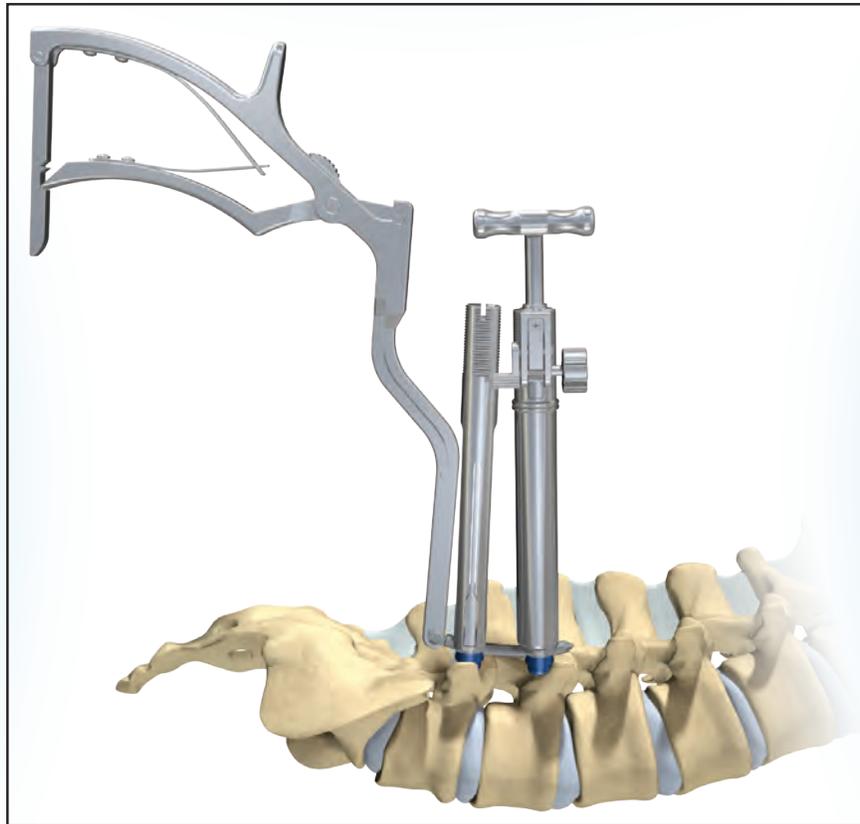




X-spineSM Surgical Technique



XPRESSTM MI Pedicle Screw System

 X-spineSM
X-treme Innovations





XPRESS[™]
Minimally Invasive Pedicle Screw System

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INSTRUCTIONS FOR USE

X-spine Systems, Inc. Xpress™ Minimally Invasive Pedicle Screw System

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 Xpress Minimally Invasive Pedicle Screw System consists of rods, pedicle screws, screw caps and hand instruments. Various forms and sizes of these implants are available so that adaptations can be made to take into account the pathology and anatomy of an individual patient. The system implant components are made of Ti6Al4V ELI, a titanium-based alloy which complies with ASTM F136, and Co28Cr6Mo, a cobalt chromium alloy which complies with ASTM F1537.

INDICATIONS FOR USE

The Xpress Minimally Invasive Pedicle Screw System is indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

In addition, the Xpress Minimally Invasive Pedicle Screw System is intended to provide immobilization and stabilization of the spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

CONTRAINDICATIONS

Contraindications for the Xpress Minimally Invasive Pedicle Screw System are similar to those of other systems of similar design, and include, but are not limited to:

1. Active infectious process in the patient, particularly in or adjacent to the spine or spinal structures.
2. Morbid obesity.
3. Pregnancy.
4. Grossly distorted anatomy due to congenital abnormalities.
5. Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
6. Rapid joint disease, bone absorption, osteopenia, osteomalacia, or osteoporosis. Osteopenia or osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.
7. Suspected or documented metal allergy or intolerance.

8. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
9. Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcohol or drug abuse, occupation or life-style may interfere with their ability to follow post-operative instructions.
10. Any time implant utilization would interfere with anatomical structures or expected physiological performance.
11. Any case not needing a bone graft and fusion or where fracture healing is not required.
12. Other medical or surgical conditions which would preclude the potential benefit of spinal implant surgery such as the presence of tumors, congenital abnormalities, elevation of white blood cell count (WBC), or a left shift in the WBC differential count.

PRECAUTIONS

The implants must be implanted only by experienced surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient. The use of implants must be decided upon with regard to the surgical and medical indications, the potential risks, and limitations related to this type of surgery. The surgeon and patient should demonstrate knowledge of the contraindications, side effects, precautions, metallurgic and biological characteristics of the implants to be used. Xpress implants must not be used together with implants from a different source, a different manufacturer or made from a different material.

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

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.

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



INSTRUCTIONS FOR USE

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.

Due to the presence of implants, interference with roentgenographic, CT and/or MR imaging may result. The Xpress Minimally Invasive Pedicle Screw System has not been evaluated for safety and compatibility in the MR environment. The Xpress Minimally Invasive Pedicle Screw 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.

WARNINGS:

The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar and sacral spine secondary to severe spondylolisthesis (Grade 3 and 4) of L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

Benefits of spinal fusion utilizing any pedicle screw fixation system has not been adequately established in patients with stable spine. Potential risks associated with the use of this system, which may require additional surgery, include; device component neurological injury, and vascular or visceral injury. Discard all damaged or mishandled implants. Never reuse an implant, even though it may appear undamaged.

Internal fixation devices cannot withstand activity and load levels equal to those placed on normal healthy bone. Until maturation of the fusion mass is confirmed, do not subject this device to the stress of full weight bearing, or implant failure may result.

Contouring and bending of a system component may reduce its fatigue strength and cause failure under load. If spinal screws are bent or otherwise damaged during insertion or adjustment, they must not be implanted and must be replaced. Rods should only be contoured with the proper contouring instruments. Incorrectly contoured rods or rods which have been repeatedly or excessively contoured must not be implanted.

Mixing Metal; some degree of corrosion occurs on all implanted metal and alloys. Contact of dissimilar metals, however, may accelerate this corrosion process. The presence of corrosion may accelerate fatigue fracture of implants, and the amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, screws, etc., which come in contact with other metal objects, must be made from like or compatible metals. Because different manufacturers employ different materials, varying tolerances and manufacturing specifications, and differing design parameters, the components of Xpress should not be used in conjunction with components from any other manufacturer's spinal system.

Removal of an unloosened spinal screw may require the use of special instruments to disrupt the interface at the implant surface. This technique may require practice in the laboratory before attempted clinically. Any decision by a surgeon to remove the internal fixation device should take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal. Implant removal should be followed by adequate postoperative management to avoid fracture.

INSTRUCTIONS FOR USE

A successful result is not achieved in every surgical case, especially in spinal surgery where many extenuating circumstances may compromise results. Preoperative planning and operating procedures, including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are critical considerations in achieving a successful result. Use of the X-Spine Xpress Minimally Invasive Pedicle Screw System should only be considered when the following preoperative, intraoperative and postoperative conditions exist. For complete instructions regarding the proper use and application of all Xpress implants and instruments, please refer to the Xpress Surgical Technique Manual (available at no charge upon request).

Preoperative:

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those mentioned in the contraindications should be avoided.



INSTRUCTIONS FOR USE

3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments.
4. The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
5. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The X-spine Xpress System components are not to be combined with the components from another manufacturer. Different metal types should not be used together.
6. All components and instruments should be cleaned and sterilized prior to use. Additional sterile components should be available in case of unexpected need.

Intraoperative:

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. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
4. Caution should be taken in handling the implants; Damage to the implants may affect their performance.
5. Implants should not be reused under any circumstances.
6. If the X-spine Xpress system implants are being used in conjunction with X-spine Fortex system components, care must be taken to use the persuader instrument with the gray-colored handle only and not the blue-colored handle.

Postoperative:

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.

1. Detailed instructions on the use and limitations of the device should be given to the patient. The patient should be instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. Patients should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent restriction in body motion. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.
2. If a non-union develops or the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or nonunion of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause eventual bending, loosening or breakage of the device(s).

