

The Fortex™ Pedicle Screw System *Features & Specifications*

Fortex Pedicle Screw System

- Low torque system, final locks at 70 in-lbs.
- Self-retaining Final Locking Driver/Cap Introducer
- Trocar and Blunt k-wire
- All taps undersized by 10%
- 3.1mm above the rod profile

Fortex Pedicle Screws

- 70 degrees polyaxial motion
- 15.7mm construct height
- All screws cannulated
- 30 - 55mm lengths (increments of 5)
- 4.75, 5.5, 6.5, 7.5, 8.25mm Diameters
- Screw assembly includes: screw shaft, yolk, and cup
- Self-tapping threads
- Cancellous and cortical threads for strong purchase
- Fortex screw cannula is 1.32mm
- 11.3mm run on the rod

Fortex Rods

- Lengths: **Straight:** 35-70mm (increments of 5mm),
80-100mm (increments of 10mm),
120mm, 180mm, 300mm
Continuous Radius:
35-50mm (increments of 5mm),
60-100 (increments of 10mm)
- 5.5mm diameter aluminum-oxide blasted rods provides additional friction

Fortex Caps

- Recessed marker line gives visual identifier of lead-in thread to minimize cross threading
- Rectangular threads allow immediate screw engagement instead of after 3 threads
- Conical shape provides multiple point fixation
- Higby notch helps prevent cross threading

The Fortex™ Pedicle Screw System FAQ's

Q. How many times can a Fortex screw be locked?

A. X-spine suggests that all Fortex caps not be final-locked more than 3 times before they need to be replaced.

Q. Why does the Fortex screw thread appear different than other pedicle screw?

A. Fortex threads are designed to be pedicle sparing threads vs. standard buttress threads. Pedicle sparing threads maximize bone purchase while minimizing cortical wall violation.

Q. How is the Fortex Cap locked using only 2.5 threads?

A. This is due to the unique rectangular thread profile of the Fortex Cap and the Higy Notch which provides a lead-in thread to help prevent cross-threading. In addition, the Conical Locking Ring creates a cold weld providing multiple-point fixation.

Q. What locking driver is intended to be used with the Tower Persuader and Pistol Grip Reducer?

A. The Final Locking Cap Driver is the only intended locking instrument to be used with the Tower Persuader and Pistol Grip Reducer instruments.

Q. What is the diameter of the Fortex Cap hex?

A. The Fortex Cap and Fortex Screw hexes are the same diameter, 4mm.

Q. What instrument is used to adjust the Fortex Screw once implanted?

A. The Adjustment Screwdriver is intended to adjust the Fortex Screw once it has been implanted.

Q. Why are there notches/slots on the side of the screw?

A. The only instrument that utilizes the notches/slots is the blue-handled Tower Persuader.

The Fortex™ Pedicle Screw System **FAQ's**

Q. Where does the Pistol-Grip Reducer and Rod Fork engage the screw?

A. Both instruments must engage the screw from beneath the cup. These instruments do not engage the notches/slots on the side of the Fortex screw.

Q. Why are there multiple colored handles?

A.

- The grey T-handle is the Torque Limiting handle designed to be only used with the Final Locking Driver.
- The blue ratcheting handles (T-handle or In-line) are designed to be used with all instruments except the Final Locking Driver or Cross Connector Driver.
- The black handles are non-ratcheting and designed to be used with all instruments except the Final Locking Driver or Cross Connector Driver.
- The green handle is the torque handle for the Crosslinks. It is set at 40 in.-lbs. Do not use with anything other than Crosslinks.

Q. Are Fortex screws self-drilling?

A. No, Fortex screws are self-tapping only.

Q. Does X-spine offer a Fortex Reduction Screw?

A. Yes, Fortex Reduction Screws with removable tabs are offered in all diameters and lengths as the standard Fortex Screws.

Q. What is the intended use of the Head Turner?

A. The Head Turner is used to align the screw cup in the desired orientation.

Q. Does X-spine offer any instruments not included in the tray?

A. X-spine has a limited quantity of non-standard instruments. Please contact Corporate Headquarters for more information.

