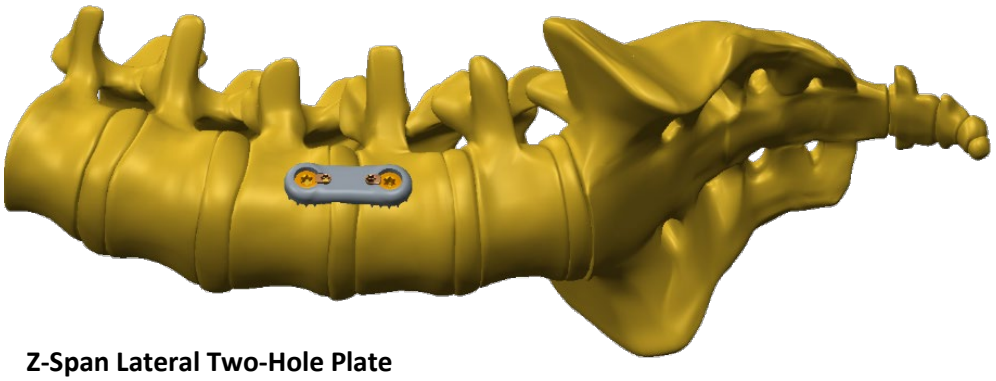
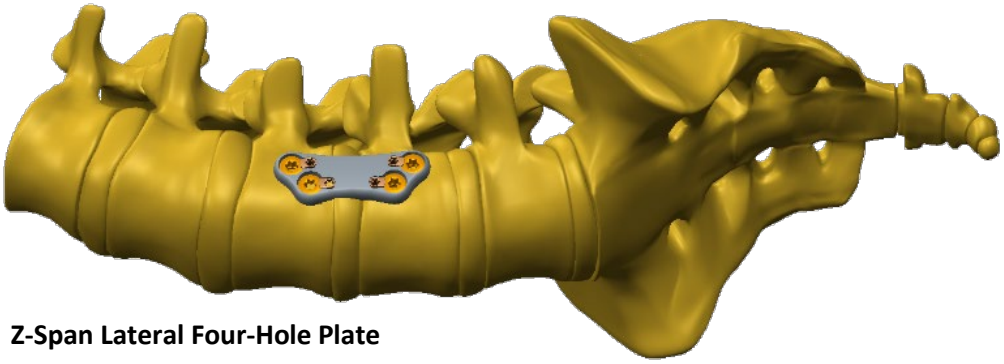
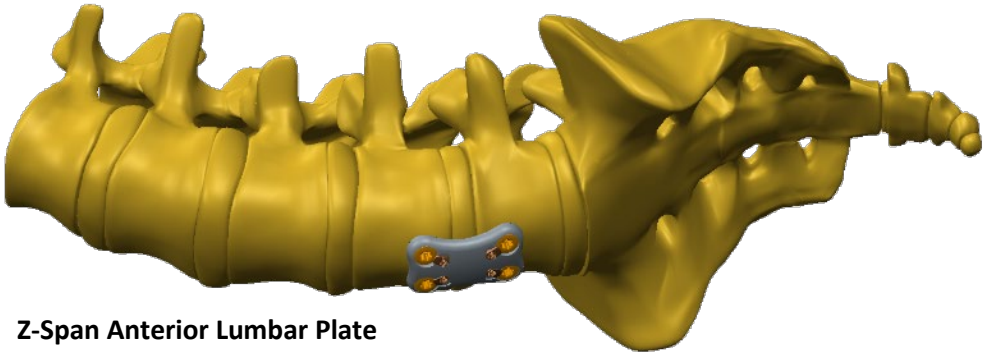


