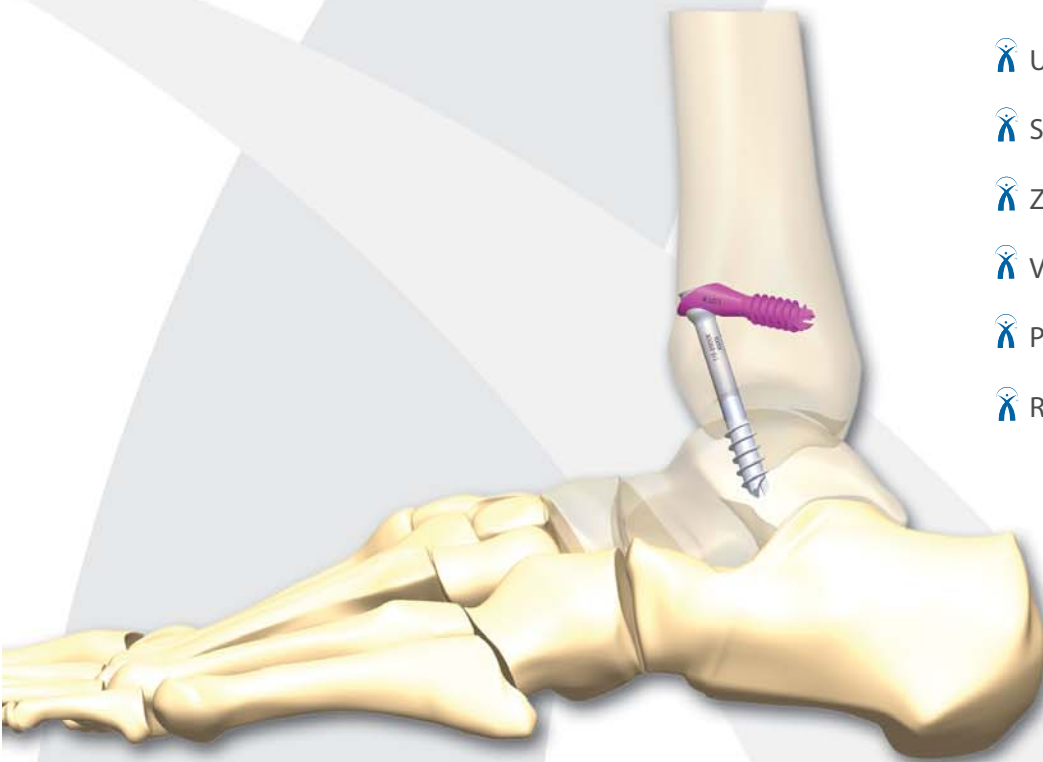


# IO Fix

IntraOsseous Fixation

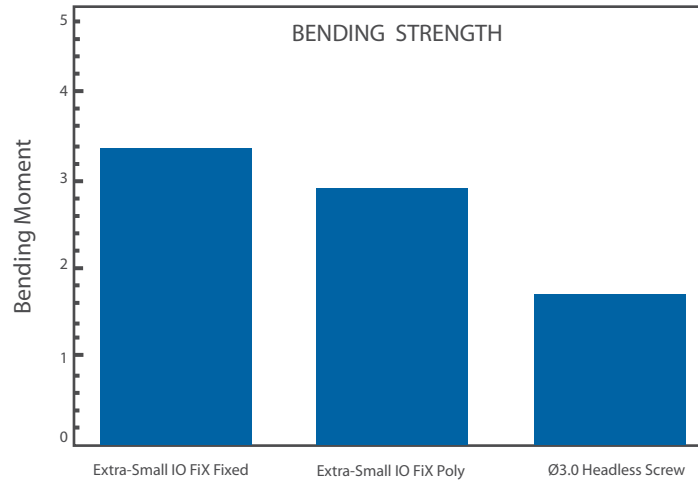
## Surgical Technique Ankle Fusion



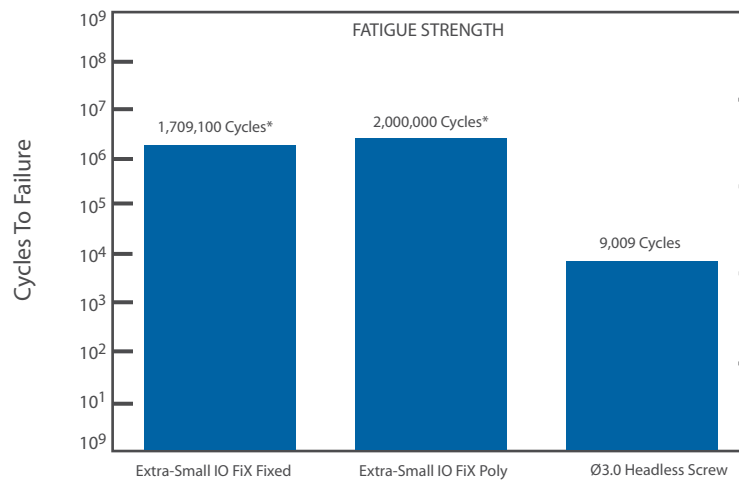
- Uniform Compression
- Stable Fixation
- Zero Profile
- Versatile Applications
- Precise Instrumentation
- Reinforced Bone Bridge

Patent Pending

## Reliable Strength and Holding Power



2x the strength of a 3.0mm headless screw



220x the fatigue strength of a 3.0mm headless screw

**Superior strength and fatigue resistance decrease the likelihood of a construct failure**

\* Test Stopped

As described by Chris DiGiovanni, MD; Brian Donley, MD; and Selene Parekh, MD

### 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, Tarsometatarsal, and Tibiotalar joints, as well as for Metatarsal Osteotomies.

