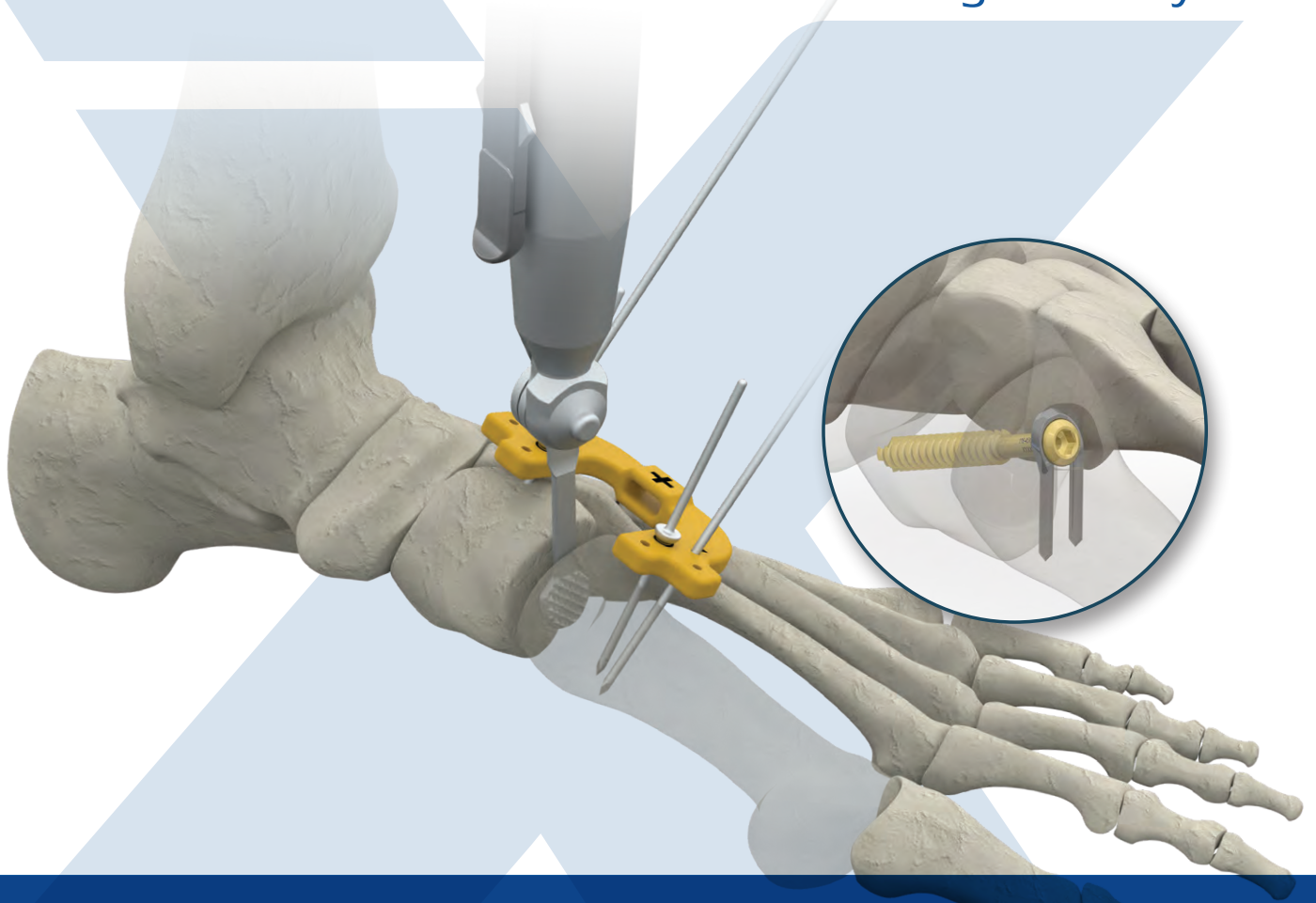


FREEDOM

Lapidus Joint Preparation
and Alignment System



IO Freedom Lapidus Surgical Technique

Featuring

← THE →
CARTILAGINATOR™

Advanced 1st TMT Joint Prep Technology

EXTREMITY®
MEDICAL

Real change *starts* here™

Lapidus Instrumentation

Joint Preparation and Alignment

Instrument Overview



THE CARTILAGINATOR™

A revolutionary joint preparation technology designed to efficiently prepare the 1st TMT joint while minimizing shortening.

Single Sided

Double Sided



Cartilaginator

Customized for Stryker Power Unit



1.6mm Olive Wire Tack, Smooth



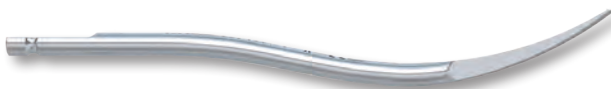
1.6mm Guidewire and Guidewire Holder



Joint Prep Cup Curette



2.0mm Guidewire (150mm) and Guidewire Holder (180mm)



Joint Preparation Rasp

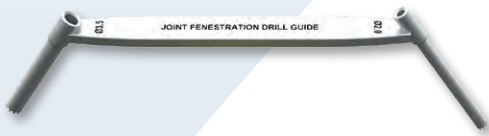
Customer Service: 888.499.0079

www.extremitymedical.com

Instrument Overview



Slim Fenestrating Drill



Fenestrating Drill Guide



Distraction Guide

Joint Seeker Tab



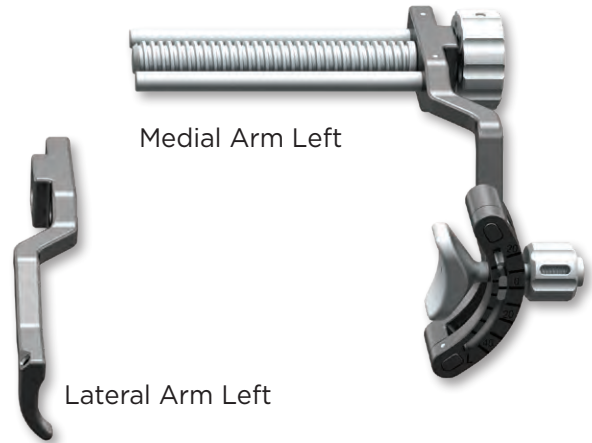
Joint Seeker



Paddle Distractor

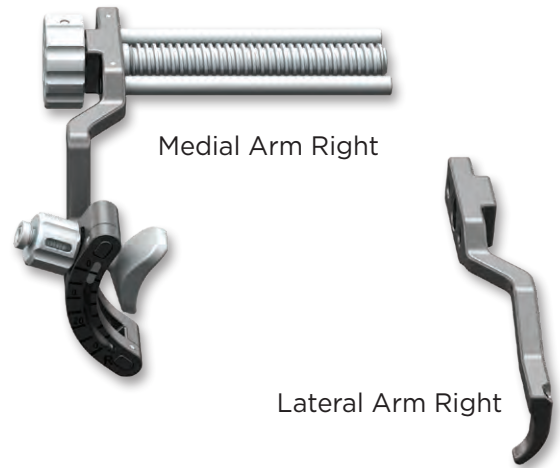


Metatarsal Base Spacer



Medial Arm Left

Lateral Arm Left



Medial Arm Right

Lateral Arm Right

Real change *starts* here™

IO Freedom™

Fusion Fixation

Implants



Cannulated Short and Long
Thread Screws, X-Posts and Screw Washers

4.5mm

General Instruments



Ratcheting Handle, Medium



Ratcheting Handle, Mini



X-Post Inserter



Cleaning Brush



Guidewires — (1.4mm, 1.6mm, 2.0mm)



Drill Pin (2.0mm, 2.5mm) X 125mm



Drill Pin (2.0mm, 2.5mm) X 200mm



Joint Preparation Rasp



Fenestrating Drill

General Instruments



1.6mm Wire Depth Gauge



3.0mm Cannulated Drill



4.5mm Lag Screw Countersink



4.5mm X-Post Countersink



3.0mm Hex Driver



4.5mm X-Post Drill Guide



4.5mm Screw Stop Key



4.5mm Screw Stop Washer

Real change *starts* here™

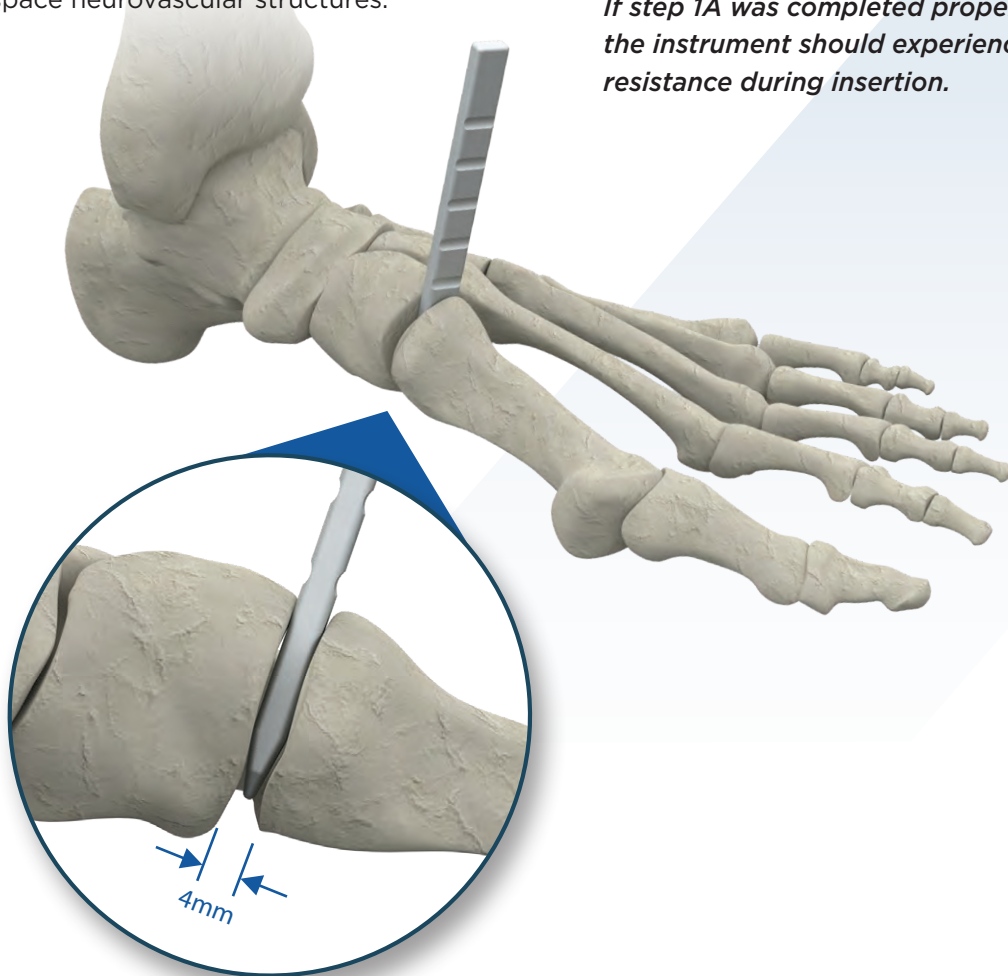
Scope:

This surgical technique guide is intended to illustrate the joint preparation and alignment steps of a Lapidus procedure utilizing a small incision (~1-2cm), either dorsally, medially or dorsomedially with the implantation of IO Freedom. If an open procedure is preferred, the surgeon can distract the joint using his/her own means and skip to “Step 5 – Joint Preparation with the Cartilaginator”.