3. 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.
4. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the Xpress components should ever 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 the components.
2. Disassembly, bending or breakage of any or all of the components.
3. Foreign body (allergic) reaction to the implants.
4. Infection.
5. Non-union (pseudarthrosis).
6. Loss of neurological function, including paralysis (complete or incomplete), radiculopathy, dysesthesia, hyperesthesia, anesthesia, paresthesia, development or continuation of pain, numbness, neuroma, tingling sensation, dural tears, neuropathy, neurological deficits (transient, permanent, or delayed), reflex deficits, bilateral paraplegia, and/or arachnoiditis.
7. Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, or wound dehiscence.
8. Misalignment of anatomical structures or loss of spinal mobility.
9. Bone graft donor complications including pain, fracture or wound healing problems.
10. Atelectasis.
11. Cessation of any potential growth of the operated portion of the spine.
12. Vascular damage resulting in excessive bleeding.
13. Loss or impairment of bowel, sexual, and/or bladder function and other types of urological compromise.
14. Fracture, damage, degenerative changes or instability of any bone above and/or below the level or surgery.
15. Gastrointestinal system compromise.
16. Bone loss due to resorption or stress shielding.
17. Death.

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



INSTRUCTIONS FOR USE

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

All Xpress Minimally Invasive Pedicle Screw System implants and 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 parameters:

Saturated steam method, pre-vacuum air removal, 270° F (132° C), 4-minute minimum exposure time, 30-minute minimum drying 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	3:00
	Thoroughly rinse each instrument with deionized water including all channels to remove detergent for a minimum of three (3) minutes.	
3. Inspection	Unaided eye	1:00
	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)	10:00
	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.	



INSTRUCTIONS FOR USE

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:



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

Authorized Representative:



EMERGO EUROPE
Molenstraat 15
2513 BH, The Hague
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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
X073-2003 A



X-treme Innovations

XPRESS™ IMPLANTS



Four indentation design secures screw and extension connection



Conical shape cap provides multiple point fixation to rod

Size	Yoke Color
5.5mm	Magenta
6.5mm	Dark Blue
7.5mm	Green

Bulleted nose for ease of insertion and tissue distraction

Splined end to stabilize during rod insertion



Xpress™ Continuous Radius Rod

Xpress™ Straight Rod



Xpress™ Pedicle Screw and Cap

Item #	Description
X073-5530	5.5mm x 30mm Xpress Pedicle Screw
X073-5535	5.5mm x 35mm Xpress Pedicle Screw
X073-5540	5.5mm x 40mm Xpress Pedicle Screw
X073-5545	5.5mm x 45mm Xpress Pedicle Screw
X073-5550	5.5mm x 50mm Xpress Pedicle Screw
X073-5555	5.5mm x 55mm Xpress Pedicle Screw
X073-6530	6.5mm x 30mm Xpress Pedicle Screw
X073-6535	6.5mm x 35mm Xpress Pedicle Screw
X073-6540	6.5mm x 40mm Xpress Pedicle Screw
X073-6545	6.5mm x 45mm Xpress Pedicle Screw
X073-6550	6.5mm x 50mm Xpress Pedicle Screw
X073-6555	6.5mm x 55mm Xpress Pedicle Screw
X073-7530	7.5mm x 30mm Xpress Pedicle Screw
X073-7535	7.5mm x 35mm Xpress Pedicle Screw
X073-7540	7.5mm x 40mm Xpress Pedicle Screw
X073-7545	7.5mm x 45mm Xpress Pedicle Screw
X073-7550	7.5mm x 50mm Xpress Pedicle Screw
X073-7555	7.5mm x 55mm Xpress Pedicle Screw
X073-0025	Xpress Cap

Xpress™ Rods

Item #	Description
X073-0040-CR	40mm Xpress Continuous Radius Rod
X073-0045-CR	45mm Xpress Continuous Radius Rod
X073-0050-CR	50mm Xpress Continuous Radius Rod
X073-0055-CR	55mm Xpress Continuous Radius Rod
X073-0060-CR	60mm Xpress Continuous Radius Rod
X073-0065-CR	65mm Xpress Continuous Radius Rod
X073-0070-CR	70mm Xpress Continuous Radius Rod
X073-0080-CR	80mm Xpress Continuous Radius Rod
X073-0090-CR	90mm Xpress Continuous Radius Rod
X073-0100-S	100mm Xpress Straight Rod
X073-0120-S	120mm Xpress Straight Rod
X073-0140-S	140mm Xpress Straight Rod
X073-0160-S	160mm Xpress Straight Rod
X073-0300-S	300mm Xpress Straight Rod
N60001091	35mm Continuous Radius Rod
N60001092	40mm Continuous Radius Rod
N60001093	45mm Continuous Radius Rod
N60001068	50mm Continuous Radius Rod
N60001069	60mm Continuous Radius Rod
N60001070	70mm Continuous Radius Rod





XPRESS™ MI Pedicle Screw System Surgical Technique

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 and/or reliance of said information.

PREOPERATIVE PLANNING:

Patient is prone, lying flat on the table.

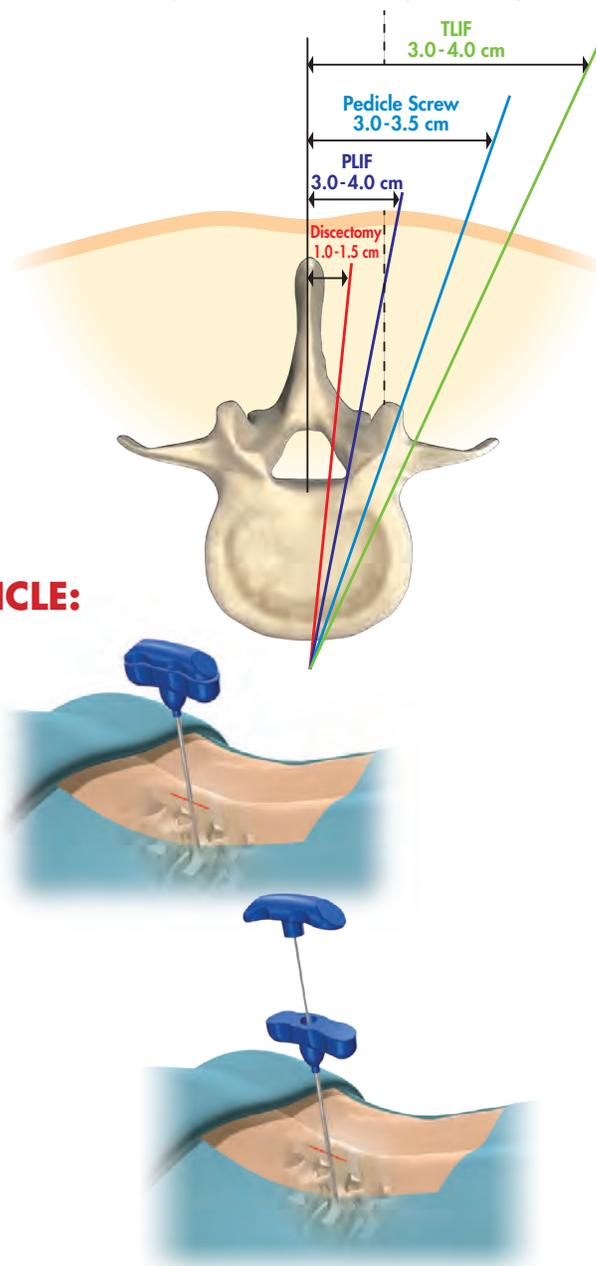
Confirm in AP and Lateral views that adequate fluoroscopy images of the pedicles can be achieved.

OR SETUP AND PREPARATION OF PEDICLE:

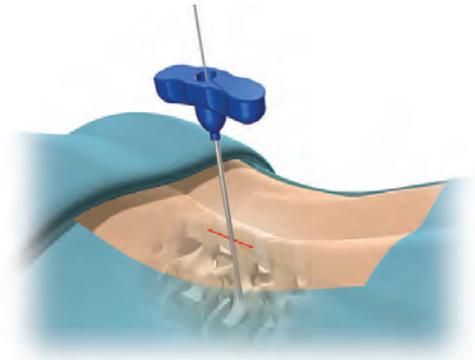
Step 1: Pedicle Targeting

Locate the pedicle using standard intra-operative techniques under fluoroscopy. Firmly seat a Jamshidi needle at the intersection of the facet and transverse process into the pedicle. During placement, ensure the Jamshidi does not breach the pedicle wall.

Once desired needle location is achieved, using a mallet, impact on the flat of the Jamshidi needle to enter the pedicle, then remove inner component of the needle.



