EMINENT
SPINE

3D Titanium Pedicle Screw System

Surgical Technique

3D Pedicle Screw System

Surgical Technique

EMINENT SPINE

PRODUCT FEATURES

- Aggressive teeth to resist migration
- Sharp Tip to easily penetrate bone
- Central opening for K-wire insertion
- Accepts 1.40mm K-Wire
- Fenestrated holes

SCREW OPTIONS

Diameter	Length
6.00mm	40-60mm | 5mm
6.50mm	40-60mm | 5mm
7.00mm	40-60mm | 5mm
7.50mm	40-60mm | 5mm
8.00mm	40-60mm | 5mm

EMINENT SPINE

Step 1: Patient Positioning

Place the patient in the prone position on the operating table with hips flexed and the legs adjusted to provide the desired sagittal alignment. Surgical draping and exposure are performed in the routine fashion. Expose the Spine.

Confirm there is enough clearance for a fluoroscopic C-arm to rotate freely for AP, oblique, and lateral views.

Step 2: Pedicle Identification

The junction of the transverse process and superior articular facet is the typical landmark for entry into the pedicle. Anatomic variations in the individual patients may cause a slight difference of the entry site. Open or MIS options are available to insert the screw.

After the pedicle entry point has been identified, decorticate the entry point with a rongeur or burr, then use a sharp-tipped awl to penetrate the entry point (Figure 1, 2).

Figure 1

Figure 2

Step 2: Pedicle Identification

MODULAR KOCHER

Radiolucent Tip

Small Hole = K-Wire

Middle Hole = Inner Shaft of Targeting Device

Large Hole = Outer Shaft on Targeting Device

Grips the rings on the targeting device, does not slip

9 inches long - Gets surgeons hand out of X-ray beam

1.4mm K-Wire

Step 2: Pedicle Identification

Insert the MIS targeting device through the incision and dock the tip on the pedicle entry point (Figure 3). Using both AP and lateral fluoroscopy, confirm that the appropriate pedicle starting point has been determined. Tap the MIS Targeting Device gently to engage the trocar tip in the pedicle. Insert the trocar tip into the vertebral body. Ensure that the trocar tip does not penetrate the pedicle wall.

Remove the MIS Targeting Device inner stylet (Figure 4).

Figure 3

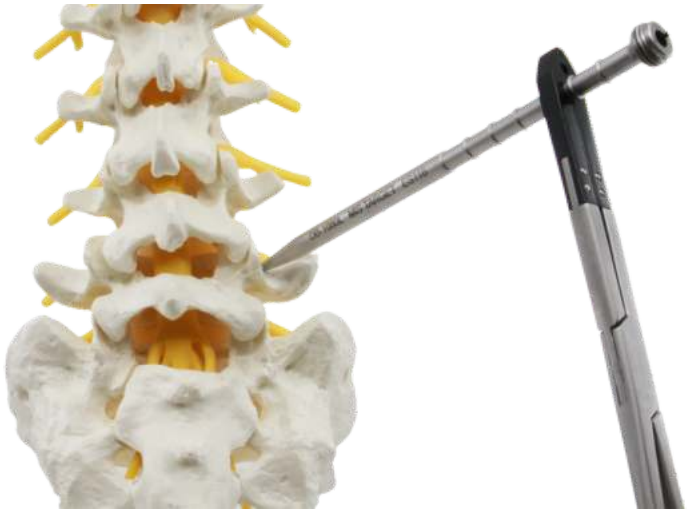


Figure 4

MIS TARGETING DEVICE

Inner and Outer Shaft Combined

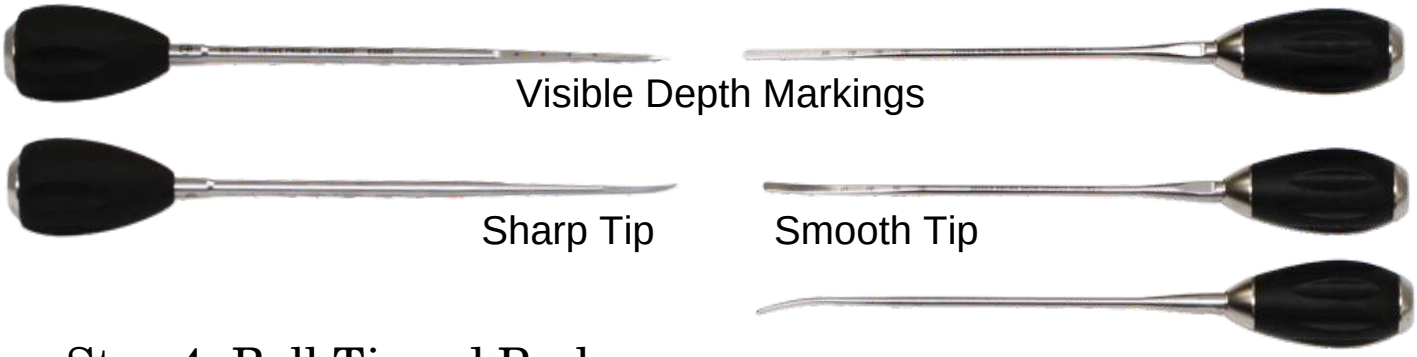
Step 3: Pedicle Probe

Enter the pedicle with a straight or curved probe. Fluoroscopy may be utilized to confirm proper positioning in the sagittal and axial planes (Figures 5, 6).

Figure 5

Figure 6

LENKE PROBE (STRAIGHT & CURVED)



Step 4: Ball Tipped Probe

A ball-tipped probe (Depth Sounder) is placed into the pedicle to check for intact walls (Figure 7, 8).

