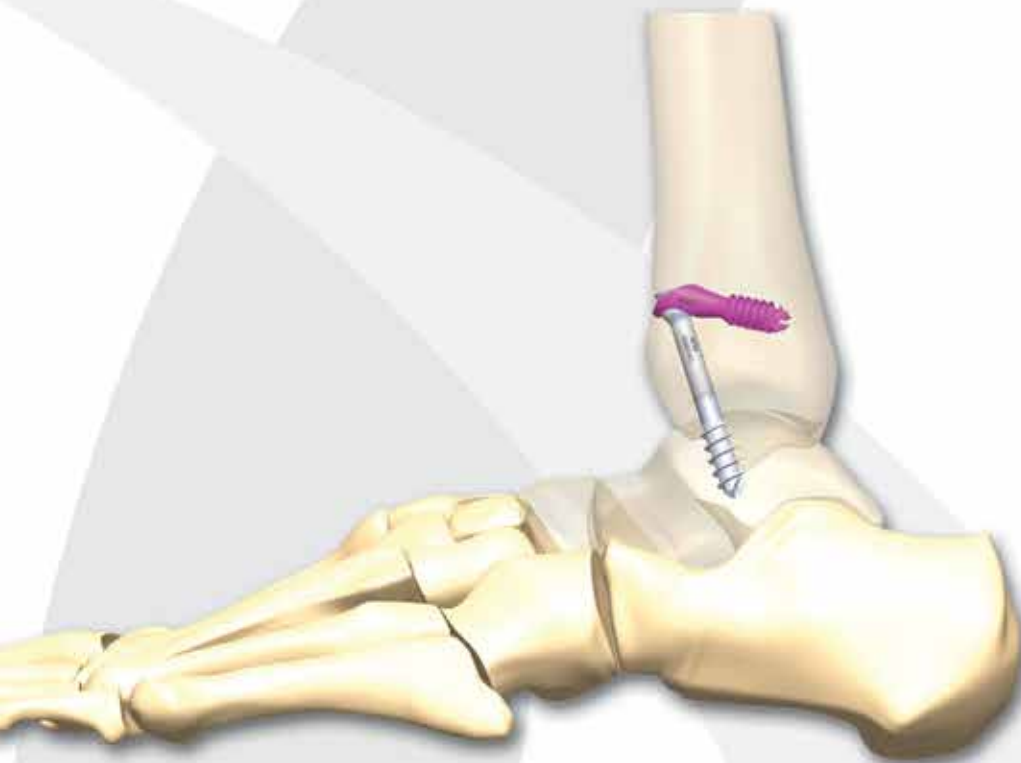


IO FiXTM Plus

INTRAOSSSEOUS FIXATION

Surgical Technique Ankle Fusion



Patent and Patent Pending

INDICATIONS FOR USE

The Extremity Medical Screw and Washer System is intended for reduction and internal fixation of arthrodeses, osteotomies, intra- and extrarticular fractures and nonunions of the small bones and joints of the foot and ankle. The two-part construct is specifically intended for Talonavicular, Calcaneocuboid, Metatarsocuneiform, and Ankle, as well as Metatarsal Osteotomies.

NOTE: This technique describes the steps for hardware implantation as used in a Tibia-Talar fusion.

Pre-Operative Planning - Templating

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

STEP 1 - Exposure and Joint Preparation

A standard longitudinal incision is first performed over the proximal aspect of the dorsal tibialtalar joint. The length is determined by exposure requirements. Once the appropriate dissection to the subperiosteal level has been performed, manual joint exposure of the tibialtalar joint and exposure to the articulating cartilage can be achieved. Standard denuding techniques should then be performed.