Joint Preparation and Alignment

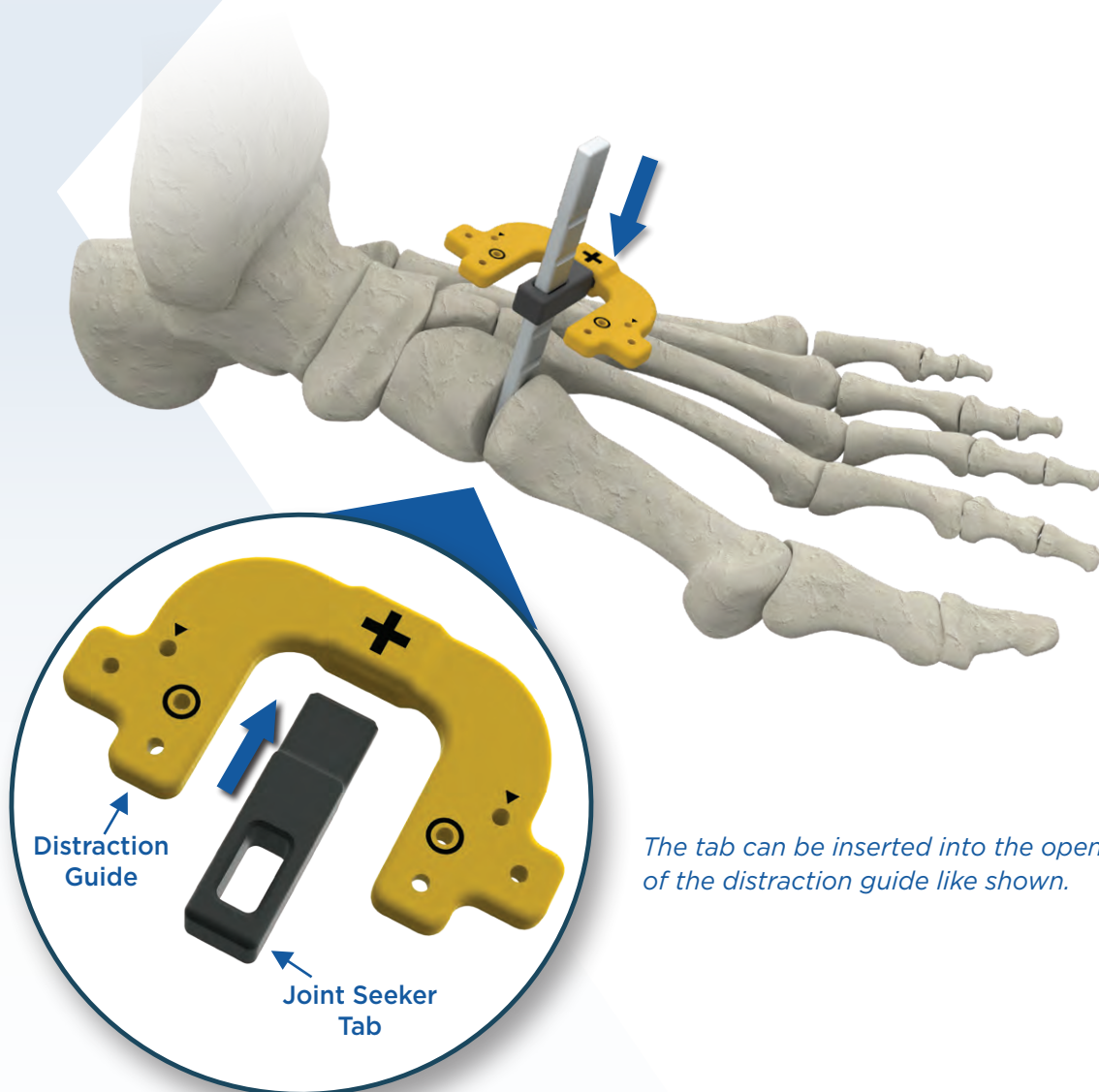
STEP 1. Joint Seeker

- A. Use an osteotome to fully mobilize the 1st TMT joint and detach from any surrounding soft tissue, especially on the plantar edge. Take precaution to preserve the 1st webspace neurovascular structures.
- B. Insert the Joint Seeker into the joint with the beveled end entered first. The Joint Seeker will distract the joint 4mm when the instrument is fully inserted.
If step 1A was completed properly, the instrument should experience minimal resistance during insertion.



Step 2. Slide the Distraction Guide over the Joint Seeker

- A. Attach the Joint Seeker Tab to the Distraction Guide by inserting the tab into the opening on the guide under the “+”.
- B. Once assembled, slide the Distraction Guide over the Joint Seeker until it is touching the bone. Ensure the “+” is facing up, and laterally towards the 5th ray.



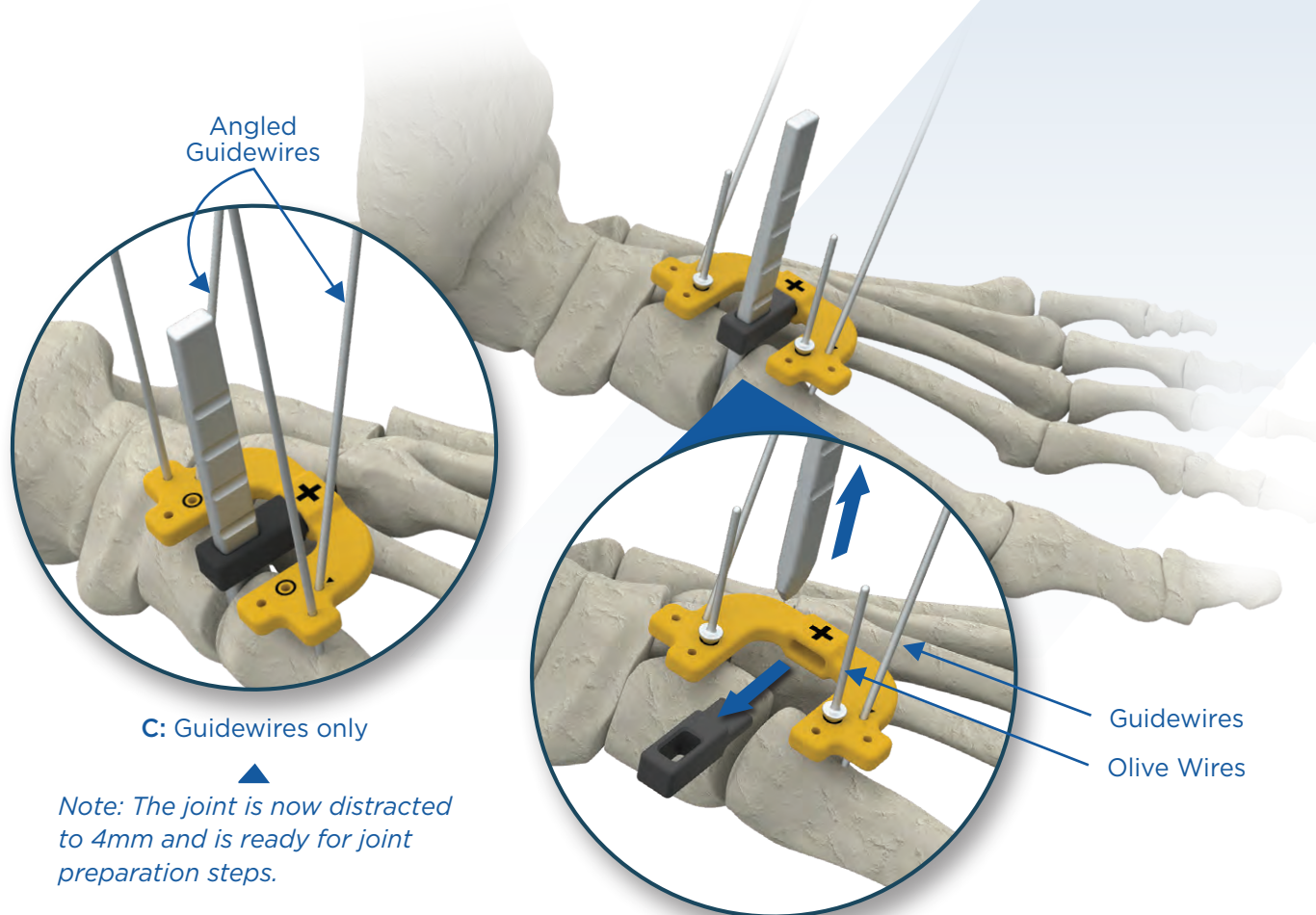
The tab can be inserted into the opening of the distraction guide like shown.

Step 3. Pin the Distraction Guide to retain joint distraction

- A.** Using the provided 1.6mm Guidewires or Olive Wires, pin the Distraction Guide in place.
- i. For maximum stability, use two points of fixation in the metatarsal and the cuneiform (four total).
 - ii. If only Guidewires are used, follow the orientation shown below on the left. Start with the two Guidewires furthest away from the joint, then place the angled Guidewires through the holes designated with an arrow.
 - iii. If the use of Olive Wires is preferred, the orientation shown below on the right is recommended.
- B.** Once the Distraction Guide has been fixated, remove the Joint Seeker and the seeker tab.