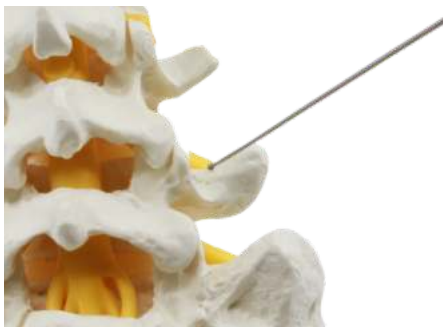
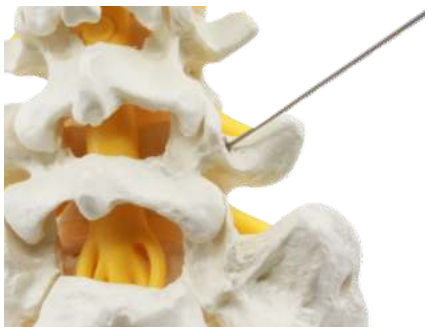


Figure 7



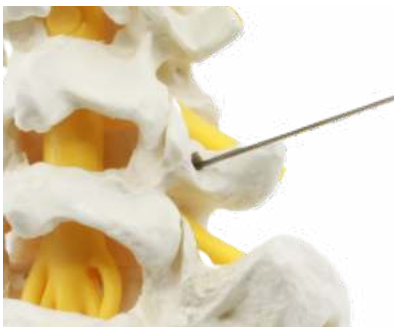


Figure 8

Step 5: K-wire Insertion

Insert the K-wire (Figure 9) through the MIS Targeting Device or simply place it in the pedicle hole. Confirm placement with AP and lateral fluoroscopy to ensure that the K-wire does not breach the pedicle or vertebral body wall.

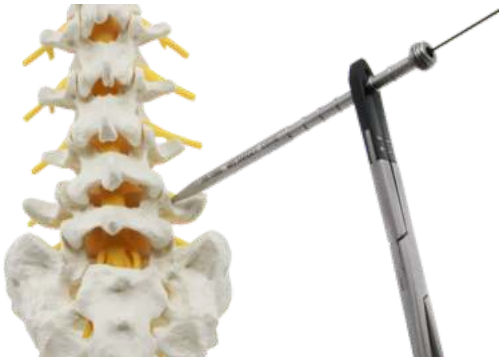


Figure 9

Figure 10

Once the K-wire has been placed to the desired depth, carefully remove the MIS Targeting Device while holding the K-wire in place (Figure 10).

1.4mm Diameter

Blunted or Sharp ends

Stainless Steel

K-wire

Step 6: Tap

Insert the Tap over the K-wire (Figure 11). Tap the pedicle with the appropriate diameter tap, which coincides with the screw diameter (Figure 12, 13).

Figure 11

Figure 12

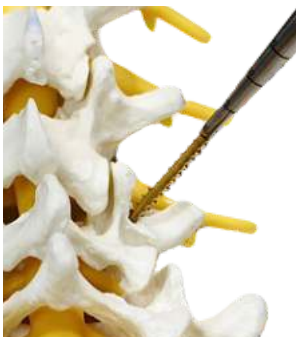


Figure 13

TAPS

HANDLES

Straight Handle

T-Handle

Palm Handle

Step 7: Screw Selection & Loading

Options include 6.0, 6.5, 7.0, 7.5 and 8.0mm screw diameter. Lengths range from 40 to 60mm in 5mm increments. The screw is placed on the driver (Figure 14) and the driver is attached to a T-handle or straight ratchet.

SCREW INSERTERS

Self Retaining

Universal

Universal Removal (3.5 Hex)

Figure 14

3.5mm Hex Tip for Screw Insertion

Step 8: Screw Insertion

Turn the driver clockwise to insert the screw into the pedicle. The screw should be parallel to the endplates and extend 50-80% into the vertebral body. Fluoroscopy should be utilized to confirm proper positioning (Figure 15, 16).

1st Screw

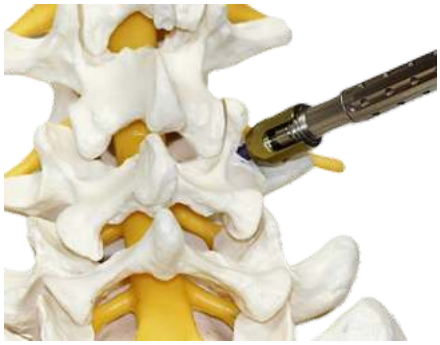
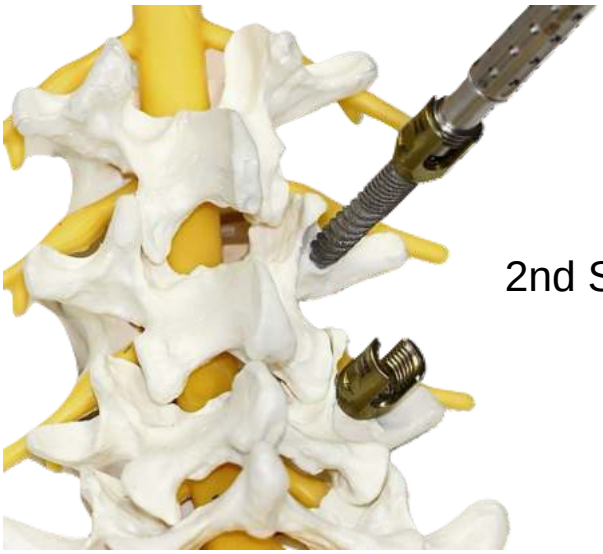


Figure 15

Repeat same process for the additional screws.



2nd Screw

Figure 16

3.5mm Hex Tip for Screw Insertion

Step 9: Rod Selection & Placement

5.5mm straight and pre-bent rods are available in lengths starting at 40mm.

Rod

ROD HOLDERS

6 Options:

Rod Holders (Open)

Rod Holders (MIS)

Step 10: Rod Selection & Placement

After all the pedicle screws are in position, insert the appropriate rod clamped by a rod holder and seat into the screw tulip (Figure 17).

Figure 17

A rod bender is available in needed (Figure 18).