STEP 2 - Alignment Guidewire

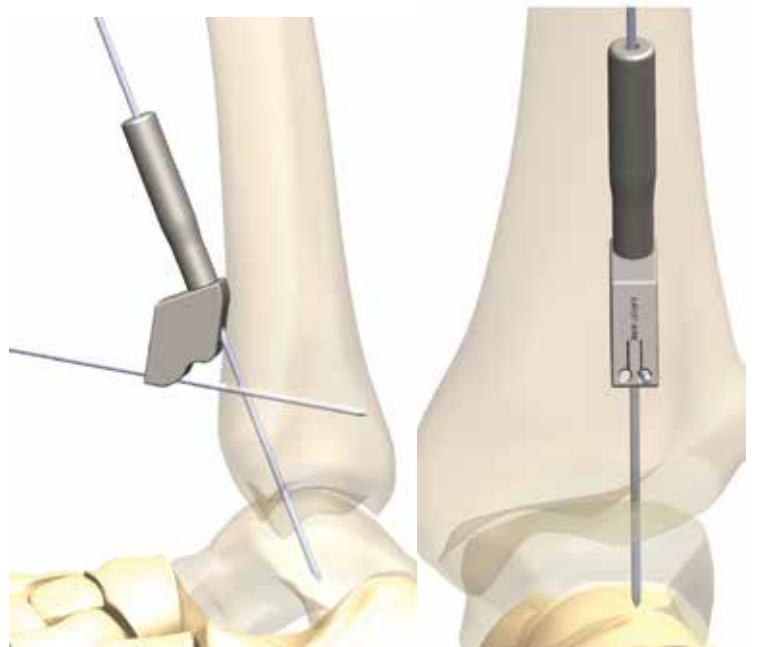
Insert the Ø1.6mm guidewire through the dorsal tibia in the direction of the ideal lag screw trajectory. This temporary wire acts as a guide for the desired trajectory of the lag screw and allows for the optimal placement of the X-PostTM. Verify the positioning of this guidewire with fluoroscopy.



STEP 3 - Alignment Guide

Place the alignment guide over the 1st guidewire and rotate the guide to the desired location in regard to X-PostTM placement.

Insert this second guidewire thru one of the two holes of the alignment guide. The placement of this second wire will determine the position of the X-PostTM and should be placed approximately 15mm proximal to the joint line. Once the placement of the second wire is confirmed with fluoroscopy, remove the initial guidewire and remove the alignment guide.



STEP 4 – X-PostTM Depth Measurement

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



STEP 5 – Preparing for the X-PostTM Drilling/Reaming

X-PostTM size is determined by choosing the desired corresponding large screw size.

Pre-drill the bone with the appropriate sized drill. Select the X-PostTM Reamer based on the desired X-PostTM size (Table 1). Place the cannulated reamer over the guidewire and advance until the depth line is no longer visible.

NOTE: Hand ream only.

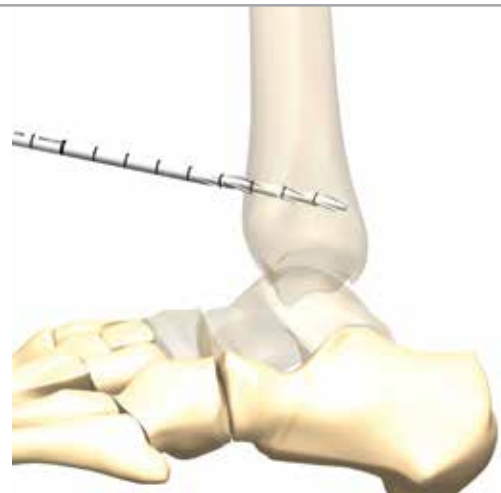


Table 1: Sizes: X-PostTM / Screws/ Drills / Reamers

X-Post TM Size	Lag Screw Size	Reamer Pilot Drill	X-Post TM Reamer Size
4.6mm X-Post TM	3.0mm Screw	2.0mm Drill	4.6 X-Post TM Reamer
6.6mm X-Post TM	4.0mm Screw	3.4mm Drill	6.6 X-Post TM Reamer
8.0mm X-Post TM	5.0mm Screw	4.5mm Drill	8.0/9.5 X-Post TM Reamer (1st line)
9.5mm X-Post TM	6.5mm Screw	4.5mm Drill	8.0/9.5 X-Post TM Reamer (2nd line)

STEP 6 – X-Post™ Insertion

Select the appropriate X-Post™ and align the implant to the screwdriver with the laser marked arrows aligning on both driver and implant. Using the appropriate sized hex driver, insert the X-Post™ until flush with cortex, and align the indicator (laser arrows) towards the intended fusion area.

