



**SURGICAL
TECHNIQUE**

PRECISION  SPINE

SURELOK™

PEDICLE SCREW SYSTEM



PRECISION  SPINE®

Discover the Difference



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SureLOK™ PEDICLE SCREW SYSTEM OVERVIEW

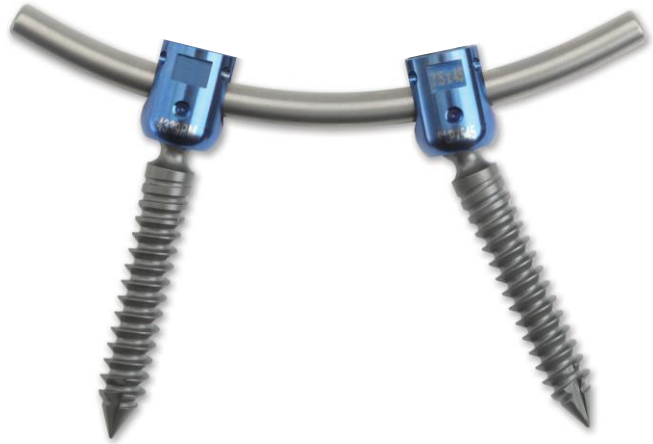
The SureLOK PSS System is a top-loading, low profile, posterior spinal fixation system which consists of pedicle screws, rods, cross-links and locking caps. All of the components are available in a variety of sizes to match more closely the patient's anatomy.

INDICATIONS:

The **SureLOK** Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

The **SureLOK** Pedicle Screw System is also intended for non-cervical pedicle screw fixation for the following indications: severe spondylolisthesis (grades 3 and 4 of the L5-S1 vertebra) in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion. It is also intended for the following indications: trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/or lordosis); spinal tumor; pseudoarthrosis; and failed previous fusion.

Please refer to package insert (LBL-IFU-004) for complete system description, indications and warnings.



IMPLANT FEATURES

- Low profile, small diameter head
- Unique polyaxial clamping interface provides a rigid locking mechanism
- Polyaxial design offers 30° of angulation about the axis of the screw allowing for ease of Rod insertion into the screw head and minimize rod contouring
- Square thread Locking Cap reduces potential for cross threading, reduces splay forces
- Self tapping, self drilling screw tip eases insertion
- Proximal tapered thread enhances pull out strength
- Cortical thread engages the pedicle, cancellous thread engages the vertebral body
- A wide range of screw diameters and lengths to accommodate patient anatomy



4.5mm Diameter (Magenta, not pictured)

Length 25-60mm in 5mm increments

5.5mm Diameter (Gold)

Length 25-60mm in 5mm increments

6.5mm Diameter (Green)

Length 25-60mm in 5mm increments

7.5mm Diameter (Dark Blue)

Length 25-60mm in 5mm increments

8.5mm Diameter (Bronze, not pictured)

Length 25-60mm in 5mm increments
70-100mm in 10mm increments

Reduction Screws Available

Polyaxial Screws - 3.5mm Hex

Cap Screws - 4.5mm Hex



IMPLANT FEATURES (continued)

STRAIGHT & CURVED TITANIUM RODS

- Reduce the need to contour
- Lengths laser etched on the Rod

Curved Rods

- Length 35-80mm in 5mm increments
- Length 90-150mm in 10mm increments
- Lengths 180mm and 200mm

Straight Rods

- Length 40-160mm in 20mm increments
- Lengths 180, 200, 250, 400 and 450mm



CROSS-LINKS

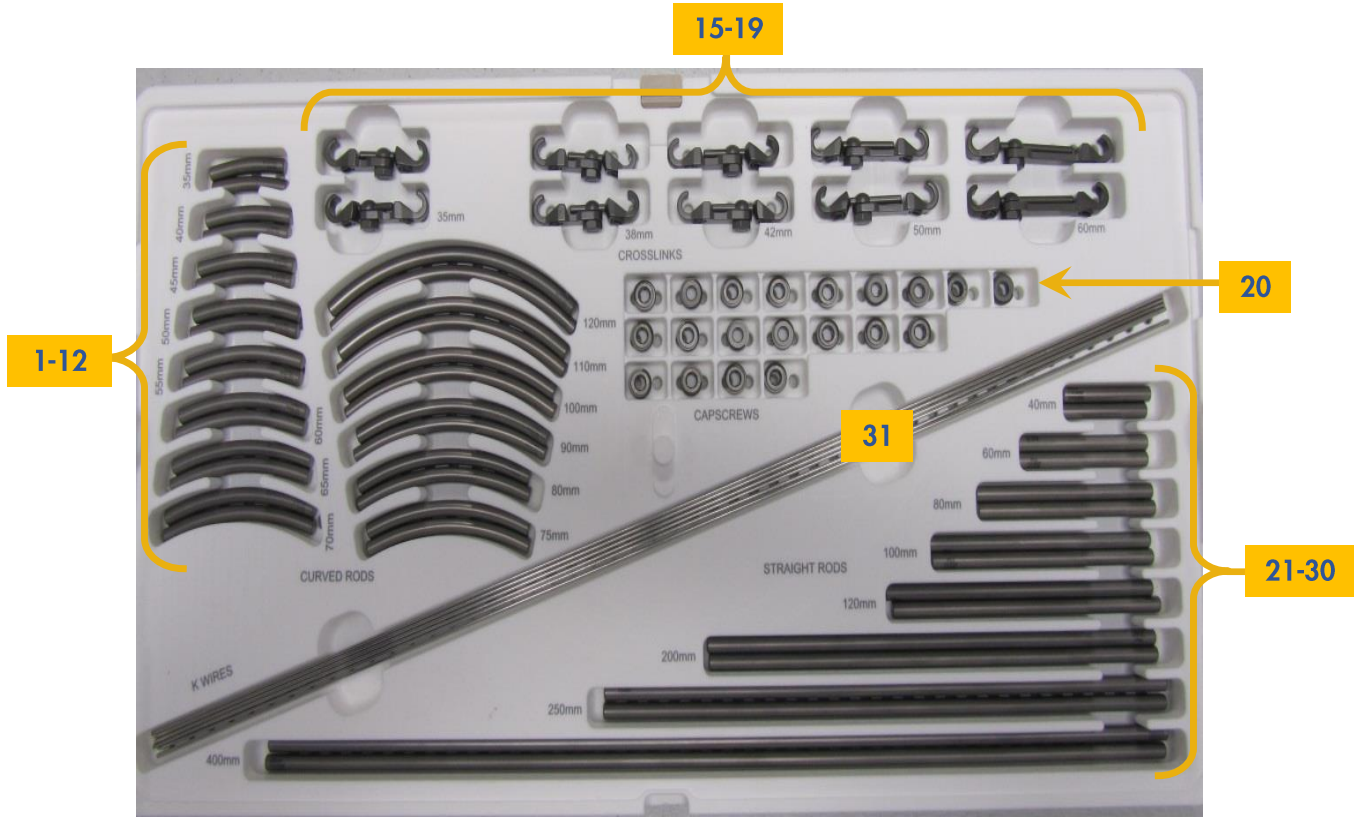
Available to provide increased rotational stability to a construct

