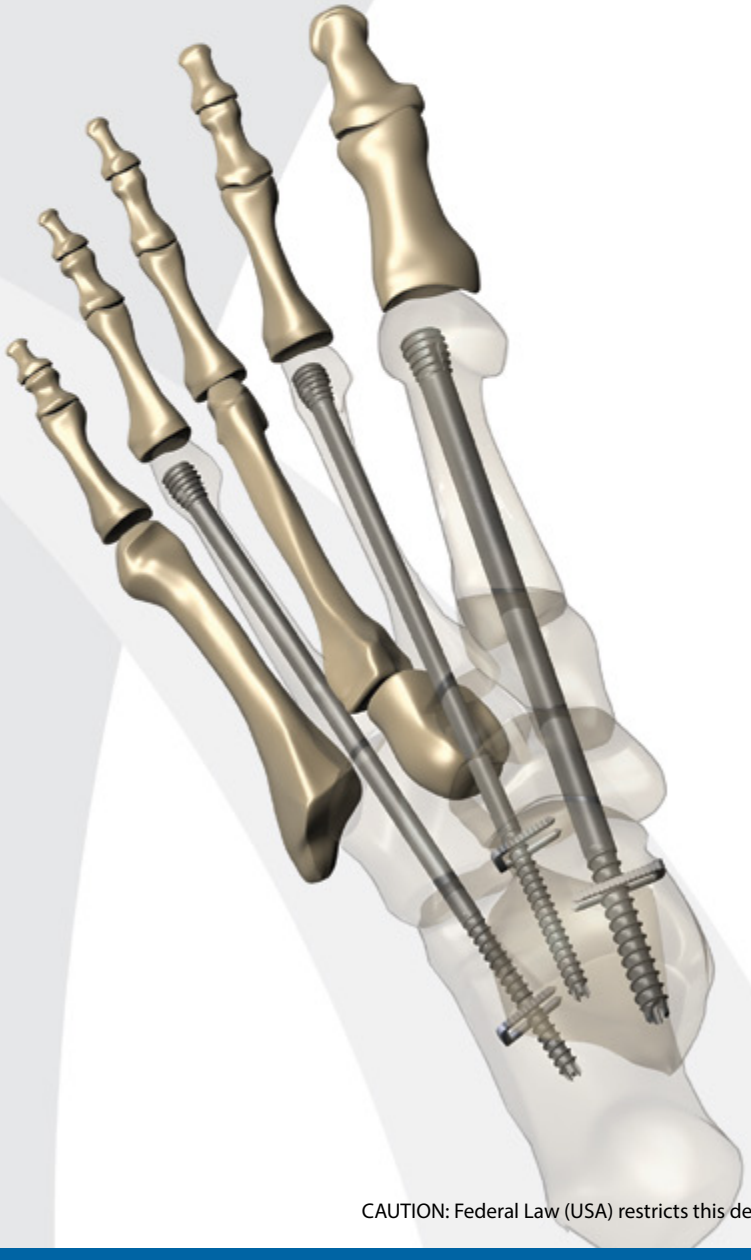
AXIS™

CHARCOT FIXATION SYSTEM

Surgical Technique



Patent and Patent Pending

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

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INDICATIONS FOR USE

The Axis Charcot Fixation System in diameters of 5.5, 6.5 and 7.5mm is indicated for reconstruction procedures, non-unions and fusions of bones in the foot and ankle including the metatarsals, cuneiforms, cuboid, navicular, calcaneus and talus; specific examples include: medial and lateral column fusion resulting from neuropathic osteoarthopathy (Charcot).

This technique guide illustrates axial fixation for a medial column. Each Axis Fusion Beam has a corresponding X-Clip. The X-Clip is designed to provide increased thread purchase, compression, and stability for patients with poor quality bone. The use of an X-Clip with an Axis Fusion Beam is optional and left to the surgeon's discretion.

Surgical Procedure Guidelines

A gastrocnemius recession or percutaneous tendo–Achilles lengthening should be considered in midfoot reconstruction to minimize stress across the midfoot and to correct an equinus contracture if present.

Surgical exposure consists of a medial incision centered at the apex of the deformity and one or two dorsal longitudinal incisions placed centrally and laterally as needed to reduce and prepare the middle and lateral columns. Preparation for the arthrodesis must include obtaining appropriate alignment of the foot. In addition to joint preparation, bone resection and soft tissue contracture release is often necessary to restore a plantigrade position to the foot. Guide wires for the beams can be used as provisional fixation of deformity correction

In many Charcot patients, the soft- tissue envelope is contracted because of chronic dislocation. In these cases, adequate bone resection to achieve realignment without excessive soft-tissue tension is advised. Osteotomy of the bony structures at the apex of deformity is incorporated into arthrodesis preparation. The amount of bone resection is left to the discretion of the surgeon and must be individualized in each case.

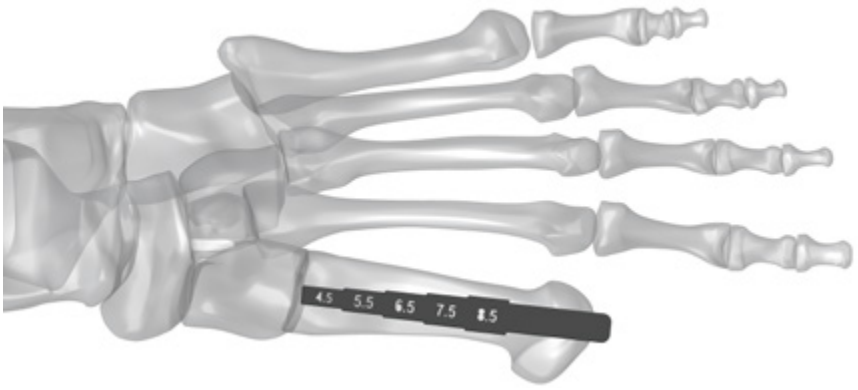
All joints where arthrodesis is intended should be prepared by removal of articular cartilage and subchondral bone, exposing bleeding cancellous bone. For example, in a medial column arthrodesis where arthrodesis of all joints is desired, the talonavicular, naviculocuneiform and first tarsometatarsal joints would be prepared as described.

