IO Fix™ Plus

INTRAOSSEOUS FIXATION

Surgical Technique
MTP Fusion

EXTREMITY MEDICAL™

Customer Service: 888.499.0079
www.extremitymedical.com

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 and joints of the foot & ankle. This two-part construct is specifically intended for use in the Talonavicular, Calcaneocuboid, Metatarsocuneiform, and Ankle, as well as for Metatarsal Osteotomies.

NOTE: This technique guide describes the steps for the hardware implantation of IO FiX™ as used in MTP fusion with a medial approach.

Pre-Operative Planning - Templating

Use the templates provided to determine the optimal size and position of the construct for the intended application.

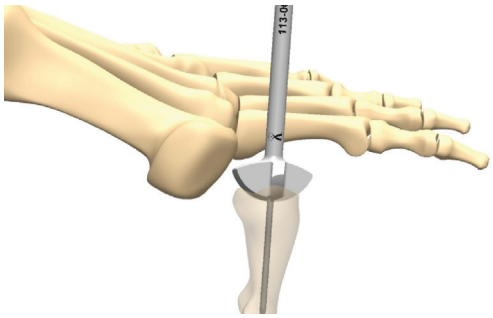
STEP 1 - Exposure and Joint Preparation

Perform standard medial incision and denuding techniques to the metatarsal phalangeal joint.

Optional Cup and Cone Rasps
Extremity Medical Cup and Cone Rasps are available upon request.

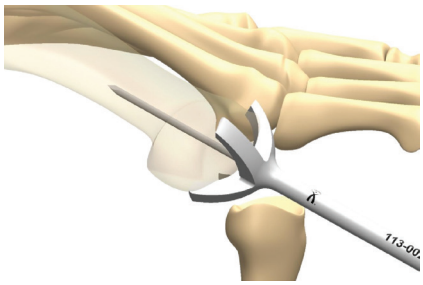
Phalanx Preparation

Insert the Ø1.6mm guidewire in the center of the phalanx and locate the cone rasp over the wire. Gradually remove the articulating cartilage until bleeding bone is observed. Remove the guidewire.



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.



Once the joint is adequately prepared, provisionally pin the MTP joint utilizing a guidewire with the desired dorsiflexion.

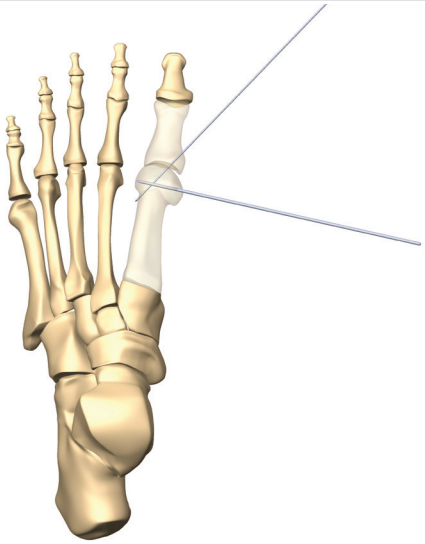
In placing this provisional guidewire, keep in mind that this wire can also be utilized as a guidewire for a second point of fixation - an anti-rotation screw.

<u>Anti-rotation Screw/Guidewire</u>
- 3.0mm diameter screw - 0.9mm Guidewire
- 4.0mm diameter screw - 1.6mm Guidewire

STEP 2 - X-Post™ Guidewire Placement

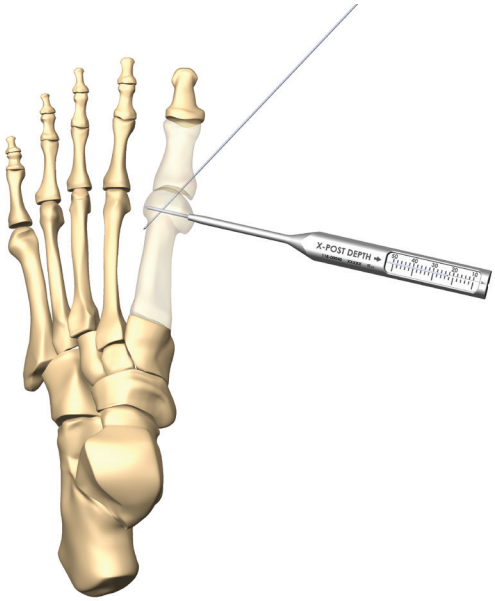
IO FiX™ is a fixed angle device (60˚). The X-Post™ placement determines the Lag Screw trajectory. Determine the proper placement for this cannulated X-Post™ by utilizing the appropriate size guidewire. Insert the guidewire in a medial to lateral fashion into the metatarsal head. Ideal placement of the guidewire is parallel to the joint – 5-10 mm from the joint line. Verify positioning with fluoroscopy.

