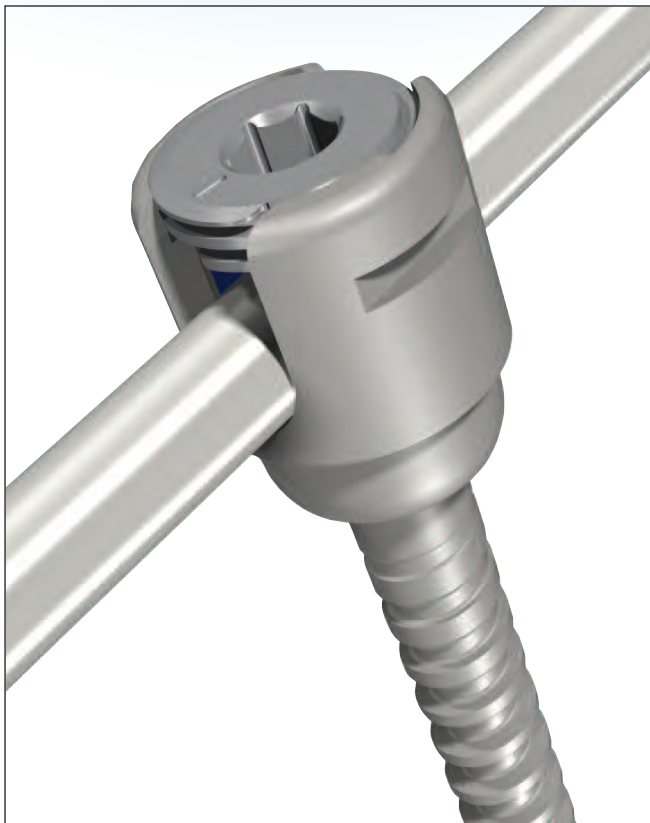




X-spine™ Surgical Technique



The Fortex™ Pedicle Screw System
Simplicity Reinvented

 **X·spine™**
X·treme Innovations

yourspine 

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X-spine Surgical Technique

The Fortex™ Pedicle Screw System

Simplicity Reinvented

Introduction

The X-spine Fortex Pedicle Screw System consists of titanium alloy bone screws, rods, cross-connectors and associated instruments. The system is indicated for attachment to the pedicles of the thoracic, lumbar, and sacral spine. This technique guide is for informational purposes and is not intended as a substitute for appropriate surgical training and judgment.

The Fortex 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 system is intended to provide immobilization and stabilization of 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). Please refer to the package insert for specific labeling limitations and information.

CAUTION – Failure to incorporate appropriate anterior support for a posterior pedicle screw construct may result in abnormal loading, failure or loosening of the construct.

Patient Positioning and Approach

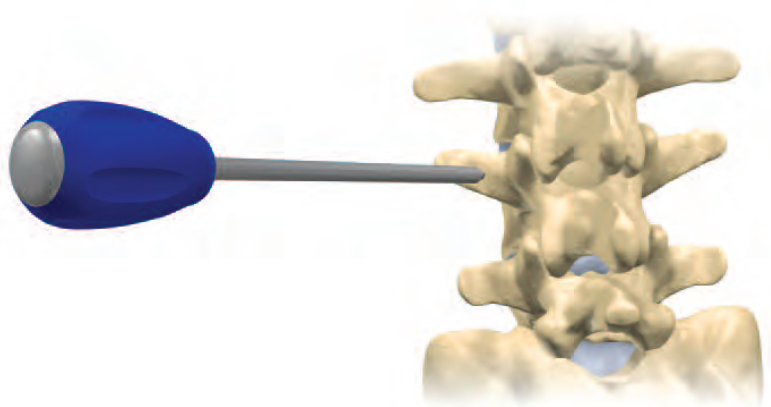
The patient is positioned on the operating table in the prone position. The patient should be positioned on an appropriate support frame in order to minimize intraabdominal pressure to avoid venous congestion, excess intraoperative bleeding and allow adequate ventilation under anesthesia. The patient's hips should be extended to preserve lumbar lordosis for fusion and instrumentation of the lumbosacral junction.

The spine is exposed via a posterior surgical approach. Decortication and bone grafting is performed per desired technique. Meticulous fusion techniques are critical for success of the procedure. The Fortex Pedicle Screw System is intended to be used in conjunction with anterior column support, such as interbody structural bone graft placement or vertebral body replacement device. Failure to place anterior column support may result in premature failure and/or loosening of any pedicle screw system. The pedicles are identified using standard surgical landmarks and their position is confirmed using AP and lateral intraoperative fluoroscopy or radiography.