- Crosslink Set Screw - 3.6mm Hex
- Crosslink Central Nut - 9mm Hex
- 35mm (35 – 37.5mm)
- 38mm (37.5 – 40mm)
- 42mm (40 – 45mm)
- 50mm (45 – 55mm)
- 60mm (55 – 75mm)



IMPLANTS – TOP TRAY

TRAY NUMBER 21-1011-CA

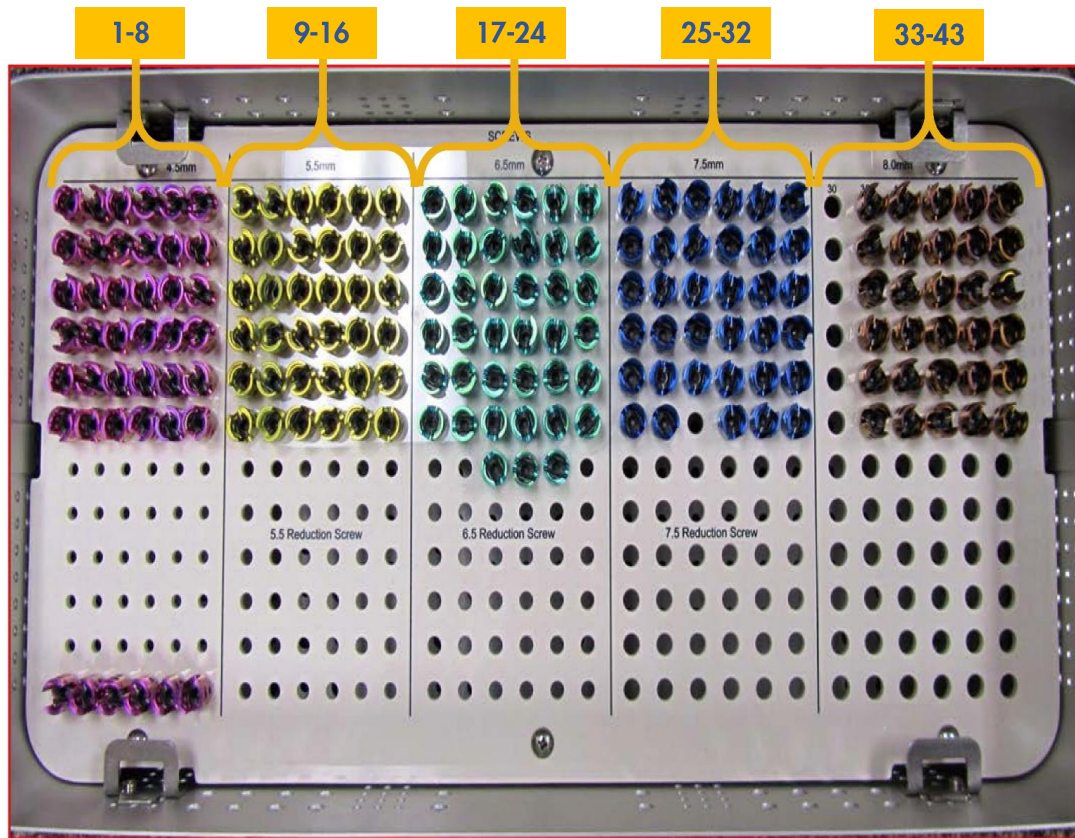


#	Part No.	Description	Qty	#	Part No.	Description	Qty
1.	100-5535	5.5mm x 35mm Rod Curved	2	15.	CL-035	Crosslink 35mm (Adjusts 35-37.5mm)	0*
2.	100-5540	5.5mm x 40mm Rod Curved	2	16.	CL-038	Crosslink 38mm (Adjusts 37.5-40mm)	2
3.	100-5545	5.5mm x 45mm Rod Curved	2	17.	CL-042	Crosslink 42mm (Adjusts 40-45mm)	2
4.	100-5550	5.5mm x 50mm Rod Curved	2	18.	CL-050	Crosslink 50mm (Adjusts 45-55mm)	2
5.	100-5555	5.5mm x 55mm Rod Curved	2	19.	CL-060	Crosslink 60mm (Adjusts 55-75mm)	0*
6.	100-5560	5.5mm x 60mm Rod Curved	2	20.	SL1000	Cap Screw, 4.5mm Hex	20
7.	100-5565	5.5mm x 65mm Rod Curved	2	21.	110-5540	5.5mm x 40mm Rod Straight	2
8.	100-5570	5.5mm x 70mm Rod Curved	2	22.	110-5560	5.5mm x 60mm Rod Straight	2
9.	100-5575	5.5mm x 75mm Rod Curved	2	23.	110-5580	5.5mm x 80mm Rod Straight	2
10.	100-5580	5.5mm x 80mm Rod Curved	2	24.	110-5100	5.5mm x 100mm Rod Straight	2
11.	100-5590	5.5mm x 90mm Rod Curved	2	25.	110-5120	5.5mm x 120mm Rod Straight	2
12.	100-5100	5.5mm x 100mm Rod Curved	2	26.	110-5140	5.5mm x 140mm Rod Straight	0*
13.	100-5110	5.5mm x 110mm Rod Curved	0*	27.	110-5160	5.5mm x 160mm Rod Straight	0*
14.	100-5120	5.5mm x 120mm Rod Curved	0*	28.	110-5200	5.5mm x 200mm Rod Straight	2
	100-5130	5.5mm x 130mm Rod Curved	0*	29.	110-5250	5.5mm x 250mm Rod Straight	0*
	100-5140	5.5mm x 140mm Rod Curved	0*	30.	110-5400	5.5mm x 400mm Rod Straight	2
	100-5150	5.5mm x 150mm Rod Curved	0*	31.	09-9001	K-wires, 1.6mm x 457mm	0*
	100-5180	5.5mm x 180mm Rod Curved	0*				
	100-5200	5.5mm x 200mm Rod Curved	0*				

