



IO Fix

Intra Osseous Fixation

MCP

Launch Binder



Included in this binder

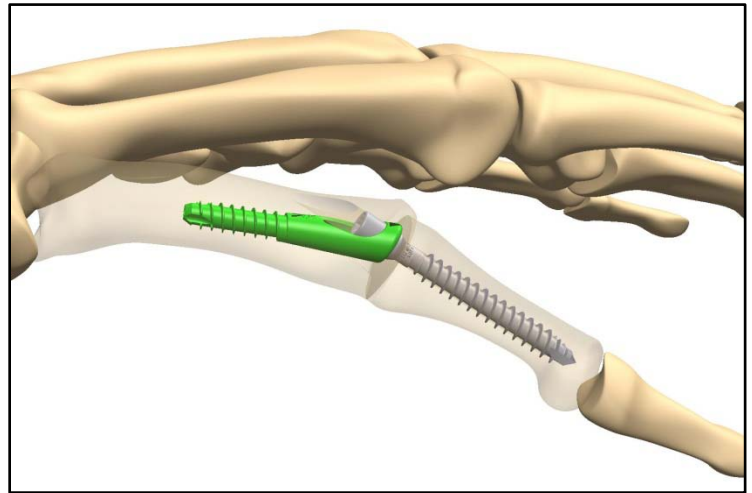
- Product description
- FAQ's
- Case report
- Price list
- Sales order form
- Surgical technique
- Sawbones technique

Introducing IO FiX MCP, Intraosseous Fixation of MCP

Product description

IO Fix MCP is the first of its kind intramedullary fixation device for fusion of the Metacarpal Phalangeal joint of the hand. This represents the first product for the hand that utilizes intraosseous fixation for fusion of joints in the hand.

IO FiX MCP provides a stronger construct than alternative methods such as plates and screws, delivers greater compression, and avoids any soft tissue irritation associated with plates and screws. IO FiX MCP is a fixed 25° angle which allows for reproducible results.



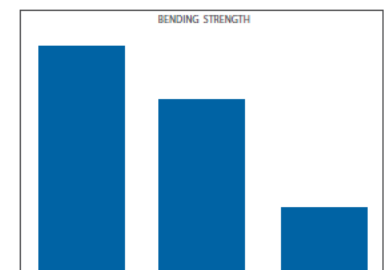
“In addition to significant biomechanical strength advantages, the device offers benefits of intramedullary fixation where traditionally, pins, plates or tension band wiring were used but were commonly associated with hardware related irritation.”

Brian Adams, M.D., Iowa City, Iowa

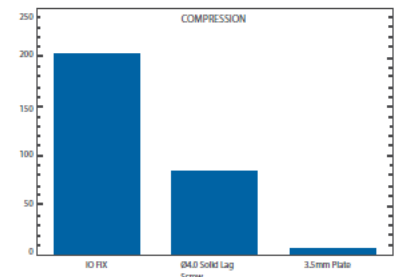
Key Advantages:

- Stable intramedullary fixation
- Fixed 25° angle for reproducible results
- Implant compresses across joint
- Superior bending resistance minimizing implant cut out
- Simple reproducible procedure
- Avoids hardware irritation commonly caused by pins, plates, or tension band wiring
- Advanced instrumentation reduces procedure time
- Removable

Instrument sets are available for use after June 1, 2010.



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

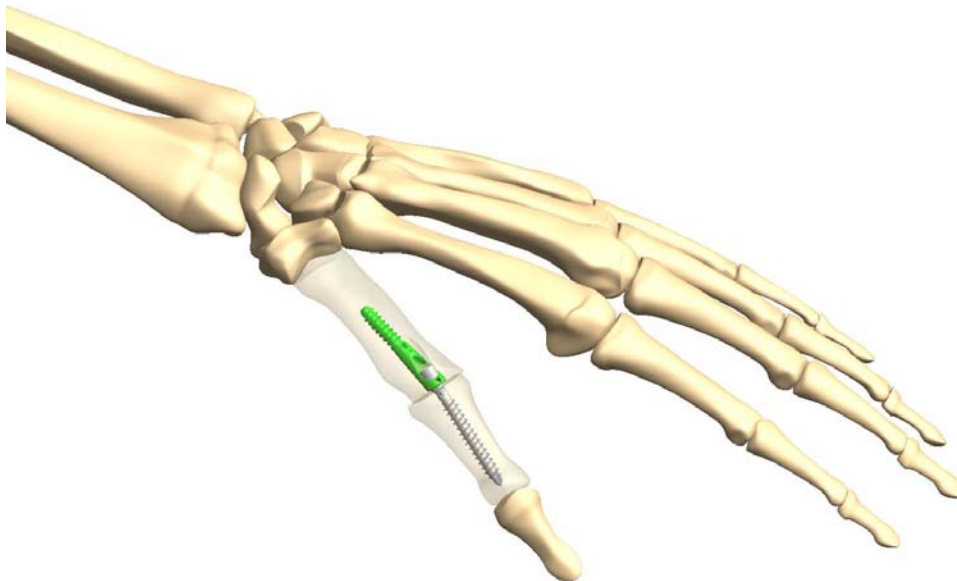


2.5X more delivered compression than to Ø4.0 screw construct
45X more delivered compression than plate and screw construct

