

Axle®

Interspinous Fusion System



SURGICAL TECHNIQUE

Axle Interspinous Fusion System Surgical Technique

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SURGICAL TECHNIQUE – Axle and Axle-X

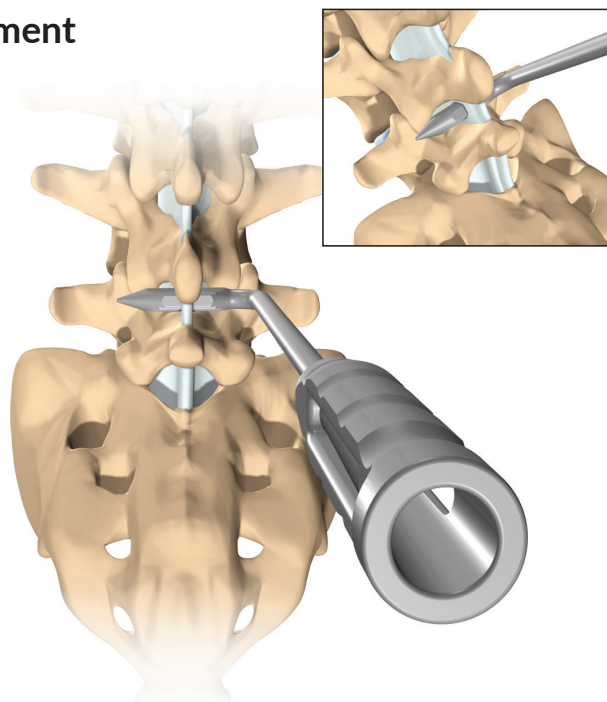
Step 1: Patient Positioning and Approach

- Position the patient in the prone position on the operating table.
- Identify the spinous processes at the level to be instrumented, using manual palpation and intraoperative imaging.
- Make a midline incision about 3 cm in length to expose the spinous processes at the correct level.
- Elevate the paraspinal musculature and other soft tissue to expose the spinous processes and lamina to the medial border of the facet joints. Depending on the surgeon's preferred technique, the supraspinous ligament may be left intact, reflected or removed entirely.
- Clear the fusion site of connective and soft tissues, lightly decorticating the bone surfaces. When fusing through the spinous processes, a burr, ronguer or rasp may be used to remove the interspinous ligament. The interspinous ligament may optionally be incised/dilated without complete removal.
- If a decompression procedure is desired, perform a conservative laminotomy, partial facetectomy, foraminotomy or other decompression procedure as needed, using care to leave the spinous process intact.
- If the facets are hypertrophied and do not allow for proper anterior placement of the implant, the facets may be trimmed. Do not perform a complete facetectomy. Preserving a sufficient portion of the facets to provide biomechanical stability for axial rotation and transverse shear loads is required.

Step 2: Initial Dilation of the Interspinous Ligament

- If the interspinous ligament has been left intact, insert the Interspinous Ligament Piercer-Rasp and puncture the interspinous ligament, placing it as far anterior as possible.

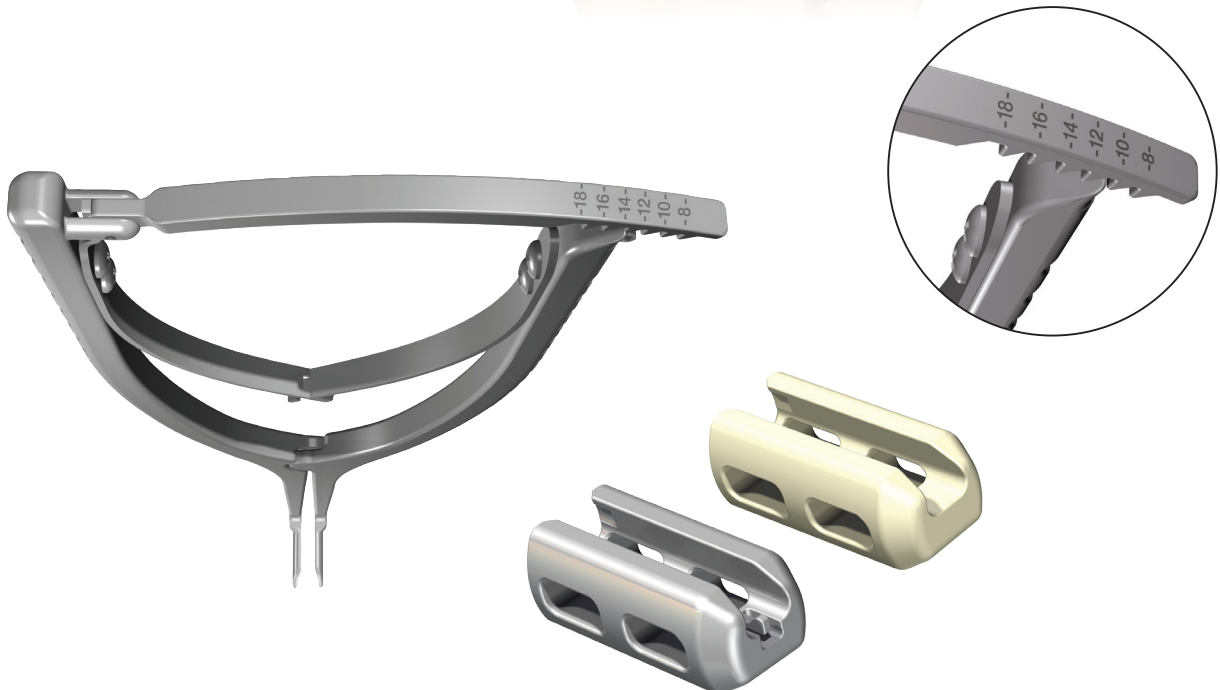
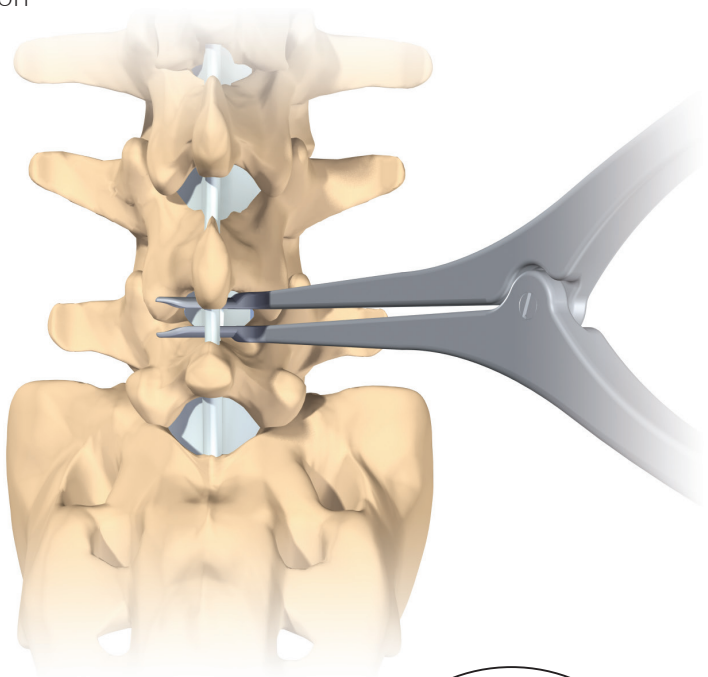
Warning : Do not direct the Piercer-Rasp in a ventral direction which could result in damage to neurological elements.