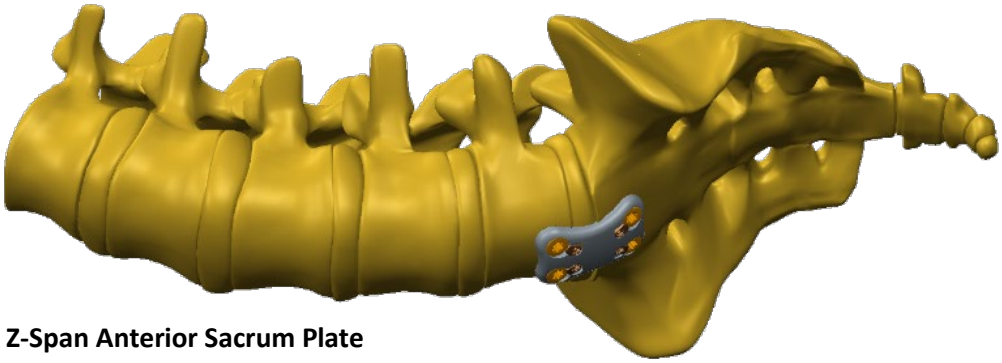
Z-Span Lateral Two-Hole Plate



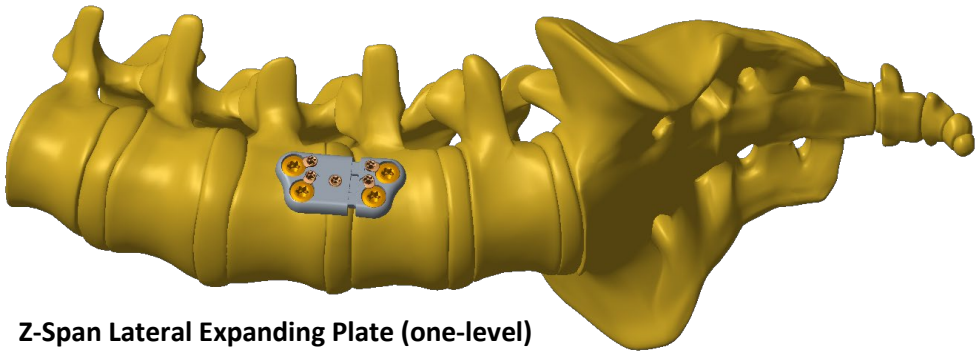
Z-Span Lateral Four-Hole Plate



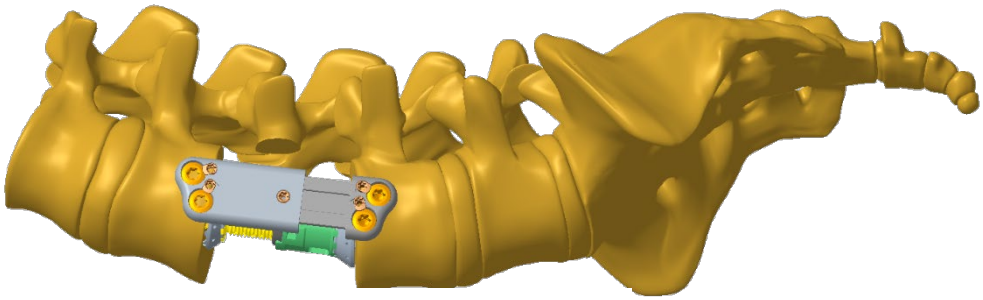
Z-Span Anterior Lumbar Plate



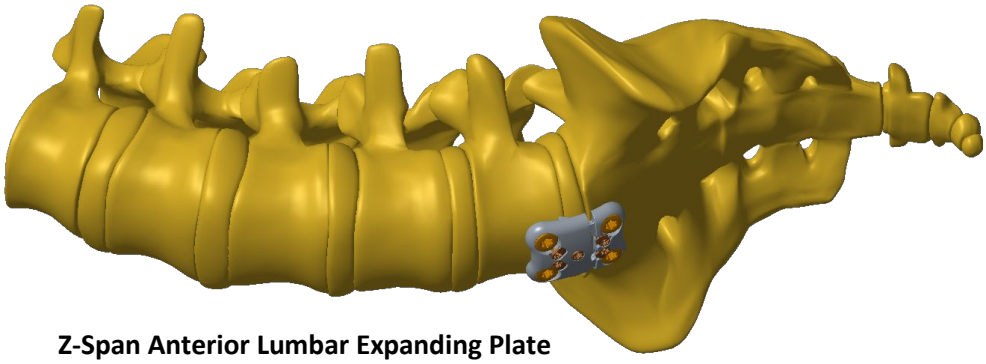
Z-Span Anterior Sacrum Plate



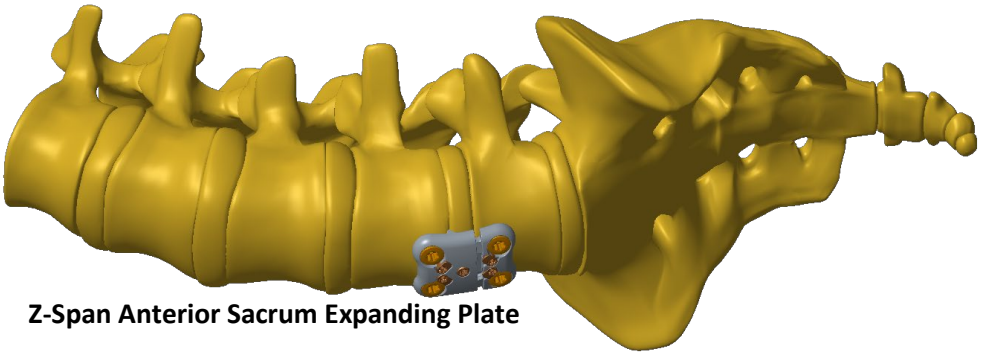
Z-Span Lateral Expanding Plate (one-level)



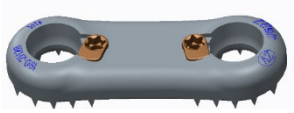
Z-Span Lateral Expanding Plate (multi-level)



Z-Span Anterior Lumbar Expanding Plate

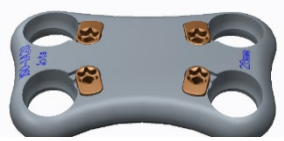


Z-Span Anterior Sacrum Expanding Plate

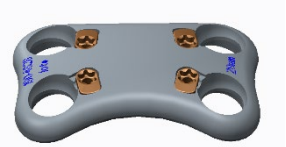


Z-Span Lateral Two-Hole Plate

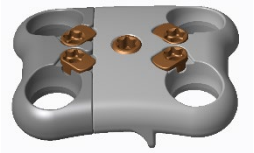
Z-Span Lateral Four-Hole Plate



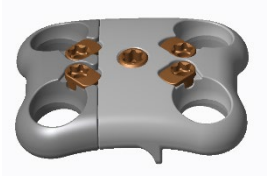
Z-Span Anterior Lumbar Plate



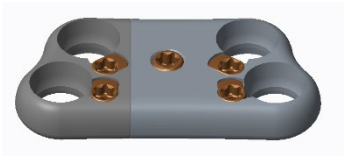
Z-Span Anterior Sacrum Plate



Z-Span Anterior Lumbar Expanding Plate



Z-Span Anterior Sacrum Expanding Plate



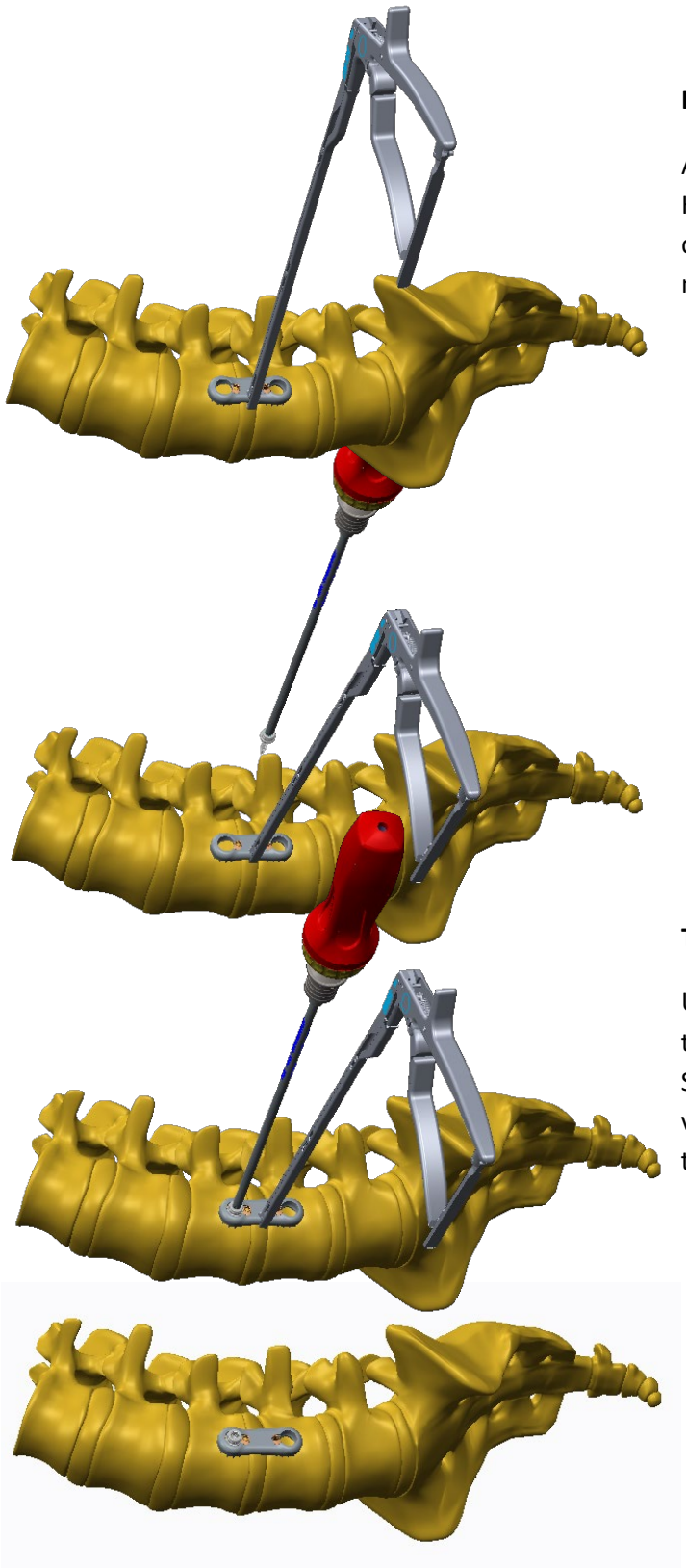
Z-Span Lateral Expanding Plate

Other than the approach the procedure for implantation of the Z-Span Plate device is the same for the lateral and anterior plates.

Implant Selection

The selection of the proper size, shape, and design of the implant for each patient is crucial to the success of the procedure. Metallic surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

Two options of lateral plates (Two-Hole and Four-Hole) are available in lengths from 18mm to 40mm in 2mm increments. The expanding lateral plates are available in lengths from 22-140mm. For anterior approach the Anterior Lumbar Plate is used from L1 – L5. For anterior approach the Anterior Sacrum Plate is used at the L5-S1. Both Anterior Plates are available in lengths from 18mm to 40mm in 2mm increments.

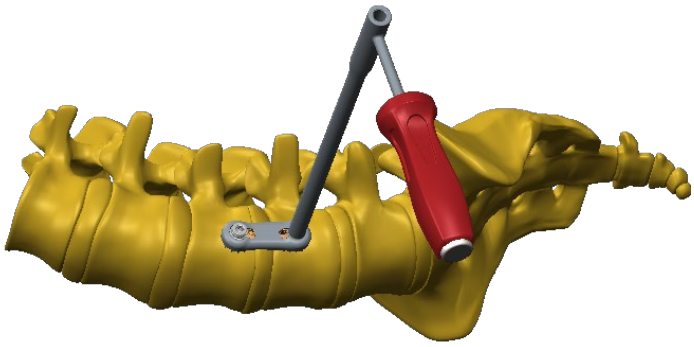


Implant Insertion

Attach the Plate Holder instrument to the plate. The Plate Holder instrument should be attached to the approximate center of the plate as shown. Locate the plate at the midline of the vertebral body.