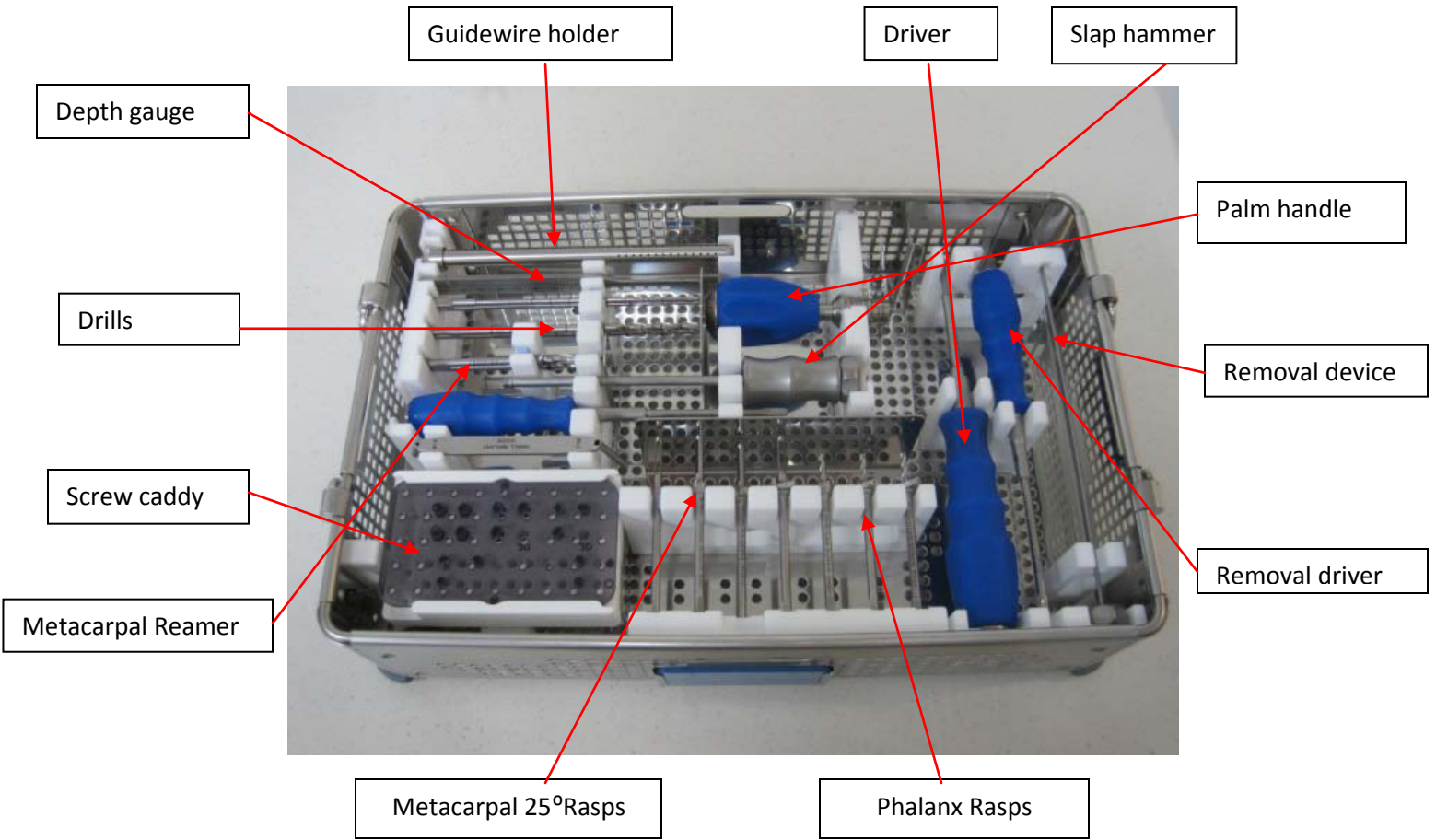


Implants and pricing

IO FIX MCP IMPLANTS			IO FIX MCP DISPOSABLES		
102-40020	Cannulated Lag Screw - 4.0mm x 20mm	\$650	101-00023	Cleaning Brush - 1.6mm	\$95
102-40024	Cannulated Lag Screw - 4.0mm x 24mm	\$650	102-00002	Cannulated Drill - 3.0mm	\$167
102-40028	Cannulated Lag Screw - 4.0mm x 28mm	\$650	102-00018	Cannulated Drill - 6.0mm	\$167
102-40032	Cannulated Lag Screw - 4.0mm x 32mm	\$650	102-00023	Double-Ended Guidewire - 1.6mm	\$12
102-40036	Cannulated Lag Screw - 4.0mm x 36mm	\$650	120-00002	MCP X-Ray Template	\$5
113-40020	Solid Lag Screw - 4.0mm x 20mm	\$650	120-01000	Metacarpal Reamer	\$280
113-40024	Solid Lag Screw - 4.0mm x 24mm	\$650	120-05000	Dorsal Window Drill	\$196
113-40028	Solid Lag Screw - 4.0mm x 28mm	\$650	120-02012	12mm Dorsal Window Rasp	\$280
113-40032	Solid Lag Screw - 4.0mm x 32mm	\$650	120-02016	16mm Dorsal Window Rasp	\$300
113-40036	Solid Lag Screw - 4.0mm x 36mm	\$650	120-04012	12mm Lag Screw Rasp	\$260
120-12530	Small Metacarpal implant - 4.0mm x 25.0° x 30	\$1,250	120-04016	16mm Lag Screw Rasp	\$300
120-22530	Medium Metacarpal implant - 5.0mm x 25.0° x 30	\$1,250			
120-32530	Large Metacarpal implant - 6.0mm x 25.0° x 30	\$1,250			



Instrument tray layout

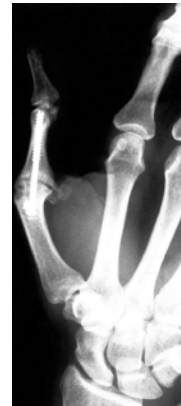


Current treatment options

- Plates & Screws
 - Do not provide compression
 - Less Strength
 - Tissue irritation can be problem
 - May need to bend



- Lag and compression screws
 - Hard to get head fully buried because of angle, resulting in tissue irritation.
 - Hard to get consistent 25° fixation angle



- Tension band wires
 - Tissue irritation
 - Lack compression
 - Hard to obtain fixed angle
 - Difficult to position



FAQ's

Why is IO FiX MCP a better option for MCP fusion than other methods?

Other methods rely on fixation methods that leave hardware or screw heads on the outer surface of the bone that can lead to irritation of surrounding soft tissue, and potential reoperation for hardware removal.

IO FiX MCP provides a stronger construct and delivers more compression than other methods which leads to a higher union rate.

Because the IO FiX MCP is a fixed angle of 25° the surgeon can obtain consistent reproducible results.



Can IO FiX MCP be used with TrapEZ for CMC arthroplasty?

Yes. It is common for surgeons to fuse the MCP of the thumb in conjunction with CMC arthroplasty.

How do the two implants lock together?

The two implants lock together via a morse taper lock. This provides compression prior to locking as well as firm construct when locked. Because it locks it insures against screw backing out.

Can it be used for all MCP fusions?

Yes, it is indicated for fusion of all metacarpal phalangeal joints.

What about using for a failed fusion?