* Special Order

IMPLANTS – BOTTOM TRAY

TRAY NUMBER 21-1011-CA

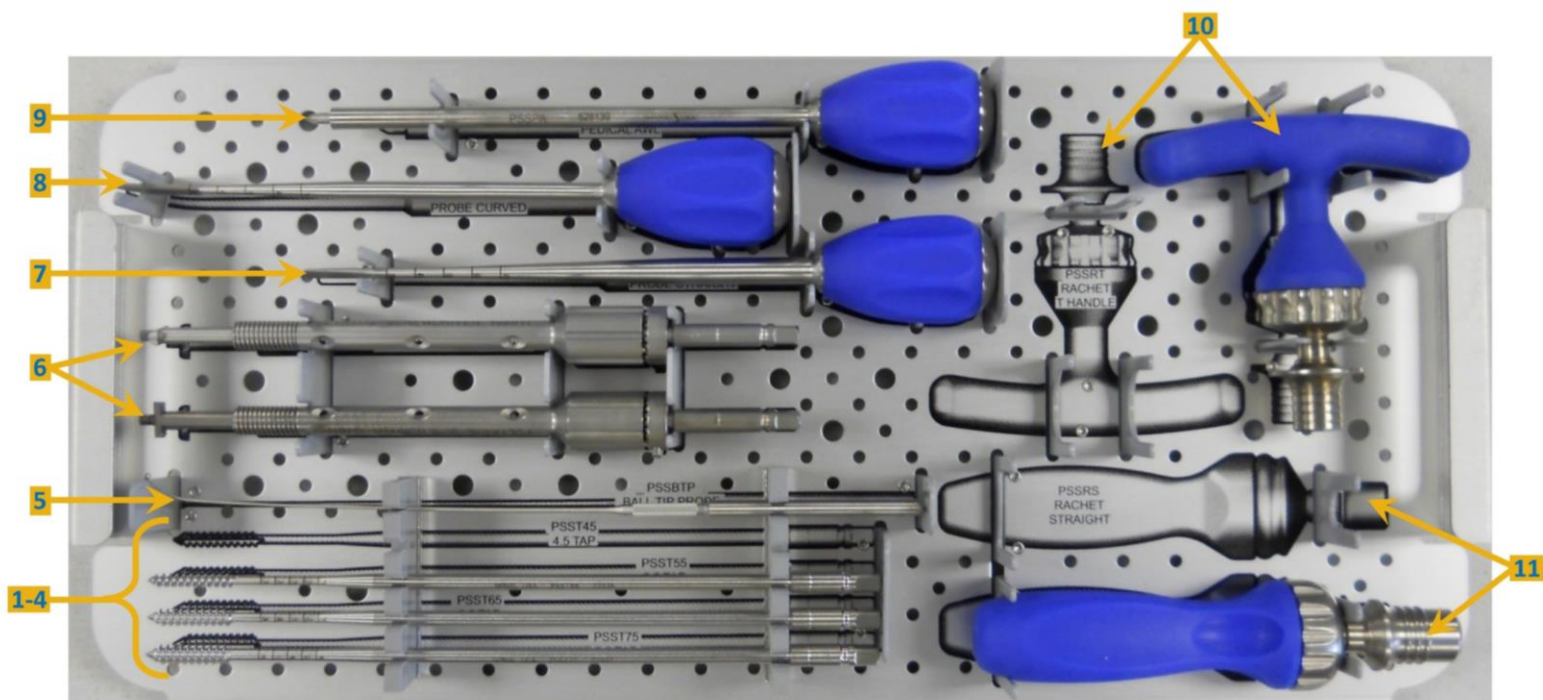


#	Part No.	Description	Qty	#	Part No.	Description	Qty
1.	SLP4525	4.5mm x 25mm SureLOK Polyaxial Screw	0*	25.	SLP7525	7.5mm x 25mm SureLOK Polyaxial Screw	0*
2.	SLP4530	4.5mm x 30mm SureLOK Polyaxial Screw	0*	26.	SLP7530	7.5mm x 30mm SureLOK Polyaxial Screw	6
3.	SLP4535	4.5mm x 35mm SureLOK Polyaxial Screw	0*	27.	SLP7535	7.5mm x 35mm SureLOK Polyaxial Screw	6
4.	SLP4540	4.5mm x 40mm SureLOK Polyaxial Screw	0*	28.	SLP7540	7.5mm x 40mm SureLOK Polyaxial Screw	6
5.	SLP4545	4.5mm x 45mm SureLOK Polyaxial Screw	0*	29.	SLP7545	7.5mm x 45mm SureLOK Polyaxial Screw	6
6.	SLP4550	4.5mm x 50mm SureLOK Polyaxial Screw	0*	30.	SLP7550	7.5mm x 50mm SureLOK Polyaxial Screw	6
7.	SLP4555	4.5mm x 55mm SureLOK Polyaxial Screw	0*	31.	SLP7555	7.5mm x 55mm SureLOK Polyaxial Screw	6
8.	SLP4560	4.5mm x 60mm SureLOK Polyaxial Screw	0*	32.	SLP7560	7.5mm x 60mm SureLOK Polyaxial Screw	0*
9.	SLP5560	5.5mm x 25mm SureLOK Polyaxial Screw	0*	33.	SLP8525	8.5mm x 25mm SureLOK Polyaxial Screw	0*
10.	SLP5530	5.5mm x 30mm SureLOK Polyaxial Screw	6	34.	SLP8535	8.5mm x 35mm SureLOK Polyaxial Screw	0*
11.	SLP5535	5.5mm x 35mm SureLOK Polyaxial Screw	6	35.	SLP8540	8.5mm x 40mm SureLOK Polyaxial Screw	0*
12.	SLP5540	5.5mm x 40mm SureLOK Polyaxial Screw	6	36.	SLP8545	8.5mm x 45mm SureLOK Polyaxial Screw	0*
13.	SLP5545	5.5mm x 45mm SureLOK Polyaxial Screw	6	37.	SLP8550	8.5mm x 50mm SureLOK Polyaxial Screw	0*
14.	SLP5550	5.5mm x 50mm SureLOK Polyaxial Screw	6	38.	SLP8555	8.5mm x 55mm SureLOK Polyaxial Screw	0*
15.	SLP5555	5.5mm x 55mm SureLOK Polyaxial Screw	6	39.	SLP8560	8.5mm x 60mm SureLOK Polyaxial Screw	0*
16.	SLP5560	5.5mm x 60mm SureLOK Polyaxial Screw	0*	40.	SLP8570	8.5mm x 70mm SureLOK Polyaxial Screw	0*
17.	SLP6525	6.5mm x 25mm SureLOK Polyaxial Screw	0*	41.	SLP8580	8.5mm x 80mm SureLOK Polyaxial Screw	0*
18.	SLP6530	6.5mm x 30mm SureLOK Polyaxial Screw	6	42.	SLP8590	8.5mm x 90mm SureLOK Polyaxial Screw	0*
19.	SLP6535	6.5mm x 35mm SureLOK Polyaxial Screw	6	43.	SLP8100	8.5mm x 100mm SureLOK Polyaxial Screw	0*
20.	SLP6540	6.5mm x 40mm SureLOK Polyaxial Screw	8				
21.	SLP6545	6.5mm x 45mm SureLOK Polyaxial Screw	8				
22.	SLP6550	6.5mm x 50mm SureLOK Polyaxial Screw	6				
23.	SLP6555	6.5mm x 55mm SureLOK Polyaxial Screw	6				
24.	SLP6560	6.5mm x 60mm SureLOK Polyaxial Screw	0*				