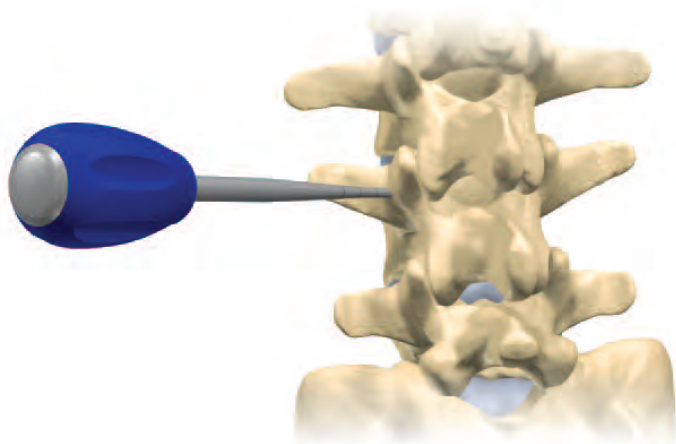
❑ Step 1

A Bone Awl is used to penetrate the cortical bone at the pedicle entry point. The pedicle entry zone is identified and should be decorticated and free of osteophytes to allow for proper polyaxial motion of the screws.



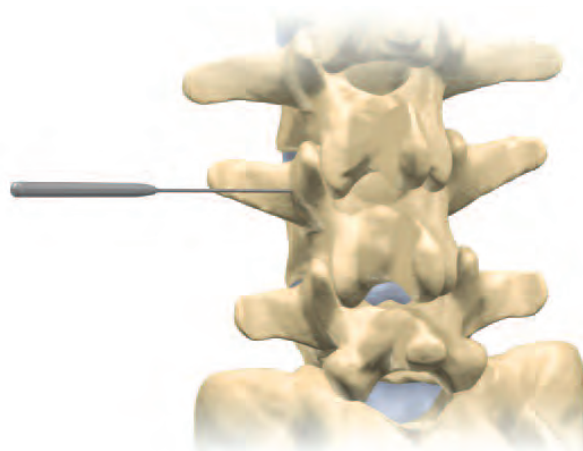
❑ Step 2

A Pedicle Probe is used to create a pilot hole for the Fortex Pedicle Screw. The Pedicle Probe is driven into the pilot hole and pedicle under radiological guidance. Note the depth markings on the side of the instrument. Straight and Curved Probes are available. It is recommended that electrophysiological testing of the probe be performed to rule out abnormal conductance between the Probe and the nerve root.



❑ Step 3

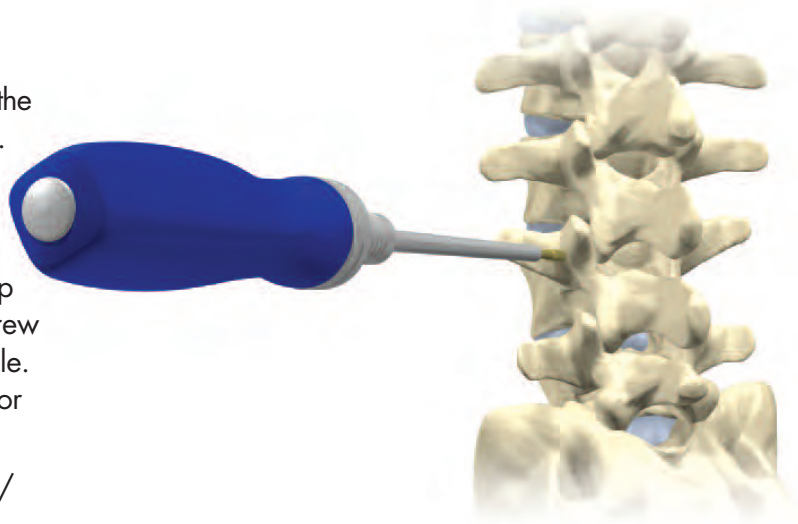
A Ball-Tipped Pedicle Sounder is used to confirm there is no pedicle wall violation prior to screw placement. Straight and Curved Sounders are available.



❑ Step 4

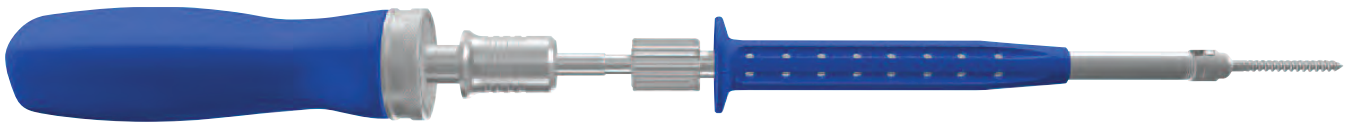
Using preoperative and intraoperative radiographs, the appropriate Fortex Pedicle Screw size is determined. The screws are available in 4.75, 5.5, 6.5, 7.5 and 8.25mm diameters and 30, 35, 40, 45, 50 and 55mm lengths. An appropriately sized Tap is used to tap the pilot hole. It is recommended that the Tap be rotated only deep enough to facilitate initial screw purchase. Taps for all diameter screws are available. Taps are undersized 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.