Step 3: Determine Size of Implant

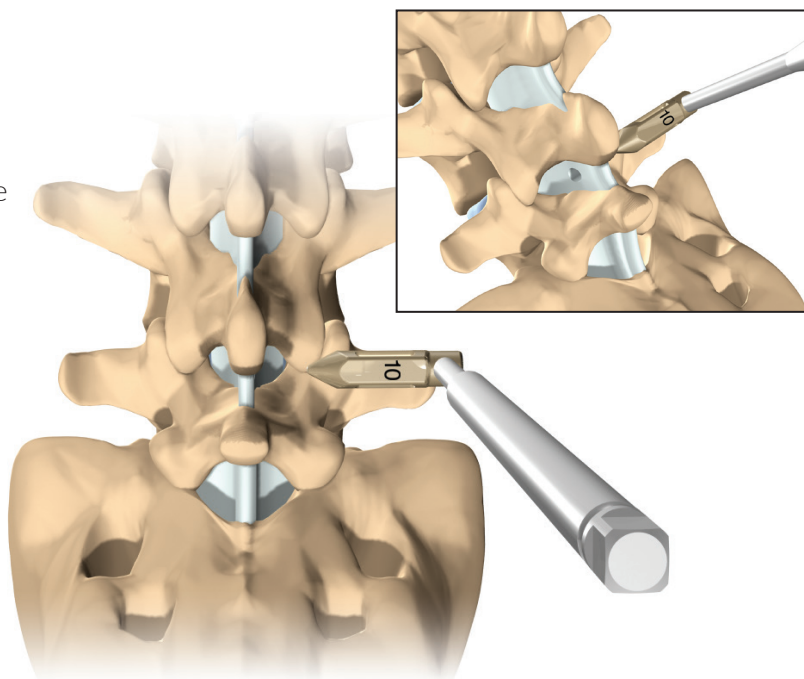
- Using the Spreader, insert into the interspinous ligament where the initial dilation was performed. Squeeze the handle until the desired distraction is achieved and insert size is determined.

Note : As a precaution leave the ratcheting mechanism up until desired distraction is felt. Once the desired distraction is felt, drop the ratchet bar down to determine correct implant size.



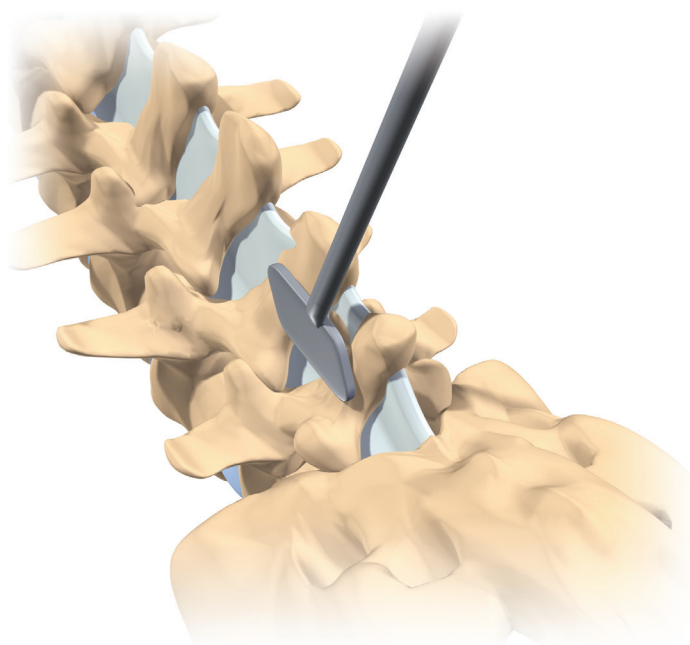
Step 4: Trial-Rasps

- Once the Insert size has been determined, use the correlating Trial-Rasp to decorticate the spinous processes. Work the Trial-Rasp in a cephalad to caudad motion to achieve best results.



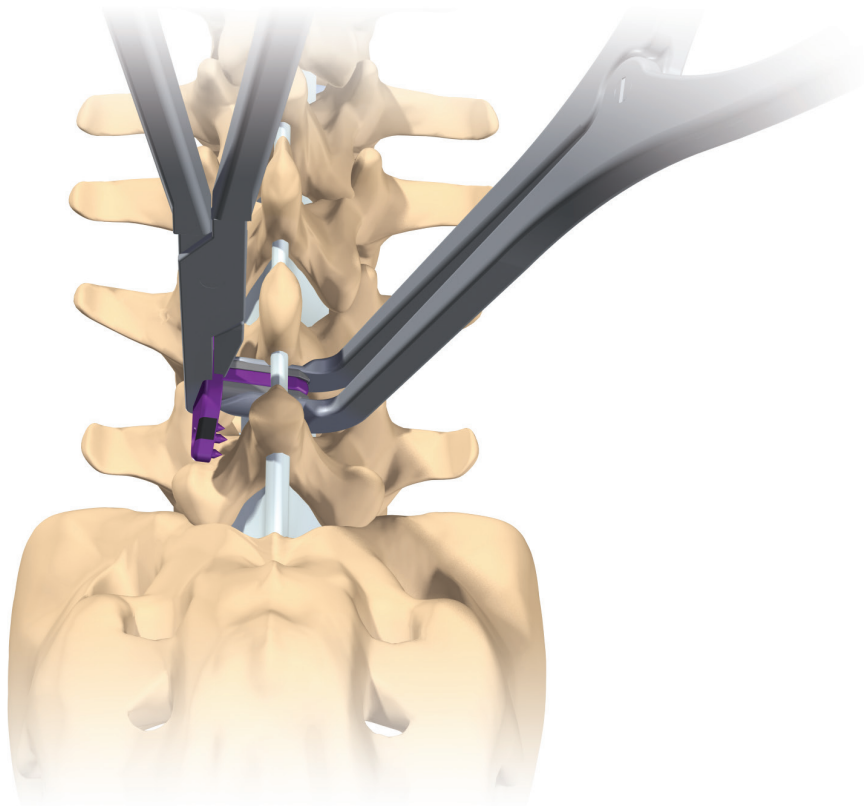
Step 5: Plate Sizing (Length)

- Place the Plate Sizer instrument laterally, (28mm, 32mm, 36mm, 40mm or 55mm) to visually determine the length of the plate.



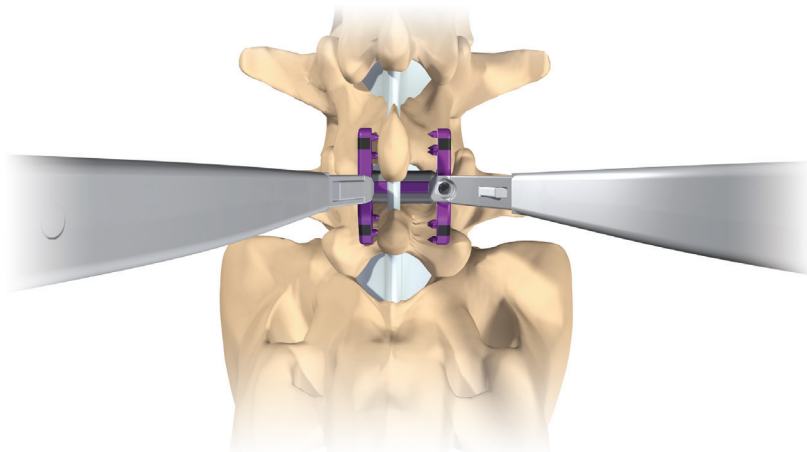
Step 6: Cross Bar Plate Insertion

- **Technique 1** (shown) : Re-insert the Spreader into the interspinous space and ratchet to the previously determined implant size. Introduce the implant, via the Cross Bar Plate Inserter, into the Spreader until the implant insert has been fully pushed through the interspinous space.
- **Technique 2** (not shown) : Utilizing the Cross Bar Plate Inserter, press the implant through the previously dilated space until the bullet tip of the Insert is fully through.



