



IO FixTM
IntraOsseous Fixation

Surgical Technique
Ankle Fusion

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

INDICATIONS FOR USE

The Extremity Medical Lag Screw and X-Post™ System is intended for the reduction and internal fixation of arthrodesis, osteotomy, 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, Calcanealcuboid, Metatarso-Cuneiform, and Tibia-Talar joints, as well as for 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

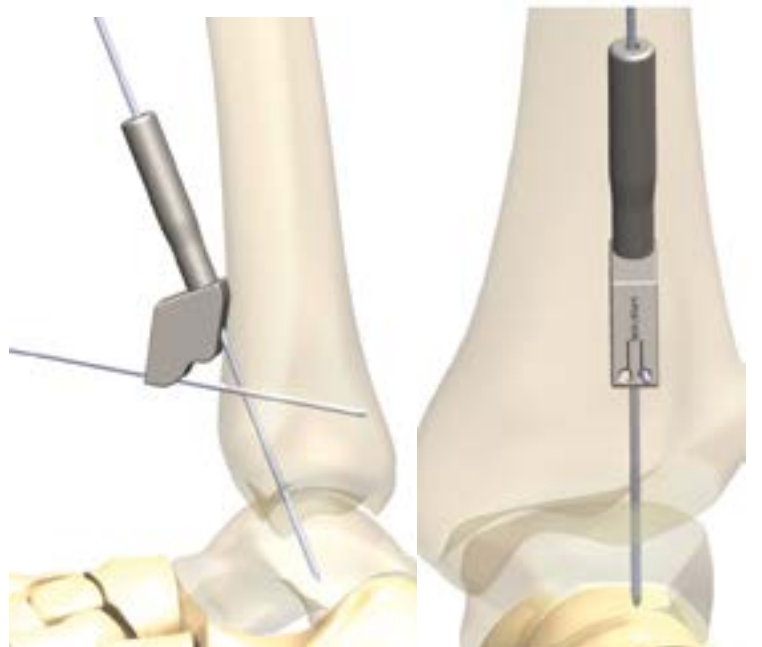
Insert the Ø1.6mm guidewire through the dorsal tibia in the direction of the ideal lag screw trajectory. This temporary wire acts as a guide for the desired trajectory of the lag screw and allows for the optimal placement of the X-PostTM. Verify the positioning of this guidewire with fluoroscopy.



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 between 10-30mm 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

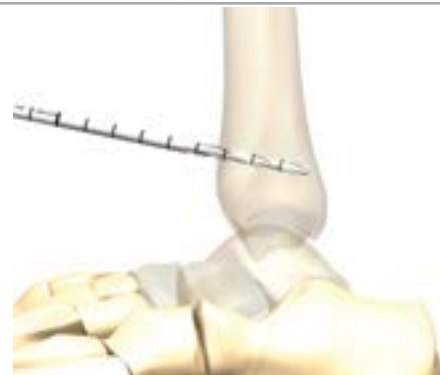
X-PostTM size is typically determined by choosing the desired corresponding large screw size.

The X-PostTM Reamers are recommended for patients with good quality bone only. 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 Reaming is highly recommended as these reamers are aggressive.

Table 1: X-PostTM Reamers & Sizes

Screw Sizes	X-Post TM Size (Color)	X-Post TM Reamer
3.0mm screw	4.6 (Gold)	4.6 X-Post TM Reamer
3.0mm screw	6.6 x 60° (Green)	6.6 X-Post TM Reamer
3.0mm screw	6.6 x 45° (Teal)	
3.0mm screw	8.0 (Blue)	8.0/ 9.5 X-Post TM Reamer (1st Line)
3.0mm screw	9.5 (Magenta)	8.0/ 9.5 X-Post TM Reamer (2nd Line)



