EMINENT
SPINE

Scoliosis Deformity Pedicle Screw System

Surgical Technique

Eminent Spine

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Surgical Technique

PRODUCT FEATURES

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

SCREW OPTIONS

PEDICLE SCREW OPTIONS

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

ILIAC SCREW OPTIONS

Diameter	Length
5.50mm	40-110mm | 5mm
6.50mm	40-110mm | 5mm
7.50mm	40-110mm | 5mm
8.50mm	40-110mm | 5mm
9.00mm	40-110mm | 5mm
9.50mm	40-110mm | 5mm
10.50mm	40-110mm | 5mm
11.50mm	40-110mm | 5mm

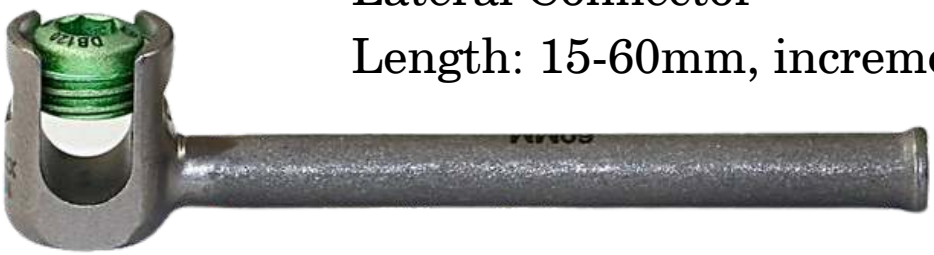
PRODUCT FEATURES

Closed Side by Side Connector

Open Side by Side Connector

End to End Connector

Lateral Connector
Length: 15-60mm, increments of 5



4.0mm Hex set caps

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

1.4mm K-Wire

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

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 3, 4).

Figure 3

Figure 4

MIS TARGETING DEVICE

Inner and Outer Shaft Combined

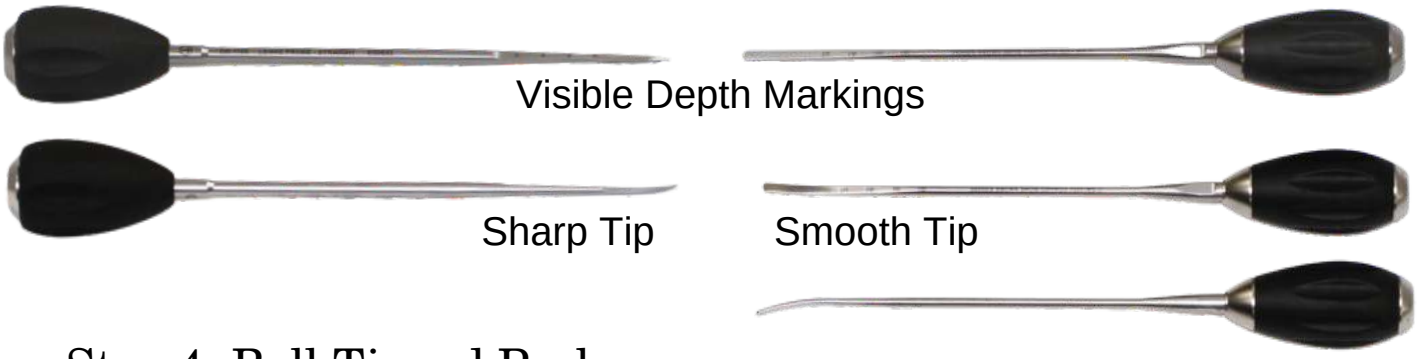
Step 3: Pedicle Probe

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

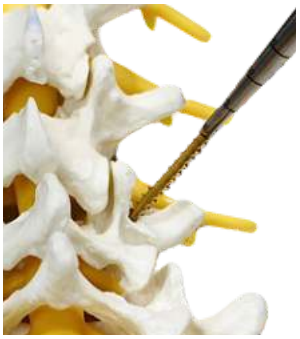
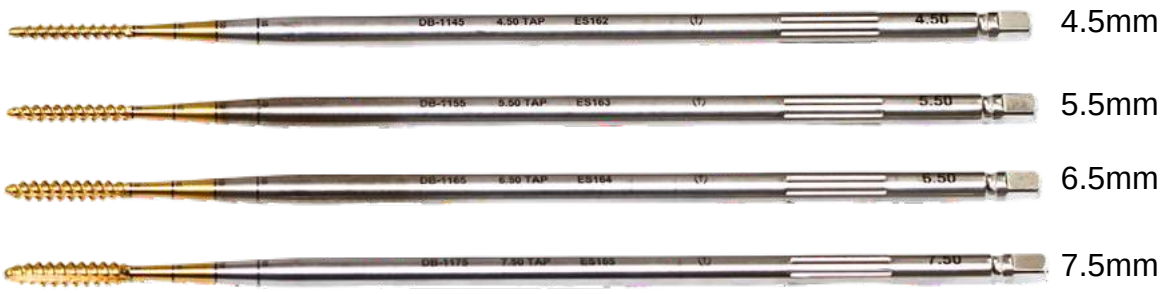