Step 7: Locking Plate Introduction

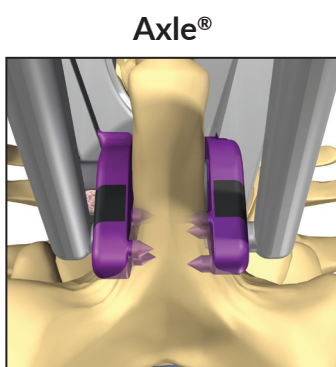
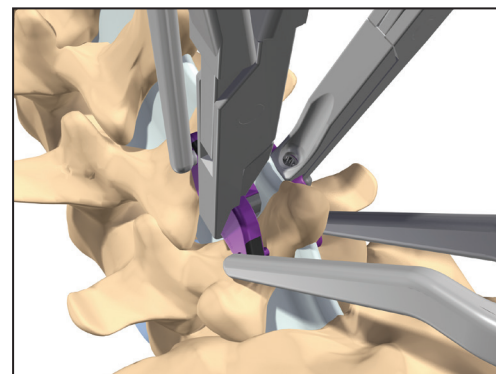
- Using the corresponding Locking Plate based upon the predetermined Insert size, slide the Locking Plate over the Insert/ Cross Bar Plate until it comes in contact with the spinous processes.



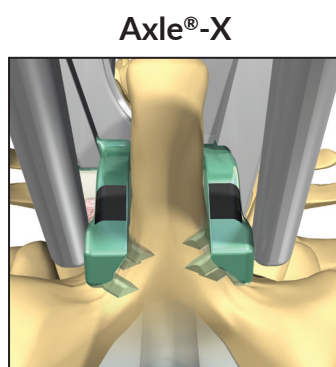
Step 8: Compression of Plate

- Align the spherical tips of the Compressors into the round lateral pockets in each Axle/Axle-X Plate. Prior to applying compression, take a lateral X-ray to confirm proper positioning. Using the Compressors, clamp the plates against the spinous processes, driving the spikes into the bone.

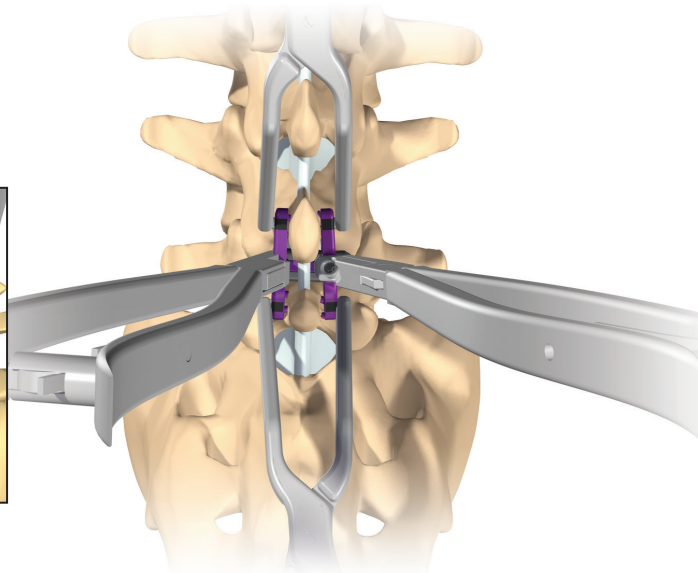
Warning : Placement of excessive force on Compressors may result in spinous process failure.



Axle®

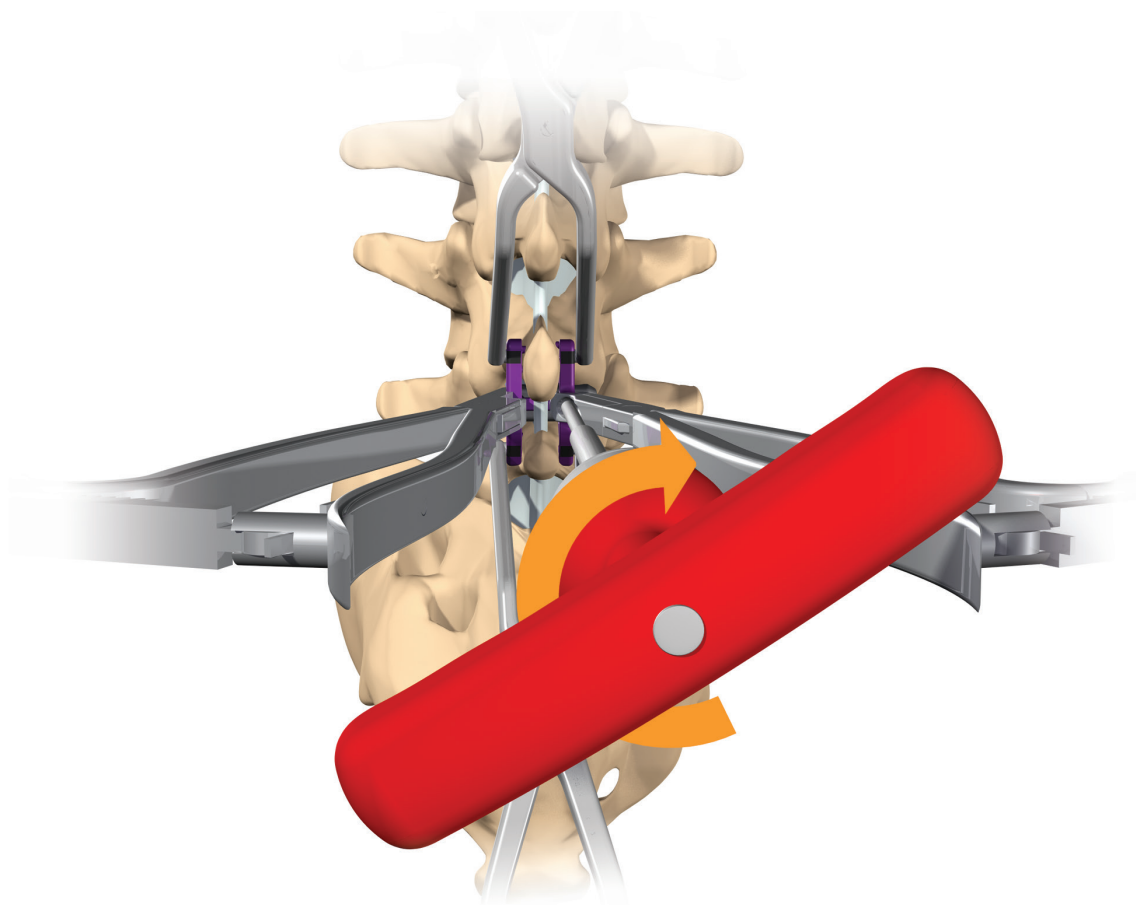
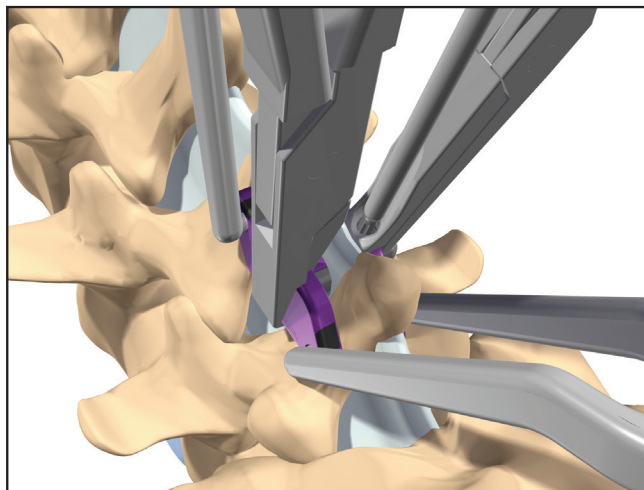


