



# OPTIMA™ ZS Spinal Fixation System



The low-profile, in-line, polyaxial pedicle screw system



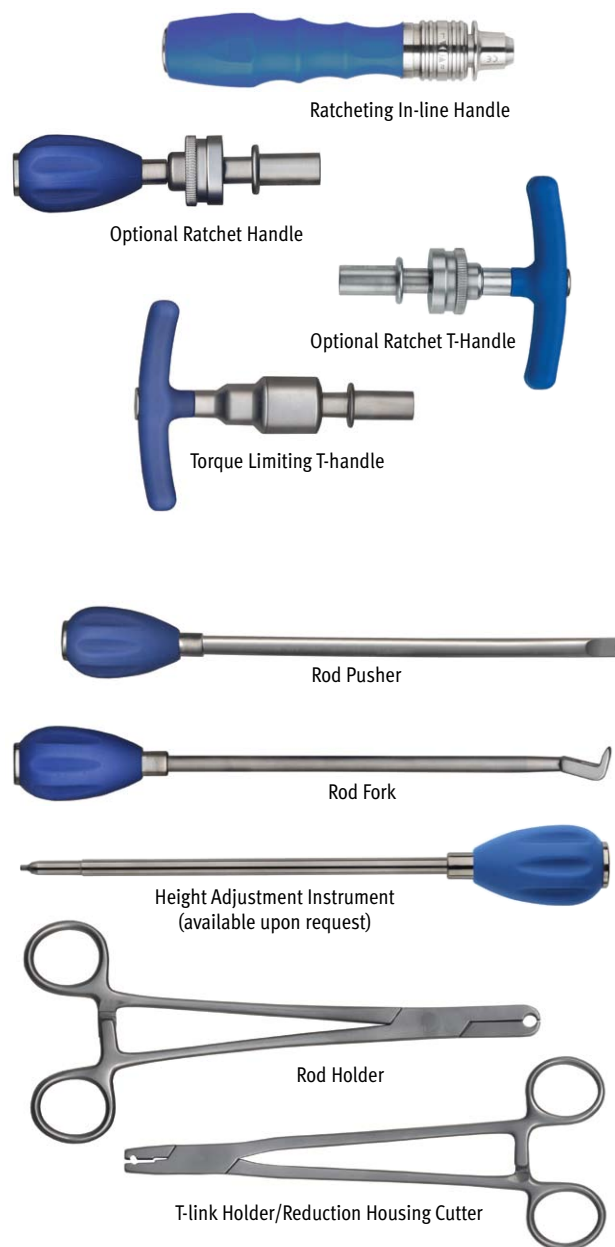