* Special Order

INSTRUMENTS – TOP TRAY

TRAY NUMBER 21-1010-CA

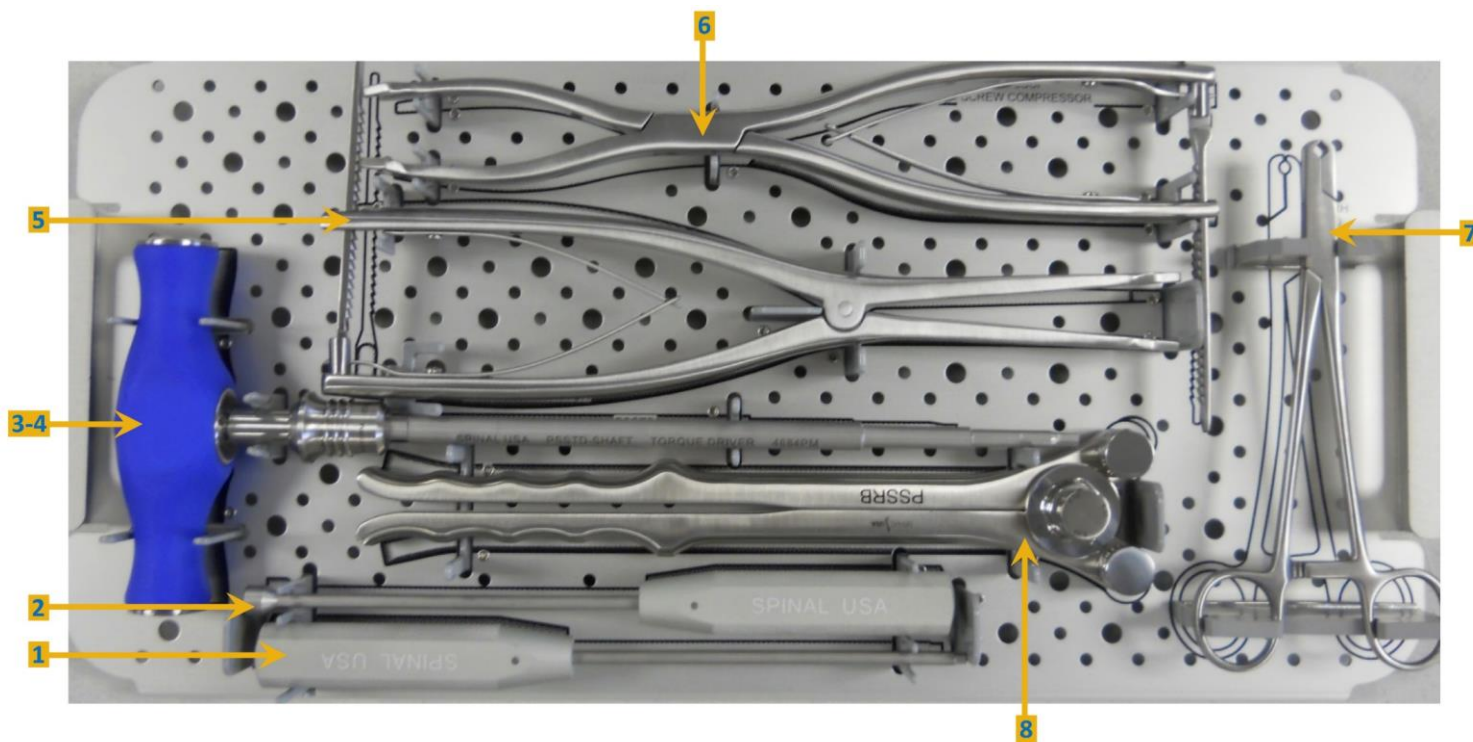


#	Part No.	Description	Qty
1.	PSST45	4.5mm Tap (0.5mm undersized)	0*
2.	PSST55	5.5mm Tap (0.5mm undersized)	1
3.	PSST65	6.5mm Tap (0.5mm undersized)	1
4.	PSST75	7.5mm Tap (0.5mm undersized)	1
5.	PSSBTP	Ball Tip Probe, Curved	1
6.	00-9002	Locking Polyaxial Screwdriver, 3.5mm Hex	2
7.	PSSPPS	Pedicle Probe, Straight	1
8.	PSSPCL	Pedicle Probe, Curved	1
9.	PSSPA	Pedicle Awl (4mm x 10mm)	1
10.	PSSRT	Ratchet, T-Handle	2
11.	PSSRS	Ratchet, Straight Handle	2