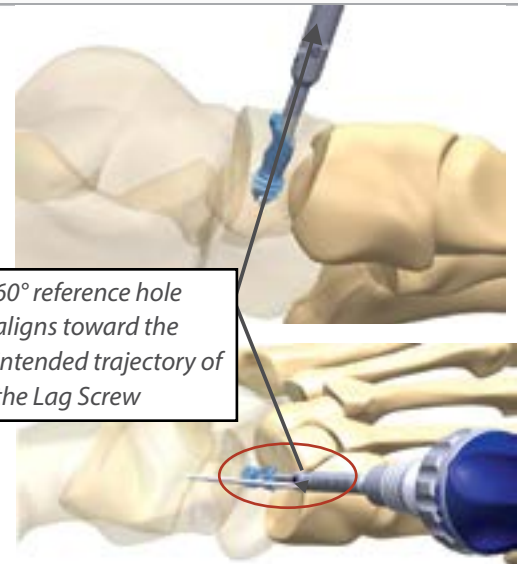
WARNING: For poor or questionable quality bone, utilize the appropriate drill to prepare the bone for the X-PostTM. Often, pre-drilling marginal quality bone will be the only preparatory step required for the placement of the X-PostTM. Reaming for the X-PostTM for a patient with questionable bone quality can be done post drilling if the surgeon feels it is needed. Once again, hand reaming is highly recommended.

STEP 6 – X-PostTM Insertion

Select the appropriate X-PostTM 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-PostTM until flush with cortex, and align the indicator (laser arrows) towards the intended fusion area.

Table 2: Hex Sizes

X-Post TM Size (Color)	Hex Size (mm)
4.6 (Gold)	2.0
6.6 x 60° (Green)	3.0
6.6 x 45° (Teal)	3.0
8.0 (Blue)	3.0
9.5 (Magenta)	3.0



A visual check may be done by inserting a guidewire through the reference holes on the hex drivers

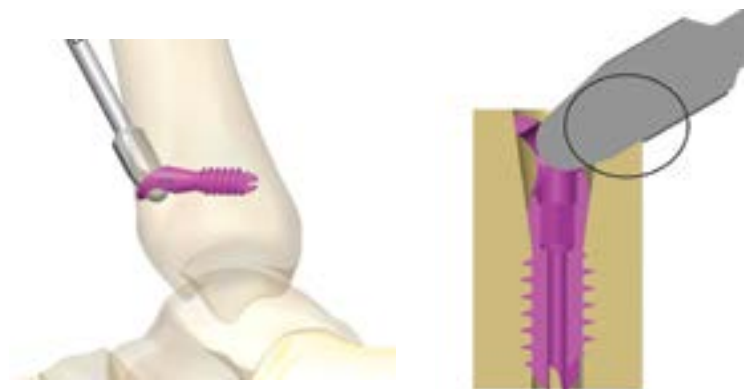
STEP 7 – Clear Additional Bone

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

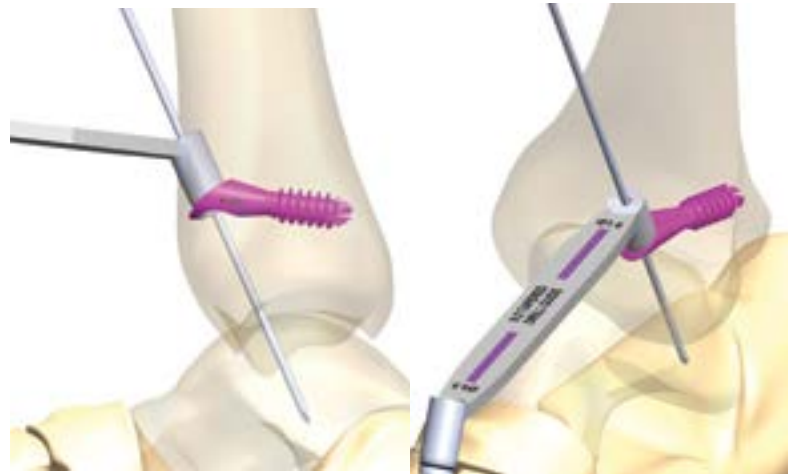
X-Post TM	Clearing Tool
4.6 (Gold)	4.6 Clearing Tool
6.6 x 60° (Green)	6.6 Clearing Tool
6.6 x 45° (Teal)	6.6 Clearing Tool
8.0 (Blue)	8.0 Clearing Tool
9.5 (Magenta)	9.5 Clearing Tool



STEP 8 - Insert Lag Screw Guidewire

Insert the appropriate guidewire guide in the X-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.



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.