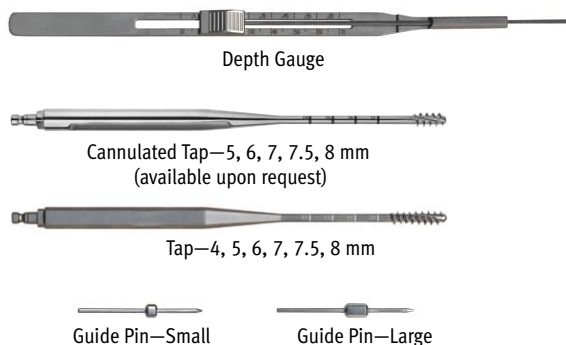
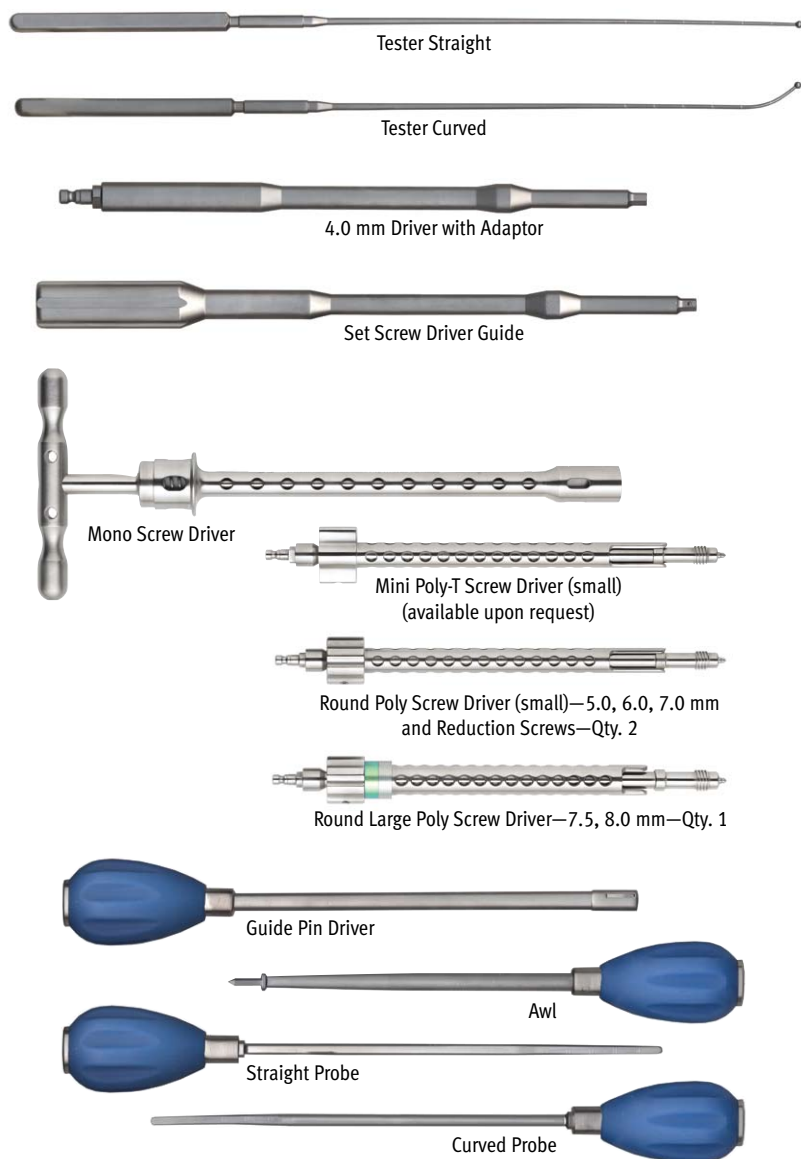
## OPTIMA™ ZS Spinal Fixation System