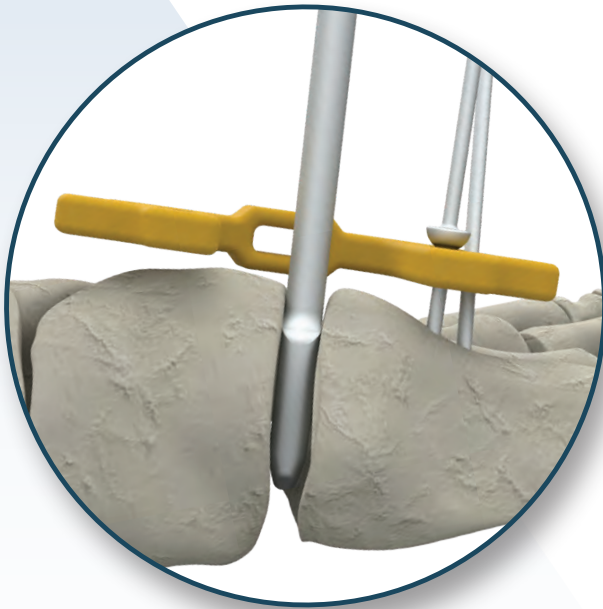
Note: The angled holes on the Distraction Guide are labeled with an arrow.

Note: The circled holes are intended for Olive Wire use.

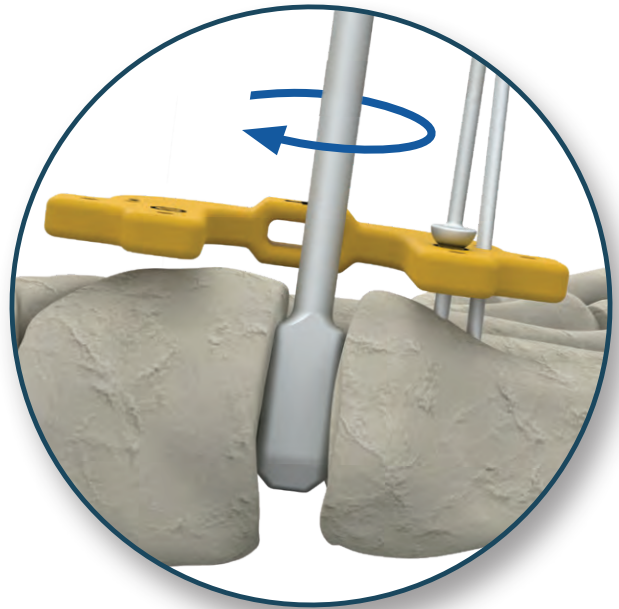


STEP 4. Paddle Distractor (Optional) – Utilize to open the joint from 4mm to 8mm.

- A. Remove all Guidewires inserted in the cuneiform from the Distraction Guide. Insert the Paddle Distractor in the joint with the flattened side inserted first (as shown in the left image below).
- B. Rotate the Paddle Distractor 90°, which will distract the space to an 8mm width.
- C. While keeping the Paddle Distractor engaged, replace the Guidewires into the cuneiform to hold the Distraction Guide in its new position. At this point, the joint will be distracted 8mm.
- D. This tool and technique can be used to increase the distraction space of the 1st TMT at anytime in the surgical technique.



Initial Insertion - 4mm Distraction



After 90° Rotation - 8mm Distraction

Step 5. Joint Preparation with the Cartilaginator

- A. Attach the Cartilaginator to a sagittal saw power unit.

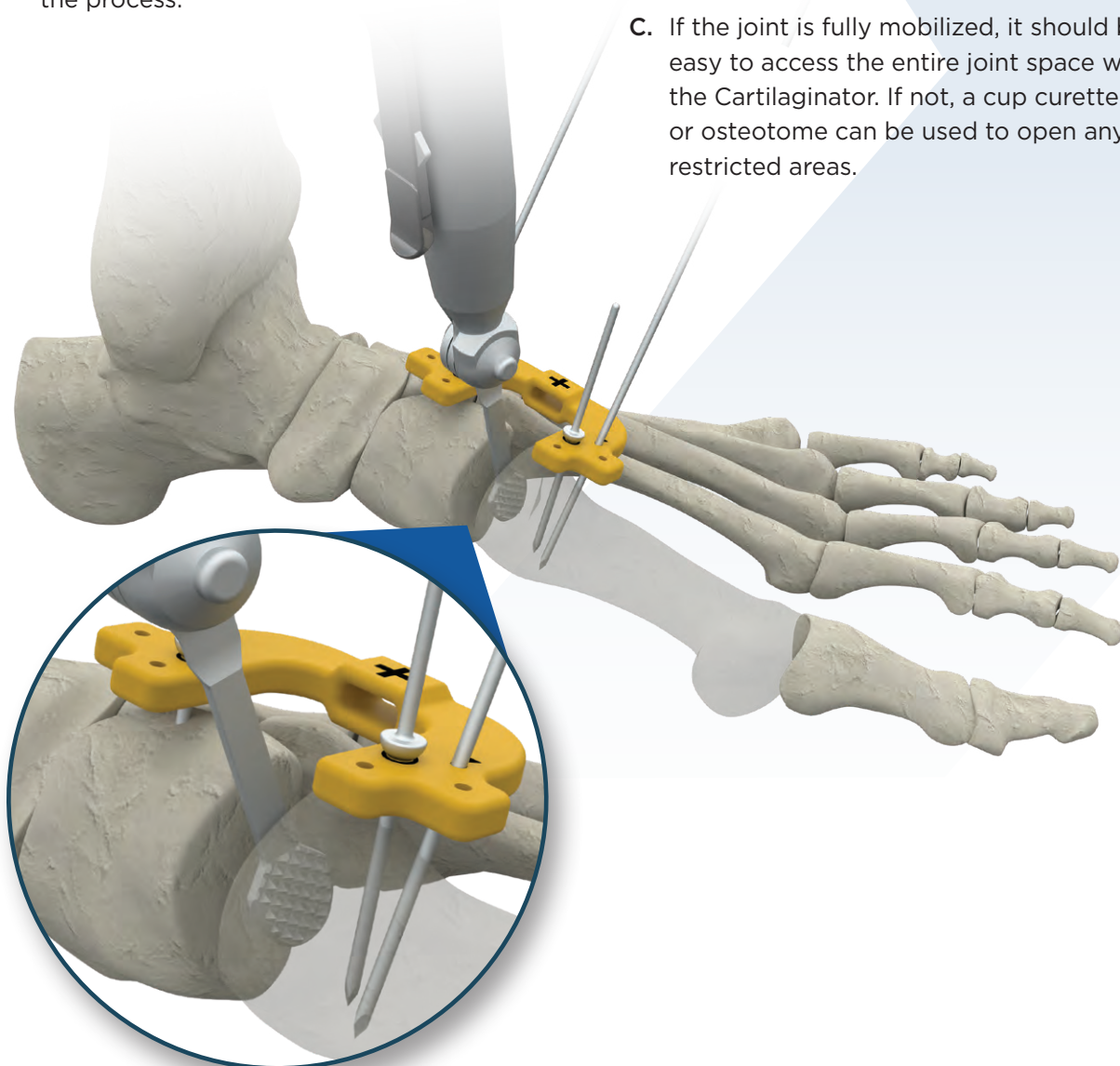
Note: A single and double sided Cartilaginator option is available.

- B. Use the Cartilaginator like a saw rasp to remove cartilage down to the subchondral bone. Minimal pressure should be applied to ensure control is maintained throughout the process.

Note: During use, cartilage and bone material may build up in the Cartilaginator. This can be cleared out using gauze or the sharp end of a guidewire.

WARNING. To avoid excessive heat, the **Cartilaginator should only be run at lower speeds (50% power or less)** in standard saw modes. Lower speed settings like “Oscillate” or “Ream” are equally effective and recommended.

- C. If the joint is fully mobilized, it should be easy to access the entire joint space with the Cartilaginator. If not, a cup curette or osteotome can be used to open any restricted areas.

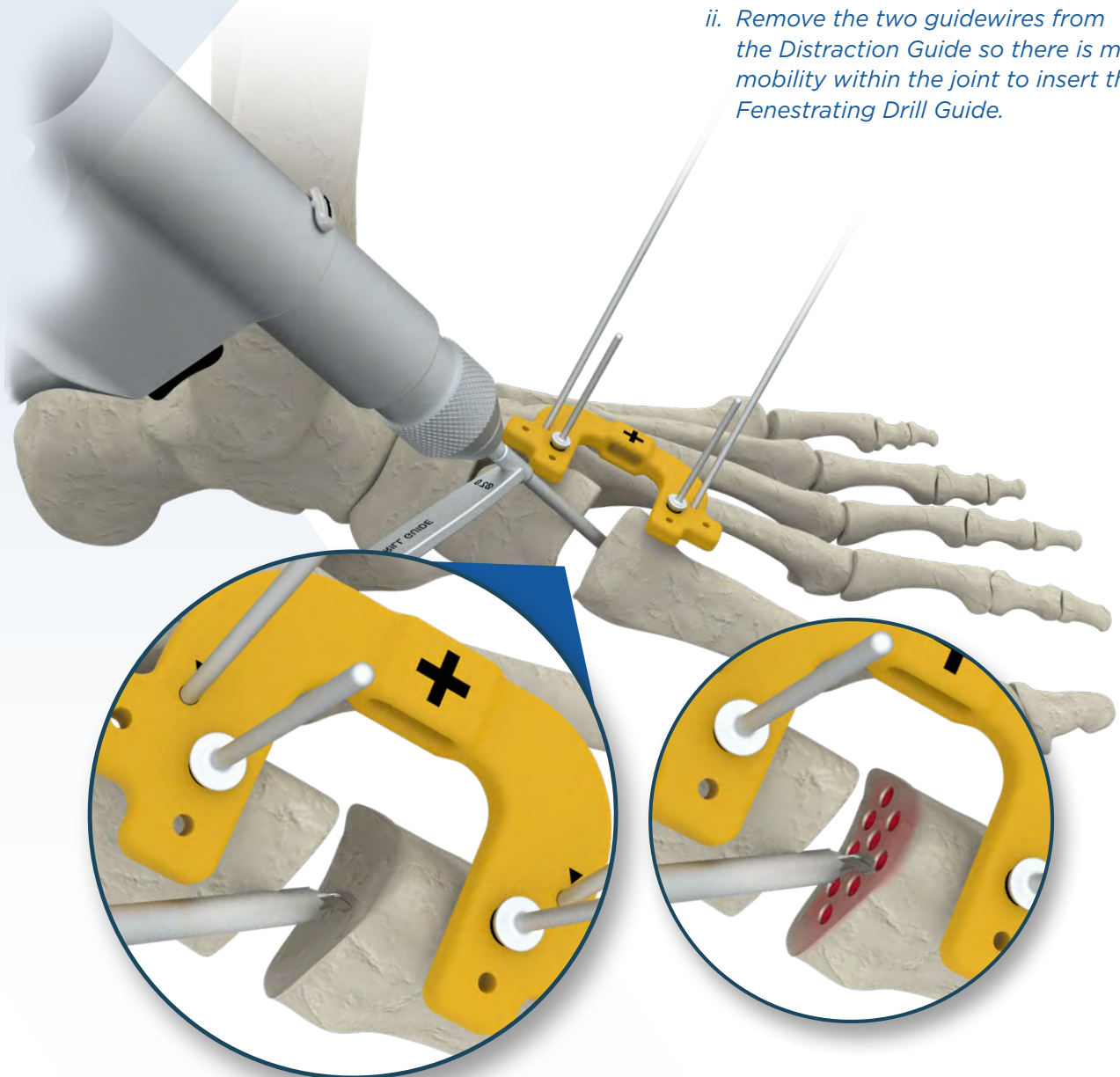


Step 6. Joint Fenestration

A. If fenestration is desired to create an enhanced bleeding surface, a 2.0mm Fenestrating Drill and Fenestrating Drill Guide is provided. The drill guide enhances the placement of holes in a small incision technique, and provides protection of the soft tissue.”

