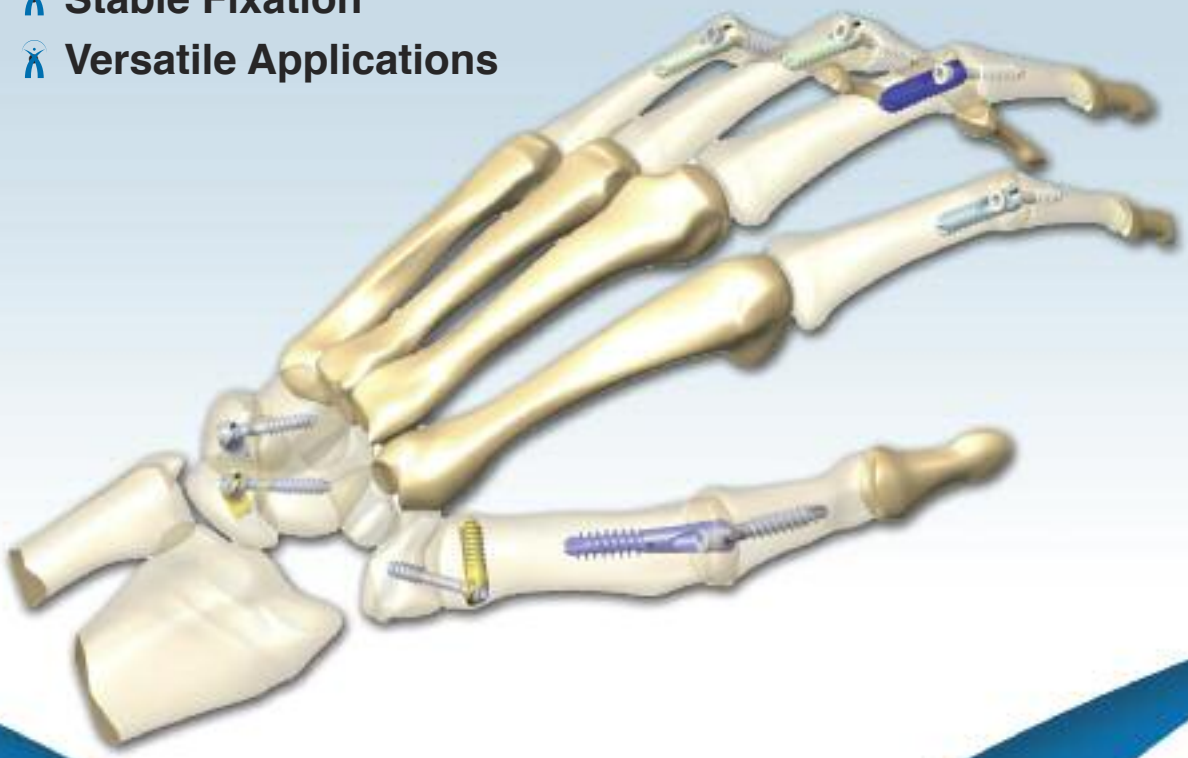
UpperFiX™

Fusion Fixation

Intraosseous Fixation Platform

The UpperFiX™ Advantage: *Designed* for Fusion

- Zero Profile
- Stable Fixation
- Versatile Applications



EXTREMITY MEDICAL™

CarpalFiX™

Fusion Fixation

The CarpalFiX™ Advantage: *Designed* for Fusion

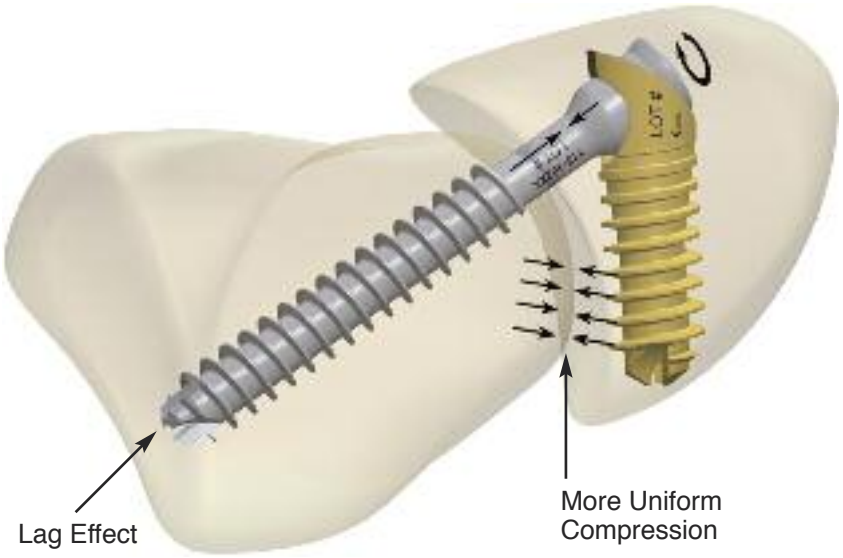
Zero Profile

Stable Fixation

- Uniform Compression
- X-Post acts as a reinforced cortical bone bridge
- Morse Taper Lock

Versatility

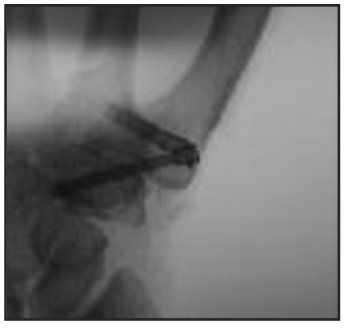
- Multiple angles (45˚, 60˚, 75˚) allow for versatile placement



Midcarpal Joint Arthrodesis with Scaphoid Excision

Radio-Lunate Arthrodesis

Radio-Scaphoid-Lunate Arthrodesis



Carpometacarpal (CMC) Fusion

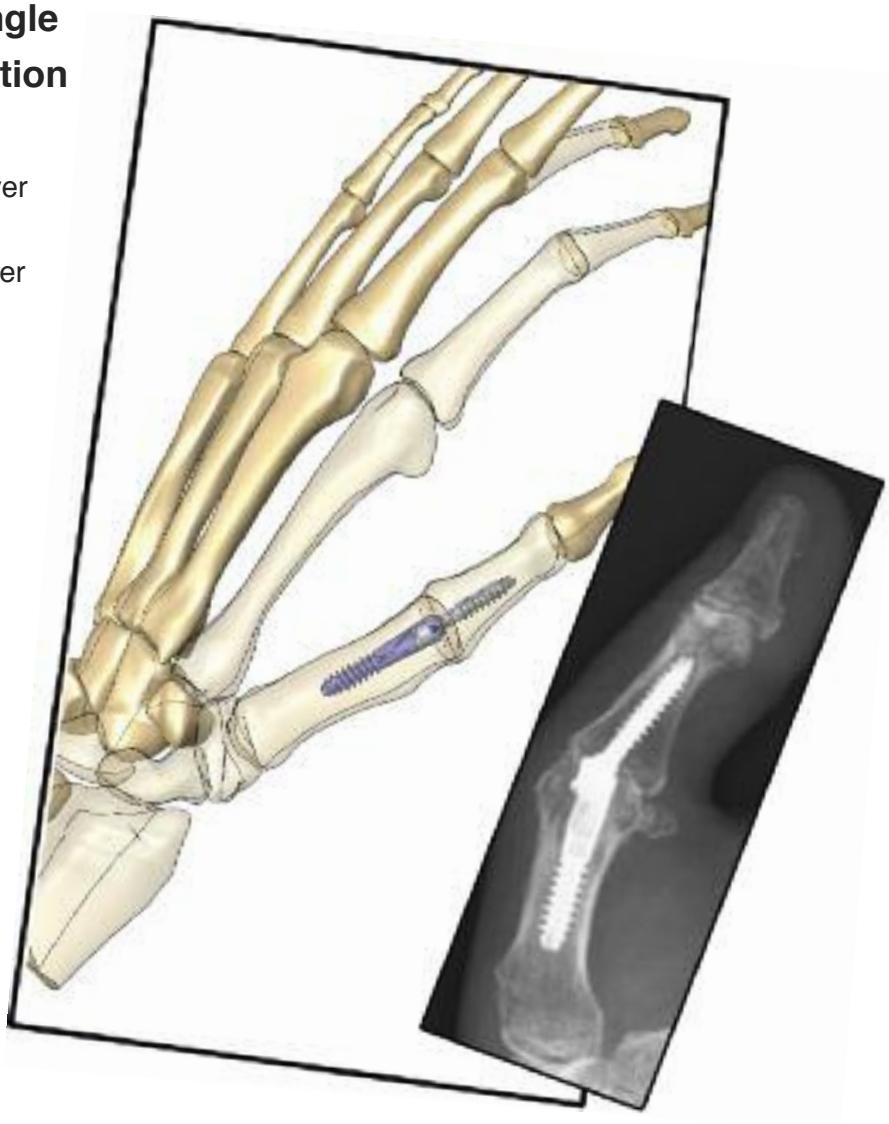
The CarpalFiX System is intended for the reduction and internal fixation of arthrodesis, osteotomies, intra- and extraarticular fractures and nonunions of the small bones of the hand and wrist. This two-part construct is specifically intended for Capito-Lunate, and Triquetral-Hamate arthrodesis.

MCP

Fusion Fixation

The Intramedullary Fixation Advantage: *Designed* for Fusion

- **Zero Profile**
- **Fixed Reproducible 25° Angle**
- **Stable Intramedullary Fixation**
  - Strong Compression
  - Post distributes bending forces over a greater surface area
  - Post/Screw lock with a Morse Taper



MCP is intended for arthrodesis fixation of the Metacarpal-phalangeal joints.

APEX
Fusion Fixation

The Intramedullary Fixation Advantage: *Designed* for Fusion

- **Zero Profile**
- **Fixed Reproducible Angles (30˚ & 45˚)**
- **Stable Intramedullary Fixation**
  - Strong Compression
  - Post distributes bending forces over a greater surface area
  - Post/Screw lock with a Morse Taper

APEX is intended for reduction and internal fixation of arthrodesis of the interphalangeal joints of the hand.

Before use, physicians should review all risk information and essential prescribing information which can be found in each of the products instruction for use.

300 Interpace Parkway
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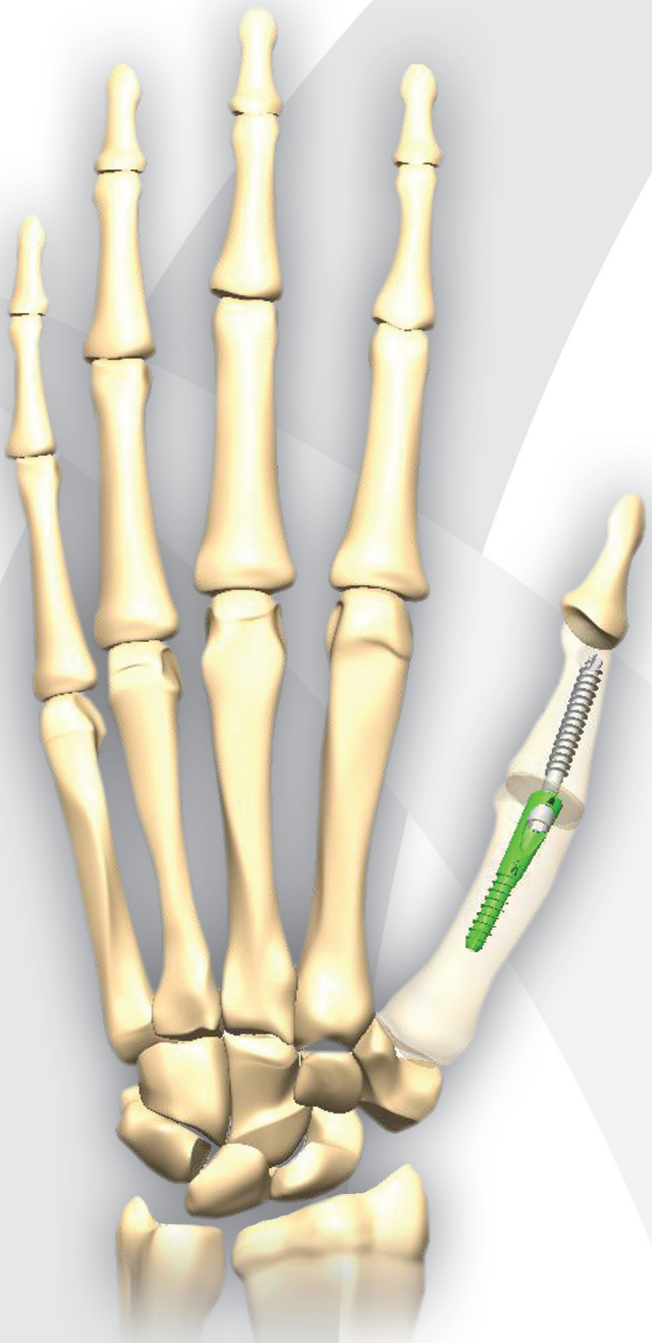

MCP™

INTRAMEDULLARY FUSION DEVICE

- Stable intramedullary fixation
- Fixed 25° angle for reproducible results
- Implant compresses across joint
- Superior bending resistance minimizing implant cut out
- Avoid hardware complications from tissue irritation caused by plates and wires
- Advanced instrumentation reduces procedure time
- Avoids the need to bend plates or hardware
- Removable