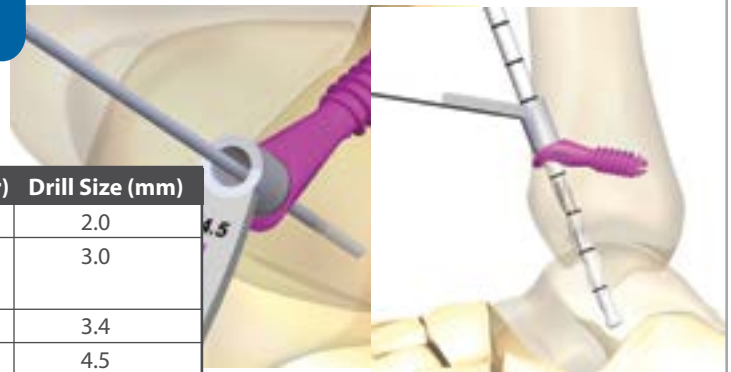


STEP 10 – Pilot Drill

Select the appropriate drill based on the X-Post™ 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-Pos TM Size (Color)	Drill Size (mm)
4.6 (Gold)	2.0
6.6 x 60° (Green)	3.0
6.6 x 45° (Teal)	3.4
8.0 (Blue)	3.4
9.5 (Magenta)	4.5



STEP 11 – Lag Screw

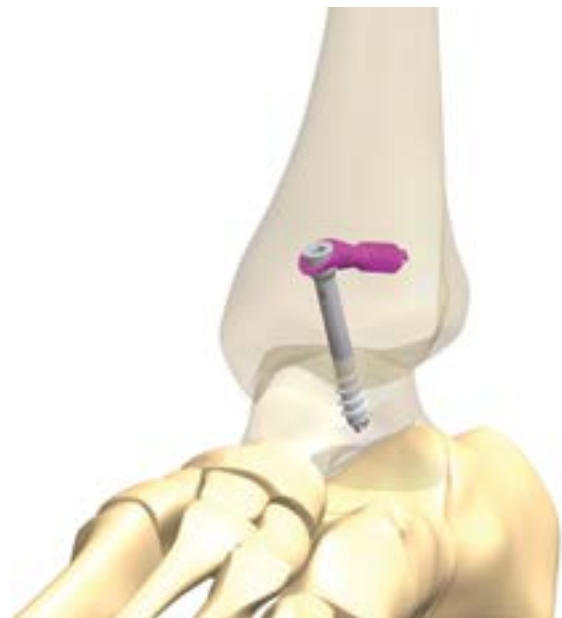
Insert the Lag Screw under TWO finger pressure until tactile compression is felt, and the visualization shows the Lag Screw flush against X-PostTM. With the tapered Lag Screw, the Morse Taper engagement should be felt as the tapers engage. With the polyaxial Lag Screw, tighten until an appropriate compression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



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 any tissue in growth 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 to remove. Insert removal driver into the X-PostTM and remove by turning counterclockwise.

NOTES

Table 5: INSTRUMENT LIST

Instrument	Description
101-00004	Guide Wire- 0.9mm *
101-00006	Guide Wire- 1.6mm *
101-00008	Guide Wire Holder- 0.9mm
101-00009	Guide Wire Holder- 1.6 mm
101-00010	Screw Measuring Device
101-00011	Cannulated Drill- 2.0mm *
101-00012	Cannulated Drill- 3.4mm*
101-00013	Cannulated Drill- 4.5mm *
101-00022	Cleaning Brush- 0.9mm
101-00023	Cleaning Brush- 1.6mm
102-00002	Cannulated Drill- 3.0mm *
102-00017	AO Quick Connect Handle
102-00020	Removal Screw Driver
102-00021	Removal Tool
118-00000	IO FiX™ Instrument Tray
118-00001	IO FiX™ Implant Caddy
118-00004	4.6 X-Post™ Reamer*
118-00005	6.6 X-Post™ Reamer*
118-00006	8.0/9.5 X-Post™ Reamer*
118-00007	4.6 Tapered Drill Guide
118-00008	6.6 Tapered Drill Guide
118-00009	8.0 Tapered Drill Guide
118-00010	9.5 Tapered Drill Guide
118-00011	4.6 Polyaxial Drill Guide
118-00012	6.6 Polyaxial Drill Guide
118-00013	8.0 Polyaxial Drill Guide
118-00014	9.5 Polyaxial Drill Guide
118-00015	6.6 Clearing Tool
118-00016	9.5 Clearing Tool
118-00017	4.6 Clearing Tool
118-00018	8.0 Clearing Tool
118-00020	2.0 Hex Driver
118-00021	IO FiX™ X-Ray Template*
118-00030	3.0 Hex Driver
118-00031	1.6 x 60° Alignment Guide
118-00039	Ratcheting AO Handle