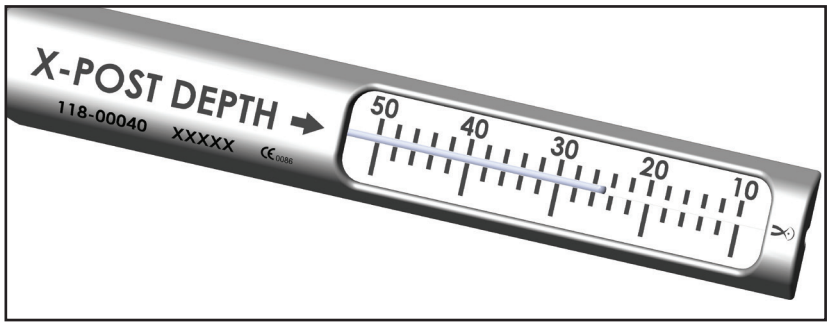
Note: *It is helpful to utilize the X-ray template to verify the X-Post™ and Lag Screw placement prior to preparing the bone for the X-Post™.*



STEP 3 - X-Post™ Depth Measurement

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





STEP 4 - Preparation for the X-Post™, Drill then Ream

DRILL 1st
Select the cannulated drill based on the desired X-Post™ size (Table 1). Place the drill over the guidewire and advance to the pre-determined length.

Ream
Preparation of the metatarsal with the X-Post™ Reamer is recommended. Select the appropriate X-Post™ Reamer, place the cannulated reamer over the guidewire and advance it to the laser line.

Note: Ream by hand only. *Under reaming is recommended for bone of marginal quality.*

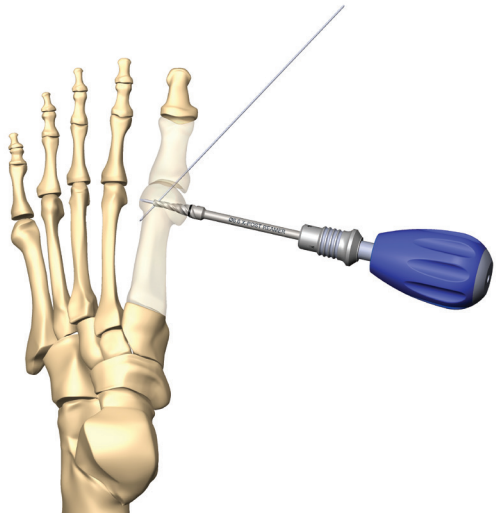


Table 1: Sizes X-Post™ / Reamers/ Drills

X-Post™	X-Post™ Reamer	Pre-Drill Ø
Gold (4.6)	4.6 X-Post™ Reamer	2.0mm
Green (6.6)	6.6 X-Post™ Reamer	3.4mm

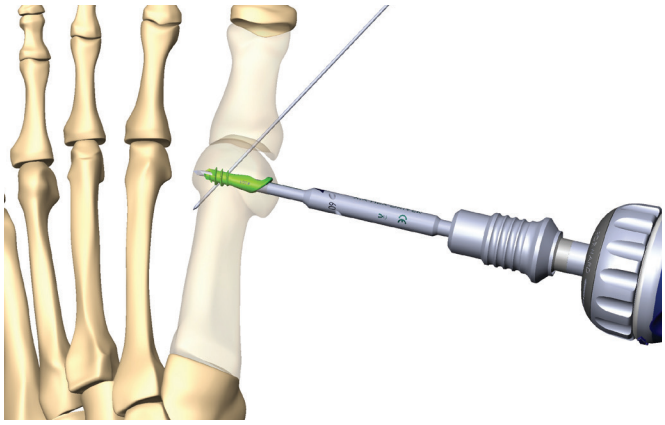
STEP 5 – X-Post™ Insertion

Select the appropriate X-Post™ and align the implant to the screwdriver with the laser marked arrow aligned on both driver and implant.

Table 2: Hex Sizes

X-Post™ Size	Hex Size (mm)
Ø 4.6 (Gold)	Ø 2.0
Ø 6.6 (Green)	Ø 3.0

Insert the X-Post™ until flush with cortex. The alignment arrows should face towards the intended fusion area to optimize the proper trajectory of the Lag Screw.