Temporary Fixation

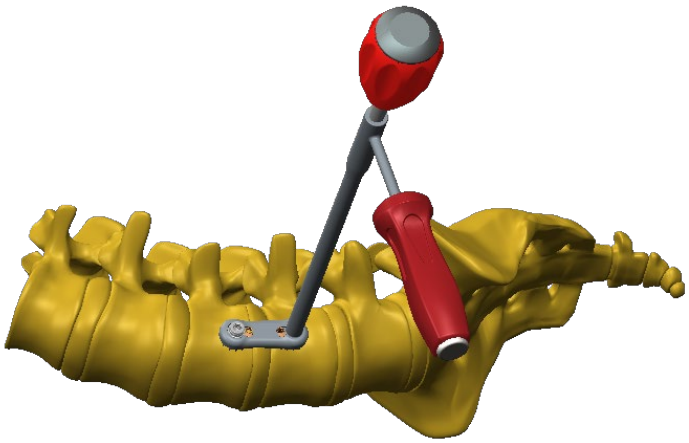
Using the self-retaining T25 Screwdriver temporary attach the plate to the vertebral body using the 3mm Temporary Screw. The Temporary Screw will penetrate 15mm into the vertebral body. The plate holder can be removed once the temporary screw is inserted.



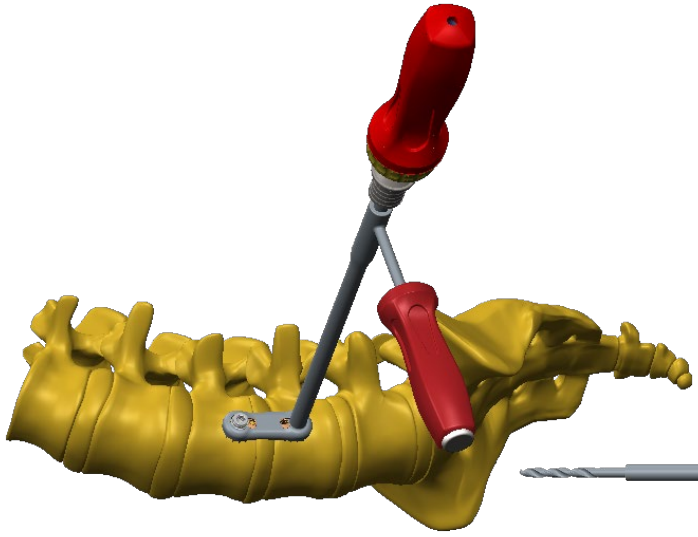
Prepare For Screw Insertion

Insert the Fixed Drill Guide into the screw hole of the plate. The distal tip of the Fixed Drill Guide aligns itself coaxial to the plate screw hole.

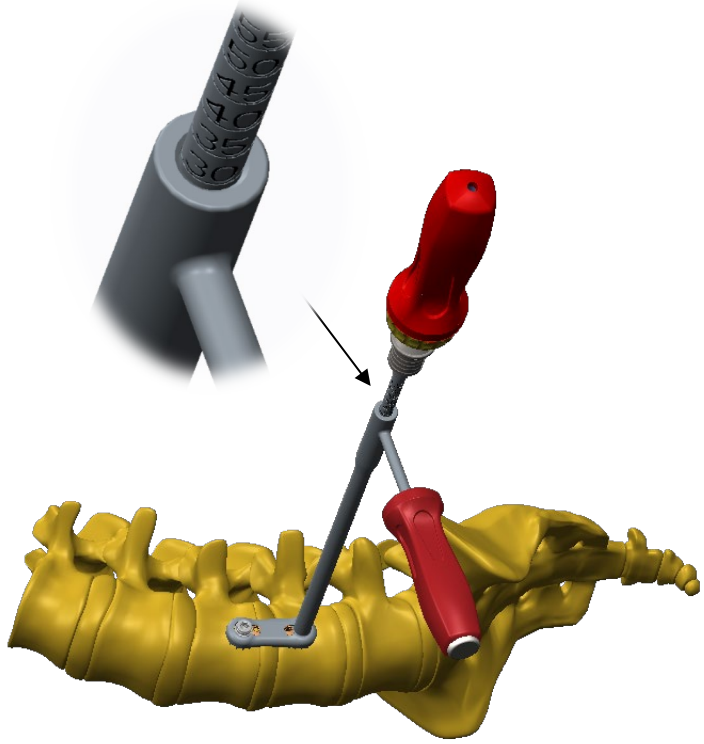
Optional Method: Depending on patient anotomy it may become necessary to angle the screw off axis from the screw hole in order to provide increased bone purchase. The Variable Drill Guide allows the hole to angle 14 degrees included angle from the plate hole axis.



Using the Awl prepare a hole in the veterbral body. Advance the Awl until the stop feature contacts the proximal surface of the Drill Guide.

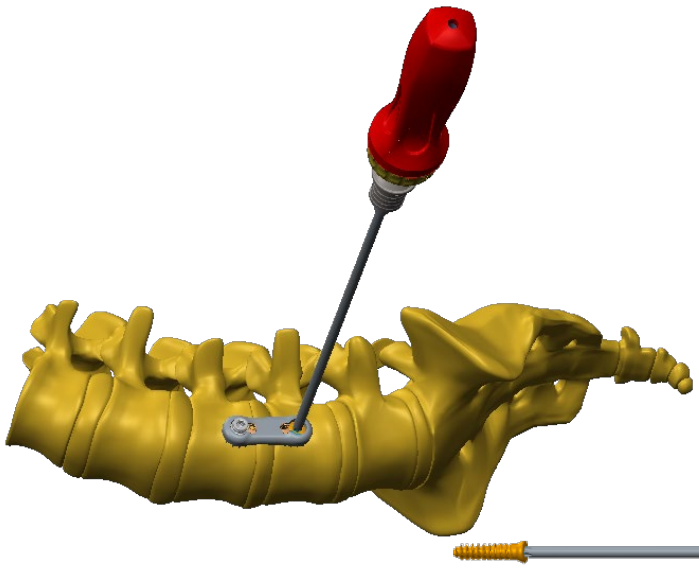


Optional Method: Using the Drill prepare a hole in the veterbral body. Advance the Drill until the stop feature contacts the proximal surface of the Drill Guide.



Prepare For Screw Insertion (cont.)

Using the Tap prepare a hole in the veterbral body. Advance the Tap to the desired depth. The depth marking on the tap indicates the tapped hole depth and indicates the screw length to be used.



Screw Insertion

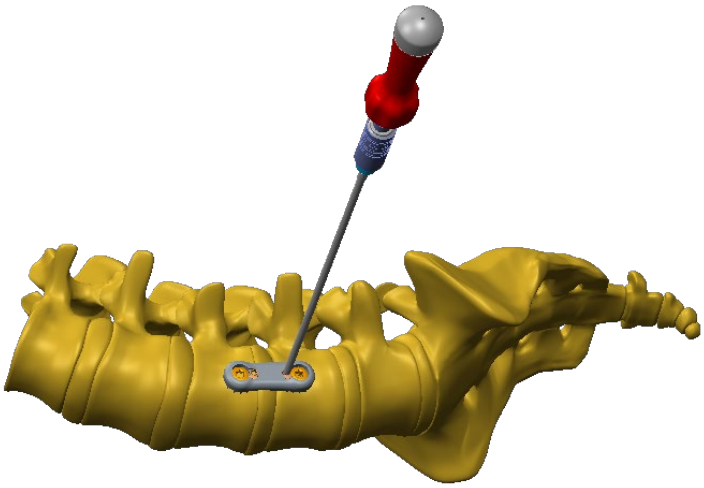
Using the T25 Retaining Screw Driver, insert the desired screw type and length into the prepared screw hole. Advance the screw until the plate is firmly held in place against the veterbral body. Excessive tightening may strip the threads in the bone.

Temporary Screw Removal

Remove the Temporary Screw from the plate construct using the T25 Retaining Screwdriver.

Prepare Remaining Holes for Screw Insertion

Repeat the steps for Screw Hole preparation for the remaining screw holes and insert the screws as defined previously.

