

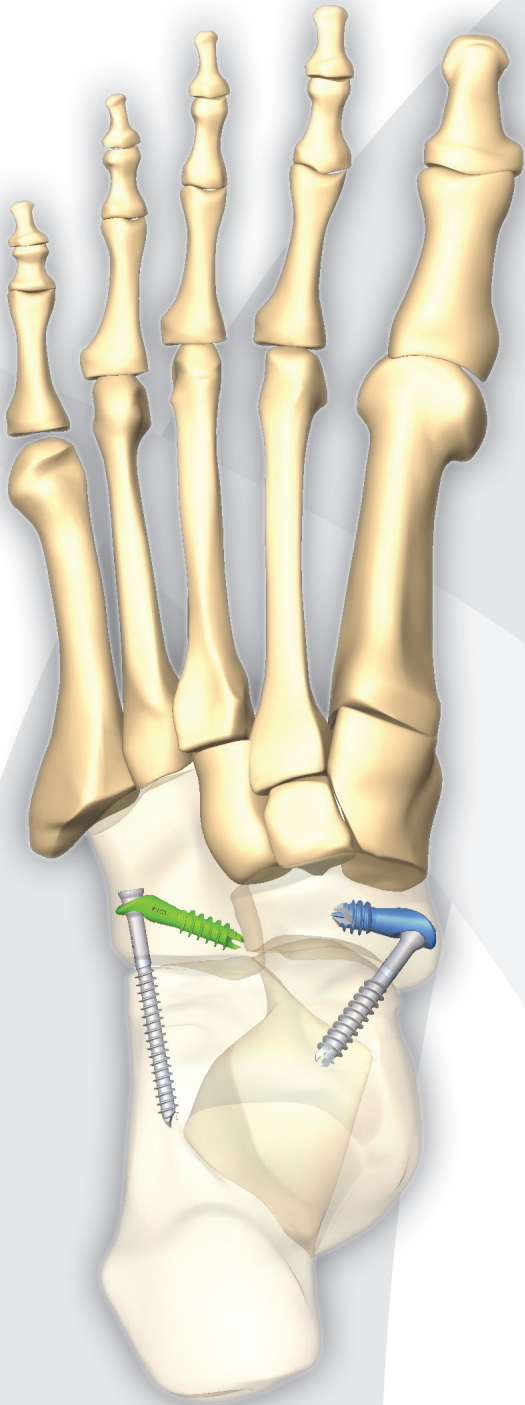


Lavender
Medical

IO FiX™

IntraOsseous Fixation

Surgical Technique



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-PostTM 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 Joint, as well as for Metatarsal Osteotomies.

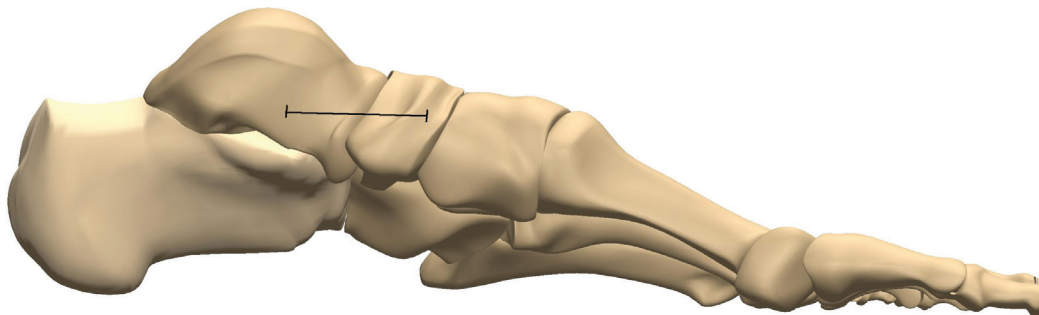
NOTE: This technique describes the steps for hardware implantation as used in a Talonavicular Fusion with a medial approach. Placement of the construct is based on surgeon preference and access. Please follow the same steps as listed in this procedure for other midfoot indications. Supplemental information is provided at the end of this guide regarding the use of IO FiXTM for Calcaneocuboid Fusion, Tarsometatarsal Fusion and Calcaneal Osteotomies.

Pre-Operative Planning - Templating

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

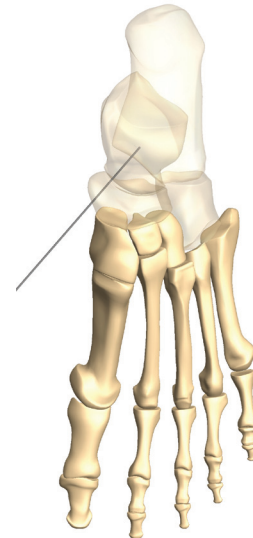
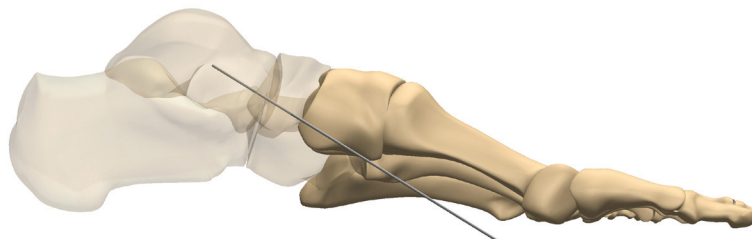
STEP 1 - Exposure and Joint Preparation

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



STEP 2 - Alignment Guidewire

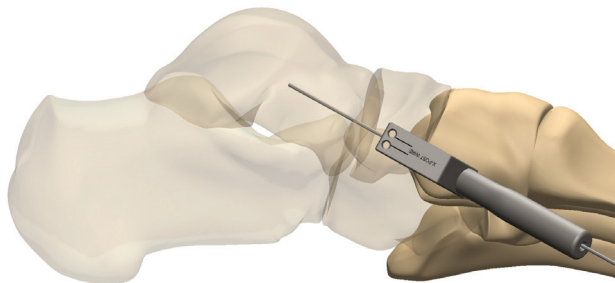
Insert a Ø1.6mm guidewire through navicular in the direction of the ideal lag screw trajectory. This guidewire will serve as an alignment wire for the X-Post™ orientation. Verify proper positioning with fluoroscopy.