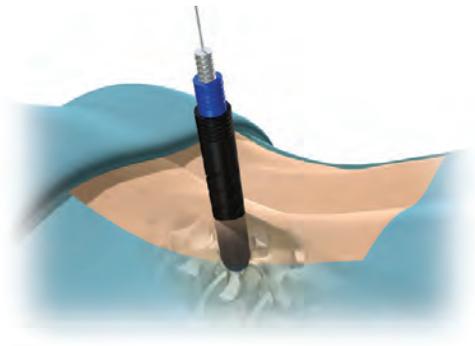
Place the Guidewire through the Jamshidi needle and tap the Guidewire into the vertebral body with the mallet, confirming with fluoroscopy. The Guidewire is available with either blunt or trocar tip.



For the remainder of the procedure, the Guidewire location should be monitored to ensure the tip is not unintentionally advanced or has not backed out. While holding the Guidewire to ensure it stays in position, remove the Jamshidi needle.

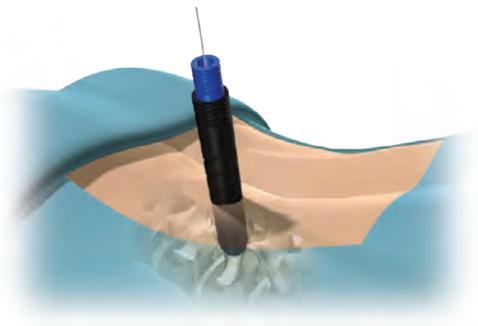
❑ **Step 2: Dilation**

Place progressively the Starting, Second, and Final Dilators over the Guidewire. Each Dilator should be rotated intermittently to create a fascial defect. Confirm that each Dilator is fully advanced to the bone surface prior to placing the next Dilator. Use depth markings to verify dilator depth.



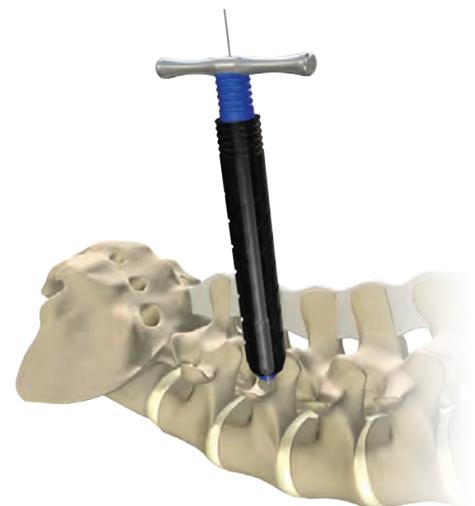
❑ **Step 3: Removal**

Remove the Starting Dilator, leaving the Guidewire, Second Dilator and Final Dilator in place. Maintain control of the Guidewire to prevent migration.



❑ **Optional: Awl**

Place the Awl over the Guidewire. Rotate Awl while advancing to appropriate depth while monitoring under fluoroscopy and monitoring the position of the Guidewire. The Awl has a 10mm trocar tip and countersink feature to aid in the starting of the tap or screw in bone.



❑ Step 4: Tapping

If tapping is desired, select the Tap that matches the preferred Pedicle Screw diameter. Place the Tap over the Guidewire. Rotate Tap clockwise to appropriate depth while monitoring under fluoroscopy, again being mindful of the position of the Guidewire. All taps are depth marked to work with the Second Dilator. See Figure 1.

TIP:

- To prevent bone from entering the Tap and then binding with the Guidewire upon removal, be careful not to advance the Tap beyond tip of the Guidewire.
- Total thread length of the Tap measures 30mm for visual reference on fluoroscopy.

During removal of the Tap, aid in maintaining placement of the Guidewire by removing the Ratcheting Handle on the Tap and manually holding the Guidewire while Tap is removed. See Figure 2. Then remove Second Dilator.



Figure 2



Figure 1

NOTE: Taps are labeled to correspond with Screw diameter. Actual Tap diameter is undersized by approximately 10% to allow for improved cancellous bone purchase.

CAUTION – Selection of an oversized Screw and/or Tap can result in pedicle fracture with loss of fixation and/or neurological injury.

SCREW EXTENSION ASSEMBLY:

With the pedicle prepared, select the desired Screw.

Step 5: Screw Extension Assembly

Attach the Screw to the Screw Extension, Pedicle Screwdriver and Ratcheting Handle.

- Firmly press the Screw Extension over the top of the Xpress™ Pedicle Screw, lining up the rod slots of the Screw cup with the rod slots of the Screw Extension. Ensure that the Screw Extension pins are seated in the notches in the top of the cup.

An audible click should be heard when the Extension attaches to the cup.

- Holding the Screw/Screw Extension assembly vertically, insert the Pedicle Screwdriver down the center shaft of the Screw Extension. Engage the hex tip into the center of the Pedicle Screw and thread the driver into the Screw top by rotating the driver sleeve clockwise.

Thumb screw may be used to lock Screwdriver in place.

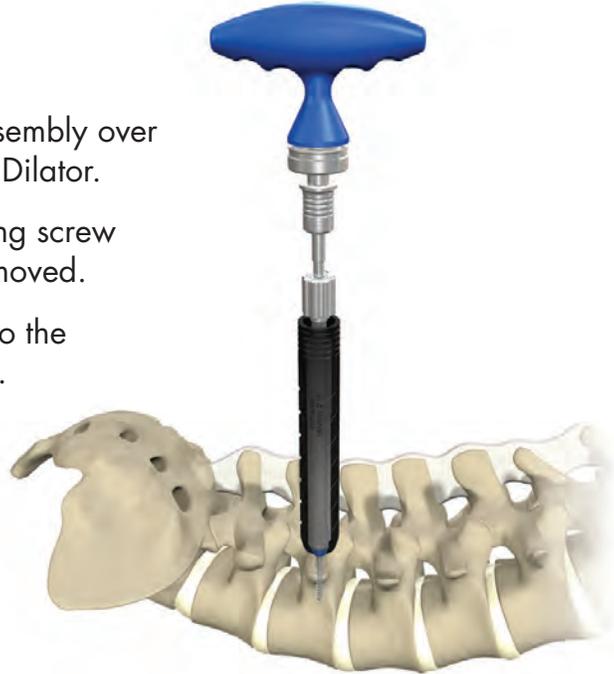
- Attach Ratcheting Handle to the Pedicle Screwdriver.



SCREW INSERTION:

❑ Step 6: Screw Insertion

- Place the Screw/Screw Extension assembly over the Guidewire and through the Final Dilator.
- After starting the screw and confirming screw trajectory, the Guidewire may be removed.
- Advance the Screw into the pedicle to the appropriate depth under fluoroscopy.



- If applicable, loosen thumb screw.
- Remove the Screwdriver by unthreading the driver sleeve.



- Remove the Final Dilator.