Figure 13

TAPS



HANDLES

Straight Handle

T-Handle

Palm Handle

Step 7: Screw Selection & Loading

Options include 6.5, 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

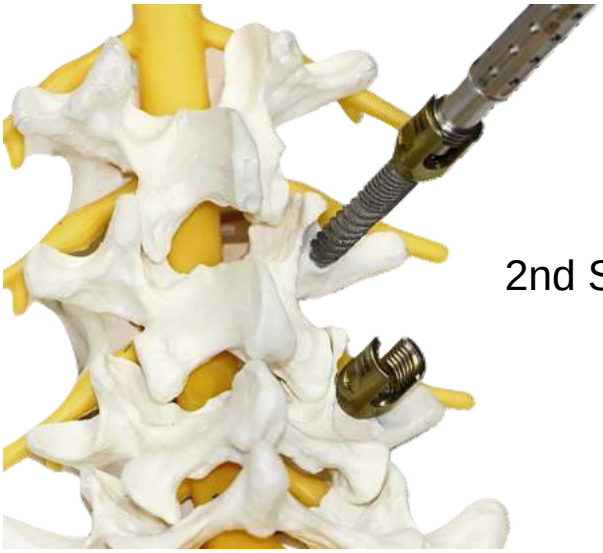
Step 8: Screw Insertion

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

Bullet nose for easier passage

Visible line marking for lordosis

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).

