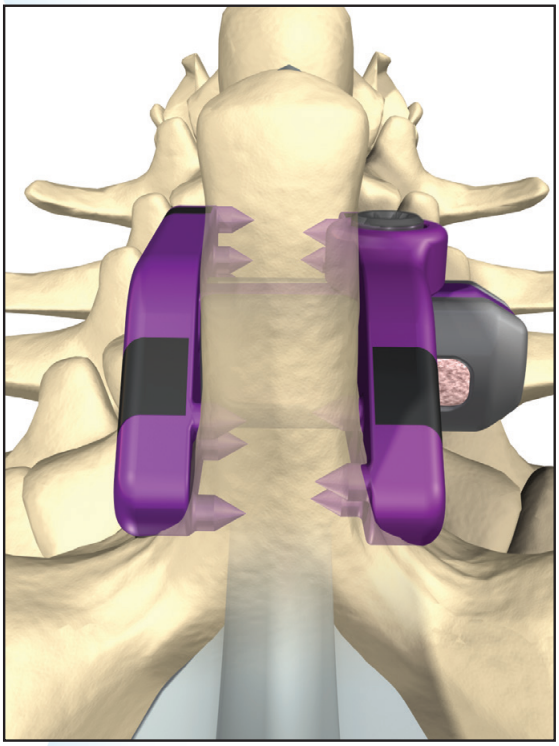
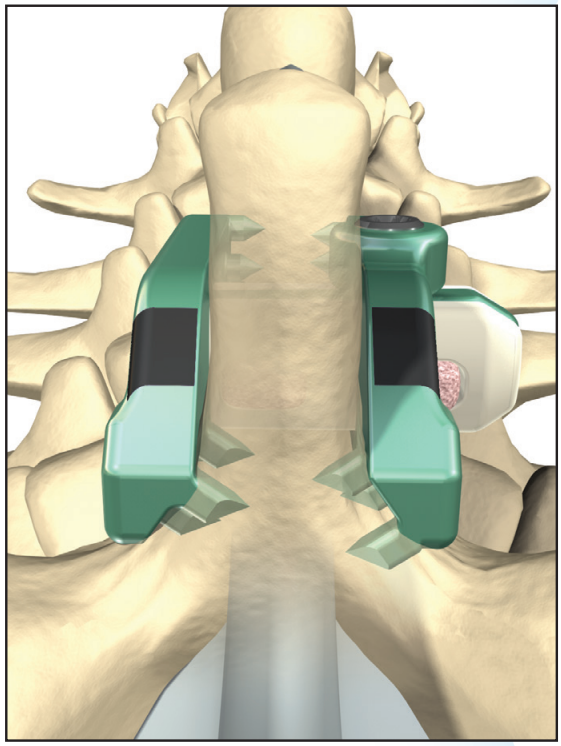
X-spine℠ Surgical Technique





AXLE® Interspinous Fusion System

AXLE-X™ Interspinous Fusion System

The AXLE® Interspinous Fusion System

X·spine℠

X·treme Innovations

yourspine

Distribuidor exclusivo em Portugal:

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⚠ IMPORTANT NOTE:

The user acknowledges that he/she has read and agreed to the conditions in this insert, which are to be considered as contractual.

GENERAL INFORMATION

The Axle Interspinous Fusion System of X-spine Systems, Inc., is an internal fixation device for spinal surgery. Various sizes of these implants are available so that adaptations can be made to take into account pathology and individual patients. The device may consist of titanium alloy (per ASTM F136), or both titanium alloy and polyetheretherketone (PEEK) (per ASTM F2026). All implants are intended for single use only and should not be reused under any circumstances.

INDICATIONS FOR USE

The Axle Interspinous Fusion System is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1 inclusive). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); and/or tumor. The Axle Interspinous Fusion System is intended for use with bone graft material, and not for stand-alone use.

CONTRAINDICATIONS

Contraindications for the Axle Interspinous Fusion System are similar to those of other systems of similar design, and include, but are not limited to:

1. Patients with probable intolerance to the materials used in the manufacture of this device.
2. Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness and other medical conditions which would prohibit beneficial surgical outcome.
3. Patients resistant to following post-operative restrictions on movement, especially in athletic and occupational activities.
4. Use with components from other systems.
5. Grossly distorted anatomy caused by congenital abnormalities.
6. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
7. Rapid joint disease, bone absorption, osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
8. Any case where the implant components selected for use would be too large or too small to achieve a successful result.

9. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
10. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
11. Any case not described in the indications for use.
12. Incompetent or missing posterior arch (e.g., laminectomy, pars defect, severe osteoporosis).
13. Reuse or multiple uses.
14. Prior fusion at the level to be treated.

⚠ WARNINGS AND PRECAUTIONS

The implantation of spinal implant systems should be performed only by experienced spinal surgeons with specific training in the use of the spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Knowledge of surgical techniques, proper reduction, selection and placement of implants, and pre- and post-operative patient management are considerations essential to a successful surgical outcome. Appropriate selection, placement and fixation of the spinal system components are critical factors which affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanics and other extrinsic factors, which limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions, and warnings for this product is essential to potentially maximize service life. (Note: While proper implant selection can minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of the implants).

Patients who smoke have been shown to have an increased incidence of pseudoarthrosis. Such patients should be advised of this fact and warned of the potential consequences. Patients with previous spinal surgery at the level to be treated may have different clinical outcomes compared to those without a previous surgery. Based on the fatigue testing results, the physician/surgeon should consider the level of implantation, patient weight, patient activity level, and other patient conditions, etc. which may have an impact on the performance of the system.

If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g. substantial walking, running, lifting, or muscle strain) resultant forces can cause failure of the device. In some cases, progression of degenerative disease may be so advanced at the time of implantation that the expected useful life of the appliance may be substantially decreased. In such cases, orthopedic devices may be considered only as a delaying technique or to provide temporary relief. Patients should be instructed in detail about the limitations of the implants, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The patient should understand that a metallic implant is not as strong as normal, healthy bone and will bend, loosen or fracture if excessive demands are placed on it. An active, debilitated, or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation.

Care must be taken to protect the components from being marred, nicked or notched as a result of contact with metal or abrasive objects. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.

As with all orthopedic and neurosurgical implants, none of the Axle Interspinous Fusion System components should ever be reused under any circumstances. Risks associated with reuse include infection, non-union (pseudarthrosis), serious patient injury or death.

Due to the presence of implants, interference with roentgenographic, CT and/or MR imaging may result. The Axle Interspinous Fusion System has not been evaluated for safety and compatibility in the MR environment. The Axle Interspinous Fusion System has not been tested for heating or migration in the MR environment. It must be noted that there are several different manufacturers and generations of MRI systems available, and X-spine cannot make any claims regarding the safety of X-spine implants and devices with any specific MR system.

Physician Note: The physician is the learned intermediary between the company and the patient. The indications, contraindications, warnings, and precautions given in this document must be conveyed to the patient. If requested, additional information, including surgical technique manuals, may be obtained through corporate sales representatives.

PREOPERATIVE MANAGEMENT

1. The surgeon should consider for surgery only those patients indicated for the use of this device.
2. The surgeon should not consider for surgery those patients contraindicated for the use of this device.
3. The surgeon should have a complete understanding of the device's indications, contraindications, and applications.
4. The surgeon should have a complete understanding of the function and limitations of each implant and instrument.
5. Device components should be received and accepted only in packages that have not been damaged or tampered with. Damaged implants and/or instruments should not be used. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
6. The type of implant to be used for the case should be determined prior to beginning the surgery.
7. All parts should be cleaned and sterilized before use.