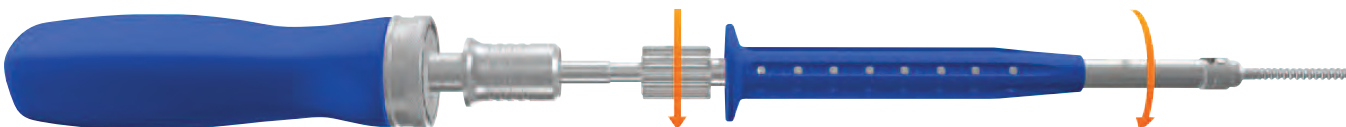
❑ Step 5

The Fortex Pedicle Screw is placed on the tip of the Fortex Pedicle Screw Driver. The Ratcheting Screwdriver Handle must first be placed in the neutral, non-ratcheting position for screw engagement. The screw shaft may need to be rotated slightly for the male and female hex couplings to align for engagement.



❑ Step 6

The screw is secured to the Fortex Pedicle Screw Driver by lowering the Inner Locking Sleeve. This step should be performed with the screw in the screw caddy or resting upon a sterile surface to avoid premature screw disengagement.



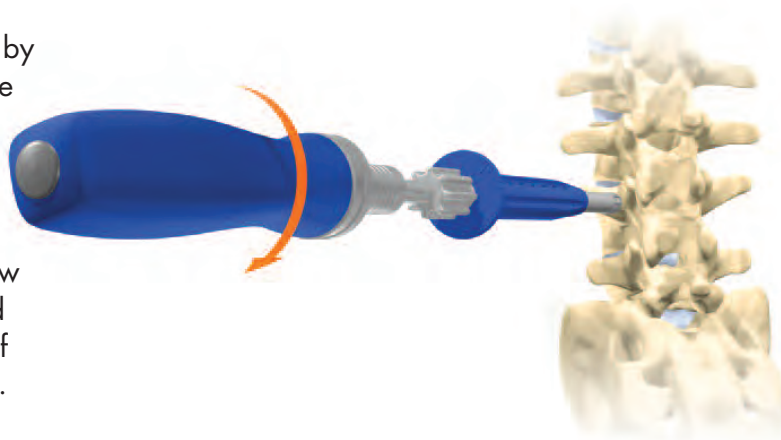
❑ Step 7

The Inner Locking Sleeve is rotated clockwise by hand until increasing resistance is felt. Rotating the Inner Locking Sleeve will firmly lock the Fortex Pedicle Screw onto the driver and prevent screw toggle under lateral forces.



Step 8

The Fortex Pedicle Screw is driven into the pedicle by gripping the Blue Outer Sleeve of the Fortex Pedicle Screw Driver and firmly rotating the Ratcheting Screwdriver Handle. Prior to placement, the screw size should be confirmed by direct measurement using the Screw Gauge located on the side of the screw caddy and re-confirmed by reading the screw size engraved into the screw top. The screw should be driven from 50% to 67% of the AP dimension of the vertebral body and centered within the pedicle. Intraoperative radiography and electrophysiology should be used to confirm screw position. The screw should be driven into the pedicle such that the polyaxial top retains appropriate range of motion.

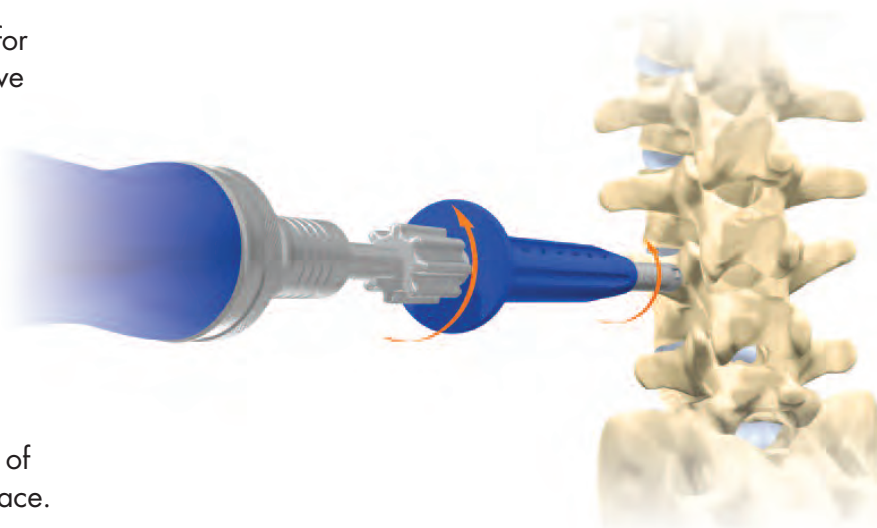


Step 9

Once the screw is in the proper position, the Ratcheting Screwdriver Handle must again be placed in the neutral, non-ratcheting position for screw disengagement. The Inner Locking Sleeve is rotated counter-clockwise. Once the Inner Locking Sleeve Threads are disengaged, lift the Fortex Pedicle Screw Driver off the screw.