*NOTE: This technique guide describes the steps for the hardware implantation as used in an Ankle Fusion with an anterior approach. Supplemental information is provided at the end of this guide regarding alternative approach options.*

### 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 tibiotalar joint. The length is determined by exposure requirements. Once the appropriate dissection to the sub-periosteal level has been performed, manual joint exposure of the tibiotalar joint and exposure to the articulating cartilage can be achieved. Standard denuding techniques should then be performed.

#### STEP 2 - Alignment Guidewire

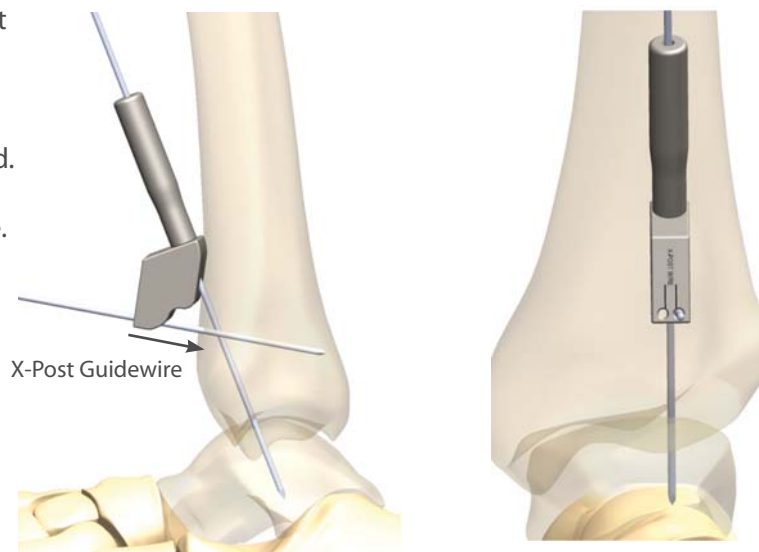
Insert a Ø1.6mm guidewire through the dorsal tibia in the direction of the ideal lag screw trajectory. This temporary guidewire will serve as an alignment guidewire for the X-Post orientation. Verify proper positioning of this guidewire with fluoroscopy.



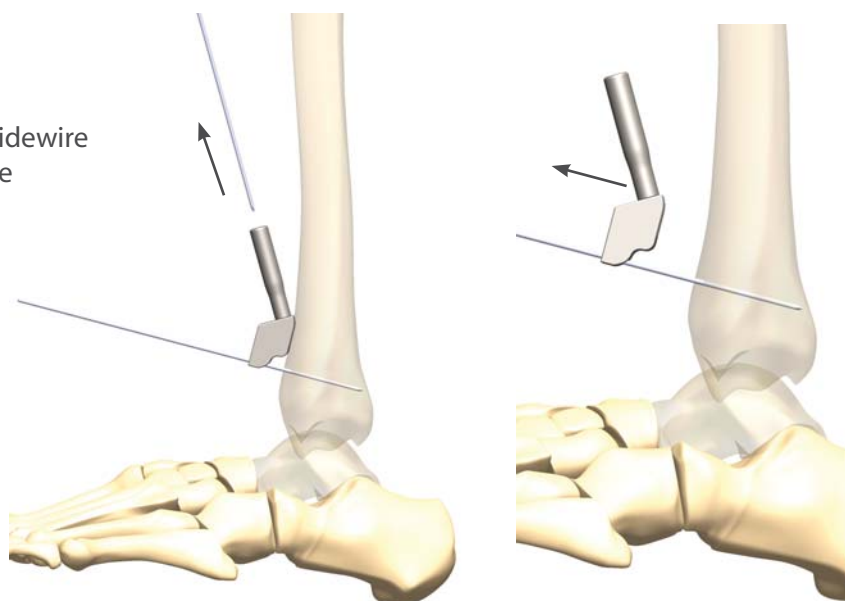
### STEP 3 - Alignment Guide

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 between 20-30mm proximal to the joint line.

