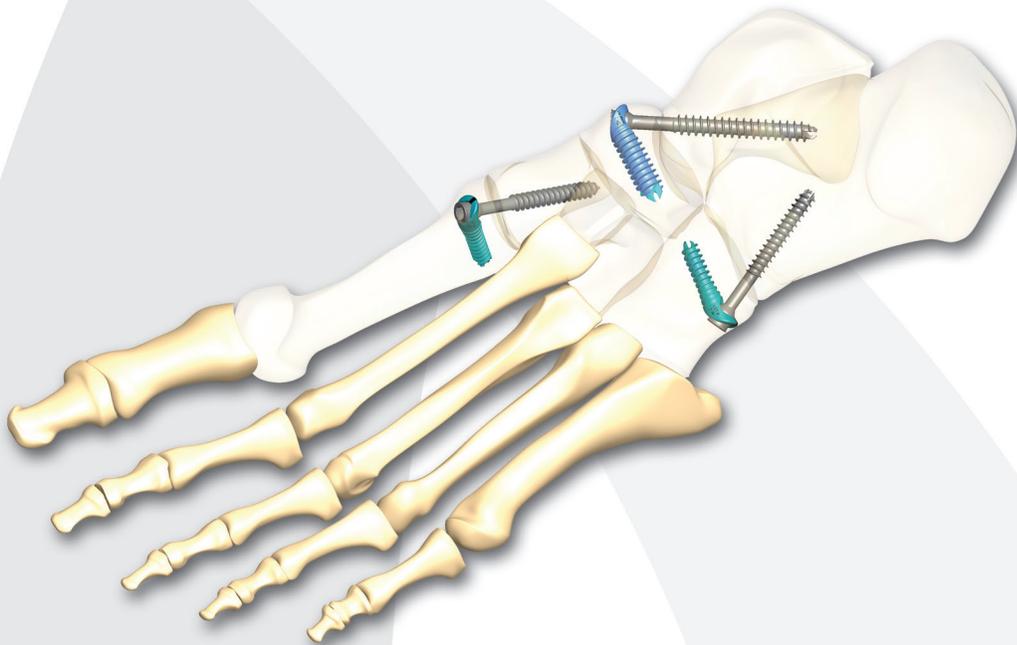


IO FiX 2.0

FUSION FIXATION

Surgical Technique

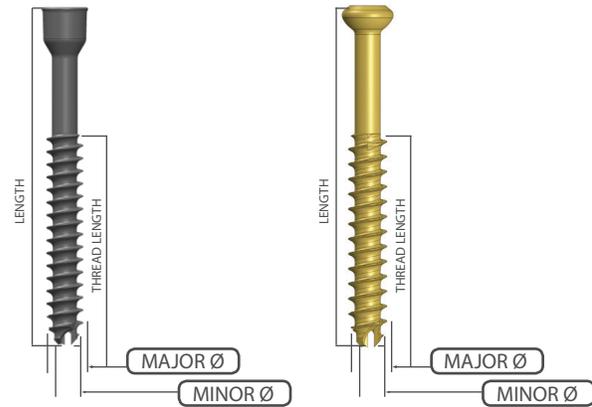
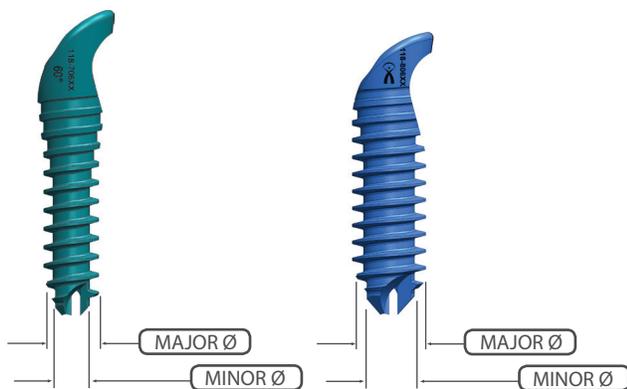


INDICATIONS FOR USE

The IO FiX Intraosseous Fixation 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 use in Talonavicular, Calcaneocuboid, Metatarsocuneiform, and ankle arthrodesis, as well as Metatarsal Osteotomies.