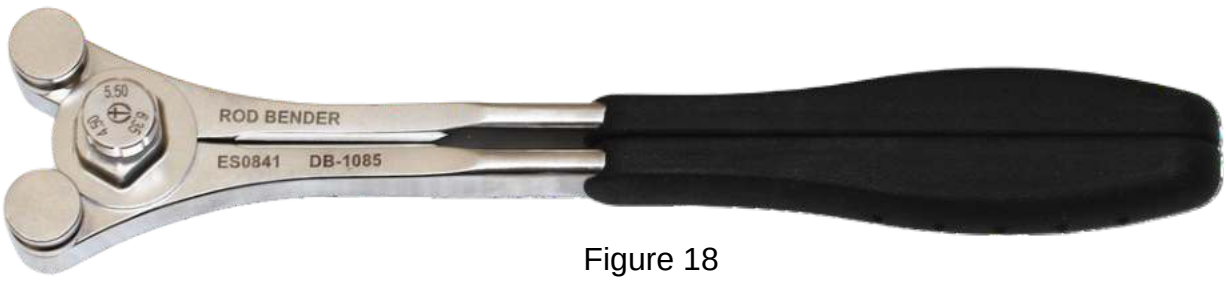


Figure 18

Step 11: Pedicle Set Screw Caps

4.0mm Hex Tip for Set Screw

Step 11 Cont: Pedicle Set Screw Caps

Six options (all with a tapered tip) are available to insert the Pedicle Set Screw Caps.

6 Options:

Palm Handled Welded Together

Straight Handled Welded Together

4.0mm Hex Tip for Set Screw

Step 11 Cont: Pedicle Set Screw Caps

Set cap screws are inserted into the threaded portion of the screw tulip using the set cap starter (Figure 19). The set cap screws should not be fully tightened but should remain loose, so that the rod can be placed in the appropriate position. After the rod is in the correct position, one of the set screws should be provisionally tightened (Figure 20).

Figure 19

Figure 20

Step 12: Compression/Distraction

If compression/ distraction is needed, provisionally tighten one set screw, and slightly loosen the other set screw to allow for the rod to slide. The compression/distraction is accomplished to the correct frontal and/or sagittal plane, then the set screw is provisionally tightened (Figure 21, 22).

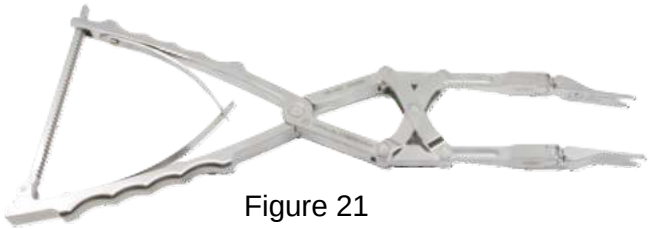


Figure 21

Figure 22

Step 13: Final Tightening

Counter Torque and Torque Wrench are available for final tightening of the pedicle set screw caps.

COUNTER TORQUE

MIS & OPEN
Visible markings for scub tech to easily identify

TORQUE WRENCH

Step 13 Cont: Final Tightening

The locking set screws are tightening to the rod using the counter-torque wrench, which is seated on the rod. The driver is then inserted through the counter-torque wrench onto the set screws. The final tightening device is a torque-limiting wrench preset to 10Nm. Turn the torque handle clockwise until a click is heard. The set screw is then fully tightened. Repeat on the remaining screws (Figure 23).

Figure 23

Step 14: Final Position

Obtain Anterior, Oblique and Lateral x-rays after final position is complete (Figure 24).