* Special Order

INSTRUMENTS – MIDDLE TRAY

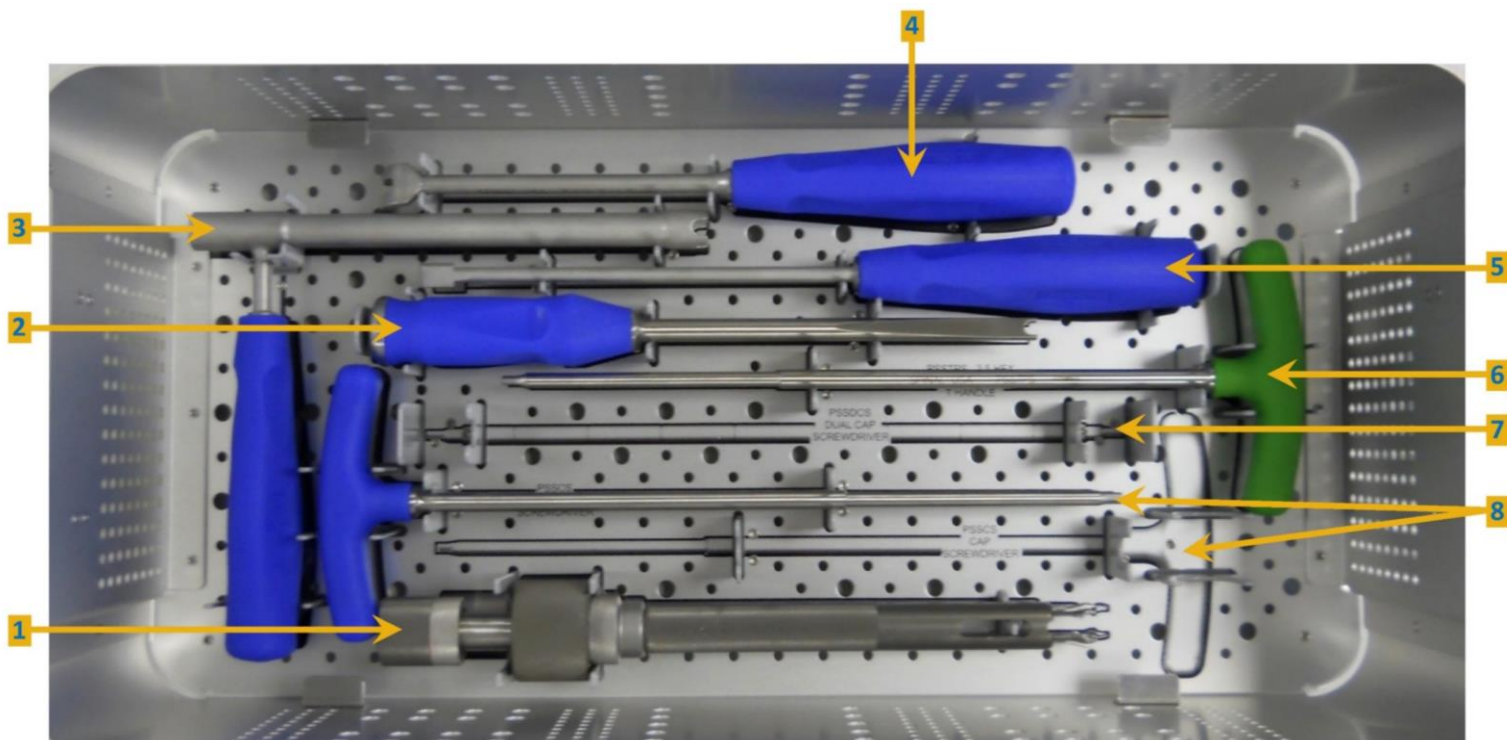
TRAY NUMBER 21-1010-CA



#	Part No.	Description	Qty
1.	PSSCLS	Crosslink Set Screw Screwdriver, 3.6mm Hex	1
2.	PSSCLR	Crosslink Hex Nut Screwdriver , 9mm Hex	1
3.	PSSTD - Handle	Torque Drive Handle – 106 in-lbs	1
4.	PSSTD - Shaft	Torque Drive Shaft, 4.5mm Hex	1
5.	PSSDT	Distractor	1
6.	PSSCP	Compressor	1
7.	PSSRH	Rod Holder	1
8.	PSSRB	Rod Bender	1

INSTRUMENTS – BOTTOM TRAY

TRAY NUMBER 21-1010-CA



#	Part No.	Description	Qty
1.	09-9009	Rod Persuader (Large)	1
2.	PSSRP	Rod Pusher	1
3.	00-9020	Anti-Torque Wrench	1
4.	SL-9002	Rod Fork	1
5.	SL-9001	Screw-Head Positioner	1
6.	PSSTPS	Screw Height Adjuster, 3.5mm Hex (GREEN Handle)	1
7.	PSSDCS	Dual Cap Screwdriver, 4.5mm Hex (not shown in image above)	1
8.	PSSCS	Cap Screwdriver, 4.5mm Hex	2

* Special Order

SURGICAL TECHNIQUE

1

PREOPERATIVE PLANNING

The Surgeon should consider for surgery only those patients indicated for the use of the SureLOK™ Pedicle Screw System. The Surgeon should have a complete understanding of the surgical technique and of the system's design rationale, indications, contraindications and applications. The Surgeon should have a complete understanding of the function and limitations of each implant and instrument in the system.

2

PEDICLE PREPARATION

- a. Locate the desired entry point in the pedicle and perforate the cortex with the Awl (PSSPA). (Figure 1)
- b. Use a Pedicle Probe (PSSPPS or PSSPCL) to open the pedicle canal. (Figure 2) A pathway and trajectory through the pedicle can be established with a Probe allowing the instrument to follow the path of least resistance. The probe should contact bone at all times. If resistance is felt while creating a pathway through the pedicle the entry point and trajectory should be re-evaluated. Laser etching on the Probe will indicate the depth of the Probe within the canal (30mm, 40mm, 50mm, 60mm, and 70mm).
- c. The prepared pathway can be explored with the Ball Tip Probe (PSSBTP) to confirm the integrity of the pedicle wall has not been violated. (Figure 3)
- d. If tapping is preferred, the appropriate Tap (PSST45, PSST55, PSST65, PSST75) may be used to prepare the pedicle for Screw insertion. (Figure 4) The Tap sizes correspond to the diameter of the Screw and are laser etched (40mm, 45mm, 50mm, 55mm, and 60mm). Taps can be utilized with the Ratchet Straight Handle (PSSRS) or the Ratchet T-Handle (PSSRT).

The Taps are .5mm undersized. It is not recommended to under tap.

- e) Repeat the preparation procedure for each pedicle that has been identified for instrumentation.