B. If the joint space is too small for adequate fenestration, the surgeon has 2 options to create more distraction space:

- i. *Utilize the Paddle Distractor as described in Step 4 to achieve 8mm of distraction.*
- ii. *Remove the two guidewires from the Distraction Guide so there is more mobility within the joint to insert the Fenestrating Drill Guide.*



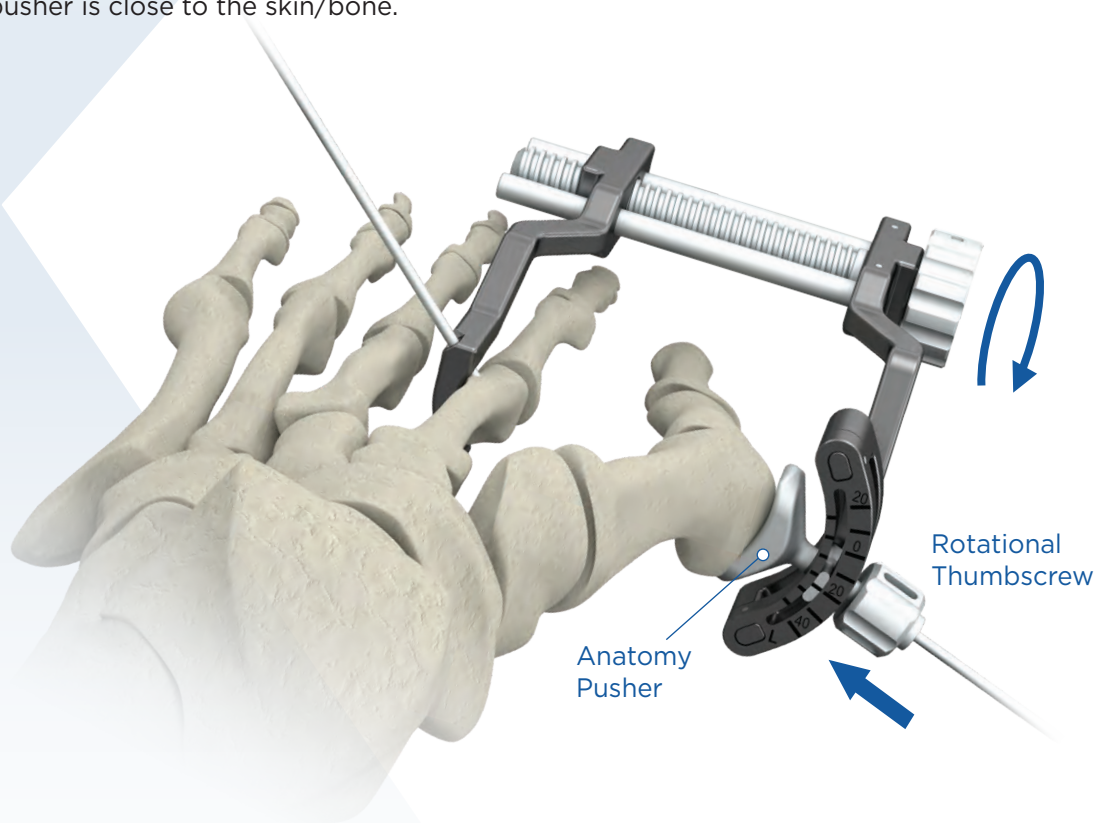
Step 7. Initial Clamp Preparation

- A.** Assemble the Reduction Clamp construct:
- Ensure both the medial and lateral arms say R or L.
 - Align the threaded rod and beams on the Medial Arm with the corresponding holes on the Lateral Arm, as shown.
 - While applying pressure, twist the large thumbscrew clockwise until the threads engage with the Lateral Arm.
- B.** Pre-Operative planning can be used to determine the rough rotational correction required for the procedure.
- C.** The clamp rotation arc has reference tick marks which can assist with the rotational correction needed for the patient.
- For example, if the surgeon has pre-determined that $\sim 20^\circ$ of rotational correction is needed, the rotation arc should be rotated to the lower 20° tick mark, shown below, prior to initial placement.
 - If rotational correction has not been predetermined, it is recommended to begin with the clamp at the lower 20° position, shown below.



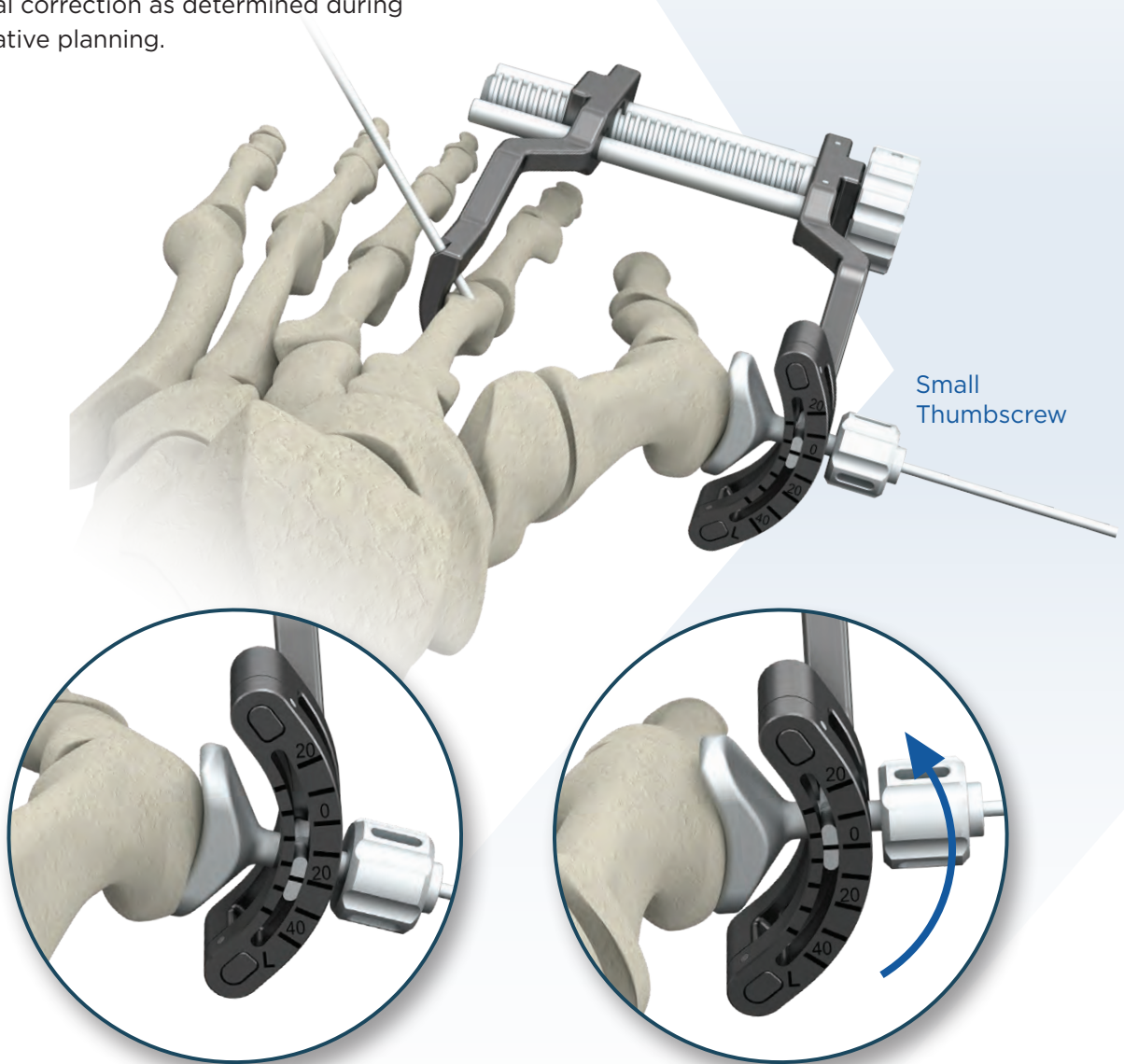
Step 8. Place the Reduction Clamp

- A. An incision over the 2nd metatarsal head is required for placement of the lateral clamp arm. This can be done with a lateral release incision or via a separate stab incision.
- B. Rotate the large thumbscrew clockwise to compress the clamp until the anatomy pusher is close to the skin/bone.
- C. Place the 2.0mm Guidewires through the lateral and medial clamp arms prior to applying compression to reduce the IM angle.



Step 9. Apply rotational correction if needed

Using the small thumbscrew as a joystick, rotate the wire along the arcs to apply the desired rotational correction as determined during preoperative planning.