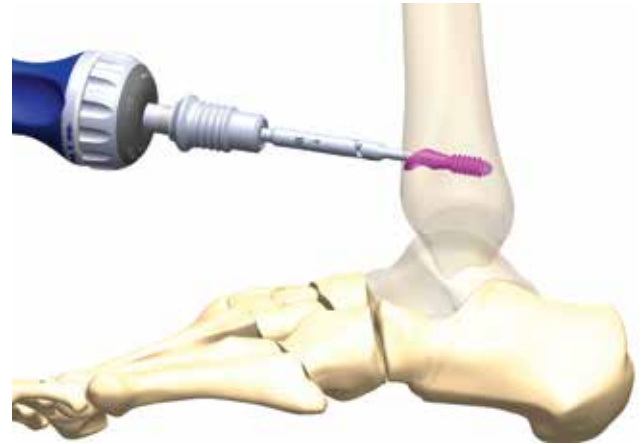


Table 2: Hex Sizes

X-Post™ Size (Color)	Hex Size (mm)
4.6 (Gold)	2.0
6.6 (Green)	3.0
8.0 (Blue)	3.0
9.5 (Magenta)	3.0

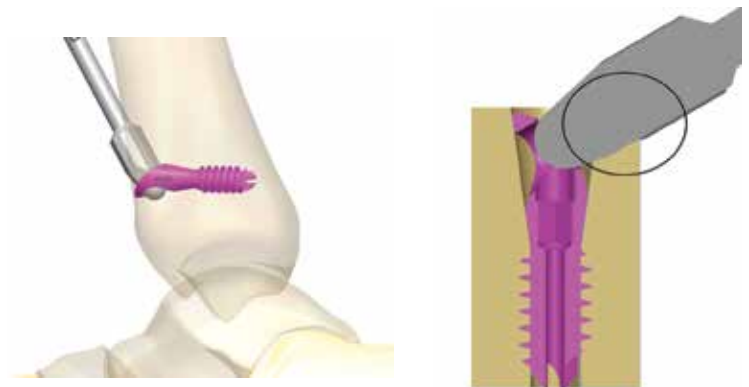
STEP 7 – Clear Additional Bone

In order to gain access to the implant eyelet, remove any obstructing bone by hand using the appropriate size clearing tool (Table 3). 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 8 could be due to bony interference at the implant eyelet.

Table 3: Clearing Tools

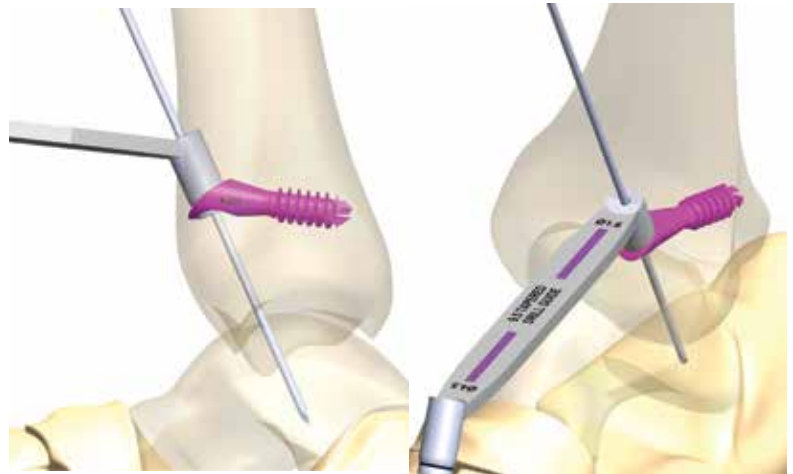
X-Post™	Clearing Tool
4.6 (Gold)	4.6 Clearing Tool
6.6 (Green)	6.6 Clearing Tool
8.0 (Blue)	8.0 Clearing Tool
9.5 (Magenta)	9.5 Clearing Tool



STEP 8 - Insert Lag Screw Guidewire

Insert the appropriate guidewire guide in the X-PostTM eyelet until only a small portion of the depth line is visible at the apex of the X-PostTM. 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.



STEP 9 - Lag Screw Depth Measurement

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

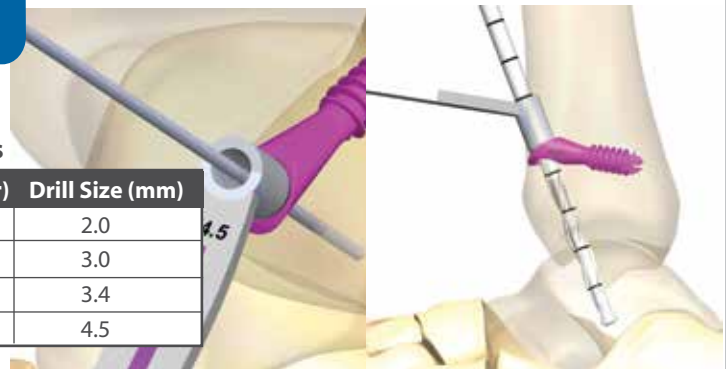


STEP 10 – Pilot Drill

Select the appropriate drill based on the X-PostTM sizes (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. Graduations on drill are in 10mm increments.