Figure 1

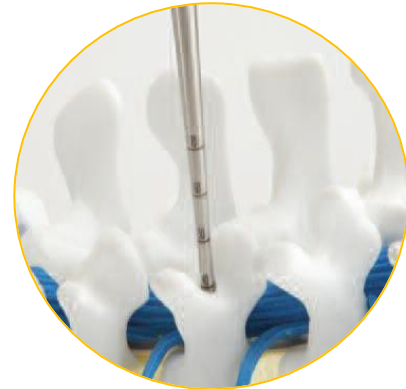


Figure 2



Figure 3



Figure 4

SURGICAL TECHNIQUE

3

POLYAXIAL SCREW INSERTION

- a. With the pedicle pathway prepared and appropriate Screw length and diameter determined, the Polyaxial Screw is loaded for insertion on the preferred Screw Driver Assembly (00-9002).
- b. The Polyaxial Screw Driver (00-9002) is attached to either the Ratchet Straight Handle (PSSRS) or Ratchet T-Handle (PSSRT). (Figure 5)
 - i. The Blue Ratchet Handle (PSSRS or PSSRT) should be towards the floor and the plunger should be facing the ceiling.
 - ii. Depress the plunger towards the Blue Handle (PSSRS or PSSRT) and insert the Polyaxial Screw Driver (00-9002). Confirm that the Driver is fully seated in the appropriate handle and will not disengage without depressing the plunger.
- c. The Polyaxial Screw is now attached to the preferred Screw Driver Assembly.
 - i. The Blue Ratchet Handle (PSSRS or PSSRT) should be towards the floor and the hex tip of the Polyaxial Screw Driver (00-9002) should be facing the ceiling with the serrated locking coupler disengaged.
 - ii. Load the appropriate Screw chosen for length and diameter onto the hex tip portion of the Polyaxial Screw Driver (00-9002). The Polyaxial Screw should be fully seated on the Driver assembly before the Screw Head Locking Sleeve of the Driver (00-9002) is engaged (Figure 6, 6a)
 - iii. With the Driver assembly in the same orientation and the Screw held firmly seated on the Driver, thread the Screw Head Locking Sleeve until fully engaged and the rod slot is flush with the convex portion of the Driver tip (00-9002). (Figure 7, 7a)
 - iv. Advance the Locking Coupler until it is flush with the base of the Screw Head Locking Sleeve and clicks when engaged. (Figure 8, 8a) The Screw Head Locking Sleeve will not disengage from the screw while the Locking Coupler is in this position.



Figure 5



Figure 6



Figure 6a - Fully seated position



Figure 7



Figure 7a - Fully seated position



Figure 8



Figure 8a - Locked position

SURGICAL TECHNIQUE

3

POLYAXIAL SCREW INSERTION (cont.)

- c. The Polyaxial Screw is now inserted into the appropriate pedicle identified for instrumentation with this screw diameter and length. (Figure 9)
- d. Repeat the procedure for Polyaxial Screw insertion in each pedicle identified for instrumentation.

Note: Do not depress the plunger on the Driver Assembly (00-9002 + PSSRS/PSSRT) during Screw insertion. (Figure 9)

Note: Do not release the Locking Coupler while inserting the Screw.



Figure 9

4

TITANIUM ROD INSERTION

- a. Once all Screws have been inserted, the appropriate length Straight Rod or Curved Rod is identified according to the required construct.
- b. Use the appropriate pre-cut Rod or cut a longer Rod using a rod cutter (rod cutter not provided).
- c. The Polyaxial Screw design will allow for some lateral Screw offset.
- d. The Rod can be contoured if desired utilizing the Rod Bender (PSSRB).

Note: Repeated bending can weaken the Rod.

- e. Once the appropriate Rod has been selected, use the Rod Holding Forceps (PSSRH) to facilitate insertion into the Screw head tulip. (Figure 10) This can be done in any sequence at the discretion of the surgeon.



Figure 10

SURGICAL TECHNIQUE

5

TITANIUM ROD REDUCTION

The Rod must be seated in the SureLOK™ Screw head in order to engage the Locking Cap (SL1000) for tightening. There are three alternative instruments used for this process.

OPTION 1

The Anti-torque Wrench (00-9020) or the Rod Pusher (PSSRP) can be used to seat the Rod. (Figures 11 and 12) For constructs with two or more levels, begin with the central Screw. Once the Rod is fully seated, the Square Thread Locking Cap (SL1000) can be secured to the implant with the T-Handle Cap Screwdriver (PSSCS). (Figure 13)

OPTION 2

The Rod Fork (SL-9002) can be utilized to seat the Rod within the Screw head. (Figure 14) The Rod Fork easily slides into the lateral slots on side of the Screw head and is rotated backwards. This levers the Rod into the head of the implant. **Note: placing the Rod Fork on the side where the Rod is higher is more effective at getting the Rod seated evenly in the implant.** Once the Rod is fully seated, the Square Thread Locking Cap (SL1000) can be secured to the implant with the T-Handle Cap Screwdriver (PSSCS). (Figure 13)

OPTION 3

The Rod Persuader (09-9009) is used when additional force is needed to seat the Rod into the Screw head. (Figure 15) The Inner Screw Head Capture Sleeve (small screw drive) and Outer Rod Reduction Sleeve (large screw drive) should be turned counter clockwise until fully opened. Engage the Rod Persuader on the Screw head with the slots on the Rod Persuader aligned with the Rod slot on the screw head. Turn the Inner Screw Head Capture Sleeve (small screw drive) clockwise until firmly compressed on the screw head. The Outer Rod Reduction Sleeve (large screw drive) is now turned clockwise to reduce the Rod into the implant. Once the Rod is fully seated the Square Thread Locking Cap (SL1000) can be secured to the implant with the T-Handle Cap Inserter (PSSCS). (Figure 13)

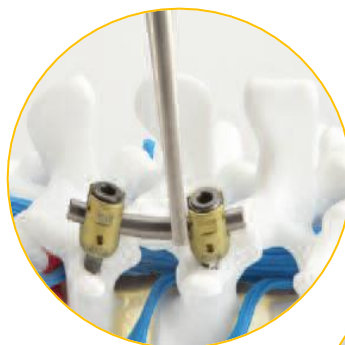


Figure 11

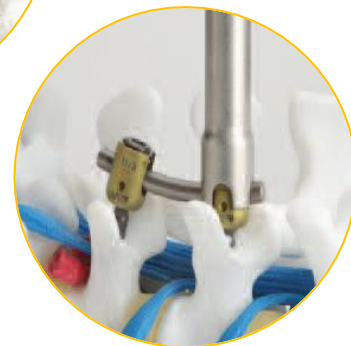


Figure 12



Figure 13



Figure 14



Figure 15

SURGICAL TECHNIQUE

6

DEFINITIVE TIGHTENING OF LOCKING CAP

Once the correction procedures have been carried out and the spine is fixed in a satisfactory position, the definitive tightening of the Locking Cap is done with the Anti-torque Wrench (00-9020) and the Torque Driver (PSSTD - Shaft/Handle). (Figure 16)

Place the Anti-torque Wrench (00-9020) over screw head until it is fully seated over the rod. Insert the Torque Driver (PSSTD - Shaft/Handle) through the Anti-torque Wrench and securely seat the distal end into the Cap Screw. Turn the Offset Torque Handle clockwise until an audible click is heard, verifying the final torque of 106 in-lbs. Repeat for the remaining screws.