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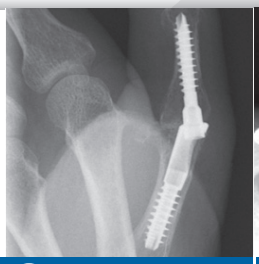
Fixation Method				
Dimension	**MCP** INTRAMEDULLARY FUSION DEVICE	**Plate**	**Tension Band**	**Screw**
Bending Strength	**6.9 Nm [1]**	**2 Nm [1]**	**0.3 Nm [2]**	**1.7 Nm [1]**
Compression	**202 N [1]**	**4 N [1]**	**80 N [3]**	**24 N [1]**
Potential for Reduced Soft Tissue Irritation	**Intramedullary**	**Exposed Hardware**	**Exposed Hardware**	**Screw Head Prominence**
Fusion Angle	**Reproducible 25°**	**Reproducible 25°**	**Varied, Inconsistent 0-40° [2]**	**Varied, Inconsistent 0-38° [4]**
Non-Union Complication Rate	• **Improved Compression** • **Stronger Fixation** • **Reduced Soft Tissue Irritation** **Study Pending**	**No Data Available**	**10% [2]**	**12% [4]**

[1] Data on File with Extremity Medical
[2] Mittelmeier et. al.; Arch Orthop Trauma Surg; (2005) 125: 145–152
[3] Wagner et. al.; International Orthopaedics; Oct 2007; 31 (5) 703-707
[4] Schmidt et. al.; The Journal of Hand Surgery; Nov 2004; 29A (6) 13-18

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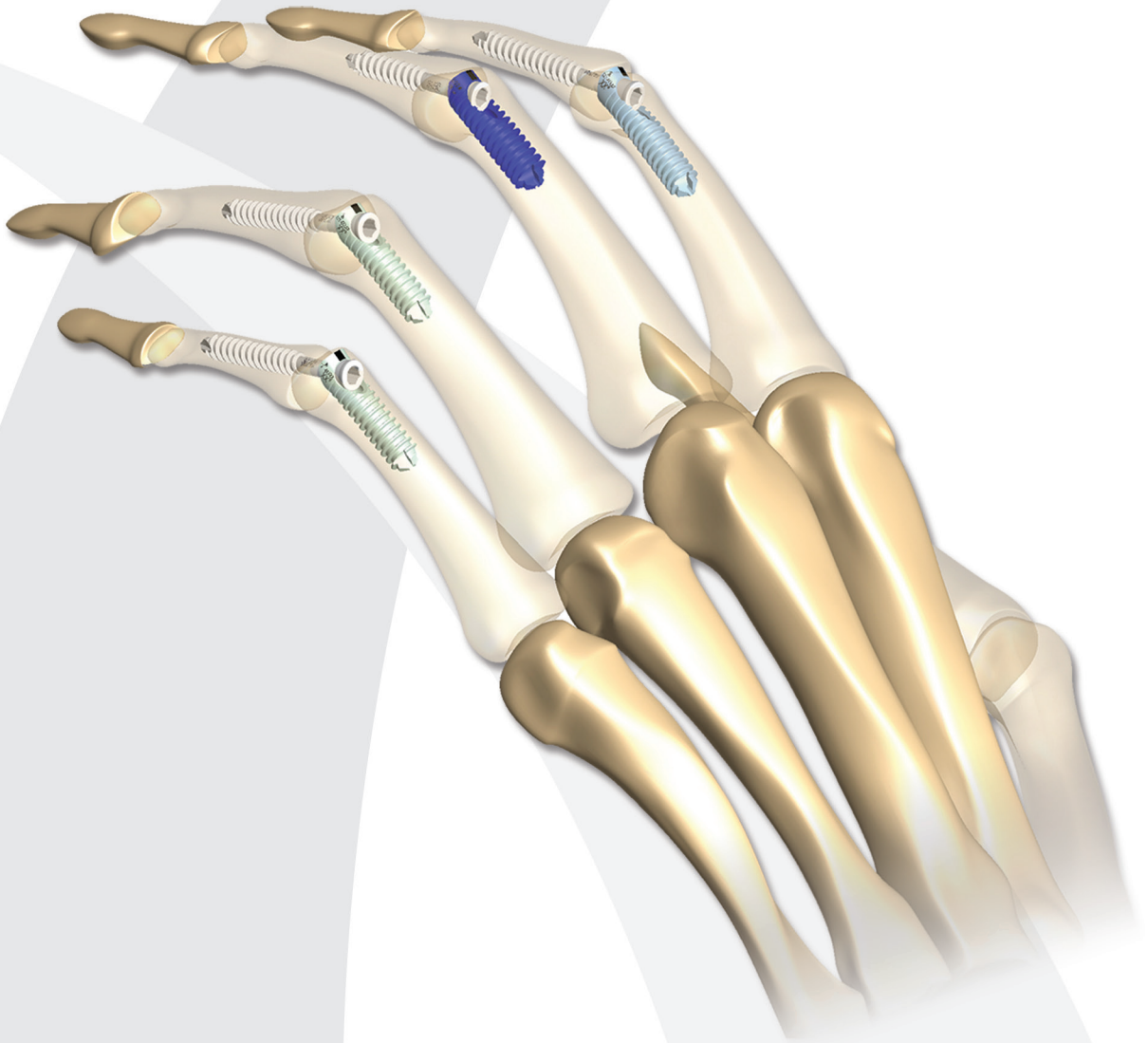
APEX™

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™

Customer Service: 888.499.0079
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APEX™
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

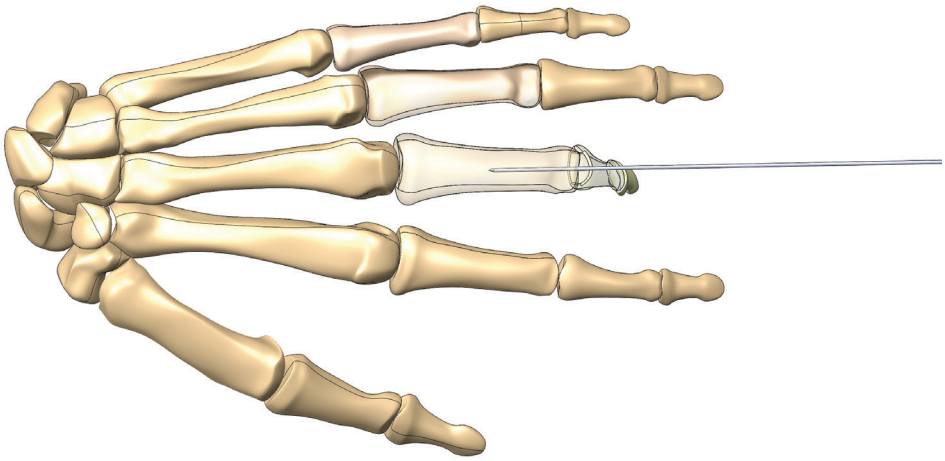
The APEX IP Fusion Device System provides several Post sizes and angles. Use the X-ray template to determine the optimal size, angle, and position of the construct for the intended application.

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.

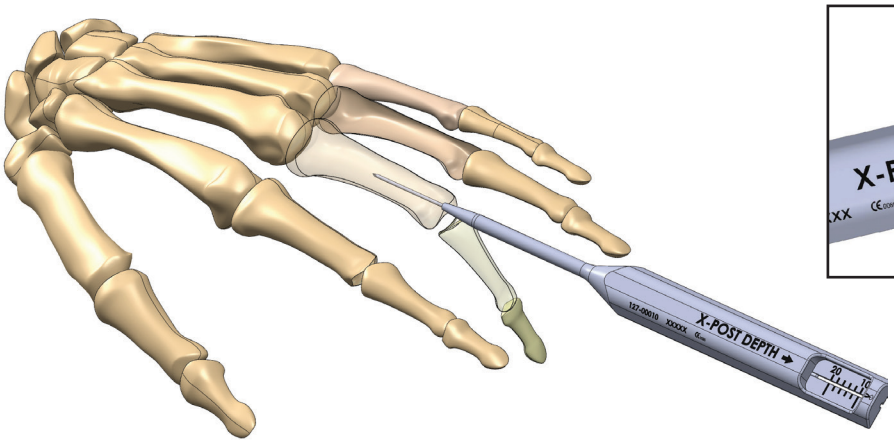
STEP 2 - Initial Guidewire

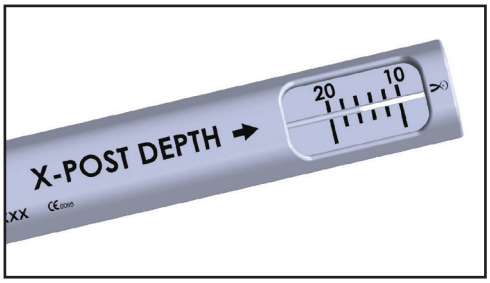
Insert a Ø0.9mm Guidewire into the canal of the proximal phalanx and confirm its central location in the canal using fluoroscopy.



STEP 3 - Post Depth Measurement

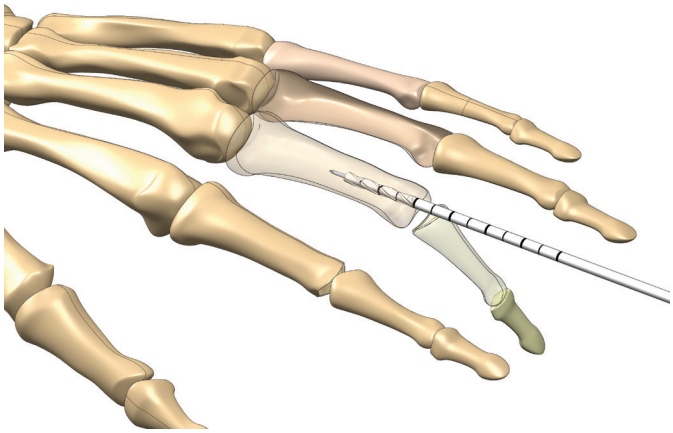
Slide the depth gauge over the Post guidewire until flush with the joint surface to measure the length of the Post. Ensure the reading is made from the side of the guide labeled "X-Post™ Depth."





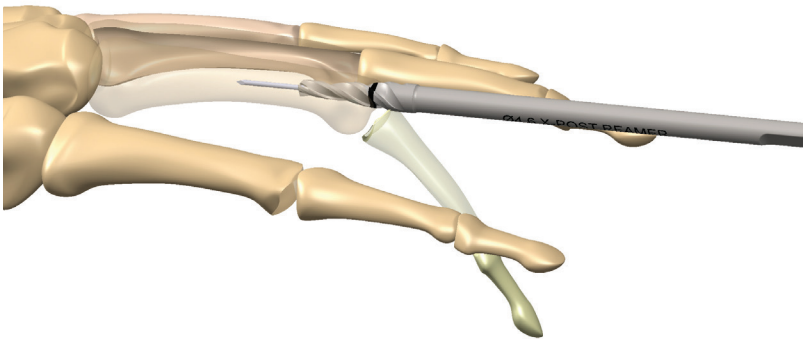
STEP 4 - Preparation for Post: Pilot Drill

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.



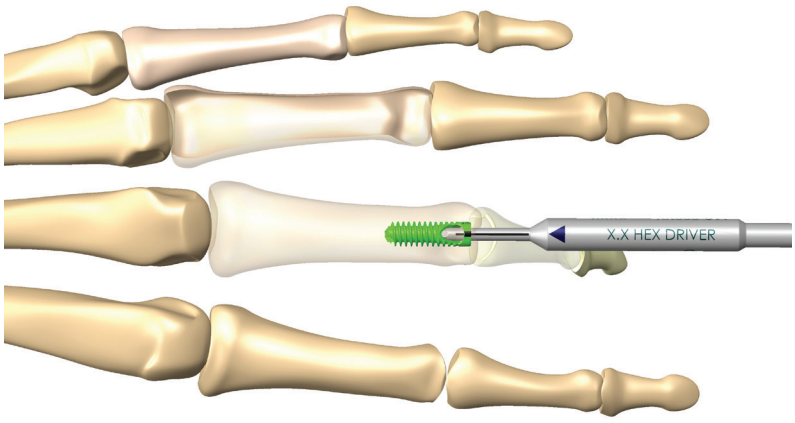
STEP 5 – Preparation for Post: Reaming

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.