INTRAOPERATIVE MANAGEMENT

1. Extreme caution should be used around the spinal cord and nerve roots. Damage to these structures will cause loss of neurological function.
2. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
3. Implants should be attached to the corresponding inserter such that they are fully seated on the inserter.
4. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.

5. Caution should be taken in handling the implants; Damage to the implants may affect their performance.
6. Implants should not be reused under any circumstances.

INSTRUCTIONS FOR USE

For complete instructions regarding the proper use and application of all Axle implants and instruments, please refer to the Axle Surgical Technique Manual (available at no charge upon request).

POSTOPERATIVE MANAGEMENT

Postoperative management by the surgeon, including instruction and warning to and compliance by the patient, of the following is essential:

1. The patient should have a complete understanding of and compliance with the purpose and limitations of the implant devices.
2. Postoperative patients should be instructed to limit activity.
3. Rigid external orthosis/bracing should be utilized until fusion is confirmed clinically and radiographically.
4. If required, the device may be disassembled for explantation. Care should be taken to avoid damaging the implant and surrounding tissue as little as possible. The explanted device should be cleaned and disinfected using the instructions provided for cleaning/disinfection of instruments. Information on the procedure and patient should be retained to assist in any investigation.
5. Retrieved implants should be properly disposed of and are not to be reused under any circumstances.

POTENTIAL COMPLICATIONS AND ADVERSE SIDE EFFECTS

Potential complications and adverse effects for this system are similar to those of other spinal instrumentation systems, and include, but are not limited to:

1. Early or late loosening of any or all of the components.
2. Disassembly, bending, and/or breakage of any or all of the components.
3. Foreign body (allergic) reaction to implants.
4. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
5. Infection.
6. Dural tears, persistent CSF leakage, meningitis.
7. Loss of neurological function including paralysis (partial or complete), radiculopathy, and/or the development or continuation of pain, numbness, spasms, or sensory loss.
8. Cauda equina syndrome, neurological deficits, paraplegia, reflex deficits, irritation, and/or muscle loss.
9. Loss of bladder control or other types of urological system compromise.
10. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
11. Fracture, micro-fracture, resorption, damage, or penetration of any spinal bone.
12. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
13. Non-union (pseudarthrosis), delayed union, mal-union.

14. Cessation of any potential growth of the operated portion of the spine.
15. Loss of or increase in spinal mobility or function.
16. Inability to perform the activities of daily living.

PACKAGING, LABELING, AND STORAGE

The implants are supplied clean and NON-STERILE. They must be sterilized (see below). The implants are delivered in packages. These must be intact at the time of receipt. All the legal information required for this type of implant is given on the label of each package. The implants may be delivered as a complete set: Implants and instruments are contained within specially designed trays or in boxes which can be sterilized directly. Use care in handling and storage of the implant components. Cutting, sharply bending, or scratching the surface can significantly reduce the strength and fatigue resistance of the implant system. This, in turn, could induce cracks and/or non-visible internal stresses that could lead to fracture of the implants. Implants and instruments in storage should be protected from corrosive environments such as salt, air, moisture, etc. Inspection and trial assembly are recommended prior to surgery to determine if instruments or implants have been damaged during the storage processes.

STERILIZATION

X-spine Axle System implants and all instruments are provided non-sterile and must be sterilized before use. All implants and instruments must be free of packaging material and bio-contaminants prior to sterilization. To achieve a sterility assurance level of not less than 10^{-6}, all non-sterile implants and instruments should be autoclave sterilized using the following validated cycle parameter:

Saturated steam method, pre-vacuum air removal, 270° F (132° C), 4-minute minimum exposure time, 30-minute minimum dry time, in a double–wrapped case configuration.

CLEANING OF INSTRUMENTS

⚠ Caution: Use of sodium hydroxide (NaOH) is prohibited. Use of corrosive products and/or instruments including abrasive sponges and metal brushes should be avoided. Cleaning must be performed by personnel trained in the general procedures involving contaminant removal. Automated washer/disinfector systems are not recommended as the sole cleaning method for surgical instruments. An automated system may be used in addition to the following manual cleaning procedure.

1. Thoroughly clean all instruments prior to use and as soon as possible after use (within a maximum of 2 hours post-operation) with intensive rinsing under cool tap water (<40°C) to remove gross soil. Do not allow blood and debris to dry on the instruments. If cleaning must be delayed, place instruments in a covered container with appropriate detergent (Enzol® Enzymatic Detergent or equivalent) to delay drying.
2. No instruments within this system require disassembly as part of the cleaning process.

3. The following table describes the required steps for thoroughly cleaning the system instruments:

Step	Agent	Minimum Time (mm:ss)
	Instructions	
1. Initial Clean	Enzol Enzymatic Detergent Solution (or equivalent)	10:00
	Add one (1) ounce (30 mL) of Enzol to one (1) gallon (3.8 L) of tap water. Soak instruments immediately after use and flush detergent through all channels until evidence of organic material is removed. Soak for a minimum of ten (10) minutes. Use a soft bristle brush (Spectrum™ M-16 or equivalent) to gently remove visible debris. Pay close attention to threads, crevices, lumens and hard to reach areas. If organic material is dried-on, extend soak time and use two (2) ounces (60 mL) of Enzol per one (1) gallon (3.8 L) of warm tap water.	
2. Rinse	Deionized water	Deionized water
	Thoroughly rinse each instrument with deionized water including all channels to remove detergent for a minimum of three (3) minutes.	
3. Inspection	Unaided eye	Unaided eye
	Inspect each instrument for evidence of organic material. Particular attention should be taken to remove all debris from instruments with cannulations, holes, and features that may be shielded from brushing action. Subject instruments to ultrasonic cleaning if organic matter is present after the initial cleaning step.	
4. Ultrasonic Clean (if required)	Enzol Enzymatic Detergent Solution (or equivalent)	Enzol Enzymatic Detergent Solution (or equivalent)
	Prepare a fresh solution by adding one (1) ounce (30 mL) of Enzol and one (1) gallon (3.8 L) of warm tap water to a sonication unit (Branson Bransonic® Ultrasonic Cleaner or equivalent). Fully immerse the instruments in the solution and sonicate for a minimum of ten (10) minutes.	
5. Ultrasonic Rinse	Deionized water	3:00
	Thoroughly rinse each instrument with deionized water including all holes and cannulations to remove detergent for a minimum of three (3) minutes.	
6. Inspection	Unaided eye	1:00
	Inspect each instrument for evidence of organic material. Repeat the ultrasonic clean and rinse steps if needed.	

4. Upon completion, visually inspect each instrument for contamination such as remaining soil and moisture or wetness. If soil remains, repeat the cleaning process. If wetness remains, use filtered pressurized air or lint-free wipes to dry.

INSPECTION

1. Carefully inspect each instrument to ensure all visible blood and soil has been removed.
2. Inspect instruments and instrument cases for damage. Check action of moving parts to ensure proper operation.
3. If damage or wear is noted that may compromise the proper function of the instrument or instrument case, do not use and contact customer service or your X-spine Systems representative for a replacement.
4. If corrosion is noted, do not use and contact customer service or your X-spine Systems representative for a replacement.