Axle®-X



Step 9: Final Locking of Plates

- Slide the Torque Limiting T-Handle with attached Screwdriver into the set screw of the Locking Plate and rotate clockwise until 2 audible clicks are heard.

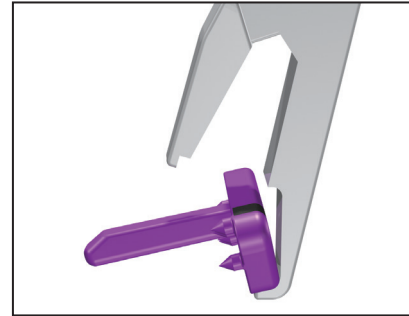


ASSEMBLY OF INSTRUMENTS

Cross Bar Plate Inserter

Step 1: Loading Cross Bar Plate onto Inserter

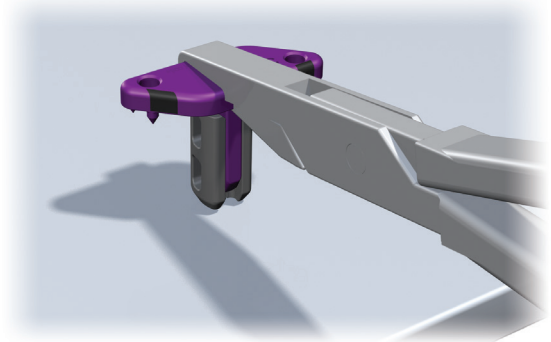
- Tilt the desired implant, bottom first, into the Cross Bar Plate Inserter while simultaneously squeezing the instrument until the implant is secured.



Step 2: Loading Insert onto Cross Bar Plate

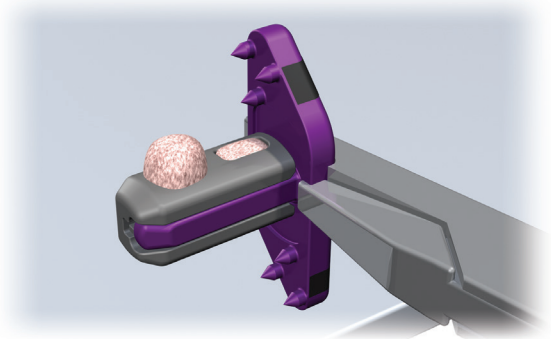
- Press the Insert firmly against a sterile table to lock the Insert onto the Cross Bar Plate.

Note : Visually inspect to make sure there is no space between the Insert and the base of the Cross Bar Plate. This will minimize the possibility of the insert slipping on the Cross Bar.



Step 3: Loading Insert with Bone Graft

- Pack the implant with the desired bone graft by hand.



Locking Plate Inserter

Step 1: Loading Locking Plate onto Inserter

- Using the correlating Locking Plate based upon the predetermined Insert size, squeeze the Locking Plate Inserter until there is no movement between the Locking Plate and Inserter.

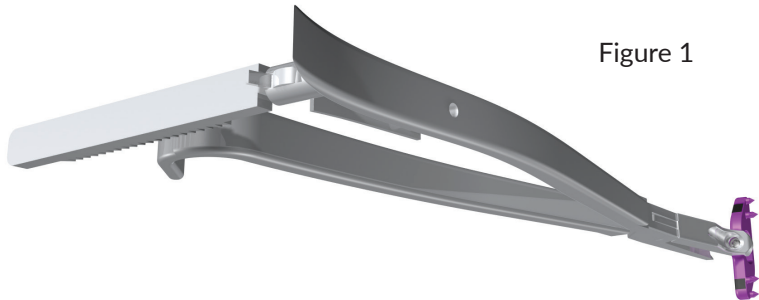


Figure 1

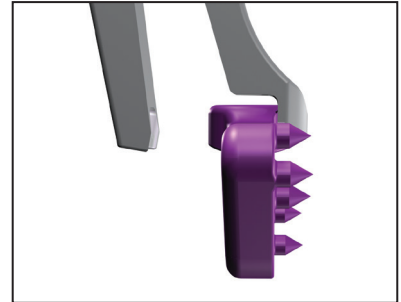


Figure 2

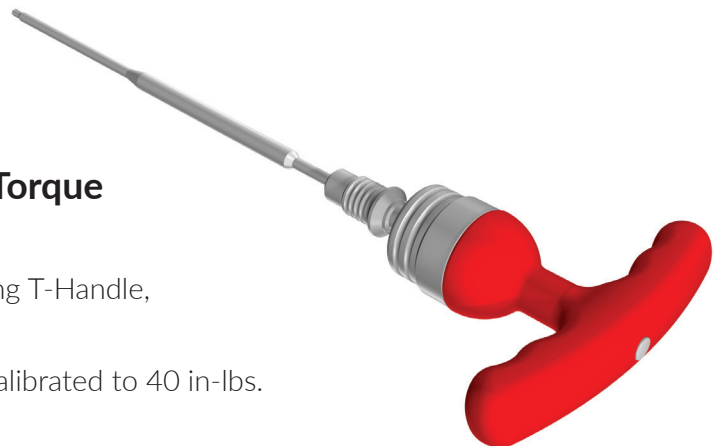


Screwdriver

Step 1: Load Screwdriver Shaft to Torque Limiting T-Handle

- Pull back the chuck on the Torque Limiting T-Handle, insert the Screwdriver Shaft and release.

Note : The Torque Limiting T-Handle is calibrated to 40 in-lbs.



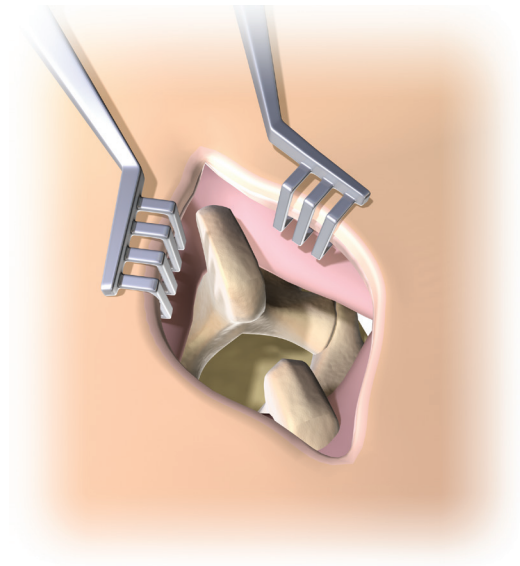
Axle® All-In-One Inserter (X060-0520) – For 36 and 40mm Plates Only

The Axle® All-In-One inserter is designed to insert, compress and final tighten the Axle® implant without the need of additional instruments.