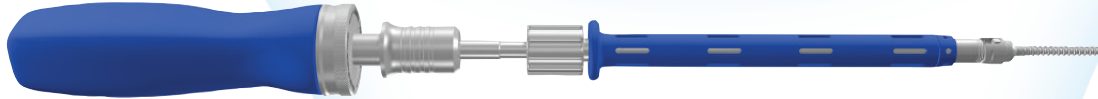
The Fortex™ Pedicle Screw System *Troubleshooting Guide*

Problem	Cause	Solution
The Fortex Torque Handle rotates without rotating the driver.	The handle is not properly engaged	Re-insert handle onto driver so that the bottom of the handle is flush with the metal ring on the driver
Final locking click is heard with minimal applied force	Cap is already torqued beyond 70 in-lbs. when introduced	Even though the cap is torqued beyond 70 in-lbs. do not replace the cap, the system will still function as designed
The screw falls off of the screwdriver upon insertion	The screw is not sufficiently tightened to the driver	Put the ratcheting handle into reverse, this will allow for additional force to be applied. Re-tighten while gripping the ratcheting handle
Surgeon is having a difficult time centering the cap on the screw	The cup is not articulated in a direction suitable for proper cap introduction	Place the Counter Torque Sleeve over the screw and use Final Locking Driver to introduce the cap
The surgeon is not able to engage the threads of the Fortex Cap	The rod is not fully seated in the screw cup	Use one of the rod reduction instruments included in the set to fully seat the rod
The Cap Introducer does not reach the screw threads through the Pistol-Grip Reducer or Tower Persuader	The Cap Introducer is not intended to be used with the Pistol-Grip Reducer or Tower Persuader	Use the Final Locking Driver and Torque Limiting Handle to introduce the cap through the Pistol-Grip Reducer or Tower Persuader

The Fortex™ Pedicle Screw System *Troubleshooting Guide*

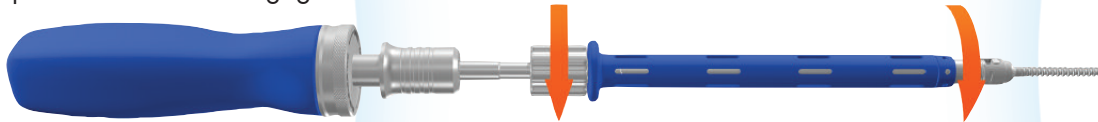
Problem	Cause	Solution
Cannot get Pistol Grip Reducer engaged over the screw cup	<ol style="list-style-type: none"> 1. Screws are placed at different heights or different alignments outside of polyaxial screw range 2. Rod is over-contoured 	<ol style="list-style-type: none"> 1. Utilize Rod Fork, Pistol Grip Rod Reducer and/or Tower Persuader instruments to translate rod into screw. Adjust screw heights by changing depth. Avoid excessively withdrawing screw from bone however. 2. Confirm that rod is not excessively bent through screws.
The Tower Persuader is not properly engaging the notches/slots of the Fortex Screw	<ol style="list-style-type: none"> 1. Persuader is not fully open 2. Tower Persuader is not properly centered over the notches/slots. 	<ol style="list-style-type: none"> 1. Turn Tower Persuader handle counter-clockwise 2. Disengage the Tower Persuader from the screw, re-position the persuader, and re-engage.
Surgeon is using the In-Line Distractor and cannot get the instrument to stay in the screws	An additional step is necessary for proper use	Use Fortex Caps to hold the instrument in place
The screw cup orientation is not suitable for rod placement	Screw cup is rotated	Utilize the Head Turner to align screw cup to the desired orientation

The Fortex™ Pedicle Screw System *Surgical Technique Highlights*



Screwdriver

The Ratcheting Screwdriver Handle must first be placed in the neutral, non-ratcheting position for screw engagement. 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.



Screwdriver

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.

Rod Bender

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.

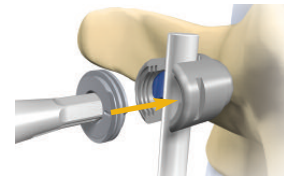
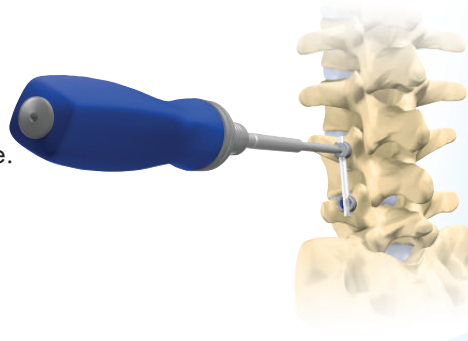


The Fortex™ Pedicle Screw System *Surgical Technique Highlights*

Cap Introducer

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.