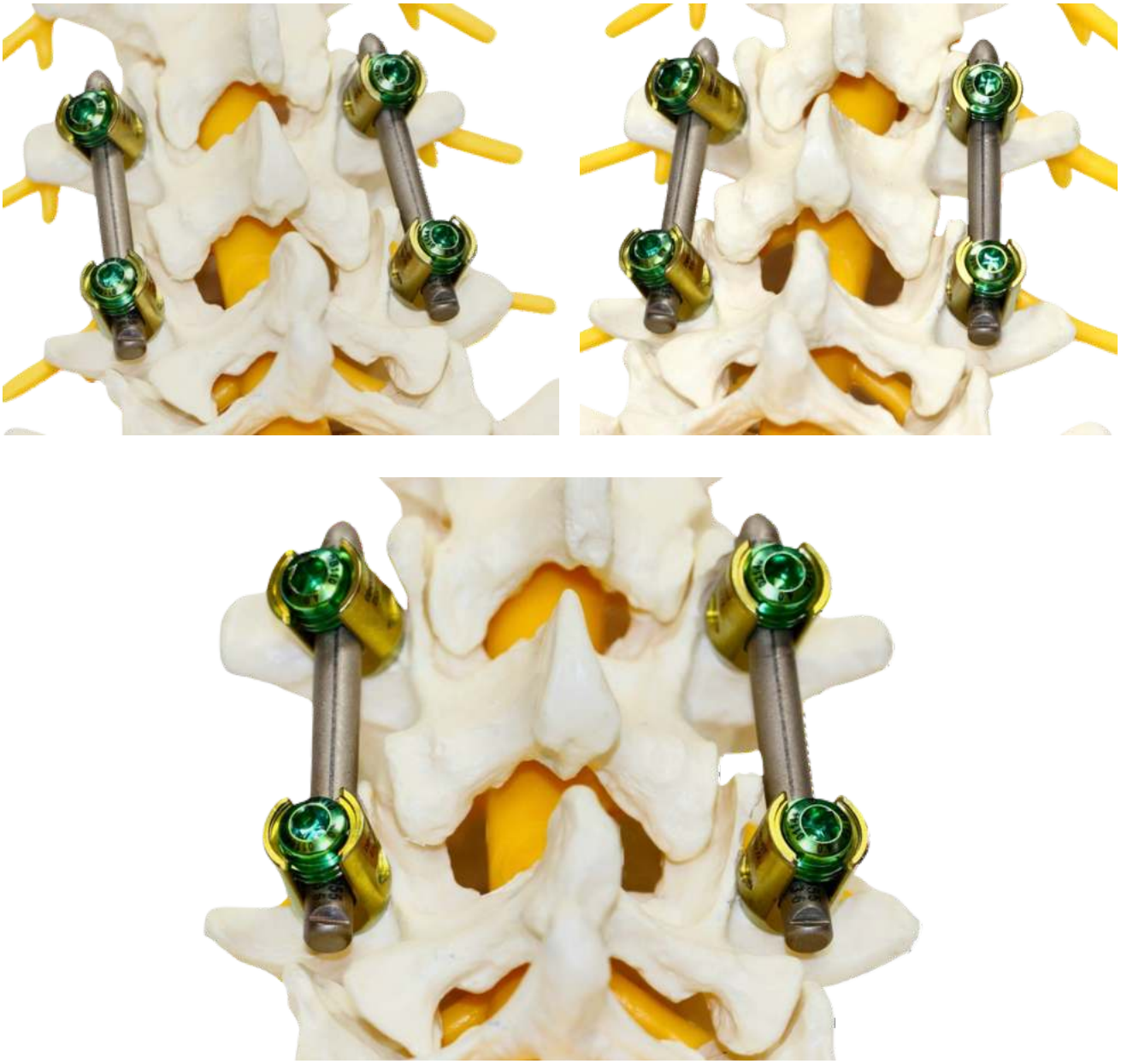


Figure 24

Step 15: Transverse Connector

Transverse connectors may be placed to connect the rods together. They may be place between the rods to enhance torsional stability of the overall construct. Three different lengths are available. The middle screw should be loosened to allow for length adjustment. The outer two screws should be loosened to the point that the end of the connector snaps over the rod. Tighten the outer 2 screws with a torque limiting wrench (preset to 3.5N/m), and then tighten the middle screw. Turn the wrench clockwise until a click is heard (Figure 25, 26).

Figure 25

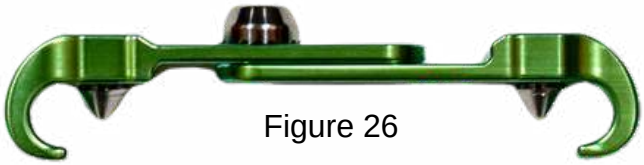


Figure 26

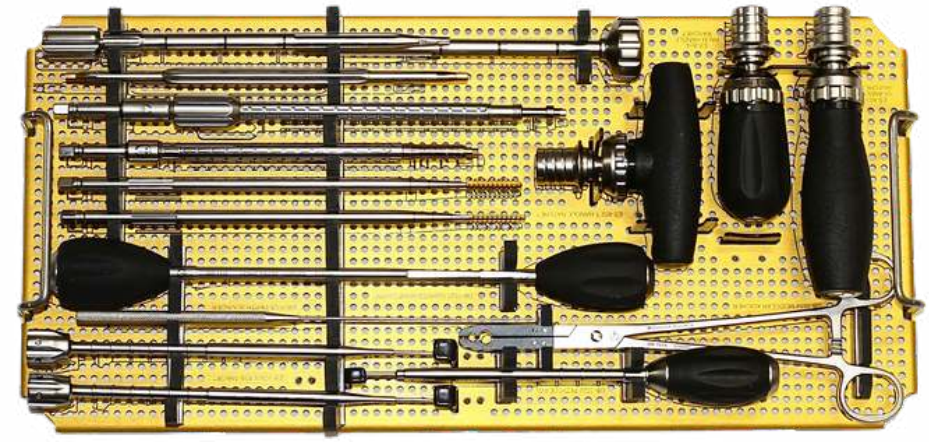
Step 13: Closure

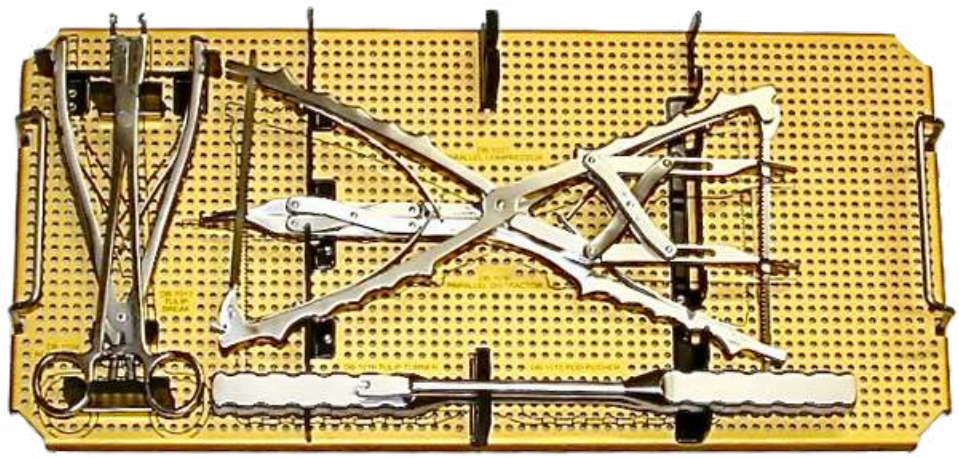
Wound closure is then performed in the customary manner.

Step 14: Revision/Removal Procedure

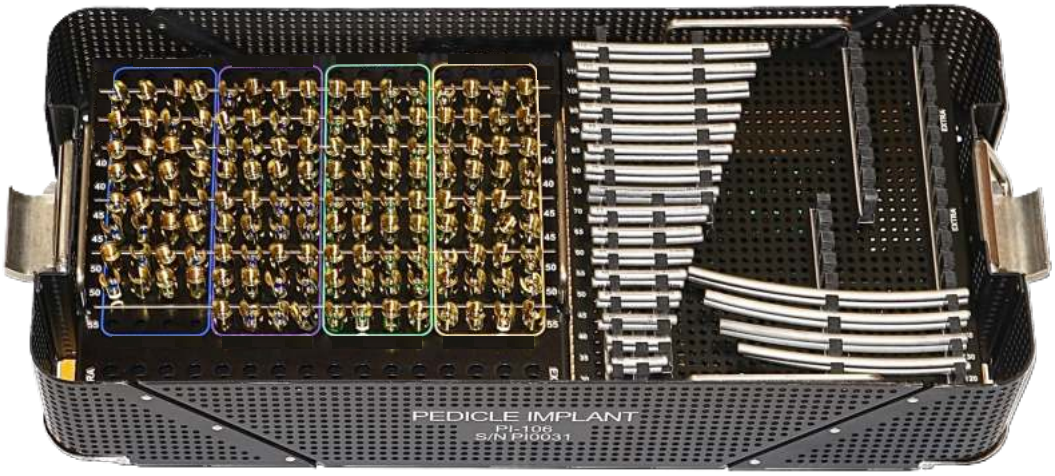
Remove the transverse connector, followed by the set screws by turning the set screw driver counter clockwise, then remove the rod. Insert the pedicle screw driver into the pedicle screw and turn the driver counter clockwise and remove the pedicle screw. If revision is required, a larger diameter pedicle screw may be needed.