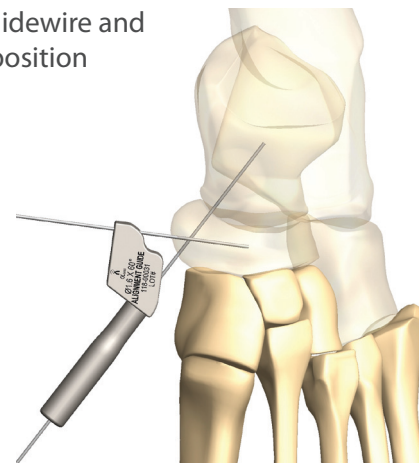
STEP 3 - Alignment Guide

Place the alignment guide over the guidewire and rotate the guide to place the X-Post™ guidewire. The alignment guidewire will need to be removed after the X-Post™ guidewire is placed. The X-Post™ guidewire should be placed 5-10mm from the joint line.

The alignment guide can be removed by removing the initial guidewire and sliding the guide over the X-Post™ guidewire. Verify depth and position of the X-Post™ guidewire via fluoroscopy.



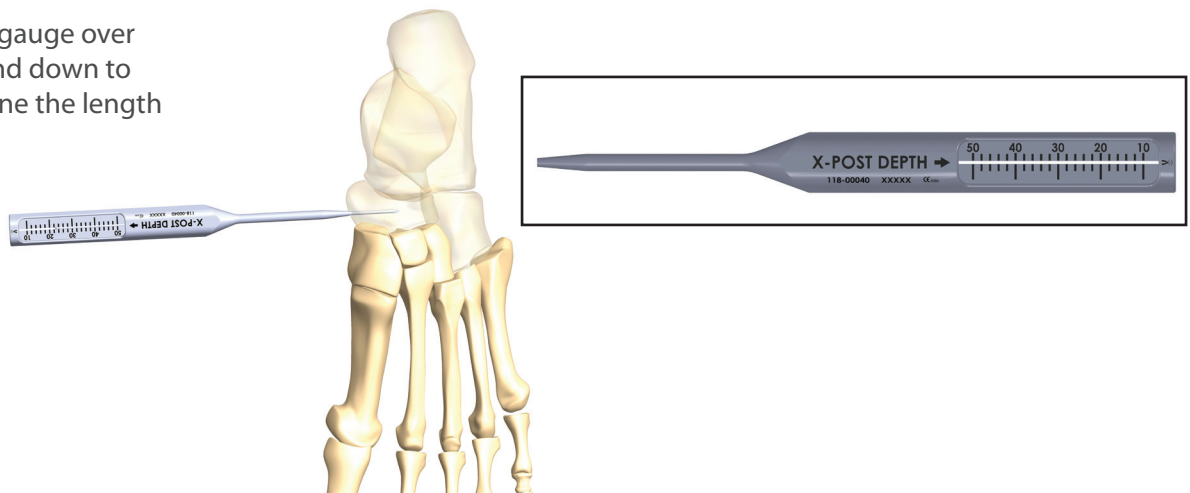
Slide guide over initial guidewire



Place X-Post™ guidewire 5-10mm from joint line

STEP 4 - X-PostTM Depth Measurement

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



STEP 5 – Preparation for X-PostTM: Drilling

DRILL 1ST

Select the cannulated drill based on the desired X-PostTM size (Table 1). Place the drill over the guidewire and advance below the pre-determined length.

NOTE: For bone of marginal quality, drilling is often the only preparatory step required for the placement of the X-PostTM.

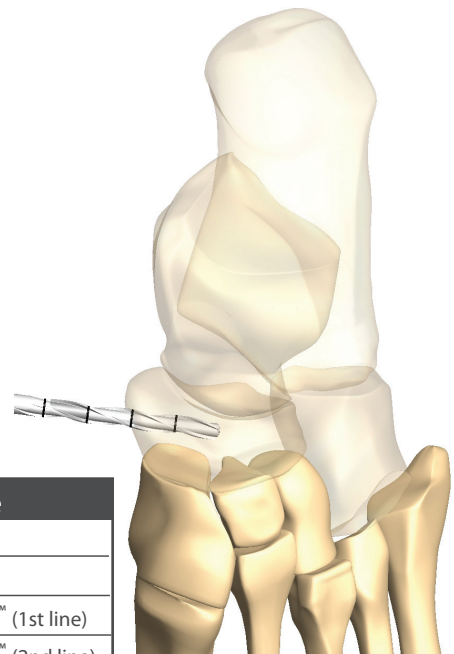


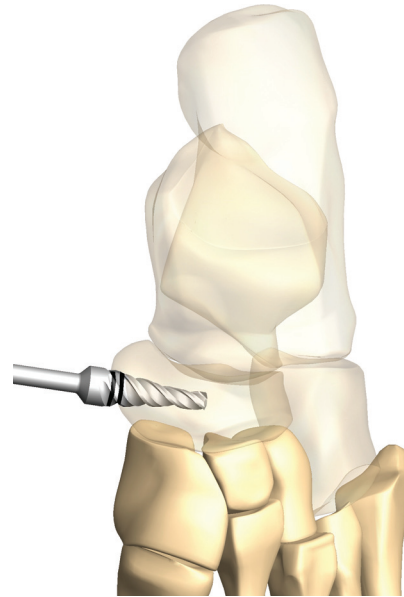
Table 1: Sizes: X-PostTM/ Screws/ Drills / Reamers

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 Reamer TM (1st line)
9.5mm X-Post TM	6.5mm Screw	4.5mm Drill	8.0/9.5 X-Post Reamer TM (2nd line)

STEP 5a - Preparation for X-Post™: Reaming Optional

If the surgeon feels reaming is required, select the X-Post™ reamer based on the desired X-Post™ size (Table1). 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.