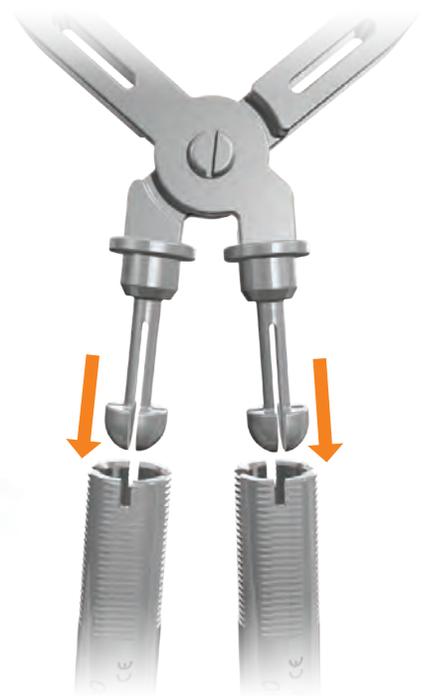
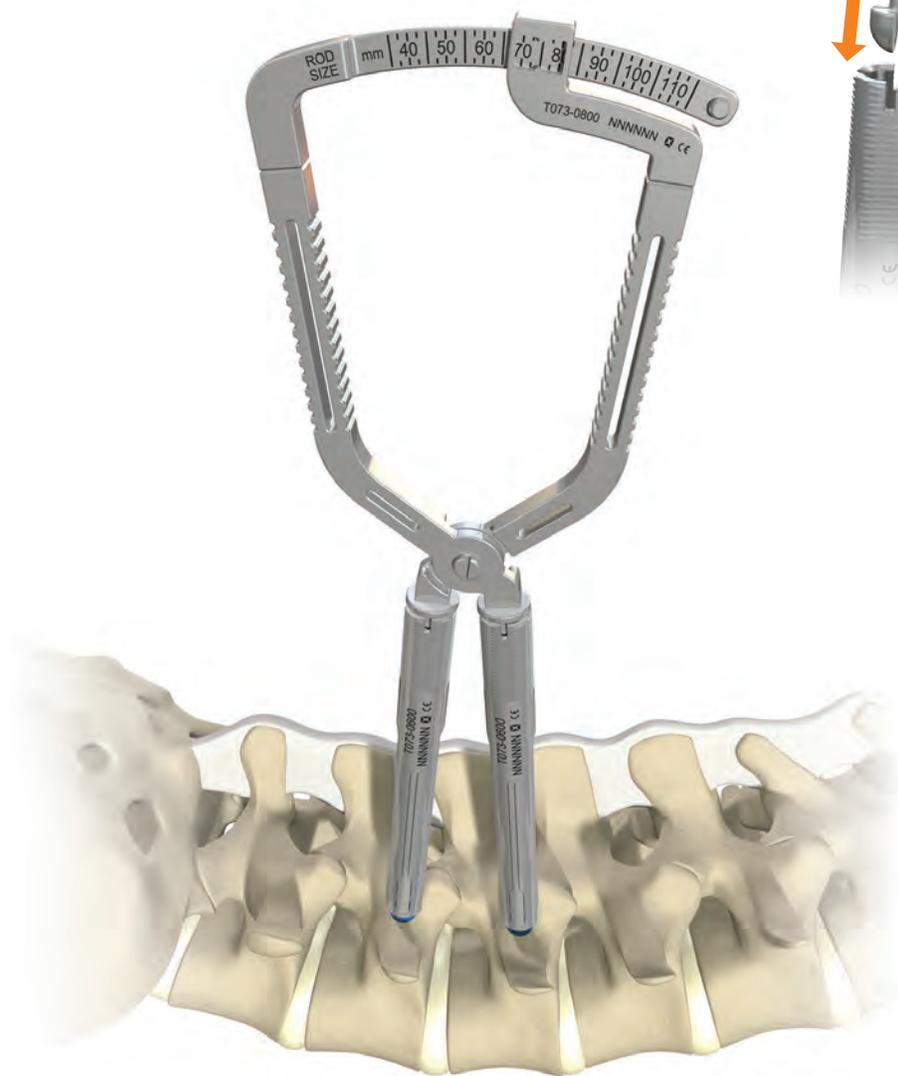
- Repeat Screw Insertion steps for remaining Pedicle Screws.

ROD SELECTION:

❑ Step 7: Rod Length Selection

Engage one arm of the Rod Length Indicator (RLI) into one Screw Extension and the other arm into the other Screw Extension. After confirming that the flanges on the RLI instrument are flush with the top of the Screw Extensions, read the RLI for the indicated rod length.

NOTE: Indicated rod length includes approximately 5mm of rod overhang on either end of construct.



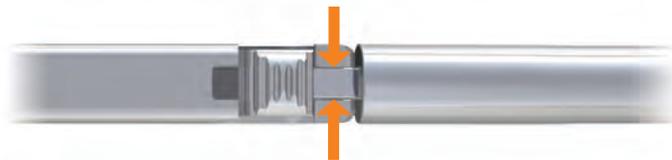
ROD INSERTION:

❑ Step 8: Rod Delivery

The Xpress™ System allows for multiple rod delivery techniques to meet surgeon preference. Those techniques include the following:

❑ Option 1: Rotatable Rod Insertion Technique

To prepare the Rotatable Rod Inserter to receive a rod, actuate the release lever on the Inserter and place an Xpress™ Percutaneous Rod in the distal hook/slot of the Inserter. Ensure rod is centered in the Inserter tip and that the spline section of the rod is facing upward with the smooth portion facing downward.



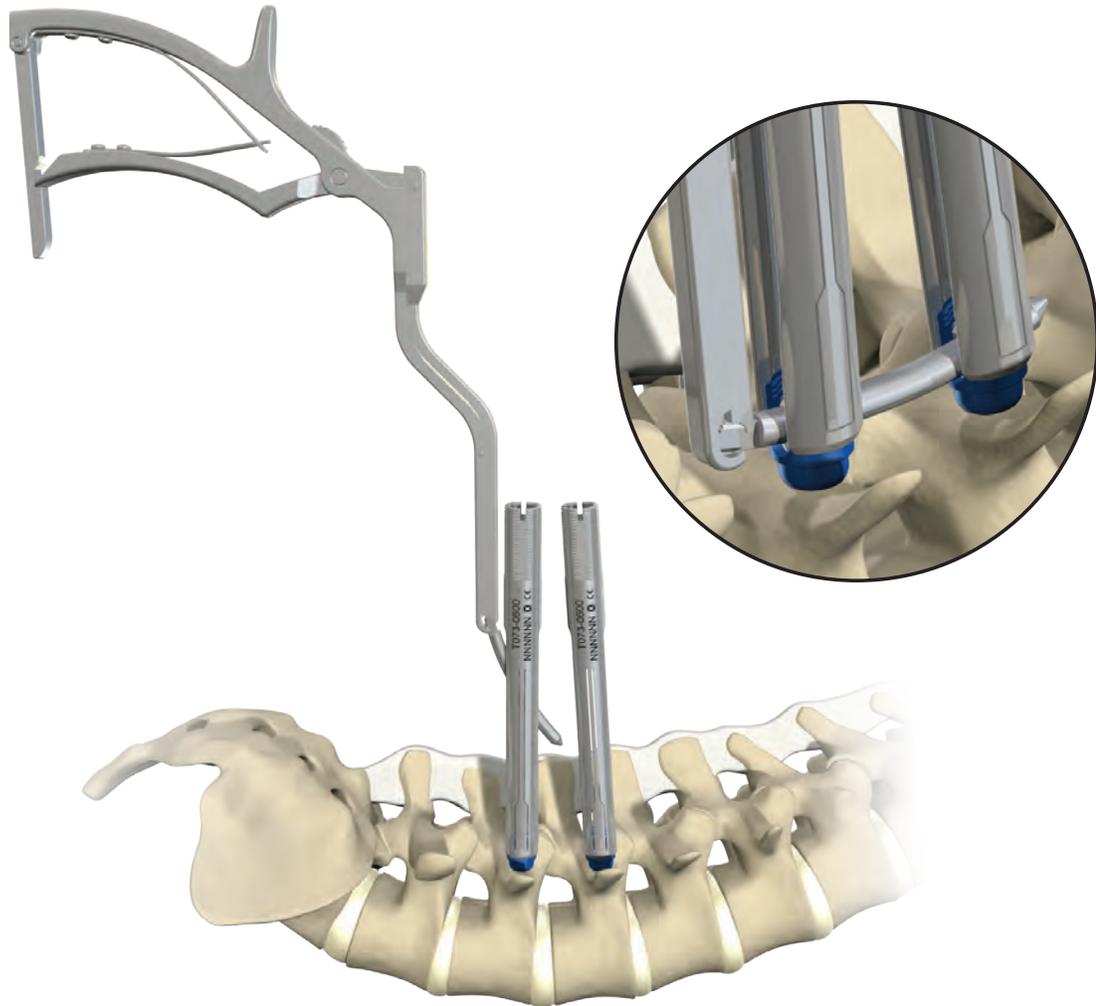
Allow release lever to pivot forward and confirm that the splines of the rod and the Inserter are properly engaged.



Squeeze the Inserter handle to engage the handle locking arm in the first slot position, provisionally locking the rod in the inserter. The rod can now rotate 90° passively without disengaging from the Inserter. (Audible clicking will occur as the rod is rotated).



Insert the tip of the rod through the existing incision and into the rod slot of the most caudal Screw Extension. While squeezing the Inserter handle, advance the rod downward through the Screw Extension. To aid in placement of the rod within the Screw Extension(s), the Inserter handle can be squeezed or released to prevent or allow in situ rotation of the rod relative to the Inserter. Alternatively, the final ratchet slot can be engaged to lock the rod at a desired position.



CAUTION – When inserting the rod, be certain that both the conical rod tip and the splined rod base are not located within the locking zone of any screw. The screws will not lock properly if the locking cap is placed within either of these areas.