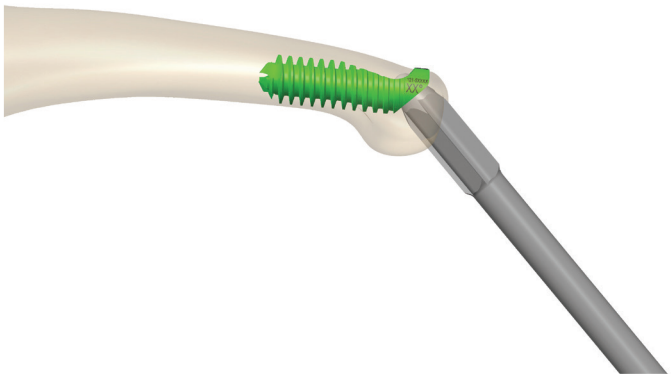
STEP 6 - Post Insertion

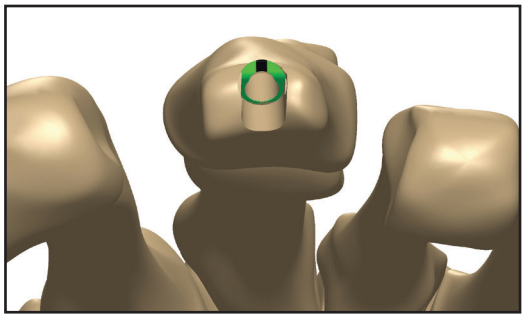
Select the proper Post and align the bold laser mark on the implant with the laser line and arrow on the 2.0 mm Hex Driver. Using the Hex Driver, insert the Post until its dorsal rim is sunk 1-2mm below the dorsal cortical rim of the phalanx, and align the laser line and arrow with the dorsal aspect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

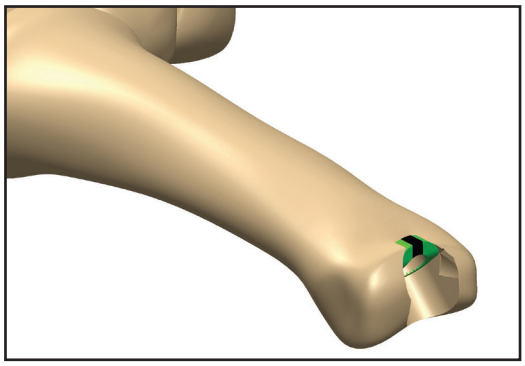


STEP 7 - Clear the Volar Aspect of the Proximal Phalanx Using the Clearing Tool

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.



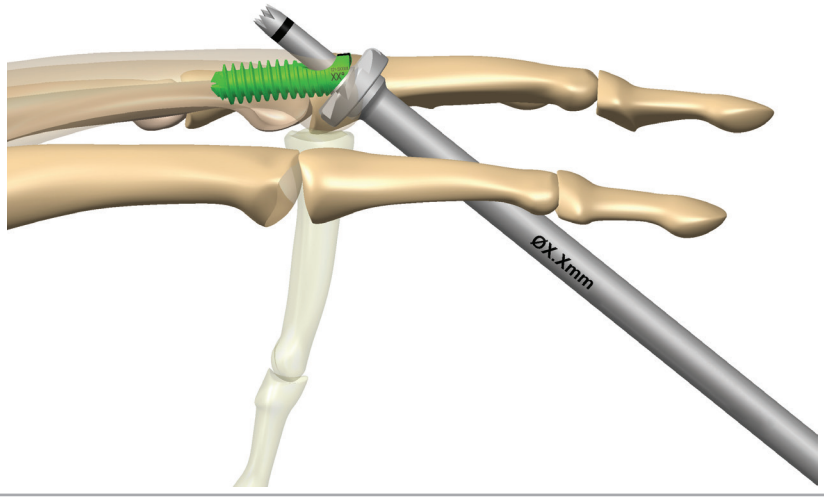




STEP 8a - Joint Preparation & Dorsal Window Creation

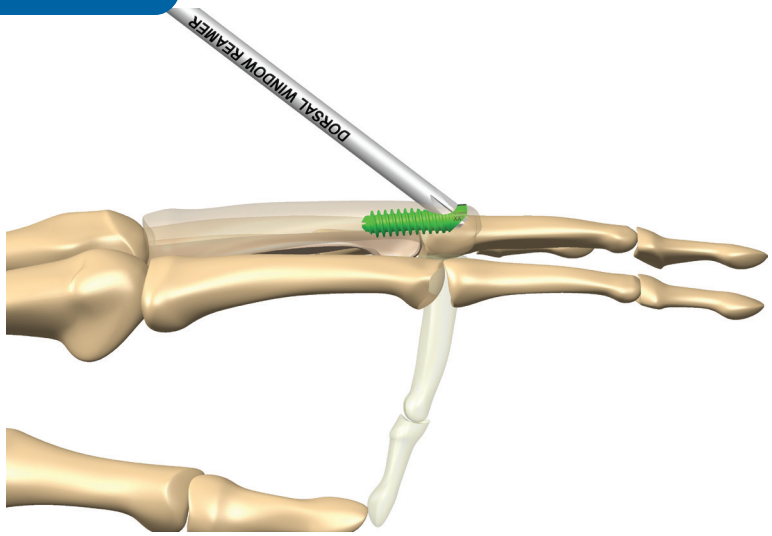
Insert the Proximal Rasp into the eyelet of the Post at the angle matching the selected Post (30 or 45 degrees) and rotate by hand until the stop on the rasp contacts the implant surface. Protect the dorsal soft tissues as the rasp exits the bone dorsally.

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.



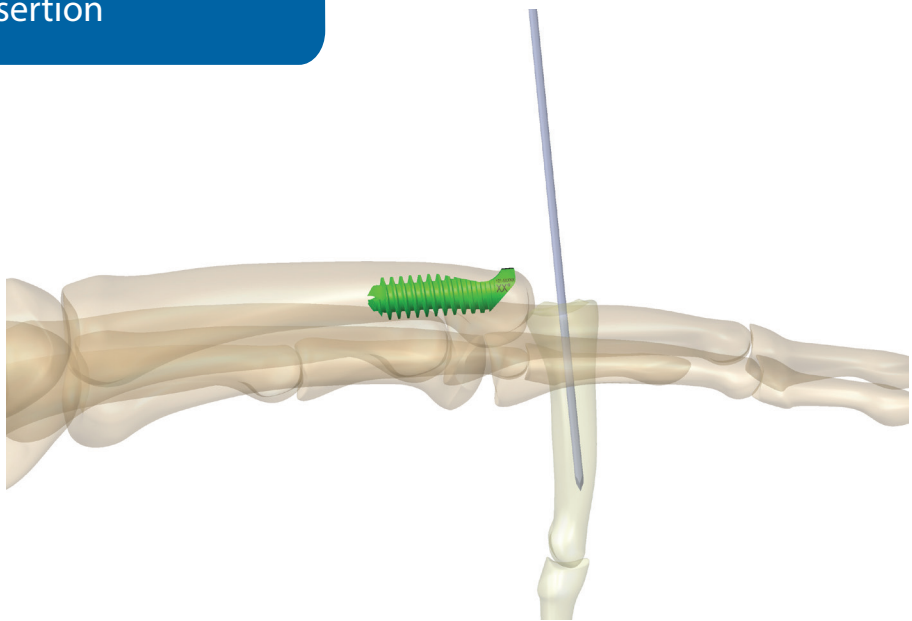
STEP 8b – Dorsal Window Clearing

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.



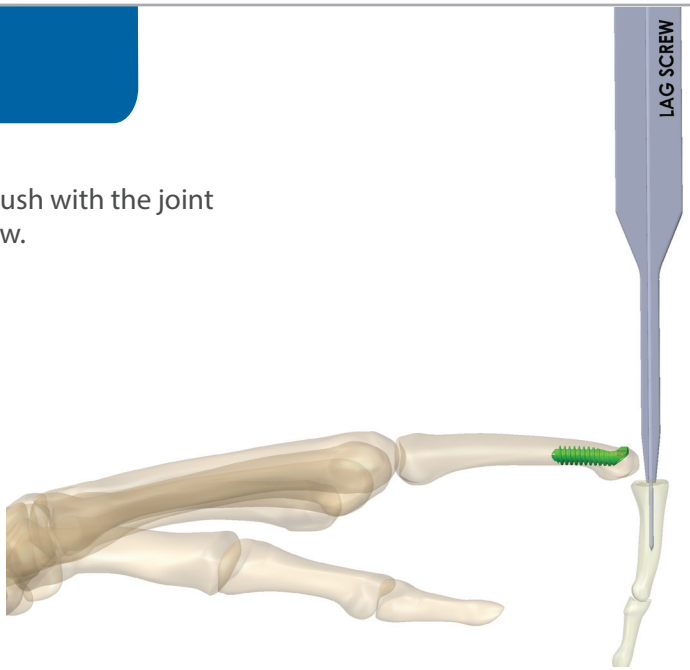
STEP 9 – Guidewire Insertion

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



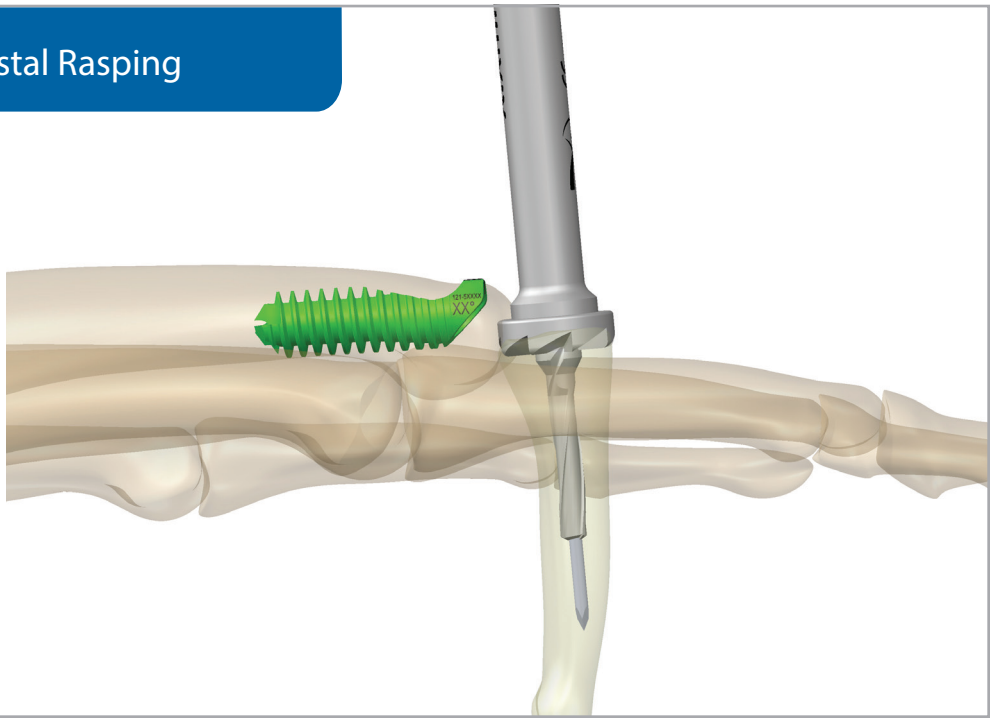
STEP 10 - Lag Screw Depth Measurement

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



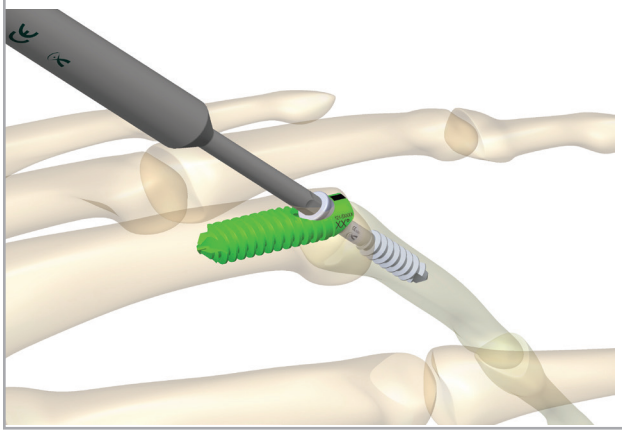
STEP 11 - Pilot & Distal Rasping

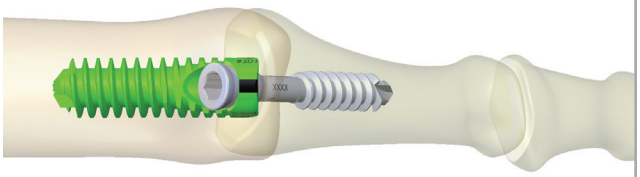
Advance the Distal Rasp over the guidewire and rasp the joint surface until it is flat and metaphyseal bone is exposed.