NOTE: This technique guide illustrates the placement of an IO FiX 2.0 construct for a Talonavicular Fusion.

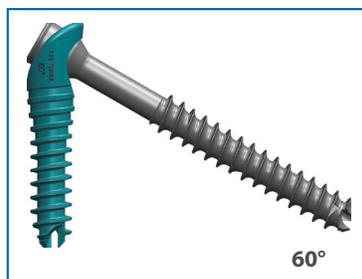
Implant Specifications



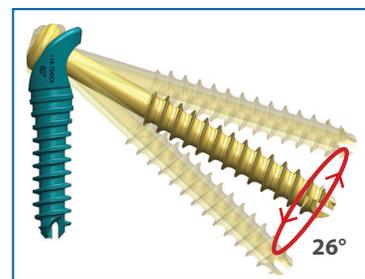
IO FiX 2.0 X-Posts	Angle	X-Post Lengths	Major Diameter	Minor Diameter
Small X-Post (Aqua)	60°	15, 20, 25, 30mm	4.5mm	3.0mm
Medium X-Post (Blue)	60°	20, 25, 30mm	6.5mm	4.5mm

Screw	Screw Lengths	Major Diameter	Minor Diameter	Thread Length
4.3mm Tapered Locking	26-40 (2 mm increments) 45, 50	4.3mm	2.8mm	Length-15mm
5.0mm Tapered Locking	26-40 (2 mm increments) 45, 50	5.0mm	3.4mm	Length-15mm
4.5mm Headed (Non-Locking)	26-40 (2 mm increments) 45, 50	4.5mm	3.0mm	Length-15mm

Locking Construct



Non-Locking Construct



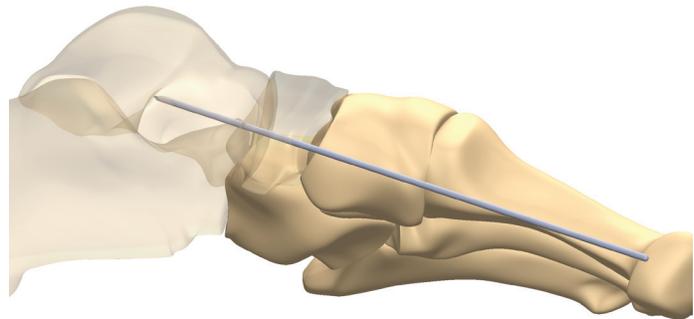
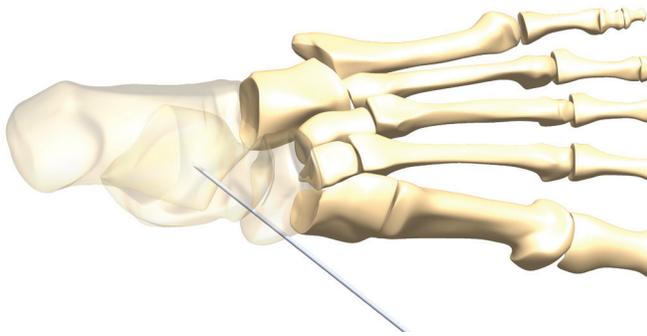
Exposure and Joint Preparation

The standard incision, dissection, joint exposure and denuding techniques for arthrodesis should be performed as per the surgeon's preference.

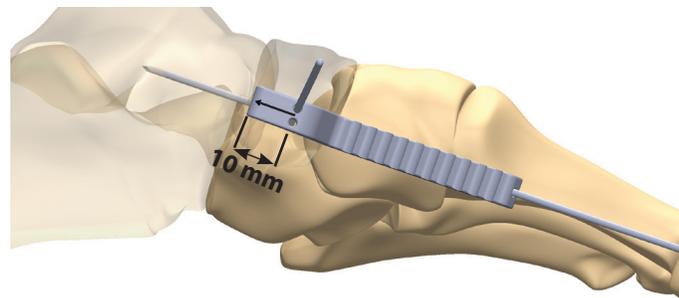
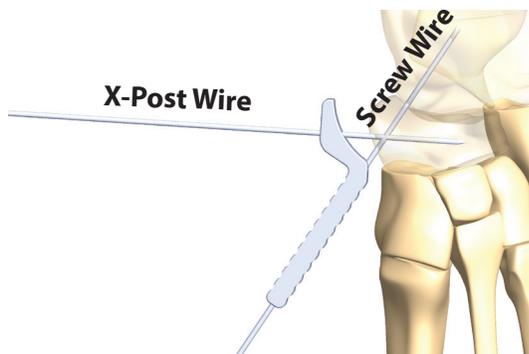
STEP 1: X-Post Wire Placement