Guide wires used for reduction and guidance of fixation devices can be applied percutaneously antegrade, from the talus and calcaneus, or retrograde from the metatarsophalangeal joints. When entering the metatarsals from the retrograde approach, the guide wires can be placed into the metatarsophalangeal joints percutaneously through the plantar aspect of the foot, or an open approach can be used utilizing a dorsal incision to expose the metatarsal head. The guide wires should be placed into the medullary canal of the metatarsal without breaching the cortical bone.

6.5 and 7.5 Beams	5.5mm Beams
70-160mm lengths for use in the 1st metatarsal (medial column)	70-150mm lengths for use in the lesser rays (2-5 metatarsals) in conjunction with a medial column beam
Utilize a 3.2mm Guidewire and all instruments labeled Large	Utilize 2.0mm Guidewire and all instruments labeled Small

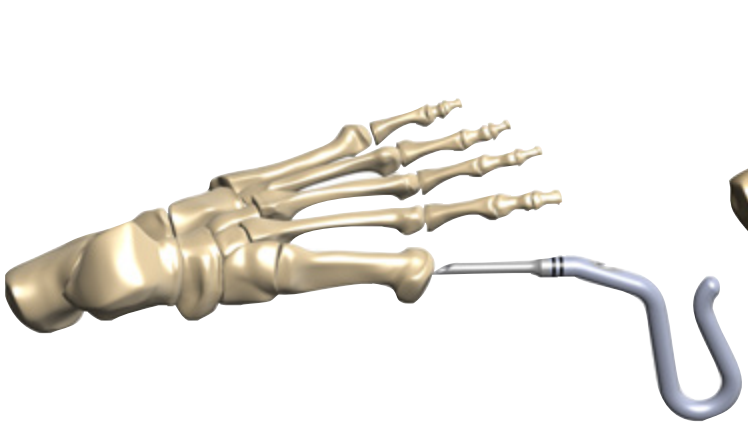
STEP 1 - Determining Diameter of the Axis Beam

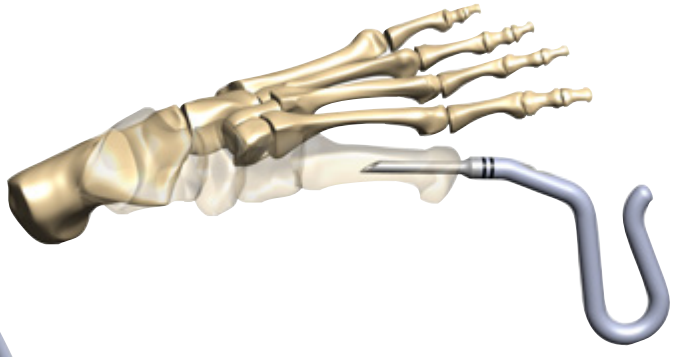
The sizing key may be used as a guide to determine the maximum diameter AXIS Beam that can be used in the metatarsal. Place the Beam Sizing Key onto the top of the 1st metatarsal. Utilizing fluoroscopy, determine the most appropriate size Beam in relation to the patient's anatomy.



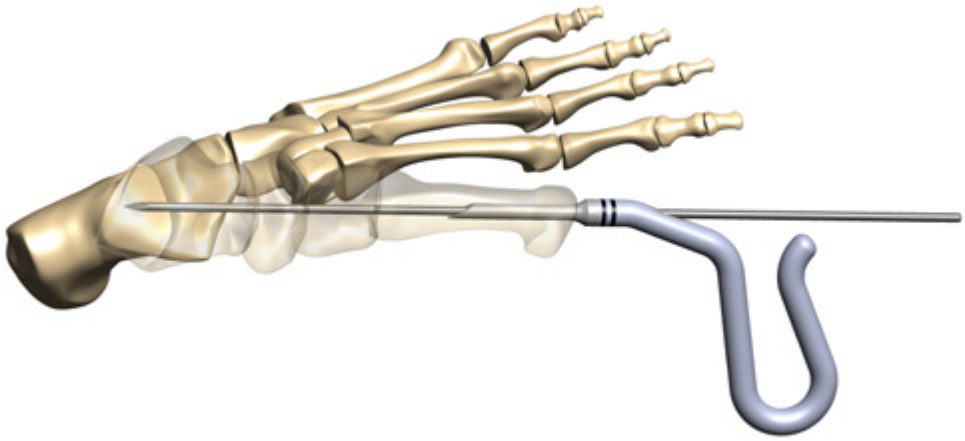
STEP 2 - Entry

The Starter Awl can be used to pierce the skin/cortex, and provide an entry point for the Guidewire.





STEP 3 - Guidewire Placement

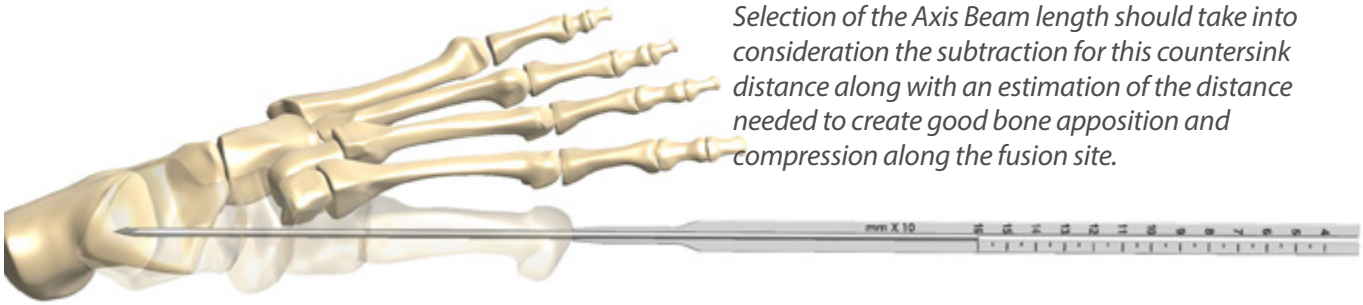


The Starter Awl and Guidewire can be used to "joystick" the bones- assisting with reduction of the deformity and alignment of the fusion. Advance the Guidewire through the Starter Awl aligning the bones as desired. Advance the wire to the desired position/depth with regard to the placement of the Axis Fusion Beam. Verify alignment and Guidewire positioning with fluoroscopy.