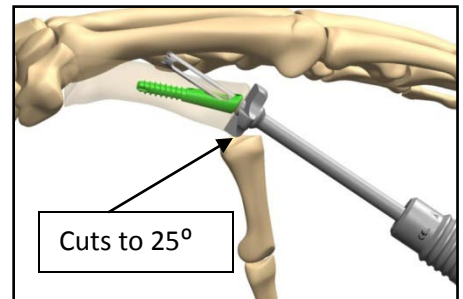
Yes, because it comes in multiple sizes it should be a good option for failed fusion.

What material is it made of?

IO FiX MCP is made of titanium.

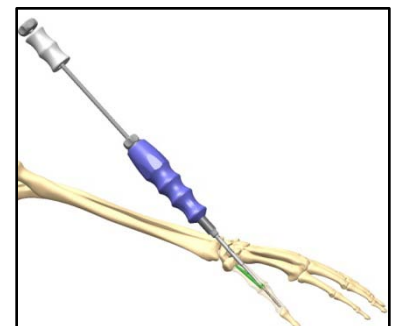
How do you get the fixed 25° angle each time

First, the implant locks in a fixed 25° angle. Second the metacarpal rasp prepares the head of the metacarpal at 25° for uniform angle.



Can it be removed?

Yes, the lag screw has threads in it that a removal tool can thread into to help remove. We also have a slap hammer device to break the morse taper.



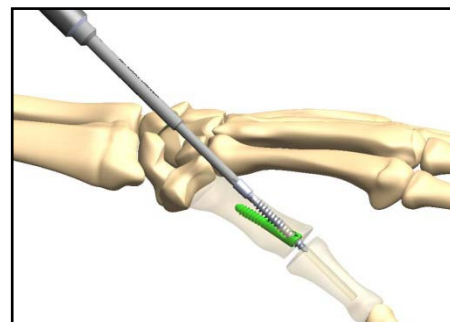
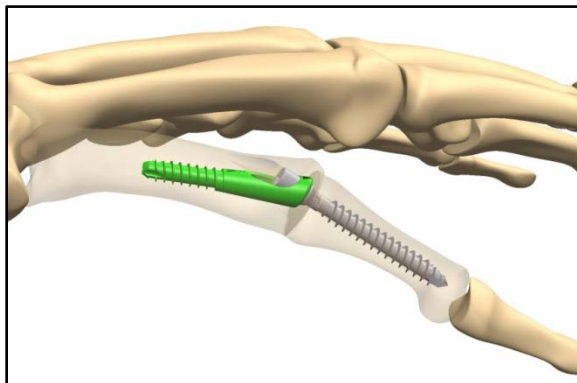
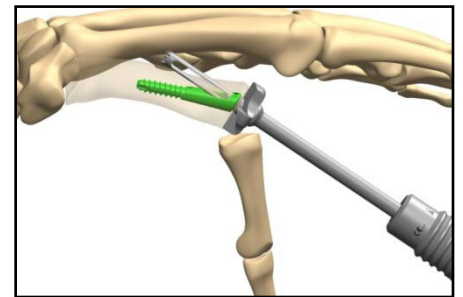
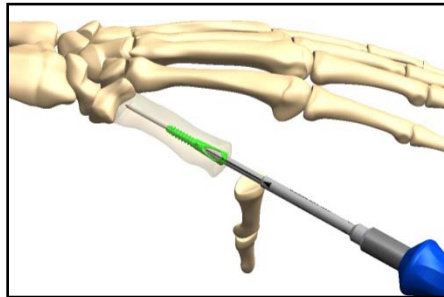
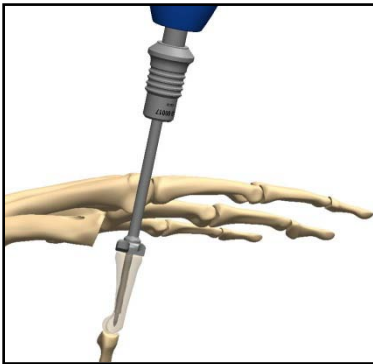
Targets for IO FiX MCP

- Hand Surgeons
- General Orthopedic Surgeons
- Upper Extremity Surgeons
- Plastic Surgeons

Ask your surgeons questions.

- How do you currently fuse MCP?
- Do you fuse at 25°?
- What do you think of Intramedullary fusion of this joint?

- Be prepared to talk about how IO FiX MCP provides rigid fixation, compresses across joint, and is a fixed 25° angle.
- Show the implant and technique and show them that the instrumentation makes for easy reproducible surgery.
- Show the graphs showing greater compression and strength.
- Ask for next case



Case Report – Metacarpal Fusion with CMC Arthroplasty

Pre-Op Assessment:

A male patient presents with a Z-deformity and unstable metacarpal phalangeal joint. The patient had difficulty with pinching and gripping. Pre-op radiographs show a total collapse of the CMC joint and severe impingement of the MCP joint.



Pre-Op Assessment:

The metacarpal phalangeal joint was prepared and the IO FIX MCP implant was used to fuse the MCP joint at a 25° angle. A trapezectomy was performed and a medium TrapezX implant was used to restore height and range of motion.