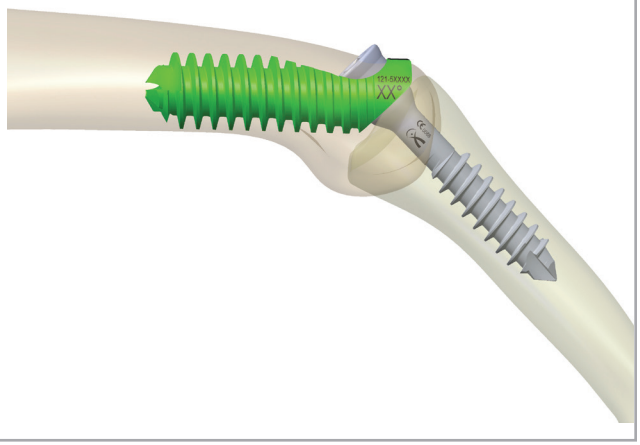


STEP 12 - Insert Lag Screw

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

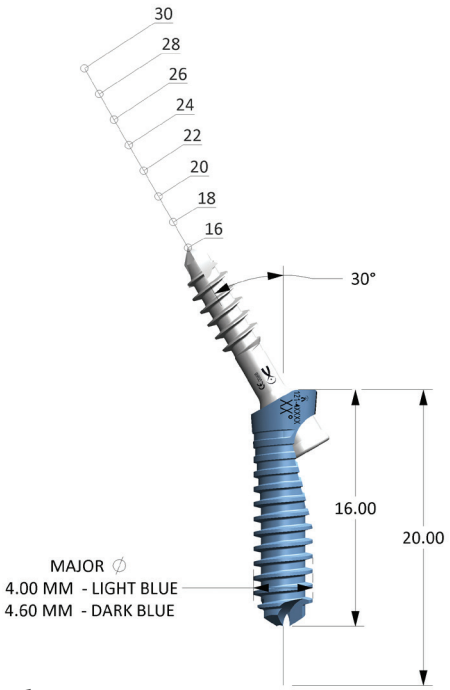
The same basic technique is used when performing an arthrodesis of the thumb IP joint however the distal phalanx of the thumb is often more curved than the middle phalanx of the finger and thus Lag Screw placement must be adjusted accordingly.

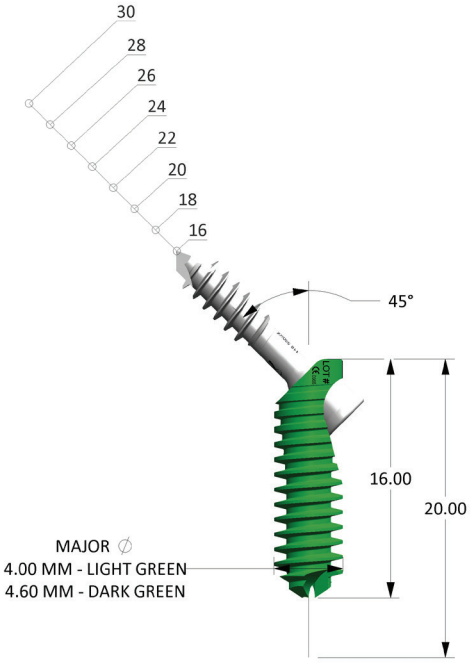
IMPLANT REMOVAL

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



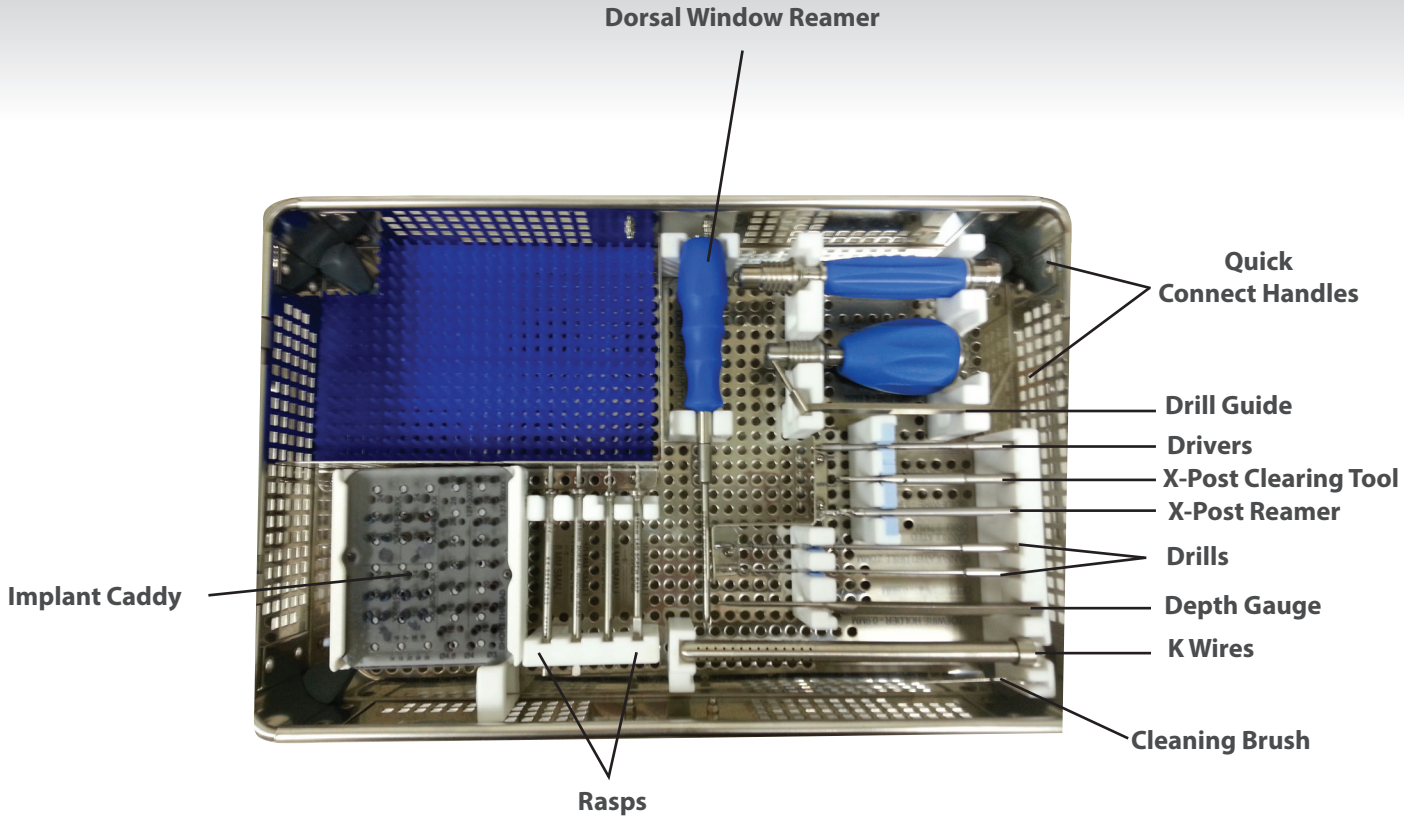


Posts

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

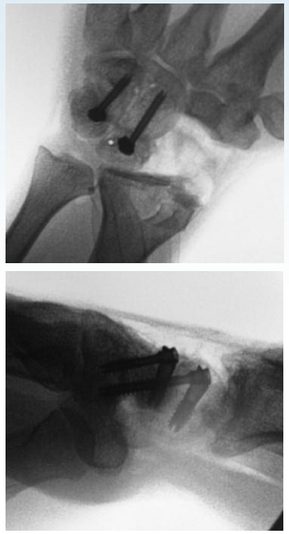
Reference #	Description	Qty
121-30016	Lag Screw (Solid Tapered) 3.0 x 16mm	2
121-30018	Lag Screw (Solid Tapered) 3.0 x 18mm	2
121-30020	Lag Screw (Solid Tapered) 3.0 x 20mm	2
121-30022	Lag Screw (Solid Tapered) 3.0 x 22mm	2
121-30024	Lag Screw (Solid Tapered) 3.0 x 24mm	2
121-30026	Lag Screw (Solid Tapered) 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

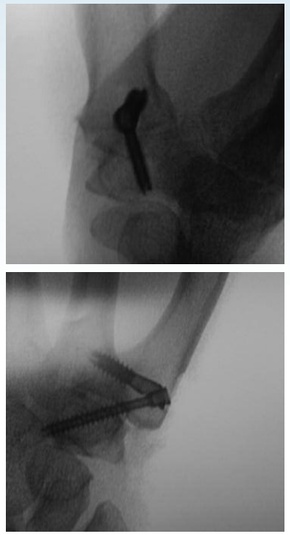
Reference #	Description	Qty
Disposable Instruments		
101-00004	Guidewire - 0.9mm	10
101-00011	Cannulated Drill – 2.0mm	2
101-00022	Cleaning Brush - 0.9mm	1
118-00004	4.6 X-Post Reamer	1
121-00108	8mm Proximal Rasp	1
121-00110	10mm Proximal Rasp	1
121-00208	8mm Distal Rasp	1
121-00210	10mm Distal Rasp	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

Versatility
Various sizes available for many foot and ankle indications



Capito-Lunate and Triquetrohamate Arthrodesis

Radio-Lunate Arthrodesis



Carpometacarpal (CMC) Fusion

Radio-Scaphoid-Lunate Arthrodesis

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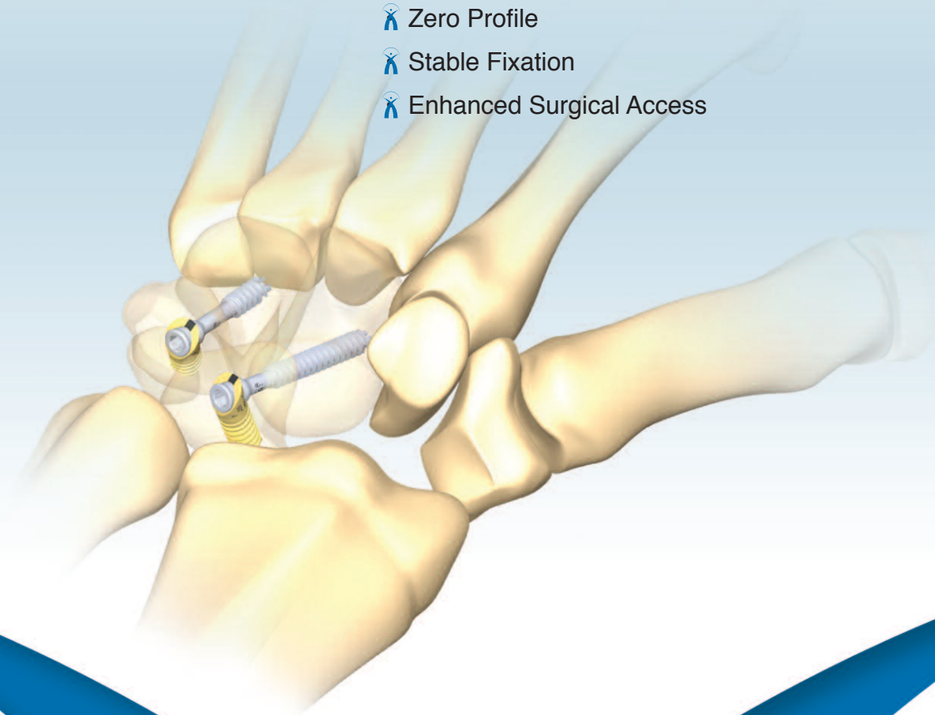
CarpalFiX™
Fusion Fixation