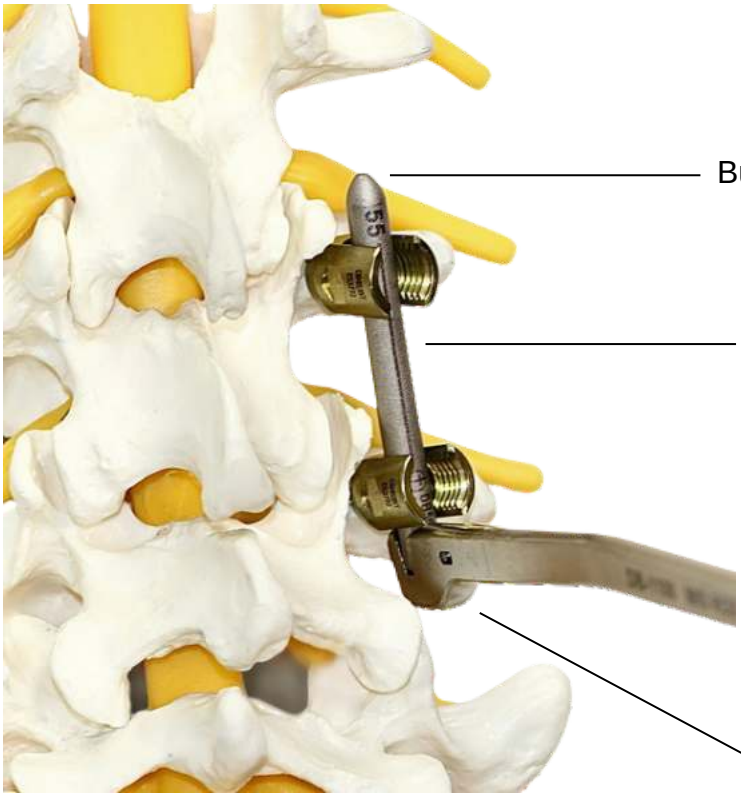


Figure 17

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

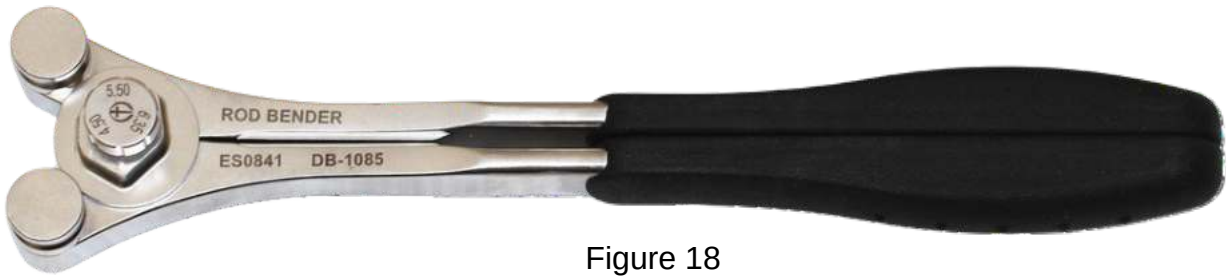


Figure 18

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).

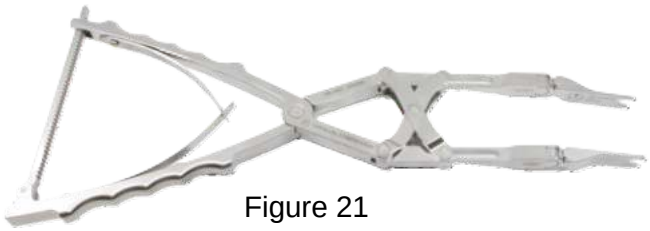


Figure 21

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).