Implants

Cannulated and solid lag screws 20-36mm in 4mm increments

Metacarpal implants – 4mm,5mm,6mm in 30mm length



Resources

Region Managers

East – Jim Elia, jelia@extremitymedical.com 914.413.8430

West – Hamid Forouzi, hforouzi@extremitymedical.com 708.602.2480

Product Development Manager – Technical questions

Jeff Tyber – jtyber@extremitymedical.com 303.717.5060

Clinical Specialists – Training & Education

East – Mat Kandell, mkandell@extremitymedical.com 631.384.3199

West – Adam Yoder, ayoder@extremitymedical.com 714.350.2273

Customer Service – Literature, techniques, demos

Camille DeLuca, cdeluca@extremitymedical.com 973.588.8982

Kathryn McGinley, kmcginley@extremitymedical.com 973.588.8905

Sales & Marketing

Scott Hunter, shunter@extremitymedical.com 770.331.7104



Resources

Surgical Techniques

Demo Implants

Sawbones

Billing code examples

Code	Description	APC	APC Description
26841	Arthrodesis, carpometacarpal joint, thumb, with or without internal fixation;	0054	Level II Hand Musculoskeletal Procedures
26842	Arthrodesis, carpometacarpal joint, thumb, with or without internal fixation; with autograft (includes obtaining graft)	0054	Level II Hand Musculoskeletal Procedures
26850	Arthrodesis, metacarpophalangeal joint, with or without internal fixation;	0054	Level II Hand Musculoskeletal Procedures
26852	Arthrodesis, metacarpophalangeal joint, with or without internal fixation; with autograft (includes obtaining graft)	0054	Level II Hand Musculoskeletal Procedures
26860	Arthrodesis, interphalangeal joint, with or without internal fixation;	0054	Level II Hand Musculoskeletal Procedures
26861	Arthrodesis, interphalangeal joint, with or without internal fixation; each additional interphalangeal joint (List separately in addition to code for primary procedure)	0054	Level II Hand Musculoskeletal Procedures
26862	Arthrodesis, interphalangeal joint, with or without internal fixation; with autograft (includes obtaining graft)	0054	Level II Hand Musculoskeletal Procedures
26863	Arthrodesis, interphalangeal joint, with or without internal fixation; with autograft (includes obtaining graft), each additional joint (List separately in addition to code for primary procedure)	0054	Level II Hand Musculoskeletal Procedures



**2010 US HOSPITAL PRICE LIST
IO FiX MCP Device**

Item Number	Description	Price
IO FiX MCP IMPLANTS		
102-40020	Cannulated Lag Screw - 4.0mm x 20mm	\$650
102-40024	Cannulated Lag Screw - 4.0mm x 24mm	\$650
102-40028	Cannulated Lag Screw - 4.0mm x 28mm	\$650
102-40032	Cannulated Lag Screw - 4.0mm x 32mm	\$650
102-40036	Cannulated Lag Screw - 4.0mm x 36mm	\$650
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120-12530	Small Metacarpal implant - 4.0mm x 25.0° x 30	\$1,250
120-22530	Medium Metacarpal implant - 5.0mm x 25.0° x 30	\$1,250
120-32530	Large Metacarpal implant - 6.0mm x 25.0° x 30	\$1,250
IO FiX MCP DISPOSABLES		
101-00023	Cleaning Brush - 1.6mm	\$95
102-00002	Cannulated Drill - 3.0mm	\$167
102-00018	Cannulated Drill - 6.0mm	\$167
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120-02016	16mm Dorsal Window Rasp	\$300
120-04012	12mm Lag Screw Rasp	\$260
120-04016	16mm Lag Screw Rasp	\$300



SALES ORDER FORM
IO FIX MCP SYSTEM

PO#

Extremity Medical, LLC
300 Interpace Parkway, Suite 410
Parsippany, NJ 07054
Customer Service Tel: 1-888-499-0079
Toll Free Fax: 1-888-499-0542

HOSPITAL NAME:
ADDRESS:
CONTACT NAME:
TEL:

SURGERY DATE: PROCEDURE:
SURGEON: () MD
() DO
() DPM

Table with columns: Part #, Description, Lot Number, Price, Qty, Extended. Section: IO FIX IMPLANTS. Includes rows for various cannulated lag screws (102-40020 to 102-40036).

Table with columns: Part #, Description, Lot Number, Price, Qty, Extended. Section: Metacarpal Implants. Includes rows for Small (120-12530), Medium (120-22530), and Large (120-32530) metacarpal implants.

Table with columns: Part #, Description, Lot Number, Price, Qty, Extended. Section: IO FIX DISPOSABLES. Includes rows for cleaning brushes, drills, guidewires, reamers, rasps, and MCP X-Ray Template.

OTHER / SPECIAL INSTRUCTIONS:
TOTAL USAGE \$ -
FREIGHT \$ 50
GRAND TOTAL

Ship Method (please circle)
Fed Ex: 2 Day Service Priority Standard Saver Early AM

Hold for Pick Up at:

RECEIVED BY (SIGNATURE / OR) PRINT NAME AND TITLE DATE
Distributor Name: Send replacements to:
Sales Rep: Kit #
Warehouse ID: Sales Order #
() Do not replenish stock (loaner kit used/bill only) Tel:

Rev. A 5/6/10

IO FiX

Intra Osseous Fixation

MCP

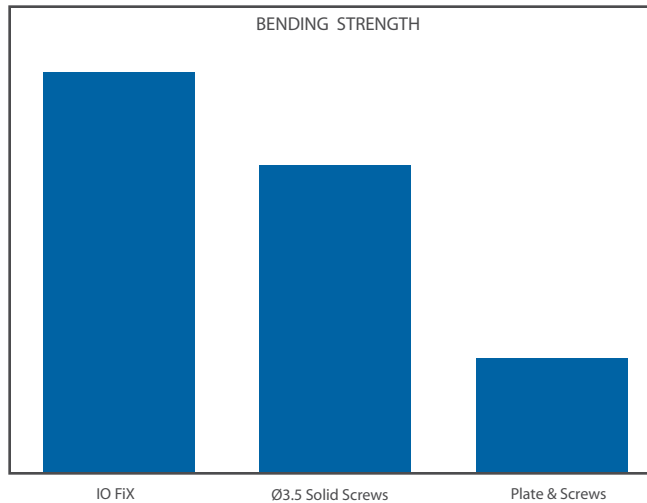
Surgical Technique



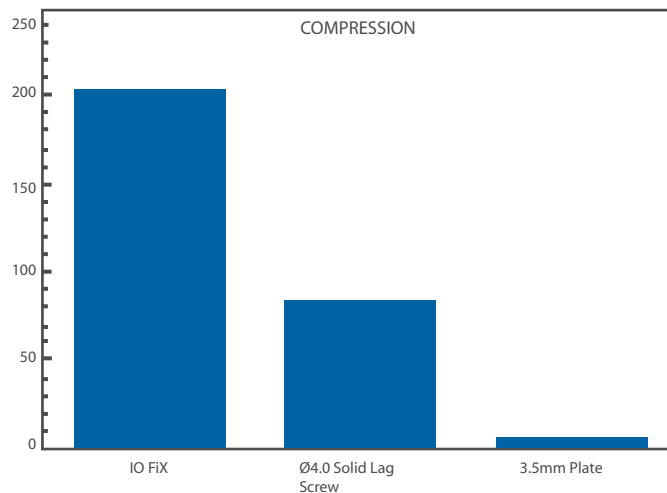
- Stable intramedullary fixation
- Fixed 25° angle for reproducible results
- Implant compresses across joint
- Superior bending resistance minimizing implant cut out
- Avoid hardware complications from tissue irritation caused by plates and wires
- Advanced instrumentation reduces procedure time
- Avoids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