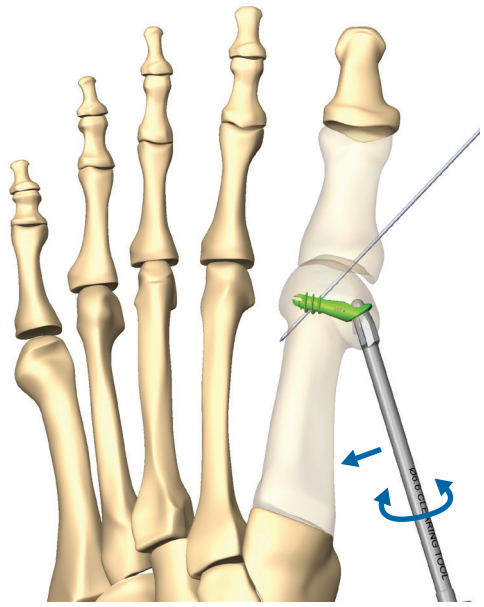
STEP 6 – Clear Additional Bone

In order to gain access to the implant eyelet, remove any obstructing bone by using the appropriate size clearing tool (Table 3). This will allow the guide to seat properly. Place the tip of the clearing tool into the X-Post™ with the handle pointing towards 12 o'clock. Drop the handle towards 6 o'clock and turn in a back and forth motion. Alternatively, a rongeur can be used to remove any impinging bone.

NOTE: Any difficulty seating the guide in Step 7 could be due to bony interference at the implant eyelet.

Table 3: Clearing Tools

X-Post™	Clearing Tool
Ø 4.6 (Gold)	4.6
Ø 6.6 (Green)	6.6

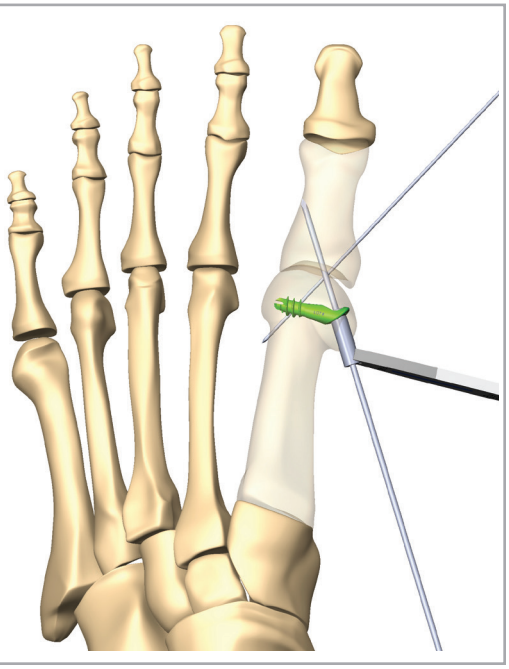


STEP 7 - Insert Lag Screw Guidewire

Insert the appropriate guidewire guide in the X-Post™ eyelet until only a small portion of the depth line is visible at the apex of the X-Post™. In the event the guide is not seated, verify the eyelet is properly cleared of bone.

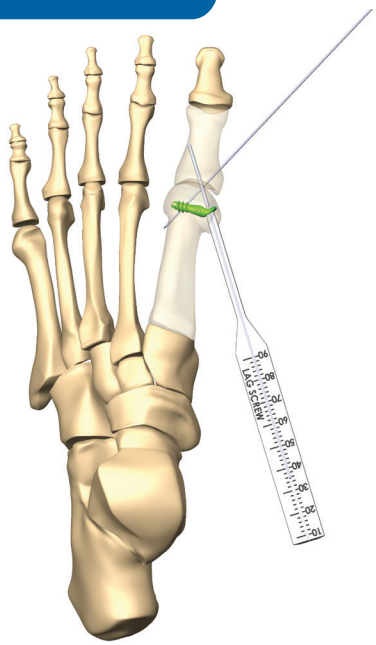
Insert the guidewire for the Lag Screw to the appropriate depth and verify position via fluoroscopy.

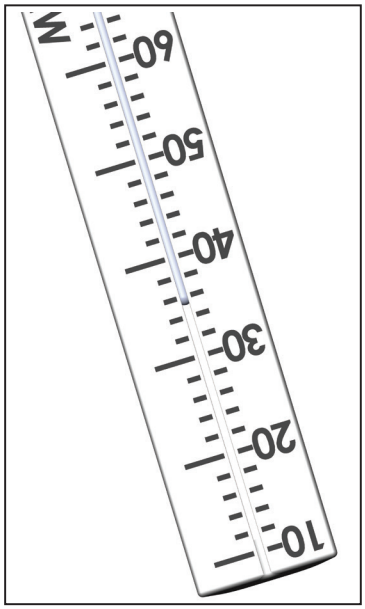
Note: The guides are marked with the same color as the corresponding X-Post™. The tapered and polyaxial screws utilize different guides.



STEP 8 - Lag Screw Depth Measurement

Measure the proper length of the Lag Screw by placing the depth gauge over the guidewire and down to the bone.