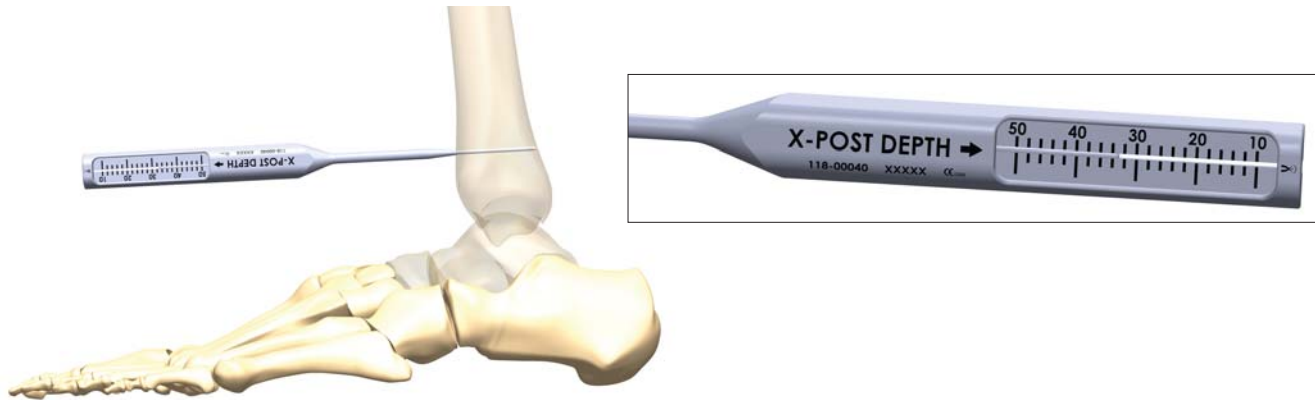


Once the placement of the X-Post guidewire is confirmed with fluoroscopy, remove the initial guidewire and remove the alignment guide.



#### STEP 4 - X-Post Depth Measurement

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

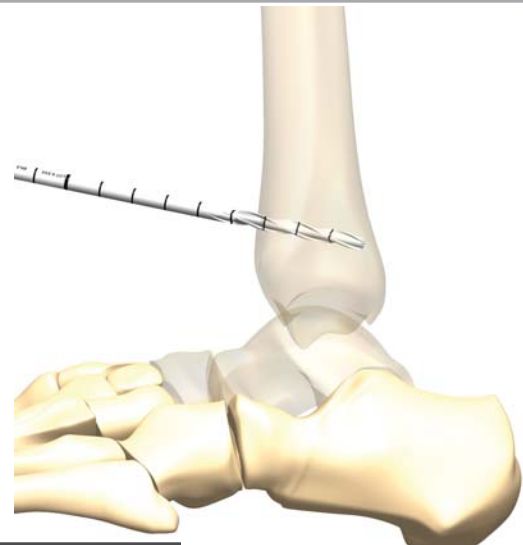


#### STEP 5 – Preparation for X-Post: Drilling

##### DRILL 1ST

Select the cannulated drill based on the desired X-Post 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-Post.*



**Table 1: Sizes: X-Post / Screws/ Drills / Reamers**

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

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

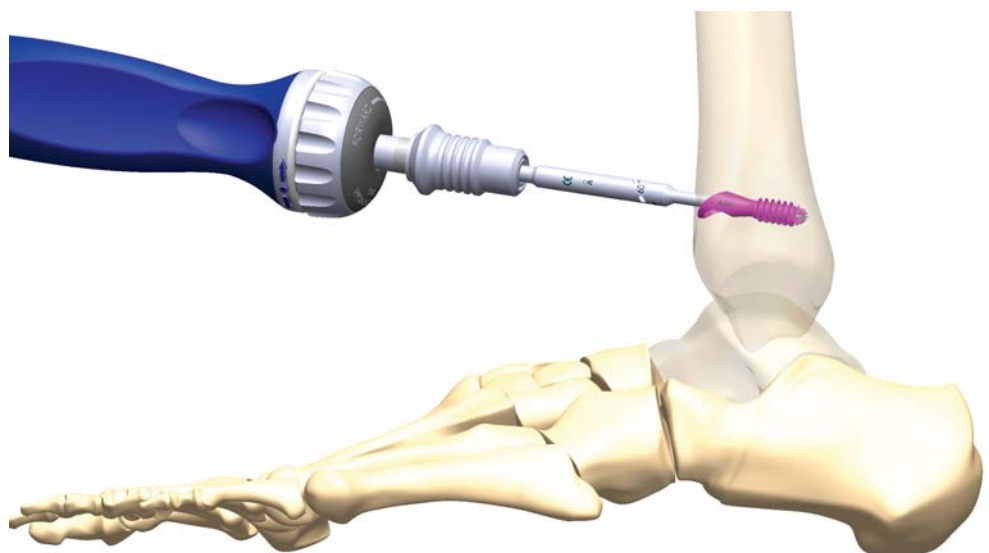
If the surgeon feels reaming is required, select the X-Post Reamer based on the desired X-Post size (Table 1). Place the X-Post Reamer over the guidewire and advance until the laser line is no longer visible. The 8.0 and 9.5mm X-Posts use the same reamer.