Manufacturer:

X-spine Systems, Inc.
452 Alexandersville Rd.
Miamisburg, OH 45342 USA
Phone: (800) 903-0640
Fax: (937) 847-8410

Authorized Representative:

EC REP **EMERGO EUROPE**
Molenstraat 15
2513 BH, The Hague
The Netherlands
Phone: +31.70.345.8570
Fax: +31.70.346.7299

⚠ **CAUTION:** Federal Law (USA) restricts these devices to use by or on the order of a physician.

CE 0086

Part Number
REF X060-2003 F

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Step 1

Position the patient in the prone position on the operating table.

Step 2

Identify the spinous processes at the level to be instrumented, using manual palpation and intraoperative imaging.

Step 3

Make a midline incision about 3 cm in length to expose the spinous processes at the correct level.

Step 4

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.

Step 5

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.

Step 6

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.

Step 7

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.

X-spine℠ Surgical Technique

The AXLE® and AXLE-X™ Interspinous Fusion System

This document is intended exclusively for experts in the field, particularly physicians, and is not intended for laypersons.

Information on the products and procedures contained in this document is general in nature and does not represent medical advice or recommendations. As with any technical guide, this information does not constitute any diagnostic or therapeutic statement with regard to a given medical case. An evaluation, examination, and advising of the patient are absolutely necessary for the physician to determine the specific requirements of the patient, and any appropriate adjustments needed, and the foregoing are not to be replaced by this document in whole or in part.

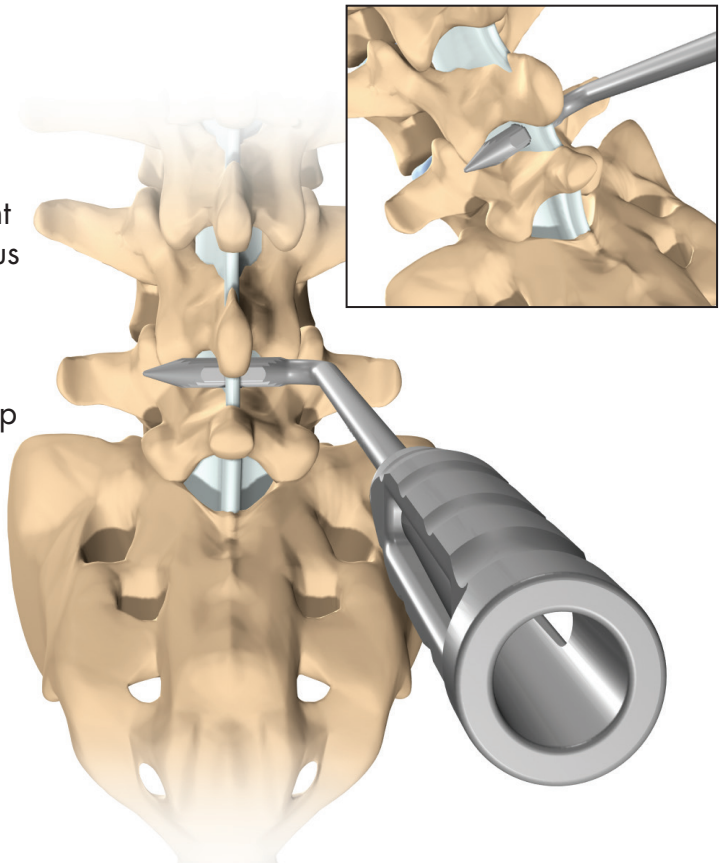
Information contained in this document was gathered and compiled by experts in the field and X-spine employees to the best of their knowledge. Care was taken to ensure the information contained herein is accurate and understandable. X-spine does not assume any liability, however, for the accuracy and/or completeness of the quality of the information, and X-spine is not liable for any losses whatsoever of any kind or any nature that may be caused by the use of said information.

Note : This surgical technique applies to both Axle® and Axle-X™. Axle-X™ has angled spikes to allow for lower engagement on the spinous process and to be closer to the lamina for variations in spinal anatomy. See Step 7 for implant variation.

Step 1: 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.

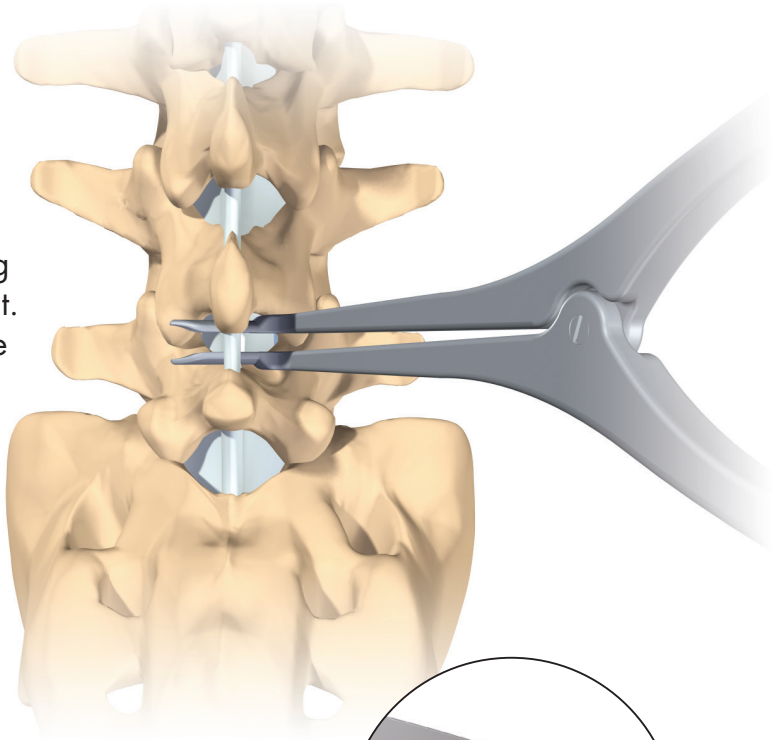
Warning : Do not direct the Piercer-Rasp in a ventral direction which could result in damage to neurological elements.



Step 2: Determine Size of Implant

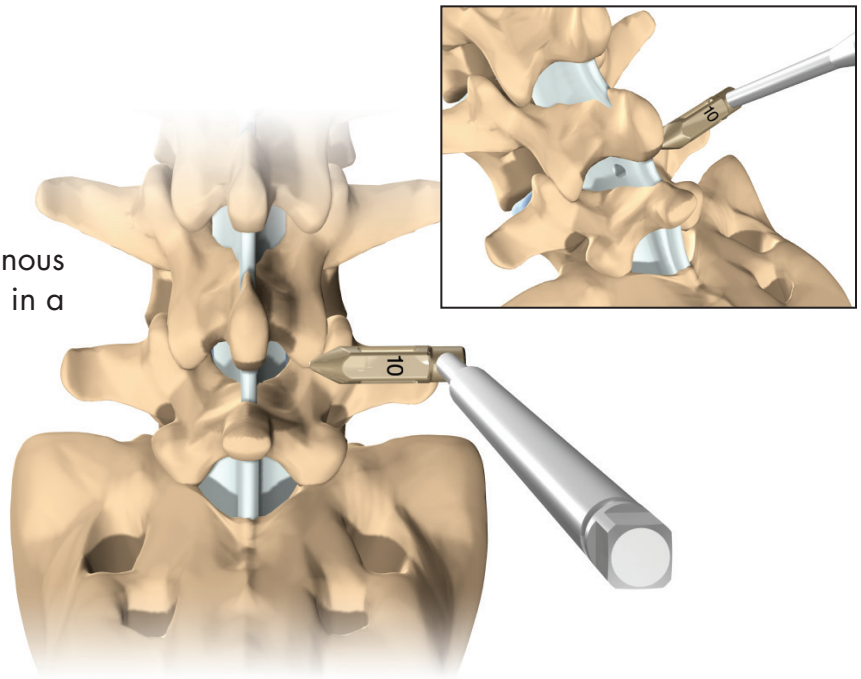
Using the Spreader, insert into the interspinous ligament where the initial dilation was performed. Squeeze the handle until the desired distraction is achieved and insert size is determined.