Table 4: Drill Sizes

X-Post TM Size (Color)	Drill Size (mm)
4.6 (Gold)	2.0
6.6 (Green)	3.0
8.0 (Blue)	3.4
9.5 (Magenta)	4.5



STEP 11 – Lag Screw

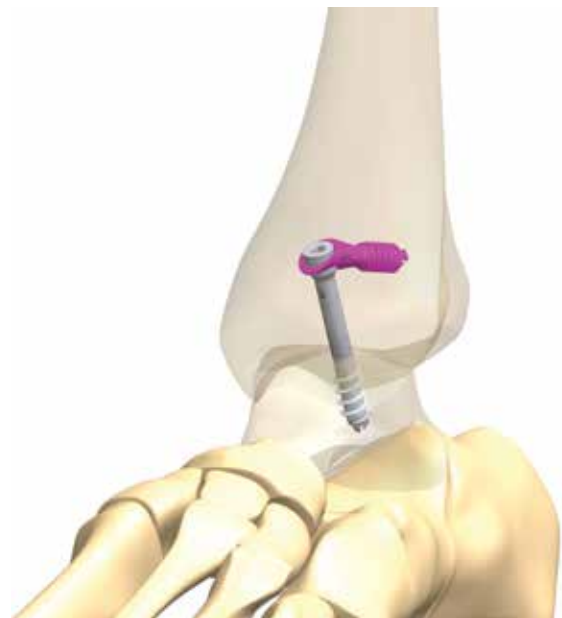
Insert the Lag Screw under TWO finger pressure until tactile compression is felt, and the visualization shows the Lag Screw flush against X-Post™. With the tapered Lag Screw, the Morse Taper engagement should be felt as the tapers engage. With the polyaxial Lag Screw, tighten until an appropriate compression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

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



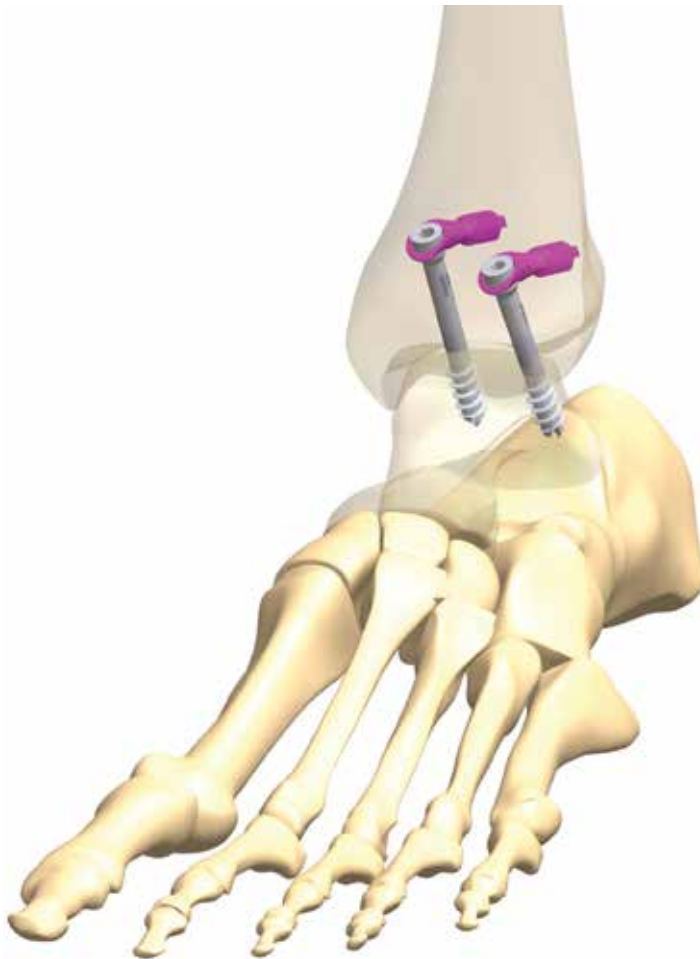
FINAL POSITIONING

If additional fixation is determined necessary, an additional headed or headless screw may be implanted per standard techniques, or a second IO FiX™ construct can be utilized.