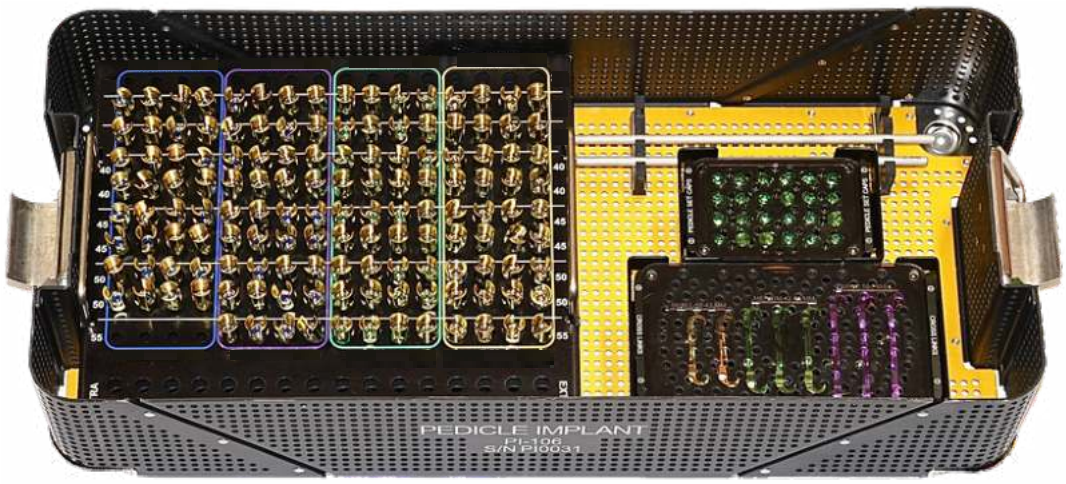
Pedicle System Instrument Tray





Pedicle System Screw Tray

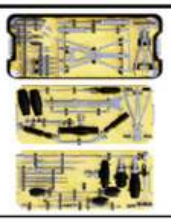
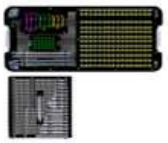




3D Pedicle Screw System

Instrument Catalog

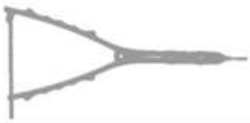
EMINENT SPINE

Part Number	Pedicle 3D Screw System	Materials	Notes	Image
PS-105	Pedicle Instrument Tray	Anodized Aluminum base, includes Nylon coated SS brackets, anodized aluminum post, electropolished TRI-corners, and 1-color silk-screened graphics on bottom and side panels	3 Level Tray	
PI-106	Pedicle Open Implant Tray	Anodized Aluminum base, includes Nylon coated SS brackets, anodized aluminum post, electropolished TRI-corners, and 1-color silk-screened graphics on bottom and side panels	2 Level Tray	
DB-1003L	Pedicle Screw Driver, Long	316 Stainless Steel per ASTM A276		
DB-1006	Set Cap Caddy	T6061 Aluminum, Smoke Polyphenylsulfone Sheet (Radel R5000)		
DB-1009	AO Cross Link Driver	455 Stainless Alloy per ASTM F899		
DB-1010	Cross Link Caddy	T6061 Aluminum, Smoke Polyphenylsulfone Sheet (Radel R5000)		
DB-1012	Set Cap Starter, Double Flex	455 Stainless Alloy per ASTM F899		
DB-1014	Radiolucent Modular Kocher	Medical Grade Polypropylene (Tecapo MT)		
DB-1020	Straight Bone Probe	17-4 Stainless Steel per ASTM A564		
DB-1021	Curved Bone Probe	17-4 Stainless Steel per ASTM A564		
DB-1022	Pedicle Awl	17-4 Stainless Steel per ASTM A564		
DB-1023	Counter Torque - Open	17-4 Stainless Steel per ASTM A564		
DB-1023L	Counter Torque - Open Long	17-4 Stainless Steel per ASTM A564		

3D Pedicle Screw System

Instrument Catalog

EMINENT SPINE

DB-1025	Wall Check, Depth Sounder	17-4 Stainless Steel per ASTM A564		
DB-1031	Counter Torque, MIS	17-4 Stainless Steel per ASTM A564		
DB-1031L	Counter Torque, MIS Long	17-4 Stainless Steel per ASTM A564		
DB-1033	Rod Inserter, MIS	17-4 Stainless Steel per ASTM A564		
DB-1034L	Pedicle Screw Driver, Threaded Universal	455 Stainless Alloy per ASTM F899		
DB-1036	Pedicle Distractor	17-4 Stainless Steel per ASTM A564		
DB-1037	Pedicle Compressor	17-4 Stainless Steel per ASTM A564		
DB-1050L	Final Cap Driver, 4.0mm Long	455 Stainless Alloy per ASTM F899		
DB-1080L	Pedicle MIS Target Tap System, Long	17-4 Stainless Steel per ASTM A564		
DB-1083L	Set Cap Starter, 4.0mm Flex Tip, Long	455 Stainless Alloy per ASTM F899		
DB-1085	Rod Bender	17-4 Stainless Steel per ASTM A564		
DB-1086	Rod Holder A, Open	17-4 Stainless Steel per ASTM A564		
DB-1105L	Cap Starter, 4.0mm, Long	455 Stainless Alloy per ASTM F899		
DB-1108	Rod Inserter, Version-K	17-4 Stainless Steel per ASTM A564		
DB-1109	Pedicle Lenke Probe, Straight	17-4 Stainless Steel per ASTM A564		
DB-1110	Pedicle Lenke Probe, Curved	17-4 Stainless Steel per ASTM A564		

3D Pedicle Screw System

Instrument Catalog

EMINENT SPINE

DB-1114	Pedicle Screw Driver - Retaining	455 Stainless Alloy per ASTM F899		
DB-1145	4.5mm Tap, Cannulated	17-4 Stainless Steel per ASTM A564		
DB-1155	5.5mm Tap, Cannulated	17-4 Stainless Steel per ASTM A564		
DB-1165	6.5mm Tap, Cannulated	17-4 Stainless Steel per ASTM A564		
DB-1175	7.5mm Tap, Cannulated	17-4 Stainless Steel per ASTM A564		
ES-802	1/4 Drive Ratchet, T-Handle	17-4 Stainless Steel per ASTM A564		
ES-803	1/4 Drive Ratchet, I-Handle	17-4 Stainless Steel per ASTM A564		
ES-804	1/4 Drive Ratchet, Palm Handle	17-4 Stainless Steel per ASTM A564		
ES-805	1/4 Drive 10Nm Final Torque	17-4 Stainless Steel per ASTM A564		
ES-806	A/O Drive 3.5NM Torque	17-4 Stainless Steel per ASTM A564		
ESP-0001	K-Wire, 1.4mm x 18", 316 SS, Flat Ends	316 Stainless Steel per ASTM A276		