NOTE: The Inserter should remain attached to the rod until at least one Locking Cap has been inserted and provisionally locked.

After provisionally tightening, release the Rod Inserter from the rod by pressing the release lever. Then rotate the Inserter toward the Screw Extension while sliding the tip downward to disengage from the rod.

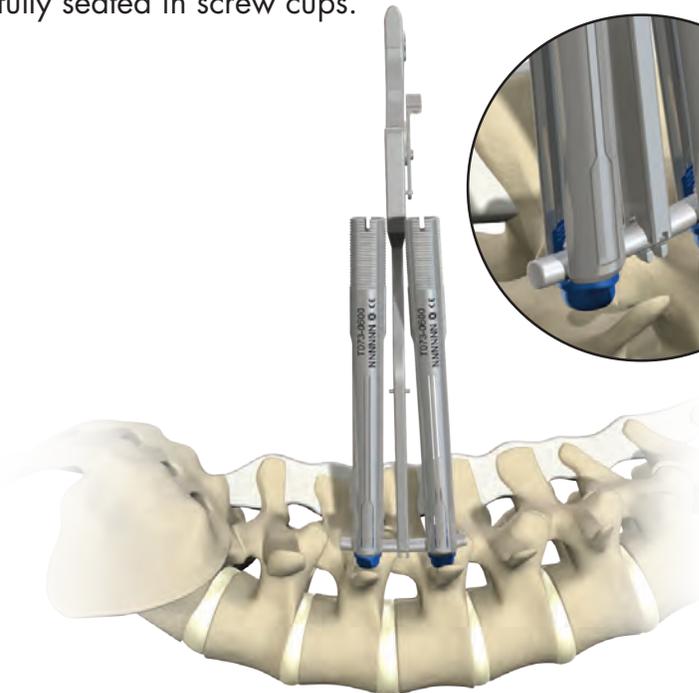
ROD INSERTION:

❑ Option 2: Paramedian (Wiltse) Rod Delivery Technique

Using the Rotatable Rod Inserter or Rod Gripper, clamp on the diameter of a standard rod and ratchet to the fixed position or until firmly held.

Place rod through rod slots on Screw Extensions.

Advance rod downward until fully seated in screw cups.



TIP: The Tissue Splitter can be used to clear interfering tissue if needed before inserting rod.

NOTE: The Inserter or Gripper should remain attached to the rod until at least one Locking Cap has been inserted and provisionally locked.

After provisionally tightening, release the Rod Inserter from the rod by pressing the release lever (Rotatable Rod Inserter) or detaching the ratchet arm (Rod Gripper). Then rotate the Inserter toward the Screw Extension while sliding the tip downward to disengage from the rod.



ROD INSERTION:

❑ Option 3: Fixed Rod Inserter Technique

To prepare the Fixed Rod Inserter to receive a rod, turn the knob on the Inserter counter-clockwise to retract the locking arm.



Place Xpress™ Percutaneous Rod into distal hook/slot of the Inserter.

Ensure that the Rod is centered in the inserter tip and that the extended spline section of the rod is facing upward with the smooth portion facing downward.

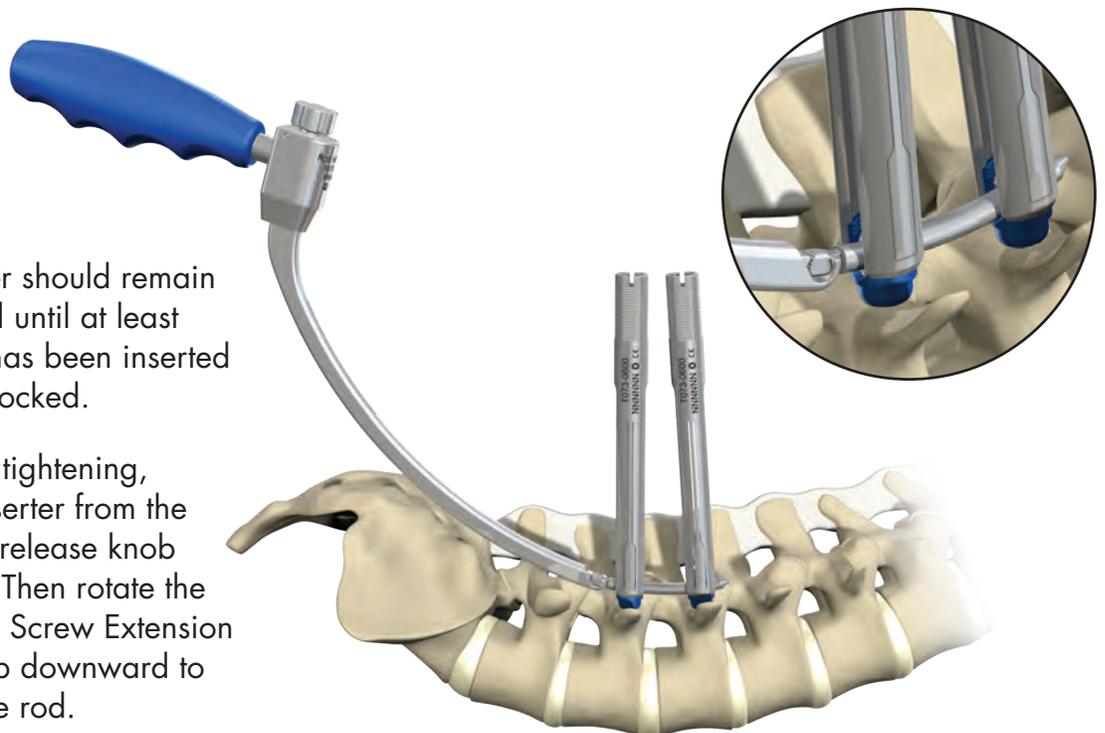


Rotate knob on inserter clockwise to engage locking arm. Confirm that the splines of the rod and the Inserter are rigidly engaged.

The Handle Extender should be used to provide sufficient tightening. The rod can now be inserted through a separate, small skin incision and guided through the caudal Screw Extension rod slots until the rod is fully seated in the screw cups.

NOTE: The Inserter should remain attached to the rod until at least one Locking Cap has been inserted and provisionally locked.

After provisionally tightening, release the Rod Inserter from the rod by turning the release knob counter-clockwise. Then rotate the Inserter toward the Screw Extension while sliding the tip downward to disengage from the rod.



ROD SEATING:

Step 9: Rod Reduction

Slide the distal end of the Rod Reducer over the desired Screw Extension orienting the gear housing of the Reducer with one of the four ratcheting features on the Screw Extension.

Rotate reduction knob counter-clockwise to advance the Rod Reducer down the Screw Extension.

The Handle Extender can be used as necessary to aid reduction.

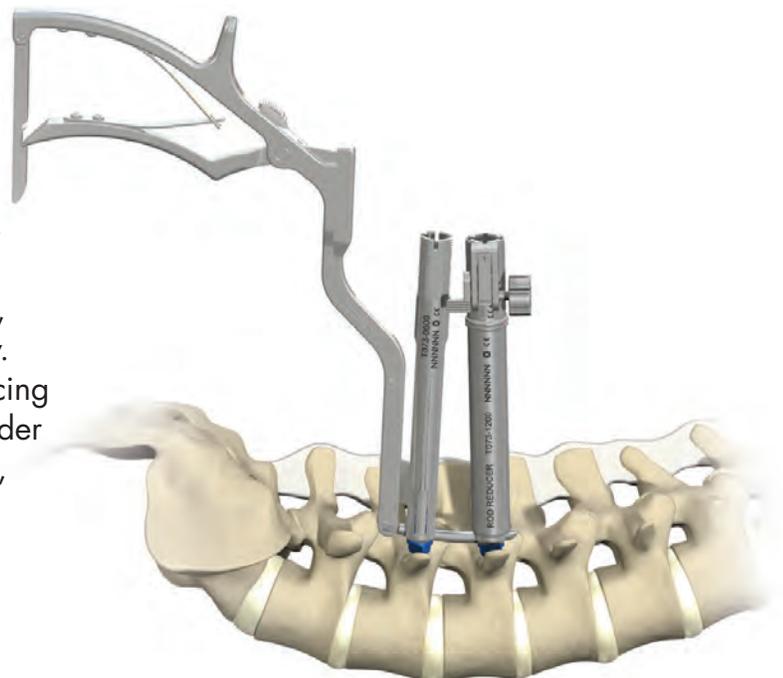
NOTE:

- Cap introduction can be performed while Reducer is in place.
- Alternatively, if minimal rod reduction is required, the Rod Pusher can be used to seat the rod.

