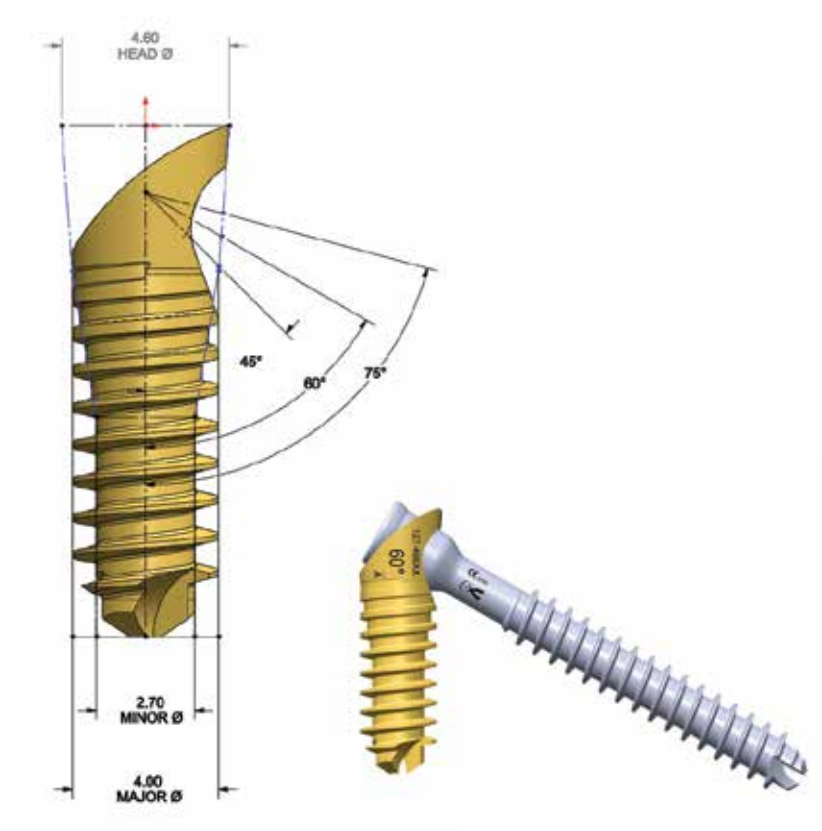
When final position has been selected and confirmed, the cutting block is applied and aligned over the distal articular surface so as to cut a tangent to the articular surface and resect a minimum of distal trapezial bone. The cutting block is stabilized with two .035" Guidewires. A Ø0.038mm oscillating saw is used to make the trapezial cut. The block is then lifted and advanced to position over the base of the thumb metacarpal, to create a parallel cut and remove the articulating cartilage and a minimum of the subchondral bone of the MC. The block and all resected bone and cartilage is then removed with a fine rongeur. Care must be taken to assure that there are no remaining spurs that would prevent perfect coaptation of the resected surfaces. If necessary, a 2mm burr can be used to further freshen the apposing articular surface. Remove the transmetacarpal Guidewire from the index MC, manually impact the thumb metacarpal against the trapezial surface, and then re-insert the transmetacarpal Guidewire into the index. Final positioning should be confirmed with fluoroscopy.



NOTES:

IMPLANT SPECIFICATIONS

X-POST™



LAG SCREWS

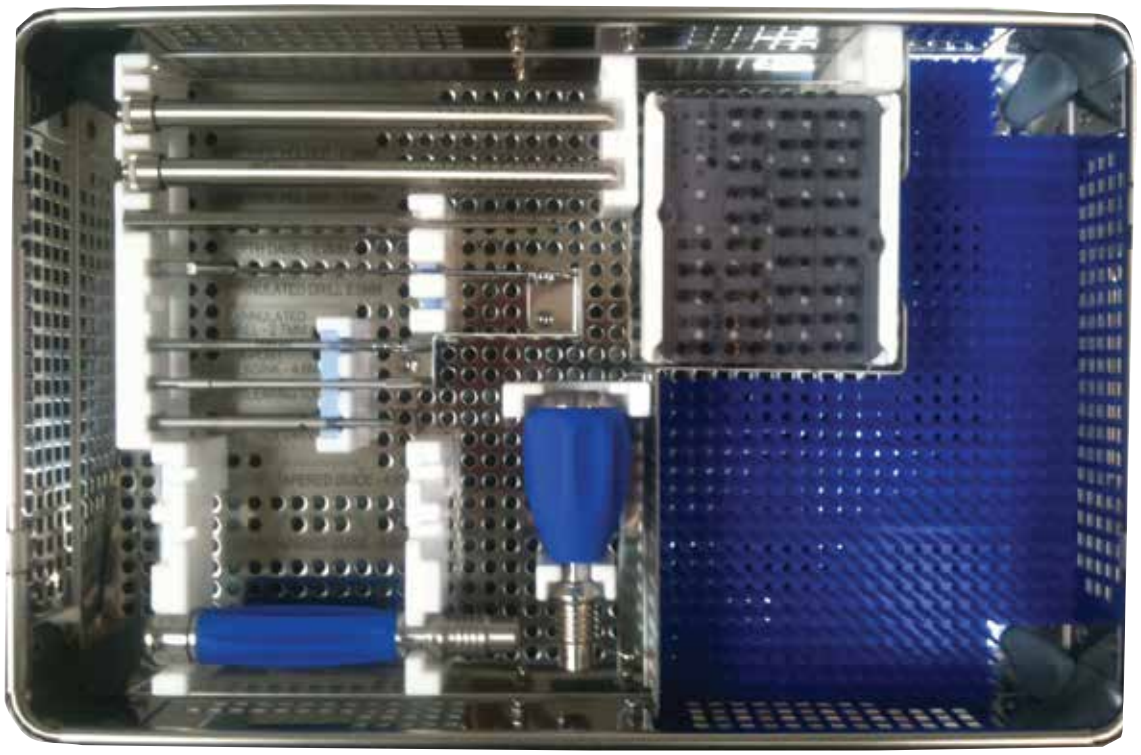


CarpalFiX™ X-Post™ (Gold) Specifications			
Angles	Lengths	Major Diameter	Minor Diameter
45°, 60°, 75°	10-18 mm (By 2mm increments)	4.0mm	2.7mm

Lag Screw Specifications				
	Length	Thread Length	Major Diameter	Minor Diameter
Standard	14-30mm (By 2mm increments)	L-8mm	3mm	2mm
Short Thread	14-30mm (By 2mm increments)	14, 16, 18mm - 6mm 20, 22mm - 8mm 24, 26mm - 10mm 28, 30mm - 12mm	3mm	2mm

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X-Posts™

Implant	Description	Qty
4.6 X-Posts™ (45˚)		
127-46410	X-Post™ (45◦) 4.6 X 10mm	2
127-46412	X-Post™ (45◦) 4.6 X 12mm	2
127-46414	X-Post™ (45◦) 4.6 X 14mm	2
127-46416	X-Post™ (45◦) 4.6 X 16mm	2
127-46418	X-Post™ (45◦) 4.6 X 1 8mm	2
4.6 X-Posts™ (60˚)		
127-46610	X-Post™ (60◦) 4.6 X 10mm	2
127-46612	X-Post™ (60◦) 4.6 X 12mm	2
127-46614	X-Post™ (60◦) 4.6 X 14mm	2
127-46616	X-Post™ (60◦) 4.6 X 16mm	2
127-46618	X-Post™ (60◦) 4.6 X 18mm	2
4.6 X-Posts™ (75˚)		
127-46710	X-Post™ (75◦) 4.6 X 10mm	2
127-46712	X-Post™ (75◦) 4.6 X 12mm	2
127-46714	X-Post™ (75◦) 4.6 X 14mm	2
127-46716	X-Post™ (75◦) 4.6 X 16mm	2
127-46718	X-Post™ (75◦) 4.6 X 18mm	2

Lag Screws

Implant	Description	Qty
3.0 Lag Screws		
127-30214	Lag Screw (Cannulated Tapered) 3.0 x 14mm	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
3.0 Short Thread Lag Screws		
127-30414	Short Thread Lag Screw (Cannulated Tapered) 3.0 x 14mm	2
127-30416	Short Thread Lag Screw (Cannulated Tapered) 3.0 x 16mm	2
127-30418	Short Thread Lag Screw (Cannulated Tapered) 3.0 x 18mm	2
127-30420	Short Thread Lag Screw (Cannulated Tapered) 3.0 x 20mm	2
127-30422	Short Thread Lag Screw (Cannulated Tapered) 3.0 x 22mm	2
127-30424	Short Thread Lag Screw (Cannulated Tapered) 3.0 x 24mm	2
127-30426	Short Thread Lag Screw (Cannulated Tapered) 3.0 x 26mm	2
127-30428	Short Thread Lag Screw (Cannulated Tapered) 3.0 x 28mm	2
127-30430	Short Thread Lag Screw (Cannulated Tapered) 3.0 x 30mm	2

System Accessories

Instrument	Description	
Disposable Instruments		
101-00004	Guidewire - 0.9mm	10
101-00006	Guidewire - 1.6mm	5
101-00011	Cannulated Drill – 2.0mm	2
101-00022	Cleaning Brush - 0.9mm	1
127-00004	X-Post™ Countersink – 4.6mm	1
127-00007	CarpalFiX™ X-Ray Template	1
127-00027	Cannulated Drill – 2.7mm	2
Re-Usable Instruments		
101-00008	Guidewire Holder - 0.9mm	1
101-00009	Guidewire Holder - 1.6mm	1
102-00017	AO Quick Connect Handle	1
118-00020	2.0 Hex Driver	2
127-00000	CarpalFiX™ Instrument Tray	1
127-00001	CarpalFiX™ Implant Caddy	1
127-00002	Long Tapered Guide – 4.6mm	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

EXTREMITY MEDICAL™
300 Interpace Parkway • Suite 410 • Parsippany, NJ 07054
Phone: 973.588.8980 • Customer Service: 888.499.0079 • Fax: 888.499.0542
www.extremitymedical.com

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Mutsaardstraat 47 - B-9550 HERZELE
+32 (0) 54 50 40 05
info@hospitalinnovations.be
www.hospitalinnovations.eu