Note : For use with Axle® 36mm and 40mm Plates only.

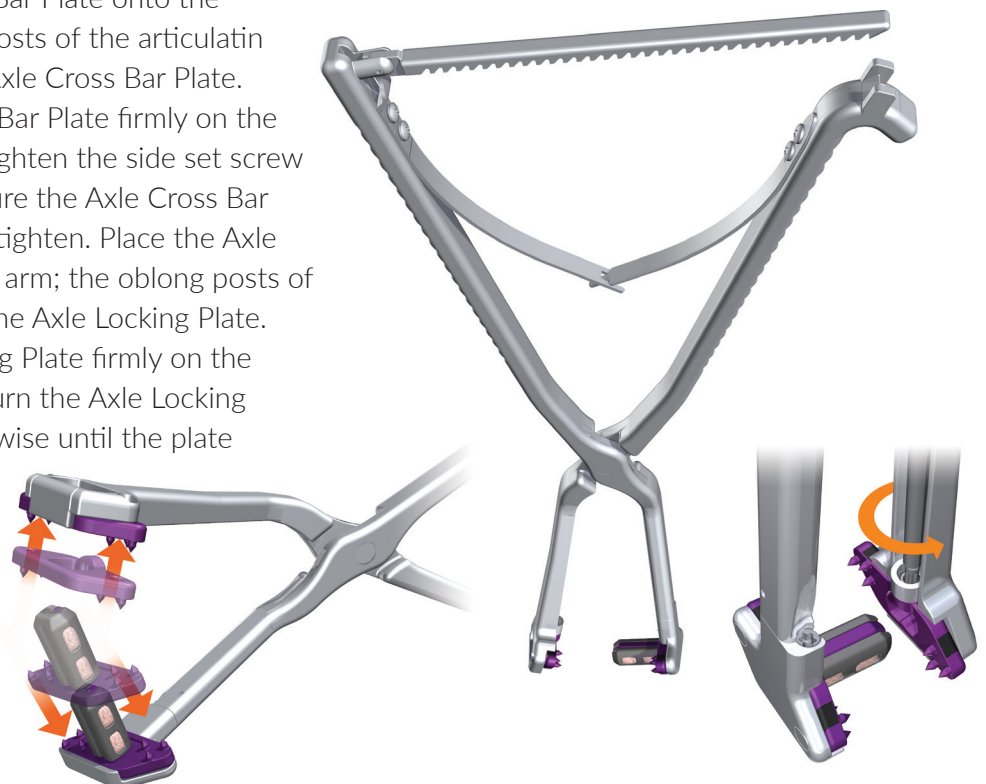
Step 1: Exposure

- Elevate the paraspinal musculature and other soft tissue to expose the spinous processes and lamina to the medial border of the facet joints. Clear the fusion site of connective and soft tissues, lightly decorticating the bone surfaces. Using a rongeur, or similar instrument, remove both the supraspinous and interspinous ligament. If a decompression procedure is desired, perform a conservative laminotomy, partial facetectomy, foraminotomy or other decompression procedure as needed, using care to leave the spinous processes intact.



Step 2: Inserter Assembly

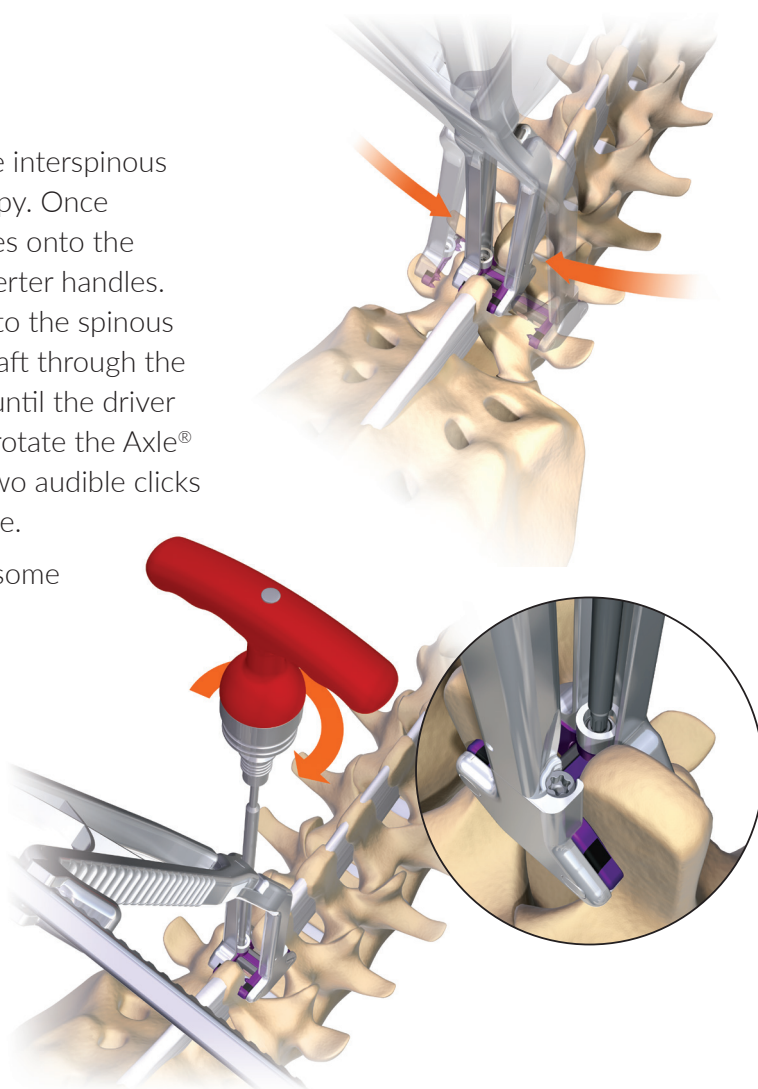
- Position the Axle All-In-One Inserter so that it is vertical. Place the Axle Cross Bar Plate onto the articulating arm; the oblong posts of the articulating arm go into the holes of the Axle Cross Bar Plate. While holding the Axle Cross Bar Plate firmly on the arm, use the Screwdriver to tighten the side set screw of the articulating arm to secure the Axle Cross Bar Plate to the arm, do not over tighten. Place the Axle Locking Plate on the opposite arm; the oblong posts of the arm go into the holes of the Axle Locking Plate. While holding the Axle Locking Plate firmly on the arm, use the Screwdriver to turn the Axle Locking Plate set screw counter-clockwise until the plate is secured.