Figure 16

OPTIONAL SURGICAL PROCEDURES

1. **Titanium Cross-Links may be added to the construct if desired.**
 - a. Choose the Cross-Link of appropriate length and assure the Cross-Link Set Screws are not advanced. (Figure 17)
 - b. Apply the Cross-Link to the Rods. Use the Cross-Link Screwdriver (PSSCLS) to secure the Cross-Link to the Rods by tightening the Set Screws turning clockwise. (Figure 18)
 - c. Lock the Central Hex Nut with the Round Hex Screwdriver (PSSCLR) turning clockwise. (Figure 19)
2. **System Removal**
 - a. In order to remove the implants, attach the Torque Driver (PSSTD-Shaft) to the Ratchet T-Handle (PSSRT). Stabilize the construct with the Anti-Torque Wrench (00-9020), insert the Torque Driver through the sleeve, securely into the cap screw, and then turn counterclockwise to loosen and remove the Cap Screws. Remove Rods. Use the 3.5mm Tapered Hex Male Fixed T-Handle (PSSTPS) to back out the screws from the pedicles.



Figure 17



Figure 18



Figure 19

ORDERING INFORMATION / IMPLANTS

Rods

Part No.	Description
09-9001	K-Wires*, 1.6mm x 457mm
100-5535	5.5mm x 35mm Rod Curved
100-5540	5.5mm x 40mm Rod Curved
100-5545	5.5mm x 45mm Rod Curved
100-5550	5.5mm x 50mm Rod Curved
100-5555	5.5mm x 55mm Rod Curved
100-5560	5.5mm x 60mm Rod Curved
100-5565	5.5mm x 65mm Rod Curved
100-5570	5.5mm x 70mm Rod Curved
100-5575	5.5mm x 75mm Rod Curved
100-5580	5.5mm x 80mm Rod Curved
100-5590	5.5mm x 90mm Rod Curved
100-5100	5.5mm x 100mm Rod Curved
100-5110	5.5mm x 110mm Rod Curved*
100-5120	5.5mm x 120mm Rod Curved*
100-5130	5.5mm x 130mm Rod Curved*
100-5140	5.5mm x 140mm Rod Curved*
100-5150	5.5mm x 150mm Rod Curved*
100-5180	5.5mm x 180mm Rod Curved*
100-5200	5.5mm x 200mm Rod Curved*
CL-035	Crosslink 35mm (Adjusts 35-37.5mm)*
CL-038	Crosslink 38mm (Adjusts 37.5-40mm)
CL-042	Crosslink 42mm (Adjusts 40-45mm)
CL-050	Crosslink 50mm (Adjusts 45-55mm)
CL-060	Crosslink 60mm (Adjusts 55-75mm)*
SL1000	Cap Screw, 4.5mm
110-5540	5.5mm x 40mm Rod Straight
110-5560	5.5mm x 60mm Rod Straight
110-5580	5.5mm x 80mm Rod Straight
110-5100	5.5mm x 100mm Rod Straight
110-5120	5.5mm x 120mm Rod Straight
110-5140	5.5mm x 140mm Rod Straight*
110-5160	5.5mm x 160mm Rod Straight*
110-5200	5.5mm x 200mm Rod Straight
110-5250	5.5mm x 250mm Rod Straight*
110-5400	5.5mm x 400mm Rod Straight

SureLOK™ SLP (Standard Polyaxial Screws)

Part No.	Description
SLP4525	4.5mm x 25mm SureLOK Polyaxial Screw*
SLP4530	4.5mm x 30mm SureLOK Polyaxial Screw*
SLP4535	4.5mm x 35mm SureLOK Polyaxial Screw*
SLP4540	4.5mm x 40mm SureLOK Polyaxial Screw*
SLP4545	4.5mm x 45mm SureLOK Polyaxial Screw*
SLP4550	4.5mm x 50mm SureLOK Polyaxial Screw*
SLP4555	4.5mm x 55mm SureLOK Polyaxial Screw*
SLP4560	4.5mm x 60mm SureLOK Polyaxial Screw*
SLP5525	5.5mm x 25mm SureLOK Polyaxial Screw*
SLP5530	5.5mm x 30mm SureLOK Polyaxial Screw
SLP5535	5.5mm x 35mm SureLOK Polyaxial Screw
SLP5540	5.5mm x 40mm SureLOK Polyaxial Screw
SLP5545	5.5mm x 45mm SureLOK Polyaxial Screw
SLP5550	5.5mm x 50mm SureLOK Polyaxial Screw
SLP5555	5.5mm x 55mm SureLOK Polyaxial Screw
SLP5560	5.5mm x 60mm SureLOK Polyaxial Screw*
SLP6525	6.5mm x 25mm SureLOK Polyaxial Screw*
SLP6530	6.5mm x 30mm SureLOK Polyaxial Screw
SLP6535	6.5mm x 35mm SureLOK Polyaxial Screw
SLP6540	6.5mm x 40mm SureLOK Polyaxial Screw
SLP6545	6.5mm x 45mm SureLOK Polyaxial Screw
SLP6550	6.5mm x 50mm SureLOK Polyaxial Screw
SLP6555	6.5mm x 55mm SureLOK Polyaxial Screw
SLP6560	6.5mm x 60mm SureLOK Polyaxial Screw*
SLP7525	7.5mm x 25mm SureLOK Polyaxial Screw*
SLP7530	7.5mm x 30mm SureLOK Polyaxial Screw
SLP7535	7.5mm x 35mm SureLOK Polyaxial Screw
SLP7540	7.5mm x 40mm SureLOK Polyaxial Screw
SLP7545	7.5mm x 45mm SureLOK Polyaxial Screw
SLP7550	7.5mm x 50mm SureLOK Polyaxial Screw
SLP7555	7.5mm x 55mm SureLOK Polyaxial Screw
SLP7560	7.5mm x 60mm SureLOK Polyaxial Screw*
SLP8525	8.5mm x 25mm SureLOK Polyaxial Screw*
SLP8530	8.5mm x 30mm SureLOK Polyaxial Screw*
SLP8535	8.5mm x 35mm SureLOK Polyaxial Screw*
SLP8540	8.5mm x 40mm SureLOK Polyaxial Screw*
SLP8545	8.5mm x 45mm SureLOK Polyaxial Screw*
SLP8550	8.5mm x 50mm SureLOK Polyaxial Screw*
SLP8555	8.5mm x 55mm SureLOK Polyaxial Screw*
SLP8560	8.5mm x 60mm SureLOK Polyaxial Screw*
SLP8570	8.5mm x 70mm SureLOK Polyaxial Screw*
SLP8580	8.5mm x 80mm SureLOK Polyaxial Screw*
SLP8590	8.5mm x 90mm SureLOK Polyaxial Screw*
SLP8100	8.5mm x 100mm SureLOK Polyaxial Screw*