The placement of the X-Post dictates the Tapered Locking Screw trajectory as they interlock at a 60° angle. Utilize the Alignment Guide to assist with X-Post placement:

- Place a 1.6mm Guidewire through the joint in the ideal screw trajectory
- Confirm the placement of this wire with fluoroscopy (AP and Lateral) as it represents screw placement



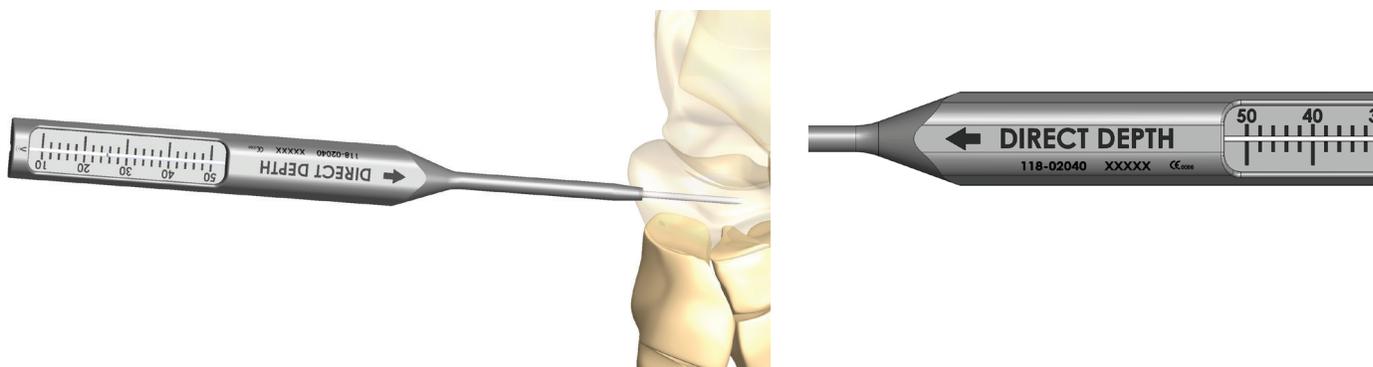
- Place the Alignment Guide over the Guidewire and slide it towards the joint
- Place the X-Post Guidewire through the Alignment Guide 10mm from the joint line (this ensures clearance of the screw threads past the joint line)
- If the X-Post is placed greater than 10mm from joint, over drill the near cortex with a 4.5mm drill
- Confirm X-Post Guidewire placement with fluoroscopy (AP and Lateral) and then remove the initial screw trajectory Guidewire



X-Post Guidewire holes are located 10mm back from the edge of the Alignment Guide

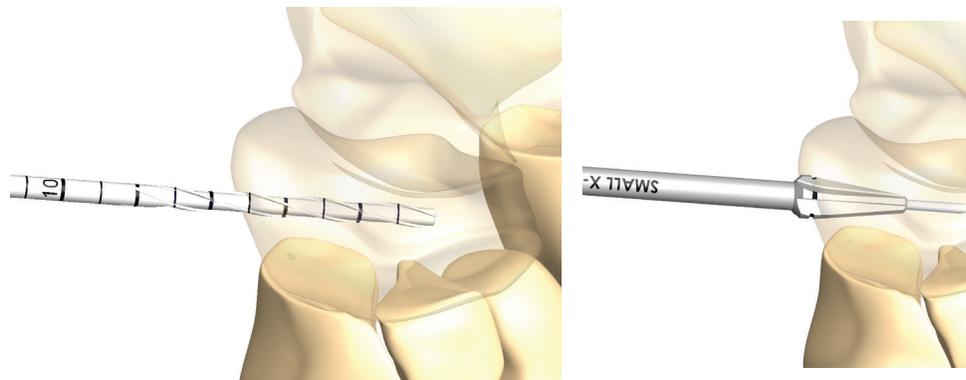
STEP 2: Determine X-Post Length

- Place the Depth Gauge (Direct Depth) over the Guidewire and down to bone to determine the length of the X-Post