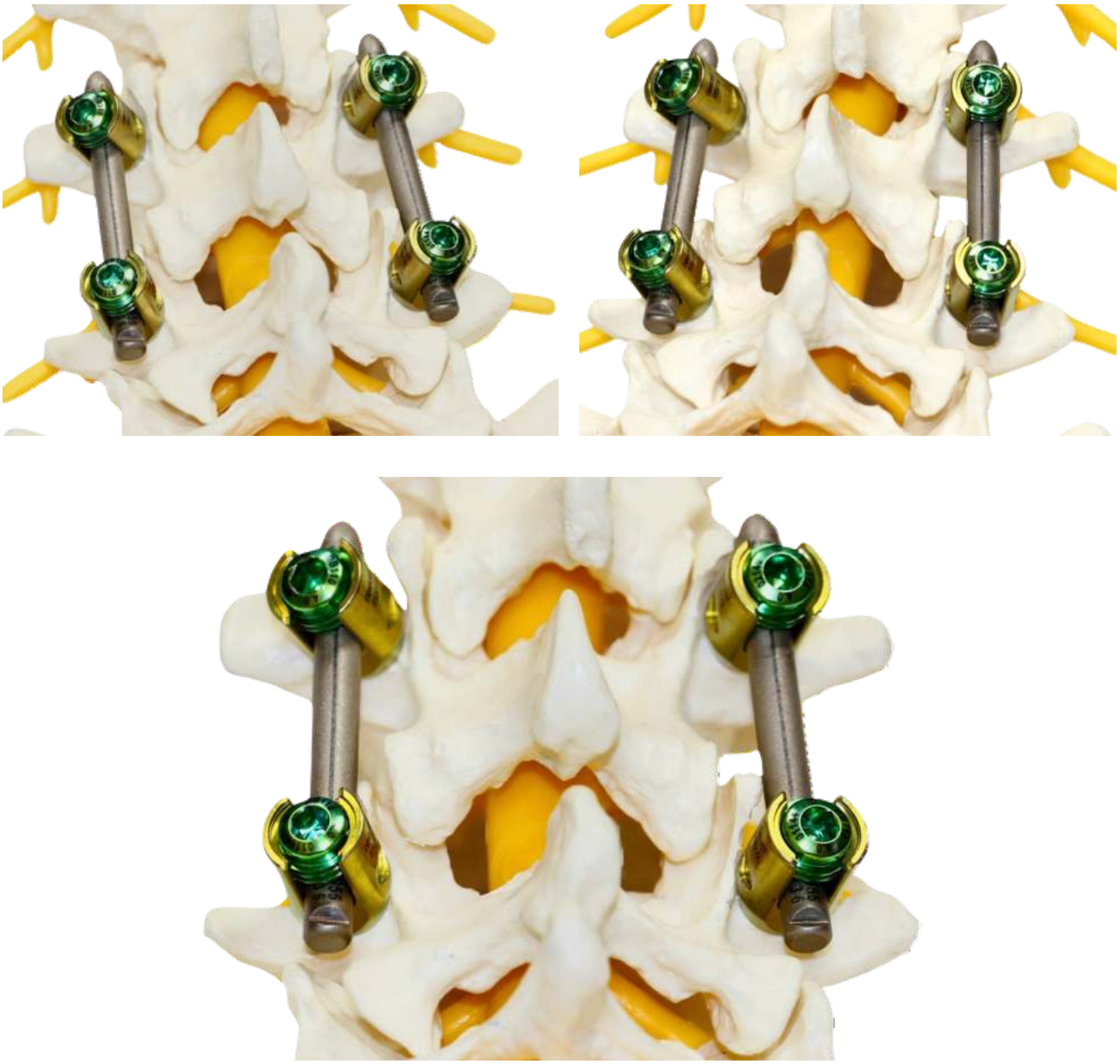


Figure 24

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

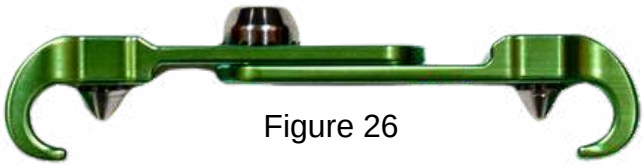


Figure 26

Step 16: Closure

Wound closure is then performed in the customary manner.

Step 17: 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.

Closed Side by Side Connector

Attach Closed Side by Side Connector to Rod. Tighten Set Screw Cap on the side connected to the Rod (Figure 1).

Figure 1

Insert Rod to Closed Side by Side Connector and Pedicle Screw (Figure 2) and tighten remaining Set Screw Cap to secure (Figure 3).

Figure 2

Figure 3

Closed Side by Side Connector

Figure 4

Insert 4.0mm Hex Set Screw Cap on opposite end of the Rod to secure (Figure 4).

Tighten the 4.0mm Hex to 10N-m (Figure 5).

Figure 5

Open Side by Side Connector

Figure 1

Attach Open Side by Side Connector to Rod (Figure 1).

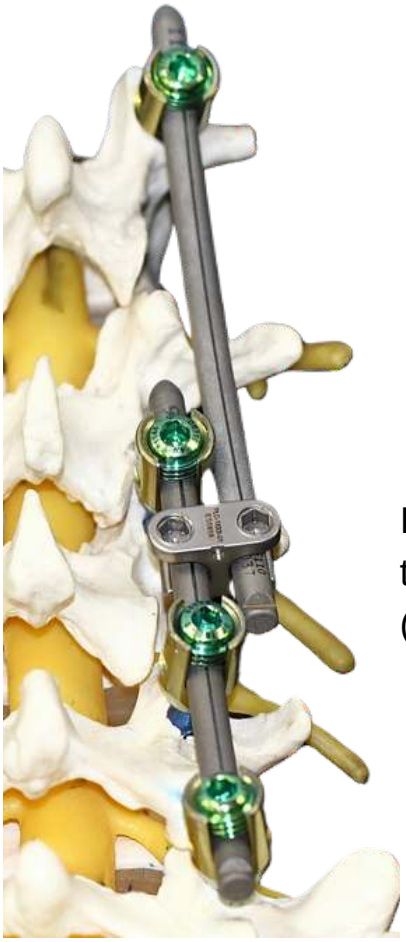


Figure 2

Insert Rod and tighten the 4.0mm Hex to 5N-m (Figure 2).

End to End Connector

Figure 1

Attach Connector to Rod (Figure 1).

Insert Rod to Connector and Pedicle Screw (Figure 2).

Figure 2

Figure 3

Insert Rod and tighten the 4.0mm Hex to 3.5N-m (Figure 3).

Lateral Connector

liac Fixation:

Iliac screw entry point is medial to the medial iliac crest wall, 2cm below PSIS, and lateral to S1 foramen (Figure 1). The trajectory is 45° caudally and laterally towards the anterior inferior iliac spine (Figure 2).

Figure 1

Figure 2

It is recommended to notch the iliac crest sufficiently to recess the tulip, to avoid implant prominence (Figure 3).

Figure 3

Lateral Connector

Insert the Lateral Connector to the Iliac Screw and secure with 4.0mm Hex Set Screw Cap (Figure 4).

Figure 4

Insert Rod into Pedicle Screw Tulip and Lateral Connector Tulip and provisionally tighten with 4.0mm Hex Set Screw Caps (Figure 5).

Figure 5

Once the set caps are tightened fully, remove the set cap driver (Figure 6).