The *OPTIMA™ ZS* Spinal Fixation System is a low-profile, in-line, polyaxial pedicle screw system that provides three-dimensional adjustability for simple, stable construct assembly.

**Round Up**—Rounded screw head with superior angulation allows polyaxial capabilities after screw placement.

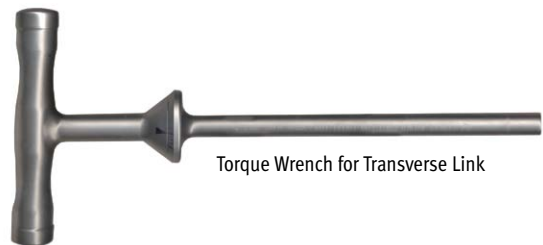
**Square Off**—Trapezoidal-threaded set screw reduces the potential for cross-threading.

**Get In-Line**—Short run-on-rod and low profile provide greater flexibility in construct assembly.





Axial Torque Wrench



Torque Wrench for Transverse Link



Housing Holder



Derotator



In-situ Rod Bender—Left  
In-situ Rod Bender—Right



Rod Bender



Poly Head Adjuster  
(available upon request)



Persuader



Anti-Torque Device



Small-Screw Anti-Torque Device  
(available upon request)



Compressor



Spreader



## Core Instrument Set

Part Number	Description
MU20003	Straight Probe
SG0001	Awl
SG0002	Small Guide Pin
SG0003	Large Guide Pin
SG0004	Guide Pin Driver
SG0005	Curved Probe
SG0006	Straight Tester
SG0007	Curved Tester
SG0008	Depth Gauge
SG0011	Rod Bender
SG0020	4mm Tap
SG0022	5mm Tap
SG0024	6mm Tap
SG0026	7mm Tap
SG0027	7.5mm Tap
SG0028	8mm Tap
SP0006	Set Screw Driver Guide
SP0010	Rod Fork
SP0011	Rod Pusher
SP0012	Mono Screw Driver
SP0014	Ratchet Handle
SP0015	Spreader
SP0016	Compressor
SP0024	4.0mm Driver w/ Adaptor
SP0037	Round Poly Screw Driver (Small)

## Hook Instrumentation

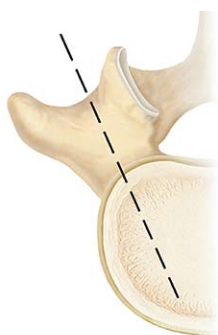
Part Number	Description
SH1010	Depth Gauge for Finder
SH1020	Hook Holder
SH1030	Hook Impactor
SH1040	Laminar Finder
SH1045	Throat Finder
SH1050	Pedicle Finder
SH1070	Long Throated Hook Holder
SH1080	Curved Hook Holder
SH1110	Derotation Wrench

## Auxiliary Tray

Part Number	Description
SH1060	Persuader
SP0019	T Link Holder/ Reduction Housing Cutter
SG0012	Rod Holder
SG0018	Derotator
SG0032	Torque Wrench for Transverse Link
SP0009	Housing Holder
SP0013	Right In- Situ Rod Bender
SP0018	Left In- Situ Rod Bender
SP0021	Anti Torque Device
SP0039	Round Large Poly Screw Driver

## Torque Wrenches and Optional Instruments

Part Number	Description
SP0030	Poly Head Adjuster
SP0032	5.0mm Cannulated Tap
SP0033	6.0mm Cannulated Tap
SP0034	7.0mm Cannulated Tap
SP0035	7.5mm Cannulated Tap
SP0036	8.0mm Cannulated Tap
SP0038	Mini-T Poly Screw Driver (Small)
SP0041	Small Anti-Torque Device
SP0042	Height Adjustment Instrument
SP0029	Ratchet Handle (Teardrop style handle)
SP0028	Ratchet T Handle
SP0017	Torque Limiting T Handle
SP0026	Axial Torque Wrench



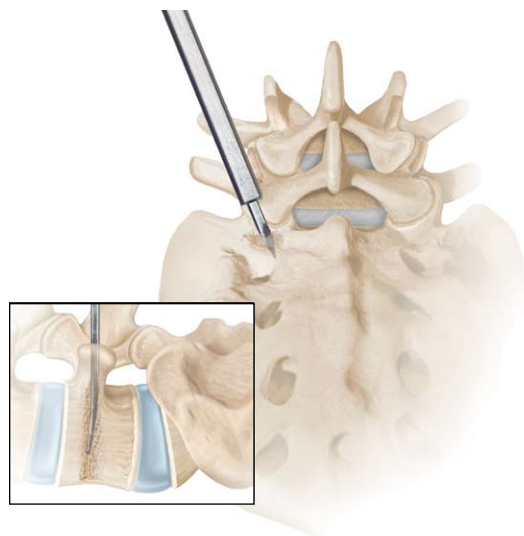
*Screw insertion should follow the angle of the pedicle canal*

### **Pedicle Preparation**

Determine the pedicle canal entry site.

Prepare the pedicle canal using preferred instrumentation.

Insert the Straight Bone Probe into the established entry site, gently pressing through the pedicle canal to determine hole depth.



Guide Pins may be placed to identify appropriate screw trajectory via lateral x-ray/fluoroscopy.