TWO CONSTRUCT PLACEMENT

If additional fixation is necessary, further constructs may be added in the preferred pattern of fixation for the surgeon.



PARALLEL IO FIX[™] CONSTRUCT



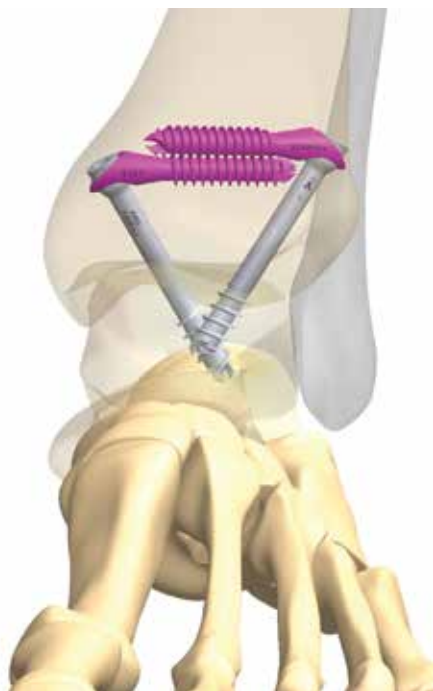
CROSSING IO FIX[™] CONSTRUCT

SUPPLEMENTAL INFORMATION

Placement of the IO FiXTM construct is based on surgeon preference and access.

1. Ankle Fusion: Lateral Approach

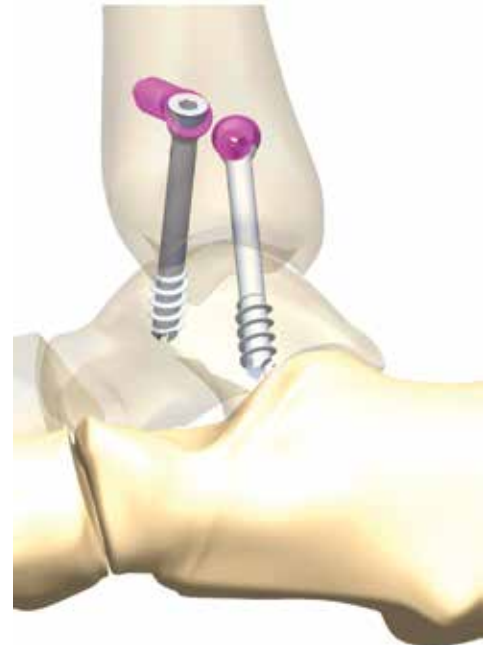
A lateral approach may be used to provide additional access to the joint depending on the surgical preference. Use standard techniques for fibula preparation and joint preparation. Once the joint is adequately prepared, follow steps 1-11 as detailed in technique. A separate construct may also be implanted via a stab incision on the medial side of the tibia for additional fixation.



AP VIEW



ISO VIEW



**LATERAL VIEW (FIBULA
REMOVED FOR CLARITY)**

POSTOPERATIVE TREATMENT

Subsequent to incision closure, patients should initially be immobilized non-weight bearing 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 to full weight-bearing 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

Clear tissue in-growth from the Lag Screw. Insert the Removal Screw Driver into Lag Screw and back out the screw. If the Morse Taper coupling between the Lag Screw and X-PostTM does not allow for this, insert the Removal Tool into the engaged Removal Screw Driver. Thread the Removal Tool into the Lag Screw. This locks the Removal Screw Driver into the Lag Screw. Apply back pressure to break the Morse Taper and then back the Lag Screw out by turning the screw counterclockwise. The Removal Screw Driver/Removal Tool can also be utilized to capture and remove an X-PostTM.