Figure 6

Lateral Connector

Tighten the 4.0mm Hex to 10N-m utilizing the Counter Torque on the pedicle screws (Figure 7).

Figure 7

Tighten the Iliac Rod Connector to 10N-m utilizing the Counter Torque (Figure 8).

Figure 8

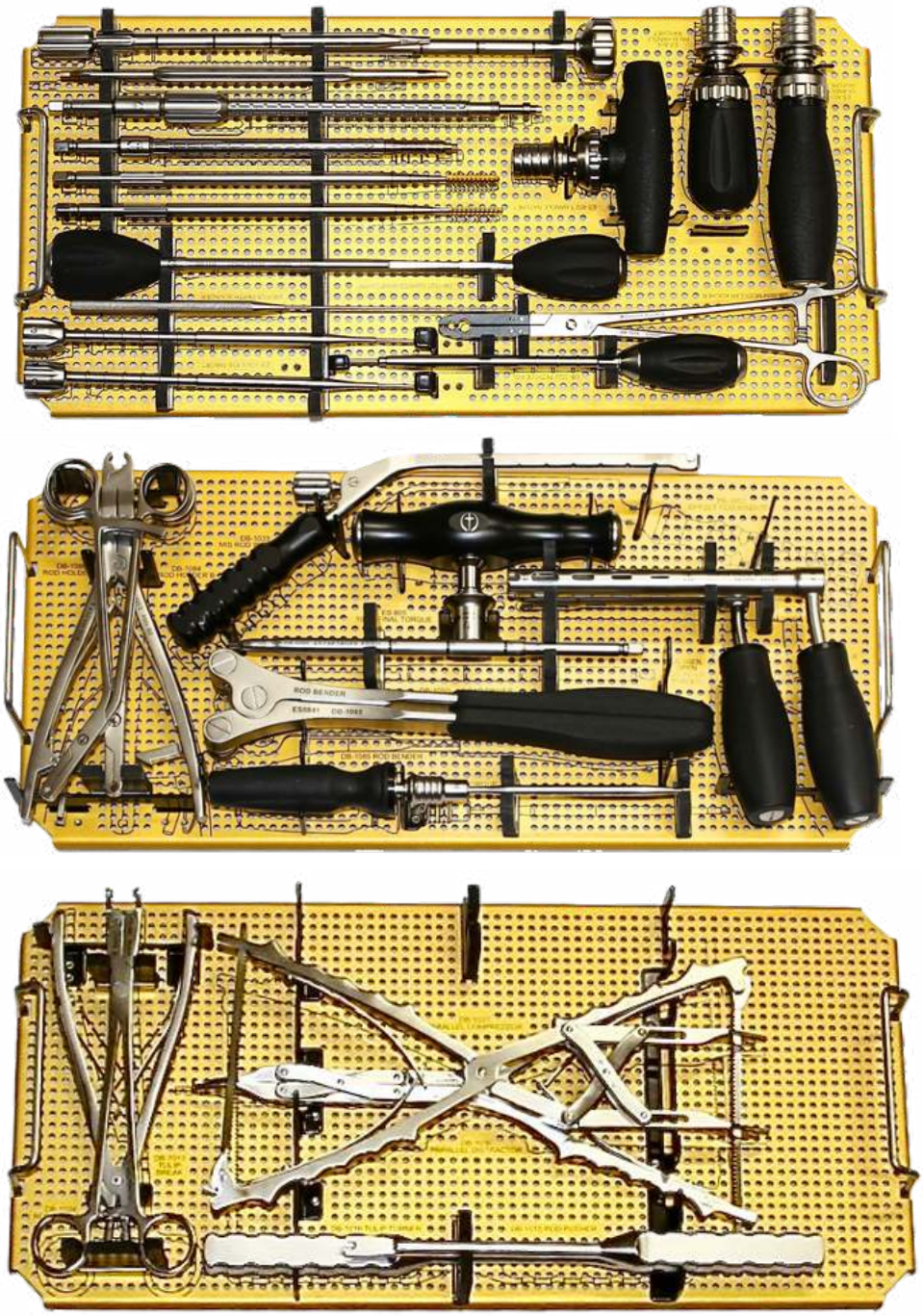
Step : Closure

Wound closure is then performed in the customary manner.