Patent Pending

As described by Brian D, Adams, M.D., Iowa City, Iowa, O. Alton Barron, M.D., New York, NY
and John Faillace, M.D., Waco, TX
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



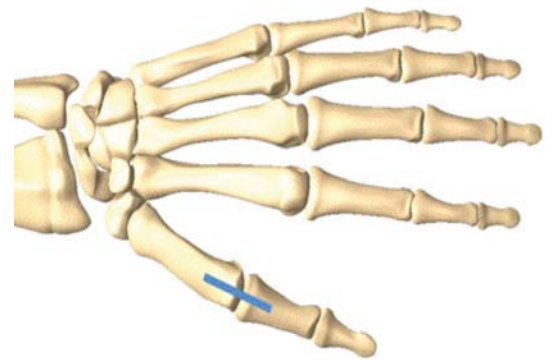
2.5X more delivered compression than to Ø4.0 screw construct
45X more delivered compression than plate and screw construct

INDICATIONS FOR USE

The Extremity Medical Screw System is intended for arthrodesis fixation of the metacarpal-phalangeal joints.

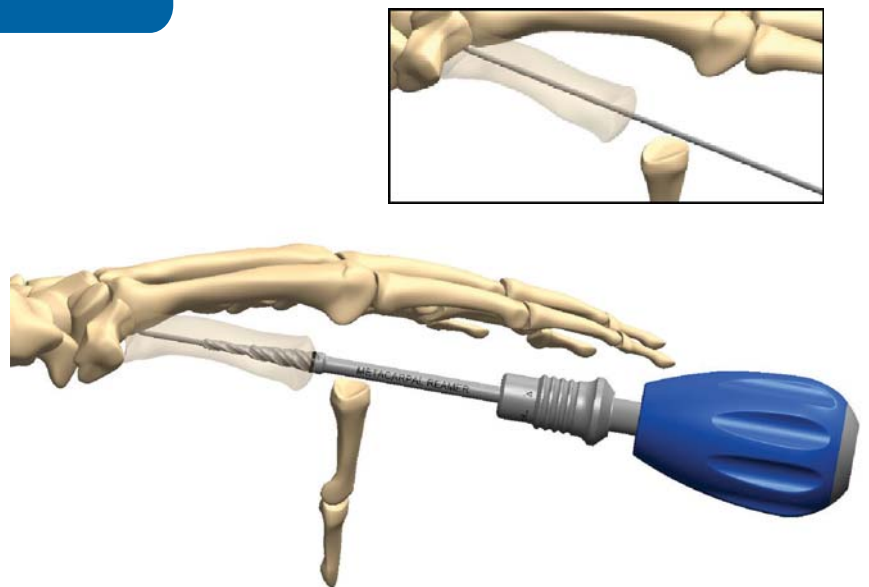
STEP 1 - Exposure

A dorsal longitudinal incision is made over the metacarpal-phalangeal joint. The metacarpal-phalangeal joint is exposed by mobilizing the extensor tendon mechanism. The joint is fully flexed to visualize the metacarpal head and proximal phalanx base.



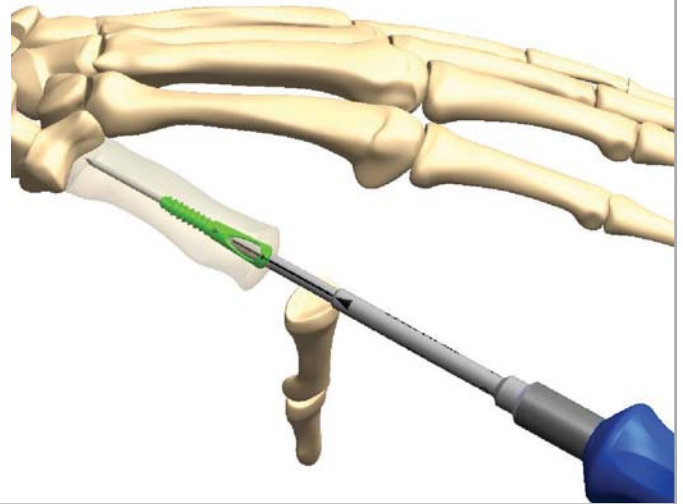
STEP 2 - Metacarpal Preparation

Insert a 1.6mm guidewire into the center of the metacarpal medullary canal and confirm its position using fluoroscopy. Place the cannulated Metacarpal Reamer over the wire and insert until the black depth line is just beneath the articular surface.



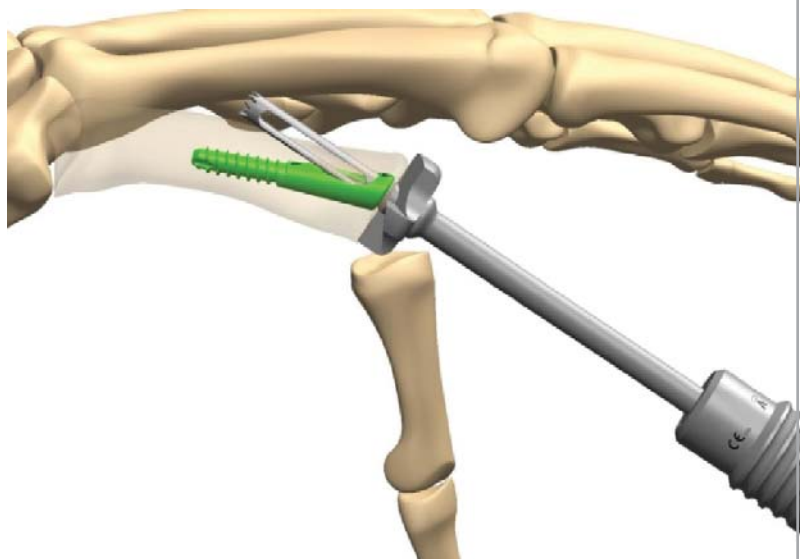
STEP 3 - Metacarpal Implant Alignment

Pre-operative x-ray templating is used to select the proper Metacarpal Implant size. Align the indicator on the Metacarpal Implant with the indicator on the Driver. Insert the Metacarpal Implant until it is recessed below the articular surface and the indicator is positioned dorsally at the apex of the desired angle of fusion as shown in the figure below.