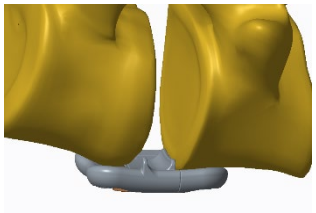


Screw Retention

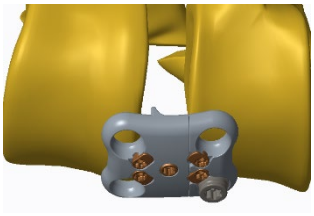
Each of the screw holes in the Z-Span Plate have screw locking tabs. Using the T15 Screw Driver rotate each of the locking tabs over the screw head.

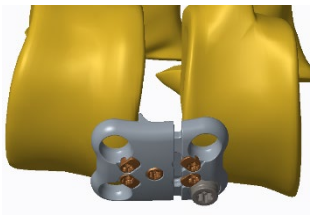
Locking Tabs in Unlocked Position

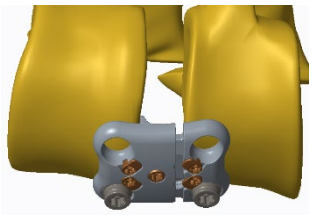
Locking Tabs in Locked Position

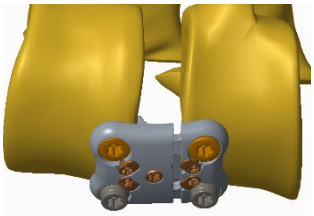


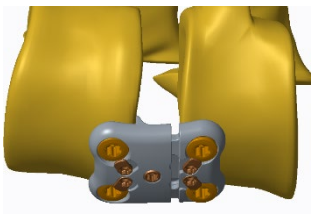
Expanding Plate with Flange Procedure











The procedure for implanting the expanding plate with docking flange is the same as the monolithic plate with the addition of the following:

Plate Alignment

Position the distal flange of the plate against the anterior rim of the distal veterbral body. Follow the temporary fixation procedure, shown in the monolithic plate procedure, to attach the distal plate half to the distal veterbral body.

Expand the proximal plate half until the flange rest against the anterior rim of the proximal veterbral body. Follow the temporary fixation procedure, shown in the monolithic plate procedure, to attach the proximal plate half to the proximal veterbral body.

Screw Insertion

Follow the steps shown in the monilithic plate procedure to install the four screws.

Screw Retention

Follow the steps shown in the monolithic plate procedure to activate the locking tabs.

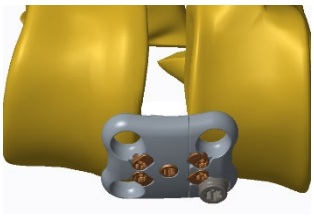
Plate Locking

Attach the torque limiting handle to the T-15 screw driver shaft. Tighten the center set screw, clockwise, until the torque limiting handle clicks.

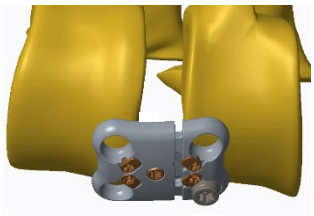
Expanding Plate without Flange Procedure

The procedure for implanting the expanding plate without flanges is the same as the monolithic plate with the addition of the following:

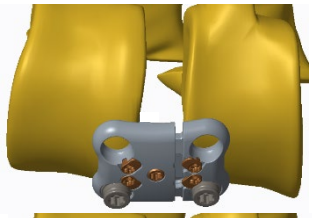
Plate Alignment



Attach the Plate Holder instrument to the plate. The Plate Holder instrument should be attached to the approximate center of the plate. Locate the plate at the midline of the vertebral body.

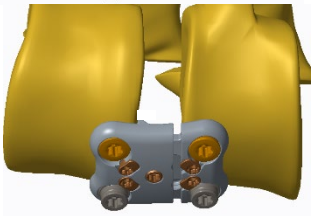


Follow the temporary fixation procedure, shown in the monolithic plate procedure, to attach the distal plate half to the distal veterbral body.



Expand the proximal plate half until the desired proximal screw location is achieved above the veterbral body endplate. Follow the temporary fixation procedure, shown in the monolithic plate procedure, to attach the proximal plate half to the proximal veterbral body.

Screw Insertion



Follow the steps shown in the monolithic plate procedure to install the four screws.

Screw Retention

Follow the steps shown in the monilithic plate procedure to activate the locking tabs.

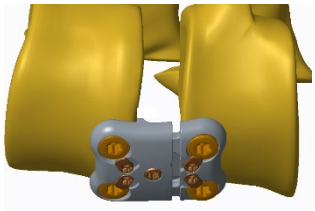
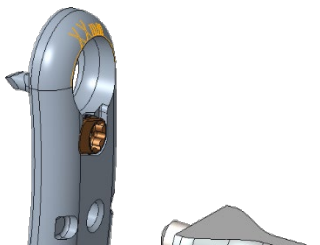


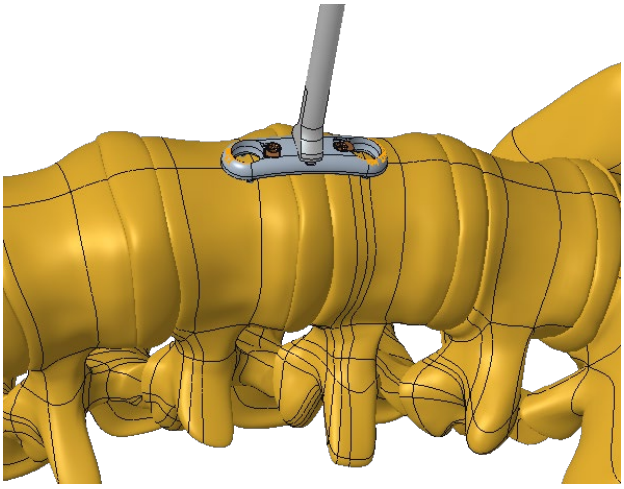
Plate Locking

Attach the torque limiting handle to the T-15 screw driver shaft. Tighten the center set screw, clockwise, until the torque limiting handle clicks.



Anterior Two Hole Plate

Two options of two-hole anterior plates (lumbar and sacral) are available. The Anterior Lumbar Plate is used from L1 – L5. The Anterior Sacrum Plate is used at the L5-S1. Both Anterior Plates are available in lengths from 20mm to 40mm in 2mm increments. Screw locking tabs are T15. Threaded inserter (190-1000-1/190-1000-2) is to be used to hold plate in desired location during screw insertion, (6.0mm or 6.5mm).



Removal Procedure

Removal of the Z-Span Plate is accomplished by the following steps:

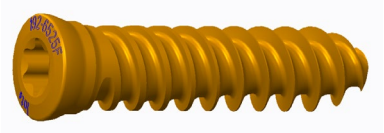
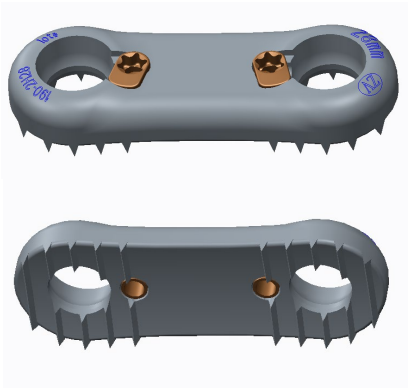
1) Using the T15 Screw Driver, rotated the locking taps to the unlocked position
2) Using the T25 Retaining Screw Driver remove the screws from the veterbral body.
3) Using the Plate Holder instrument remove the plate from the patient.