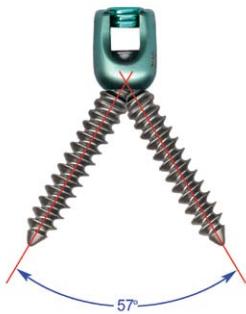
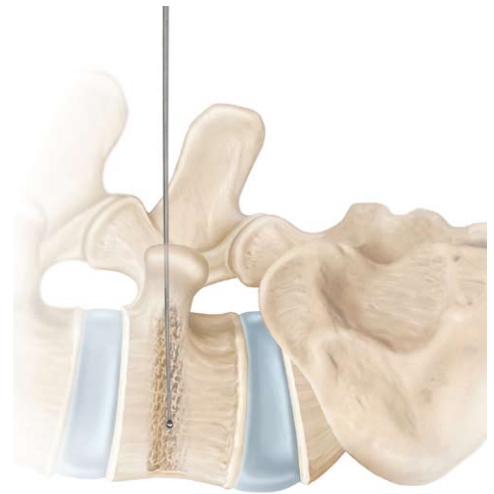
*Use large and small Guide Pins to indicate left- or right-side placement*





*Straight or Curved Testers are graduated to help determine hole depth*

Insert a Straight or Curved Tester and palpate the hole's inner surface to verify pedicle wall integrity.



*Polyaxial Screw Dimensions*

Diameter	Length
5.0 mm	30-45 mm
6.0 mm	25-60 mm
7.0 mm	30-60 mm
7.5 mm	35-60 mm
8.0 mm	35-55 mm

### Polyaxial Screw Insertion

Polyaxial screws are inserted using a Polyaxial Screw Driver.

- Insert 5.0 mm, 6.0 mm, 7.0 mm diameter and all reduction screws using the Round Polyaxial Screw Driver (Small) (SP0037).
  - » The Mini-T Poly Screw Driver (SP0038) may be used in place of the Round Polyaxial Screw Driver (Small).
- Insert 7.5 mm and 8.0 mm diameter screws using the Large Polyaxial Screw Driver (SP0039).

Use both Polyaxial Screw Drivers in conjunction with the Ratchet Handle.

To load the Polyaxial Screw, insert the tip of the Polyaxial Screw Driver into the polybody, positioning the tangs of the attached T-handled Screw Driver Sleeve into the slots on the screw body. Turn the Ratchet Handle clockwise while holding the Screw Driver Sleeve. Once fully engaged on the driver, the screw can then be inserted into the vertebral body.

*Note: Ensure that the driver is fully engaged with the screw prior to inserting. The tip of the screw will not toggle when the driver is fully engaged.*



Insert the polyaxial screw into the desired pedicle and advance to a depth where full angulation of the polyaxial head is maintained.

*Note: Further advancement limits the angulation of the polyaxial screw.*

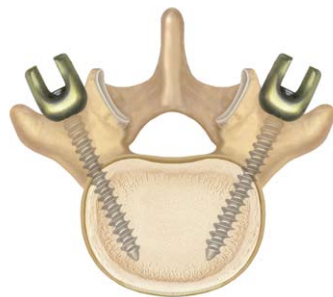
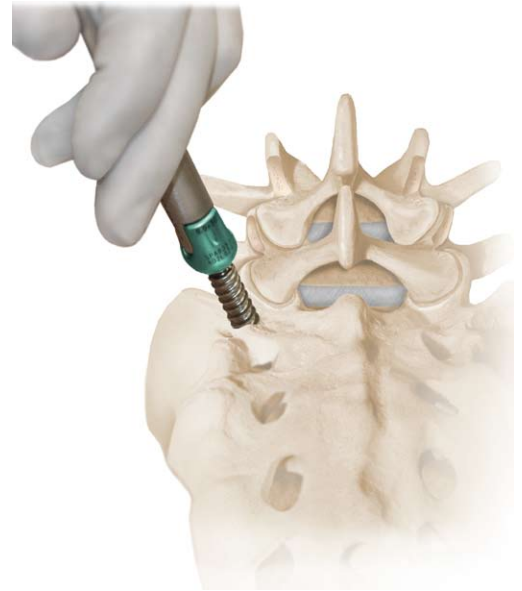
To remove the screwdriver, turn the screwdriver counterclockwise while engaging the polybody with the tangs on the T-handle Screw Driver Sleeve.