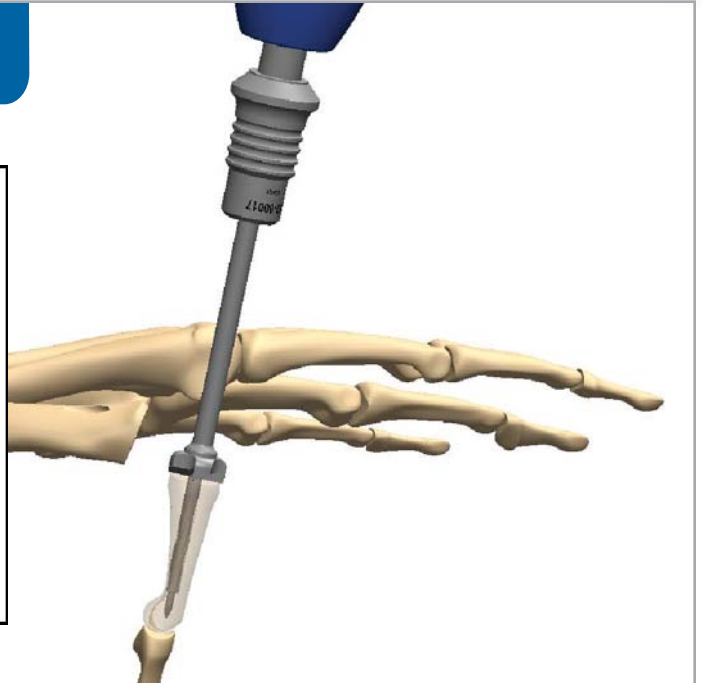
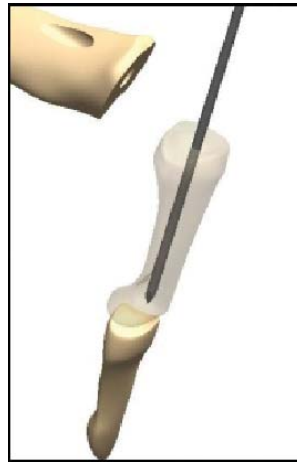
STEP 4 - Dorsal Window and Metacarpal Joint (Preparation)

The distal surface of the Metacarpal Implant has a built-in 25 degree angle. Insert the Dorsal Window Rasp into the Metacarpal Implant and advance the rasp with a rotating motion until a dorsal window is created in the metacarpal and the metacarpal head is flattened. The Dorsal Window Rasp has a positive stop designed to leave the implant 1mm recessed while creating a 25 degree angled surface. Remove any remaining bone around the resected surface.



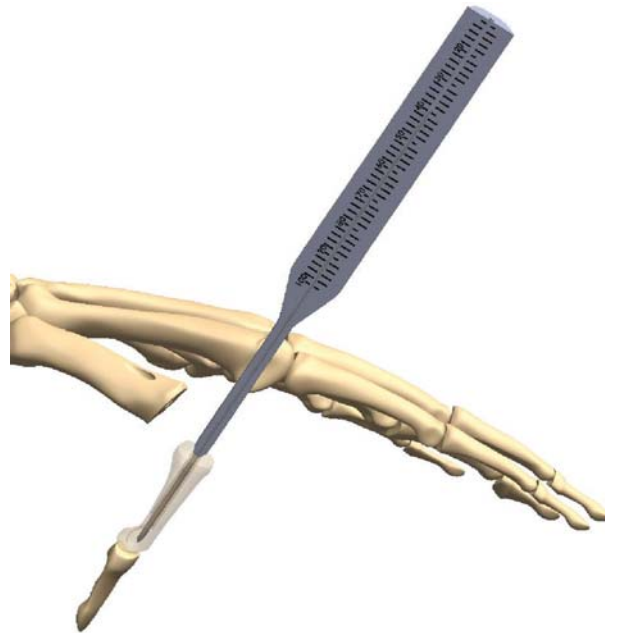
STEP 5 – Phalanx Guidewire Placement and Joint Preparation

Insert a 1.6mm guidewire into the center of the proximal phalanx and confirm its position using fluoroscopy. Select the appropriate size Lag Screw Rasp. Advance the rasp over the guidewire with a rotating motion to create a flattened surface. Remove the rasp but leave the guidewire in place.



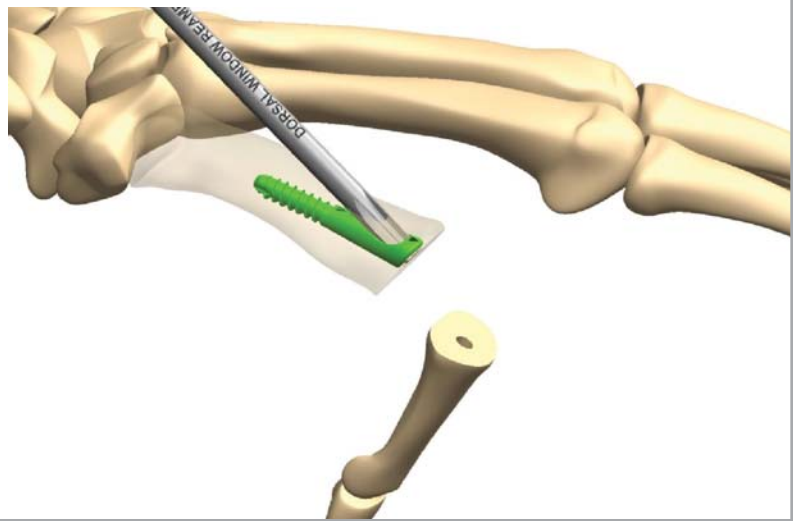
STEP 6 - Lag Screw Depth Measurement

Advance the depth gauge over the guidewire until the tip makes contact with the base of the phalanx.