Step 3: Implant Insertion

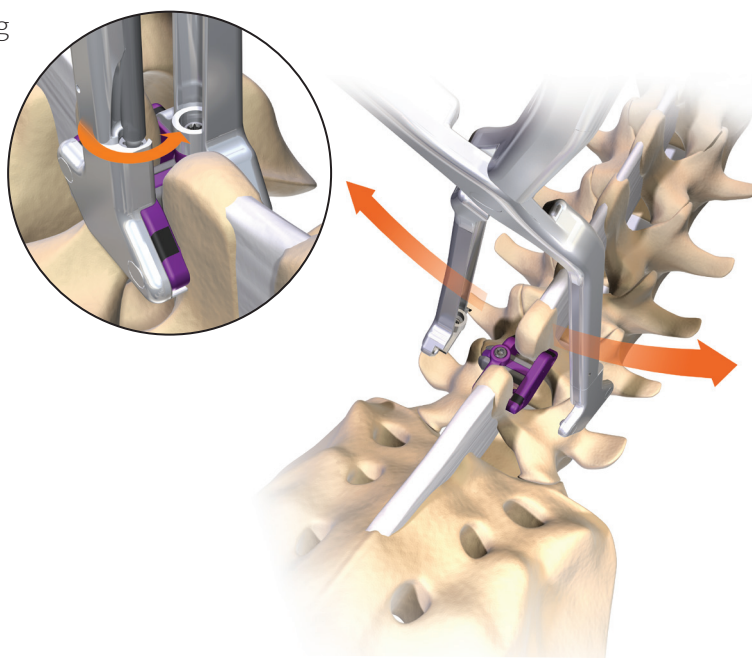
- Once loaded, lower the instrument into the interspinous space and confirm placement via fluoroscopy. Once placement is confirmed, compress the plates onto the spinous processes by squeezing on the inserter handles. After the implant has been compressed onto the spinous processes, slowly guide the Screwdriver shaft through the instrument and into the recessed channel until the driver tip is fully seated into the set screw. Then rotate the Axle® Torque Limiting T-Handle clockwise until two audible clicks are heard confirming that the plate is secure.

Note : When tightening on the Cross Bar, some initial tension could be encountered.



Step 4: Removal of Instrument

- Loosen the side set screw of the articulating arm to disengage the Axle Cross Bar Plate from the instrument. Open the ratcheting arm at the handle of the instrument to release the compression on both plates. Then slowly open both handles laterally to disengage the inserter from the implant. Once visually confirmed that the implant and inserter are fully disengaged slowly remove the inserter.



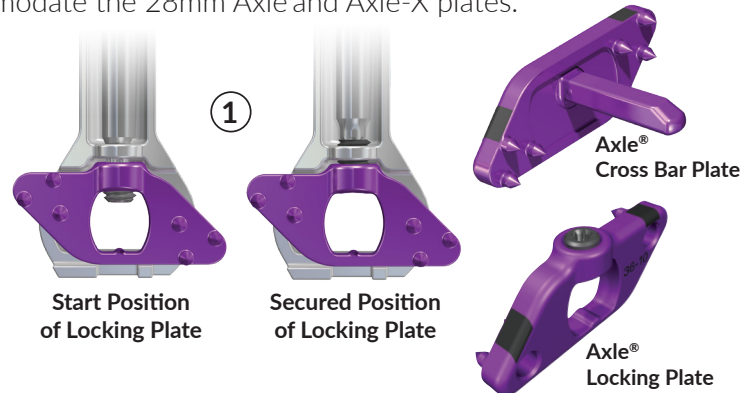
Axle/Axle-X Universal All-In-One Insertor (X060-1520) – For 32mm, 36mm, 40mm, and 55mm Plates Only

The Axle/Axle-X Universal All-In-One Insertor is designed to insert, compress and final tighten the Axle/Axle-X implant without the need of additional instruments.

Note : The Axle/Axle-X Universal AIO does not accommodate the 28mm Axle and Axle-X plates.

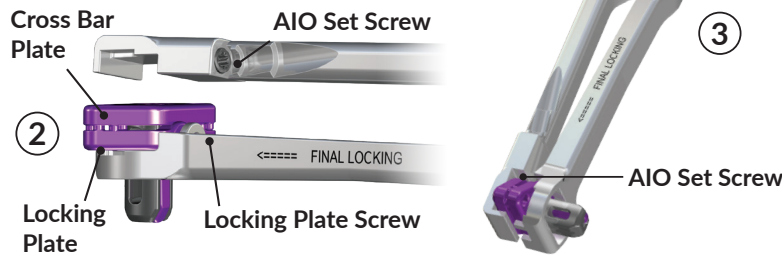
Step 1: Assembly

- Open the AIO inserter by releasing the ratchet arm. Place the Axle Locking Plate onto the AIO inserter on the Locking Plate side. Secure the Axle Locking Plate into the AIO inserter by turning the Locking Plate screw counter-clockwise with the torque driver(1).



Step 2: Assembly Continued

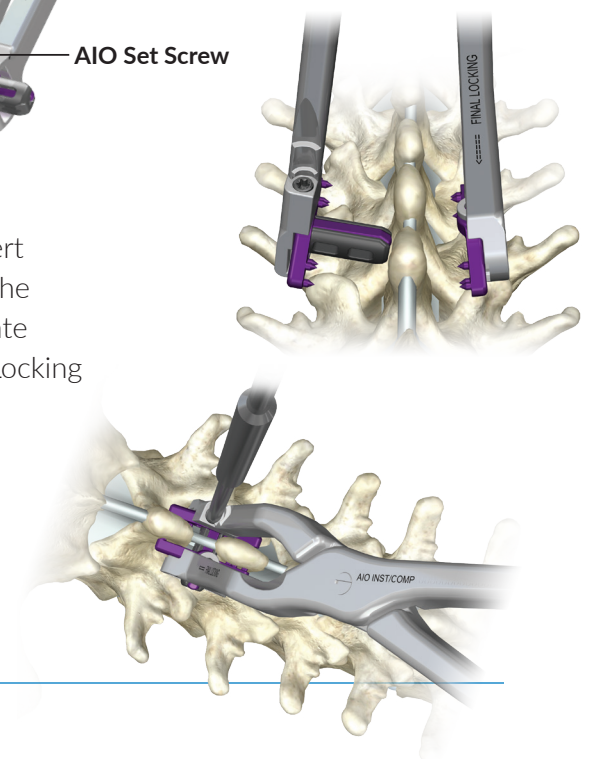
- Place the Axle Cross Bar Plate into the Axle Locking Plate(2). Close the AIO inserter by engaging the ratchet arm. Secure the Axle Cross Bar Plate onto the AIO inserter by turning the AIO Set Screw clockwise with the torque driver. Both the Axle Cross Bar Plate and the Axle Locking Plate will be secured to the AIO inserter(3).



Step 3: Implantation

- Open the AIO inserter with the secured Axle implants and insert it into the desired operative location. Once seated, compress the ratchet at the proximal end of the AIO. After compressing, locate the laser markings, "FINAL LOCKING", to identify the correct Locking Plate Screw. Use the torque driver to rotate clockwise for final tightening.

Once final tightening has occurred, disengage the AIO Set Screw that is securing the Cross Bar Plate by turning the torque driver counter-clockwise.



ALTERNATIVE INSERTION TECHNIQUES

Provisional Lock

Axle was designed with a 3 degree taper on the Cross Bar to allow the Locking Plate to be tightened into a provisionally locking position while fully removing the Locking Plate instrumentation. This allows the removal of the Locking Plate Inserter without having the plate disassemble while engaging the Compressors.