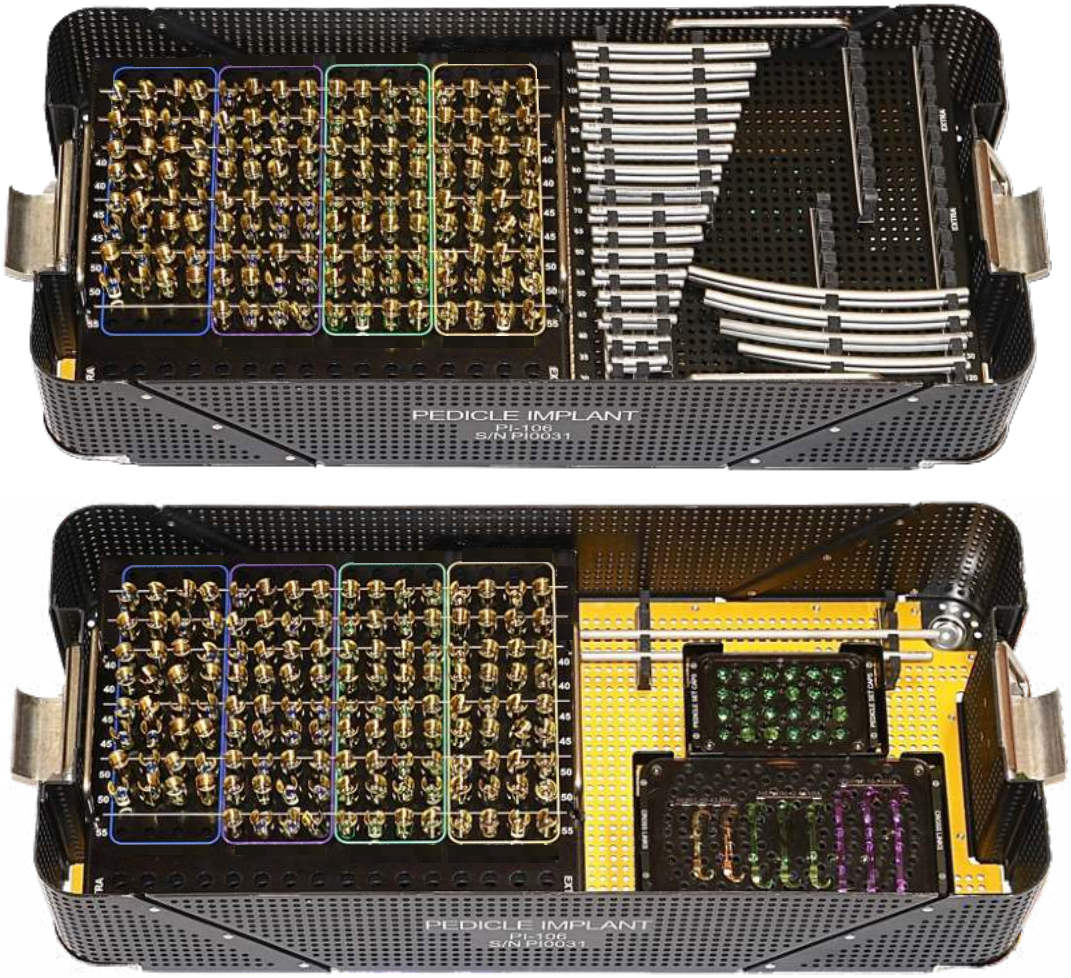
Step : Revision/Removal Procedure

Remove the set screw caps by turning the driver counter clockwise, then remove the rod connectors, rods and/or connectors. Insert the pedicle screw driver into the screw and turn the driver counter clockwise and remove the screw. If revision is required, a larger diameter screw may be needed.

Pedicle System Instrument Tray

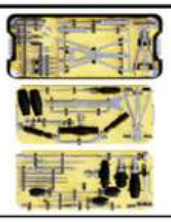
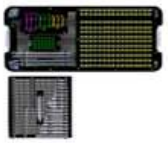


Pedicle System Screw Tray



Scoliosis Deformity Pedicle Screw System

Instrument Catalog

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		

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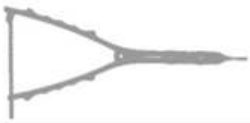
DB-1025	Wall Check, Depth Sounder	17-4 Stainless Steel per ASTM A564		
DB-1031	Counter Torque, MIS	17-4 Stainless Steel per ASTM A564		
DB-1031L	Counter Torque, MIS Long	17-4 Stainless Steel per ASTM A564		
DB-1033	Rod Inserter, MIS	17-4 Stainless Steel per ASTM A564		
DB-1034L	Pedicle Screw Driver, 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		

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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		