STEP 9 –Pilot Drill for Lag Screw

Select the appropriate drill (Table 4). Align the first depth marking to the top of the drill guide. Based on this zero reference, drill to the depth measurement previously recorded. Laser markings on the drills are in 10mm increments. Confirm drill depth via fluoroscopy.

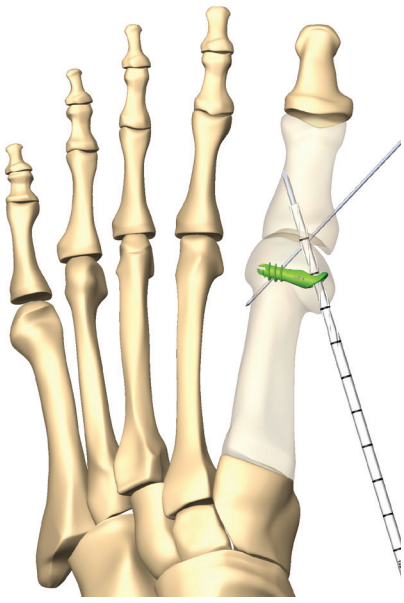


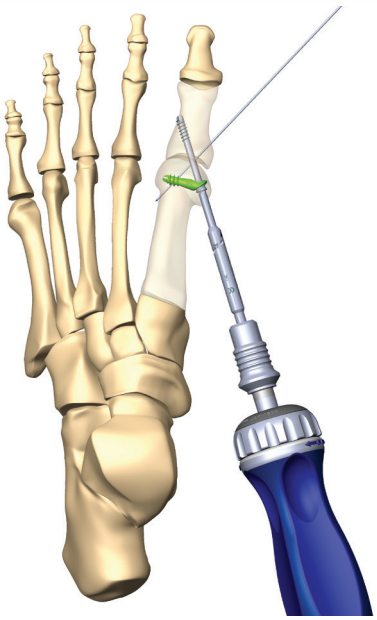
Table 4: Drill Sizes

X-Post™	Drill Size (mm)
Ø 4.6 (Gold)	Ø 2.0
Ø 6.6 (Green)	Ø 3.0

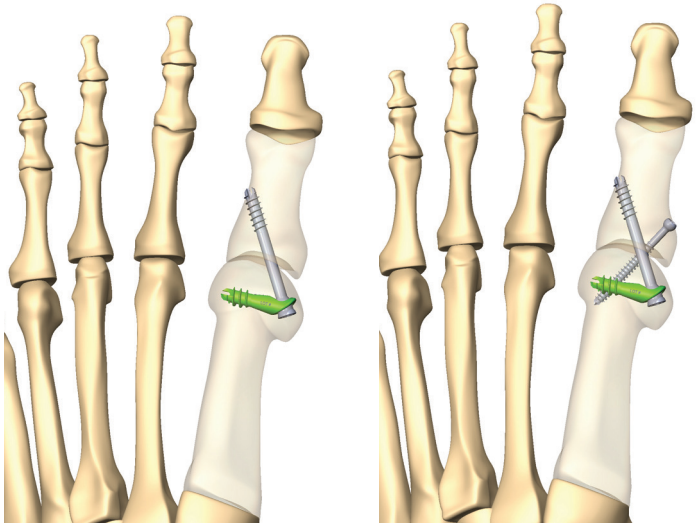
STEP 10 – Lag Screw

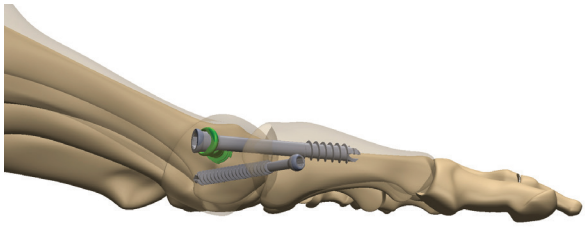
Insert the Lag Screw under TWO finger pressure until tactile compression is felt. With the tapered Lag Screw, the Morse Taper engagement should be felt as the tapers engage. With the polyaxial Lag Screw, tighten until appropriate compression is generated.

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



FINAL POSITIONING





IMPLANT REMOVAL

Clear any tissue ingrowth from the Lag Screw and insert the removal driver into Lag Screw. Insert the removal tool through removal driver, and thread into Lag Screw to allow for rigid attachment. Completely remove the Lag Screw. Insert removal driver into the X-Post™ and remove by turning counterclockwise.