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.



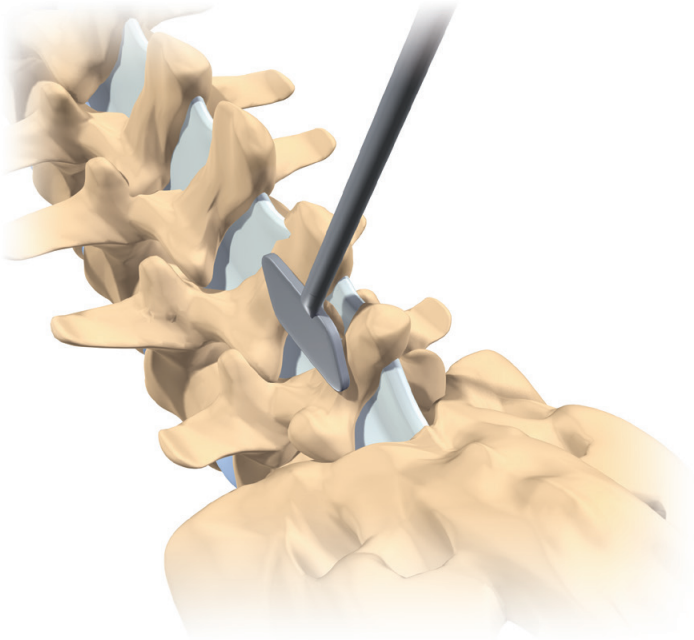
Step 3: Trial-Rasps

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 4: Plate Sizing (Length)

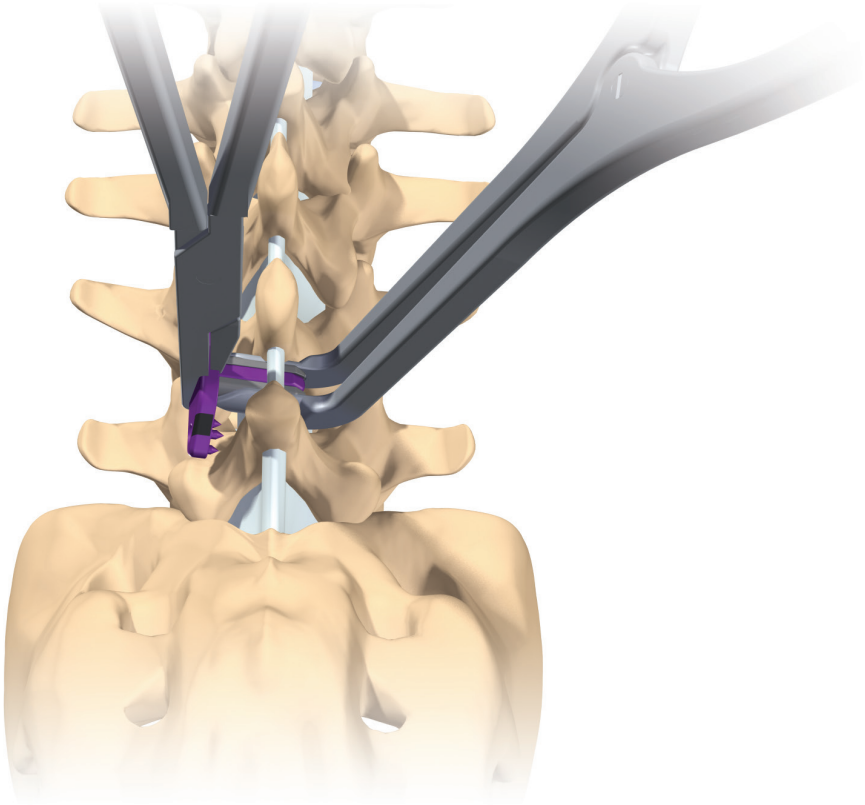
Place the Plate Sizer instrument laterally, (28mm, 32mm, 36mm, 40mm or 55mm) to visually determine the length of the plate.



Step 5: Cross Bar Plate Insertion

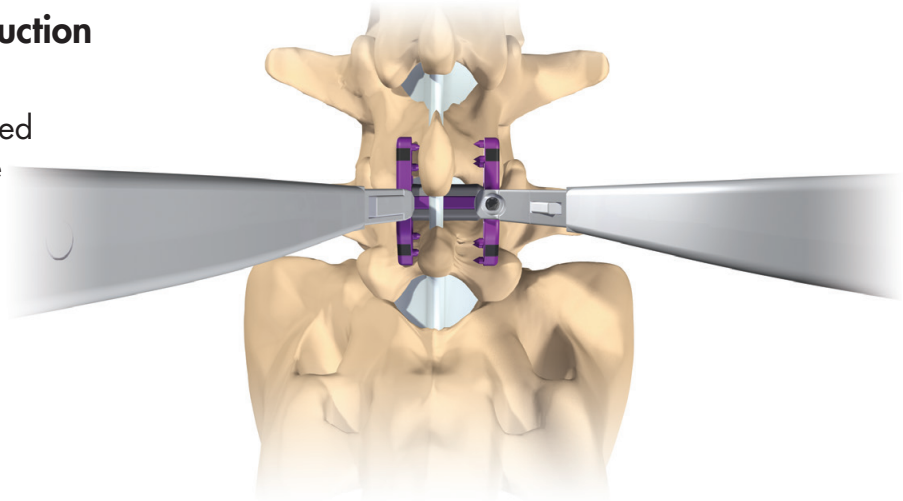
Technique 1 (shown) : Re-insert the Spreader into the interspinous space and ratchet to the previously determined implant size. Introduce the implant, via the Cross Bar Plate Inserter, into the Spreader until the implant insert has been fully pushed through the interspinous space.

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 6: Locking Plate Introduction

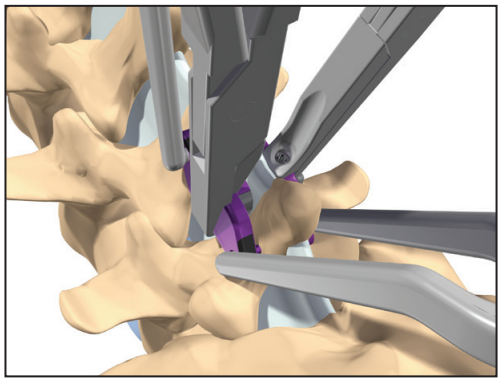
Using the corresponding Locking Plate based upon the predetermined Insert size, slide the Locking Plate over the Insert/Cross Bar Plate until it comes in contact with the spinous processes.



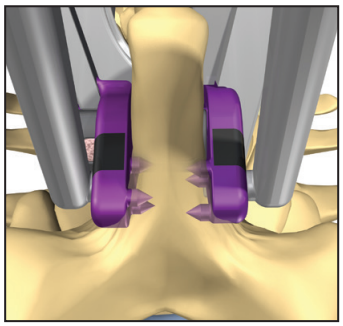
Step 7: Compression of Plates

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.