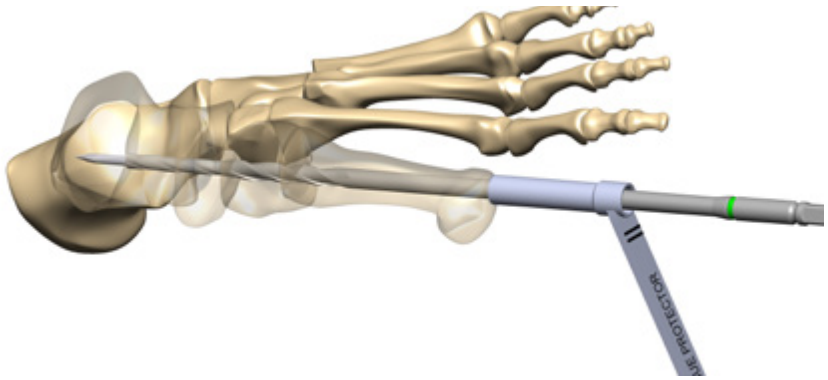
STEP 4 - Determine the Axis Beam Length

Using the appropriate Depth Gauge, measure over the Guidewire to determine the Axis Beam length.

Note: It is recommended to countersink the Beam to the distal metaphyseal/diaphyseal junction. Selection of the Axis Beam length should take into consideration the subtraction for this countersink distance along with an estimation of the distance needed to create good bone apposition and compression along the fusion site.



STEP 5 - Drill



Drill Size	Color
5.5	Green
6.5	Blue
7.5	Magenta

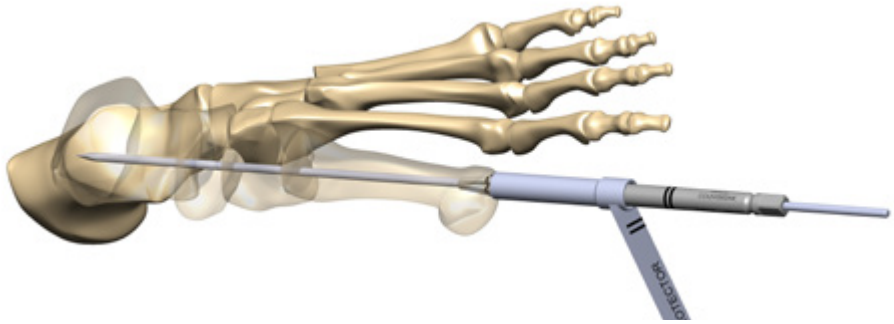
Utilizing the Tissue Protector, place the appropriate sized Drill over the Guidewire, and drill the full length of the Beam as determined in the previous step. The Drills are stepped to maximize purchase, and the reference lines on the drills are calibrated with the Tissue Protector. Each line represents 5mm. The Tissue Protector should be in contact with bone in order to ensure accurate calibration with the Drill. For surgical power connections that do not have a 1/4 Square connection, utilize the 1/4 Square to Jacobs Chuck adapter with a tri-lobe Jacobs Chuck.

Note: If hard bone is encountered, it is recommended to drill in a sequential fashion – for example, for a 7.5mm Beam, start with the 6.5 mm Drill and progress to the 7.5 mm Drill

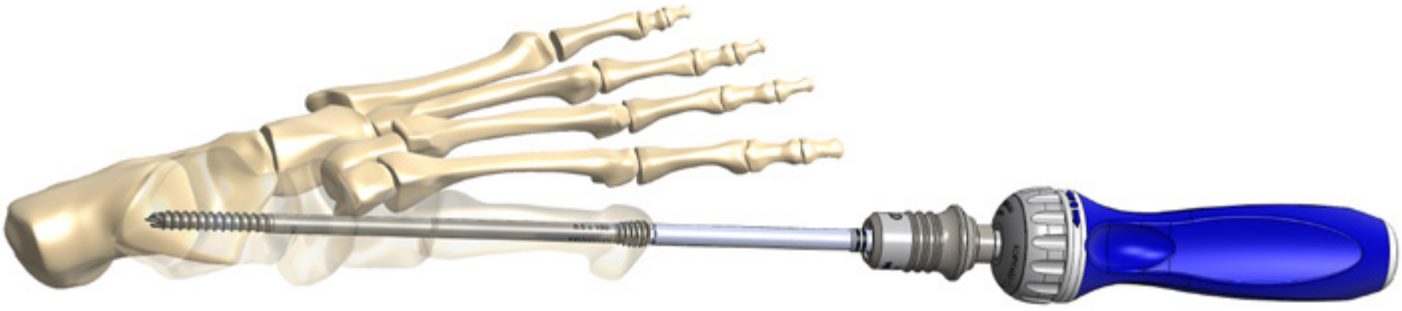
STEP 6 - Countersink

Advance the Countersink over the Guidewire taking care to bury the laser marking. The countersink can be used in conjunction with the appropriate sized drill sleeve.

Use the Small Countersink for 5.5mm Axis Beams. Use the Large Countersink for 6.5mm & 7.5mm Axis Beams.



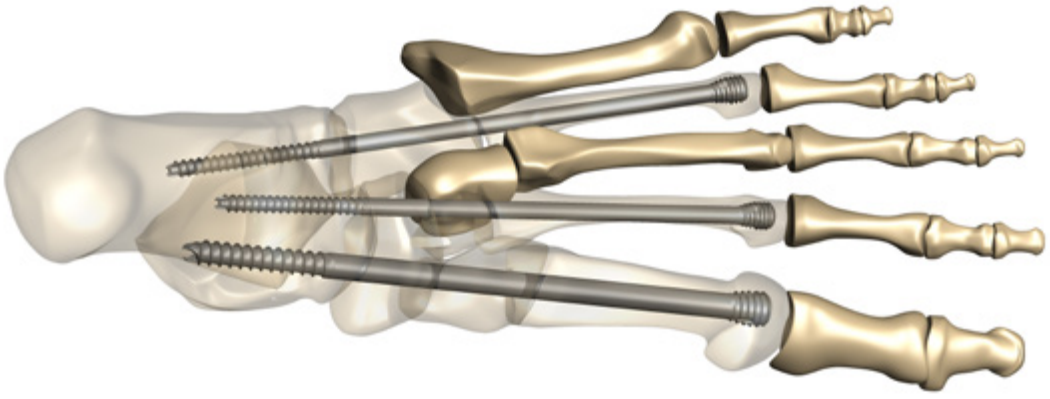
STEP 7 - Insert Axis Fixation Beam



Insert the Beam to the desired depth utilizing the appropriate sized hex driver. Verify final positioning with fluoroscopy.