**Turn Torque Limiting
T-Handle until hand-tight.
Do not overturn.**

Step 1: Securing the Locking Plate onto the Cross Bar Plate

- After completing steps 1-6, insert the Screwdriver into the set screw of the Locking Plate and hand tighten until secure. Remove the Screwdriver from the Locking Plate.

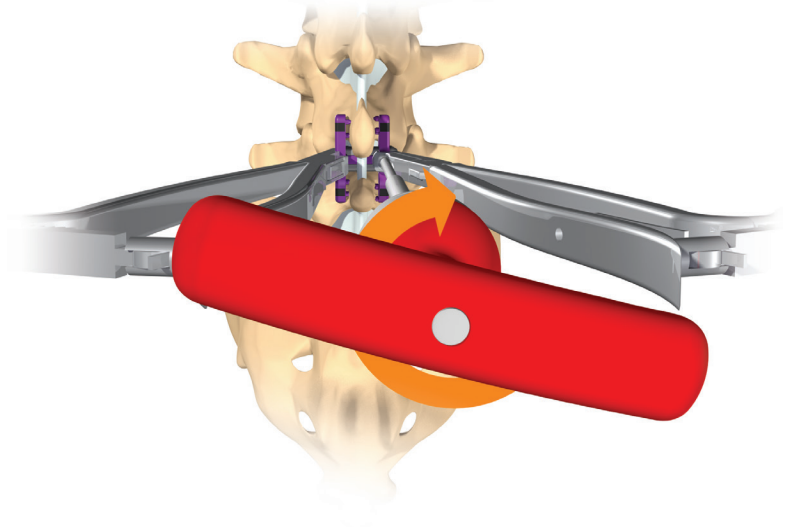


Fig. 1

Step 2: Removal of Inserter

- Flip the ratcheting mechanism up to release the Inserter from the implant and compress the plates.

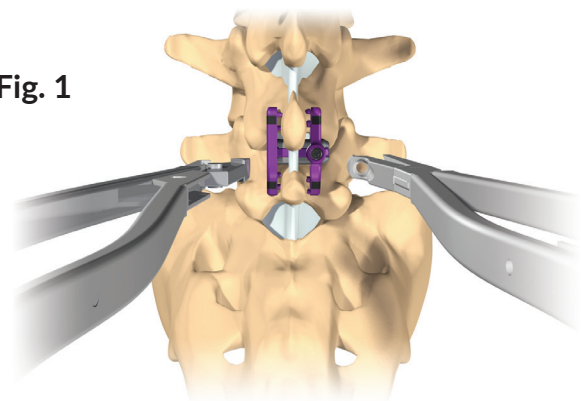
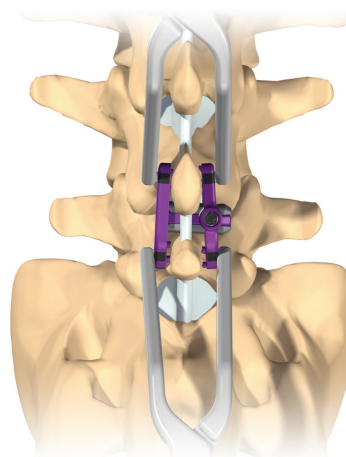


Fig. 2



Pre-Assembly

If desired the Axle Implant can be pre-assembled on the back table to allow for insertion. This technique includes the removal of the supraspinous and interspinous ligaments to allow the implant to be lowered into place utilizing a single instrument.

Step 1:

- Attach the appropriate Insert to the pre-sized Cross Bar Plate.

Step 2:

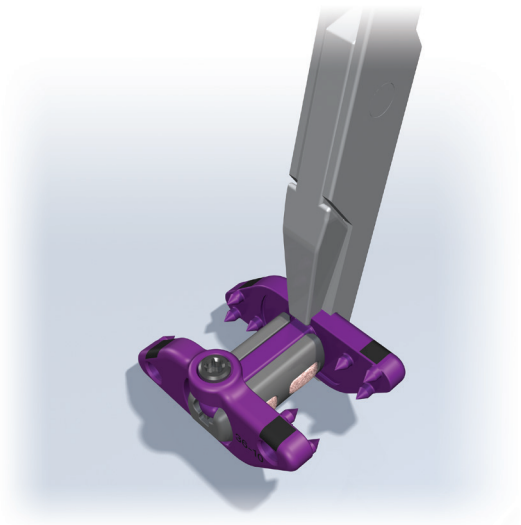
- Using the corresponding Locking Plate based upon the predetermined Insert size, slide the Locking Plate over the Insert/Cross Bar Plate until just the tip of the Cross Bar Plate is showing.

Step 3:

- Insert the Screwdriver and hand tighten until secure..

Step 4:

- Tilt the implant, bottom first, into the Cross Bar Plate Inserter while simultaneously squeezing the instrument until the Insert is secured.



Axle® Removal

Step 1:

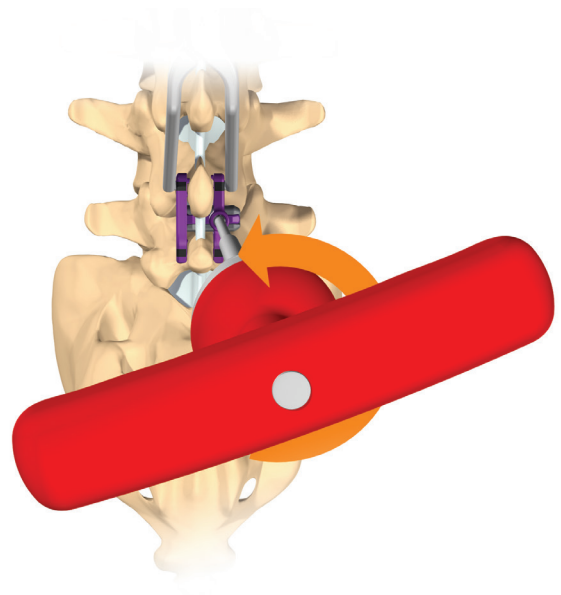
- Place a single Compressor onto the implant and compress until the spherical tips are fully seated into the round lateral pockets of the Axle plate.

Step 2:

- Insert the Screwdriver into the set screw and, while maintaining compression on the single Compressor, turn the Torque Limiting T-Handle counter clockwise until the Locking Plate has been loosened.

Step 3:

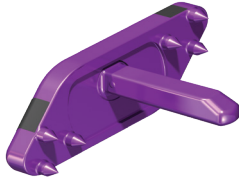
- Using an elevator or forceps, gently push the Insert through the interspinous space and remove the Locking Plate, Cross Bar Plate, and Insert.