CAUTION – Placement of the Fortex Pedicle Screw outside of the pedicle can result in neurological injury, vascular injury, and/or inadequate fixation.

CAUTION – Placement of high torque force during screw tightening may result in stripping of bone and weakening of the bone/screw interface. If screw stripping or other compromise of the bone/screw interface occurs, placement of a wider and/or longer screw is advised, within anatomical limitations. If screw replacement fails to establish adequate strength, repositioning of the screw and/or extension of the construct is advised. Following screw placement, intraoperative lateral and A/P radiography must be performed to confirm appropriate positioning.



❑ Step 10

The Rod Bender is used for rod contouring, if needed. Care should be taken to place rod contours between the points of rod fixation, rather than through them. Alternatively, pre-bent rods are available.

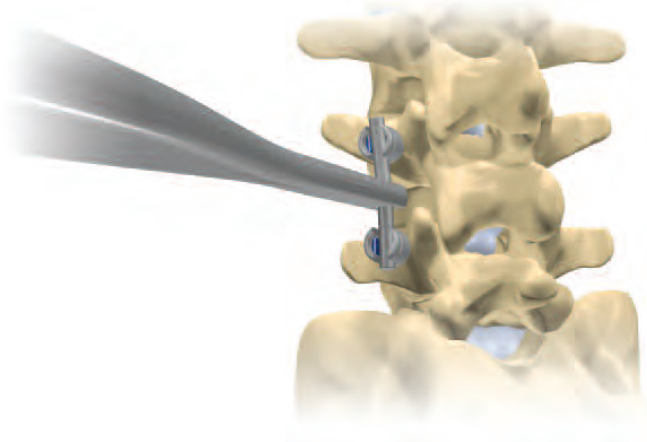
CAUTION – Once bent, avoid reverse bending the rod in the same location. This may result in rod weakening and premature fatigue fracture.



❑ Step 11

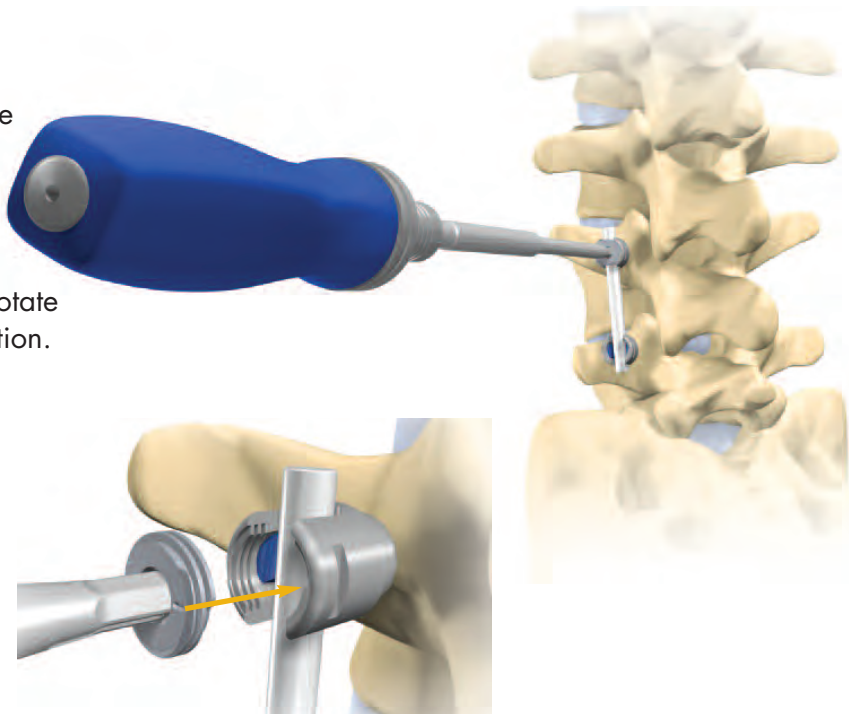
The Rod Gripper is used to introduce the rod into the Fortex Pedicle Screws. The rod should extend at least 5mm beyond the end screws of the construct.

CAUTION – Avoid placement of a bent-rod apex into the locking zone of a screw. This may result in abnormal locking torque, screw damage, or weakening of fixation.