Small
Thumbscrew

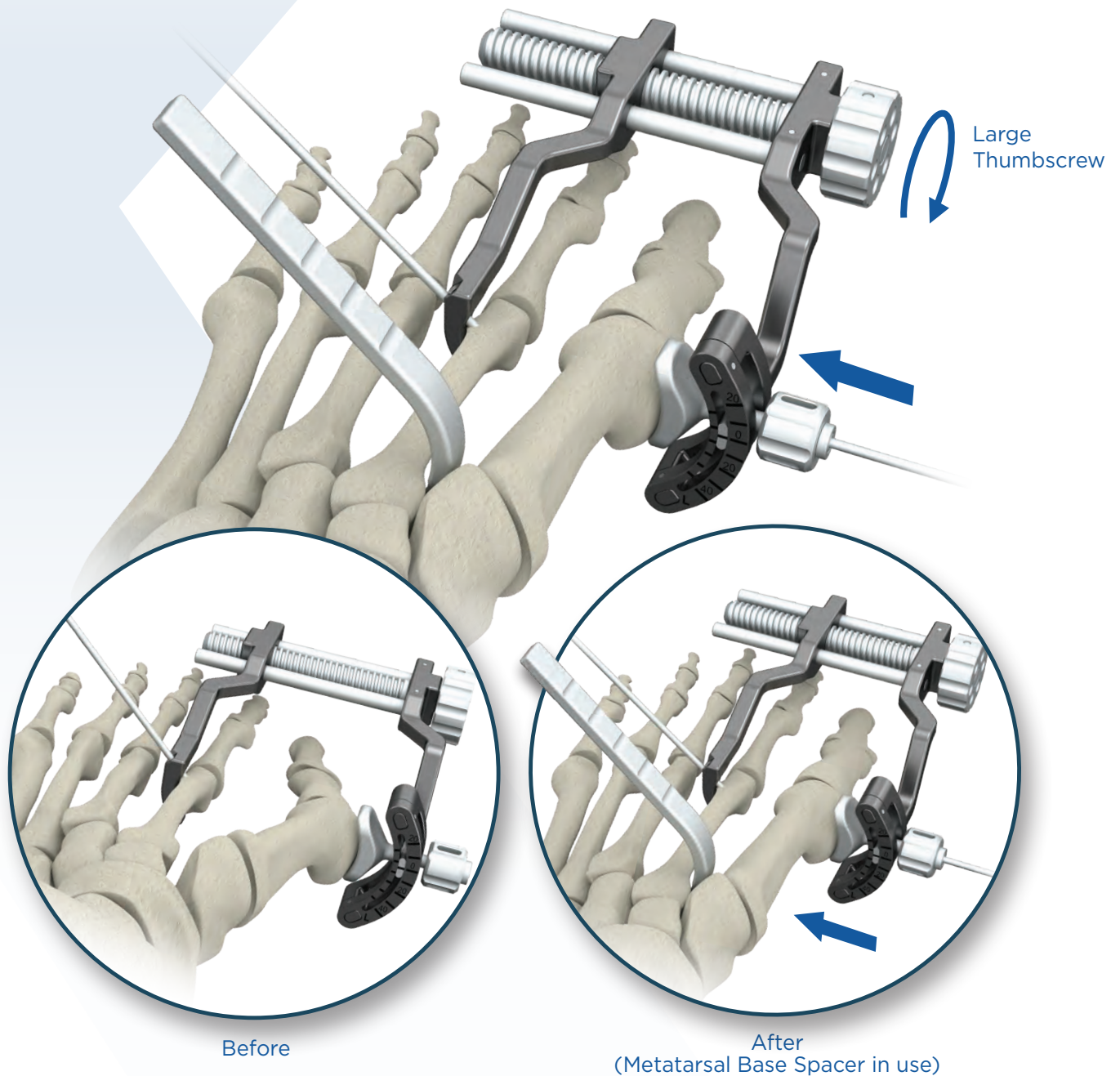
-20° Before rotational correction

0° After rotational correction

Step 10. Translate the distal metatarsal to reduce the IM angle

- A. The large thumbscrew will compress the two clamp arms and can be used to close the IM angle between the 1st and 2nd metatarsals.

Note: The Metatarsal Base Spacer instrument can be placed between the 1st and 2nd metatarsal base during this step. This will keep the metatarsal base in the preferred location while translating the distal metatarsal.



Step 11. Confirm desired position under fluoroscopy

- A. After reducing the IM angle, confirm the desired position under fluoroscopy.

Note: The clamp mainly corrects the frontal and transverse planes — NOT the sagittal plane. Ensure the 1st ray is not excessively plantar or dorsiflexed prior to placing hardware.

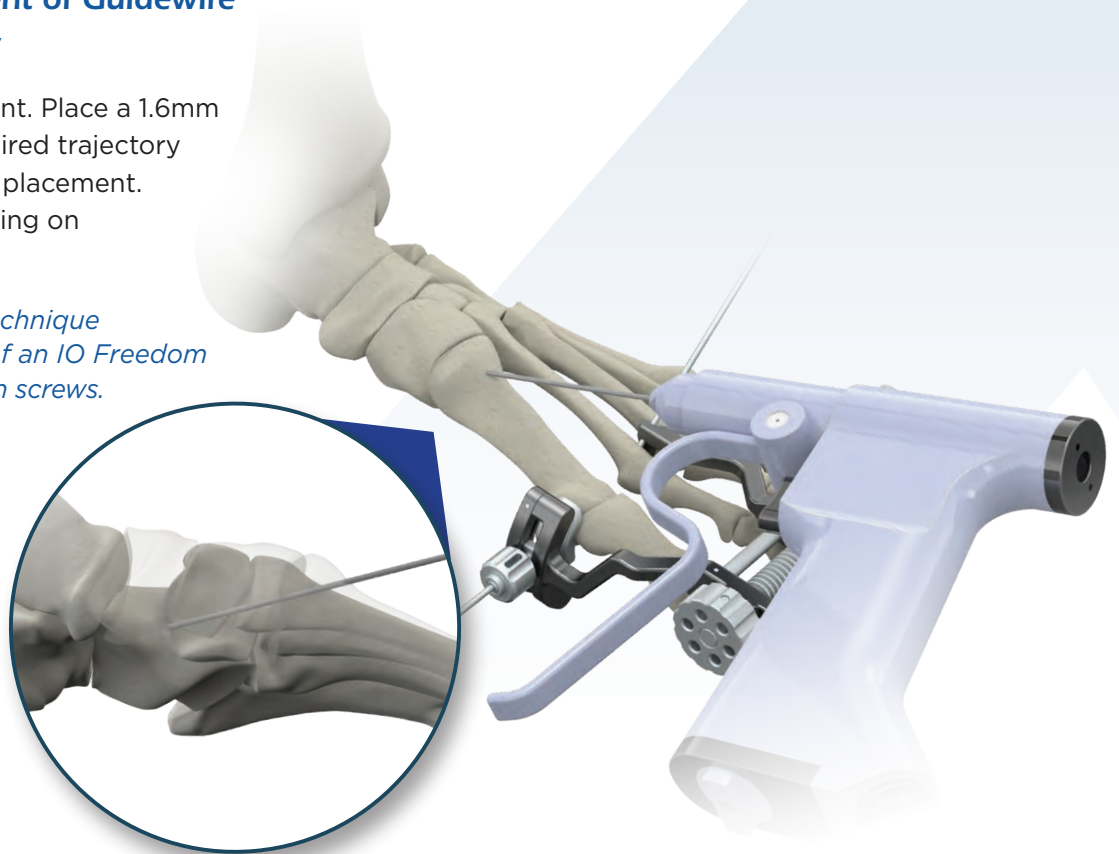
Note: The joint has now been prepared and is ready for IO Freedom insertion. The following steps demonstrate the technique with the clamp kept in place, as illustrated by the figures, although it can be removed if preferred.

IO Freedom Implantation

STEP 12. Placement of Guidewire for the Lag Screw

Pre-compress the joint. Place a 1.6mm Guidewire at the desired trajectory and depth for screw placement. Confirm the positioning on fluoroscopy.

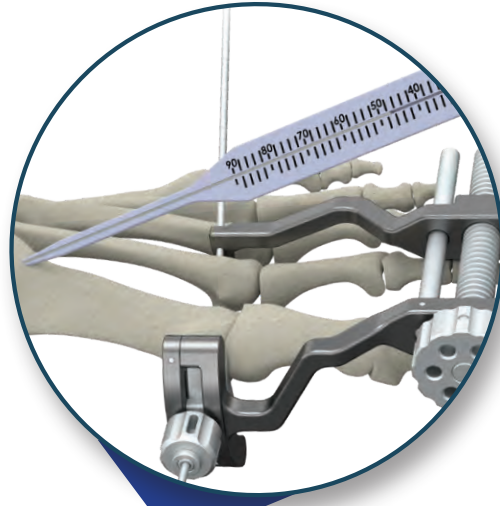
Note: The surgical technique describes insertion of an IO Freedom construct with 4.5mm screws.



STEP 13. Determine the Lag Screw Length

Utilizing the 1.6mm Wire Depth Gauge, measure the depth of the placed Guidewire to determine the length of the Lag Screw.

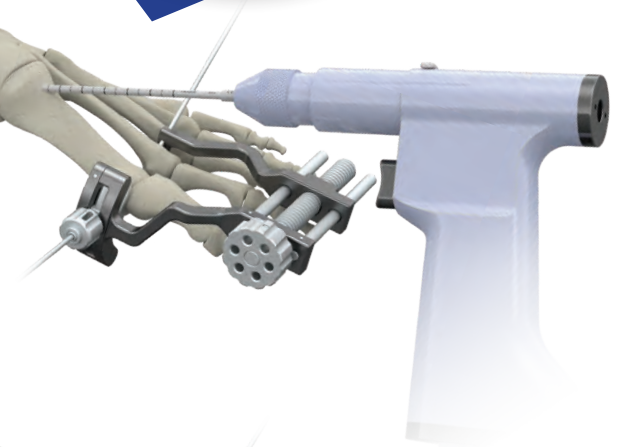
Note: It is recommended to use a short-threaded lag screw, and to place it 15mm from the joint line.



STEP 14. Drill Screw Pilot Hole

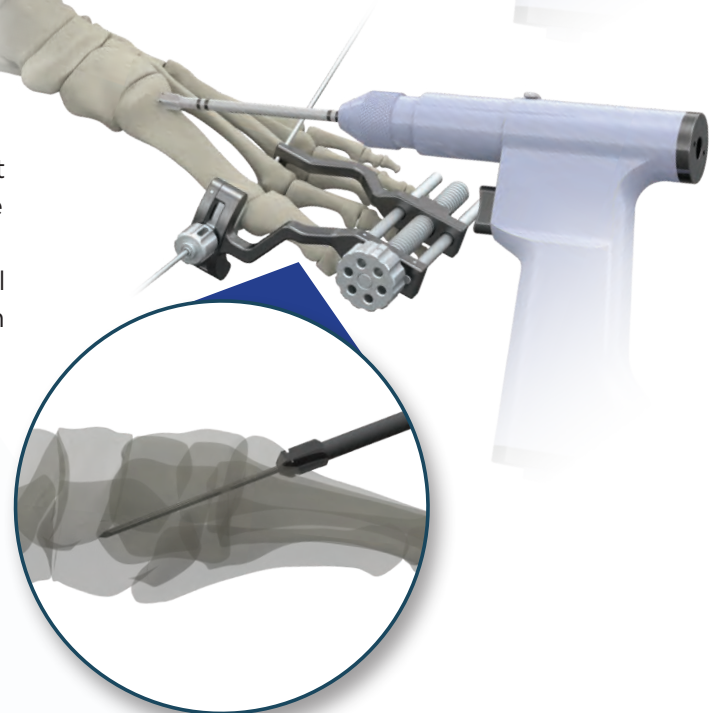
Drill over the placed Guidewire with the 3.0mm Cannulated Drill. The depth of drilling is left up to the surgeon's discretion. Each laser marked line on the drill represents 5mm.