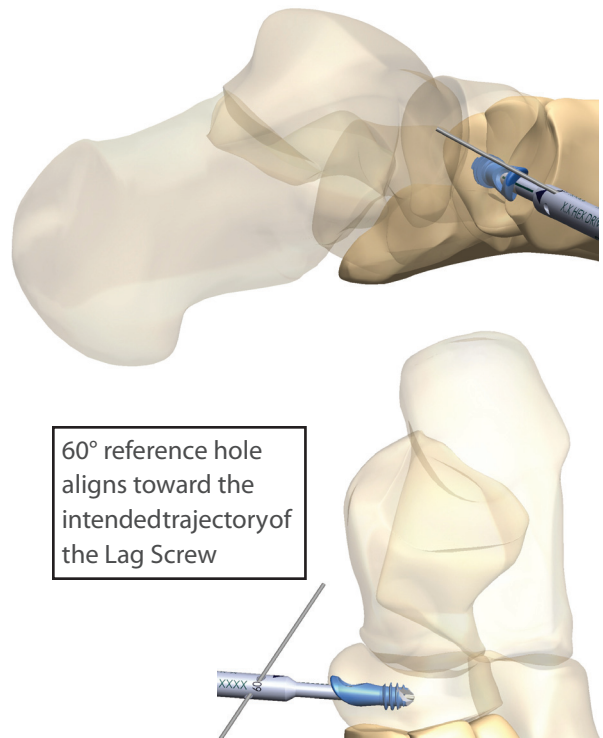
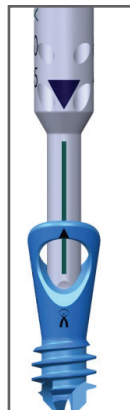


STEP 6 - X-Post™

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 marked arrow) towards the intended fusion area.

Table 2: Hex Sizes

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



60° reference hole aligns toward the intended trajectory of the Lag Screw

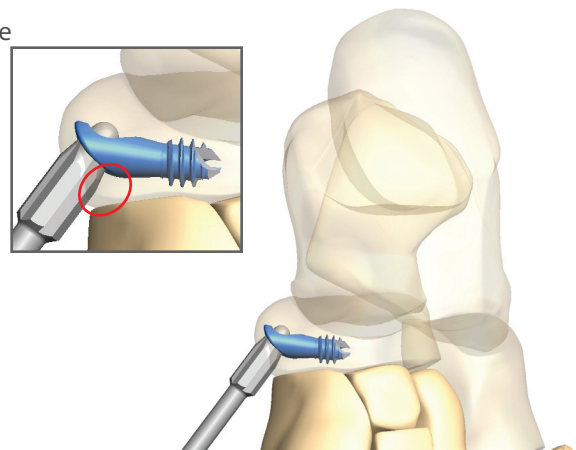
STEP 7 – Clear Additional Bone

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. Place the tip of the clearing tool into the X-PostTM with the handle pointing towards 12 o'clock. Drop the handle towards 6 o'clock and turn. 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° (Light Green)	
8.0 (Blue)	8.0 Clearing Tool
9.5 (Magenta)	9.5 Clearing Tool

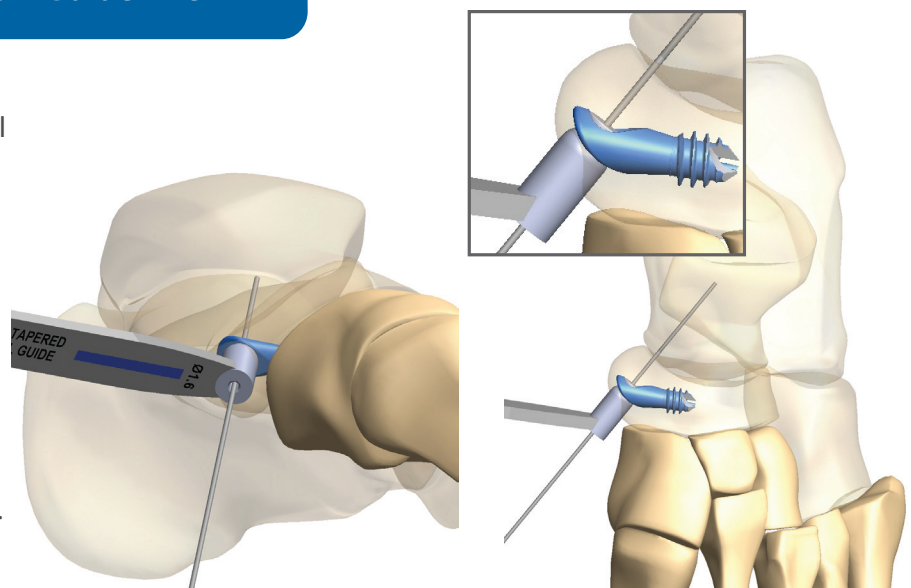


STEP 8 - Insert Lag Screw Guidewire

Insert the appropriate 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.

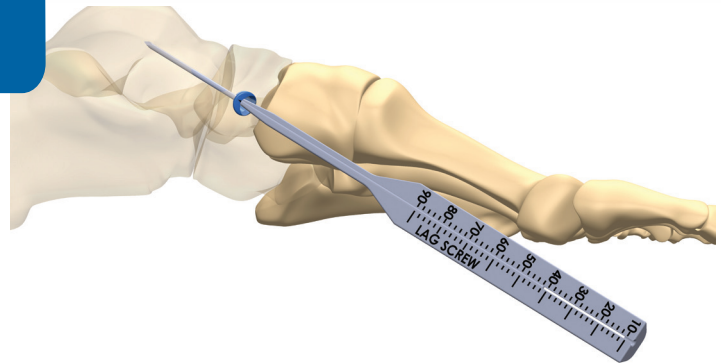
Insert the guidewire for the Lag Screw to the appropriate depth and verify position via fluoroscopy.

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



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.

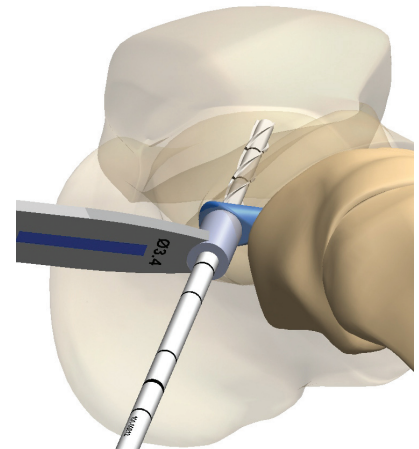


STEP 10 – Pilot Drill for Lag Screw

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 short of the depth measurement previously recorded. Graduations on drill are in 10mm increments.