3D Pedicle Screw System

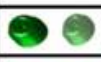
Implant Catalog

EMINENT SPINE

Part Number	3D Titanium Pedicle Screw System	Material	Manufacturer	Image
P3C16040	3D Pedicle Screw, Cannulated, 6.0mm x 40mm	Ti-6Al-4V per ASTM F3001	Eminent Spine	
P3C16045	3D Pedicle Screw, Cannulated, 6.0mm x 45mm	Ti-6Al-4V per ASTM F3001	Eminent Spine	
P3C16050	3D Pedicle Screw, Cannulated, 6.0mm x 50mm	Ti-6Al-4V per ASTM F3001	Eminent Spine	
P3C16055	3D Pedicle Screw, Cannulated, 6.0mm x 55mm	Ti-6Al-4V per ASTM F3001	Eminent Spine	
P3C16060	3D Pedicle Screw, Cannulated, 6.0mm x 60mm	Ti-6Al-4V per ASTM F3001	Eminent Spine	
P3C16540	3D Pedicle Screw, Cannulated, 6.5mm x 40mm	Ti-6Al-4V per ASTM F3001	Eminent Spine	
P3C16545	3D Pedicle Screw, Cannulated, 6.5mm x 45mm	Ti-6Al-4V per ASTM F3001	Eminent Spine	
P3C16550	3D Pedicle Screw, Cannulated, 6.5mm x 50mm	Ti-6Al-4V per ASTM F3001	Eminent Spine	
P3C16555	3D Pedicle Screw, Cannulated, 6.5mm x 55mm	Ti-6Al-4V per ASTM F3001	Eminent Spine	
P3C16560	3D Pedicle Screw, Cannulated, 6.5mm x 60mm	Ti-6Al-4V per ASTM F3001	Eminent Spine	
P3C17040	3D Pedicle Screw, Cannulated, 7.0mm x 40mm	Ti-6Al-4V per ASTM F3001	Eminent Spine	
P3C17045	3D Pedicle Screw, Cannulated, 7.0mm x 45mm	Ti-6Al-4V per ASTM F3001	Eminent Spine	
P3C17050	3D Pedicle Screw, Cannulated, 7.0mm x 50mm	Ti-6Al-4V per ASTM F3001	Eminent Spine	
P3C17055	3D Pedicle Screw, Cannulated, 7.0mm x 55mm	Ti-6Al-4V per ASTM F3001	Eminent Spine	
P3C17060	3D Pedicle Screw, Cannulated, 7.0mm x 60mm	Ti-6Al-4V per ASTM F3001	Eminent Spine	
P3C17540	3D Pedicle Screw, Cannulated, 7.5mm x 40mm	Ti-6Al-4V per ASTM F3001	Eminent Spine	
P3C17545	3D Pedicle Screw, Cannulated, 7.5mm x 45mm	Ti-6Al-4V per ASTM F3001	Eminent Spine	
P3C17550	3D Pedicle Screw, Cannulated, 7.5mm x 50mm	Ti-6Al-4V per ASTM F3001	Eminent Spine	
P3C17555	3D Pedicle Screw, Cannulated, 7.5mm x 55mm	Ti-6Al-4V per ASTM F3001	Eminent Spine	
P3C17560	3D Pedicle Screw, Cannulated, 7.5mm x 60mm	Ti-6Al-4V per ASTM F3001	Eminent Spine	
P3C18040	3D Pedicle Screw, Cannulated, 8.0mm x 40mm	Ti-6Al-4V per ASTM F3001	Eminent Spine	
P3C18045	3D Pedicle Screw, Cannulated, 8.0mm x 45mm	Ti-6Al-4V per ASTM F3001	Eminent Spine	
P3C18050	3D Pedicle Screw, Cannulated, 8.0mm x 50mm	Ti-6Al-4V per ASTM F3001	Eminent Spine	
P3C18055	3D Pedicle Screw, Cannulated, 8.0mm x 55mm	Ti-6Al-4V per ASTM F3001	Eminent Spine	
P3C18060	3D Pedicle Screw, Cannulated, 8.0mm x 60mm	Ti-6Al-4V per ASTM F3001	Eminent Spine	
DB1040	Pedicle Rod, Straight, 5.5mm x 40mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB1045	Pedicle Rod, Straight, 5.5mm x 45mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB1050	Pedicle Rod, Straight, 5.5mm x 50mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB1055	Pedicle Rod, Straight, 5.5mm x 55mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB1060	Pedicle Rod, Straight, 5.5mm x 60mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB1065	Pedicle Rod, Straight, 5.5mm x 65mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB1070	Pedicle Rod, Straight, 5.5mm x 70mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB1075	Pedicle Rod, Straight, 5.5mm x 75mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB1080	Pedicle Rod, Straight, 5.5mm x 80mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB1085	Pedicle Rod, Straight, 5.5mm x 85mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB1090	Pedicle Rod, Straight, 5.5mm x 90mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB1095	Pedicle Rod, Straight, 5.5mm x 95mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB1100	Pedicle Rod, Straight, 5.5mm x 100mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB1110	Pedicle Rod, Straight, 5.5mm x 110mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB1120	Pedicle Rod, Straight, 5.5mm x 120mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB1130	Pedicle Rod, Straight, 5.5mm x 130mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB1140	Pedicle Rod, Straight, 5.5mm x 140mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB1150	Pedicle Rod, Straight, 5.5mm x 150mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB1160	Pedicle Rod, Straight, 5.5mm x 160mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB1170	Pedicle Rod, Straight, 5.5mm x 170mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB1180	Pedicle Rod, Straight, 5.5mm x 180mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB1190	Pedicle Rod, Straight, 5.5mm x 190mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB1200	Pedicle Rod, Straight, 5.5mm x 200mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB1250	Pedicle Rod, Straight, 5.5mm x 250mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB1300	Pedicle Rod, Straight, 5.5mm x 300mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB1350	Pedicle Rod, Straight, 5.5mm x 350mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB1400	Pedicle Rod, Straight, 5.5mm x 400mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB1500	Pedicle Rod, Straight, 5.5mm x 500mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB1600	Pedicle Rod, Straight, 5.5mm x 600mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB2040	Pedicle Rod, Curved, 5.5mm x 40mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB2045	Pedicle Rod, Curved, 5.5mm x 45mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB2050	Pedicle Rod, Curved, 5.5mm x 50mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB2055	Pedicle Rod, Curved, 5.5mm x 55mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB2060	Pedicle Rod, Curved, 5.5mm x 60mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB2065	Pedicle Rod, Curved, 5.5mm x 65mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB2070	Pedicle Rod, Curved, 5.5mm x 70mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB2075	Pedicle Rod, Curved, 5.5mm x 75mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB2080	Pedicle Rod, Curved, 5.5mm x 80mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB2085	Pedicle Rod, Curved, 5.5mm x 85mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB2090	Pedicle Rod, Curved, 5.5mm x 90mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB2095	Pedicle Rod, Curved, 5.5mm x 95mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB2100	Pedicle Rod, Curved, 5.5mm x 100mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB2110	Pedicle Rod, Curved, 5.5mm x 110mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB2120	Pedicle Rod, Curved, 5.5mm x 120mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB2130	Pedicle Rod, Curved, 5.5mm x 130mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB2140	Pedicle Rod, Curved, 5.5mm x 140mm	Ti-6Al-4V per ASTM F136	Eminent Spine	