Table 5: INSTRUMENT LIST

Instrument #	Description	Qty
101-00004	Guidewire- 0.9mm *	10
101-00006	Guidewire- 1.6mm *	10
101-00008	Guidewire Holder- 0.9mm	1
101-00009	Guidewire Holder- 1.6 mm	1
101-00011	Cannulated Drill- 2.0mm *	2
102-00002	Cannulated Drill- 3.0mm *	2
101-00012	Cannulated Drill- 3.4mm*	2
101-00013	Cannulated Drill- 4.5mm *	2
101-00022	Cleaning Brush- 0.9mm	1
101-00023	Cleaning Brush- 1.6mm	1
102-00017	AO Quick Connect Handle	1
102-00020	Removal Screw Driver	1
102-00021	Removal Tool	1
118-00004	4.6 X-Post™ Reamer*	1
118-00005	6.6 X-Post™ Reamer*	1
118-00006	8.0/9.5 X-Post™ Reamer*	1
118-00007	4.6 Tapered Drill Guide	1
118-00008	6.6 Tapered Drill Guide	1
118-00009	8.0 Tapered Drill Guide	1
118-00010	9.5 Tapered Drill Guide	1
118-00011	4.6 Polyaxial Drill Guide	1
118-00012	6.6 Polyaxial Drill Guide	1
118-00013	8.0 Polyaxial Drill Guide	1
118-00014	9.5 Polyaxial Drill Guide	1
118-00015	6.6 Clearing Tool	1
118-00016	9.5 Clearing Tool	1
118-00017	4.6 Clearing Tool	1
118-00018	8.0 Clearing Tool	1
118-00020	2.0 Hex Driver	2
118-00030	3.0 Hex Driver	2
118-00031	1.6 x 60° Alignment Guide	1
118-00039	Ratcheting AO Handle	1
118-00040	Depth Gauge	1
118-00000	IO FiX Instrument Tray	1
126-01000	IO FiX Plus Implant Caddy	1
126-00004	IO FiX Plus X-Ray Template*	1

*disposable

Implant #	Description	Qty
4.6 X-Posts (Gold)		
118-46614	X-Post™ (60 deg) 4.6 x 14mm	2
118-46616	X-Post™ (60 deg) 4.6 x 16mm	2
118-46618	X-Post™ (60 deg) 4.6 x 18mm	2
3.0 Lag Screw (Cannulated Tapered)		
118-30220	Lag Screw (Cannulated Tapered) 3.0 x 20mm	2
118-30222	Lag Screw (Cannulated Tapered) 3.0 x 22mm	2
118-30224	Lag Screw (Cannulated Tapered) 3.0 x 24mm	2
118-30226	Lag Screw (Cannulated Tapered) 3.0 x 26mm	2
118-30228	Lag Screw (Cannulated Tapered) 3.0 x 28mm	2
118-30230	Lag Screw (Cannulated Tapered) 3.0 x 30mm	2
118-30232	Lag Screw (Cannulated Tapered) 3.0 x 32mm	2
118-30234	Lag Screw (Cannulated Tapered) 3.0 x 34mm	2
118-30236	Lag Screw (Cannulated Tapered) 3.0 x 36mm	2
118-30238	Lag Screw (Cannulated Tapered) 3.0 x 38mm	2
118-30240	Lag Screw (Cannulated Tapered) 3.0 x 40mm	2
3.0 Lag Screw (Short Thread Cannulated Tapered)		
118-30420	Short Thread Lag Screw (Cannulated Tapered) 3.0 x 20mm	2
118-30422	Short Thread Lag Screw (Cannulated Tapered) 3.0 x 22mm	2
118-30424	Short Thread Lag Screw (Cannulated Tapered) 3.0 x 24mm	2
118-30426	Short Thread Lag Screw (Cannulated Tapered) 3.0 x 26mm	2
118-30428	Short Thread Lag Screw (Cannulated Tapered) 3.0 x 28mm	2
118-30430	Short Thread Lag Screw (Cannulated Tapered) 3.0 x 30mm	2
118-30432	Short Thread Lag Screw (Cannulated Tapered) 3.0 x 32mm	2
118-30434	Short Thread Lag Screw (Cannulated Tapered) 3.0 x 34mm	2
118-30436	Short Thread Lag Screw (Cannulated Tapered) 3.0 x 36mm	2
118-30438	Short Thread Lag Screw (Cannulated Tapered) 3.0 x 38mm	2
118-30440	Short Thread Lag Screw (Cannulated Tapered) 3.0 x 40mm	2