*NOTE: Hand reaming is highly recommended as these reamers are very aggressive.*



### STEP 6 - X-Post Placement

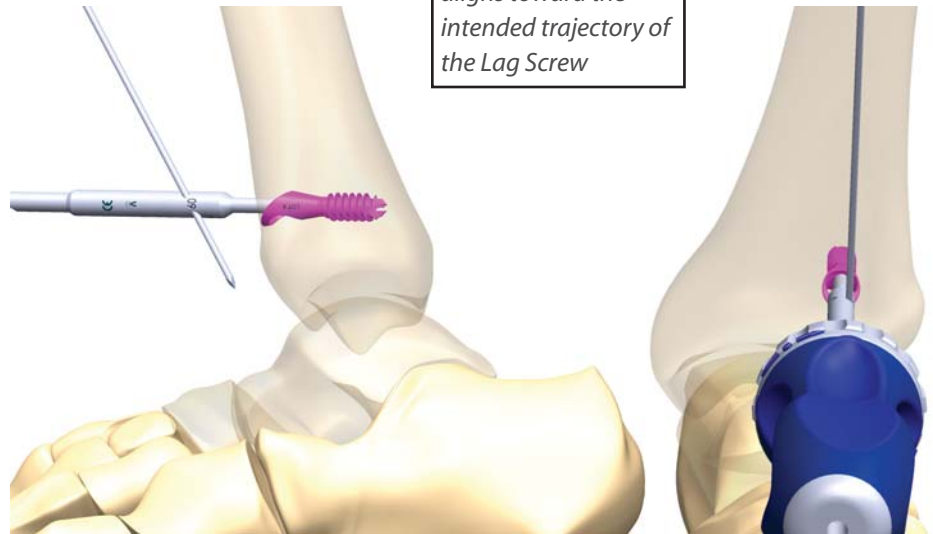
Select the appropriate X-Post and align the implant to the Screwdriver with the laser marked arrow aligned on both driver and implant.



#### STEP 6 - X-Post Placement (continued)

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.

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



**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

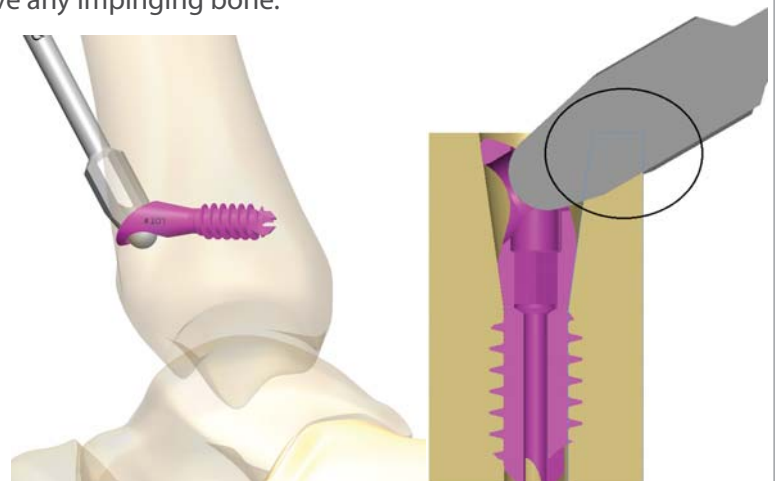
#### STEP 7 – Clear Additional Bone

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 the 12 o'clock position. Drop the handle toward 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	Clearing Tool
4.6 (Gold)	4.6 Clearing Tool
6.6 x 60° (Green)	6.6 Clearing Tool
6.6 x 45° (Light Green)	6.6 Clearing Tool
8.0 (Blue)	8.0 Clearing Tool
9.5 (Magenta)	9.5 Clearing Tool



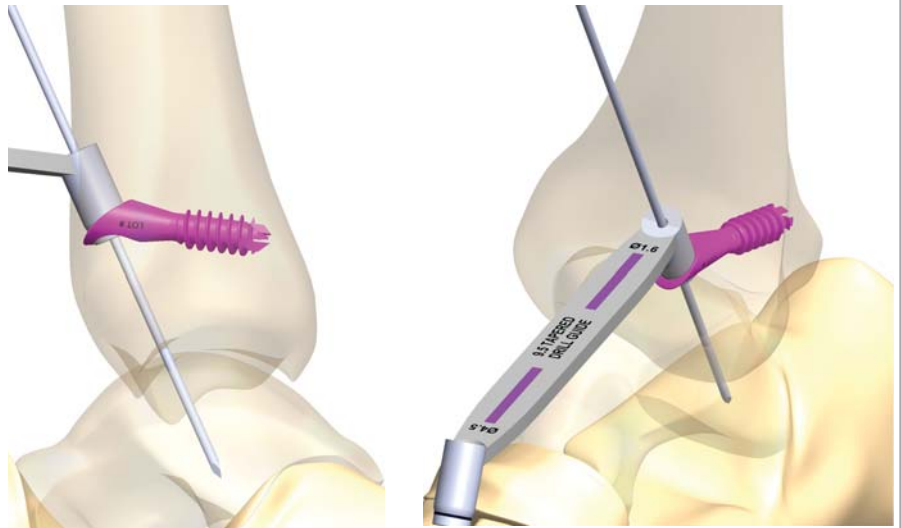


### STEP 8 - Insert Lag Screw Guidewire

Insert the appropriate guidewire guide in the X-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.