Note: If the placement of an X-Clip is desired, advance the beam approximately 80% of the desired insertion depth and follow the steps outlined in the next section of this guide.

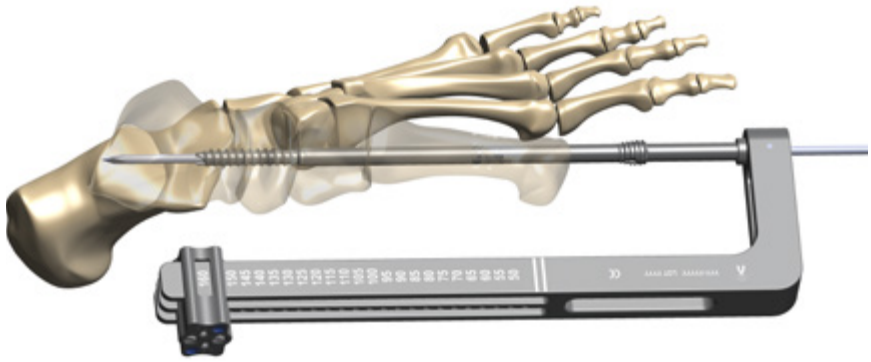
If no placement of an X-Clip is desired advance the Beam to the desired position. Repeat all steps for other columns as desired.



X-Clip Placement (Optional)
Step 1. Attach Targeting Guides

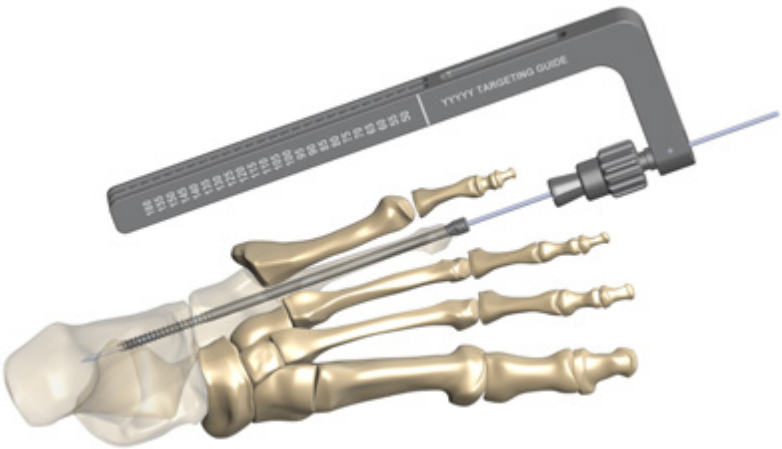
To utilize an X-Clip with an AXIS Beam, advance the Beam approximately 80% of the desired insertion depth. Attach the appropriate sized Targeting Guide over the Guidewire to engage the Beam.

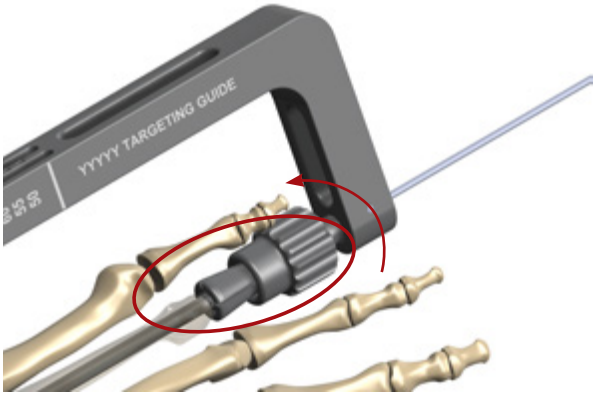
Large Targeting Guide (works with the 6.5 & 7.5 Beams) – slide the Targeting Guide over the 3.2mm Guidewire and fully seat within the internal hex of the Beam.



Drill Guide Size	Color
5.5	Green
6.5	Blue
7.5	Magenta

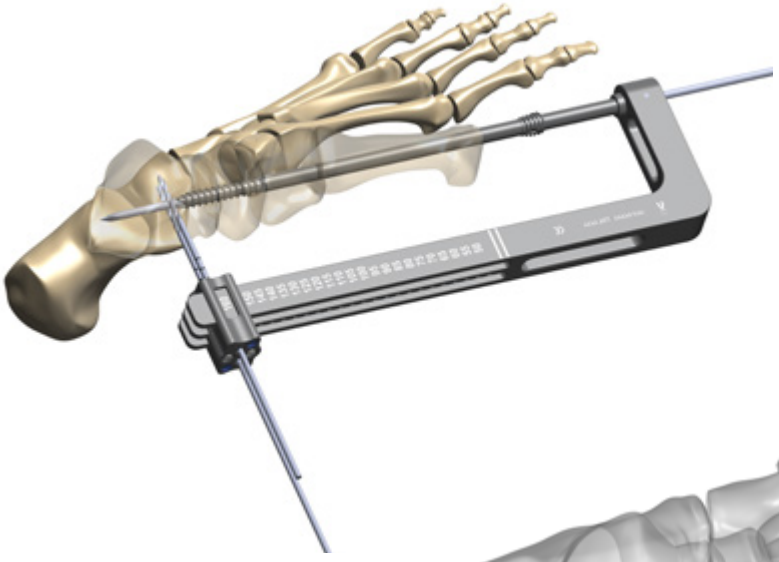
Small Targeting Guide (works with the 5.5mm Beams) – slide the Targeting Guide over the 2.0 mm Guidewire taking care to mate the beam with the external coupler. This coupler will engage the head of the beam and is locked into place by rotating the coupler in a clockwise fashion.