Z-Span Plate System

Surgical Technique

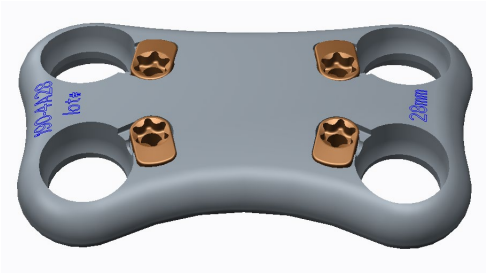
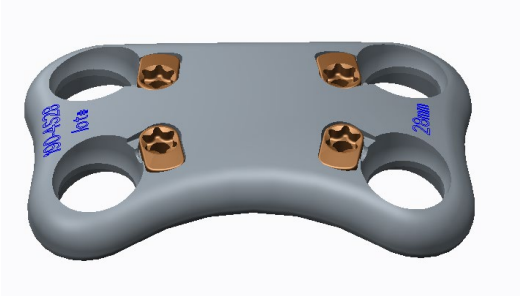
ZAVATION

Device Description

Device View	Part #	Description
 Variable Screw  Fixed Screw	192-XXYY	**Screw:** • 6.0mm & 6.5mm Diameters • 25mm – 55mm in 5mm increments • Variable and Fixed Angles • Double Lead Thread • T-25 Hexalobe Drive Feature • Material: Titanium
	190-2HXX	**Z-Span Lateral Two-Hole Plate:** • Two Screw Holes • Screw Locking Tabs (T-15 Hexalobe Drive Feature) • Anchoring Teeth (increases torsional strength) • 18mm-40mm Lengths in 2mm increments (length measured between center of screw holes) • 4.5mm thick • 15.2mm wide • Material: Titanium
	190-4LXX	**Z-Span Lateral Four-Hole Plate:** • Four Screw Holes • Screw Locking Tabs (T-15 Hexalobe Drive Feature) • 18mm-40mm Lengths in 2mm increments (length measured between center of closest two screw holes) • 4.8mm thick • 19.5mm wide • Material: Titanium

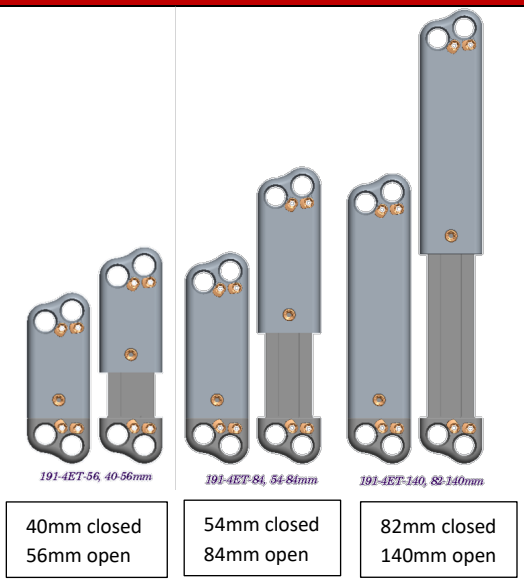
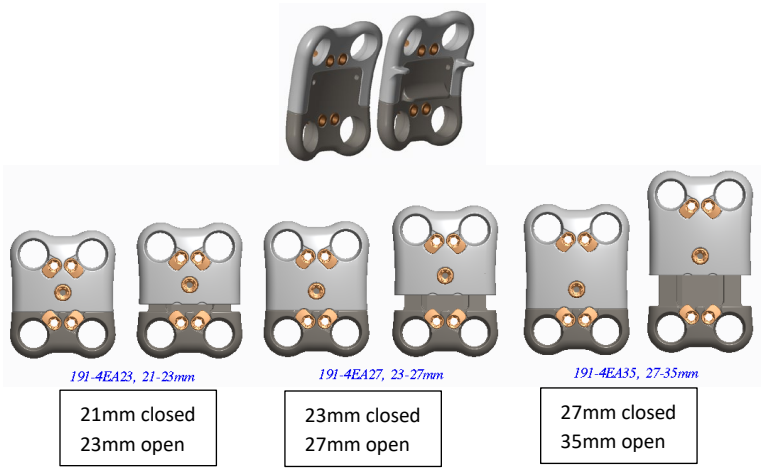
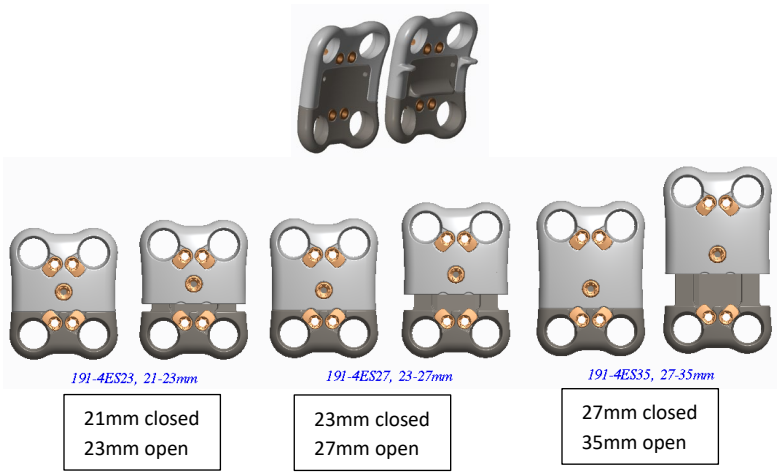
Z-Span Plate System

Surgical Technique

Device View	Part #	Description
	190-4AXX	**Z-Span Anterior Lumbar Plate:** • Four Screw Holes • Screw Locking Tabs (T-15 Hexalobe Drive Feature) • 18mm-40mm Lengths in 2mm increments (length measured between center of closest two screw holes) • 100mm Radius Curvature • 4mm thick • 25.7mm wide • Material: Titanium
	190-4SXX	**Z-Span Anterior Sacrum Plate:** • Four Screw Holes • Screw Locking Tabs (T-15 Hexalobe Drive Feature) • 18mm-40mm Lengths in 2mm increments (length measured between center of closest two screw holes) • 46mm Radius Curvature • 4mm thick • 25.7mm wide • Material: Titanium
	191-4ELXX	**Z-Span Lateral Expanding Plate:** • Four Screw Holes • Screw Locking Tabs (T-15 Hexalobe Drive Feature) • 22mm-40mm Lengths (length measured between center of closest two screw holes) • 5mm thick • 22mm wide • Material: Titanium

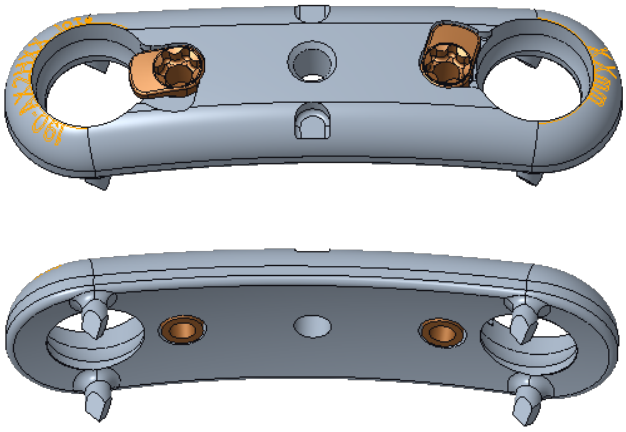
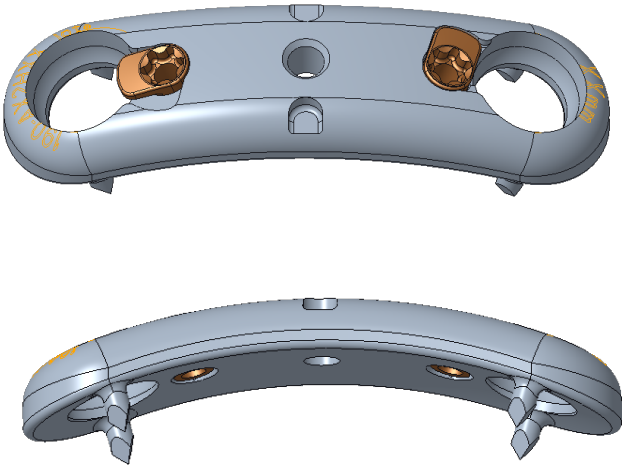
Z-Span Plate System

Surgical Technique

Device View	Part #	Description
	191-4ETXX	**Z-Span Expanding Trauma Plate:** • Four Screw Holes • Screw Locking Tabs (T-15 Hexalobe Drive Feature) • 40mm-140mm Lengths (length measured between center of closest two screw holes) • 5.5mm thick • 22mm wide Material: Titanium
	191-4EAXXX	**Z-Span Anterior Lumbar Expanding Plate:** • Four Screw Holes • Screw Locking Tabs (T-15 Hexalobe Drive Feature) • 21mm-35mm Lengths (length measured between centers of screw holes) • Available with or without Plate Positioning Flange • 5mm thick • 28mm wide • Material: Titanium
	191-4ESXXX	**Z-Span Anterior Sacrum Expanding Plate:** • Four Screw Holes • Screw Locking Tabs (T-15 Hexalobe Drive Feature) • 21mm-35mm Lengths (length measured between centers of screw holes) • Available with or without Plate Positioning Flange • 5mm thick • 28mm wide • Material: Titanium