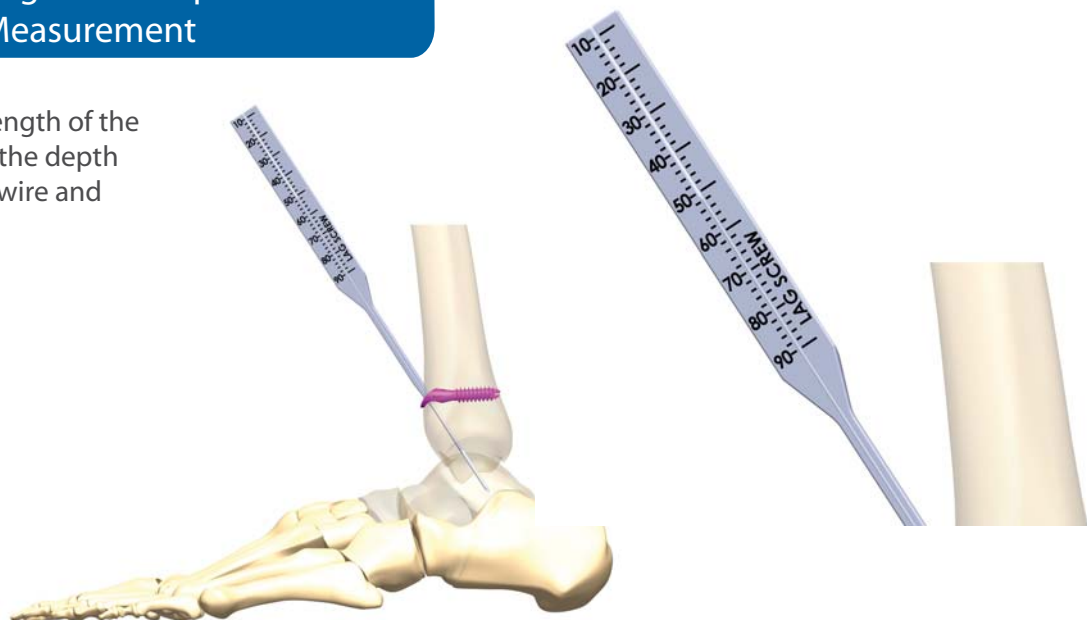
Insert the guidewire for the Lag Screw to the appropriate depth and verify position via fluoroscopy.

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



### STEP 9 - 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.



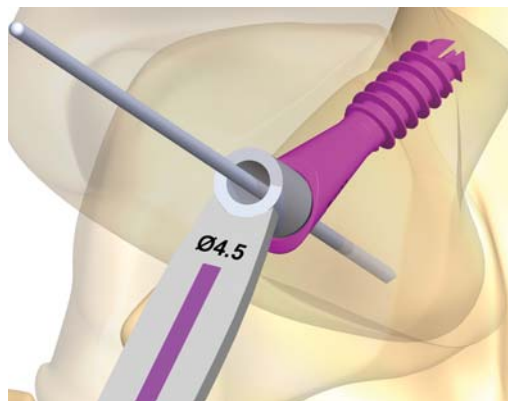


## STEP 10 – Pilot Drill for Lag Screw

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. Confirm drill depth via flouroscopy.