Repeat the process until all screws are placed.

Use the Poly Head Adjuster as needed to position the polyaxial screw heads in preparation for rod placement.

If a screw is placed too deep, adjust the screw height using the Screw Adjustment Instrument. To interface the Height Adjustment Instrument with the screw, insert the 2.5 mm hex tip of the instrument into the hex of the polyaxial screw; adjust the screw height as needed.

*Note: The instrument must be lined up with the trajectory of the screw. The Height Adjustment Instrument should be used for adjustments only and should not be used to insert the screw.*





### Mono Screw Dimensions

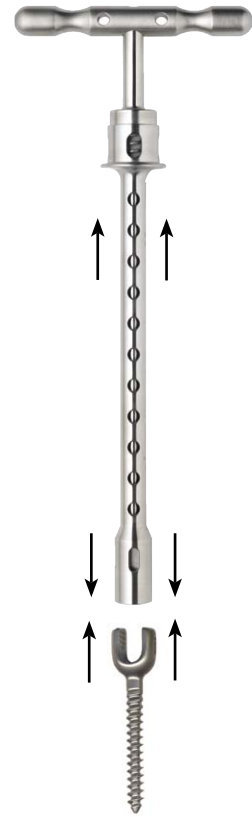
Diameter	Length
4.0 mm	25-45 mm
5.0 mm	30-45 mm
6.0 mm	35-55 mm
7.0 mm	35-55 mm
7.5 mm	35, 45-60 mm
8.0 mm	35-55 mm

### Mono Screw Insertion

Select the appropriate mono screw length.

Insert the mono screw into the desired pedicle until the bottom of the mono screw body contacts the bone surrounding the screw insertion site.

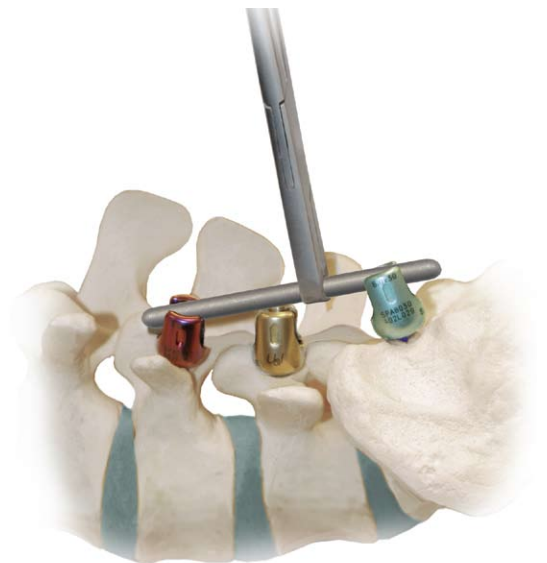
Repeat the process until all screws are placed.



6.0 mm diameter rods are available in the following lengths:  
40, 50, 60, 70,  
80, 90, 100, 120,  
150, 200, 300,  
400 mm

### Rod Selection

Once screws have been placed, the appropriate rod length is determined. The rod should extend approximately 5 mm beyond the distal edge of the superior screw polybody and the most proximal edge of the inferior screw polybody.





*6.0 mm diameter curved rods are available in the following lengths: 40, 50, 60, 70, 80, 100 mm*

### Rod Bending

Provisionally place the rod into each screw and determine the amount of contouring required to achieve the desired sagittal profile.