*disposable

Table 6: IMPLANT LIST

Implant	Description
118-30016	Lag Screw (Solid Tapered) 3.0 x 16mm
118-30020	Lag Screw (Solid Tapered) 3.0 x 20mm
118-30024	Lag Screw (Solid Tapered) 3.0 x 24mm
118-30116	Lag Screw (Solid Polyaxial) 3.0 x 16mm
118-30120	Lag Screw (Solid Polyaxial) 3.0 x 20mm
118-30124	Lag Screw (Solid Polyaxial) 3.0 x 24mm
118-40020	Lag Screw (Cannulated Tapered) 4.0 x 20mm
118-40025	Lag Screw (Cannulated Tapered) 4.0 x 25mm
118-40030	Lag Screw (Cannulated Tapered) 4.0 x 30mm
118-40035	Lag Screw (Cannulated Tapered) 4.0 x 35mm
118-40040	Lag Screw (Cannulated Tapered) 4.0 x 40mm
118-40045	Lag Screw (Cannulated Tapered) 4.0 x 45mm
118-40050	Lag Screw (Cannulated Tapered) 4.0 x 50mm
118-40120	Lag Screw (Cannulated Polyaxial) 4.0 x 20mm
118-40125	Lag Screw (Cannulated Polyaxial) 4.0 x 25mm
118-40130	Lag Screw (Cannulated Polyaxial) 4.0 x 30mm
118-40135	Lag Screw (Cannulated Polyaxial) 4.0 x 35mm
118-40140	Lag Screw (Cannulated Polyaxial) 4.0 x 40mm
118-40145	Lag Screw (Cannulated Polyaxial) 4.0 x 45mm
118-40150	Lag Screw (Cannulated Polyaxial) 4.0 x 50mm
118-40220	Lag Screw (Solid Polyaxial) 4.0 x 20mm
118-40225	Lag Screw (Solid Polyaxial) 4.0 x 25mm
118-40230	Lag Screw (Solid Polyaxial) 4.0 x 30mm
118-40235	Lag Screw (Solid Polyaxial) 4.0 x 35mm
118-40240	Lag Screw (Solid Polyaxial) 4.0 x 40mm
118-40245	Lag Screw (Solid Polyaxial) 4.0 x 45mm
118-40250	Lag Screw (Solid Polyaxial) 4.0 x 50mm
118-40320	Lag Screw (Solid Tapered) 4.0 x 20mm
118-40325	Lag Screw (Solid Tapered) 4.0 x 25mm
118-40330	Lag Screw (Solid Tapered) 4.0 x 30mm
118-40335	Lag Screw (Solid Tapered) 4.0 x 35mm
118-40340	Lag Screw (Solid Tapered) 4.0 x 40mm
118-40345	Lag Screw (Solid Tapered) 4.0 x 45mm
118-40350	Lag Screw (Solid Tapered) 4.0 x 50mm
118-46614	X-Post™ (60°) 4.6 x 14mm
118-46616	X-Post™ (60°) 4.6 x 16mm
118-46618	X-Post™ (60°) 4.6 x 18mm
118-50020	Lag Screw (Cannulated Tapered) 5.0 x 20mm
118-50025	Lag Screw (Cannulated Tapered) 5.0 x 25mm
118-50030	Lag Screw (Cannulated Tapered) 5.0 x 30mm