3D Pedicle Screw System

Implant Catalog

DB2150	Pedicle Rod, Curved, 5.5mm x 150mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB2160	Pedicle Rod, Curved, 5.5mm x 160mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB2170	Pedicle Rod, Curved, 5.5mm x 170mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB2180	Pedicle Rod, Curved, 5.5mm x 180mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB2190	Pedicle Rod, Curved, 5.5mm x 190mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB2200	Pedicle Rod, Curved, 5.5mm x 200mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB2250	Pedicle Rod, Curved, 5.5mm x 250mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB2300	Pedicle Rod, Curved, 5.5mm x 300mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB2350	Pedicle Rod, Curved, 5.5mm x 350mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB2400	Pedicle Rod, Curved, 5.5mm x 400mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB2500	Pedicle Rod, Curved, 5.5mm x 500mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB2600	Pedicle Rod, Curved, 5.5mm x 600mm	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB110	Pedicle Set Cap, 4.0mm Hex	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB120	Pedicle Set Cap, 4.0mm Hex, Surfaced	Ti-6Al-4V per ASTM F136	Eminent Spine	
DB3248	Pedicle Cross Link, 32mm-48mm Span	Ti-6Al-4V per ASTM F134	Eminent Spine	
DB4856	Pedicle Cross Link, 48mm-56mm Span	Ti-6Al-4V per ASTM F135	Eminent Spine	
DB5874	Pedicle Cross Link, 56mm-74mm Span	Ti-6Al-4V per ASTM F136	Eminent Spine	

3D Pedicle Screw System

IFU

Eminent Spine LLC 3D Titanium Pedicle Screw System

Eminent Spine, LLC
2004 Ventura Drive, Suite #100
Plano, TX 75093

System Contents

•Non-Sterile Implants – Single Use Only
•Non-Sterile Instruments - Reusable

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Carefully read all instructions and be familiar with the surgical technique(s) prior to using this product.

DESCRIPTION:
The 3D Titanium Pedicle Screw System consists of rods, pedicle screws with caps, locking set screws and cross connectors with lock screws. Rods are available either straight or pre-contoured in a variety of lengths. Polyaxial screws are available in a variety of diameter-length combinations.

INDICATIONS:
The 3D Titanium Pedicle Screw System is designed to provide immobilization and stabilization to the thoracic, lumbar and sacral spinal segments as an adjunct to fusion. The system is intended for posterior, pedicle fixation in skeletally mature patients for the treatment of the following acute and chronic instabilities or deformities: severe spondylolisthesis (grades 3 or 4) of the L5-S1 vertebrae, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, spinal stenosis, scoliosis, kyphosis, lordosis, spinal tumor, pseudoarthrosis and failed previous fusion.

CONTRAINDICATIONS:
1. Active systemic infection or infections localized to the site of the proposed implantation are contraindications to implantation.
2. Known sensitivity to Titanium alloy 6Al-4V per ASTM F136 and 6Al-4V per ASTM F3001 materials.
3. Severe osteoporosis is a relative contraindication because it may
result in implant subsidence and loss of fixation.
4. Any condition that significantly affects the likelihood of fusion may be a relative contraindication (e.g. cancer, diabetes, osteomalacia, heavy smoker, morbid obesity) and the surgeon must evaluate the relative risks and benefits individually with each patient.
5. Other relative contraindication may include mental illness, drug abuse or alcoholism as these may cause the patient to be non-compliant with post-operative guidance (e.g. bracing and physical therapy).
6. Prior fusion at the levels to be treated.
7. Any condition not described in the indications for use.

MATERIALS:
The implants for pedicle screw systems are manufactured from Titanium alloy 6Al-4V per F136 and 6Al-4V per F3001 materials. Surgical instruments provided with the pedicle screw systems are manufactured from stainless steel.

CLEANING of INSTRUMENTS and IMPLANTS:
1. Clean all instruments and implants prior to use, and as soon as possible after use. Do not allow blood or debris to dry on the instruments that were used in surgery. If cleaning must be delayed, place instruments that were used in surgery in a covered container with neutral pH detergent or enzymatic solution to delay drying.
2. Loosen and/or disassemble instruments with removable parts. Remove implants (in caddies) from set cases.
3. Immerse the instruments and implants in a neutral pH detergent or enzymatic solution prepared in accordance with the manufacturer's instructions and soak for 15 minutes.
4. Use a soft-bristle brush and a pipe cleaner to gently clean each instrument and implant (particular attention shall be given to cannulations, holes, and other hard-to-clean areas) until all visible soil has been removed.
5. Rinse the instruments and implants in running water for at least 3 minutes. Thoroughly flush cannulations, holes, and other hard-to-clean areas.
6. After manual cleaning has been completed, load the parts into a suitable automated cleaner and follow the manufacturer's recommended practices. Use only neutral pH enzymatic cleaners and detergents. Avoid excessively acidic or alkaline solutions.