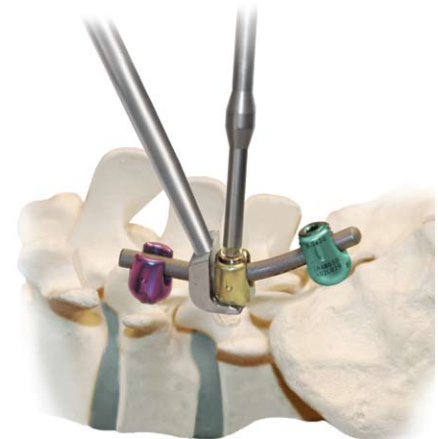
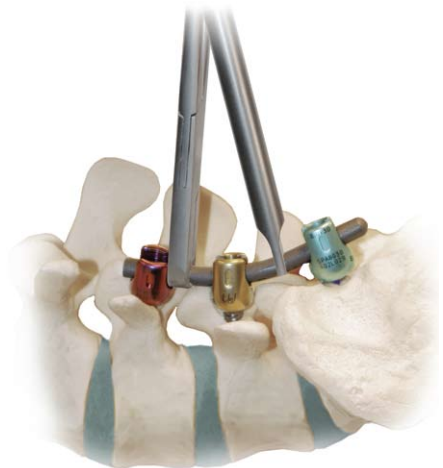
Contour the rods as needed using the Rod Bender. A contoured rod should fit into the bottom of each polyaxial screw body.

The bend radius is variable. By pulling out and rotating the central button of the Rod Bender, a small, medium, or large radius may be selected. To help prevent off-plane bending, ensure that the centerline laser mark on the rod is facing the central button when bending the rod.



### Rod Placement

When screw insertion and rod bending are complete, place the rod in the screw polybodies using the Rod Holder. The Rod Pusher and/or the Rod Hook may be used to seat the rod while inserting set screws with the Set Screw Inserter.





*Small set screw*



*Large set screw*

*5.0 mm, 6.0 mm, and 7.0 mm polyaxial screws, all reduction screws and all mono screws utilize the small set screw*

*7.5 mm and 8.0 mm polyaxial screws utilize the large set screw*

### **Set Screw Insertion**

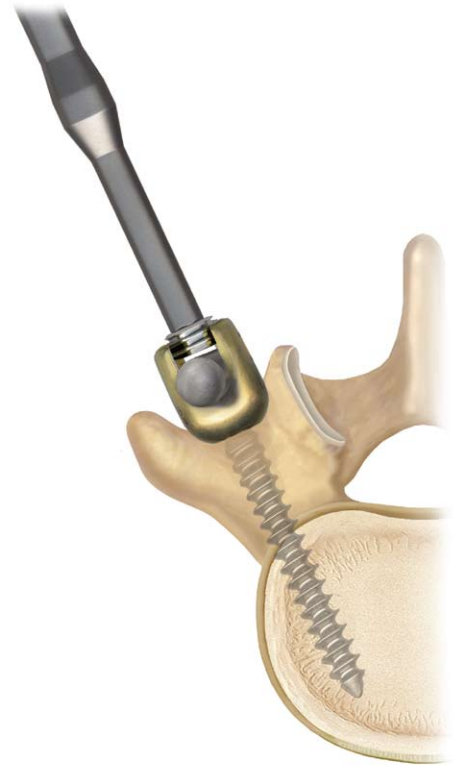
Position the set screw with its shiny side up. Lower the Set Screw Driver Guide onto the set screw and push to snap into place.

*Note: To reduce the possibility of cross-threading, turn the Set Screw Driver Guide counterclockwise until you feel a “click.”*

Turn the Set Screw Driver Guide clockwise to start the set screw.

The set screw starts easily when properly aligned. If incorrectly aligned, the set screw will exhibit noticeable resistance during the initial threading. If this occurs, back the set screw completely off the screw and check that it is properly seated on the Set Screw Driver Guide.

Repeat the process until all set screws are inserted.



### Rod Derotation

When the set screws have been inserted, the Derotator may be used to rotate the contoured rod into lordosis. The proper position of the rod is confirmed by ensuring that the centerline laser mark on the rod is visible from the top and parallel to the floor. While the rod is held in place with the Derotator, the set screw in the superior position is tightened using the Axial Torque Wrench (106 in-lb). The remaining set screws are left loose to allow for compression and distraction.