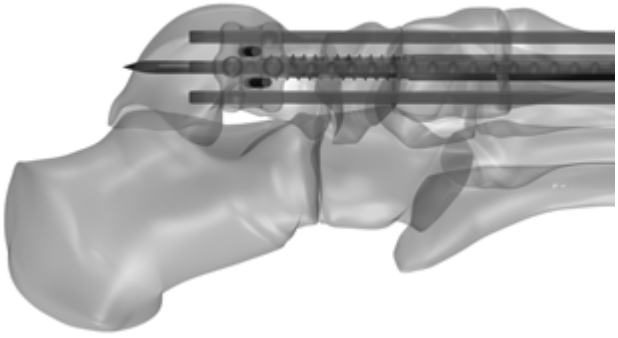


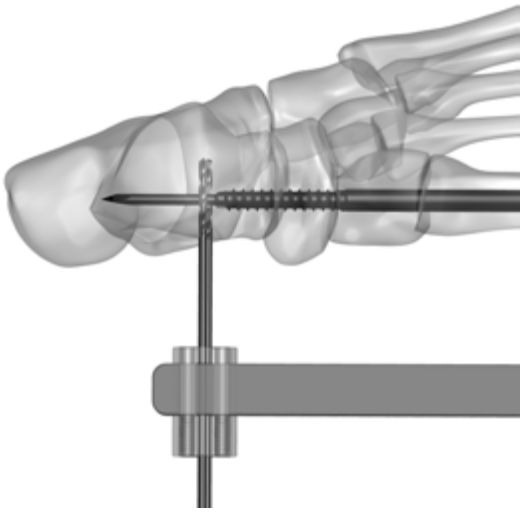


X-Clip Placement
Step 2. Drilling for the X-Clip

Make an incision and dissect down to bone taking care to resect the soft tissue directly under the Drill Guide. Utilizing a wire driver, advance the appropriately sized Drill Pin to the desired depth of X-Clip leg length. To avoid interference, use the Short Drill Pin for the first hole and the Long Drill Pin for the second hole. Verify the position of the Drill Pins with fluoroscopy in both the AP and lateral views. The tip of the Drill Pins should coincide with the desired X-Clip length and should be positioned on either side of the Beam.

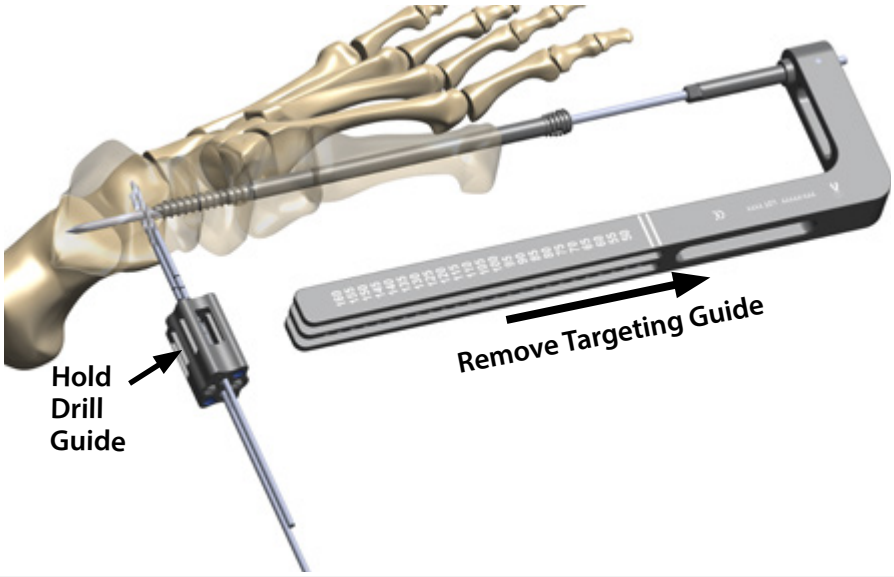






	1st Drill Pin	2nd Drill Pin
Small (2.0 mm)	Short Drill Pin, Small	Long Drill Pin, Small
Large (2.5 mm)	Short Drill, Pin, Small	Long Drill Pin, Large

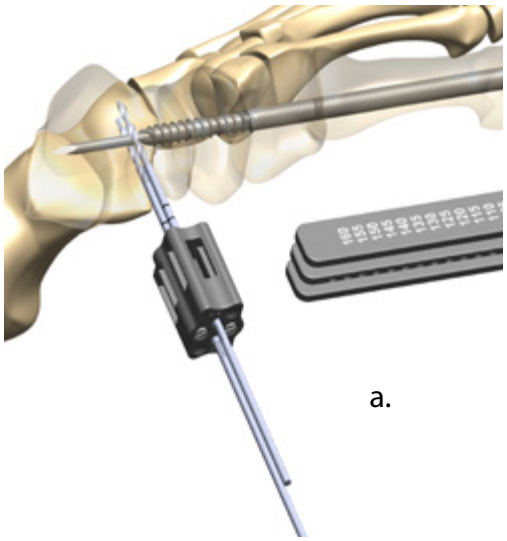
X-Clip Placement
Step 3. Remove Targeting Guide



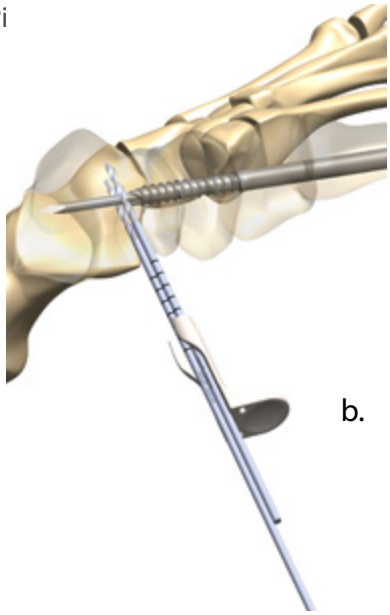
Once the position of the Drill Pins are verified, hold the Drill Guide in place and remove the Targeting Guide by sliding it distally.