❑ Step 12

After rod placement, the self-retaining Cap Introducer is pressed down into the Cap. To establish Loose Rod Capture, align the recessed marker on the Cap with the lead in thread on the screw head and rotate clockwise. Note that the Cap Introducer is not designed to rotate the Cap into the final, fully locked position.



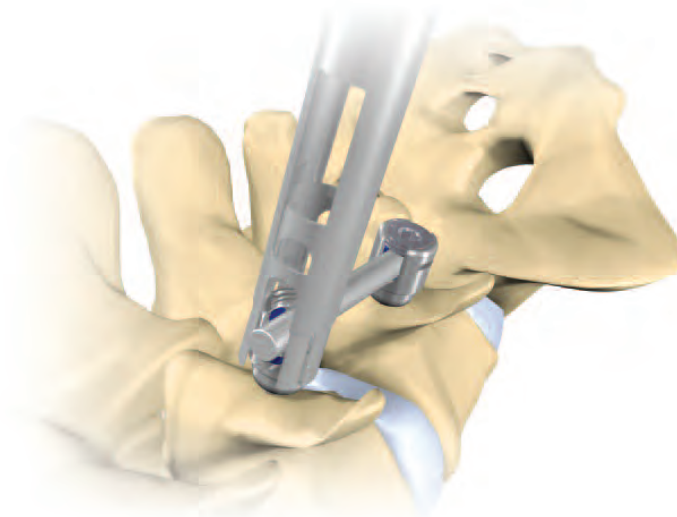
❑ Step 13

In lieu of using the Cap Introducer for Loose Capture Locking, the Pistol Grip Reducer can be used to perform rod reduction into the screw.



❑ Step 14

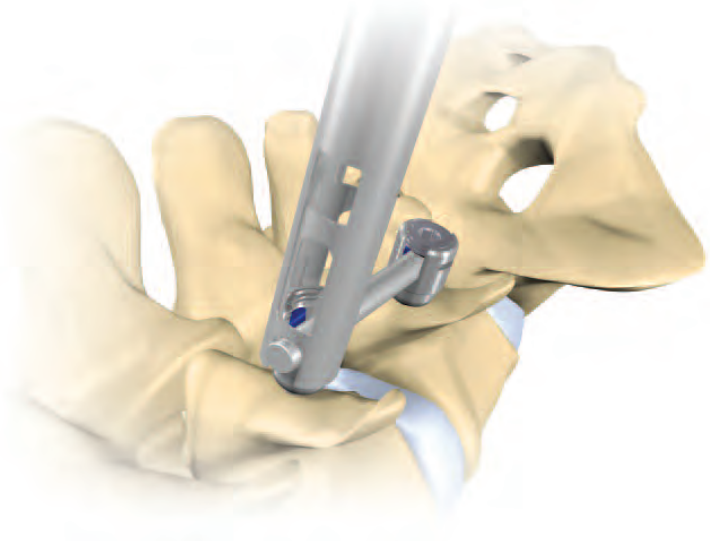
The Pistol Grip Reducer tip is placed over the rod and screw such that the instrument tip fully engages the entire screw head. The area around the screw should be free of bony protrusion to ensure full engagement.



❑ Step 15

The pistol grip handles on the Pistol Grip Reducer are squeezed to perform rod reduction.

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



❑ Step 16

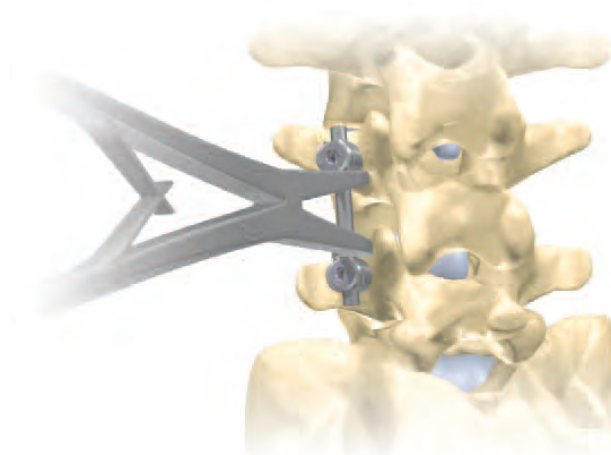
Once reduction has been performed, the Final Locking Cap Driver can be engaged through the center of the Pistol Grip Reducer to perform screw locking. The Final Locking Cap Driver can be used for either Loose Rod Capture or Final Locking.