STEP 3: Bone Preparation for the X-Post Drill & Countersink

- Select the appropriate Cannulated Drill and Countersink based on the desired X-Post
- Place the Cannulated Drill over the Guidewire and advance to the pre-determined X-Post length
- Advance the appropriate sized Countersink until the laser mark comes in contact with the cortical bone

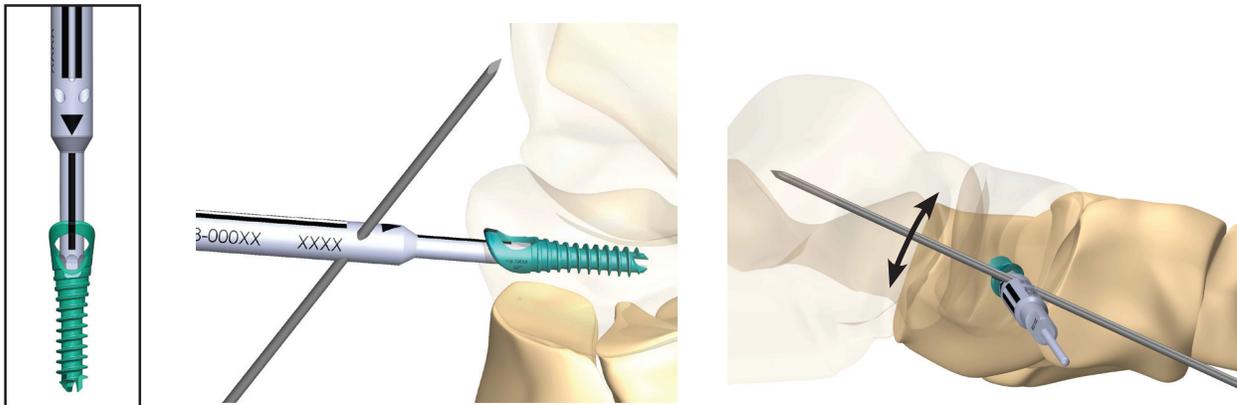


X-Post	X-Post Drill	Countersink
Small (Aqua)	3.0mm	Small
Medium (Blue)	3.4mm	Medium

STEP 4: X-Post Placement

- Align the X-Post and 3.0 Hex Driver with the laser marked arrow and black line as depicted below
- Using two hands, pass the X-Post over the Guidewire and rotate until flush with the cortex. The laser marking on the driver/implant should orient towards the intended fusion area

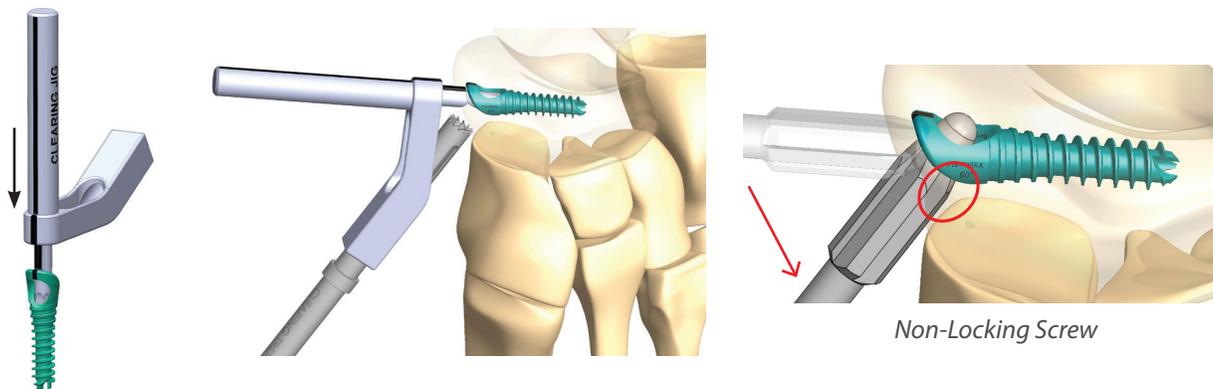
TIP: Place a wire through the hole on the driver, as shown, to confirm and fine tune screw trajectory.