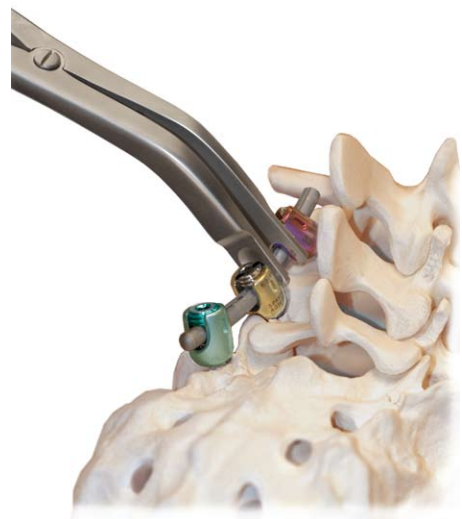


### Compression/Distracton

Provisionally tighten the set screw on one side of the segment being translated while leaving the set screw on the contra-lateral side loose.

Perform compression or distraction against the provisionally tightened assembly.

After achieving the desired amount of correction, perform final tightening of the set screw.





*Initial torque position*



*Final torque position  
(106 in-lbs.)*

### Final Set Screw Tightening

Position the Anti-Torque Device over the polybody of the screw to be tightened.

Insert the Axial Torque Wrench through the cannulated Anti-Torque Device into the set screw.

Tighten the set screw until the line and arrow on the Torque Wrench Handle align (106 in-lbs.).

Repeat the process until the remaining set screws are tightened.



### Alternative Technique:

#### Final Set Screw Tightening

Position the Anti-Torque Device over the polybody of the screw to be tightened.

*Note: The Small Anti-Torque Device may be used as an alternative for 5.0 mm, 6.0 mm and 7.0 mm screws.*

Assemble the 4 mm Hex Driver and the Torque Limiting T-handle.

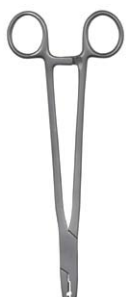
Insert the 4 mm Hex Driver through the cannulated Anti-Torque Device into the set screw.

Tighten the set screw until the Torque Limiting T-handle breaks over/clicks at 106 in-lbs.

Repeat the process until the remaining set screws are tightened.

*Note: The Axial Torque Wrench or 4 mm Hex Driver and Torque Limiting T-Handle used in conjunction with the Anti-Torque Device are the only instruments acceptable for final set screw tightening.*





*T-Link Holder/  
Reduction Housing  
Cutter*



*Torque Wrench for  
transverse link*

## Transverse Link Placement

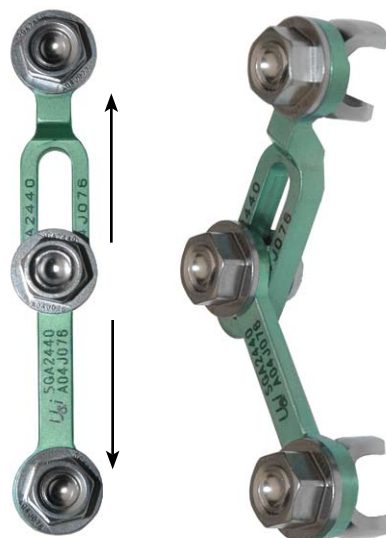
Transverse links may be used to connect rod segments.



*Adjustable transverse links  
are color-coded according  
to connector length:*

*Light Blue 33 - 40 mm  
Green 40 - 50 mm  
Yellow 50 - 60 mm  
Blue 60 - 70 mm  
Yellow 70 - 80 mm  
Magenta 80 - 90 mm*

If necessary, loosen the adjustable  
transverse link central lock nut  
to allow free movement of the link.