The CarpalFiX™ Advantage: *Designed* for Fusion

- Zero Profile
- Stable Fixation
- Enhanced Surgical Access



Superior Fatigue and Strength Resistance

EXTREMITY MEDICAL™

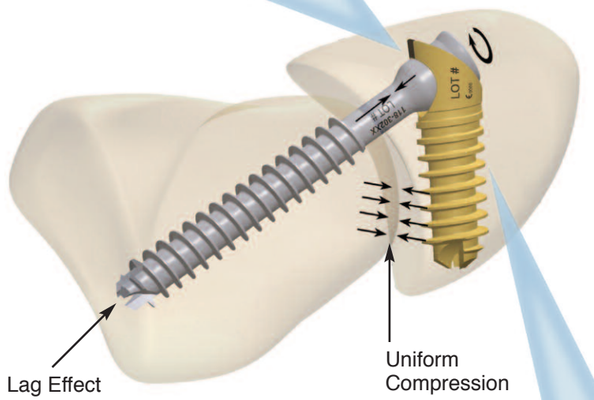
How CarpalFiX™ Works

Zero Profile
Implants are placed within the bone

- Decreases the likelihood of impingement
- Minimizes soft tissue irritation
- Decreases need for hardware removal

Enhanced Surgical Access
Lag screw is placed through the X-Post

- No need to violate the articular surface of an additional joint
- No need to hyper-flex the wrist to gain access in four corner fusions



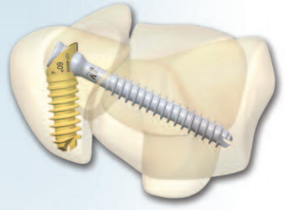
Stable Fixation

X-Post™
Compressive forces are distributed across a greater surface area

- Uniform compression
- Greater peak compression

Screws lag against a reinforced cortical bone bridge

- Enhanced stability in poor quality bone

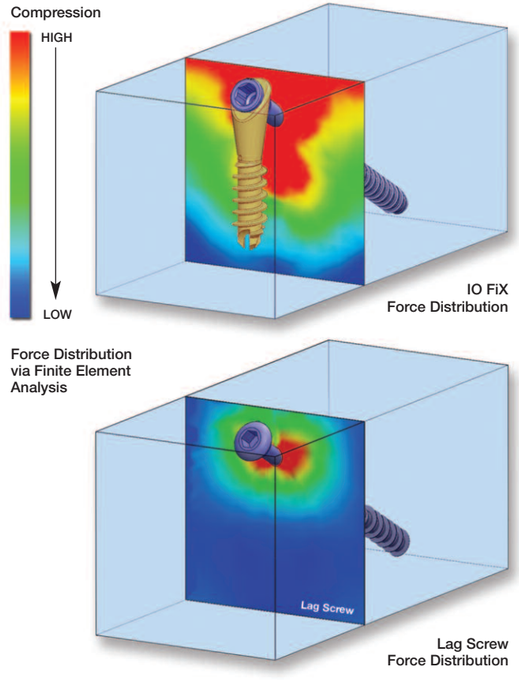


X-Lock™
Lag screw locks into X-Post via a Morse Taper friction lock

- Decreases the likelihood of screw back out
- Fixed angle stability

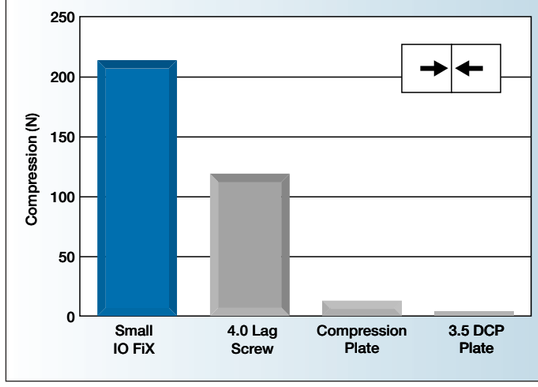
Designed with Stability in Mind

Uniform Compression*



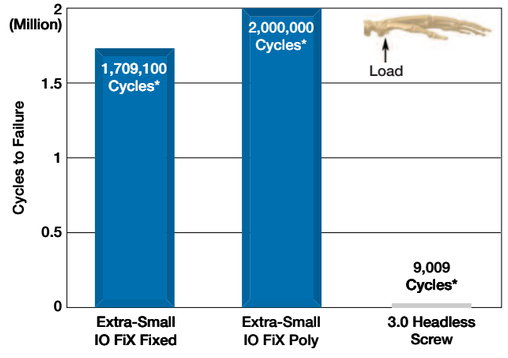
The X-Post™ distributes compressive forces across a greater surface area, delivering a more uniform and a higher peak compression.* The unique Morse Taper Locking System (X-Lock™) lags and locks simultaneously against a reinforced metallic bone bridge. Unlike screws, CarpalFix™ maintains compression if the cortical bridge is compromised.

Peak Compression*

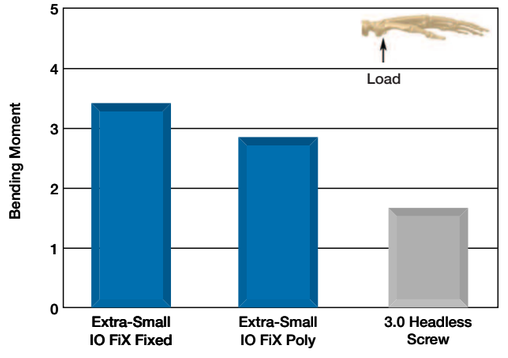


Stability**
Superior fatigue and strength resistance decrease the likelihood of a construct failure

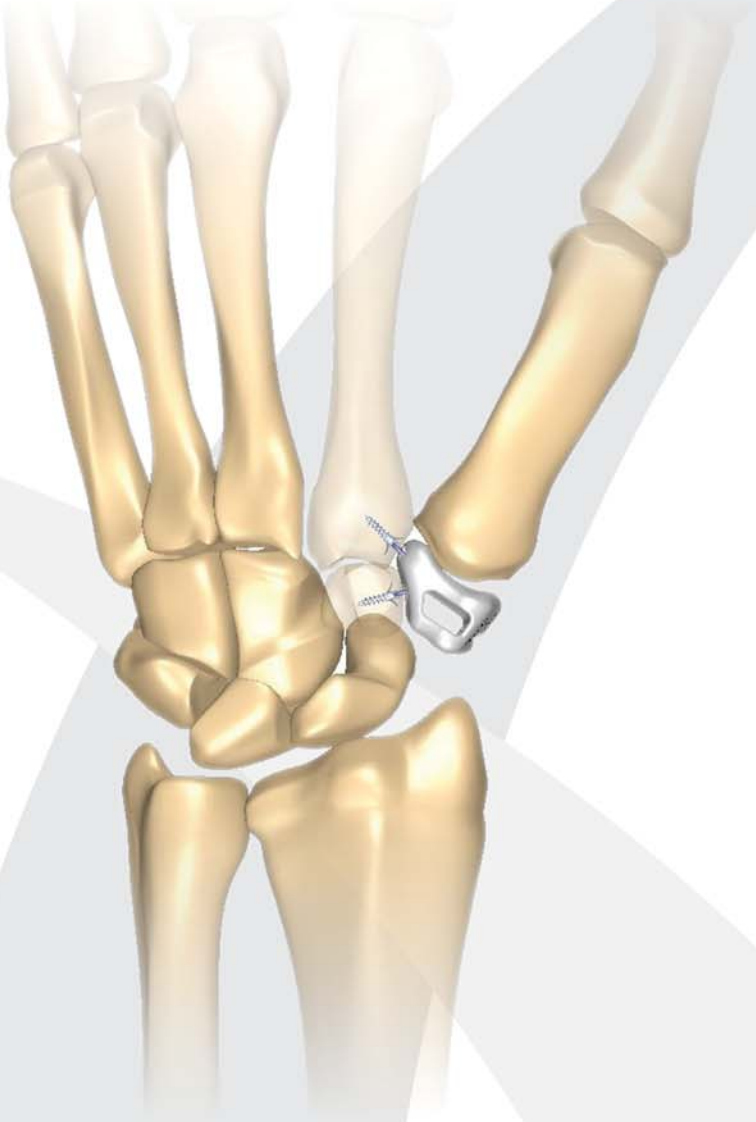
Fatigue Strength*



Bending Strength*



* Data on file, Extremity Medical ** Manual of Internal Fixation - AO



TrapEZ™

TRAPEZIUM REPLACEMENT

Surgical Technique

Features and Benefits

- Anatomic Trapezium Replacement
- Simple, fast procedure without complex instrumentation
- No secondary procedure to harvest tendon
- Preserves revision options
- New alternative for failed LRTI
- Suture anchor may be used for short term stability
- Open space for the potential of soft tissue ingrowth
- Restores biomechanical anatomy

TrapEZ™
TRAPEZIUM REPLACEMENT
Surgical Technique

Designed in conjunction with:
Amy Ladd, MD • Professor & Chief, Robert A. Chase Hand & Upper Extremity Limb Center, Stanford University Medical School

Arnold Peter Weiss, MD • Professor of Orthopedics, Alpert Medical School of Brown University

John Faillace, MD • FAAOS, Hand and Orthopedic Surgery, Waco, Texas

The biomechanics of the device were developed in collaboration with Professor J.J. Trey Crisco, Ph.D
Director Bioengineering Laboratory, Department of Orthopaedics, Alpert Medical School of Brown University

INDICATIONS FOR USE

The Extremity Medical Trapezium Prosthesis is a surgical implant indicated for use in degenerative or post-traumatic (e.g. following an old Bennett fracture) arthritis of the thumb trapezial-metacarpal ("basal") joint with:

- Localized pain and palpable crepitus at the base of the thumb on the "grind test" (circumduction with axial compression of the thumb)
- Decreased motion, pinch, and grip strength
- X-ray evidence of arthritic changes of the trapeziometacarpal joint; as well as trapezioscaphoid, trapeziotrapezoid, and trapezium-second metacarpal joints, singly or in combination.
- Associated unstable, stiff, or painful distal joints of the thumb, including metacarpo-phalangeal hypermobility or hyperextension

SURGICAL TECHNIQUE

The following surgical procedure is applicable for the size 1, 2, & 3 Right and Left side Extremity Medical Trapezium Prosthesis implants. All implants and instruments are laser marked to help distinguish between three different sizes. The only instruments specific to the implant(s) are the sizing trials. All other instruments used in the surgical technique are common access instruments that are readily available to a physician.

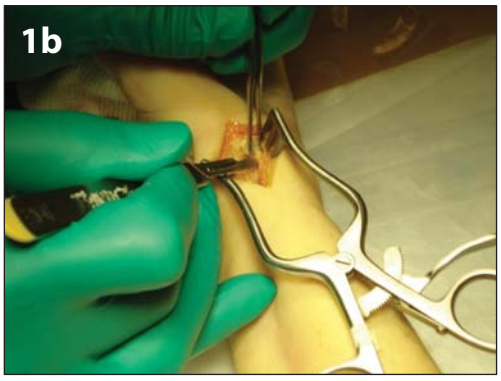
The implant approximates the anatomy of the trapezium. The straight side represents the radial and thus most superficial side of the implant, and the angled side includes the articulations of the trapezoid and second metacarpal. The scaphoid articulation slopes proximally on its volar side.

STEP 1 – Approach

Two standard approaches are recommended, volar and dorsal.

Volar approach: An incision is made about the dorsal-radial longitudinal base of the thumb CMC joint between the dorsal, loose skin and the glabrous skin of the palm. Sensory branches in this area are identified and protected. The interval between the APL (Abductor Pollicis Longis) and thenar muscles is developed, releasing an accessory slip of APL inserting into the thenars if necessary. The capsule including the CMC (Carpometacarpal) and ST (Scapho-Trapezial) joints and the periosteum on the trapezium is divided and reflected; the volar branch of the radial artery is a useful landmark for identifying the ST joint.