**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



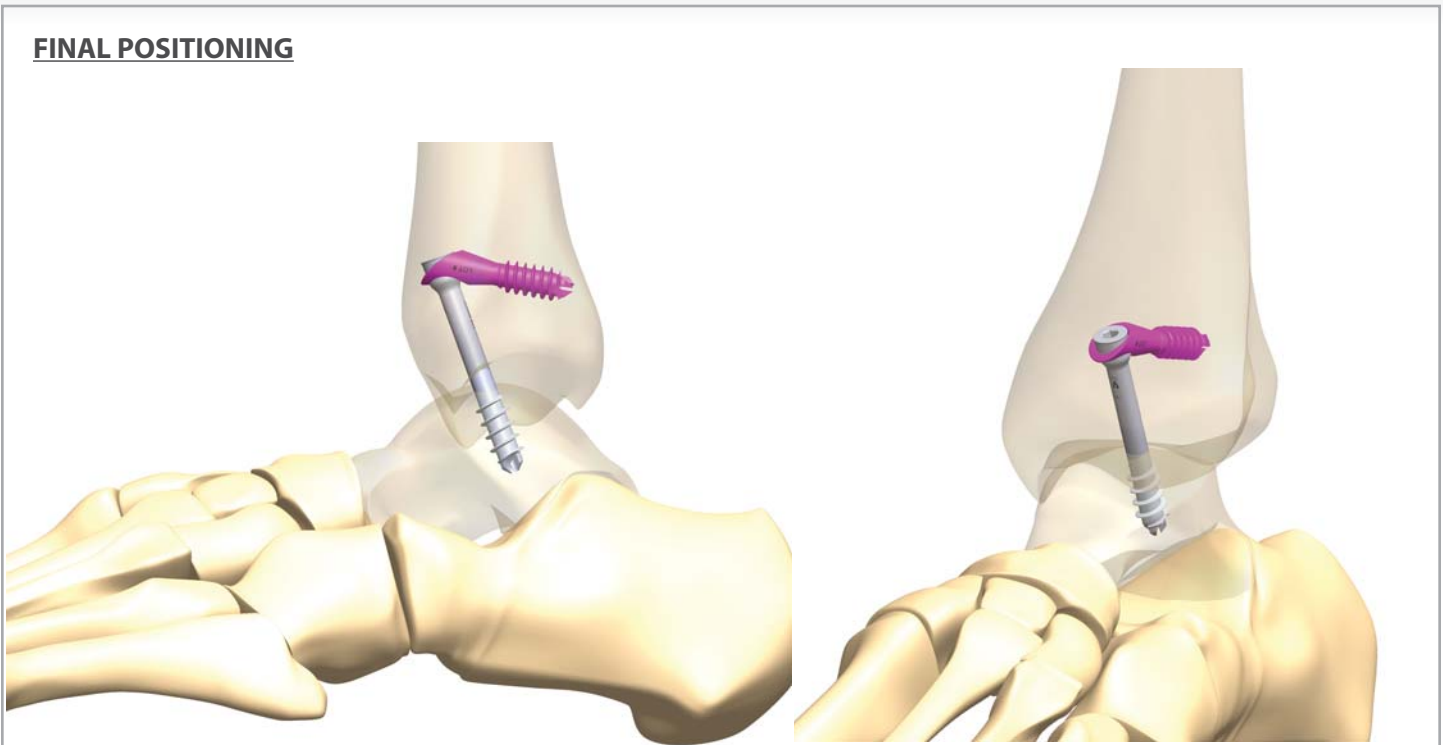
## STEP 11 – Lag Screw

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 appropriate compression is generated.

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



### FINAL POSITIONING



### POSTOPERATIVE TREATMENT

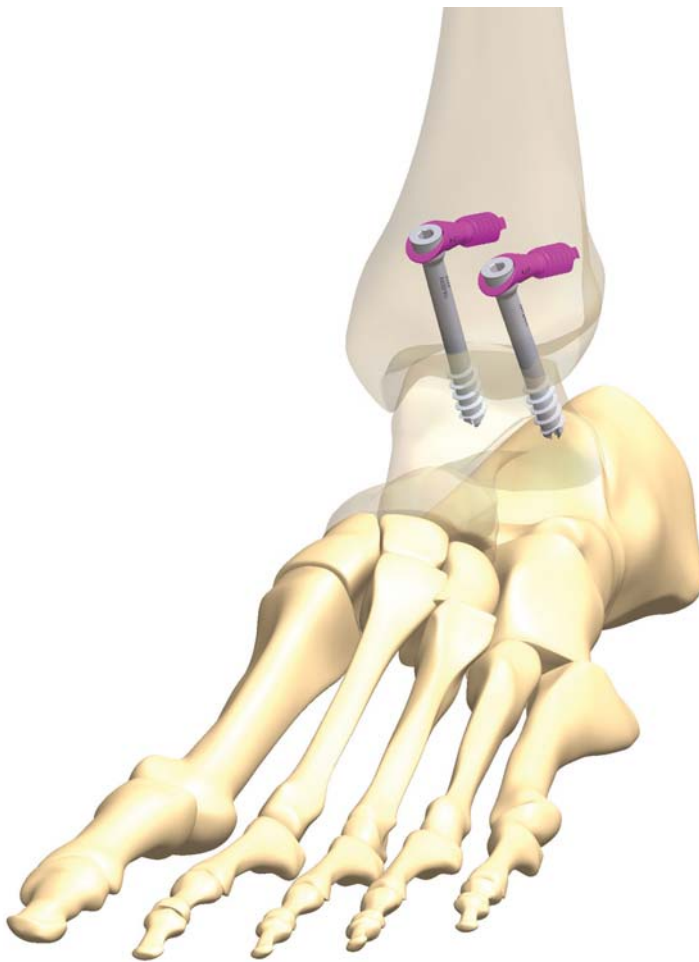
Subsequent to incision closure, patients should initially be immobilized non-weight bearing in a well padded splint for the first two weeks postoperatively. Following repeat incision assessment and suture removal, standard post-operative protocols for arthrodesis, as determined by the surgeon, should be followed. Progression to full weight-bearing and transition out of cast immobilization should be based on bone quality and healing rates, and would likely be individualized on a case by case basis.