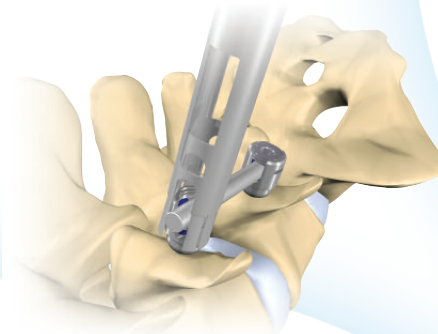
Tip: Handle is not required for this step



Pistol Grip Reducer

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.

Tip: Make sure Pistol Grip Reducer is completely unlocked before engaging the screw.



* For additional information, please see Fortex Surgical Technique

The Fortex™ Pedicle Screw System *Surgical Technique Highlights*

Pistol Grip Reducer

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.

Tip: Do not put Cap Introducer through Pistol Grip Reducer.

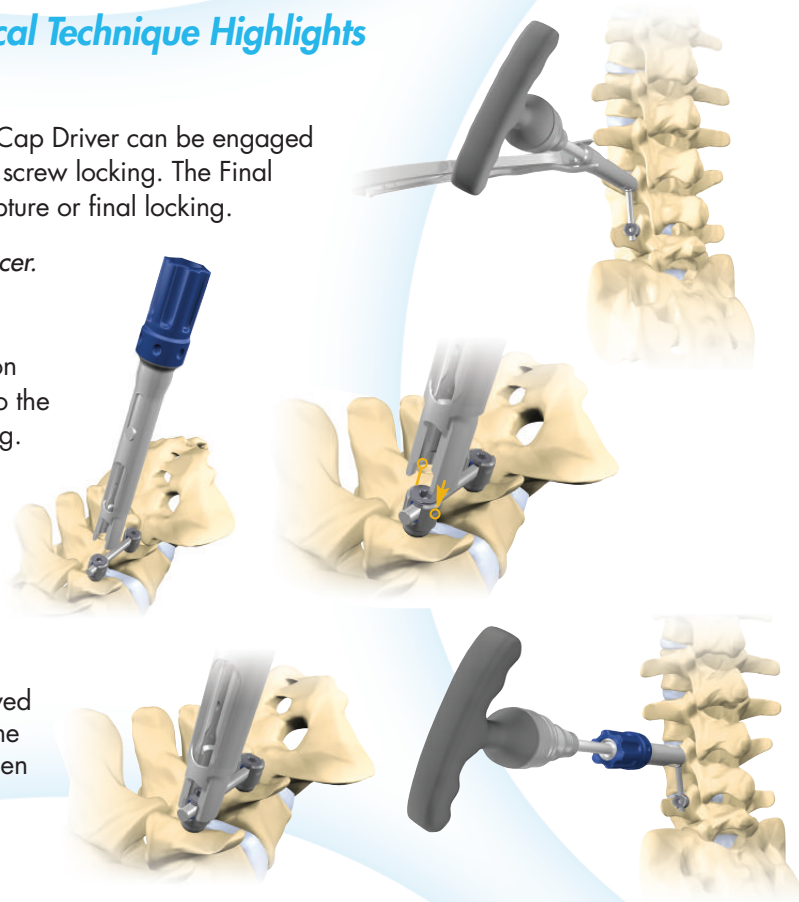
Tower Persuader

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

Tip: Rotate handle counter-clockwise until Tower Persuader is completely unlocked before engaging the screw.

Tower Persuader

The Tower Persuader 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 Tower Persuader handle is then rotated clockwise to reduce the rod into the screw cup. The Final Locking Cap Driver can be used for either loose rod capture or final locking.



The Fortex™ Pedicle Screw System *Surgical Technique Highlights*

Rod Fork

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.

Tip: The Rod Fork engages under the screw cup.



Final Locking

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.

Tip: Make sure handle is properly positioned on the Final Locking Driver.