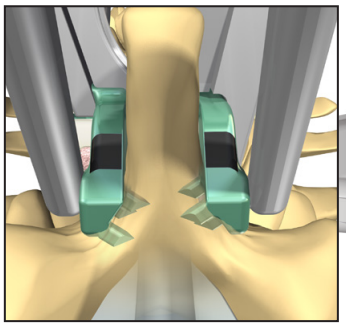
Warning : Placement of excessive force on Compressors may result in spinous process failure.

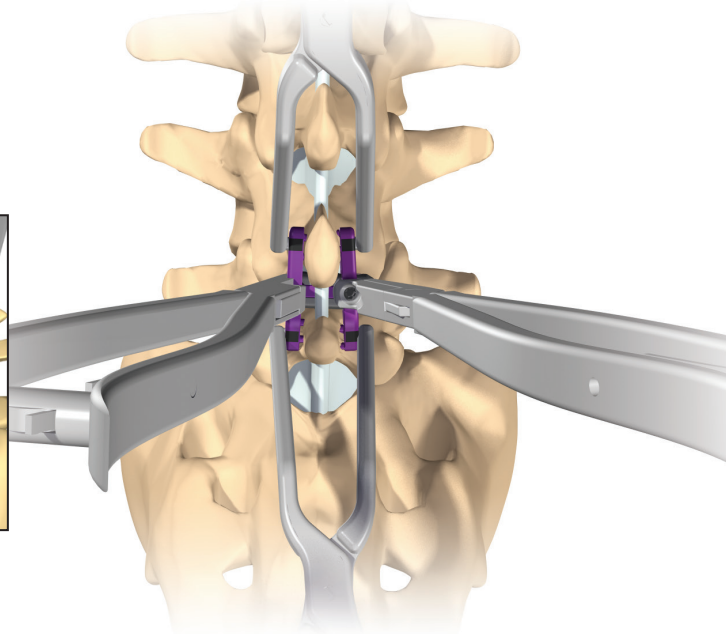


Axle®



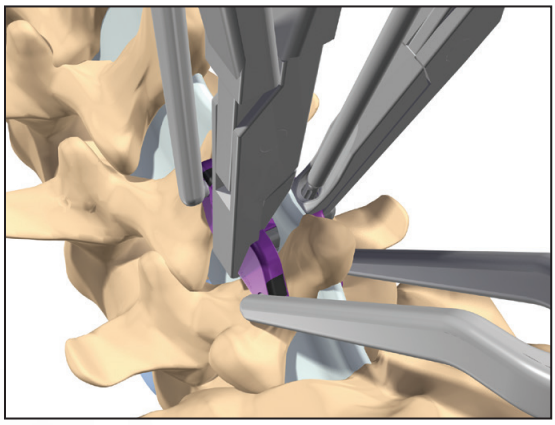
Axle-X™

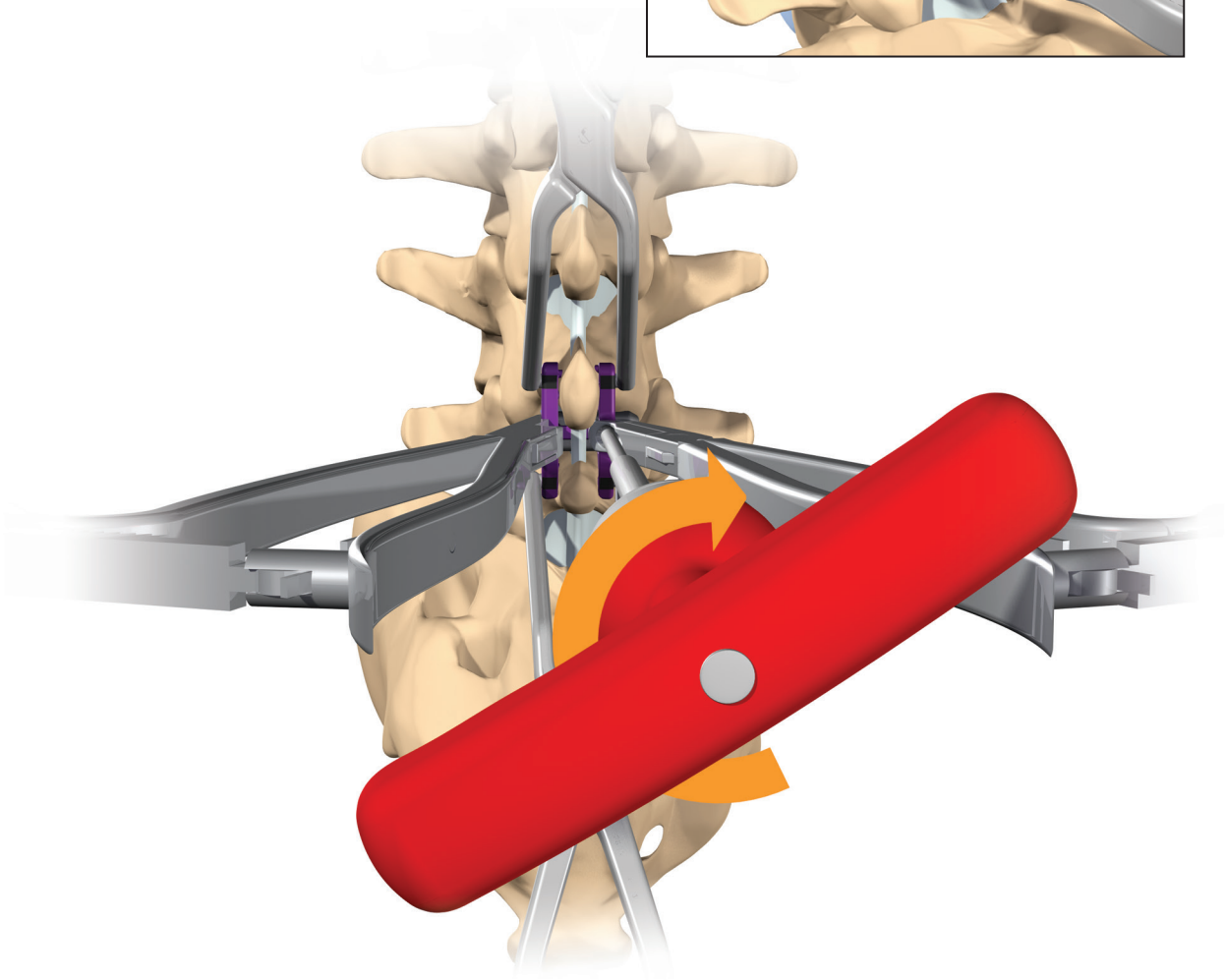




Step 8: Final Locking of Plates

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.





Cross Bar Plate Inserter

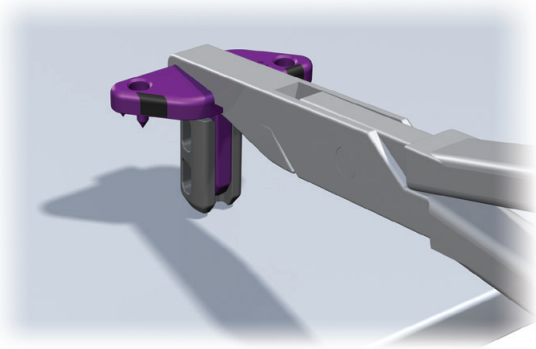
Step 1: Loading Cross Bar Plate onto Inserter

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

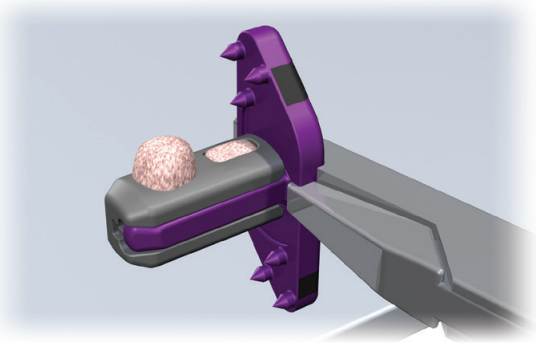
Press the Insert firmly against a sterile table to lock the Insert onto the Cross Bar Plate.