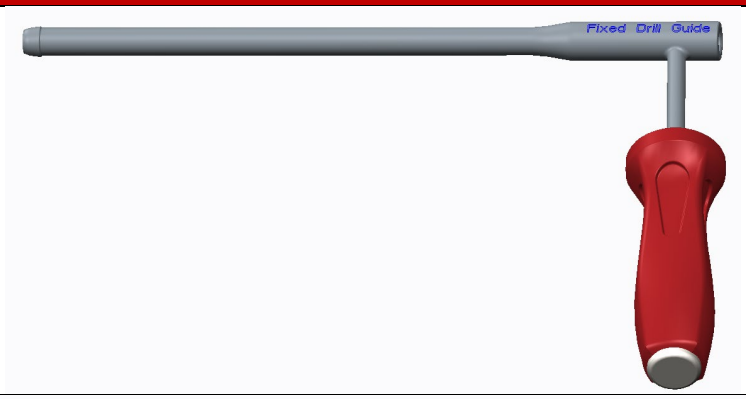
Z-Span Plate System

Surgical Technique

Device View	Part #	Description
	190-AL2HXX	**Anterior Lumbar Two Hole Plate** • Two screw holes • Screw locking tabs (T-15 Hexalobe drive feature) • 20mm-40mm (length measured between center of screw holes) • 4mm thick • 12.2mm wide • Threaded inserter attachment • Material: Titanium
	190-AS2HXX	**Anterior Sacral Two Hole Plate** • Two screw holes • Screw locking tabs (T-15 Hexalobe drive feature) • 20mm-40mm (length measured between center of screw holes) • 4mm thick • 12.2mm wide • Threaded inserter attachment Material: Titanium
	198-1004	**T25 Screwdriver – Retaining** • T-25 Hexalobe Drive Feature • ¼" Square Drive Handle Attachment • Screw Retaining Tip Design • Material: Stainless Steel
	198-1016	**T15 Screwdriver – AO** • T-15 Hexalobe Drive Feature • AO Handle Attachment • Material: Stainless Steel

Z-Span Plate System

Surgical Technique

Device View	Part #	Description
	198-1006	**Fixed Drill Guide** • Aligns Coaxial with Plate Screw Holes • Can be used with Awl and Drill • Material: Stainless Steel
	198-1007	**Variable Drill Guide** • Aligns Coaxial with Plate Screw Holes within 7 degrees. • Can be used with Awl and Drill • Material: Stainless Steel
	198-1008	**Drill 3.8 dia X 20mm long** • 3.8mm Diameter • 20mm Drill Depth • Use with Fixed or Variable Drill Guides • ¼" Square Drive handle Attachment • Material: Stainless Steel
	198-1009	**Awl 3.8 dia. X 20mm long** • 3.8mm Diameter • 20mm Depth • Use with Fixed or Variable Drill Guides • Impact Handle Provided • Material: Stainless Steel
	198-1010-XX	**Tap** • 5.0, 5.5, 6.0mm Diameters • Depth Markings • Use with Fixed or Variable Drill Guides • ¼" Square Drive handle Attachment • Material: Stainless Steel

Z-Span Plate System

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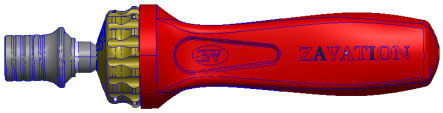
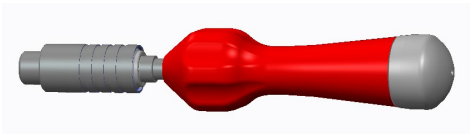
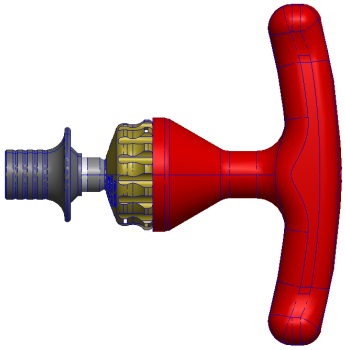
Device View	Part #	Description
	198-1011	**Plate Holder** • Fits all Plates • Material: Stainless Steel
	198-1015	**Temporary Screw** • 3.0mm Diameter • 15mm long • T-25 Hexalobe Drive Feature • Material: Titanium
	Z-1003	**Straight Handle, Ratcheting** • Silicone Grip • Forward, Locked and Backward Ratcheting Mechanism • ¼" Square Drive handle Attachment • Material: Stainless Steel and Silicone
	Z-1004	**Universal AO Handle** • Silicone Grip • Spinner Top • AO Handle Attachment • Material: Stainless Steel and Silicone
	Z-1008	**Tee Handle, Ratcheting** • Silicone Grip • Forward, Locked and Backward Ratcheting Mechanism • ¼" Square Drive handle Attachment • Material: Stainless Steel and Silicone

Z-Span Plate System

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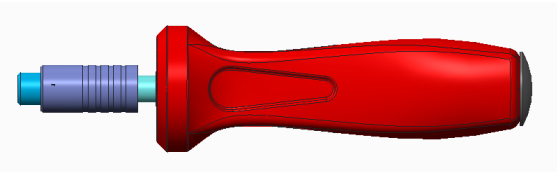
Device View	Part #	Description
	198-1012	**Torque Limiting Handle** • Silicone Grip • AO connection • Material: Stainless Steel and Silicone
	190-1000-1 190-1000-2	**Inserter Handle/Torque Rod** • Threaded inserter for 190-AX2HXX plates • Material: Stainless Steel

System Parts List

IMPLANTS	
PART NUMBER	**DESCRIPTION**
192-6025V	Screw, 6.0mmx25mm variable
192-6030V	Screw, 6.0mmx30mm variable
192-6035V	Screw, 6.0mmx35mm variable
192-6040V	Screw, 6.0mmx40mm variable
192-6045V	Screw, 6.0mmx45mm variable
192-6050V	Screw, 6.0mmx50mm variable
192-6055V	Screw, 6.0mmx55mm variable
192-6025F	Screw, 6.0mmx25mm fixed
192-6030F	Screw, 6.0mmx30mm fixed
192-6035F	Screw, 6.0mmx35mm fixed
192-6040F	Screw, 6.0mmx40mm fixed
192-6045F	Screw, 6.0mmx45mm fixed
192-6050F	Screw, 6.0mmx50mm fixed
192-6055F	Screw, 6.0mmx55mm fixed
192-6525V	Screw, 6.5mmx25mm variable
192-6530V	Screw, 6.5mmx30mm variable
192-6535V	Screw, 6.5mmx35mm variable
192-6540V	Screw, 6.5mmx40mm variable
192-6545V	Screw, 6.5mmx45mm variable
192-6550V	Screw, 6.5mmx50mm variable
192-6555V	Screw, 6.5mmx55mm variable
192-6525F	Screw, 6.5mmx25mm fixed
192-6530F	Screw, 6.5mmx30mm fixed