Axle and Axle-X Implants

Axle Cross Bar Plates

Description
Cross Bar Plate, 28mm
Cross Bar Plate, 32mm
Cross Bar Plate, 36mm
Cross Bar Plate, 40mm
Cross Bar Plate, 55mm



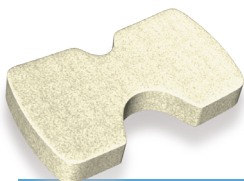
Axle Locking Plates

Description	Description
Locking Plate, 28mm, 8mm	Locking Plate, 36mm, 16mm
Locking Plate, 28mm, No Insert	Locking Plate, 36mm, No Insert
Locking Plate, 32mm, 8mm	Locking Plate, 40mm, 8mm
Locking Plate, 32mm, 10mm	Locking Plate, 40mm, 10mm
Locking Plate, 32mm, 12mm	Locking Plate, 40mm, 12mm
Locking Plate, 32mm, No Insert	Locking Plate, 40mm, 14mm
Locking Plate, 36mm, 8mm	Locking Plate, 40mm, 16mm
Locking Plate, 36mm, 10mm	Locking Plate, 40mm, 18mm
Locking Plate, 36mm, 12mm	Locking Plate, 40mm, No Insert
Locking Plate, 36mm, 14mm	Locking Plate, 55mm, No Insert



Axle Inserts

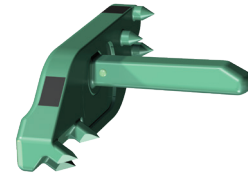
Description	Description
Insert, Titanium, 8mm	Insert, PEEK, 8mm
Insert, Titanium, 10mm	Insert, PEEK, 10mm
Insert, Titanium, 12mm	Insert, PEEK, 12mm
Insert, Titanium, 14mm	Insert, PEEK, 14mm
Insert, Titanium, 16mm	Insert, PEEK, 16mm
Insert, Titanium, 18mm	Insert, PEEK, 18mm



H-shaped cortical allograft block available in 2mm increments from 8mm to 20mm.

Axle-X Cross Bar Plates

Description
Cross Bar Plate, 32mm
Cross Bar Plate, 36mm
Cross Bar Plate, 40mm



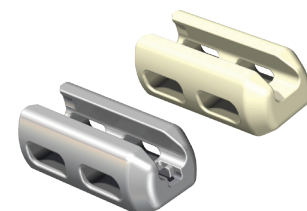
Axle-X Locking Plates

Description
Locking Plate, 32mm, 8mm
Locking Plate, 32mm, No Insert
Locking Plate, 36mm, 8mm
Locking Plate, 36mm, 10mm
Locking Plate, 36mm, 12mm
Locking Plate, 36mm, No Insert
Locking Plate, 40mm, 8mm
Locking Plate, 40mm, 10mm
Locking Plate, 40mm, 12mm
Locking Plate, 40mm, 14mm
Locking Plate, 40mm, 16mm
Locking Plate, 40mm, No Insert



Axle-X Inserts

Description	Description
Insert, Titanium, 8mm	Insert, PEEK, 8mm
Insert, Titanium, 10mm	Insert, PEEK, 10mm
Insert, Titanium, 12mm	Insert, PEEK, 12mm
Insert, Titanium, 14mm	Insert, PEEK, 14mm
Insert, Titanium, 16mm	Insert, PEEK, 16mm



AXLE® INSTRUMENTS

Piercer-Rasp X060-0307



Plate Sizers



Size	Item #
Plate Sizer 36mm	X060-0336
Plate Sizer 40mm	X060-0340

Screwdriver X060-0320



Trial Rasps



Size	Item #
Trial Rasp 8mm	X060-0440
Trial Rasp 10mm	X060-0441
Trial Rasp 12mm	X060-0442
Trial Rasp 14mm	X060-0443
Trial Rasp 16mm	X060-0444
Trial Rasp 18mm	X060-0445

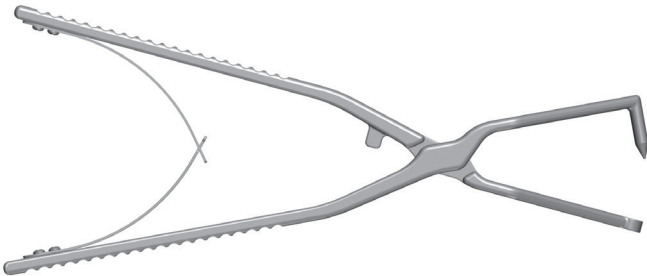
Inserters, Cross Bar Plate X060-0318



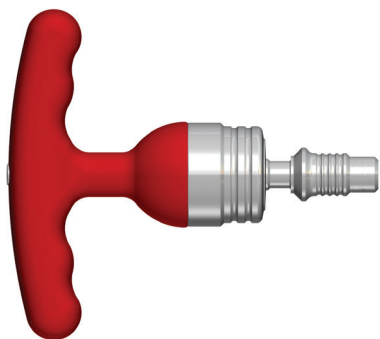
Inserters, Locking Plate X060-0319



Compression-Piercer X060-0328



Torque Limiting T-Handle X060-0322



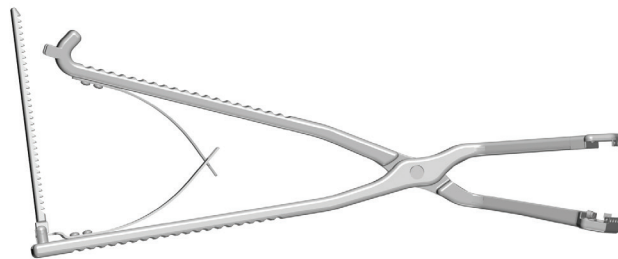
Torque Limiting Handle, AO Connect X060-0323



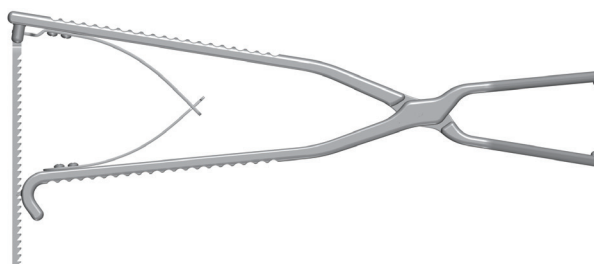
Fixed In-Line Handle, Square Connect X060-0324



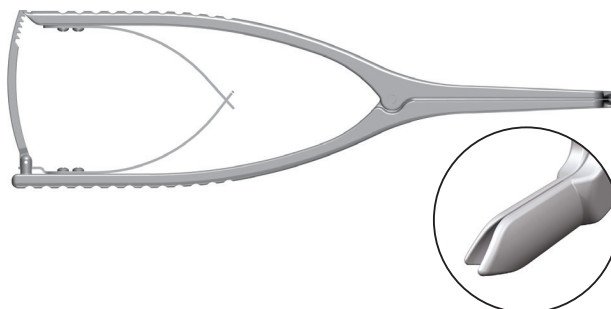
All-In-One Inserter X060-0520



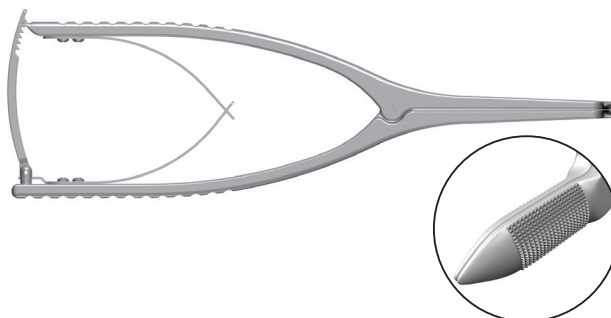
Compressor X060-0370



Spreader X060-0390



Variable Rasp X060-0410





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✉ cs@xtantmedical.com
🌐 xtantmedical.com

INDICATIONS: See Package Insert for a more complete listing of indications, contraindications, warnings, precautions, and other important information.

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WARNING: In the USA, this product has labeling limitations. See package insert for complete information. CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

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