X-Clip Placement
Step 4. Position the X-Clip Guide

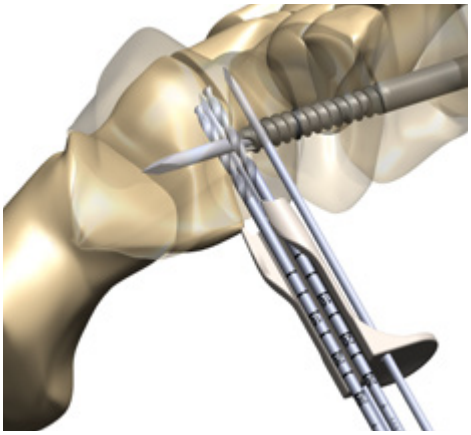
a. Slide the Drill Guide off of the Drill Pins and replace it with the Clip Guide. b. Slide the Clip Guide down to bone. c. Two 2.0 mm wire should be used to provisionally pin the Clip Guide in place. Note: the laser lines on the drill pins are calibrated to 5 mm increments, with the first line starting at "0". The leg length of the X-Clip can be determined using the position of Drill Pins relative to the top of the Clip Guide. d. Remove the Drill Pi



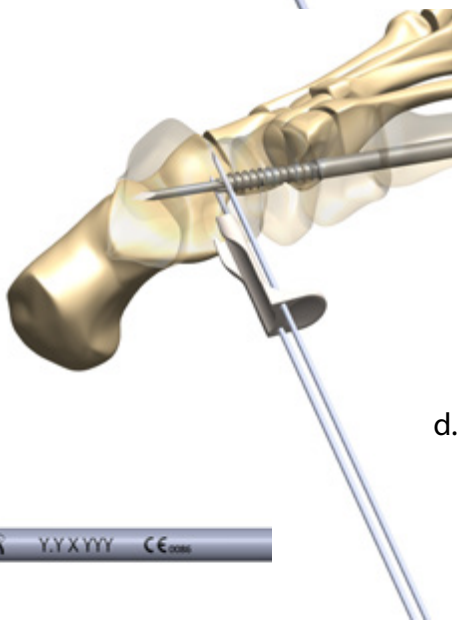
a.



b.



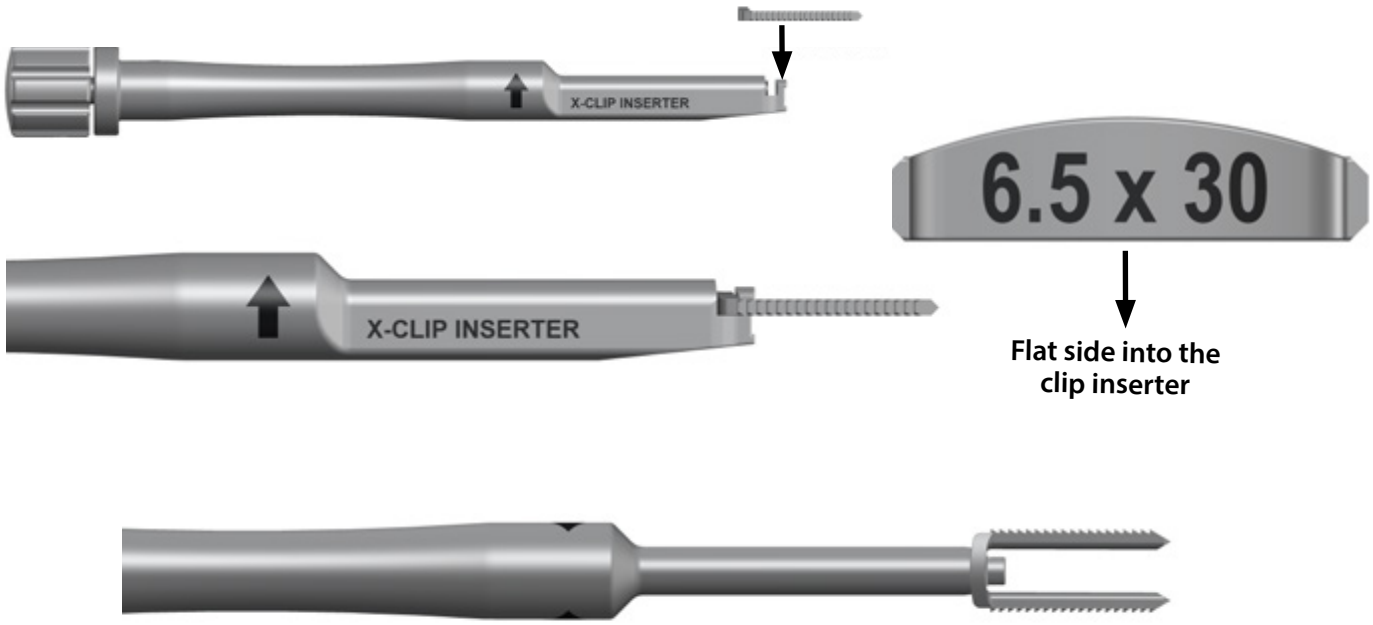
c.



d.