*Provisional torque position (26 in-lbs.)*



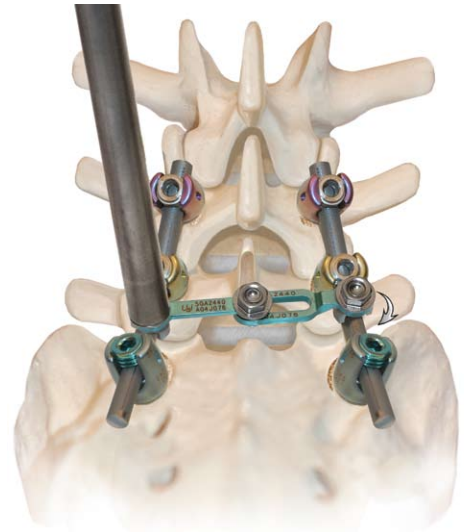
*Final torque position (70 in-lbs.)*

The T-Link Axial Driver has three lines to indicate torque level. The first (right) line on the driver indicates the driver is in the neutral position. The second (middle) line indicates the driver is at provisional tightening torque (26 in-lbs). The third (left) line indicates the driver is at full torque (70 in-lbs).

Using the T-link Axial Driver, snap the link over one rod and provisionally tighten the lock nut.

Using the T-link Axial Driver, snap the link over the contralateral rod and provisionally tighten the lock nut.

Fully tighten the outer lock nuts to 70 in-lbs.



Fully tighten center lock nut to 70 in-lbs.



**BASIC STRUCTURE:**

The *OPTIMA™ ZS* Spinal Fixation System is an internal fixation device for spinal surgery comprising pedicle screws, connectors, rods, housings and transverse link assemblies. Various forms and sizes of these implants are available so that adaptations can be made to take into account the pathology and individual patient.

**INDICATIONS FOR USE:**

The *OPTIMA ZS* Spinal Fixation System is a pedicle screw fixation system 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 with removal of the implants after the attainment of a solid fusion.

In addition, the *OPTIMA ZS* 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 of the vertebral body; dislocation; scoliosis; kyphosis; spinal tumor and failed previous fusion (pseudoarthrosis).

When used as an anterior screw fixation system the *OPTIMA ZS* system is indicated for patients with degenerative disc disease which is defined as back pain of the discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, fracture, spinal stenosis, spinal deformities such as scoliosis, kyphosis, lordosis, tumor, pseudoarthrosis, or revision of failed fusion attempts.

**CONTRAINDICATIONS:**

- Any active or suspected latent infection in or about the spine
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in post-operative care
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and or fixation to the implant
- Obesity: an overweight or obese patient can produce loads on the spinal system which can lead to failure of the fixation of the device or to failure of the device itself
- Recent infection, fever or leukocytosis
- Bony abnormalities preventing safe screw fixation
- Open wounds
- Metal sensitivity, documented or suspected
- Bone absorption, osteopenia and/or osteoporosis
- Patients having inadequate tissue coverage over the operative site
- Pregnancy
- Excessive local inflammation
- 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 sedimentation rate unexplained by other diseases, elevation of white blood cell count (WBC), or marked left shift in the WBC differential count.

**WARNING:**

The benefit 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 fracture, loss of fixation, non-union, fracture of the vertebra, 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 loads 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 or bending of a screw or hook may reduce its fatigue strength and cause failure under load. If spinal screw or hooks are bent or otherwise damaged during insertion or adjustment, they may 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 may also increase. Internal fixation devices such as rods, connectors, screw, hook, etc., which come into contact with other metal objects must be made from like or compatible metals. Because different manufacturers employ different materials, varying tolerances, manufacturing specifications and differing design parameters, components of the *OPTIMA ZS* Spinal System should not be used in conjunction with components from any other manufacturer's spinal systems. Any such use will negate the responsibility of U&i Corporation for the performance of the resulting mixed component implant. 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 being 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.

## Notes



The *OPTIMA™* ZS Spinal System is:  
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