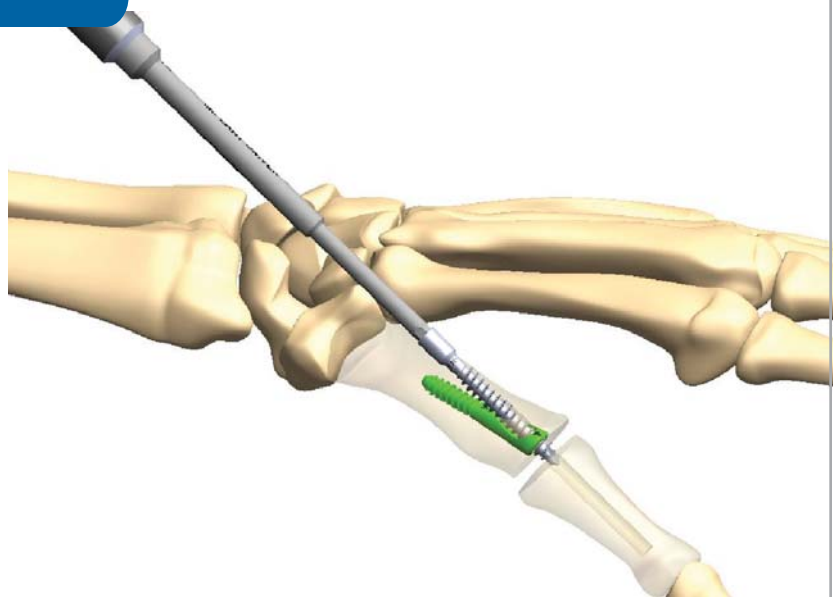
STEP 7 – Dorsal Window Reaming

Insert the Dorsal Window Reamer into the dorsal window of the Metacarpal Implant and gently rotate to widen the dorsal bony window for the Lag Screw head.



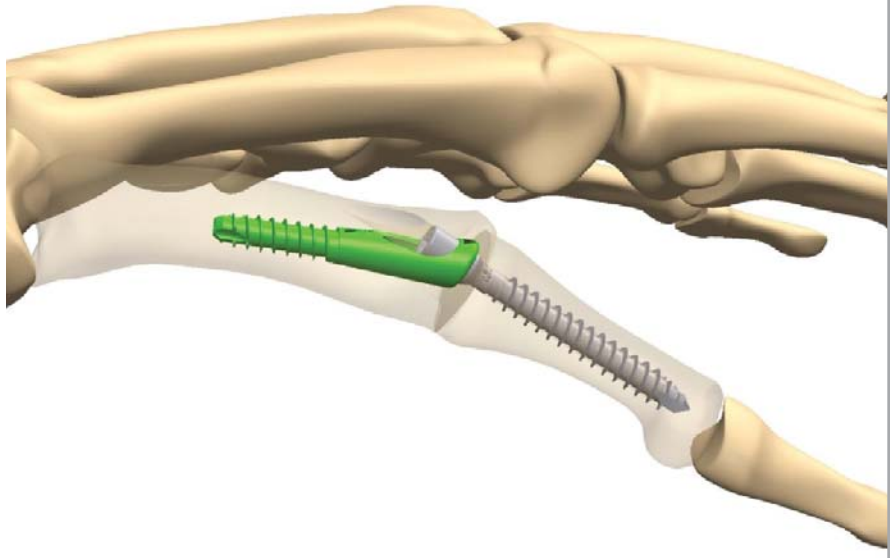
STEP 8 - Lag Screw and Phalanx Alignment

Insert the proper size Lag Screw through the dorsal window of the Metacarpal Implant. Position the tip of the Lag Screw into the pilot hole previously created in the phalanx. While firmly holding the phalanx, advance the lag screw into the phalanx until increased torque is felt which signals engagement and locking of the Morse Taper between the Lag Screw and Metacarpal Implant. *Avoid over tightening and over stressing the bone screw interface.*



STEP 9 – Closure

Verify under fluoroscopy that the Lag Screw is fully seated. The extensor mechanism is repaired and the skin closed in standard fashion.

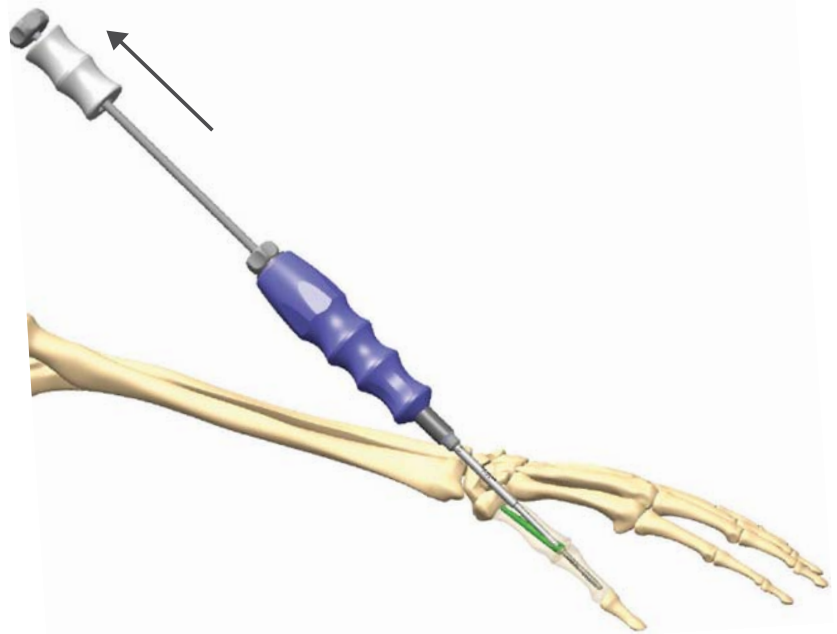


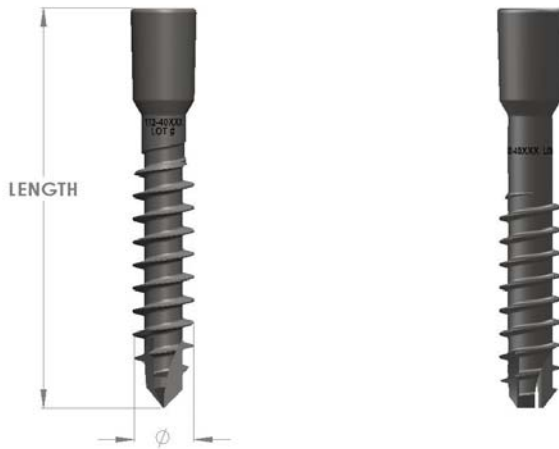
POSTOPERATIVE TREATMENT

A cast or splint is used to protect and support the thumb during healing and only limited load bearing is allowed until the fusion is complete.