Implant #	Description	Qty
6.6 X-Posts (Green)		
118-66615	X-Post™ (60 deg) 6.6 x 15mm	2
118-66620	X-Post™ (60 deg) 6.6 x 20mm	3
118-66625	X-Post™ (60 deg) 6.6 x 25mm	3
118-66630	X-Post™ (60 deg) 6.6 x 30mm	2
118-66635	X-Post™ (60 deg) 6.6 x 35mm	2
118-66640	X-Post™ (60 deg) 6.6 x 40mm	2
4.0 Lag Screw (Cannulated Tapered)		
118-40020	Lag Screw (Cannulated Tapered) 4.0 x 20mm	2
118-40022	Lag Screw (Cannulated Tapered) 4.0 x 22mm	2
118-40024	Lag Screw (Cannulated Tapered) 4.0 x 24mm	2
118-40026	Lag Screw (Cannulated Tapered) 4.0 x 26mm	2
118-40028	Lag Screw (Cannulated Tapered) 4.0 x 28mm	2
118-40030	Lag Screw (Cannulated Tapered) 4.0 x 30mm	2
118-40032	Lag Screw (Cannulated Tapered) 4.0 x 32mm	2
118-40034	Lag Screw (Cannulated Tapered) 4.0 x 34mm	2
118-40036	Lag Screw (Cannulated Tapered) 4.0 x 36mm	2
118-40038	Lag Screw (Cannulated Tapered) 4.0 x 38mm	2
118-40040	Lag Screw (Cannulated Tapered) 4.0 x 40mm	2
118-40045	Lag Screw (Cannulated Tapered) 4.0 x 45mm	2
118-40050	Lag Screw (Cannulated Tapered) 4.0 x 50mm	2

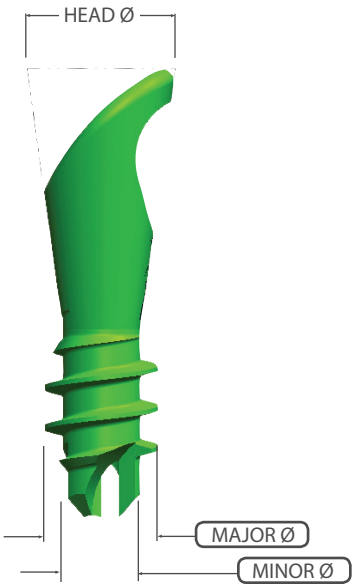
Implant #	Description	Qty
4.0 Lag Screw (Short Thread Cannulated Tapered)		
118-40420	Short Thread Lag Screw (Cannulated Tapered) 4.0 x 20mm	2
118-40422	Short Thread Lag Screw (Cannulated Tapered) 4.0 x 22mm	2
118-40424	Short Thread Lag Screw (Cannulated Tapered) 4.0 x 24mm	2
118-40426	Short Thread Lag Screw (Cannulated Tapered) 4.0 x 26mm	2
118-40428	Short Thread Lag Screw (Cannulated Tapered) 4.0 x 28mm	2
118-40430	Short Thread Lag Screw (Cannulated Tapered) 4.0 x 30mm	2
118-40432	Short Thread Lag Screw (Cannulated Tapered) 4.0 x 32mm	2
118-40434	Short Thread Lag Screw (Cannulated Tapered) 4.0 x 34mm	2
118-40436	Short Thread Lag Screw (Cannulated Tapered) 4.0 x 36mm	2
118-40438	Short Thread Lag Screw (Cannulated Tapered) 4.0 x 38mm	2
118-40440	Short Thread Lag Screw (Cannulated Tapered) 4.0 x 40mm	2
118-40445	Short Thread Lag Screw (Cannulated Tapered) 4.0 x 45mm	2
118-40450	Short Thread Lag Screw (Cannulated Tapered) 4.0 x 50mm	2
Lag Screw (Cannulated Polyaxial)		
118-40120	Lag Screw (Cannulated Polyaxial) 4.0 x 20mm	2
118-40122	Lag Screw (Cannulated Polyaxial) 4.0 x 22mm	2
118-40124	Lag Screw (Cannulated Polyaxial) 4.0 x 24mm	2
118-40126	Lag Screw (Cannulated Polyaxial) 4.0 x 26mm	2
118-40128	Lag Screw (Cannulated Polyaxial) 4.0 x 28mm	2
118-40130	Lag Screw (Cannulated Polyaxial) 4.0 x 30mm	2
118-40132	Lag Screw (Cannulated Polyaxial) 4.0 x 32mm	2
118-40134	Lag Screw (Cannulated Polyaxial) 4.0 x 34mm	2
118-40136	Lag Screw (Cannulated Polyaxial) 4.0 x 36mm	2
118-40138	Lag Screw (Cannulated Polyaxial) 4.0 x 38mm	2
118-40140	Lag Screw (Cannulated Polyaxial) 4.0 x 40mm	2
118-40145	Lag Screw (Cannulated Polyaxial) 4.0 x 45mm	2
118-40150	Lag Screw (Cannulated Polyaxial) 4.0 x 50mm	2