Table 4: Drill Sizes

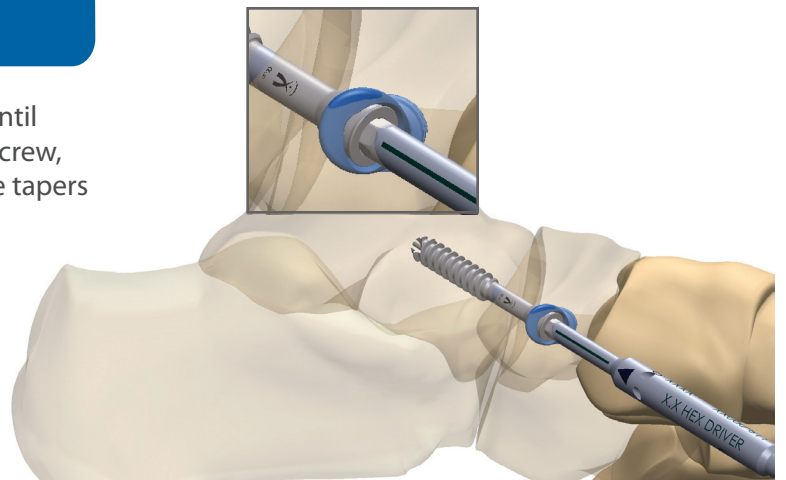
X-Post™ Size (Color)	Drill Size (mm)
4.6 (Gold)	2.0
6.6 x 60° (Green)	3.0
6.6 x 45° (Light Green)	3.4
8.0 (Blue)	3.4
9.5 (Magenta)	4.5



STEP 11 – Lag Screw

Insert the Lag Screw under TWO finger pressure until tactile compression is felt. 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. Verify under fluoroscopy.

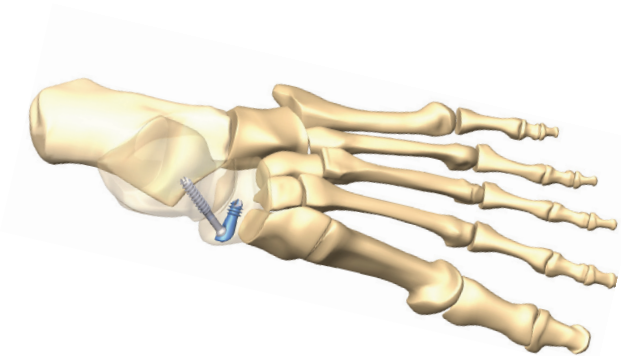
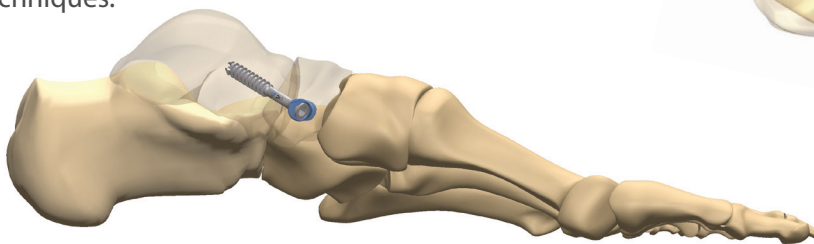
Note: Remove any provisional guidewires prior to final tightening. This will ensure maximum compression is applied.



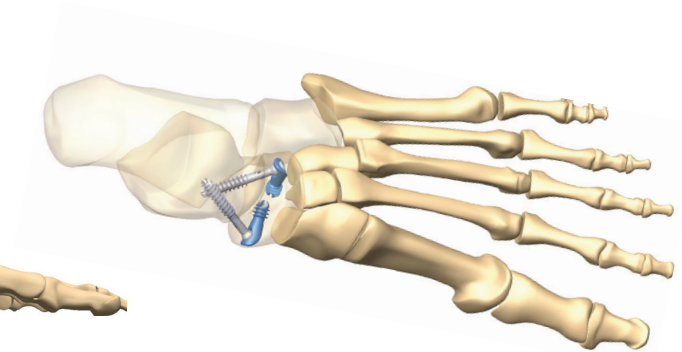
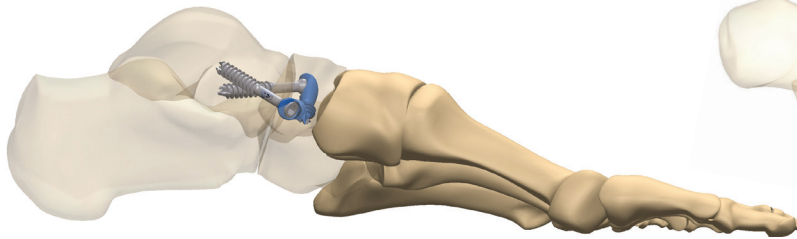
Talonavicular Fusion

FINAL POSITIONING

If additional fixation is determined necessary, an additional Lag Screw, headless screw, or IO FiX construct may be implanted per standard techniques.



OPTIONAL TWO CONSTRUCT PLACEMENT



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 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 to remove. Insert removal driver into the X-PostTM and remove by turning counterclockwise.