TIP: When rod is fully seated in the screw cup, the top of the Reducer will be flush with or slightly below the top of the Screw Extension.

To disengage and remove the Rod Reducer, rotate and hold the release arm upward and lift the Rod Reducer off of the Screw Extension.

CAUTION – Application of excessive torque onto the Rod Reducer can result in screw damage, instrument damage, screw pullout, pedicle fracture, and/or neurological injury. Do not exceed physiological forces in reducing spondylolisthesis. If unable to reduce, consider additional rod contouring, screw relocation, screw height adjustment, or in situ fusion.

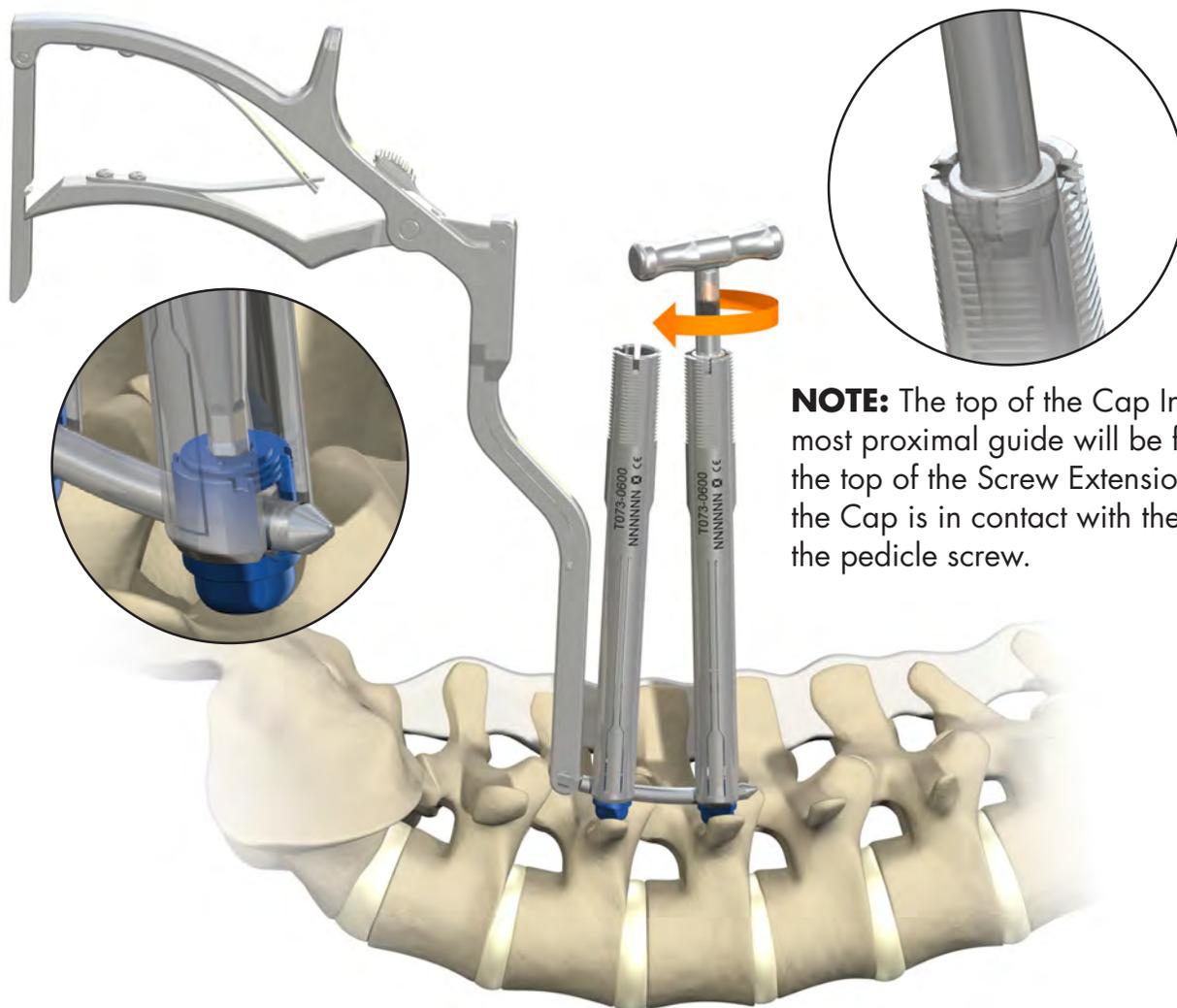


CAP INTRODUCTION:

Step 10: Cap Introduction

After the rod placement, insert an Xpress™ Cap through the Screw Extension and provisionally tighten using either the T-Handle or Inline Cap Introducer.

TIP: Ensure Screw Extension is normal to the curvature of the rod to aid cap introduction.



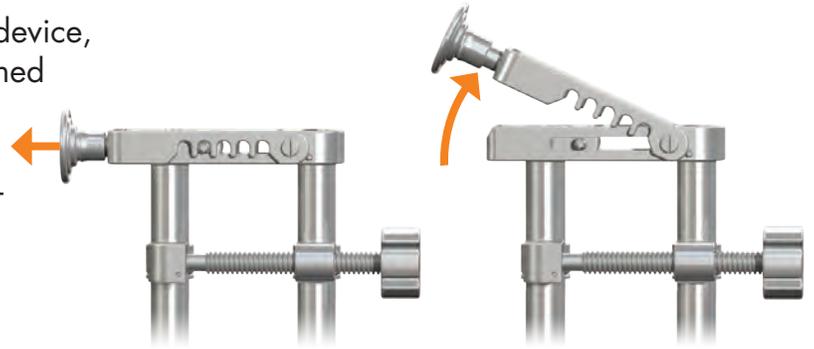
NOTE: The top of the Cap Introducer's most proximal guide will be flush with the top of the Screw Extension when the Cap is in contact with the top of the pedicle screw.



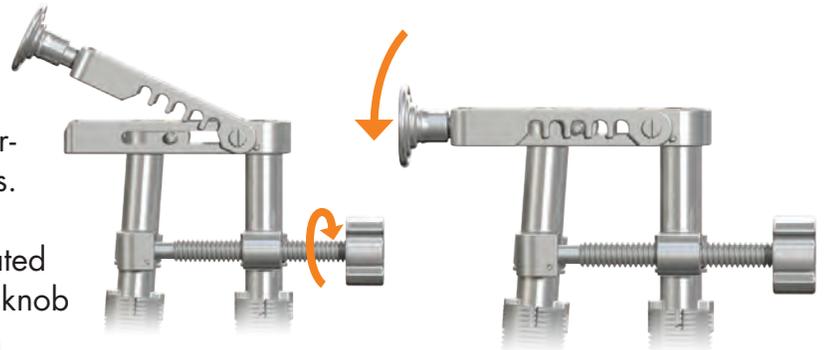
COMPRESSION AND DISTRACTION (Optional):

❑ Step 11: Compression and Distraction

Before using the Compressor-Distractor device, at least one screw should be final tightened (see Step 12) and used as a fulcrum to be distracted or compressed against. Retract the pull knob on the Compressor-Distractor and rotate upwards to disengage the locking arm.



Adjust the drive screw knob until the distal ends of the posts of the Compressor-Distractor align with the Screw Extensions. Then advance the Compressor-Distractor down until the proximal tabs are fully seated in the Screw Extensions. The drive screw knob may need to be adjusted during insertion to aid alignment and proper seating.



Re-engage the locking arm.

Slide the Handle Extender over the drive screw knob and rotate clockwise to distract or counter-clockwise to compress.



The Final Cap Driver and Torque Limiting Handle can then be used to final lock the remain Cap through the Compressor-Distractor.

To remove the Compressor-Distractor, retract the pull knob and rotate upwards to disengage the locking arm. Next, lift the Compressor-Distractor posts out of the Screw Extensions, adjusting the drive screw knob as necessary to aid in instrument release.