Implant #	Description	Qty
8.0 X-Posts (Blue)		
118-80620	X-Post™ (60 deg) 8.0 x 20mm	2
118-80625	X-Post™ (60 deg) 8.0 x 25mm	2
118-80630	X-Post™ (60 deg) 8.0 x 30mm	2
5.0 Lag Screw (Cannulated Tapered)		
118-50020	Lag Screw (Cannulated Tapered) 5.0 X 20mm	2
118-50025	Lag Screw (Cannulated Tapered) 5.0 X 25mm	2
118-50030	Lag Screw (Cannulated Tapered) 5.0 X 30mm	2
118-50035	Lag Screw (Cannulated Tapered) 5.0 X 35mm	2
118-50040	Lag Screw (Cannulated Tapered) 5.0 X 40mm	2
118-50045	Lag Screw (Cannulated Tapered) 5.0 X 45mm	2
118-50050	Lag Screw (Cannulated Tapered) 5.0 X 50mm	2
5.0 Lag Screw (Short Thread Cannulated Tapered)		
118-50420	Short Thread Lag Screw (Cannulated Tapered) 5.0 X 20mm	2
118-50425	Short Thread Lag Screw (Cannulated Tapered) 5.0 X 25mm	2
118-50430	Short Thread Lag Screw (Cannulated Tapered) 5.0 X 30mm	2
118-50435	Short Thread Lag Screw (Cannulated Tapered) 5.0 X 35mm	2
118-50440	Short Thread Lag Screw (Cannulated Tapered) 5.0 X 40mm	2
118-50445	Short Thread Lag Screw (Cannulated Tapered) 5.0 X 45mm	2
118-50450	Short Thread Lag Screw (Cannulated Tapered) 5.0 X 50mm	2

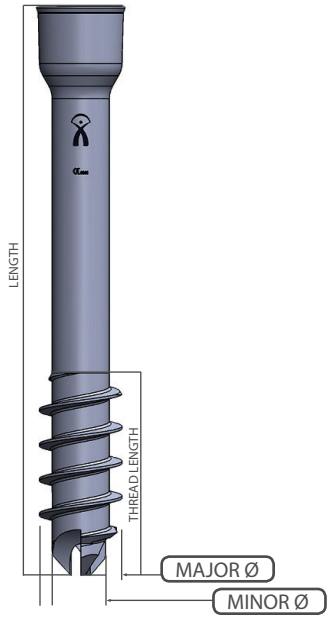
Implant #	Description	Qty
9.5 X-Posts (Magenta)		
118-95625	X-Post™ (60 deg) 9.5 x 25mm	2
118-95630	X-Post™ (60 deg) 9.5 x 30mm	2
118-95635	X-Post™ (60 deg) 9.5 x 35mm	2
6.5 Lag Screw (Cannulated Tapered)		
118-65030	Lag Screw (Cannulated Tapered) 6.5 x 30mm	2
118-65035	Lag Screw (Cannulated Tapered) 6.5 x 35mm	2
118-65040	Lag Screw (Cannulated Tapered) 6.5 x 40mm	2
118-65045	Lag Screw (Cannulated Tapered) 6.5 x 45mm	2
118-65050	Lag Screw (Cannulated Tapered) 6.5 x 50mm	2
118-65055	Lag Screw (Cannulated Tapered) 6.5 x 55mm	2
118-65060	Lag Screw (Cannulated Tapered) 6.5 x 60mm	2
6.5 Lag Screw (Cannulated Polyaxial)		
118-65130	Lag Screw (Cannulated Polyaxial) 6.5 x 30mm	2
118-65135	Lag Screw (Cannulated Polyaxial) 6.5 x 35mm	2
118-65140	Lag Screw (Cannulated Polyaxial) 6.5 x 40mm	2
118-65145	Lag Screw (Cannulated Polyaxial) 6.5 x 45mm	2
118-65150	Lag Screw (Cannulated Polyaxial) 6.5 x 50mm	2
118-65155	Lag Screw (Cannulated Polyaxial) 6.5 x 55mm	2
118-65160	Lag Screw (Cannulated Polyaxial) 6.5 x 60mm	2
118-65165	Lag Screw (Cannulated Polyaxial) 6.5 x 65mm	2
118-65170	Lag Screw (Cannulated Polyaxial) 6.5 x 70mm	2
118-65175	Lag Screw (Cannulated Polyaxial) 6.5 x 75mm	2
118-65180	Lag Screw (Cannulated Polyaxial) 6.5 x 80mm	2
118-65185	Lag Screw (Cannulated Polyaxial) 6.5 x 85mm	2
118-65190	Lag Screw (Cannulated Polyaxial) 6.5 x 90mm	2
118-65195	Lag Screw (Cannulated Polyaxial) 6.5 x 95mm	2
118-65100	Lag Screw (Cannulated Polyaxial) 6.5 x 100mm	2

IMPLANT SPECIFICATIONS

X-POST™



LAG SCREWS (Tapered & Polyaxial)