SUPPLEMENTAL INDICATION INFORMATION

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

1: Calcanealcuboid Fusion

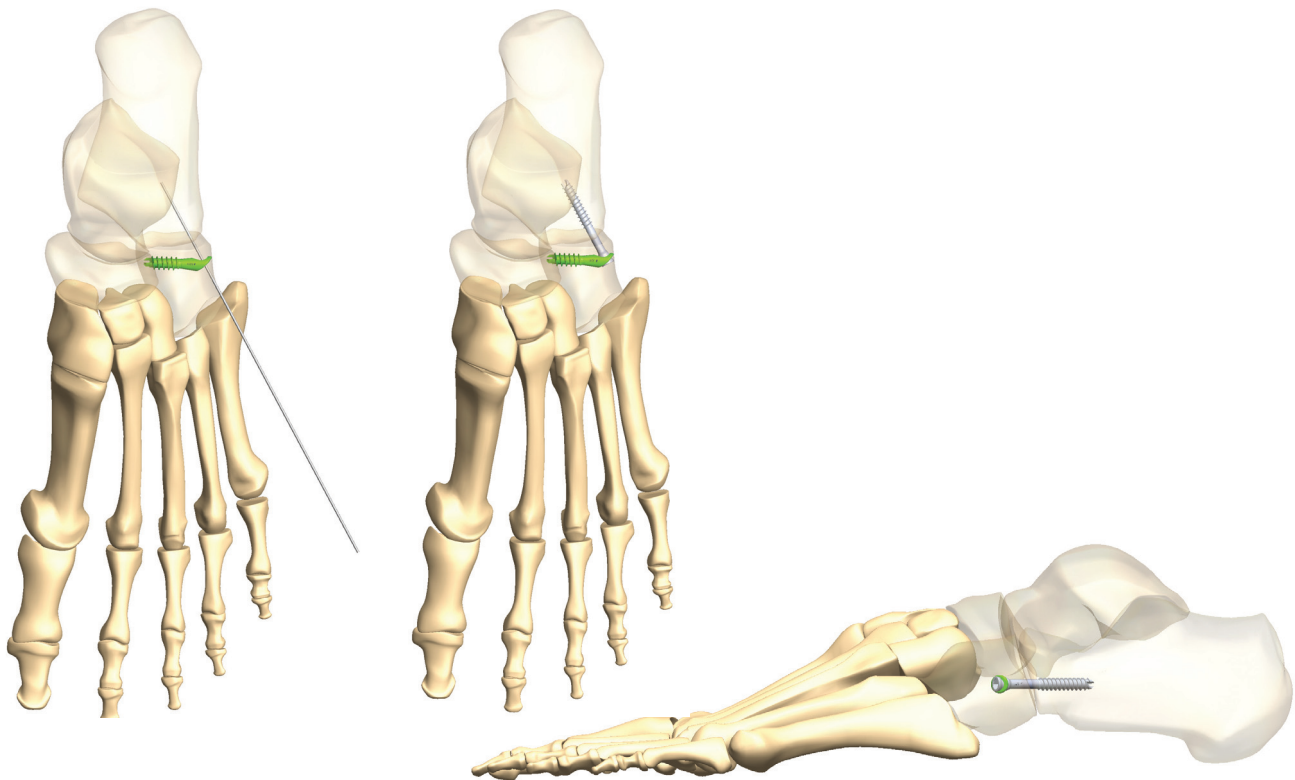
Approach and Exposure

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

X-Post Placement

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

Typically, the X-Post™ is placed in the cuboid approximately 5-10mm from the joint line.