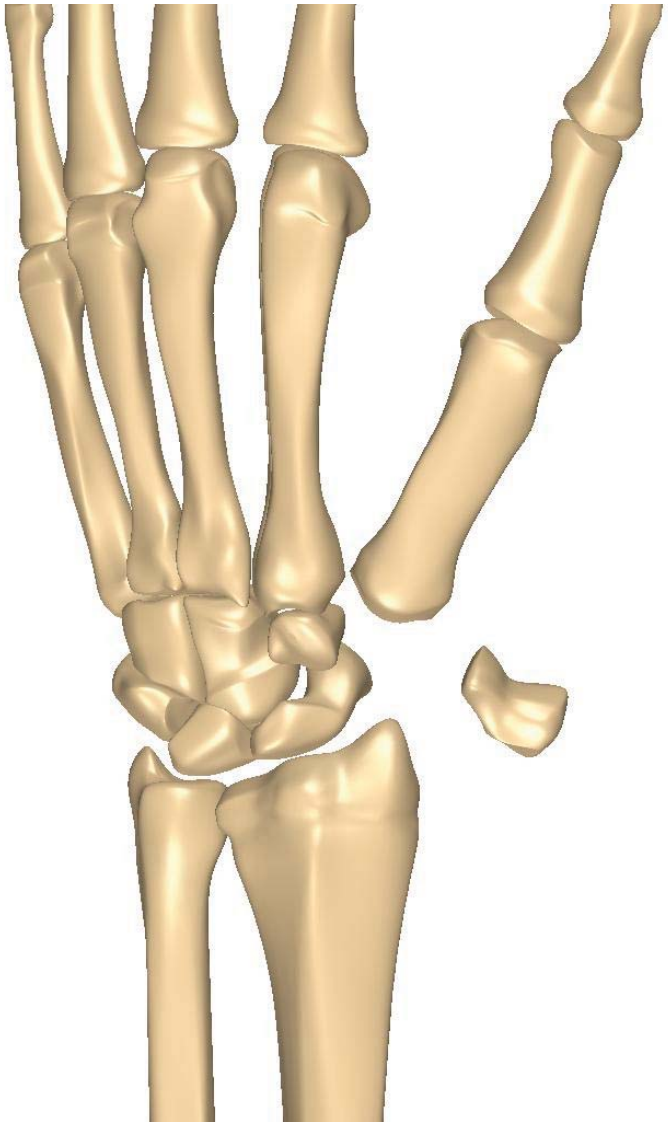
Dorsal Approach (Illustrated at right): A 3-4 cm incision is made centered over the trapezium. Subcutaneous dissection with scissors is used to identify the sensory branch fibers of the Radial nerve and to dissect down to the retinacular sheath overlying the APL and Extensor Pollicis Brevis (EPB) tendons. A knife is used to open the interval between the APL and EPB tendon sheaths, sharply going through the joint capsule down to the bone from the base of the thumb metacarpal to the proximal portion of the trapezium. Care should be taken proximally in this incision, as once fatty tissue is seen, a branch of the radial artery is in that region. Essentially the proximal portion of this incision should stop at the Scaphotrapeziotrapezoid (STT) joint. A knife is used to reflect the capsule off the trapezium so that it is fully visualized.



1a: *Designation of longitudinal incision along CMC joint*
1b: *Capsular incision*
1c: *Exposure of the trapezium*

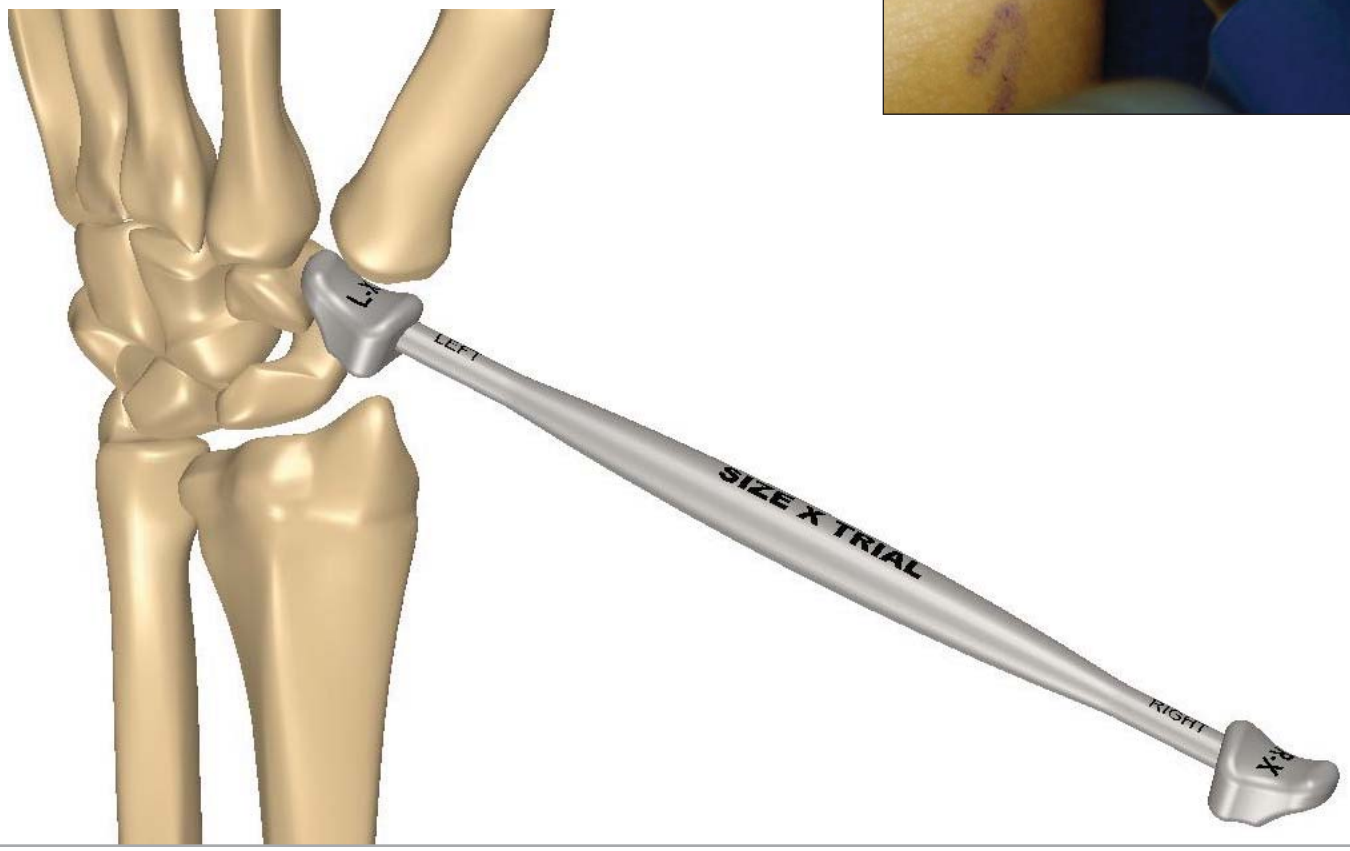
STEP 2 - Remove the Trapezium

Remove the trapezium (trapeziectomy), either *en bloc* or piecemeal. Use great care to avoid injury to the surrounding structures, especially the Flexor Carpi Radialis (FCR), which runs obliquely across the volar trapezium toward the second metacarpal. Osteophytes and small loose bodies often are found in the deep ulnar capsule, and should be removed. If necessary, fluoroscopic imaging may confirm complete trapeziectomy.



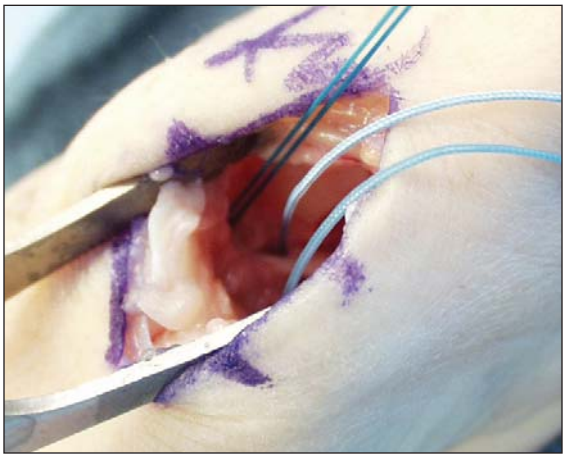
STEP 3 - Select the correct size implant

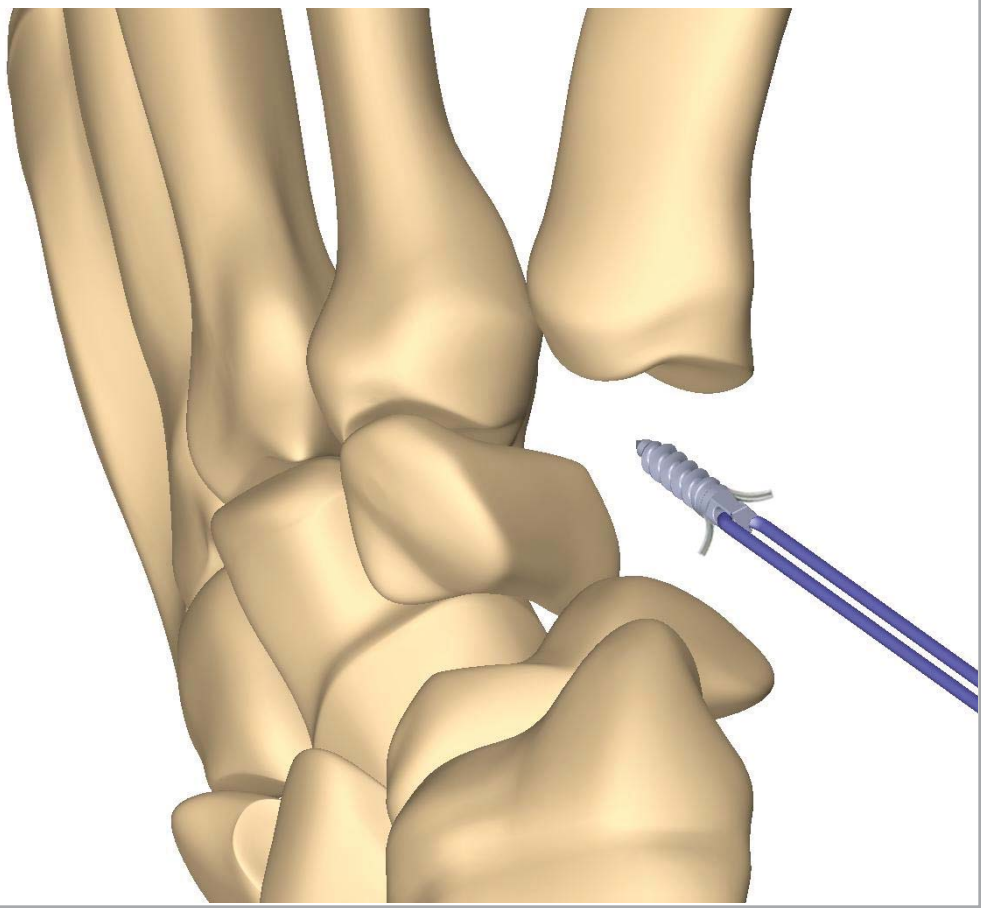
Select the correct size implant by using the available trials, starting with the smallest first. The Extremity Medical Trapezium Prosthesis is made in sizes 1, 2, & 3 for the Right and Left sides. The implant size selected should fit within the trapeziectomy space and permit smooth range of motion of the metacarpal on the implant. This should be confirmed with fluoroscopy. If substantial erosion or significant subsidence of the metacarpal is present, then smoothing of the metacarpal base to fit the surface of the implant may be required.



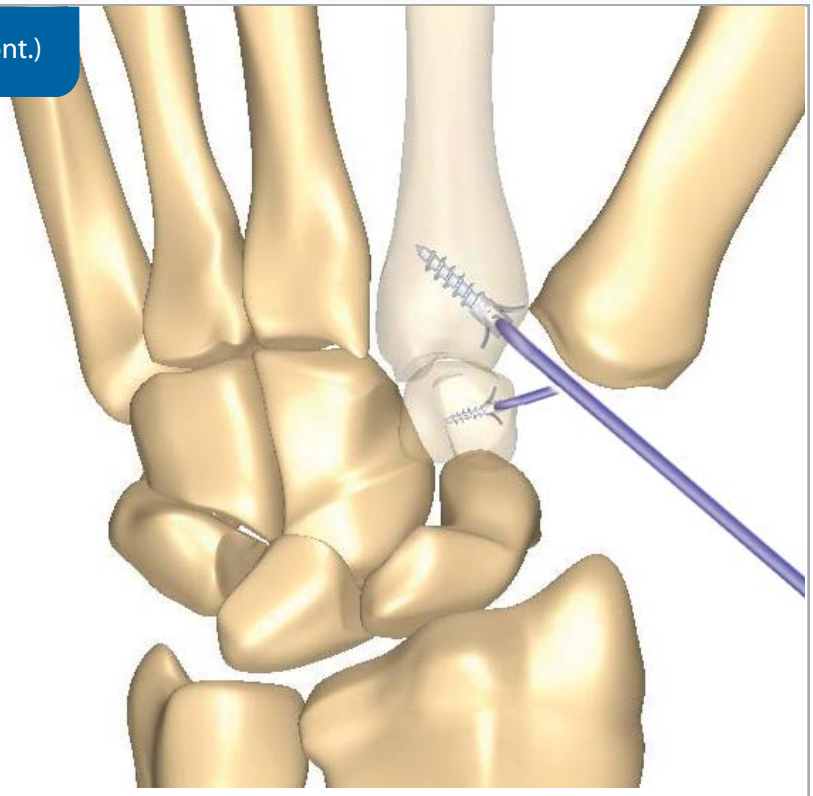
STEP 4 – Insert Suture Anchor

Insert a general, currently marketed suture anchor with a durable suture into the base of the 2nd metacarpal and or the Trapezoid. For additional volar-ulnar support, an additional suture may be placed through the base of the FCR at its insertion into the 2nd metacarpal. The two limbs of these sutures may be passed with the sutures of the 2nd metacarpal through the implant as described below.