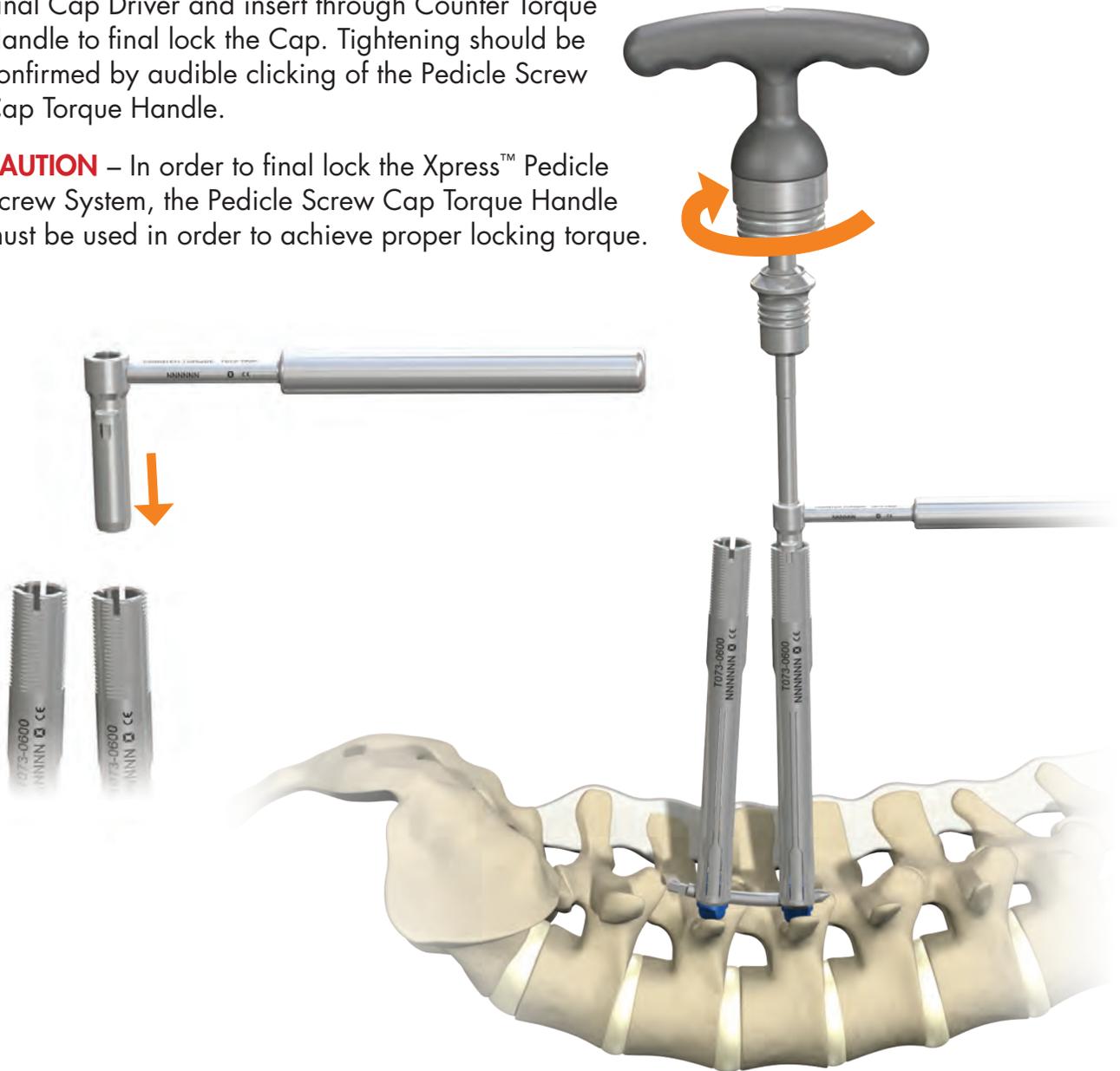
FINAL TIGHTENING:

❑ Step 12: Final Tightening

Insert the Counter Torque Handle into the Screw Extension and seat tabs.

Attach the Pedicle Screw Cap Torque Handle to the Final Cap Driver and insert through Counter Torque Handle to final lock the Cap. Tightening should be confirmed by audible clicking of the Pedicle Screw Cap Torque Handle.

CAUTION – In order to final lock the Xpress™ Pedicle Screw System, the Pedicle Screw Cap Torque Handle must be used in order to achieve proper locking torque.



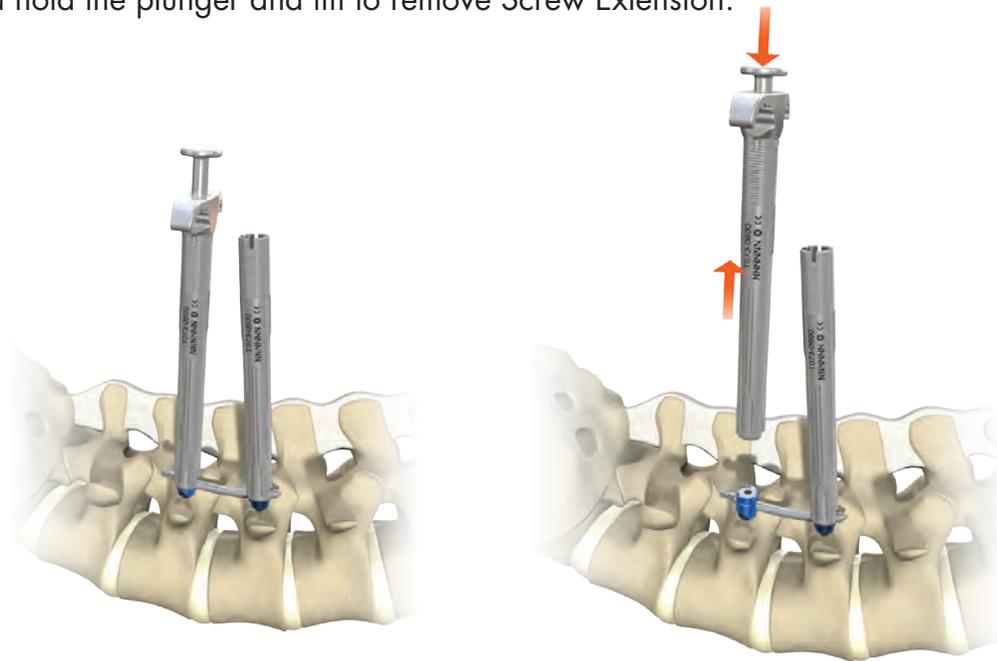
DISASSEMBLY:

Step 13: Disassembly

To remove the Screw Extension from the screw after final tightening, slide the Extension Release Instrument into the Screw Extension, aligning the arrows on the plunger axially with the rod, until fully seated.



Depress and hold the plunger and lift to remove Screw Extension.



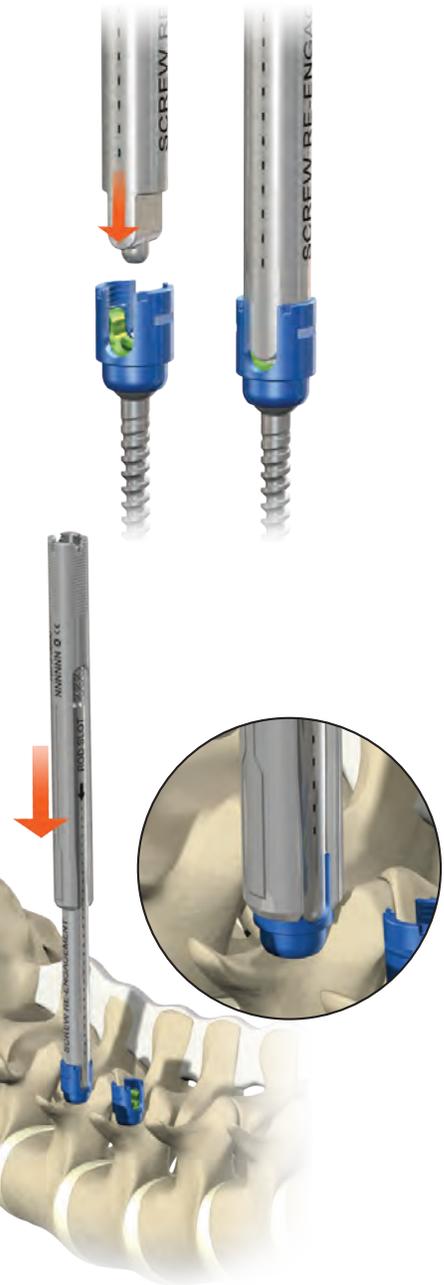
NOTE:

- If the Extension Release Instrument is misaligned and/or not fully seated, the Screw Extension will not properly disengage.
- Excessive force should not be used when removing Screw Extension.