SUPPLEMENTAL INDICATION INFORMATION

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

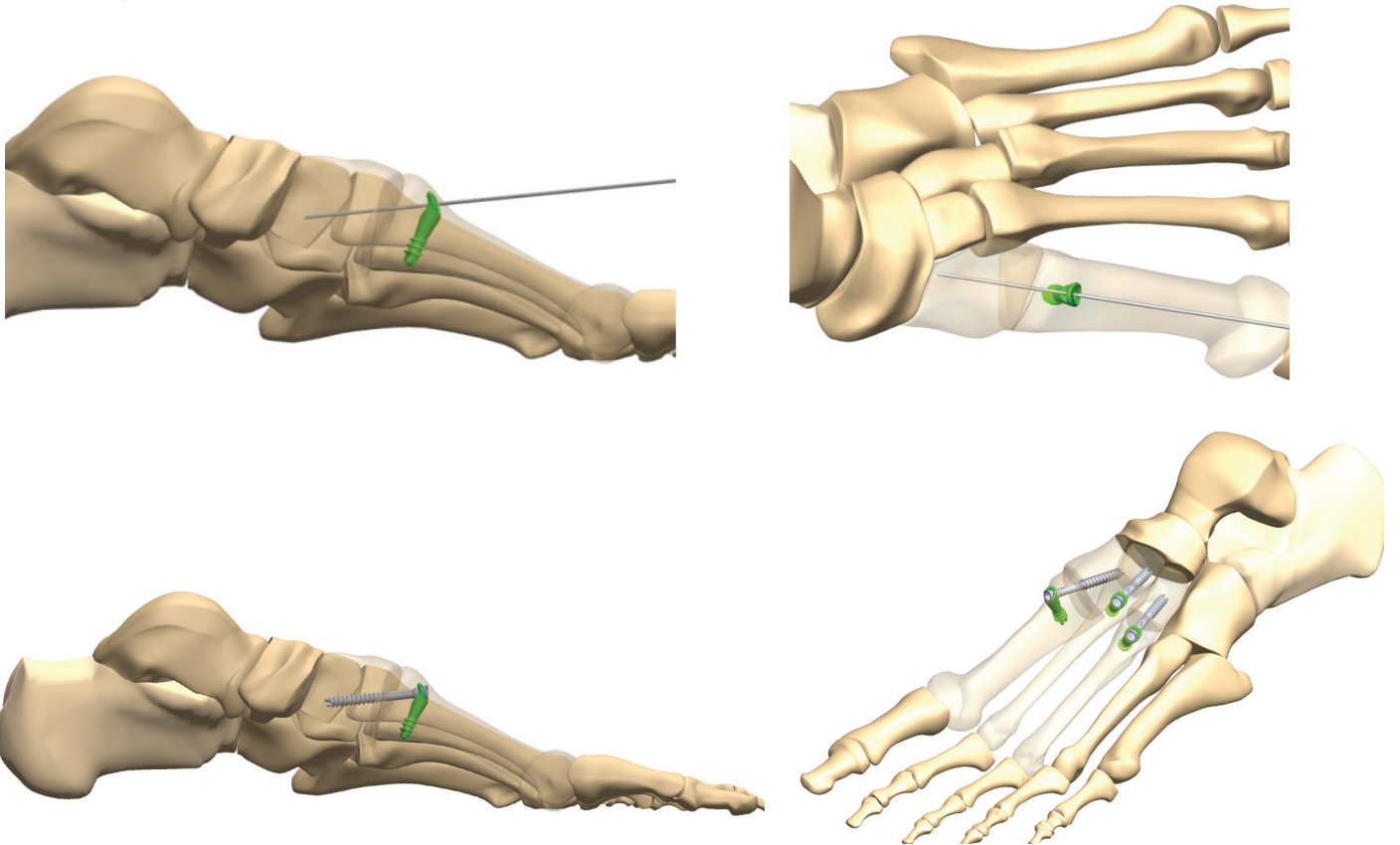
2: Tarsometatarsal (TMT) Fusion

Approach and Exposure

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

Option 1: Metatarsal X-Post™ Placement

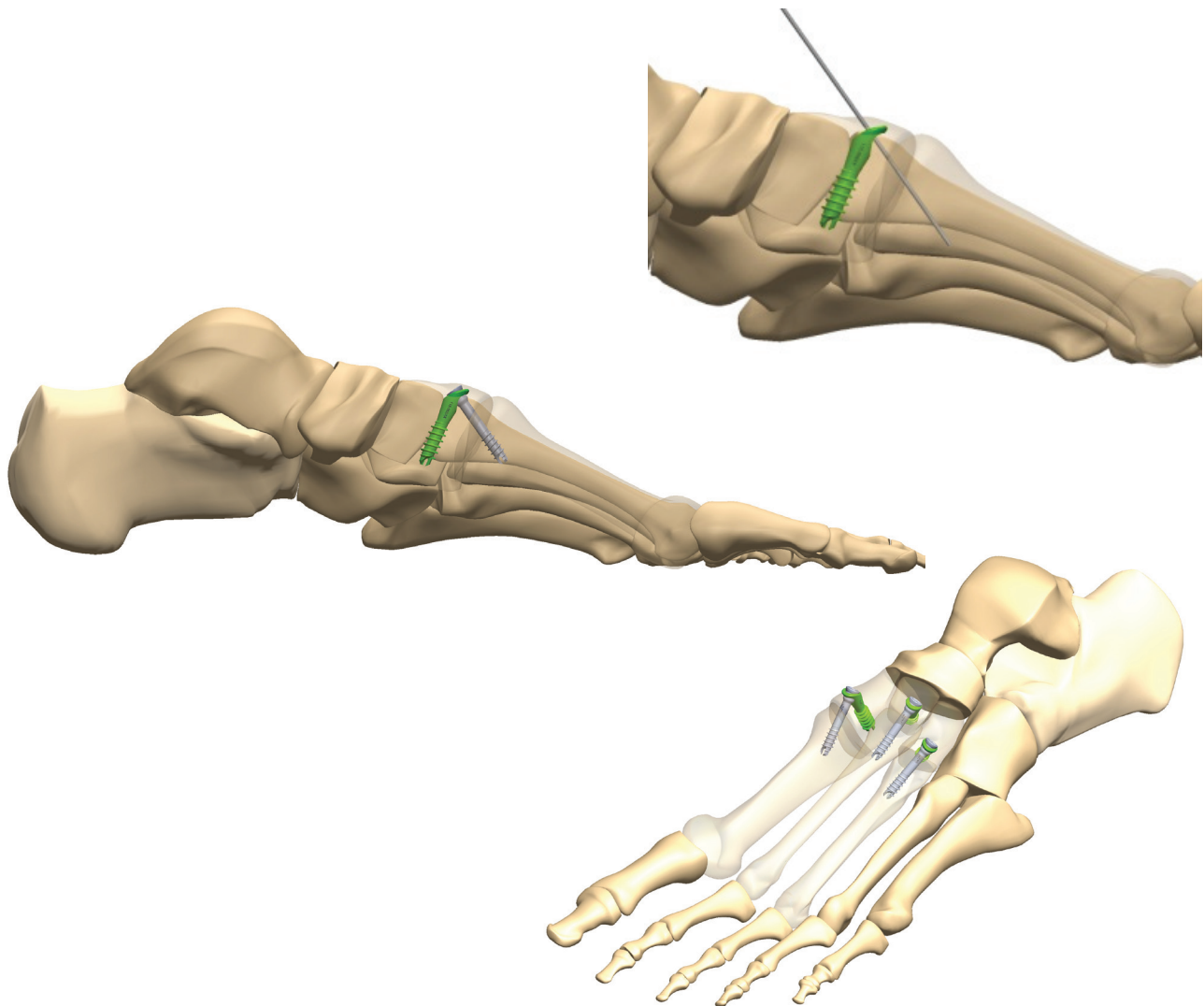
Typically, the X-Post™ is placed within the metatarsal base parallel to the joint - approximately 7-10mm from the joint line.



2: Tarsometatarsal (TMT) Fusion (continued)

Option 2: Cuneiform X-Post™ Placement

The X-Post™ may also be placed in the cuneiform. Caution should be used with this approach in regard to access and potential impingement with the leg during the subsequent drilling steps.



SUPPLEMENTAL INDICATION INFORMATION

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

3: Calcaneal Osteotomy

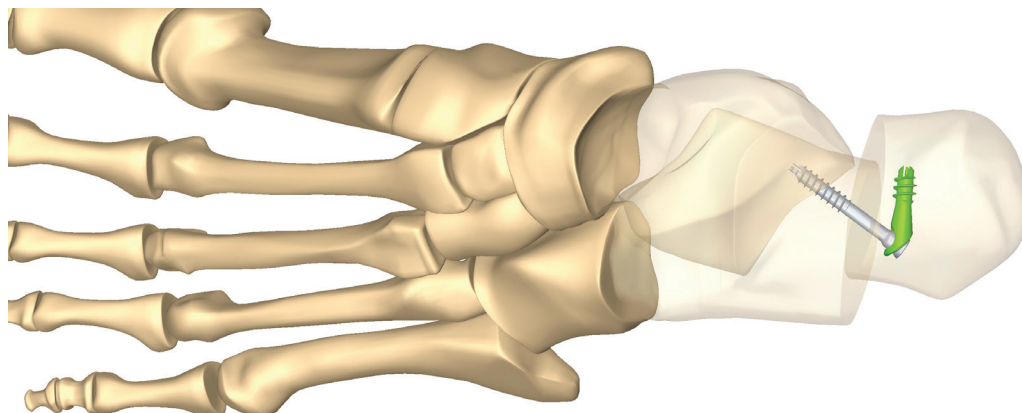
Approach and Exposure

An oblique incision is performed over the lateral aspect of the calcaneal tuberosity. The length is determined by exposure requirements. Carefully avoid the sural nerve during dissection to the periosteum.