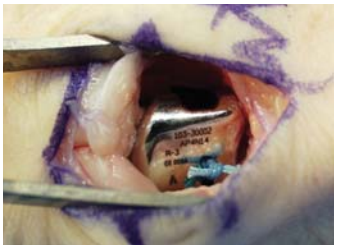


STEP 4 – Insert Suture Anchor (cont.)



STEP 5 – Insert the Implant

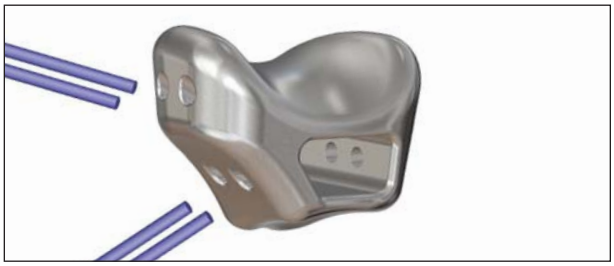
Insert the implant into the trapezium cavity and tension the sutures placed through the suture holes to position the implant. As the sutures are firmly tied, the implant is securely reduced into the desired position within the trapezium space. Ensure excess suture ends are removed. Verify the position and sizing of the implant.

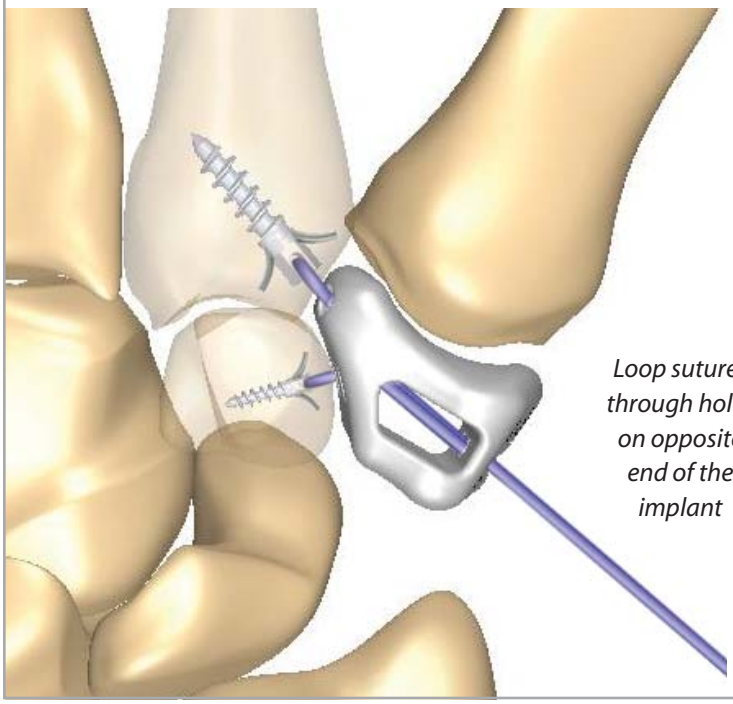


STEP 5 – Insert the Implant (cont.)

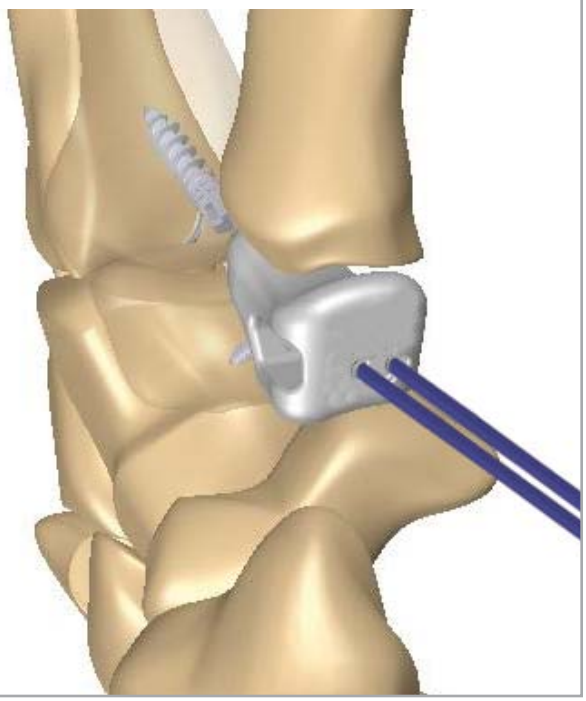
See Laser marking to verify implant size and side

Align and insert sutures into designated holes of implant





Loop sutures through holes on opposite end of the implant

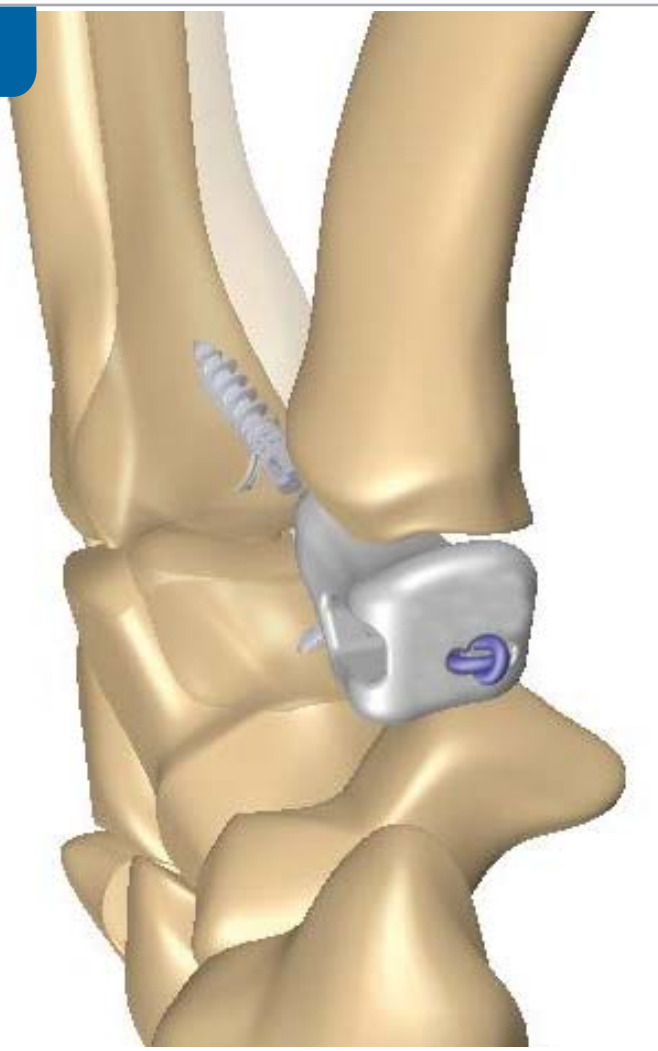


STEP 6 – Close the Capsule

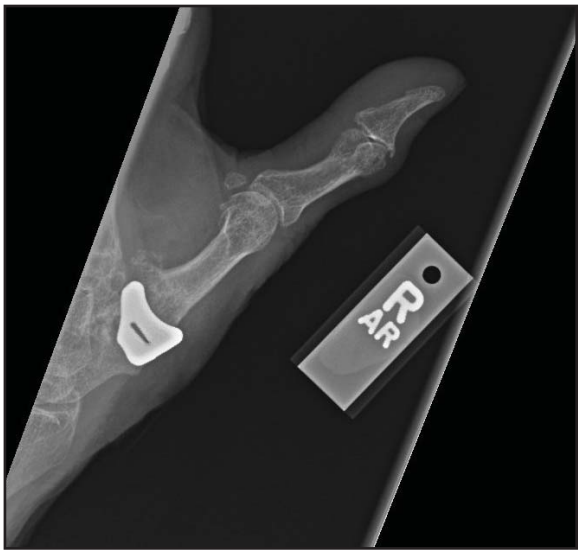
Close the capsule / periosteum using general, currently marketed suture. Closing the overlying soft tissues provides additional support for the implant localization. Type of skin closure and injection of local anesthetic is at the surgeon's discretion. Additional fluoroscopic visualization may be desired.

Closing of capsule

X-Ray of Extremity Medical Trapezium Prosthesis



CASE EXAMPLES



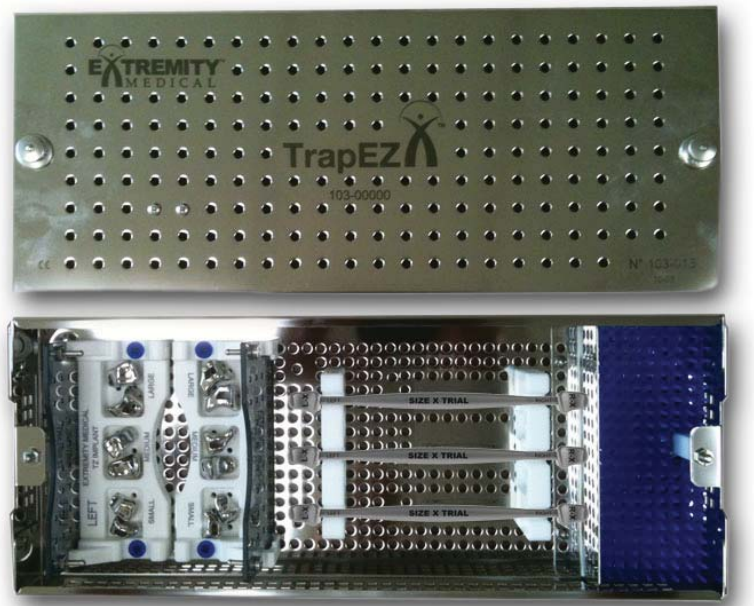
TRAPEZX REFERENCE NUMBERS

Implants

Catalog #	Description
103-11001	Trapezium Prosthesis (Size 1) - Left
103-11002	Trapezium Prosthesis (Size 1) - Right
103-21001	Trapezium Prosthesis (Size 2) - Left
103-21002	Trapezium Prosthesis (Size 2) - Right
103-31001	Trapezium Prosthesis (Size 3) - Left
103-31002	Trapezium Prosthesis (Size 3) - Right