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ZAVATION

192-6535F	Screw, 6.5mmx35mm fixed
192-6540F	Screw, 6.5mmx40mm fixed
192-6545F	Screw, 6.5mmx45mm fixed
192-6550F	Screw, 6.5mmx50mm fixed
192-6555F	Screw, 6.5mmx55mm fixed
190-2H18	Z-Span Lateral Two-Hole Plate, 18mm
190-2H20	Z-Span Lateral Two-Hole Plate, 20mm
190-2H22	Z-Span Lateral Two-Hole Plate, 22mm
190-2H24	Z-Span Lateral Two-Hole Plate, 24mm
190-2H26	Z-Span Lateral Two-Hole Plate, 26mm
190-2H28	Z-Span Lateral Two-Hole Plate, 28mm
190-2H30	Z-Span Lateral Two-Hole Plate, 30mm
190-2H32	Z-Span Lateral Two-Hole Plate, 32mm
190-2H34	Z-Span Lateral Two-Hole Plate, 34mm
190-2H36	Z-Span Lateral Two-Hole Plate, 36mm
190-2H38	Z-Span Lateral Two-Hole Plate, 38mm
190-2H40	Z-Span Lateral Two-Hole Plate, 40mm
190-4L18	Z-Span Lateral Four-Hole Plate, 18mm
190-4L20	Z-Span Lateral Four-Hole Plate, 20mm
190-4L22	Z-Span Lateral Four-Hole Plate, 22mm
190-4L24	Z-Span Lateral Four-Hole Plate, 24mm
190-4L26	Z-Span Lateral Four-Hole Plate, 26mm
190-4L28	Z-Span Lateral Four-Hole Plate, 28mm
190-4L30	Z-Span Lateral Four-Hole Plate, 30mm
190-4L32	Z-Span Lateral Four-Hole Plate, 32mm
190-4L34	Z-Span Lateral Four-Hole Plate, 34mm
190-4L36	Z-Span Lateral Four-Hole Plate, 36mm
190-4L38	Z-Span Lateral Four-Hole Plate, 38mm
190-4L40	Z-Span Lateral Four-Hole Plate, 40mm
190-4A18	Z-Span Anterior Lumbar Plate, 18mm
190-4A20	Z-Span Anterior Lumbar Plate, 20mm
190-4A22	Z-Span Anterior Lumbar Plate, 22mm
190-4A24	Z-Span Anterior Lumbar Plate, 24mm
190-4A26	Z-Span Anterior Lumbar Plate, 26mm
190-4A28	Z-Span Anterior Lumbar Plate, 28mm
190-4A30	Z-Span Anterior Lumbar Plate, 30mm
190-4A32	Z-Span Anterior Lumbar Plate, 32mm
190-4A34	Z-Span Anterior Lumbar Plate, 34mm
190-4A36	Z-Span Anterior Lumbar Plate, 36mm
190-4A38	Z-Span Anterior Lumbar Plate, 38mm
190-4A40	Z-Span Anterior Lumbar Plate, 40mm

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ZAVATION

190-4S18	Z-Span Anterior Sacrum Plate, 18mm
190-4S20	Z-Span Anterior Sacrum Plate, 20mm
190-4S22	Z-Span Anterior Sacrum Plate, 22mm
190-4S24	Z-Span Anterior Sacrum Plate, 24mm
190-4S26	Z-Span Anterior Sacrum Plate, 26mm
190-4S28	Z-Span Anterior Sacrum Plate, 28mm
190-4S30	Z-Span Anterior Sacrum Plate, 30mm
190-4S32	Z-Span Anterior Sacrum Plate, 32mm
190-4S34	Z-Span Anterior Sacrum Plate, 34mm
190-4S36	Z-Span Anterior Sacrum Plate, 36mm
190-4S38	Z-Span Anterior Sacrum Plate, 38mm
190-4S40	Z-Span Anterior Sacrum Plate, 40mm
191-4EL25	Z-Span Lateral Expanding Plate, 22-25mm
191-4EL30	Z-Span Lateral Expanding Plate, 25-30mm
191-4EL40	Z-Span Lateral Expanding Plate, 30-40mm
191-4ET56	Z-Span Expanding Trauma Plate, 40-56mm
191-4ET84	Z-Span Expanding Trauma Plate, 54-84mm
191-4ET140	Z-Span Expanding Trauma Plate, 82-140mm
191-4EA23F	Z-Span Anterior Expanding Plate, 21-23mm
191-4EA27F	Z-Span Anterior Expanding Plate, 23-27mm
191-4EA35F	Z-Span Anterior Expanding Plate, 27-35mm
191-4EA23X	Z-Span Anterior Expanding Plate, 21-23mm, without Flanges
191-4EA27X	Z-Span Anterior Expanding Plate, 23-27mm, without Flanges
191-4EA35X	Z-Span Anterior Expanding Plate, 27-35mm, without Flanges
191-4ES23F	Z-Span Sacrum Expanding Plate, 21-23mm
191-4ES27F	Z-Span Sacrum Expanding Plate, 23-27mm
191-4ES35F	Z-Span Sacrum Expanding Plate, 27-35mm
191-4ES23X	Z-Span Sacrum Expanding Plate, 21-23mm, without Flanges
191-4ES27X	Z-Span Sacrum Expanding Plate, 23-27mm, without Flanges
191-4ES35X	Z-Span Sacrum Expanding Plate, 27-35mm, without Flanges
190-AL2H20	Anterior Lumbar Plate Two Hole 20mm
190-AL2H22	Anterior Lumbar Plate Two Hole 22mm
190-AL2H24	Anterior Lumbar Plate Two Hole 24mm
190-AL2H26	Anterior Lumbar Plate Two Hole 26mm
190-AL2H28	Anterior Lumbar Plate Two Hole 28mm
190-AL2H30	Anterior Lumbar Plate Two Hole 30mm
190-AL2H32	Anterior Lumbar Plate Two Hole 32mm
190-AL2H34	Anterior Lumbar Plate Two Hole 34mm
190-AL2H36	Anterior Lumbar Plate Two Hole 36mm
190-AL2H38	Anterior Lumbar Plate Two Hole 38mm
190-AL2H40	Anterior Lumbar Plate Two Hole 40mm

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190-AS2H20	Anterior Sacral Plate Two Hole 20mm
190-AS2H22	Anterior Sacral Plate Two Hole 22mm
190-AS2H24	Anterior Sacral Plate Two Hole 24mm
190-AS2H26	Anterior Sacral Plate Two Hole 26mm
190-AS2H28	Anterior Sacral Plate Two Hole 28mm
190-AS2H30	Anterior Sacral Plate Two Hole 30mm
190-AS2H32	Anterior Sacral Plate Two Hole 32mm
190-AS2H34	Anterior Sacral Plate Two Hole 34mm
190-AS2H36	Anterior Sacral Plate Two Hole 36mm
190-AS2H38	Anterior Sacral Plate Two Hole 38mm
190-AS2H40	Anterior Sacral Plate Two Hole 40mm
INSTRUMENTS	
PART NUMBER	**DESCRIPTION**
198-1004	T25 Screwdriver - Retaining
198-1016	T15 Screwdriver - AO
198-1006	Fixed Drill Guide
198-1007	Variable Drill Guide
198-1008	Drill 3.8 dia. X 20mm long
198-1009	Awl 3.8 dia. X 20mm long
198-1010-50	Tap 5.0mm
198-1010-55	Tap 5.5mm
198-1010-60	Tap 6.0mm
Z-1003	Straight Handle
Z-1008	Tee Handle - Ratcheting
198-1015	Temporary Screw
Z-1004	AO spinner top handle
198-1011	Plate Holder
198-1012	Torque Limiting Handle
190-1000-1	Inserter Handle
190-1000-2	Torque Rod

Device Description: The Z-Span Plate System is supplemental fixation device consisting of a variety of shapes and sizes of thoracic, lumbar, and sacral plates and screws. The plates attach to the thoracic, lumbar, and lumbosacral spine (L1-S1). The implant components are made of titanium alloy per ASTM F-136 (Ti-6AL-4V ELI). Subject instruments are intended for use only with Zavation pedicle or OCT screws.

Indications: The Z-Span Plate System is intended for use via the lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of the thoracolumbar spine (T1-L5) or via the anterior approach below the bifurcation of the great vessels in the treatment of the lumbar and lumbosacral spine (L1-S1).

The Z-Span Plate System is intended to provide immobilization and stabilization as an adjunct to fusion in skeletally mature patients in the treatment of the following:

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- Fracture (including dislocation and subluxation)
- Tumor
- Degenerative Disc Disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
- Pseudoarthrosis
- Spondylolysis
- Spondylolisthesis
- Scoliosis
- Lordotic deformities of the spine
- Spinal stenosis
- Failed previous spine surgery

Materials: The Z-Span Plate System components are manufactured from titanium alloy (Ti-6Al-4V) as described by ASTM F136.