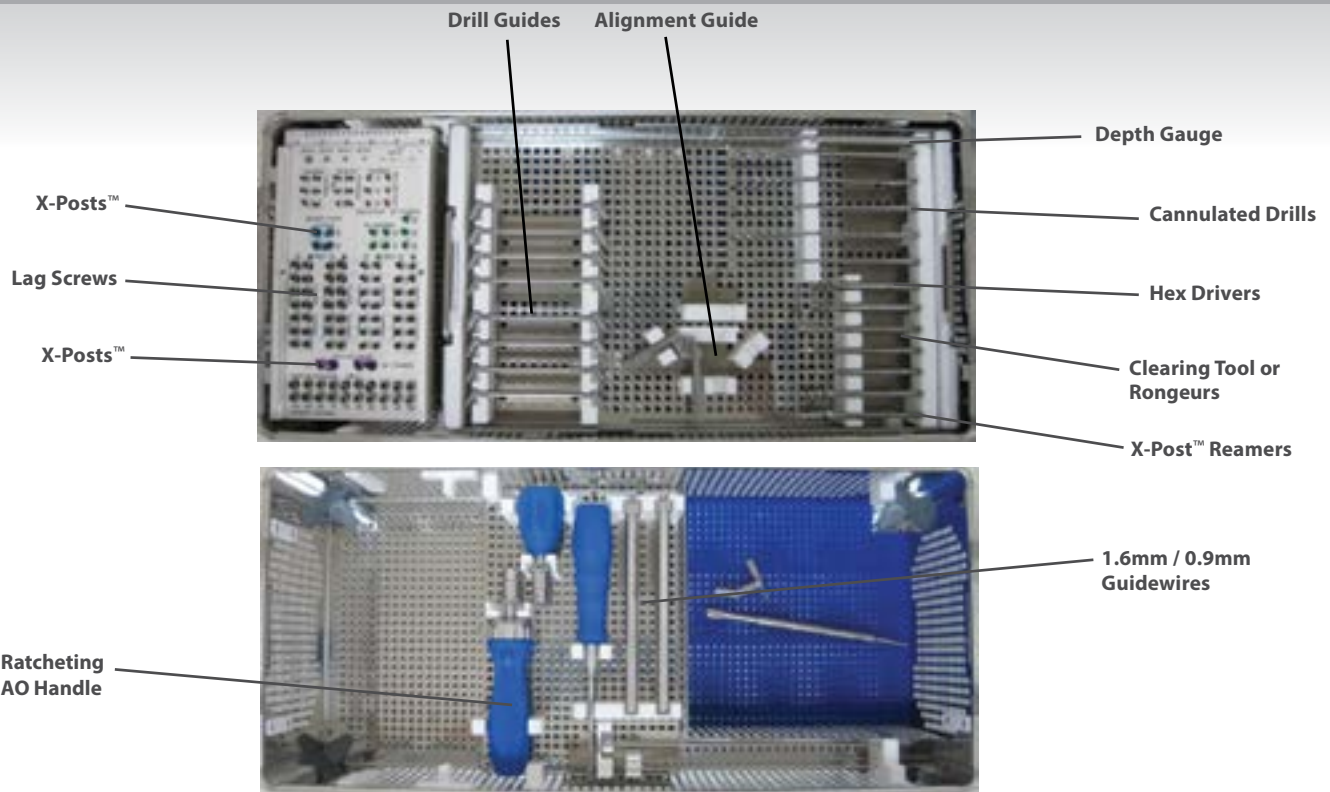
IMPLANT LIST, CONTINUED

Instrument	Description
118-50035	Lag Screw (Cannulated Tapered) 5.0 X 35mm
118-50040	Lag Screw (Cannulated Tapered) 5.0 X 40mm
118-50045	Lag Screw (Cannulated Tapered) 5.0 X 45mm
118-50050	Lag Screw (Cannulated Tapered) 5.0 X 50mm
118-50120	Lag Screw (Cannulated Polyaxial) 5.0 X 20mm
118-50125	Lag Screw (Cannulated Polyaxial) 5.0 X 25mm
118-50130	Lag Screw (Cannulated Polyaxial) 5.0 X 30mm
118-50135	Lag Screw (Cannulated Polyaxial) 5.0 X 35mm
118-50140	Lag Screw (Cannulated Polyaxial) 5.0 X 40mm
118-50145	Lag Screw (Cannulated Polyaxial) 5.0 X 45mm
118-50150	Lag Screw (Cannulated Polyaxial) 5.0 X 50mm
118-50220	Lag Screw (Solid Polyaxial) 5.0 X 20mm
118-50225	Lag Screw (Solid Polyaxial) 5.0 X 25mm
118-50230	Lag Screw (Solid Polyaxial) 5.0 X 30mm
118-50235	Lag Screw (Solid Polyaxial) 5.0 X 35mm
118-50240	Lag Screw (Solid Polyaxial) 5.0 X 40mm
118-50245	Lag Screw (Solid Polyaxial) 5.0 X 45mm
118-50250	Lag Screw (Solid Polyaxial) 5.0 X 50mm
118-50320	Lag Screw (Solid Tapered) 5.0 X 20mm
118-50325	Lag Screw (Solid Tapered) 5.0 X 25mm
118-50330	Lag Screw (Solid Tapered) 5.0 X 30mm
118-50335	Lag Screw (Solid Tapered) 5.0 X 35mm
118-50340	Lag Screw (Solid Tapered) 5.0 X 40mm
118-50345	Lag Screw (Solid Tapered) 5.0 X 45mm
118-50350	Lag Screw (Solid Tapered) 5.0 X 50mm
118-66430	X-Post™ (45°) 6.6 X 30mm
118-66435	X-Post™ (45°) 6.6 X 35mm
118-66440	X-Post™ (45°) 6.6 X 40mm
118-66620	X-Post™ (60°) 6.6 X 20mm
118-66625	X-Post™ (60°) 6.6 X 25mm
118-65140	Lag Screw (Cannulated Polyaxial) 6.5 x 40mm
118-65150	Lag Screw (Cannulated Polyaxial) 6.5 x 50mm
118-65160	Lag Screw (Cannulated Polyaxial) 6.5 x 60mm
118-65170	Lag Screw (Cannulated Polyaxial) 6.5 x 70mm
118-65175	Lag Screw (Cannulated Polyaxial) 6.5 x 75mm
118-65180	Lag Screw (Cannulated Polyaxial) 6.5 x 80mm
118-65185	Lag Screw (Cannulated Polyaxial) 6.5 x 85mm
118-65190	Lag Screw (Cannulated Polyaxial) 6.5 x 90mm