NOTES:

NOTES:

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

Surgical Technique

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

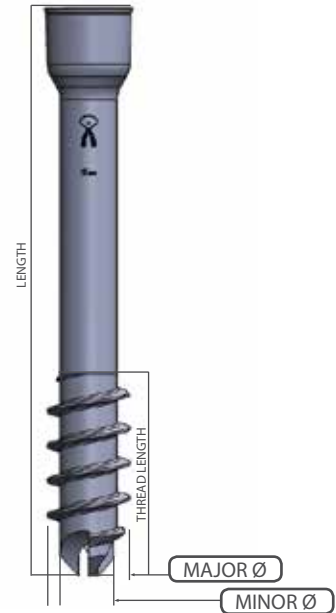
Implant #	Description	Qty
9.5 X-Posts (Magenta)		
118-95625	X-Post™ (60 deg) 9.5 x 25mm	2
118-95630	X-Post™ (60 deg) 9.5 x 30mm	2
118-95635	X-Post™ (60 deg) 9.5 x 35mm	2
6.5 Lag Screw (Cannulated Tapered)		
118-65030	Lag Screw (Cannulated Tapered) 6.5 x 30mm	2
118-65035	Lag Screw (Cannulated Tapered) 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-POSTTM



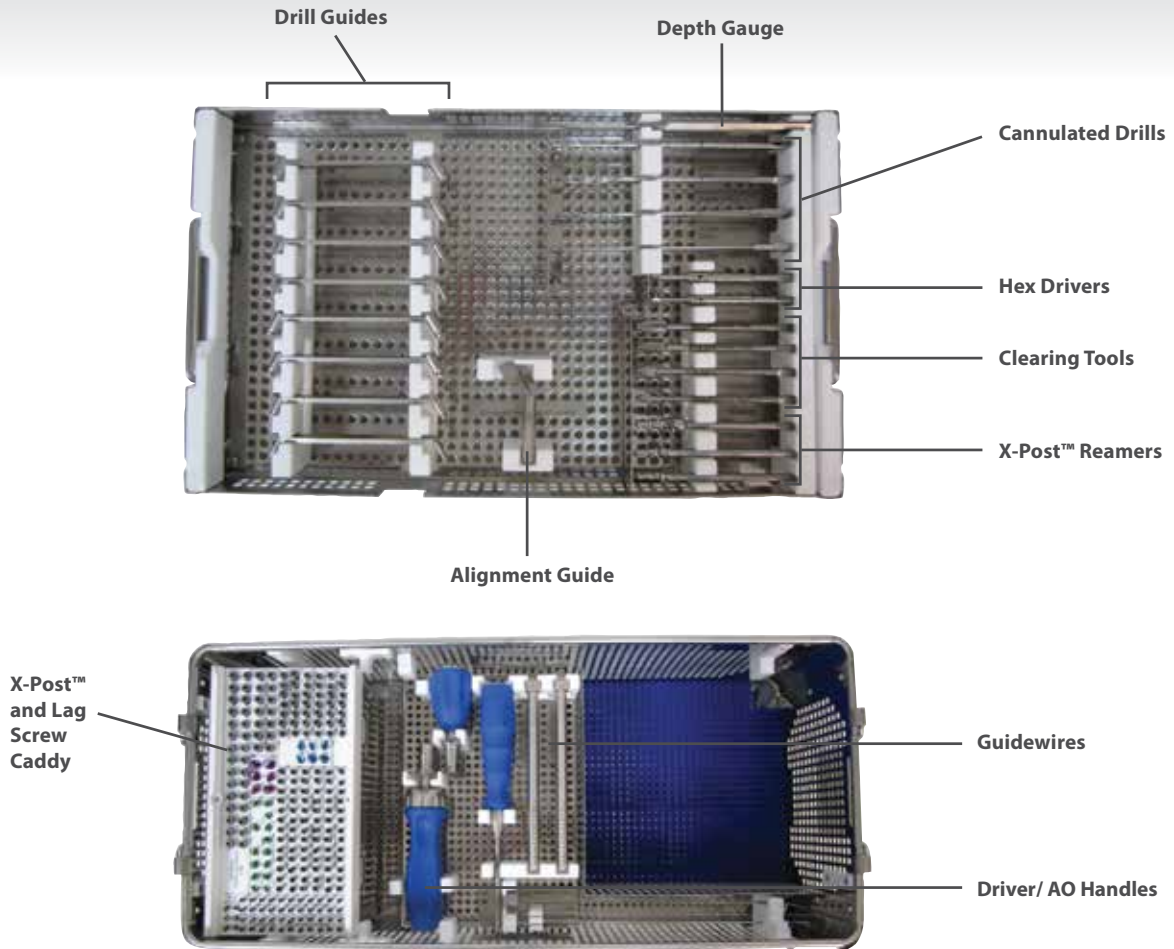
LAG SCREWS (Tapered & Polyaxial)



X-Post TM Specifications				
X-Post TM	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 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

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

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