X-Post™ Placement

Medial Displaced Calcaneal Osteotomy

For a sliding osteotomy, place the X-Post™ in the tuberosity fragment, parallel to the osteotomy. Additional guidewires may be used to provisionally fixate the fragment prior to utilizing the IO FiX™ System. Remove the provisional guidewires prior to fully engaging the Morse Taper of the Lag Screw.

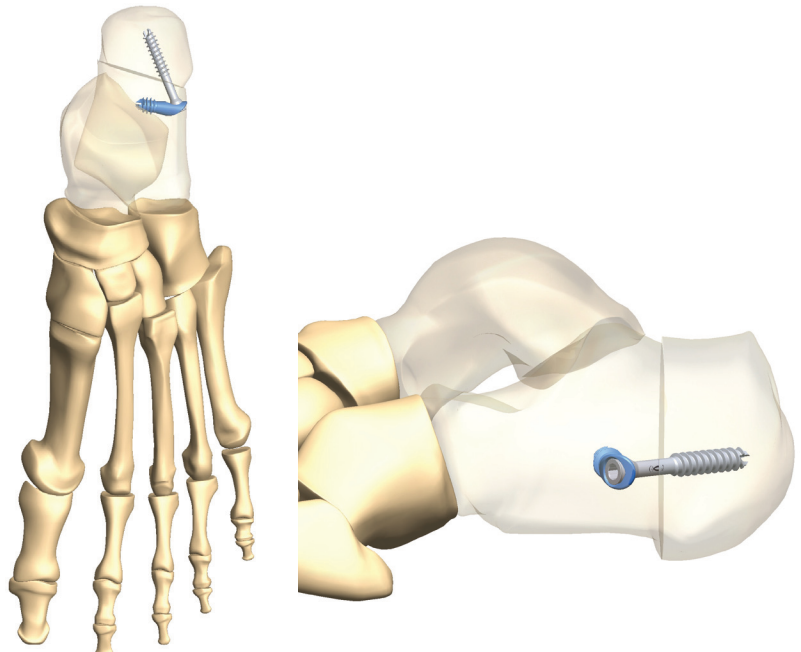


3: Calcaneal Osteotomy (continued):

X-Post™ Placement

Closing-Wedge Osteotomy

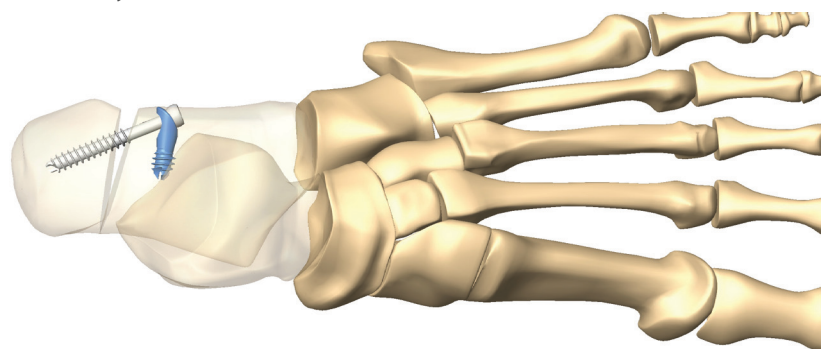
For a closing wedge osteotomy, place the X-Post™ in the proximal calcaneal body parallel to the osteotomy. Additional guidewires may be used to provisionally fixate the fragment prior to utilizing the IO FiX™ System. Remove the provisional guidewires prior to fully engaging the Morse Taper of the Lag Screw.



Pearl

Closing-Wedge Osteotomy

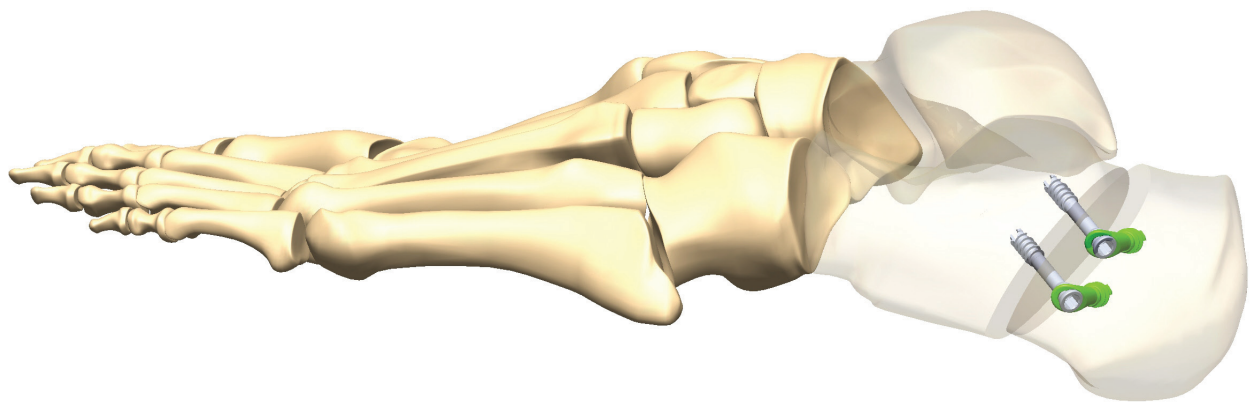
If the opening is unable to reduce fully prior to placing instrumentation, use a Polyaxial Screw. Seating the spherical head will provide an anchoring point to draw the tuberosity segment to the osteotomy site.



3: Calcaneal Osteotomy (continued):

Pearl

Medial Displaced and Closing-Wedge Osteotomies: Place the first construct off-center in order to allow room for the placement of a secondary construct if additional fixation is required.