❑ Step 17

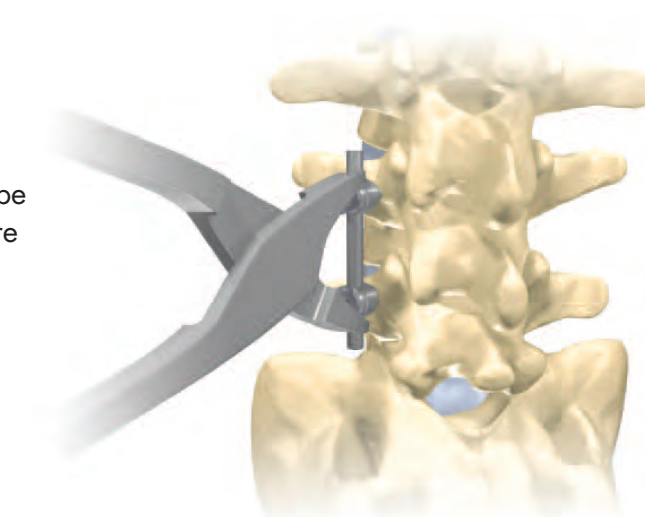
The Distractor Instrument is used to perform screw distraction while the rod is loosely captured. Alternatively, an individual screw can undergo final tightening (see Step 23) and be used as a fulcrum to be distracted or compressed against. Once the screws are in the desired position, final tightening of the Fortex Pedicle Screw is performed.

An In-line Distractor is also available.



❑ Step 18

The Compressor Instrument is used to perform screw compression while the rod is loosely captured. Alternatively, an individual screw can undergo final tightening (see Step 23) and be used as a fulcrum to be distracted or compressed against. Once the screws are in the desired position, final tightening of the Fortex Pedicle Screw is performed.



Method for Reduction of Spondylolisthesis

Step 19

The threaded Persuader Instrument is included to assist in rod reduction of spondylolisthesis. The Persuader Instrument is placed onto the corresponding collar of the Fortex Pedicle Screw housing.



Step 20

The Persuader Instrument Handle is then rotated counter-clockwise to lower the Inner Sleeve onto the screw. Keyed tabs within the Inner Sleeve engage matching slots in the Fortex Pedicle Screw. The Final Locking Cap Driver can be used for either Loose Rod Capture or Final Locking.



CAUTION – Application of excessive torque onto the Persuader Instrument 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, or *in situ* fusion.

❑ Step 21

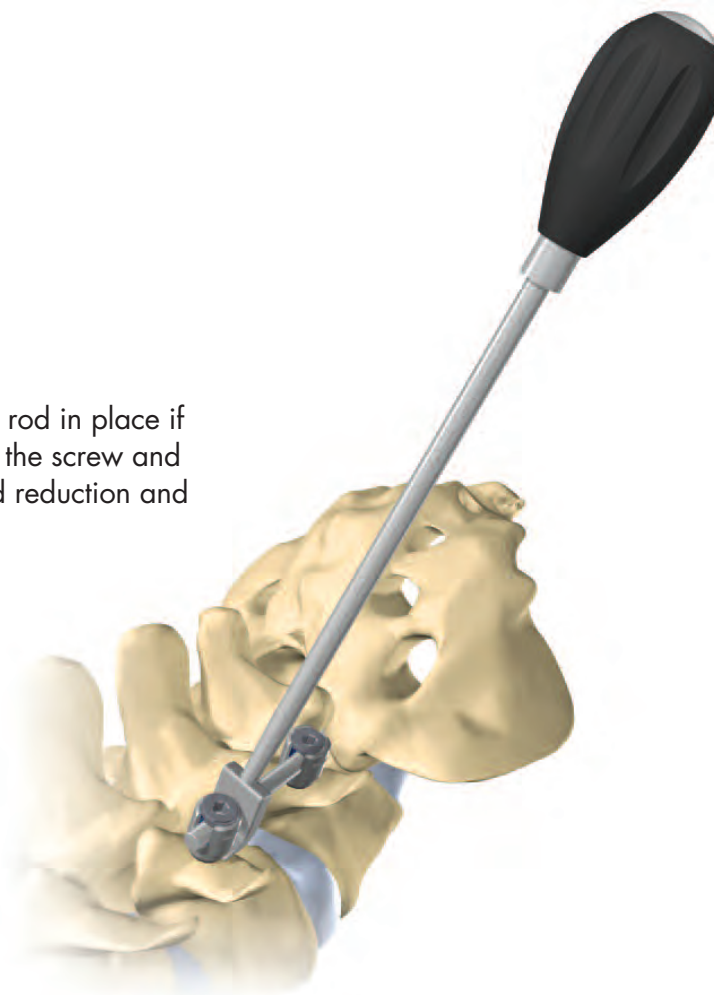
Once reduction has been performed, the Final Locking Cap Driver can be engaged through the center of the Persuader Instrument to perform screw locking. The Final Locking Cap Driver can be used for either Loose Rod Capture or Final Locking.

CAUTION – In order to Final Lock the Fortex Pedicle Screw System, the Torque-limiting Handle must be used in order to achieve proper torque force.