Note: All IO Freedom screws are self-tapping and self-drilling screws.



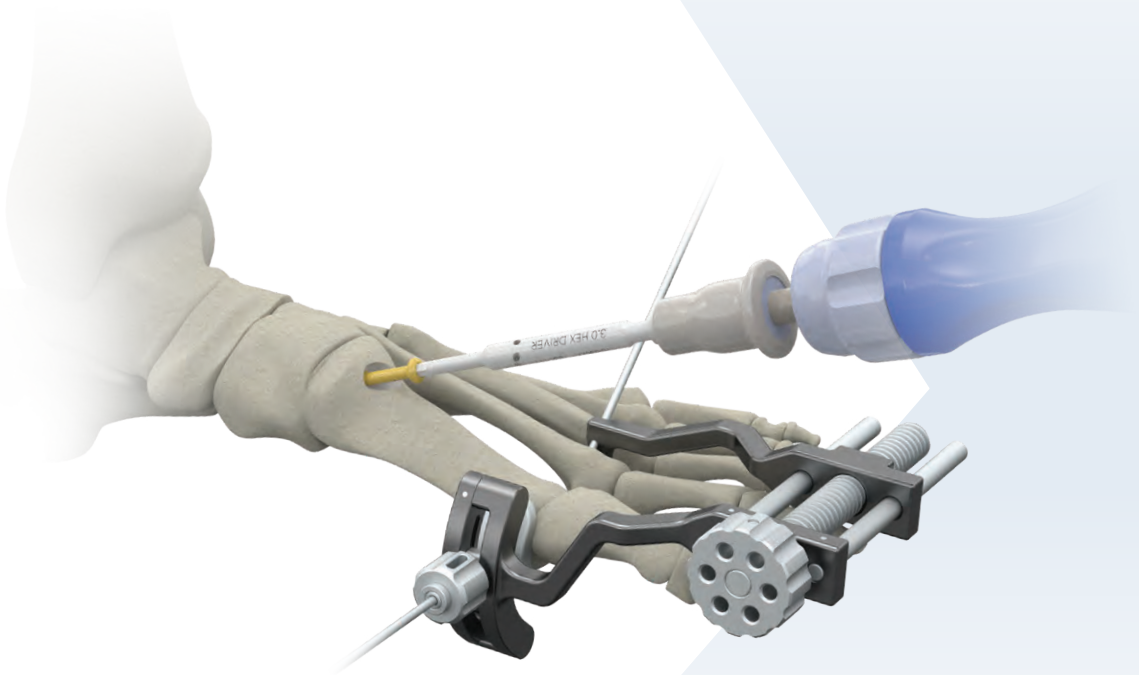
STEP 15. Countersink for the IO Freedom construct

Use the X-Post Countersink to create space for the profile of the device. Advance the instrument over the Guidewire until the laser marked groove is seated in the bone. The groove can be seen under fluoroscopy for visualization through small incision techniques. This will ensure the Freedom construct has a very low profile.



STEP 16. Lag Screw Insertion

Place the 4.5mm Lag Screw over the Guidewire and insert into the bone.



For the placement of a Screw/X-Post Construct, advance the screw until the Screw Stop Washer (attaches to the screw), or Screw Stop Key (held in place) is flush against the head of the screw and cortex of the bone. This will ensure enough space to allow the X-Post Drill Guide to be adequately seated in the next step.

Two Options

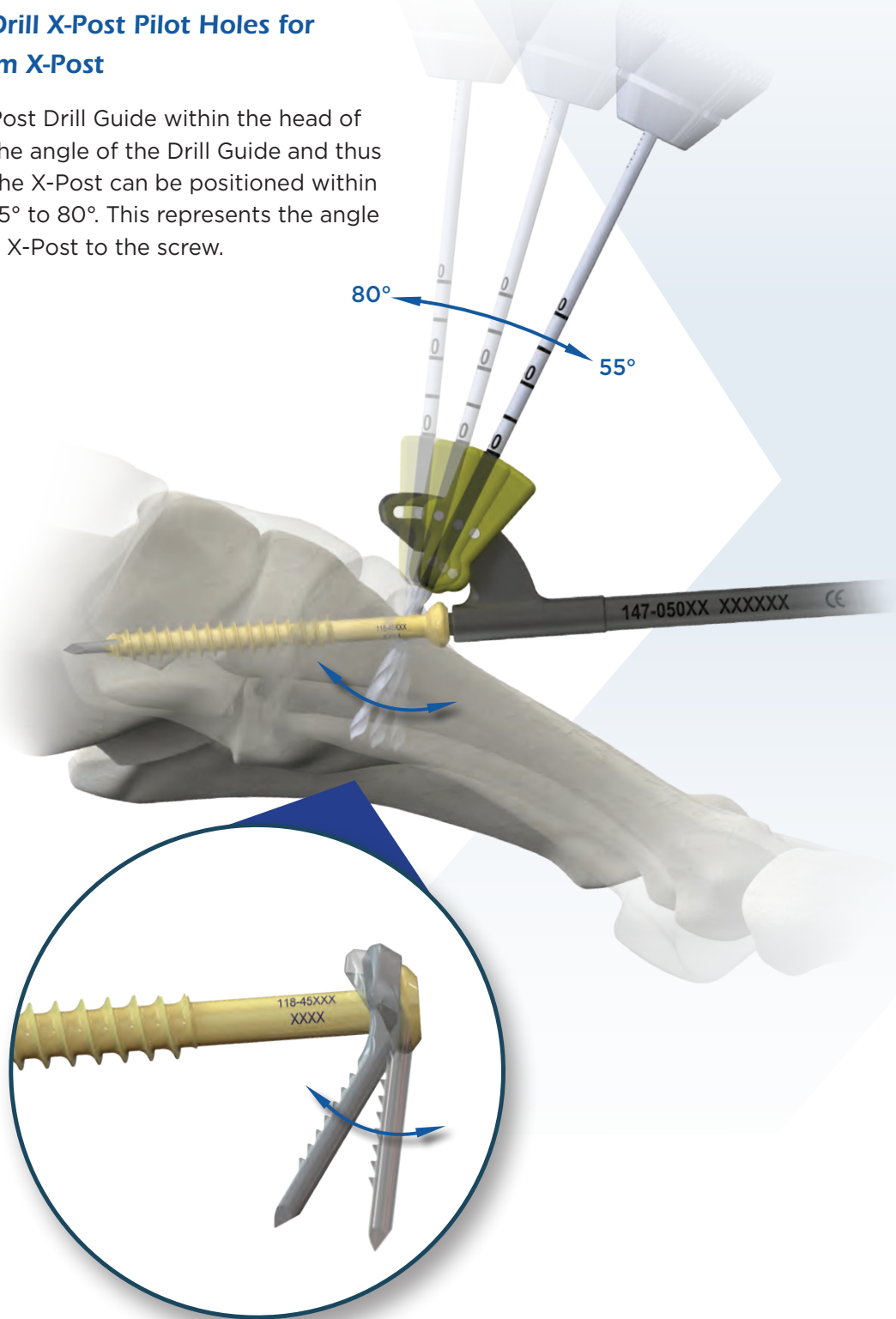
Screw Insertion with
Stop Key in Final Position



Screw Insertion with
Stop Washer in Final Position

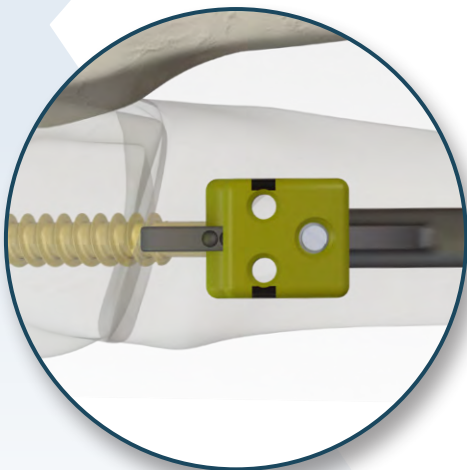
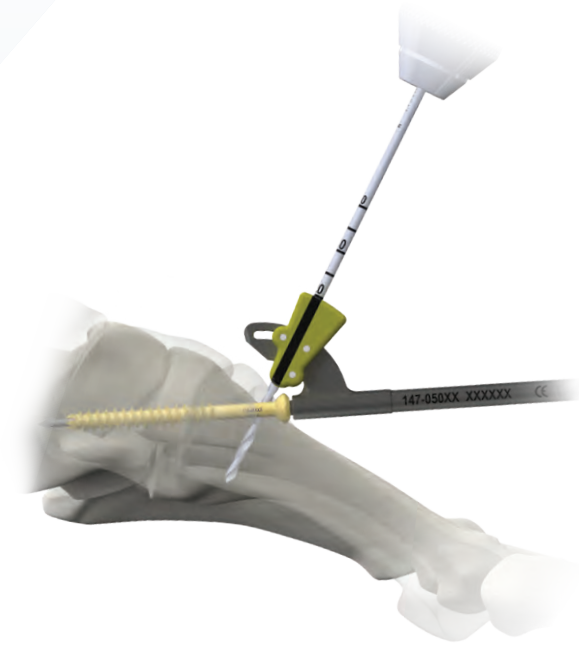
STEP 17. Drill X-Post Pilot Holes for IO Freedom X-Post

Seat the X-Post Drill Guide within the head of the screw. The angle of the Drill Guide and thus the legs of the X-Post can be positioned within a range of 55° to 80°. This represents the angle range of the X-Post to the screw.



Adjust the Drill Guide's position to the desired position for the X-Post placement. It is recommended to place the legs of the X-Post fairly parallel to the joint surface to optimize compression. The laser line on the side of the drill guide will help to visualize the positioning of the guide prior to placing the Drill Pins.