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.

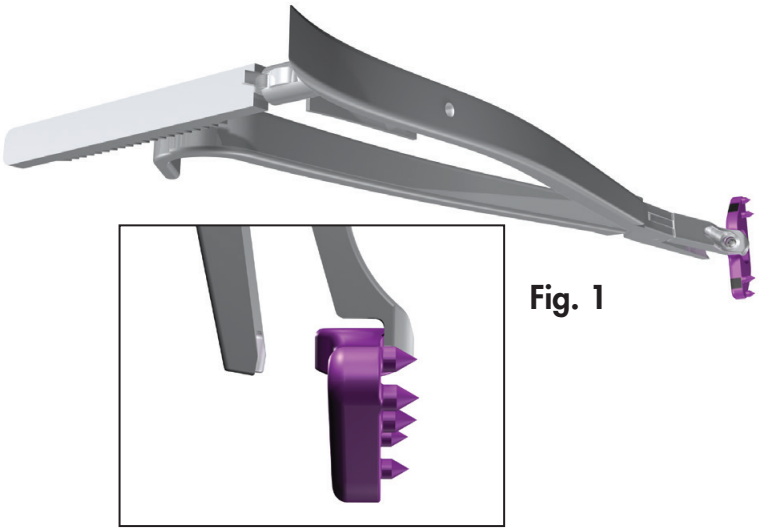


Fig. 1

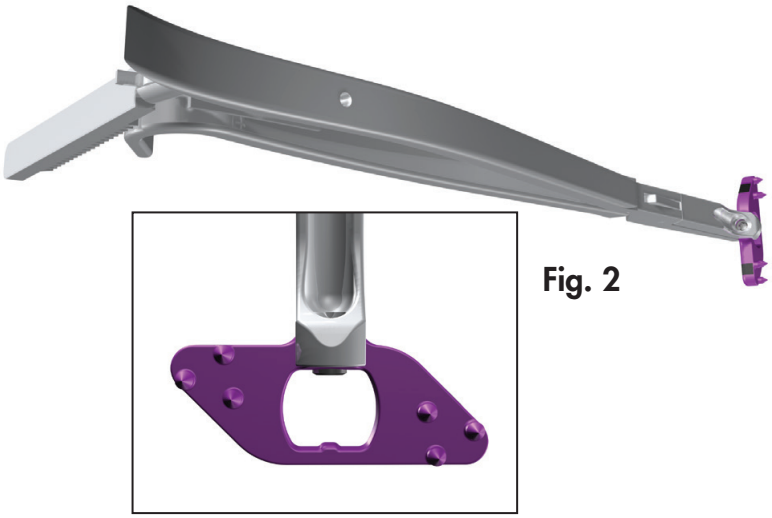


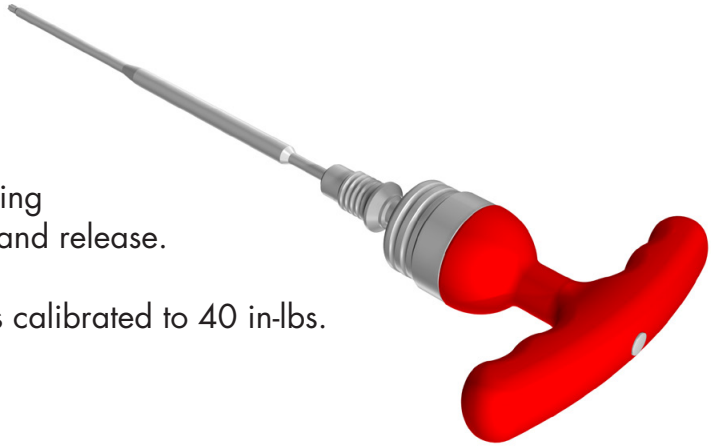
Fig. 2

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.



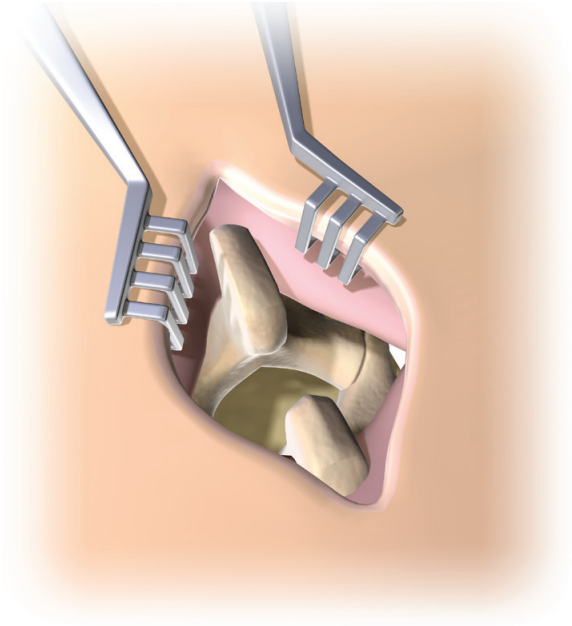
Axle® All-In-One Inserter – For 36 and 40mm Plates Only

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.

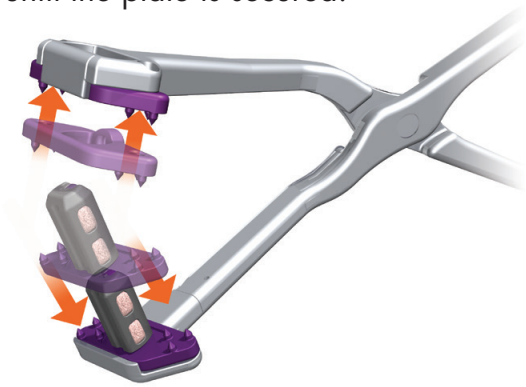
Step 1: Exposure

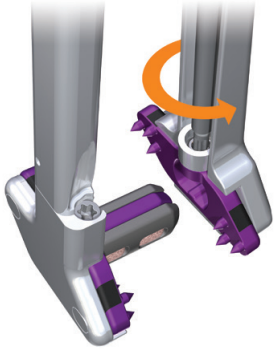
Elevate the paraspinal musculature and other soft tissue to expose the spinous processes and lamina to the medial border of the facet joints. Clear the fusion site of connective and soft tissues, lightly decorticating the bone surfaces. Using a ronguer, or similar instrument, remove both the supraspinous 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

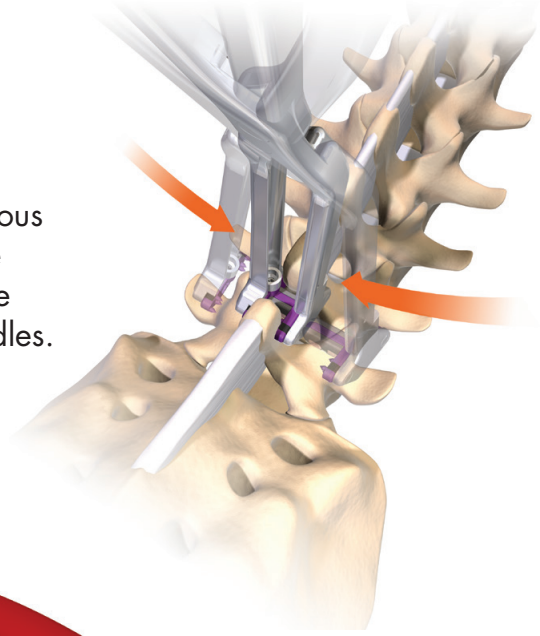
Position the Axle® All-In-One Inserter so that it is vertical. Place the Axle® Cross Bar Plate onto the articulating arm; the oblong posts of the articulating arm go into the holes of the Axle® Cross Bar Plate. While holding the Axle® Cross Bar Plate firmly on the arm, use the Screwdriver to tighten 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.