STEP 5: Clearing Step

It is critical to create an accurate path to allow for the proper orientation of the Drill Guide and subsequent Screw.

- Remove the 3.0 Hex Driver and Guidewire
- Fully seat the Clearing Jig into the X-Post (align laser marking on jig with the implant)
- Advance the Clearing Trepine (power) through the jig and down to bone
- The trephine has a positive stop and will clear the exact amount of bone at the ideal 60° orientation

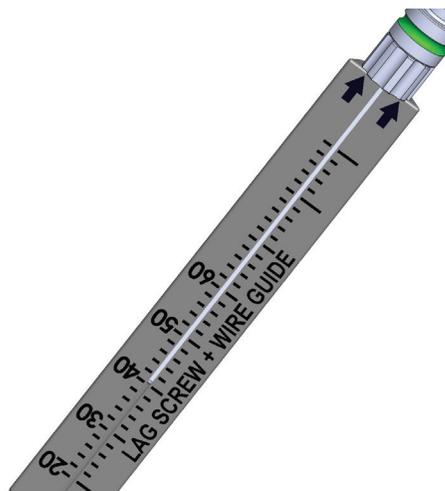
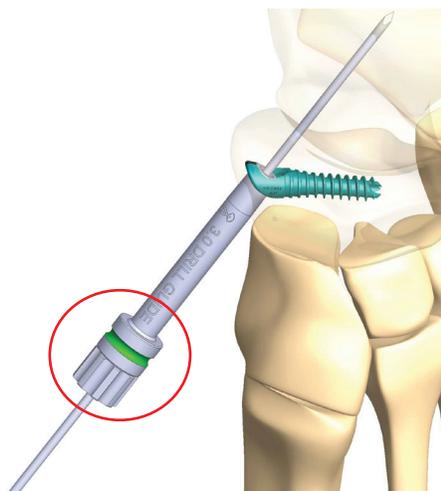


NOTE: For Headed (Non-Locking) Screws, additional clearing with the Clearing Tool or rongeurs may be required to allow for proper screw trajectory.

STEP 6: Guidewire Placement (Locking Screws)

Tapered Locking Screw Placement

- Assemble the "TOP HAT" Guidewire and Drill Guide:
 - Thread the 1.6 Guidewire Guide into the appropriate Drill Guide
- Insert the Drill Guide assembly into the eyelid of the X-Post
- Advance a 1.6mm Guidewire through the Drill Guide
- Verify Guidewire position and depth with fluoroscopy
- Determine the length of the Screw by measuring the Guidewire with the "Lag Screw + Wire Guide" side of the Depth Gauge over the Guidewire and down to the top of the Drill Guide Assembly.

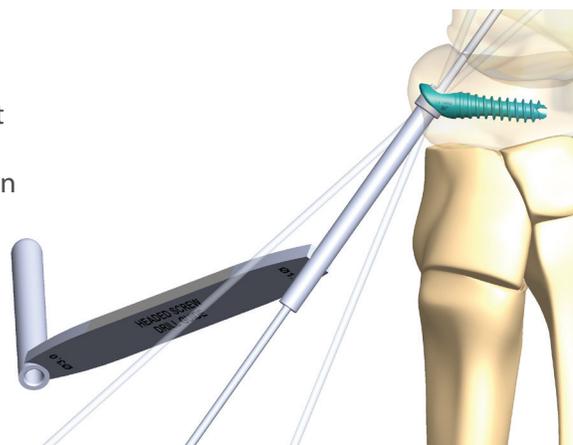


Screw	Drill Guide
4.3 mm	3.0 (Green)
5.0 mm	3.4 (Blue)

STEP 6a: Guidewire Placement (Non-Locking Screw)

The Headed (Non-Locking) Screws can be used with the X-Post and allows for variability of placement.