### IMPLANT REMOVAL

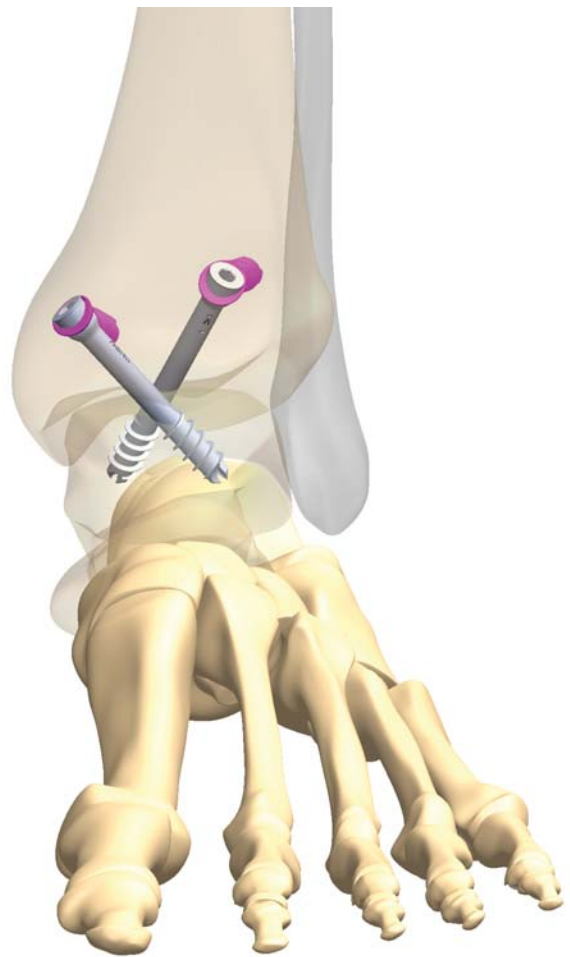
Clear any tissue in growth from the Lag Screw and insert the removal driver into Lag Screw. Insert the removal tool through removal driver, and thread into Lag Screw to allow for rigid attachment. Completely remove the Lag Screw. Insert removal driver into the X-Post and remove by turning counterclockwise.

**OPTIONAL 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**



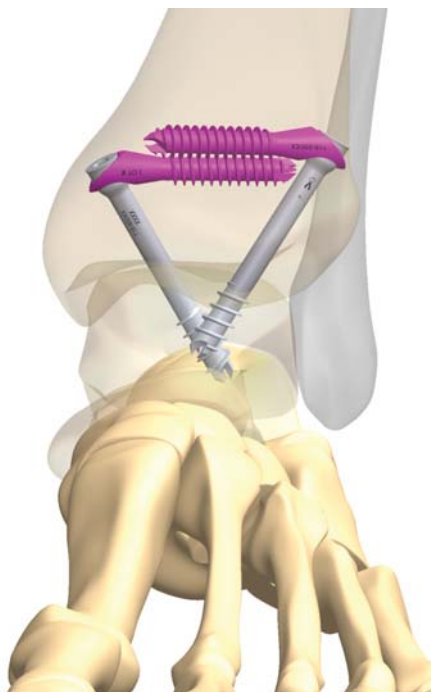
**CROSSING IO FIX CONSTRUCT**

**SUPPLEMENTAL INFORMATION**

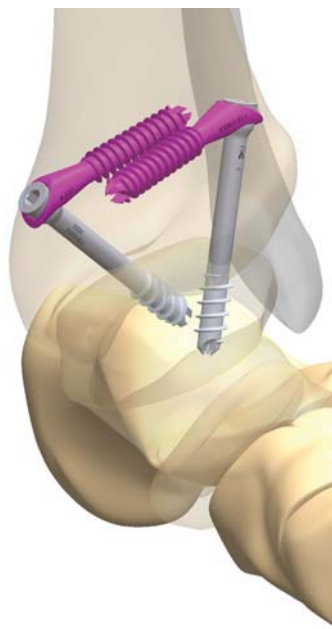
Placement of the IO FiX construct is based on surgeon preference and access.

**1. Ankle Fusion: Lateral Approach**

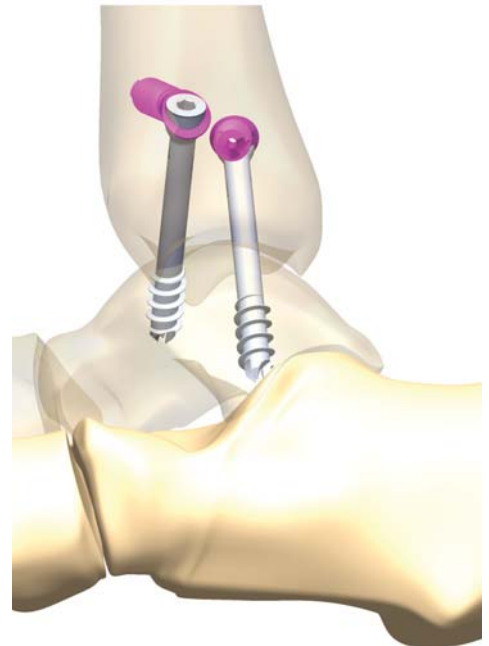
A lateral approach may be used to provide additional access to the joint depending on the surgical preference. Use standard techniques for fibula preparation and joint preparation. Once the joint is adequately prepared, follow steps 1-11 as detailed in technique. A separate construct may also be implanted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