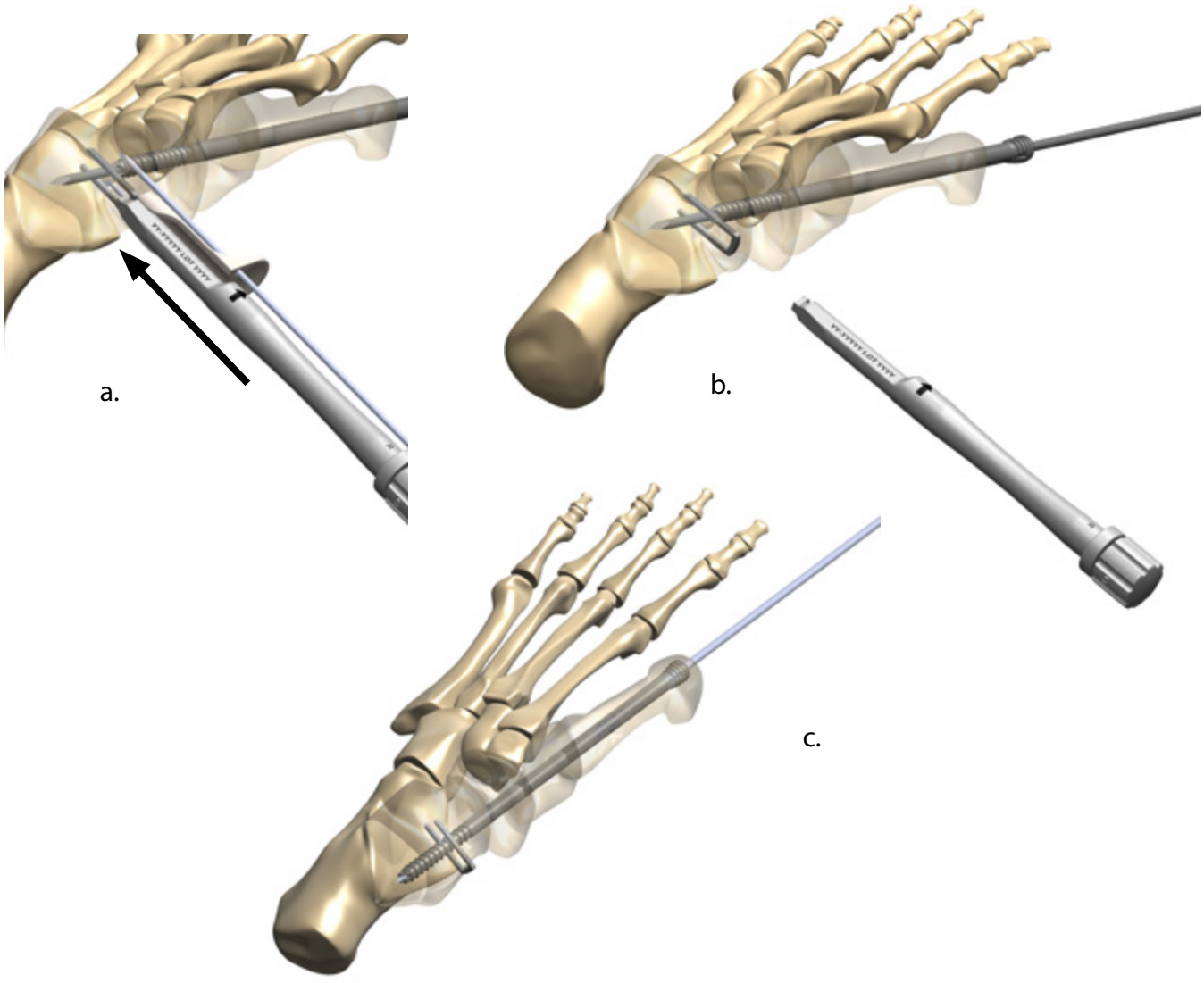
X-Clip Placement
Step. 5 Insert the X-Clip Guide

With the arrow facing toward the X-Clip guide, load the selected X-Clip onto the Clip Inserter with the flat side of the bridge of the X-Clip onto the Clip inserter. Turn the knob at the top of the Inserter clockwise to secure X-Clip ensuring that the legs of the X-Clip are loaded parallel to the inserter



Step. 5 Insert the X-Clip Guide

a. Deliver the X-Clip though the Clip Guide into the pre-drilled holes. Once fully inserted, turn the Inserter's knob counter-clockwise to release the X-Clip. Slide Inserter off of the X-Clip. b. The Tip of the Inserter can then be used as a tamp to fully seat the X-Clip. c. Advance the Axis Beam through the X-Clip into the desired position and compression is achieved.



Step 6 - Final Position of AXIS Fixation Beam.

Verify the positioning of the X-Clip and AXIS Beam with fluoroscopy. Advance the AXIS Beam through the X-Clip compressing the fusion site. Advance till the head of the beam is countersunk to the metaphysis of the metatarsal.

AXIS Removal Instructions

It is recommended to remove the AXIS Beam prior to removing the X-Clip:

Beam Removal

- Clear any tissue ingrowth from the Axis Beam
- 5.5mm Beams: Insert the Small Removal Driver (4.0mm Hex) into the Axis Beam and back out the Beam by turning counterclockwise. The Small Removal Tool can be inserted through the Removal Driver and threaded into the head of the beam to capture the internal threads and provide assistance during the removal process.
- 6.5 & 7.5mm Beams: Insert the Large Removal Driver (5.5mm Hex) into the Axis Beam and back out the Beam by turning counterclockwise. The Large Removal Tool can be inserted through the Removal Driver and threaded into the head of the beam to capture the internal threads and provide assistance during the removal process.

X-Clip Removal

- Expose the site and bridge of the X-Clip
- If the X-clip is recessed, use an elevator to lift the implant bridge
- Utilize forceps to remove the implant

Implants

5.5 Beams

Reference #	Description
130-55070	Fixation Beam, 5.5 x 70 mm
130-55075	Fixation Beam, 5.5 x 75 mm
130-55080	Fixation Beam, 5.5 x 80 mm
130-55085	Fixation Beam, 5.5 x 85 mm
130-55090	Fixation Beam, 5.5 x 90 mm
130-55095	Fixation Beam, 5.5 x 95 mm
130-55100	Fixation Beam, 5.5 x 100 mm
130-55105	Fixation Beam, 5.5 x 105 mm
130-55110	Fixation Beam, 5.5 x 110 mm
130-55115	Fixation Beam, 5.5 x 115 mm
130-55120	Fixation Beam, 5.5 x 120 mm
130-55125	Fixation Beam, 5.5 x 125 mm
130-55130	Fixation Beam, 5.5 x 130 mm
130-55135	Fixation Beam, 5.5 x 135 mm
130-55140	Fixation Beam, 5.5 x 140 mm
130-55145	Fixation Beam, 5.5 x 145 mm
130-55150	Fixation Beam, 5.5 x 150 mm

6.5 Beams

Reference #	Description
130-65070	Fixation Beam, 6.5 x 70 mm
130-65075	Fixation Beam, 6.5 x 75 mm
130-65080	Fixation Beam, 6.5 x 80 mm
130-65085	Fixation Beam, 6.5 x 85 mm
130-65090	Fixation Beam, 6.5 x 90 mm
130-65095	Fixation Beam, 6.5 x 95 mm
130-65100	Fixation Beam, 6.5 x 100 mm
130-65105	Fixation Beam, 6.5 x 105 mm
130-65110	Fixation Beam, 6.5 x 110 mm
130-65115	Fixation Beam, 6.5 x 115 mm
130-65120	Fixation Beam, 6.5 x 120 mm
130-65125	Fixation Beam, 6.5 x 125 mm
130-65130	Fixation Beam, 6.5 x 130 mm
130-65135	Fixation Beam, 6.5 x 135 mm
130-65140	Fixation Beam, 6.5 x 140 mm
130-65145	Fixation Beam, 6.5 x 145 mm
130-65150	Fixation Beam, 6.5 x 150 mm
130-65155	Fixation Beam, 6.5 x 155 mm
130-65160	Fixation Beam, 6.5 x 160 mm