X-Post™ Specifications				
X-Post™	Angle	Length	Major Diameter	Minor Diameter
Ø 4.6mm (Gold)	60°	14, 16, 18mm	4mm	3mm
Ø 6.6mm (Green)	60°	15, 20, 25, 30, 35, 40mm	5mm	3.4mm
Ø 8.0mm (Blue)	60°	20, 25, 30mm	6.5mm	4.5mm
Ø 9.5mm (Magenta)	60°	25, 30, 35mm	6.5mm	4.5mm

Lag Screw Specifications				
Lag Screw	3.0mm	4.0mm	5.0mm	6.5mm
Length	20-40mm by 2mm increments	20-50mm 20-40mm by 2mm increments 40-50mm by 5mm increments	20-50mm by 5mm increments	30-100mm by 5mm increments
Thread Length (Standard)	L – 8	20,22mm = L - 12 24-50mm = L - 15	20mm = L - 12 25-50mm = L - 15	16mm
Thread Length Range (Short Thread)	8-12mm	8-12mm	8-12mm	N/A
Major Diameter	3.1mm	4.0mm	5.0mm	6.5mm
Minor Diameter	2.1mm	3.0mm	3.4mm	4.5mm

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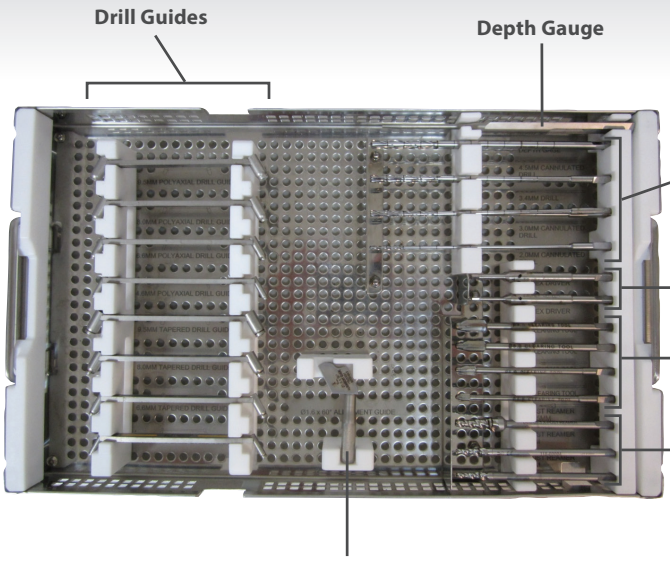
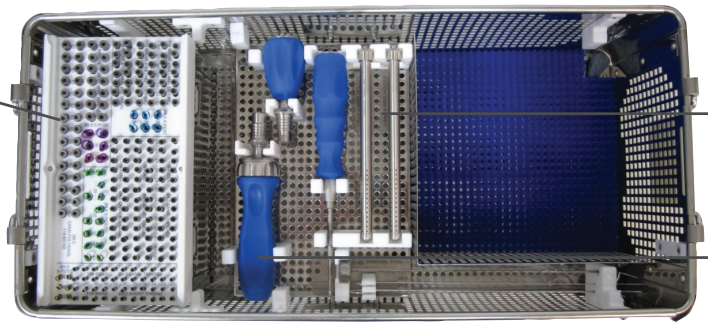
INTRAOSSEOUS FIXATION

Surgical Technique





Implants and Instruments (Listed In Order of Use)	
Number	Description
1	1.6mm/ 0.9mm Guidewires
2	Alignment Guide
3	Depth Gauge
4	X-Post™ Drill / Reamer
5	X-Posts™
6	Hex Drivers
7	Ratcheting AO Handle
8	Clearing Tool or Rongeurs
9	Drill Guides
10	Cannulated Drills
11	Lag Screws

Drill/Reamer Selection							
X-Post™ Size	Lag Screw	Guide Wire	Pilot Drill X-Post™	Reamer	Driver Hex	Clearing Tool	Screw Pilot Drill
Ø 4.6 (Gold)	Ø 3.0	Ø 0.9	Ø 2.0	Ø 4.6	Ø 2.0	4.6	Ø 2.0
Ø 6.6 (Green)	Ø 4.0	Ø 1.6	Ø 3.4	Ø 6.6	Ø 3.0	6.6	Ø 3.0
Ø 8.0 (Blue)	Ø 5.0	Ø 1.6	Ø 4.5	Ø 8.0/ 9.5 (1st Line)	Ø 3.0	8.0	Ø 3.4
Ø 9.5 (Magenta)	Ø 6.5	Ø 1.6	Ø 4.5	Ø 8.0/ 9.5 (2nd Line)	Ø 3.0	9.5	Ø 4.5

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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