INSPECTION:
1. Carefully inspect each instrument to ensure all visible blood and soil has been removed.
2. Inspect instruments and instrument cases for damage. Check action of moving parts to ensure proper operation, and ensure disassembled instruments readily assemble with mating components.
3. If damage or wear is noted that may compromise the proper function of the instrument or instrument case, do not use and contact customer service or your Eminent Spine LLC representative for a replacement.
4. If corrosion is noted, do not use and contact customer service or your Eminent Spine LLC representative for a replacement.

3D Pedicle Screw System

IFU

STERILIZATION:

All implants and instruments are supplied visually clean and non-sterile and must be sterilized prior to use. The following are the recommended sterilization cycles for both systems:

Method: Steam
Cycle: Pre-Vacuum
Temperature: 270°F (132°C)
Exposure Time: 4 minutes
Number of Pulses: 4

Drying Time:
Pedicle Screw 30 minutes
MIS Pedicle Screw 40 minutes

Implants and instruments should be positioned to allow the steam to come into contact with all surfaces. All jointed instruments should be in the open or unlocked position with ratchets not engaged.

Instruments composed of more than one part or with sliding pieces or removable parts should be dissembled.

Remove all packaging material prior to sterilization. Only sterile implants and instruments should be used in surgery. Cases (including instruments and implants) used in surgery should be cleaned and re-sterilized after surgery. Implants should not be used as templates in surgery. If an unused implant entered the surgical wound it should be cleaned and re-sterilized after surgery.

•Please consider your sterilization equipment manufacturer's written instructions for the specific sterilizer and load configuration used.
•Follow current AORN "Recommended Practices for Sterilization in Perioperative Practice Settings" and ANSI/AAMI ST79: A4 2013 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
•Flash sterilization is not recommended, but if used, should only be performed according to requirements of ANSI/AAMI ST79: A4 2013 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
•For terminally sterilized devices, only FDA-cleared sterilization barriers (e.g., wraps, pouches, containers) should be used for packaging.

POSTOPERATIVE MOBILIZATION:

The surgeon should advise the patient to be careful not to place significant loads on the spine for the first three months after surgery. The surgeon may advise the patient to limit their activity or wear a brace. Careful management of the load will enable the fusion mass to heal and reduce the likelihood of non-union. Radiographic confirmation of a mature fusion mass may be used as a guide in the lifting of these restrictions.

WARNINGS:

Following are specific warnings, precautions, and adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general but are important considerations particular to spinal fixation devices. General surgical risks should be explained to the patient prior to surgery.

1. The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar and sacral spine secondary to severe spondylolisthesis (grades 3 or 4) of the L5-S1 vertebrae, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, spinal stenosis, scoliosis, kyphosis, lordosis, spinal tumor and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other condition are unknown.
2. Patients with prior spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.
3. PATIENT SELECTION. In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:
a) A patient may have multiple pain generators due to advanced degeneration of the spine (e.g. intervertebral disc. Facets or bony stenosis). These conditions may be present at the index or adjacent levels. Careful review of the clinical record including radiographic studies and applicable diagnostic tests should be performed to make the appropriate diagnosis. Concomitant conditions may reduce the effectiveness of the surgery and should be discussed with the patient.
b) The patient's weight. An overweight or obese patient can produce loads on the device that can lead to failure of the implant or subsidence.
c) The patient's occupation or activity. If the patient is involved in an occupation or activity that includes substantial walking, running, lifting or muscle strain, the resultant forces can cause failure of the implant.
d) Patients that are non-compliant with postoperative guidance may place too much stress on the implant in the early postoperative period and compromise the maturing fusion mass.
e) Smoking. Patients who smoke have been observed to experience higher rates of pseudoarthrosis following surgical procedures where bone graft is used.
f) Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

3D Pedicle Screw System

IFU

PRECAUTIONS:

1. THE IMPLANTATION OF SPINAL FIXATION DEVICES SHOULD BE PERFORMED ONLY BY EXPERIENCED SURGEONS WITH SPECIFIC TRAINING IN THE USE OF SUCH DEVICES. THIS IS A TECHNICALLY DEMANDING PROCEDURE PRESENTING A RISK OF SERIOUS INJURY TO THE PATIENT.
2. PROPER SIZING OF THE IMPLANTS IS IMPORTANT. Based upon the fatigue test results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.
3. SURGICAL IMPLANTS MUST NEVER BE REUSED. An explanted spinal fixation device should never be re-implanted. Even though the device may appear undamaged, it may have small defects and internal stress patterns that may lead to early breakage.
4. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT. The operating surgeon should avoid any notching or scratching of the device during surgery. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.
5. ADEQUATELY INSTRUCT THE PATIENT. Postoperative care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the body's response to the implant and how the fusion mass is expected to develop. A patient that is noncompliant with postoperative guidance is particularly at risk during the early postoperative period.
6. MAGNETIC RESONANCE ENVIRONMENT. The 3D Titanium Pedicle Screw System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of 3D Titanium Pedicle Screw System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

POSSIBLE ADVERSE EFFECTS:

1. Nonunion, delayed union.
2. Bending or fracture of implant.
3. Anterior or posterior migration of the implant.
4. Allergic reaction to a foreign body.
5. Infection.
6. Decrease in bone density due to stress shielding.
7. Pain, discomfort, or abnormal sensations due to the presence of the device.
8. Loss of proper spinal curvature, correction height and/or reduction.
9. Vascular and/or nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation and paresthesia.
10. Paralysis.
11. Death.

LIMITED WARRANTY:

Eminent Spine LLC products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact Eminent Spine LLC for current information.

Eminent Spine, LLC
2004 Ventura Dr. STE #100
Plano, TX 75093
Phone: 972-499-3593

For product information or questions pertaining to sales and service, please contact your local sales representative or Eminent Spine LLC customer service.