IMPLANT LIST, CONTINUED

Instrument	Description
118-65195	Lag Screw (Cannulated Polyaxial) 6.5 x 95mm
118-65100	Lag Screw (Cannulated Polyaxial) 6.5 x 100mm
118-65040	Lag Screw (Cannulated Tapered) 6.5 x 40mm
118-65050	Lag Screw (Cannulated Tapered) 6.5 x 50mm
118-65060	Lag Screw (Cannulated Tapered) 6.5 x 60mm
118-65070	Lag Screw (Cannulated Tapered) 6.5 x 70mm
118-65075	Lag Screw (Cannulated Tapered) 6.5 x 75mm
118-65080	Lag Screw (Cannulated Tapered) 6.5 x 80mm
118-65085	Lag Screw (Cannulated Tapered) 6.5 x 85mm
118-65090	Lag Screw (Cannulated Tapered) 6.5 x 90mm
118-65095	Lag Screw (Cannulated Tapered) 6.5 x 95mm
118-65000	Lag Screw (Cannulated Tapered) 6.5 x 100mm
118-80620	X-Post™ (60°) 8.0 x 20mm
118-80625	X-Post™ (60°) 8.0 x 25mm
118-95625	X-Post™ (60°) 9.5 x 25mm
118-95630	X-Post™ (60°) 9.5 x 30mm

NOTES:



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™ Reamers
5	X-Posts™
6	Hex Drivers
7	Ratcheting AO Handle
8	Clearing Tool or Rongeurs
9	Drill Guides
10	Cannulated Drills
11	Lag Screws

X-Post™ Implant Sizes		
Catalog #	Description	Length
118-466XX*	X-Post™ (60 deg) 4.6 x XXmm	14mm, 16mm, 18mm
118-664XX*	X-Post™ (45 deg) 6.6 x XXmm	30mm, 35mm, 40mm
118-666XX*	X-Post™ (60 deg) 6.6 x XXmm	20mm, 25mm
118-806XX*	X-Post™ (60 deg) 8.0 x XXmm	20mm, 25mm
118-956XX*	X-Post™ (60 deg) 9.5 x XXmm	25mm, 30mm

*XX Denotes Implant Length

Drill/Reamer Selection						
X-Post™ Size	Lag Screw	K-Wire	Reamer	Driver Hex	Clearing Tool	Pilot Drill
4.6 (GOLD)	3.0	0.9	4.6	2.0	4.6	2.0
6.6 (GREEN)	4.0	1.6	6.6	3.0	6.6	3.0
8.0 (BLUE)	5.0	1.6	8.0/ 9.5 (1st Line)	3.0	8.0	3.4
9.5 (MAGENTA)	6.5	1.6	8.0/ 9.5 (2nd Line)	3.0	9.5	4.5

Lag Screw				
	3.0	4.0	5.0	6.5
Tapered	118-300XX*	118-403XX* 118-400XX†	118-503XX* 118-500XX†	118-650XX†
Polyaxial	118-301XX*	118-402XX* 118-401XX†	118-502XX* 118-501XX†	118-651XX†
Length	14mm–26mm 2mm Increments	20mm–50mm 5mm Increments	20mm–50mm 5mm Increments	40mm–100mm 10mm Increments

*Solid Screw †Cannulated Screw