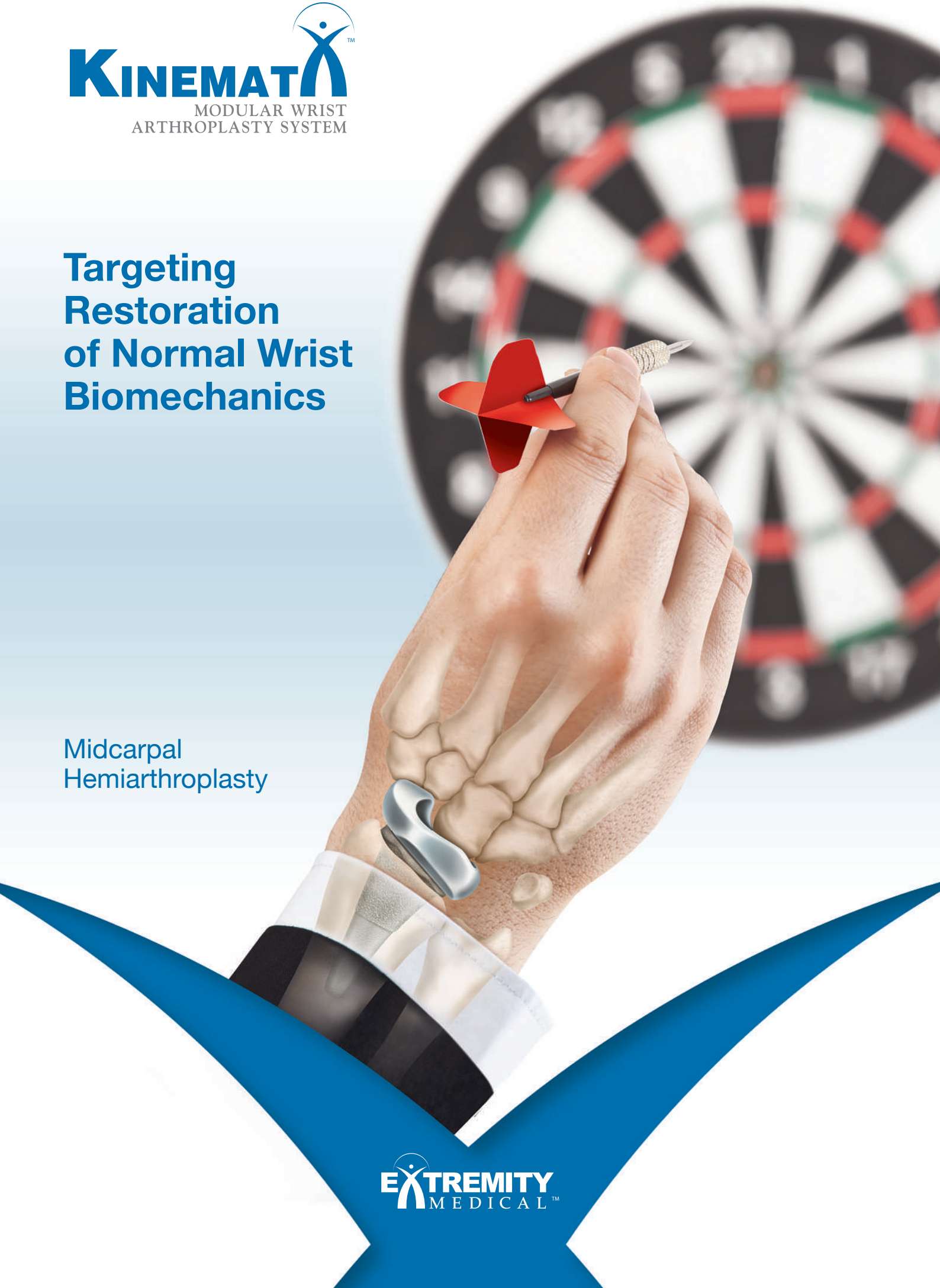
Instruments

Catalog #	Description
103-00000	TrapEZX Instrument Tray
103-00010	Size 1 Trial Assembly
103-00020	Size 2 Trial Assembly
103-00030	Size 3 Trial Assembly



KINEMATX™
MODULAR WRIST
ARTHROPLASTY SYSTEM

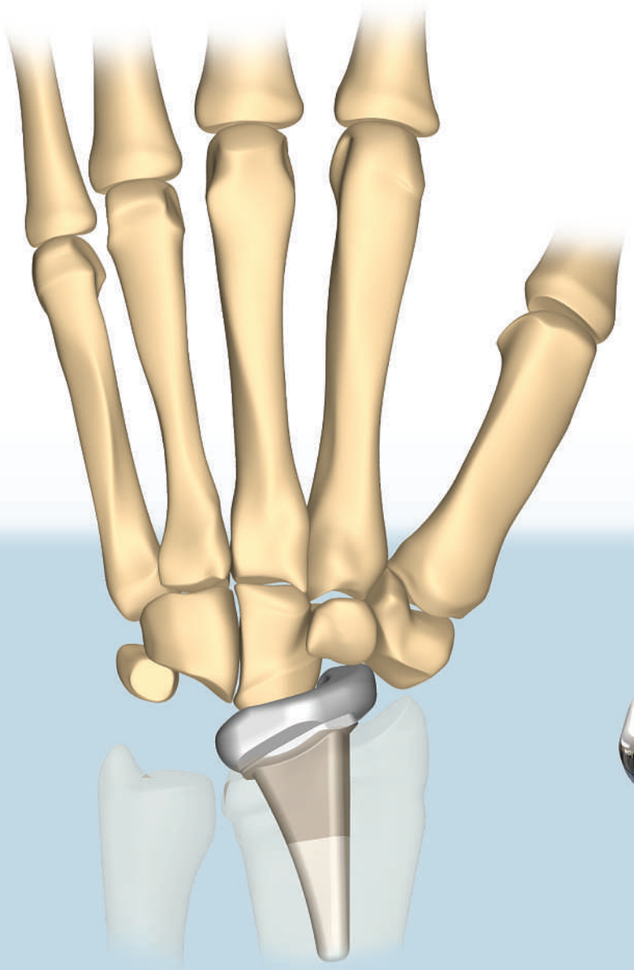
Targeting Restoration of Normal Wrist Biomechanics

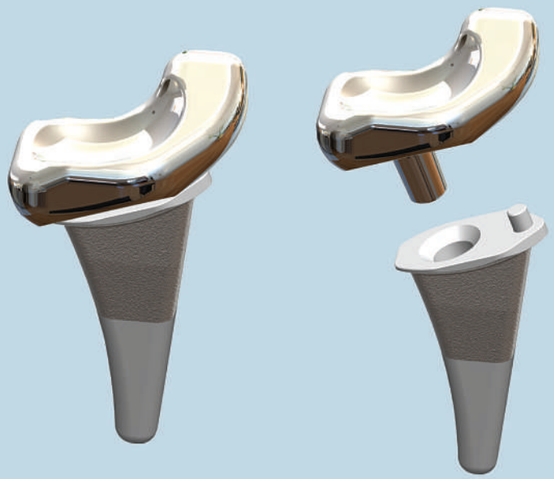


Midcarpal Hemiarthroplasty

EXTREMITY MEDICAL™

KinematX: A Breakthrough in the Restoration of Human Wrist Motion





Anatomic Design

- Emulates the Proximal Row and Restores Anatomy
- Allows for Midcarpal Articulation
- Preserves Radial Length and Inclination

Stable Radial Fixation

- Streamlined Implantation Technique
- Removes the Risk of Distal Hardware Loosening
- Cobalt Chrome Stem with Titanium Plasma Spray Coating

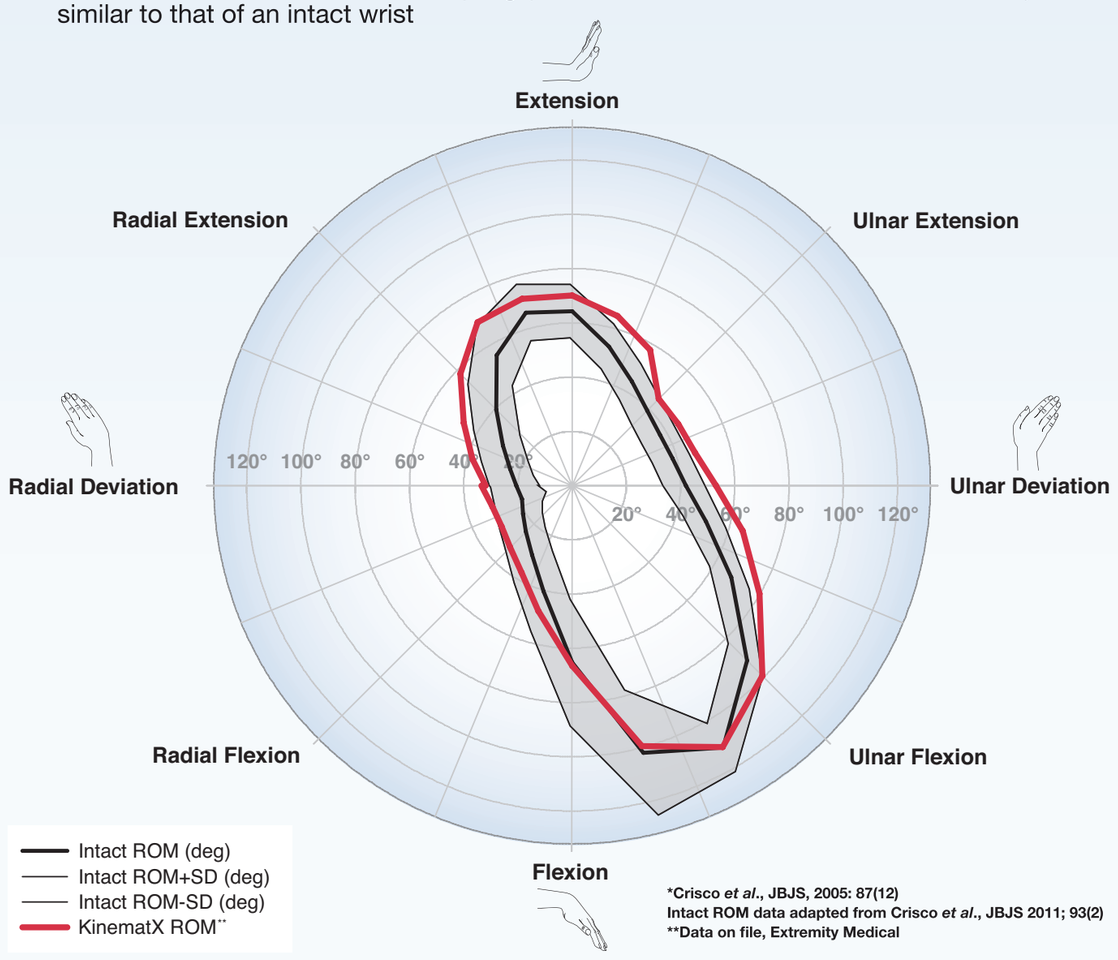
Patient Focused

- 2-Piece Modular System and Sizing for Varying Patient Anatomy
- Allows for the Future Conversion to a Total Wrist Arthroplasty

Restoring the Dart Thrower's Motion*

A Kinematic and Funtional Comparison of the Intact Wrist and the KinematX Hemi Modular Wrist Arthroplasty System

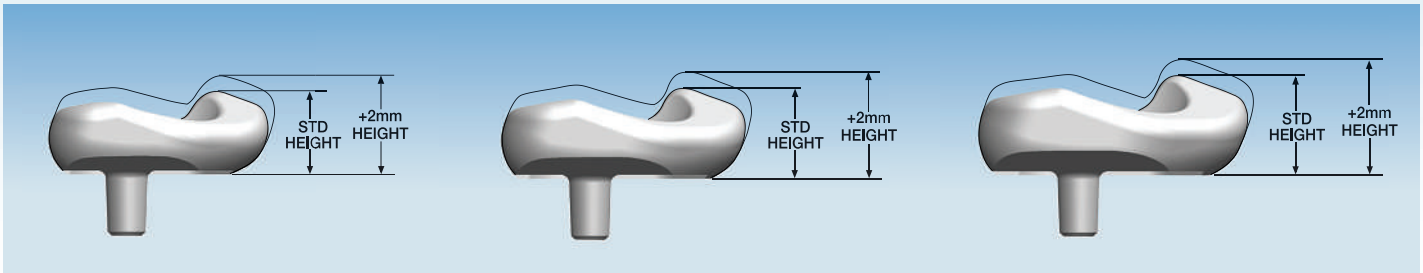
- Mechanical axes of the wrist are oriented obliquely to the anatomical axes
- The primary mechanical direction is one of radial extension and ulnar flexion—a direction along the path of the dart thrower's wrist motion
- KinematX creates an anatomic coupling (flexion/extension and radio-ulnar deviation) similar to that of an intact wrist



*Crisco *et al.*, JBJS, 2005: 87(12)
Intact ROM data adapted from Crisco *et al.*, JBJS 2011; 93(2)
**Data on file, Extremity Medical

KINEMATX™
MODULAR WRIST
ARTHROPLASTY SYSTEM

Modular System Allows for Sizing for Varying Patient Anatomy



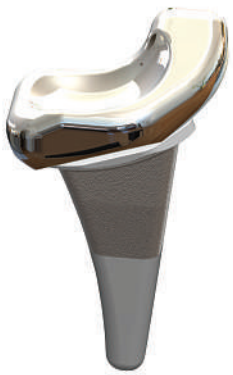
Radial Body Implants:

- Left and Right Specific
- 3 Size Options
- Each Available in Two Heights

Radial Stems are Available in 3 Sizes

Indications For Use:
The KinematX Modular Wrist Arthroplasty System is indicated for the replacement of a wrist joints disabled by pain, deformity, and/or limited motion caused by:

- Non-inflammatory degenerative joint disease of the radiocarpal joint including osteoarthritis, post-traumatic arthritis, and Kienbock's disease
- Revision where other devices or treatments have failed
- Scapholunate Advanced Collapse (SLAC)
- Rheumatoid arthritis



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EXTREMITY MEDICAL™

This device is not approved for sale in the USA

LBL-115-99105-EN Rev A 9/2016