NOTES:

Table 5: INSTRUMENT LIST

Instrument	Description
101-00004	Guidewire- 0.9mm *
101-00006	Guidewire- 1.6mm *
101-00008	Guidewire Holder- 0.9mm
101-00009	Guidewire Holder- 1.6 mm
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
118-00040	Depth Gauge

*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

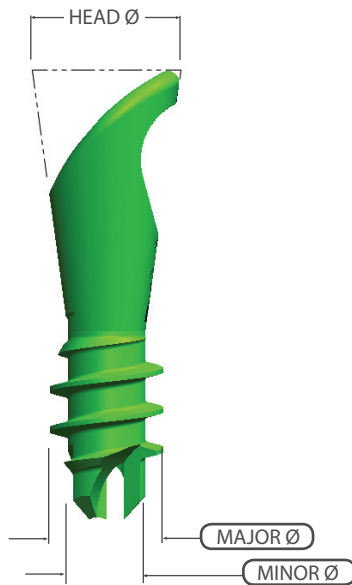
IMPLANT LIST, CONTINUED

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

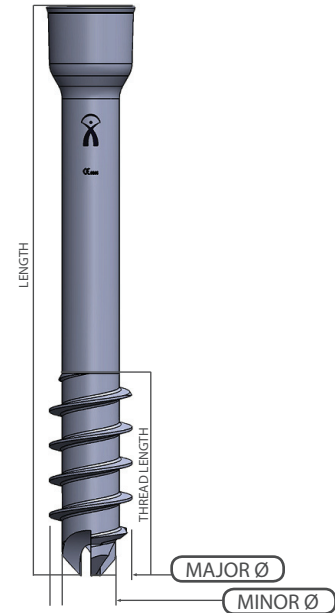
NOTES:

IMPLANT SPECIFICATIONS

X-POST™

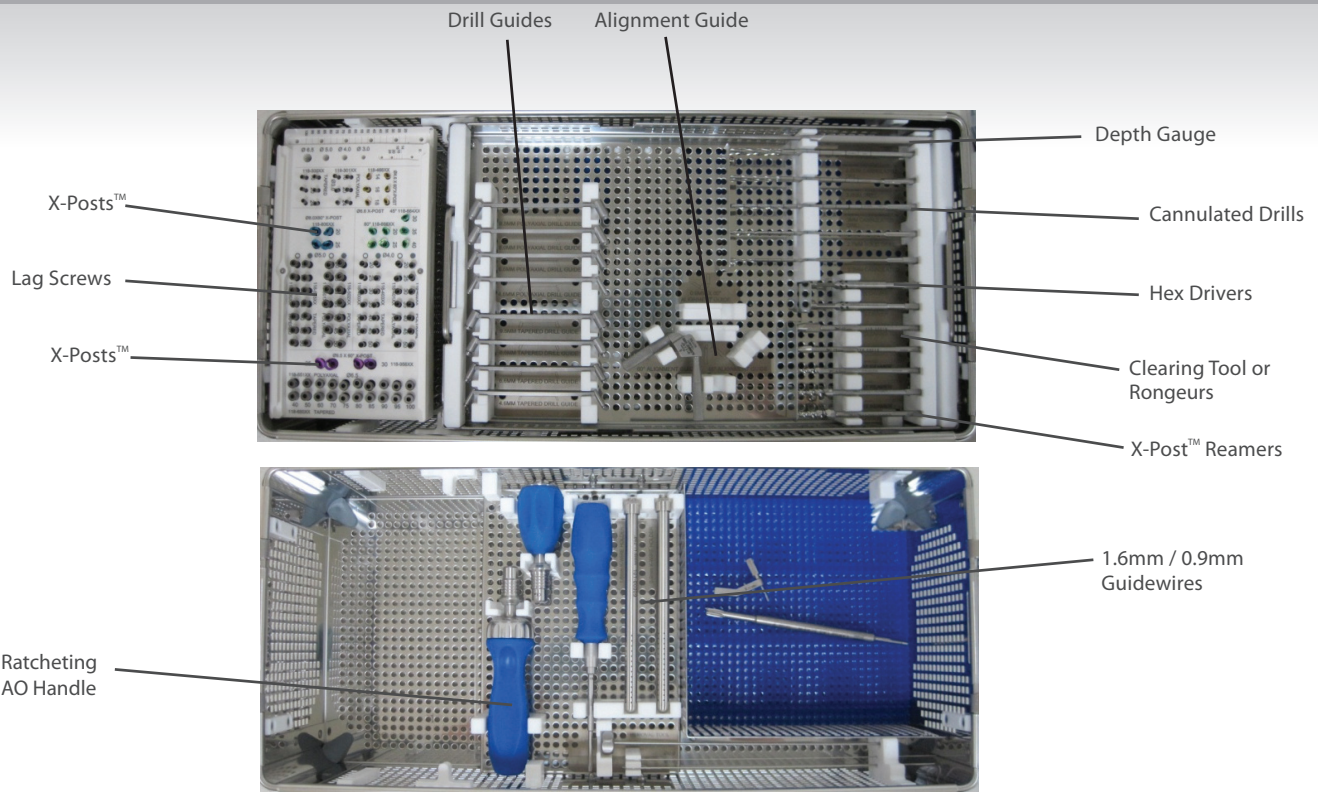


LAG SCREWS (Tapered & Polyaxial)



X-Post™ Specifications				
X-Post™	Angle	Length	Major Diameter	Minor Diameter
4.6mm (Gold)	60°	14,16, 18mm	4mm	3mm
6.6mm (Green)	60°	20,25mm	5mm	3.4mm
6.6mm (Lt. Green)	45°	30,35,40mm	5mm	3.4mm
8.0mm (Blue)	60°	20,25mm	6.5mm	4.5mm
9.5mm (Magenta)	60°	25,30mm	6.5mm	4.5mm

Lag Screw Specifications				
Lag Screws	3.0mm	4.0mm	5.0mm	6.5mm
Lengths	16, 20, 24mm	20-50mm By 5mm increments	20-50mm By 5mm increments	40, 50, 60mm 70-100mm by 5mm increments
Thread Length	L - 12mm	L - 15mm	L - 15 mm	16mm
Major Diameter	3.0mm	4.0mm	5.0mm	6.5mm
Minor Diameter (Cannulated)	-	3.0mm	3.4mm	4.5mm
Minor Diameter (Solid)	2.0mm	2.7mm	3.0mm	-



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
4.6 (GOLD)	3.0	0.9	2.0	4.6	2.0	4.6	2.0
6.6 (GREEN/LT GREEN)	4.0	1.6	3.4	6.6	3.0	6.6	3.0
8.0 (BLUE)	5.0	1.6	4.5	8.0/ 9.5 (1st Line)	3.0	8.0	3.4
9.5 (MAGENTA)	6.5	1.6	4.5	8.0/ 9.5 (2nd Line)	3.0	9.5	4.5