7.5 Beams

Reference #	Description
130-75070	Fixation Beam, 7.5 x 70 mm
130-75075	Fixation Beam, 7.5 x 75 mm
130-75080	Fixation Beam, 7.5 x 80 mm
130-75085	Fixation Beam, 7.5 x 85 mm
130-75090	Fixation Beam, 7.5 x 90 mm
130-75095	Fixation Beam, 7.5 x 95 mm
130-75100	Fixation Beam, 7.5 x 100 mm
130-75105	Fixation Beam, 7.5 x 105 mm
130-75110	Fixation Beam, 7.5 x 110 mm
130-75115	Fixation Beam, 7.5 x 115 mm
130-75120	Fixation Beam, 7.5 x 120 mm
130-75125	Fixation Beam, 7.5 x 125 mm
130-75130	Fixation Beam, 7.5 x 130 mm
130-75135	Fixation Beam, 7.5 x 135 mm
130-75140	Fixation Beam, 7.5 x 140 mm
130-75145	Fixation Beam, 7.5 x 145 mm
130-75150	Fixation Beam, 7.5 x 150 mm
130-75155	Fixation Beam, 7.5 x 155 mm
130-75160	Fixation Beam, 7.5 x 160 mm

Implants X-Clips

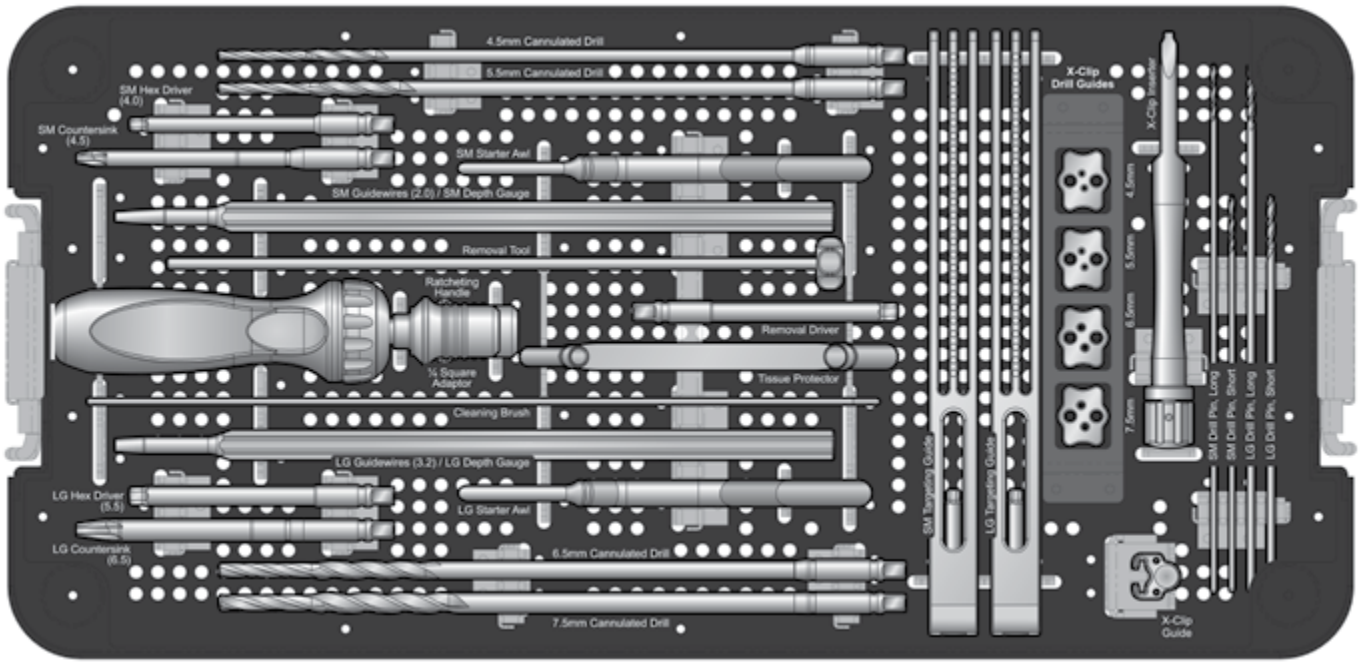
Reference #	Description
130-55915	X-Clip, 5.5 x 15 mm
130-55920	X-Clip, 5.5 x 20 mm
130-65925	X-Clip, 6.5 x 25 mm
130-65930	X-Clip, 6.5 x 30 mm
130-75925	X-Clip, 7.5 x 25 mm
130-75930	X-Clip, 7.5 x 30 mm

Disposable Instruments

Reference #	Description
130-00006	Axis X-Ray Template
130-00020	Guidewire, Small (2.0 mm)
130-00032	Guidewire, Large (3.2 mm)
130-00055	Cannulated Drill, 5.5 mm
130-00065	Cannulated Drill, 6.5 mm
130-00075	Cannulated Drill, 7.5 mm
130-00220	Cleaning Brush, 2.0 mm
130-02020	Short Drill Pin, Small
130-02025	Short Drill Pin, Large
130-02120	Long Drill Pin, Small
130-02125	Long Drill Pin, Large

Disposable Instruments

Reference #	Description
130-00003	Tissue Protector
130-00004	Ratcheting Handle
130-00005	1/4 Sq. to Jacobs Adapter
130-00025	Removal Tool, Small
130-00040	Removal Tool, Large
130-00120	Starter Awl, Small
130-00132	Starter Awl, Large
130-00140	Hex Driver, Small (4.0 mm)
130-00145	Countersink, Small
130-00155	Hex Driver, Large (5.5 mm)
130-00165	Countersink, Large
130-00230	Depth Gauge, Small (2.0 mm)
130-00232	Depth Gauge, Large (3.2 mm)
130-00240	Removal Driver, Small (4.0 mm)
130-00255	Removal Driver, Large (5.5 mm)
130-02000	X-Clip Inserter
130-02001	X-Clip Guide
130-02055	Drill Guide, 5.5 mm
130-02065	Drill Guide, 6.5 mm
130-02075	Drill Guide, 7.5 mm
130-02455	Targeting Guide, Small
130-02678	Targeting Guide, Large



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Surgical Technique