**AP VIEW**



**ISO VIEW**



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

**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

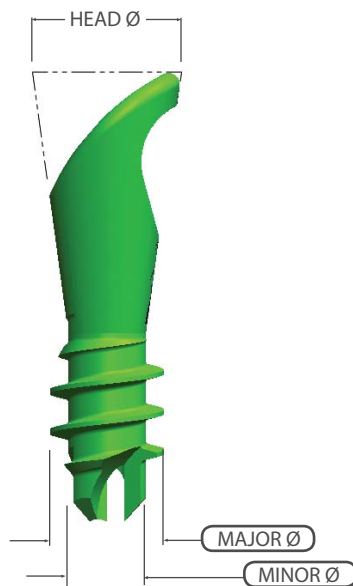
### IMPLANT LIST, CONTINUED

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



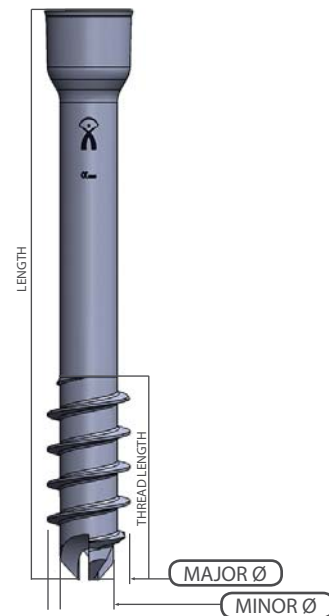
## IMPLANT SPECIFICATIONS

### X-POST



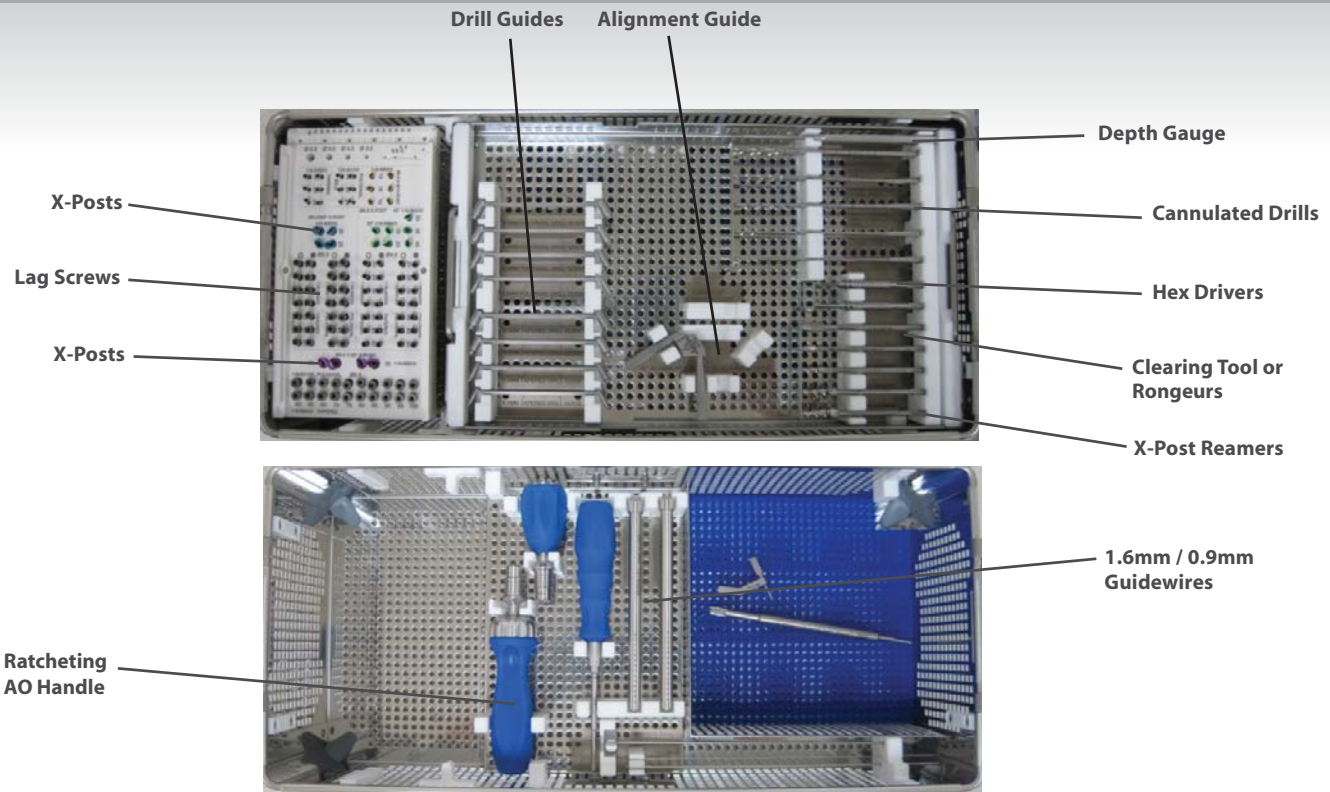
X-Post Specifications				
X-Post	Angle	Length	Major Diameter	Minor Diameter
4.6mm (Gold)	60°	14,16, 18mm	4mm	3mm
6.6mm (Green)	60°	20,25mm	5mm	3.4mm
6.6mm (Lt. Green)	45°	30,35,40mm	5mm	3.4mm
8.0mm (Blue)	60°	20,25mm	6.5mm	4.5mm
9.5mm (Magenta)	60°	25,30mm	6.5mm	4.5mm

### LAG SCREWS (Tapered & Polyaxial)



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