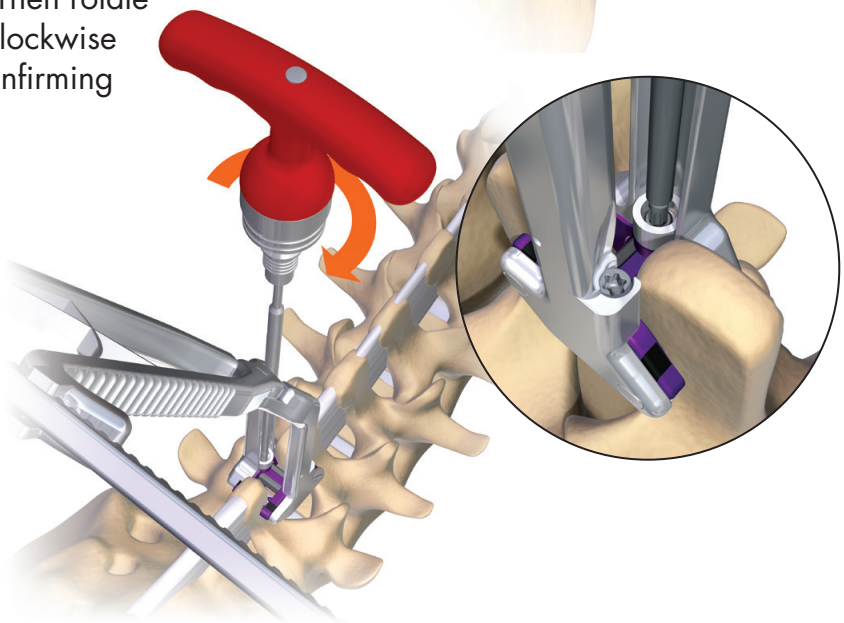
Step 3: Implant Insertion

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.



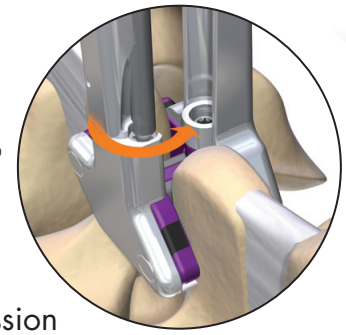
After the implant has been compressed onto the spinous processes, slowly guide the Screwdriver shaft through the instrument and into the recessed channel until the driver tip is fully seated into the set screw. Then rotate the Axle® Torque Limiting T-Handle clockwise until two audible clicks are heard confirming that the plate is secure.

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

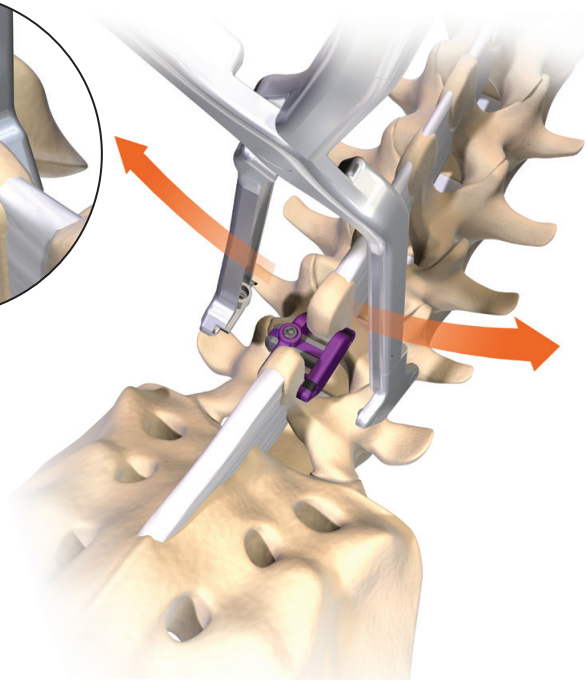


Step 4: Removal of Instrument

Loosen the side set screw of the articulating arm to disengage the Axle® Cross Bar Plate from the instrument.



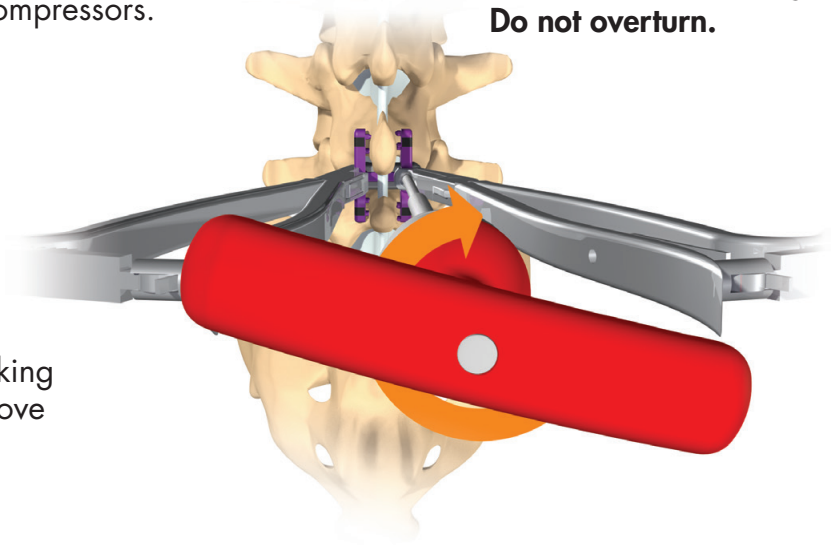
Open the ratcheting arm at the handle of the instrument to release the compression on both plates. Then slowly open both handles laterally to disengage the inserter from the implant. Once visually confirmed that the implant and inserter are fully disengaged slowly remove the inserter.



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.