* Special Order

ORDERING INFORMATION/INSTRUMENTS

Part No.	Description
PSST45	4.5mm Tap* (0.5mm undersized)
PSST55	5.5mm Tap (0.5mm undersized)
PSST65	6.5mm Tap (0.5mm undersized)
PSST75	7.5mm Tap (0.5mm undersized)
PSSBTP	Ball Tip Probe, Curved
00-9002	Locking Polyaxial Screwdriver, 3.5mm Hex
PSSPPS	Pedicle Probe, Straight
PSSPCL	Pedicle Probe, Curved (Replaces PSSPPC)
PSSPA	Pedicle Awl (4mm x 10mm)
PSSRT	Ratchet, T-Handle
PSSRS	Ratchet, Straight Handle
PSSCLS	Crosslink Set Screw Screwdriver, 3.6mm Hex
PSSCLR	Crosslink Hex Nut Screwdriver, 9mm Hex
PSSTD - Handle	Torque Drive Handle - 106 in-lbs
PSSTD - Shaft	Torque Drive Shaft, 4.5mm Hex
PSSDT	Distractor
PSSCP	Compressor
PSSRH	Rod Holder
PSSRB	Rod Bender
09-9009	Rod Persuader (Large)
PSSRP	Rod Pusher
00-9020	Anti-Torque Wrench
SL-9002	Rod Fork
SL-9001	Screw-Head Positioner
PSSTPS	Screw Height Adjuster, 3.5mm Hex (GREEN Handle)
PSSDCS	Dual Cap Screwdriver, 4.5mm Hex
PSSCS	Cap Screwdriver, 4.5mm Hex

* Special Order

Indications, Contraindications, Warnings, and Precautions

INDICATIONS:

The SureLOK Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

The SureLOK Pedicle Screw System is also intended for non-cervical pedicle screw fixation for the following indications: severe spondylolisthesis (grades 3 and 4 of the L5-S1 vertebra) in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion. It is also intended for the following indications: trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/or lordosis); spinal tumor; pseudoarthrosis; and failed previous fusion.

PRECAUTIONS:

The SureLOK Pedicle Screw System should be implanted only by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. All system implants are single-use only. Reuse of the device may result in the following:

1. Infection
2. Loosening
3. Fracture / mechanical failure of the device
4. Inability to properly engage surgical instrumentation
5. Pyrogenic reaction

CONTRAINDICATIONS:

The SureLOK Pedicle Screw System contraindications include, but are not limited to:

1. Morbid obesity
2. Mental illness
3. Alcoholism or drug abuse
4. Fever or leukocytes
5. Pregnancy
6. Severe osteopenia
7. Metal sensitivity/allergies
8. Patients unwilling or unable to follow post-operative care instructions
9. Active infectious process or significant risk of infection
10. Any circumstances not listed in the indication of the device

POTENTIAL ADVERSE EFFECTS:

All of the possible adverse effects associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of potential adverse events includes, but is not limited to:

1. Non-Union
2. Fracture of the vertebra
3. Neurological injury
4. Vascular or visceral injury
5. Early or late loosening of any or all of the components
6. Loss of fixation
7. Device component fracture
8. Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, straining, tumor formation, and/or autoimmune disease
9. Disassembly and/or bending of any or all of the components
10. Infection
11. Hemorrhage
12. Change in mental status
13. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain
14. Pain, discomfort, or abnormal sensations due to the presence of the device
15. Post-operative change in spinal curvature, loss of correction, height, and/or reduction
16. Cessation of any potential growth of the operated portion of the spine
17. Loss of or increase spinal mobility or function
18. Death

Note: Additional surgery may be required to correct some of these potential adverse events.

WARNINGS:

The following are warnings for this device.

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 degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, hypnosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other condition is unknown.
2. When used as a pedicle screw system, this system is intended for Grade 3 or 4 spondylolisthesis at the fifth lumbar/first sacral (L5-S1) vertebral joint.
3. Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, fracture of the vertebrae, neurological injury, and vascular or visceral injury.
4. Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
5. Single use only.
6. Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct.
7. To facilitate fusion, a sufficient quantity of autograft bone should be used.
8. Do not reuse implants. Discard used, damaged, or otherwise suspect implants.
9. The implantation of the pedicle screw system should be performed only by experienced spinal surgeons with specific training in the use of pedicle screw spinal systems because this is a technically demanding procedure presenting a risk of serious injury to the patient.
10. 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.
11. Non-sterile; the screws, rods, locking cap screws, cross-links, connectors, hooks, and instruments are sold non-sterile, and therefore must be sterilized before use.
12. The components of this system should not be used with components of any other system or manufacturer.
13. Titanium components should not be used with stainless steel components within the same system.
14. Do not reuse implants. Discard used, damaged, or otherwise suspect implants. **AN IMPLANT SHOULD NEVER BE RE-USED.** Any implant, once used, should be discarded. Even though it appears undamaged, it may have small defects and internal stress patterns that may lead to failure. Reuse can potentially compromise device performance and patient safety.



Precision Spine, Inc.

2050 Executive Drive, Pearl, MS 39208

Customer Service: 1.888.241.4773

Phone: 601.420.4244

Toll Free: 877.780.4370

Fax: 601.420.5501

www.precisionspineinc.com

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