- Utilize the Headed Screw Drill Guide taking care to stay within the allowable 26° cone of angulation when advancing the Guidewire through the guide
- Determine the length of the screw with "Lag Screw + Wire Guide" side of the Depth Gauge over the wire and down to the top of the Drill Guide

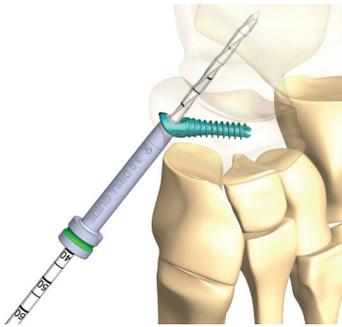


STEP 7: Screw Pilot Hole

All screws are self drilling and self tapping. Pre-drilling with a cannulated drill is left up to the surgeon's discretion.

Pre-drilling for the Tapered Locking Screws:

- Unthread and remove the Wire Guide from the Top Hat Assembly
- Select the appropriate Cannulated Drill based on the desired Screw
- Advance the Cannulated Drill over the Guidewire and down to the desired depth

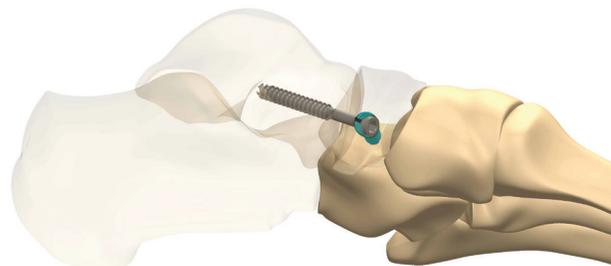


Screw Type and Size	Pilot Drill
4.3mm Tapered Locking	3.0mm
5.0mm Tapered Locking	3.4mm
4.5mm Headed (Non-Locking)	3.0mm

NOTE: Utilize the Headed Screw Drill Guide for the Low Profile Headed Screw (Non-Locking)

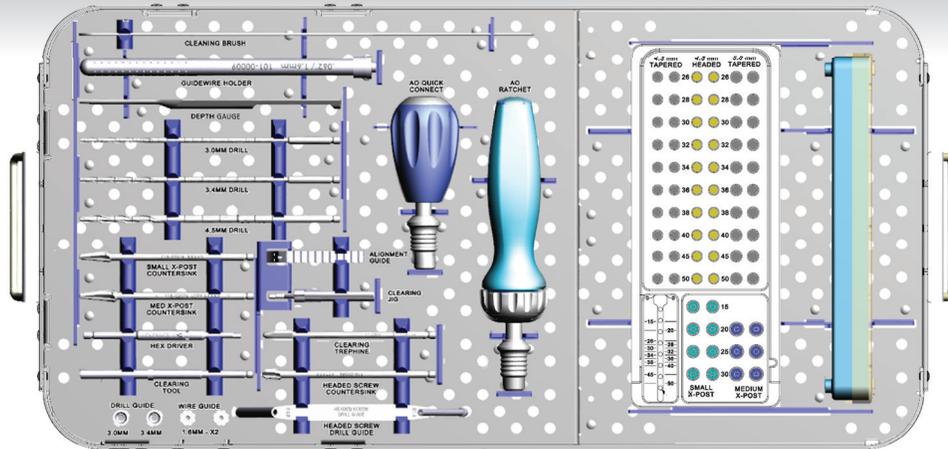
STEP 8: Screw Insertion

- Prior to inserting the screw, ensure the joint is manually compressed
- Insert the screw over the Guidewire with the 3.0mm Hex Driver
- Final tightening of the Tapered Locking Screw should be applied with two finger pressure and care should be taken not to over tighten the construct