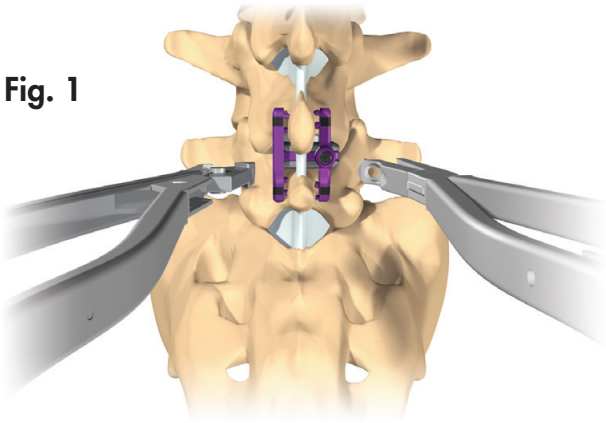


Fig. 1

Step 2: Removal of Inserter

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

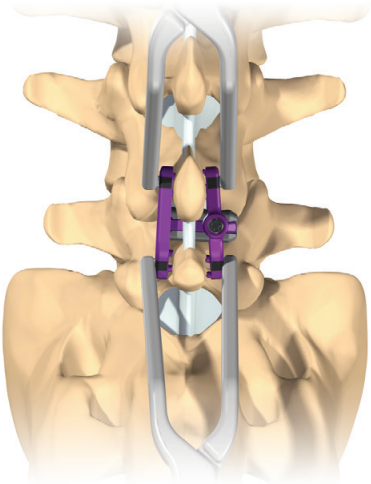


Fig. 2

Pre-Assembly

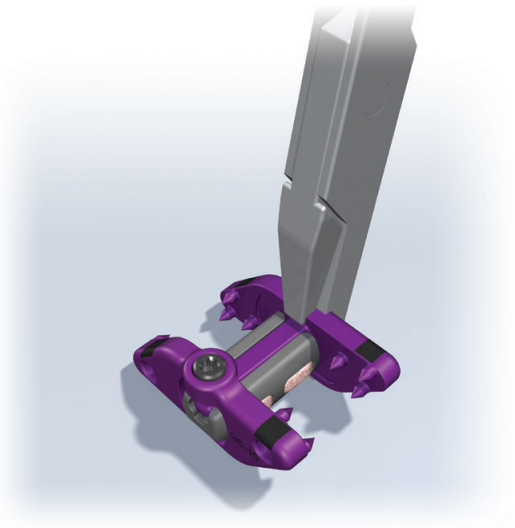
If desired the Axle® Implant can be pre-assembled on the back table to allow for insertion. This technique includes the removal of the supraspinous and interspinous ligaments to allow the implant to be lowered into place utilizing a single instrument.

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.

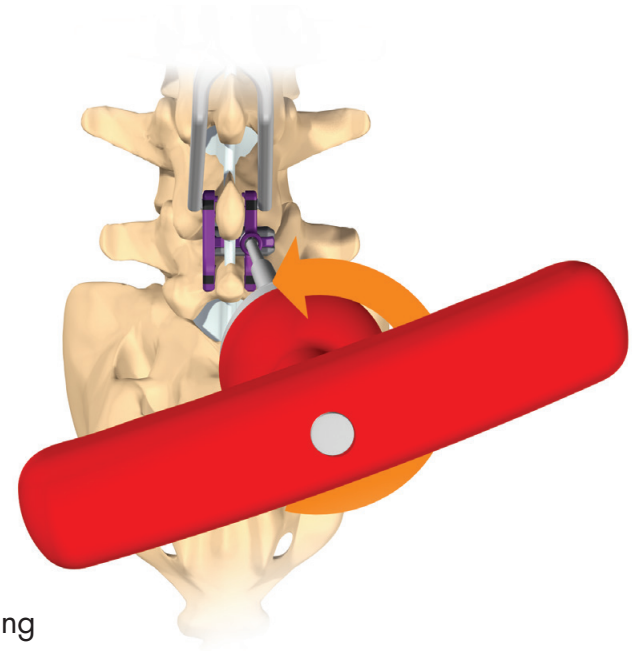
Axle® Removal

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

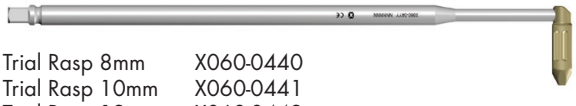
Using an elevator or forceps, gently push the Insert through the interspinous space and remove the Locking Plate, Cross Bar Plate, and Insert.

INSTRUMENTS

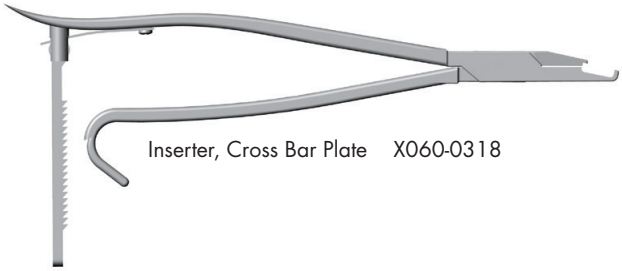
Piercer-Rasp X060-0307

Plate Sizer 28mm X060-0360
Plate Sizer 32mm X060-0364
Plate Sizer 36mm X060-0336
Plate Sizer 40mm X060-0340
Plate Sizer 55mm X060-0369

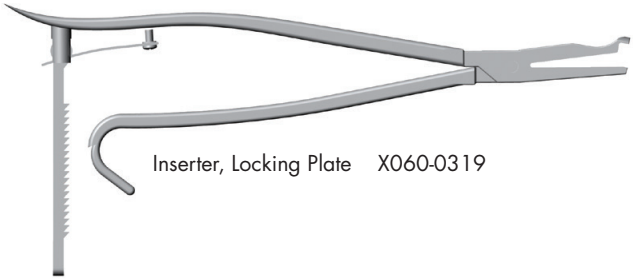
Screwdriver X060-0320



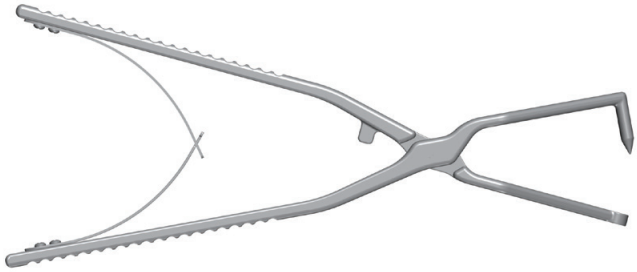
Trial Rasp 8mm X060-0440
Trial Rasp 10mm X060-0441
Trial Rasp 12mm X060-0442
Trial Rasp 14mm X060-0443
Trial Rasp 16mm X060-0444
Trial Rasp 18mm X060-0445



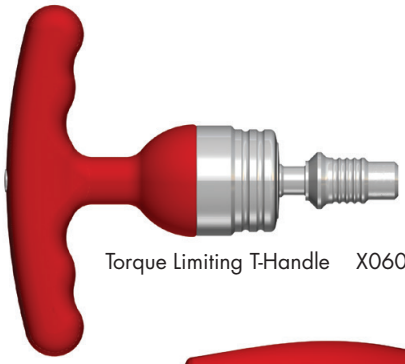
Inserter, Cross Bar Plate X060-0318



Inserter, Locking Plate X060-0319



Compression-Piercer X060-0328

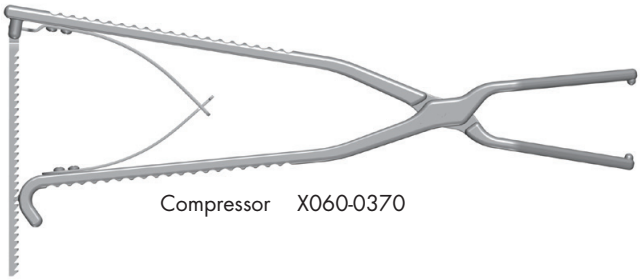


Torque Limiting T-Handle X060-0322

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

X·spine

X-treme Innovations

NOTES

WARNING: In the USA, this product has labeling limitations.
See package insert for complete information.

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

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This product is covered by U.S. Patent No. 8,262,697.

All products are not currently available in all markets.

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X-treme Innovations

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