Screw Removal

Remove tissue in-growth from the dorsal metacarpal window and Lag Screw head hex recess. Insert the removal driver and removal tool to the Lag Screw. Unscrew the Lag Screw counterclockwise a half turn. In the event the locking mechanism is still engaged, attach the slap hammer and apply slight pressure to disengage the Morse Taper. Continue turning the screw driver counterclockwise until the entire Lag Screw is removed. The Metacarpal Implant can be removed by exposing the metacarpal-phalangeal joint and clearing all tissue in-growth in the hex recess. Attach the Implant Driver and turn counterclockwise to remove the implant.





LAG SCREWS

Catalog#	Description	QTY
102-40020	Small Lag Screw - 4.0mm x 20 mm	1
102-40024	Small Lag Screw - 4.0mm x 24 mm	1
102-40028	Small Lag Screw - 4.0mm x 28 mm	1
102-40032	Small Lag Screw - 4.0mm x 32 mm	1
102-40036	Small Lag Screw - 4.0mm x 36 mm	1
113-40020	Solid Lag Screw - 4.0mm x 20 mm	1
113-40024	Solid Lag Screw - 4.0mm x 24 mm	1
113-40028	Solid Lag Screw - 4.0mm x 28 mm	1
113-40032	Solid Lag Screw - 4.0mm x 32 mm	1
113-40036	Solid Lag Screw - 4.0mm x 36 mm	1

METACARPAL IMPLANTS

Catalog#	Description	QTY
120-12530	Small Metacarpal Implant – 4.0mm x 30mm	2
120-22530	Medium Metacarpal Implant – 5.0mm x 30mm	2
120-32530	Large Metacarpal Implant – 6.0mm x 30mm	2

**All Metacarpal Implants have built in 25 degrees of dorsiflexion*

DISPOSABLE INSTRUMENTS

Catalog #	Description	QTY
102-00023	Double-Ended Guidewire - 1.6 mm	5
102-00002	Cannulated Drill - 3.0 mm	2
120-01000	Metacarpal Reamer	2
101-00023	Cleaning Brush - 1.6mm	2
120-00002	MCP X-Ray Template	1
120-05000	Dorsal Window Drill	1
120-02012	12mm Dorsal Window Rasp	1
120-02016	16mm Dorsal Window Rasp	1
120-04012	12mm Lag Screw Rasp	1
120-04016	16mm Lag Screw Rasp	1

RE-USABLE INSTRUMENT

Catalog#	Description	QTY
120-00000	IO FiX MCP Tray	1
120-00001	IO FiX MCP Implant Caddie	1
101-00009	Guide wire holder 1.6mm	1
113-00003	Depth Gauge	1
102-00003	Small Implant Guide	1
120-03000	Dorsal Window Reamer	1
102-00009	3.0 Screw Driver	1
102-00017	AO Quick Connect Handle	1
102-00020	Removal Screw Driver	1
102-00021	Removal Tool	1
102-00022	Slap Hammer	1



Sawbones Instructions

Step 1: Sawbones Placement

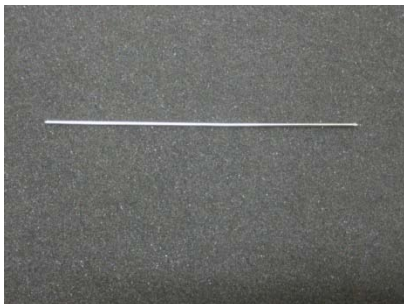


Sawbones MCP Articulating Joint



Sawbones Mounted in a Vice

Step 2: Guidewire Placement (Powered)



1.6mm Guidewire



Guidewire Placed in Center of Medullary Canal

Step 3: Metacarpal Reamer (Powered)



Metacarpal Reamer



Reamer Powered and Advanced Past Black Line

Step 4: Metacarpal Implant Insertion (Use 3.0 Hex Driver)



Align Arrows on driver and implant

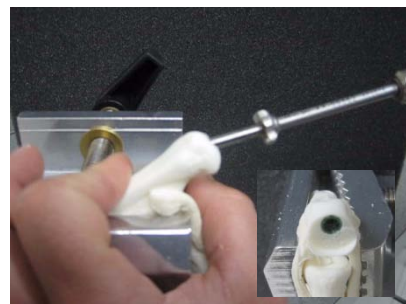


Position towards Apex of Desired Angle
(Remove Guidewire)

Step 5: Dorsal Window Rasp (Hand Powered)



Dorsal Window Rasp
(Connect to AO Palm Handle)

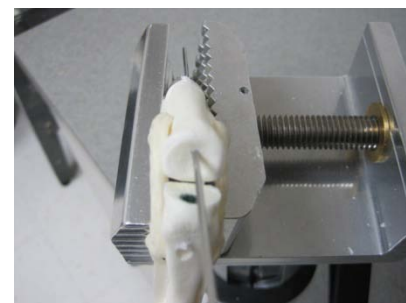


Create Dorsal Window and Angled Resection
(Remove Remaining Rim with Rongeurs)

Step 6: Phalanx Guidewire (Powered)



Reposition Sawbones
(Grip Phalanx Side)



Place 1.6mm Guidewire down Phalanx Center

Step 7: Lag Screw Rasp (Hand Powered)



Lag Screw Rasp
(Attach Rasp to AO Palm Handle)



Advance Lag Screw Rasp and Create a Flat Face
(Remove Rim with Rongeurs)

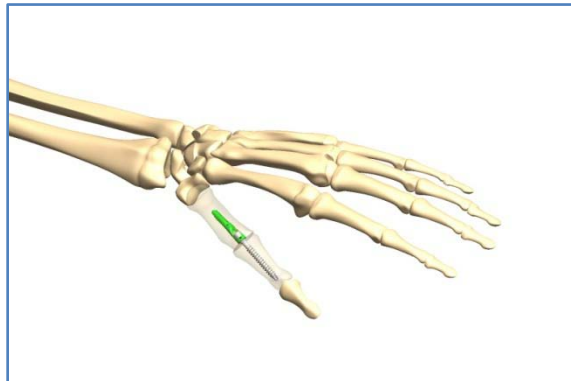
Step 8: Measure, Clear Window and Insert Lag Screw (Hand Powered)



Measure Lag Screw
(Optional)



Advance Lag Screw Until Compressed
(20mm or Greater Lag Screw Recommended)



To order MCP Sawbones Set

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