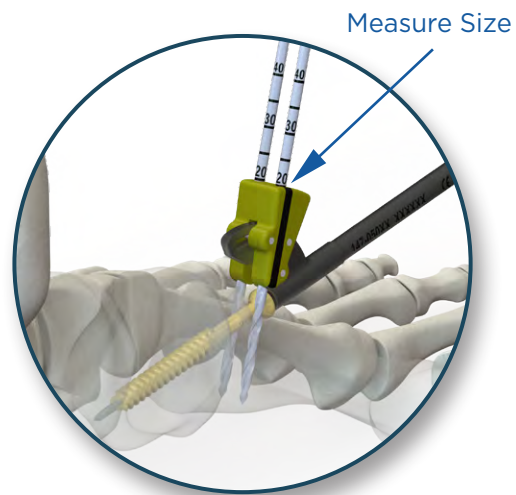
Advance the 2.0mm Drill Pin at the desired angle to the desired depth for the X-Post legs. It is recommended that the Drill Pins be placed a minimum of $\approx 10\text{mm}$ from the joint-line.



Top View

To avoid interference during Pin placement, place the short Drill Pin (125mm) first.

Verify the position of the Drill Pins with fluoroscopy in both the AP and lateral views. The tip of the Drill Pins will coincide with the desired X-Post length. Verify that the Drill Pins have been placed in an acceptable angle. They should be

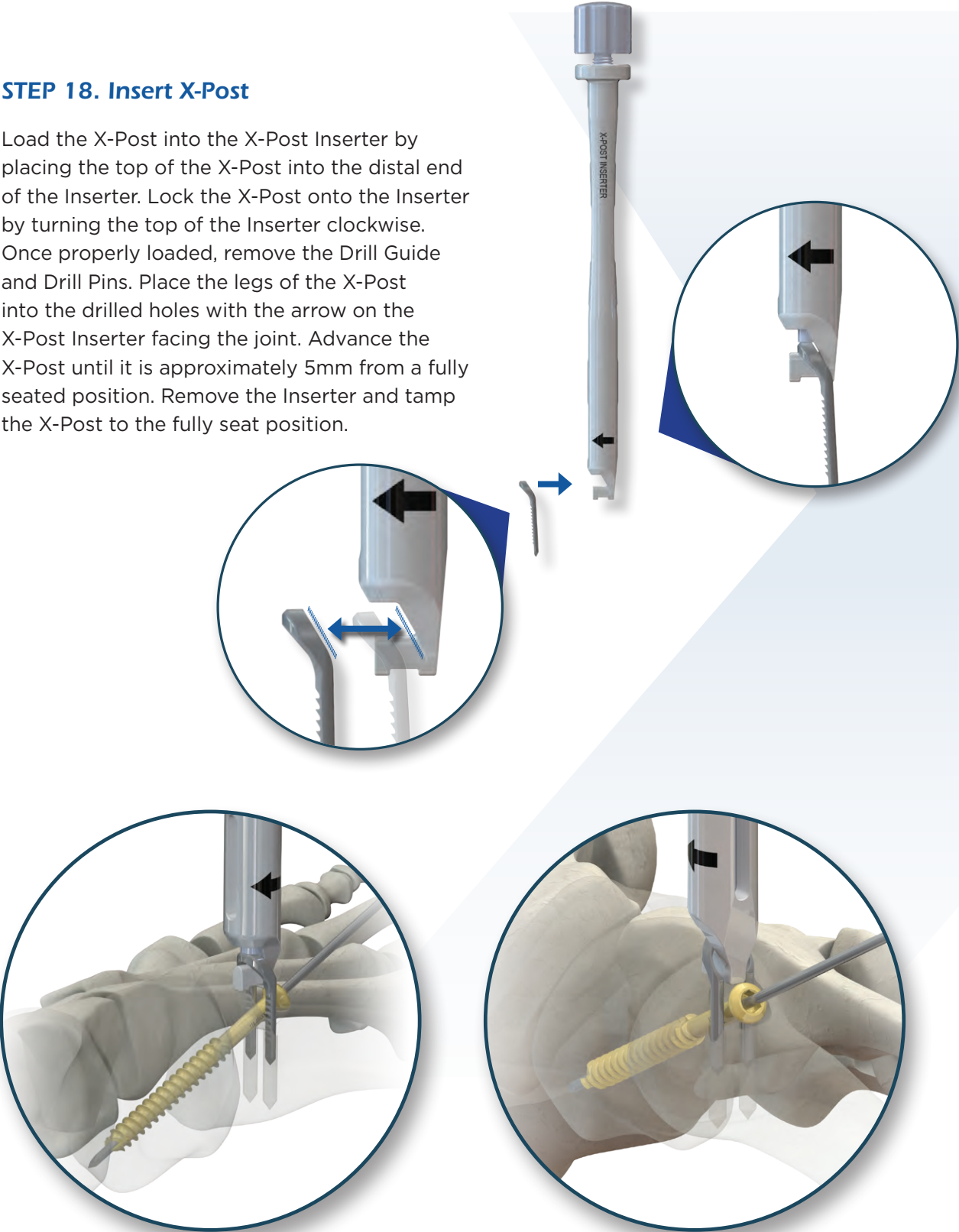


positioned on either side of the screw. The length can be determined based on the calibrated measurement of either Drill Pin and the top of the X-Post Drill Guide.

The Leg Length Options are the following: 15mm, 20mm, 25mm, and 30mm.

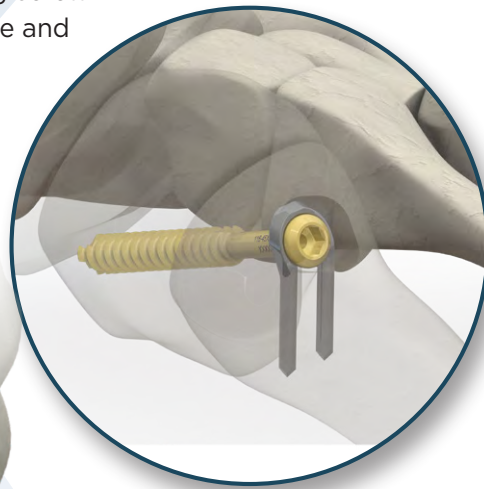
STEP 18. Insert X-Post

Load the X-Post into the X-Post Inserter by placing the top of the X-Post into the distal end of the Inserter. Lock the X-Post onto the Inserter by turning the top of the Inserter clockwise. Once properly loaded, remove the Drill Guide and Drill Pins. Place the legs of the X-Post into the drilled holes with the arrow on the X-Post Inserter facing the joint. Advance the X-Post until it is approximately 5mm from a fully seated position. Remove the Inserter and tamp the X-Post to the fully seat position.



STEP 19. Final Tightening of Lag Screw

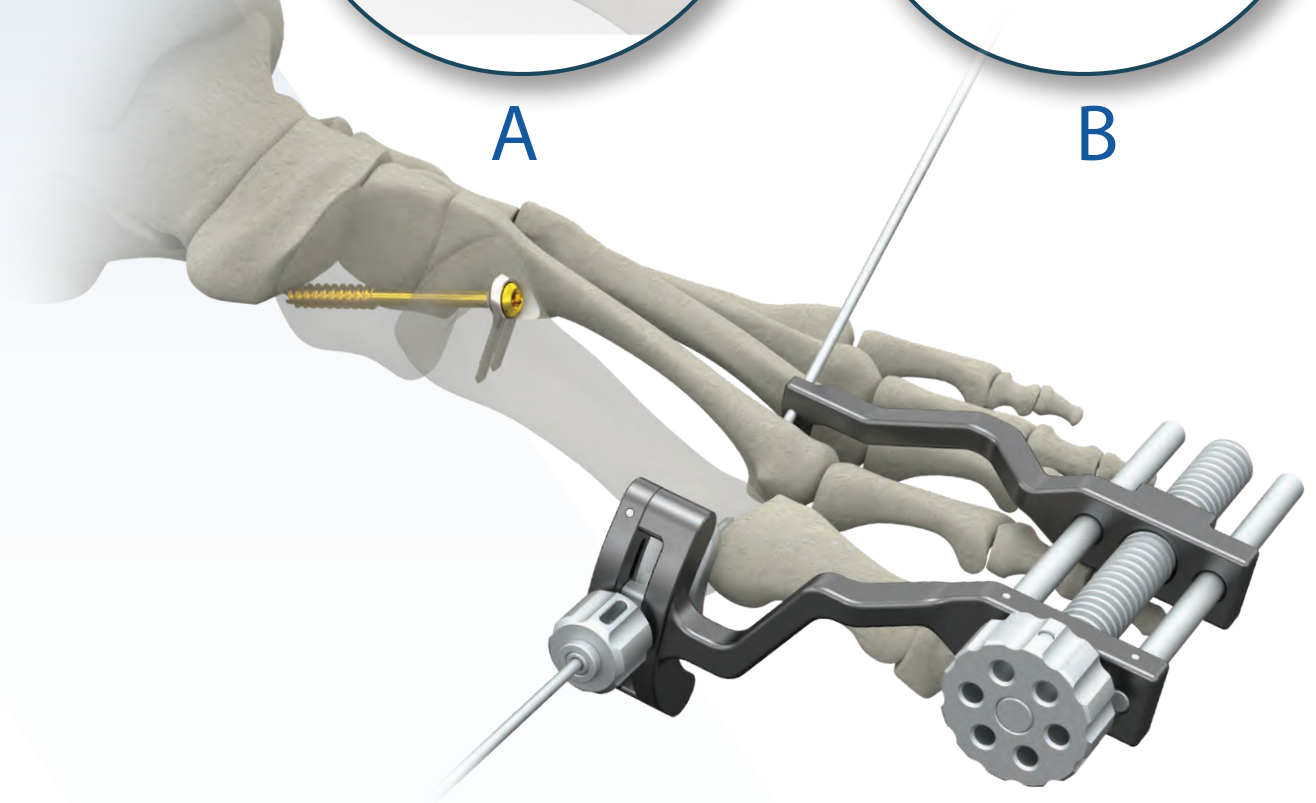
Once the X-Post is fully inserted, advance the Lag Screw into the screw head recess of the X-Post. The X-Post will act as a “stop” for the screw. Continue to advance the screw until tactile compression is felt. Care should be taken not to over tighten the construct, as this is not a locking screw. Remove the Guidewire and Reduction clamp.