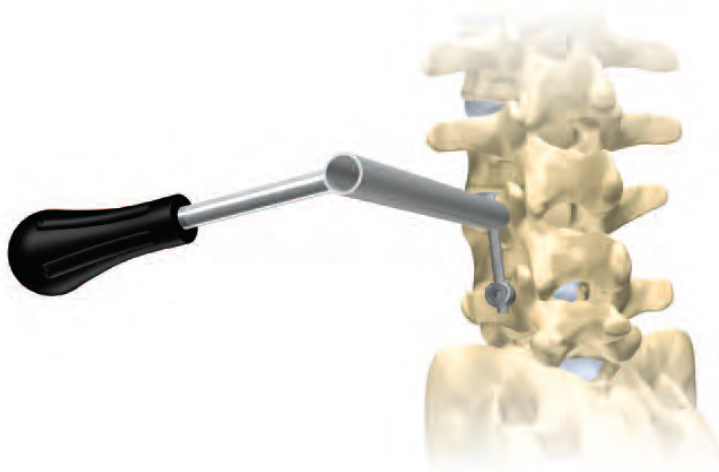
❑ Step 22

A Rod Fork is provided to reduce the rod in place if required. The Rod Fork jaws engage the screw and the Rod Fork is rocked to achieve rod reduction and allow for Loose Rod Capture.



Step 23

Once satisfactory anatomical alignment has been achieved, final tightening of the Fortex Pedicle Screws can be performed. The Final Locking Sleeve is placed over the screw heads prior to final screw locking. Care must be taken to ensure that the instrument is FULLY SEATED over the screw and rod prior to introduction of the Final Locking Cap Driver.



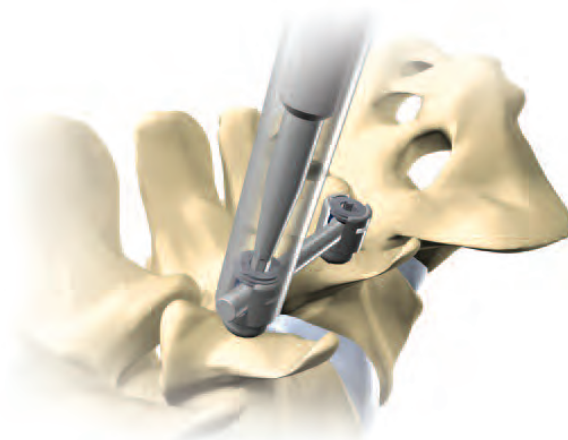
Step 24

The Final Locking Sleeve with the Final Locking Cap Driver in place.



Step 25

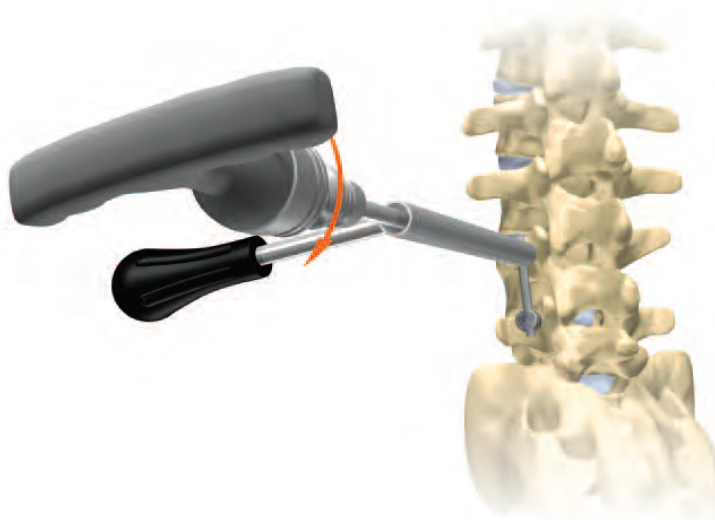
With the Final Locking Sleeve fully engaged, the Final Locking Cap Driver is placed such that the hex on the Final Locking Cap Driver is engaged with the Cap. A tactile feel will confirm engagement.



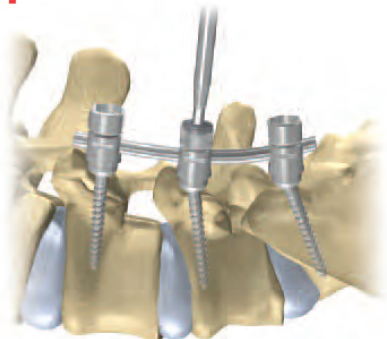
Step 26

The Torque-limiting Handle is used to rotate the Final Locking Cap Driver until resistance is felt. Tightening should be confirmed by audible clicking of the Torque-limiting Handle.