RE-ENGAGEMENT:

❑ Screw/Screw Extension Re-engagement

If Screw/Screw Extension re-engagement is desired, insert the distal tip of the Screw Re-engagement Instrument into the bone screw polyaxial head, aligning the tabs of the instrument with the rod slot of the screw cup. Advance until fully seated.



Once the Screw Re-engagement Instrument is seated, slide a Screw Extension over the shaft of the Screw Re-engagement Instrument aligning the rod slot with the dashed lines. Advance the Screw Extension down until the Extension snaps onto the polyaxial screw. An audible click should be heard when the Extension attaches to the cup.

System Removal/Revision

For System removal or revision, the Fortex® System instrumentation will be required. If a rod needs to be removed or repositioned, the Final Locking Sleeve is introduced over the screw and rod. The Final Locking Cap Driver is introduced into the sleeve such that its tip engages the Cap. The Final Locking Cap Driver is then rotated counter-clockwise to loosen the Cap. The rod can then be removed or repositioned. It is advised that a screw undergo no more than three locking cycles. If additional cycles are required, a new screw and cap is required. The Xpress™ Pedicle Screw is removed using the Fortex® Pedicle Screw Driver and Ratcheting Handle. If a screw is replaced, it is recommended that a larger screw be utilized to maintain bone purchase, provided that the larger screw size is within anatomical limitations.

NOTE: Use the standard Fortex® Pedicle Screw System instrumentation.



XPRESS™ INSTRUMENTS

T073-0330 Final Dilator



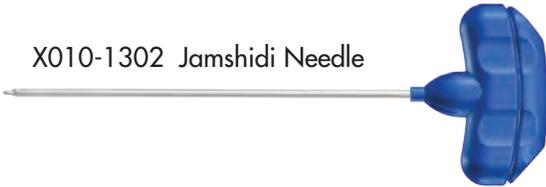
T073-0320 Second Dilator



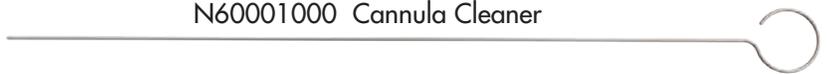
T073-0310 Starting Dilator



X010-1302 Jamshidi Needle



N60001000 Cannula Cleaner



X010-0177 Guide Wire, Trocar



X010-0178 Guide Wire, Blunt



T073-0500-475 4.75mm Tap, Cannulated

T073-0500-55 5.5mm Tap, Cannulated

T073-0500-65 6.5mm Tap, Cannulated

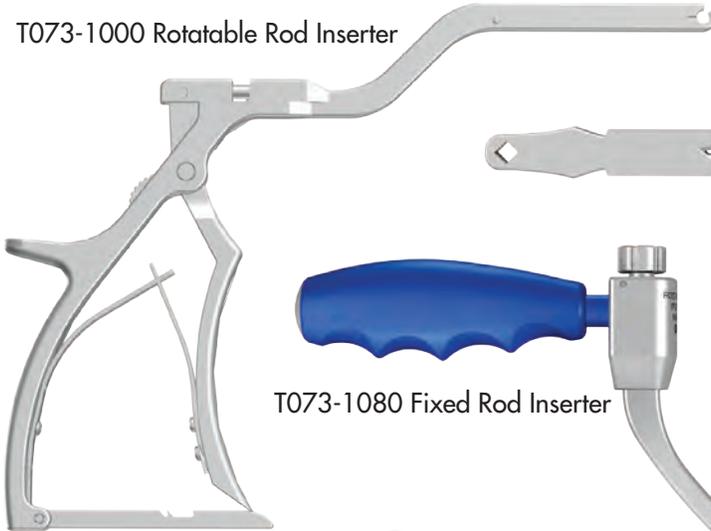
T073-0500-75 7.5mm Tap, Cannulated



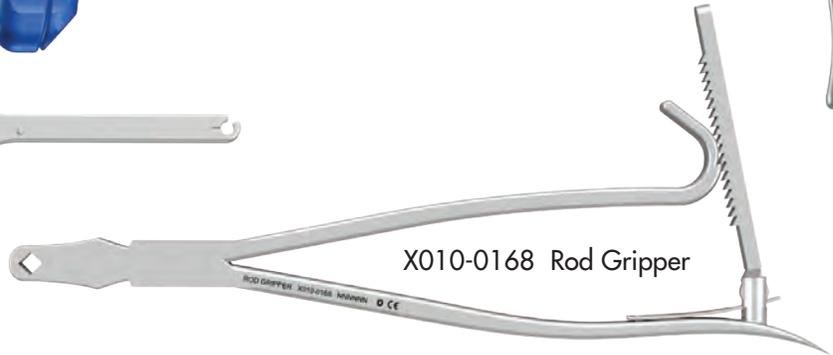
T073-0400 Awl, Cannulated



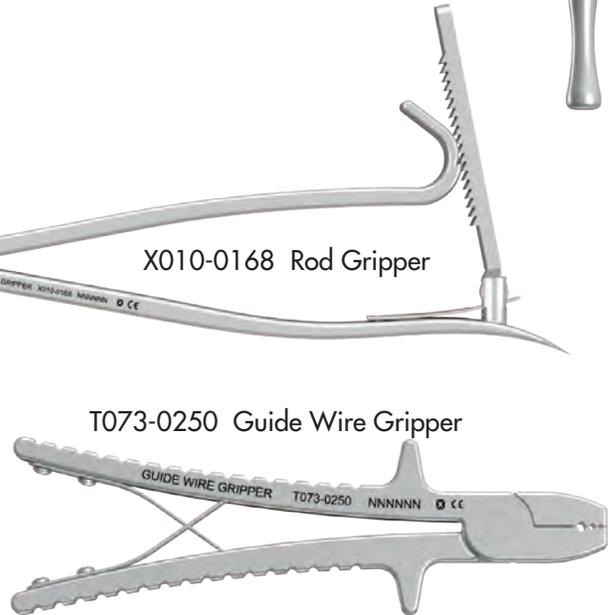
T073-1000 Rotatable Rod Inserter



X010-0168 Rod Gripper



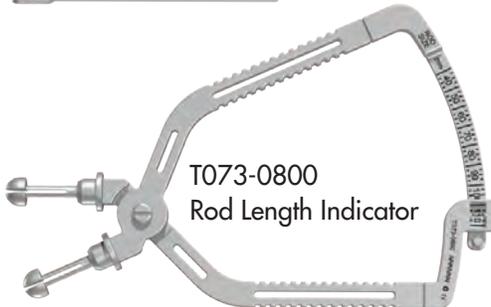
T073-0250 Guide Wire Gripper



T073-1080 Fixed Rod Inserter



T073-0800 Rod Length Indicator



T073-1100 Rod Pusher



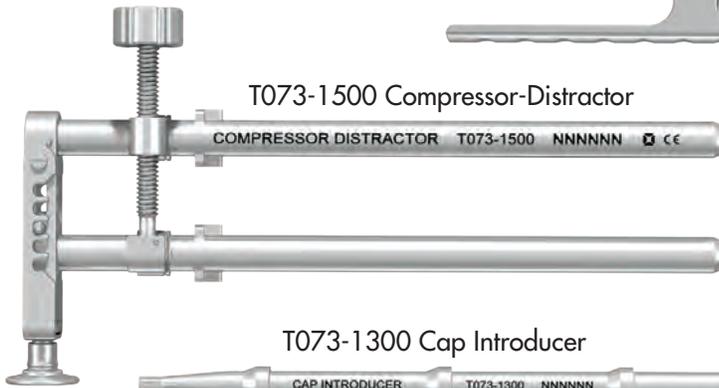
N60000481 Rod Bender



X034-0915 Mallet



T073-1500 Compressor-Distractor



T073-1300 Cap Introducer



T073-1400 Counter Torque Handle



T073-1800 Extension Release



T073-0600 Screw Extension



T073-0700 Pedicle Screwdriver



T073-1310 Final Cap Driver



T073-1320 Inline Cap Introducer



T073-1900 Screw Re-engagement



T073-1200 Rod Reducer



T073-0900 Tissue Splitter



T073-2000 Handle Extender



N60000473 Ratcheting Inline Handle



N60000472 Ratcheting T-Handle



X022-0131 Pedicle Screw Cap Torque Handle



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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Products Patented and Patents Pending

All products are not currently available in all markets.

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