A

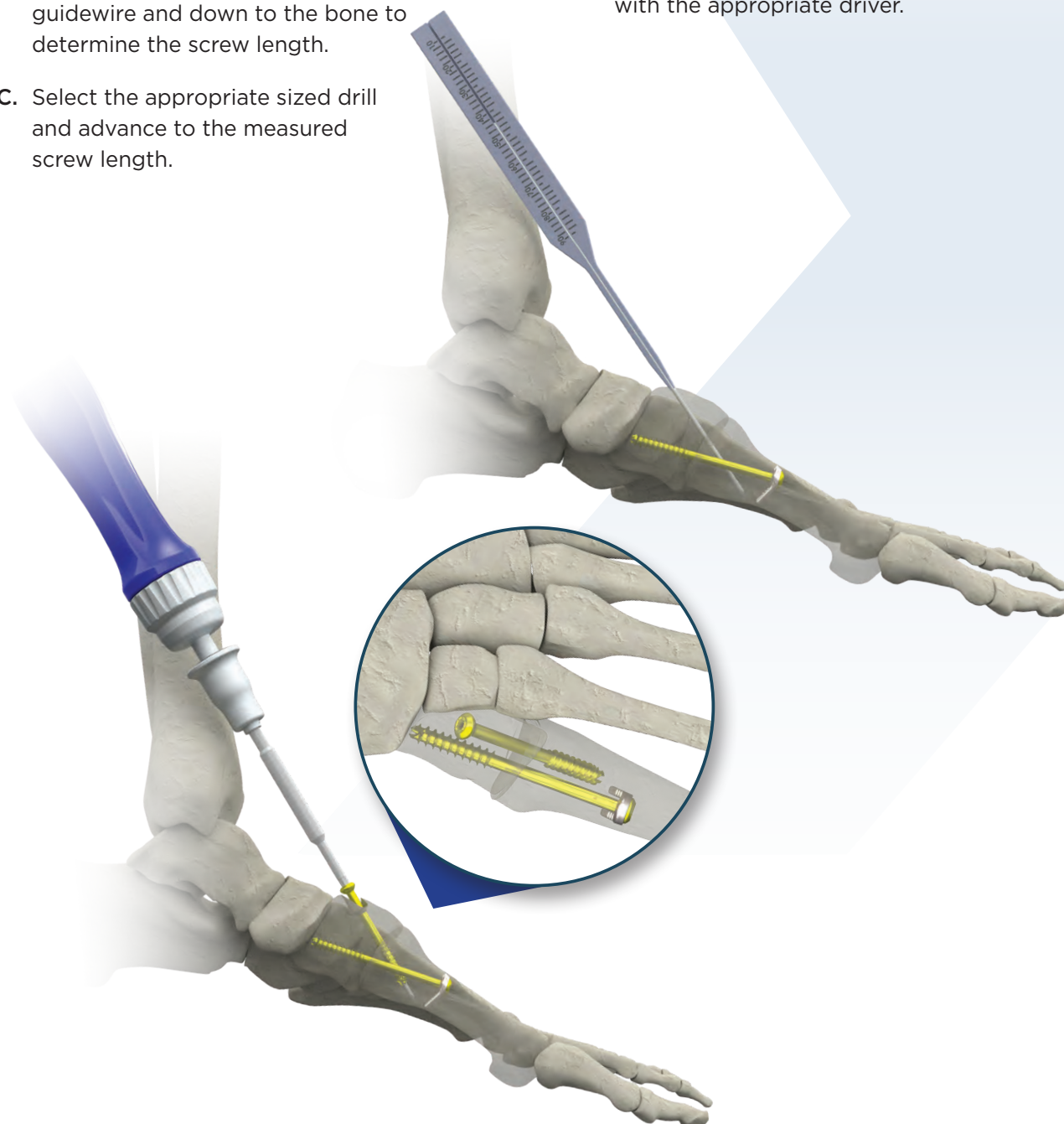


B



STEP 20. Supplemental Fixation (Optional) Insert Lag Screw to Provide Additional Stability

- A. Advance a 1.6mm guidewire to the desired screw placement location.
- B. Slide the depth gauge over the 1.6mm guidewire and down to the bone to determine the screw length.
- C. Select the appropriate sized drill and advance to the measured screw length.
- D. Advance the countersink over the Guidewire until the depth line is no longer visible.
- E. Insert the screw to the desired position with the appropriate driver.



Removal Instructions:

It is recommended to remove the Lag Screw prior to removing the X-Post:

Lag Screw Removal

Clear any tissue or bony ingrowth from the screw head. A Guidewire may be introduced into the cannulation for guidance of the implant driver. Insert the Driver into the screw and back out the screw by turning counterclockwise.

X-Post Removal

Expose the site and bridge of the X-Post. If the X-Post is recessed, use an elevator to lift the implant bridge. Reattach the X-Post Insert or utilize forceps to remove the implant by tamping outward.

Indications for use:

- *The IO Freedom System is intended for reduction and internal fixation of arthrodeses, osteotomies, intra-and extra-articular fractures, and nonunions of the small bones and joints of the foot and ankle, appropriate for the size of the device.*
- *Lapidus Instruments are designed to facilitate joint preparation and deformity correction of the 1st metatarsal prior to fusion of the first TMT joint.*

Lapidus System Components

Part #	Description
168-00000	Lapidus System — Joint Prep and Alignment Tray
168-01001	Hallux Valgus Reduction Clamp, Medial Arm Assembly, Right
168-01002	Hallux Valgus Reduction Clamp, Medial Arm Assembly, Left
168-02001	Hallux Valgus Reduction Clamp, Lateral Arm, Right
168-02002	Hallux Valgus Reduction Clamp, Lateral Arm, Left
168-05010	Cartilaginator (Saw Rasp), Single-Sided, Stryker
168-05020	Cartilaginator (Saw Rasp), Double-Sided, Stryker
168-00010	Distraction Guide
168-00020	Seeker Tab
168-00030	Joint Seeker, 4mm x 8mm
168-00040	Paddle Distractor, 4mm x 8mm
168-00050	Joint Prep Cup Curette, 7mm x 5mm
168-00060	2.0mm Guidewire Holder, 180mm
168-00070	2.0mm Guidewire, 150mm
168-00080	Metatarsal Base Spacer
147-00010	Fenestrating Drill Guide
147-00020	Slim Fenestrating Drill
101-00006	1.6mm Guidewire
101-00009	1.6mm Guidewire Holder
144-00030	Joint Prep Rasp
168-00100	1.6mm Olive Wire Tack, Smooth, 30mm

IO Freedom Component List: Implants

IO Freedom X-Posts

Part #	Description
147-35815	3.5mm FREEDOM X-Post 15mm
147-35820	3.5mm FREEDOM X-Post 20mm
147-35825	3.5mm FREEDOM X-Post 25mm
147-35830	3.5mm FREEDOM X-Post 30mm
147-45815	4.5mm FREEDOM X-Post 15mm
147-45820	4.5mm FREEDOM X-Post 20mm
147-45825	4.5mm FREEDOM X-Post 25mm
147-45830	4.5mm FREEDOM X-Post 30mm
147-65820	6.5mm FREEDOM X-Post 20mm
147-65825	6.5mm FREEDOM X-Post 25mm
147-65830	6.5mm FREEDOM X-Post 30mm
147-65835	6.5mm FREEDOM X-Post 35mm

IO Freedom Washers

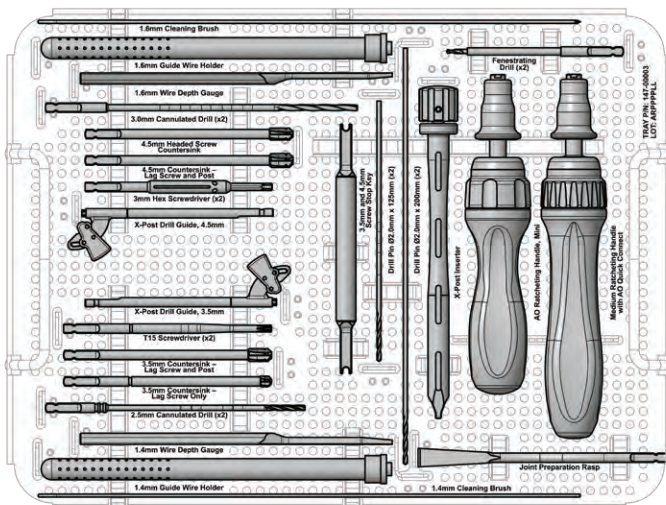
Part #	Description
147-35600	3.5mm Screw Washer
148-35451	4.5mm Screw Washer
147-65600	6.5mm Screw Washer

IO Freedom Reusable Instruments

Part #	Description
101-00009	Guidewire Holder - 1.6mm
118-00030	3.0mm Hex Driver
118-02039	Ratcheting Handle, medium
101-00010	1.6mm Wire Depth Gauge
132-00214	1.4mm Guidewire Holder
136-00006	2.0mm Guidewire Holder
136-00022	2.0mm Wire Depth Gauge
136-00024	T25 Driver
144-00013	1.4mm Wire Depth Gauge
144-00015	T15 Driver
147-01000	X-Post Inserter
147-05035	X-Post Drill Guide, 3.5mm
147-05045	X-Post Drill Guide, 4.5mm
147-05065	X-Post Drill Guide, 6.5mm
147-06043	3.5mm and 4.5mm Screw Stop Key
147-06064	4.5mm and 6.5mm Screw Stop Key
148-02039	Ratcheting Handle, mini

IO Freedom Disposable Instruments

Part #	Description
101-00006	1.6mm Guidewire
101-00023	1.6mm Cleaning Brush
118-02030	3.0mm Cannulated Drill
118-02045	4.5mm Lag Screw Countersink
147-02012	Drill Pin, 2.0 x 125mm
147-02020	Drill Pin, 2.0 x 200mm
147-02512	Drill Pin, 2.5 x 125mm
147-02520	Drill Pin, 2.5 x 200mm
130-02200	2.0mm Cleaning Brush
136-00005	2.0mm Guidewire
136-00145	4.5mm Cannulated Drill
144-00012	3.5mm Lag Screw Countersink
144-00014	1.4mm Guidewire
144-00025	2.5mm Cannulated Drill
147-00023	1.4mm Cleaning Brush
147-01035	3.5mm X-Post Countersink
147-01045	4.5mm X-Post Countersink
147-01065	6.5mm X-Post Countersink
147-03065	6.5mm Lag Screw Countersink
147-07035	3.5mm Lag Screw Stop Washer
147-07045	4.5mm Lag Screw Stop Washer
147-07065	6.5mm Lag Screw Stop Washer
144-00032	Fenestrating Drill
144-00030	Joint Preparation Rasp



Lapidus Instrumentation

Joint Preparation and Alignment

Delivering
a smarter approach for fracture
Period.

Real change *starts* here™

EXTREMITY[®]
MEDICAL

Real change *starts* here™

888.499.0079

973.588.8980

ExtremityMedical.com

customerservice@ExtremityMedical.com

300 Interpace Parkway, Building A, Floor 2 | Parsippany, NJ 07054