CAUTION – In order to Final Lock the Fortex Pedicle Screw System, the Torque-limiting Handle must be used in order to achieve proper torque force.

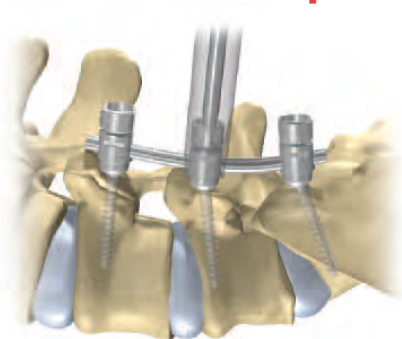


Optional Fortex Reduction Screw Technique



- ❑ Introduce the rod into Fortex Reduction Pedicle Screws. Using the Cap Introducer, thread the cap into the extended tabs so that the rod is fully seated into the screw cup.

Optionally: Anti-Splay Rings may also be used.



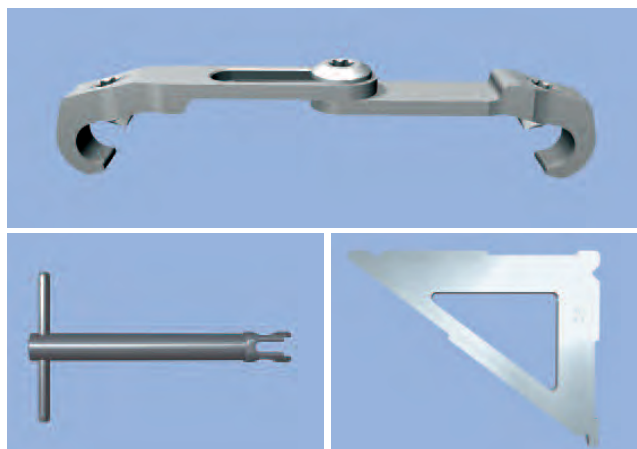
- ❑ Place the Counter Torque Sleeve over the screw head and lock down the cap using the Final Locking Driver and Torque-Limiting Handle.



- ❑ Using the Tab Removal Tool, remove the tabs of all Fortex Reduction Screws in the construct.

Cross Connector Placement (if required)

Cross Connectors are available in both fixed and variable configurations. Prior to placement of a Cross I Connector, the appropriate size can be determined by using the Cross Bar Sizing Template. Once the correct size has been determined, the Cross Bar is placed spanning the rods bilaterally. The threaded portion of each Cross Bar contains a deformable ring which contacts the bottom surface of the rod. The Cross Bar is placed over the rods such that each rod is fully engaged in the Cross Connector jaws. The Cross Bar Hex Fasteners are tightened using the Cross-Connector Driver and Cross-Connector Torque Handle. The Cross Bar Hex Driver is placed through the Cross-Connector Counter-torque Instrument, which engages the Cross Connector body. When the pre-set tightening torque is achieved, a “clicking” sound will be heard and the handle will no longer transmit torque. Removal of the Cross Bar is achieved by reversing the procedure.



System Removal/Revision

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 Fortex 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.



Fortex™ Pedicle Screw System Instruments



Fortex Pedicle Screwdriver – #X022-0140



Persuader – #X022-0190



Adjustment Screwdriver with Ratcheting Handle –
#X022-139 and N60000473



Pistol Grip Reducer – #X022-0150



Cap Introducer – #X022-0130



Final Locking Driver – #X022-0161



Final Locking Sleeve – #X022-0162



Torque-limiting Handle – #X022-0131



Cross Bar Screwdriver with Cross Connector
Torque Handle – #N60000496/478



Curved Sounding Probe – #N60000471



Straight Sounding Probe – #N60000470



Counter-torque Instrument for
Cross Bar Screwdriver – #N60000494



Pedicle Screw Tap with Ratcheting Handle

4.75mm – #X010-0150

5.5mm – #X010-0151

6.5mm – #X010-0152

7.5mm – #X010-0153

8.25mm – #X010-0154



Curved Pedicle Probe – #N60000464



Straight Pedicle Probe – #N60000463



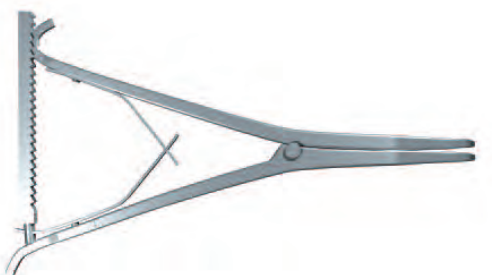
Bone Awl – #N60000461



Rod Fork – #N60001530



Rod Holder – #X010-0168



Distractor – #N60000483



Compressor – #N60000485



Rod Bender – #N60000481



Cross Bar Sizing Template – #N60000497



In-line Distractor #X010-0166



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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