Contraindications: Contraindications include, but not limited to: The Z-Span Plate System is contraindicated in patients with a systemic infection, with a local inflammation at the bone site, or with rapidly progressive joint disease or bone absorption syndromes such as Paget's disease, osteopenia, osteoporosis, or osteomyelitis. Do not use this system in patients with known or suspected metal allergies. Use of the system is also contraindicated in patients with any other medical, surgical or psychological condition that would preclude potential benefits of internal fixation surgery such as congenital abnormalities, elevation of sedimentation rate unexplained by other disease, elevation of white blood cells or a marked shift in white blood cell differential count.

Potential Adverse Events: All the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events includes, but is not limited to:
-Early or late loosening of any or all the components
-Disassembly, bending, and/or breakage of any or all the components
-Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, straining, tumor formation, and/or auto-immune disease
-Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain
-Post-operative change in spinal curvature, loss of correction, height, and/or reduction
-Infection
-Vertebral body fracture at, above, or below the level of surgery
-Loss of neurological function, including paralysis (complete or incomplete)
-Non-union, delayed union
-Pain, discomfort, or abnormal sensations due to the presence of the device
-Hemorrhage
-Cessation of any potential growth of the operated portion of the spine
-Death
Note: Additional surgery may be necessary to correct some of these anticipated adverse events

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Warnings:
-The Z-Span Plate System is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
-Excessive torque applied to the screws when seating the plate may strip the threads in the bone.
-The safety and effectiveness of spinal plate 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 (grades 3 and 4) of the 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.
-Non-sterile, the Z-Span Plate System implants and instruments are provided non-sterile, and therefore, must be sterilized before each use.
-Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct
-Do not reuse implants; discard used, damaged, or otherwise suspect implants
-Single use only
-The Z-Span Plate System components should not be used with components of any other system or manufacturer.
- The Z-Span Plate System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Z-Span Plate System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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

Implant Selection: The selection of the proper size, shape, and design of the implant for each patient is crucial to the success of the procedure. Metallic surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

Preoperative:
-Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.
-Carefully screen the patient, choosing only those that fit the indications described above
-Care should be exercised in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Store away from corrosive environments
-An adequate inventory should be available at surgery than those expected to be used
-All components and instruments should be cleaned and sterilized prior to each use. Additional sterile components should be available in case of an unexpected need.

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Intraoperative:
-Instructions should be carefully followed
-Extreme caution should be used around the spinal cord and nerve roots
-The implant surface should not be scratched or notched since such actions may reduce the functional strength of the construct

Postoperative:
-Detailed instructions should be given to the patient regarding care and limitations, if any
-To achieve maximum results, the patient should not be exposed to excessive mechanical vibrations. The patient should not smoke or consume alcohol during the healing process.
-The patient should be advised or their limitations and taught to compensate for this permanent physical restriction in body motion
-If a non-union develops, or if the components loosen, the devices should be revised or removed before serious injury occurs. Failure to immobilize the non-union, or a delay in such, will result in excessive and repeated stresses on the implant. It is important that immobilization of the spinal segment be maintained until fusion has occurred.
-The implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the spine during the normal healing process. After the spine is fused, the devices serve no functional purpose and should be removed.

Pre-Cleaning/Cleaning and Sterilization Procedure Recommended for Reusable Instruments (and Trays):
For safety reasons, reusable instruments must be pre-cleaned, cleaned and sterilized before use. Moreover, for good maintenance, reusable instruments must be pre-cleaned, cleaned and sterilized immediately after surgery following the sequence of steps described in the following table.

Sterilization trays should be thoroughly cleaned using either the Automated or Manual procedure that is detailed below for instruments. It is acceptable to skip the ultrasonic cleaner step for the sterilization trays if the inspection criteria provided below are acceptable for the tray.

Cautions: Long, narrow cannulations and blind holes require particular attention during cleaning.
Limitations on reprocessing: Repeated processing has minimal effect on these instruments. End of life is determined by wear and damage due to use.
1-Point of use: Remove all visual soil with disposable cloth/paper wipe. Soiled instruments must be kept moist to prevent soil from drying. If the instruments cannot be soaked immediately place a moist towel around them until they can be cleaned.
2-Containment and transportation: Avoid damage and minimize time before cleaning
3-Preparation for cleaning: None of the instrument require disassembly prior to cleaning other than disassemble removable handles that are left attached to the drill, tap and screw drivers and remove drills, taps and awl that are left in the drill guides. (Note that these items are normally stored in their dedicated tray already disassembled).
4 Thoroughly clean instruments per one of the following (Manual or Automated)

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Manual	Automated
4.1 Pre-Cleaning-Manual: • Prepare a pH neutral, enzymatic detergent soak per the instructions of the enzymatic solution manufacturer. • Soak the instrument for a minimum of 15 minutes. Actuate any mechanisms and slide moving parts to the extreme positions to ensure the cleaning solution contacts all the surfaces. • Change the soak solution if the solution becomes visibly soiled. • While still in the soak solution, use a soft brush the remove all exterior soil. Thoroughly scrub any grooves, slots, threads, teeth, ratchets, or hinges. Use an appropriate size cleaning brush to thoroughly brush the entire length of any internal lumens a minimum of five times per lumen. • Rinse instruments thoroughly with warm (approximately 35-40°C) critical water, such as reverse osmosis, distilled, and/or deionized water, taking care to flush all lumens or crevices, for at least one minute, until water runs clear. Use a tubing attachment to the water outlet in order to direct the rinse flow into any lumens, crevices, grooves, or slots and flush them completely until water runs clear.	**4.1 Pre-Cleaning-Automated:** Automated washing shall be conducted in a validated washer-disinfector. An example of a validated cycle used for cleaning validation includes: • Wash 45°C 4 minutes dose pump 4 (detergent) 5mL • Wash 60°C 3 minutes • Rinse with unheated critical water, such as reverse osmosis, distilled, and/or deionized water for 1 minute. • Rinse 60°C 1 minute
4.2 Cleaning-Manual: • Prepare a fresh pH neutral enzymatic cleaning solution and sonicate the instruments and subassemblies for a minimum of 15 minutes in an ultrasonic bath. After sonication, rinse instruments again under running critical water, such as reverse osmosis, distilled, and/or deionized water for a least one minute until water runs clear. Use a tubing attachment to the water outlet in order to direct the rinse flow into any lumens, crevices, grooves, or slots and flush them completely until the water runs clear.	**4.2 Washer Disinfector:** Automated washing shall be conducted in a validated washer-disinfector. An example of a validated cycle used for cleaning validation includes: • Thermal Disinfection A_0 93ºC • A_0 value: $A_0$3000 • Dry 123ºC air 14 minutes

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• Dry the exterior of the instruments with a clean, soft cloth. Use clean compressed air or 70% isopropyl alcohol to dry any lumens or crevices where water may become trapped.	
Inspection: • Visually inspect each disassembled device to ensure all visible blood and soil has been removed. If not visually clean repeat step 4 above until clean or appropriately dispose of device if unable to get visually clean. • Check disassembled instruments with long slender features for distortion. • Inspect the disassembled devices for any cracking, pitting, or other signs of deterioration	
Packaging: Instruments are loaded into dedicated instrument trays. Wrap the trays using appropriate FDA cleared wrap.	
Sterilization: See sterilization procedure	
Storage: Control environment	
Additional information: When sterilizing multiple instruments/trays in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.	
Manufacturer contact: Contact local representative or call customer service at 601-919-1119	

Sterilization: The Z-Span Plate System should be sterilized by the hospital using the recommended cycle:

Do not stack trays in the chamber.

Method	Cycle	Temperature	Minimum Exposure Time	Drying Times
Steam	Gravity	270°F (132°C)	15 Minutes	15 Minutes
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes	30 Minutes

Instrument Maintenance: Lubricate hinges, threads and other moving parts with a commercial water-based surgical grade instrument lubricant (such as instrument milk) to reduce friction and wear. Follow lubricant manufacturer's instructions.

Product Complaints: Any Healthcare Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify Zavation Medical Products LLC, 220 Lakeland Parkway, Flowood, MS 39232, USA, Telephone: 601-919-1119

Further Information: A recommended surgical technique for the use of this system is available upon request from Zavation Medical Products LLC, 3670 Flowood Drive, Flowood, MS 39232, USA, Telephone: 601-919-1119.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.