IMPLANT REMOVAL

- Clear any tissue ingrowth from the Screw
- Insert the 3.0mm Hex Driver into the Screw and back out the Screw by turning counterclockwise
- Insert the 3.0mm Hex Driver into the X-Post and back out the Screw by turning counterclockwise



X-Posts

Part Number	Description
SMALL X-POST (AQUA)	
118-70615	SMALL X-POST - 15mm
118-70620	SMALL X-POST - 20mm
118-70625	SMALL X-POST - 25mm
118-70630	SMALL X-POST - 30mm
MEDIUM X-POST (BLUE)	
118-80620	MEDIUM X-POST - 20mm
118-80625	MEDIUM X-POST - 25mm
118-80630	MEDIUM X-POST - 30mm

Screws

Part Number	Description
Ø4.3 Tapered Locking Screws	
118-43026	Ø4.3 Tapered Locking Screw x 26mm
118-43028	Ø4.3 Tapered Locking Screw x 28mm
118-43030	Ø4.3 Tapered Locking Screw x 30mm
118-43032	Ø4.3 Tapered Locking Screw x 32mm
118-43034	Ø4.3 Tapered Locking Screw x 34mm
118-43036	Ø4.3 Tapered Locking Screw x 36mm
118-43038	Ø4.3 Tapered Locking Screw x 38mm
118-43040	Ø4.3 Tapered Locking Screw x 40mm
118-43045	Ø4.3 Tapered Locking Screw x 45mm
118-43050	Ø4.3 Tapered Locking Screw x 50mm
Ø5.0 Tapered Locking Screws	
118-50026	Ø5.0 Tapered Locking Screw x 26mm
118-50028	Ø5.0 Tapered Locking Screw x 28mm
118-50030	Ø5.0 Tapered Locking Screw x 30mm
118-50032	Ø5.0 Tapered Locking Screw x 32mm
118-50034	Ø5.0 Tapered Locking Screw x 34mm
118-50036	Ø5.0 Tapered Locking Screw x 36mm
118-50038	Ø5.0 Tapered Locking Screw x 38mm
118-50040	Ø5.0 Tapered Locking Screw x 40mm
118-50045	Ø5.0 Tapered Locking Screw x 45mm
118-50050	Ø5.0 Tapered Locking Screw x 50mm
Ø4.5 Headed (Non-Locking) Screws	
118-45126	Ø4.5 Low Profile Headed Screw x 26mm
118-45128	Ø4.5 Low Profile Headed Screw x 28mm
118-45130	Ø4.5 Low Profile Headed Screw x 30mm
118-45132	Ø4.5 Low Profile Headed Screw x 32mm
118-45134	Ø4.5 Low Profile Headed Screw x 34mm
118-45136	Ø4.5 Low Profile Headed Screw x 36mm
118-45138	Ø4.5 Low Profile Headed Screw x 38mm
118-45140	Ø4.5 Low Profile Headed Screw x 40mm
118-45145	Ø4.5 Low Profile Headed Screw x 45mm
118-45150	Ø4.5 Low Profile Headed Screw x 50mm

Instruments

Part Number	Description
Disposable Instruments	
101-00006	Guidewire - 1.6mm
101-00023	Cleaning Brush - 1.6mm
118-02030	Cannulated Drill - 3.0mm
118-02034	Cannulated Drill - 3.4mm
101-00013	Cannulated Drill - 4.5mm
118-02002	IO FIX 2.0 X-Ray Template
118-02076	Small X-Post Countersink
118-02077	Medium X-Post Countersink
118-02045	Headed Screw Countersink
118-02111	Clearing Trephine
Reusable Instruments	
101-00009	Guidewire Holder - 1.6mm
102-00017	AO Quick Connect Handle
118-00030	3.0 Hex Driver
118-02000	Instrument Tray and Screw Caddy
118-02013	Headed Screw Drill Guide
118-02015	Clearing Tool
118-02031	Clearing Jig
118-02032	Alignment Guide
118-02039	Handle (Medium AO Ratchet)
118-02040	Depth Gauge
118-02160	Wire Guide - 1.6mm
118-02300	Drill Guide - 3.0mm
118-02340	Drill Guide - 3.4mm

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