Surgical Technique
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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 PSS 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, or failed previous fusion (pseudoarthrosis).

The SureLOK PSS 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**
- Length 25-55mm in 5mm increments

**5.5mm Diameter**
- Length 30-55mm in 5mm increments

**6.5mm Diameter**
- Length 30-55mm in 5mm increments

**7.5mm Diameter**
- Length 30-55mm in 5mm increments

**8.5mm Diameter**
- Length 30-55mm in 5mm increments
  - 70-100mm in 10mm increments

Reduction Screws Available
Straight & Curved Titanium Rod offerings reduce the need to contour

- Lengths laser etched on the Rod

**Curved Rods**

- Length 35-80mm in 5mm increments
- 90, 100, 110 and 120mm lengths

**Straight Rods**

- Length 40-120mm in 20mm increments
- 200, 250 and 400mm lengths

**Cross-Links**

Cross-Links are available to provide increased rotational stability to a construct

- 35mm (35 - 37.5mm)
- 38mm (37.5 - 40mm)
- 42mm (40 - 45mm)
- 50mm (45 - 55mm)
- 60mm (55 - 75mm)
**Pedicle Awl**
- Marks the entry point of the Screw within the pedicle
- Part Number - PSSPA

**Pedicle Probes**
- Create a pathway into the pedicle
- Straight - Part Number - PSSPPS
- Curved - Part Number - PSSPCL

**Ball Tip Probe**
- Checks the integrity of the pedicle wall
- Part Number - PSSBTP

**Pedicle Taps**
- Prepare the pedicle for Polyaxial Screw placement
- 4.5mm - Part Number - PSST45
- 5.5mm - Part Number - PSST55
- 6.5mm - Part Number - PSST65
- 7.5mm - Part Number - PSST75
INSTRUMENTS

Straight Handle Ratchet
- Utilized with Pedicle Taps & Screw Driver
- Part Number - PSSRS

T-Handle Ratchet
- Utilized with Pedicle Taps & Screw Driver
- Part Number - PSSRT

Polyaxial Screw Driver
- Drives Polyaxial Screw into the pedicle
- Part Number - 00-9002

Polyaxial Screw Driver Cannulated
- Cannulated to accept a K-wire
- Part Number - 09-9036

Screw Head Positioner
- Adjusts orientation of the Screw head tulip to allow for Rod alignment
- Part Number - SL-9001
**Rod Holder Forceps**
- Holds Rod securely during insertion and positioning
- Part Number - PSSRH

**3.5mm Hex Polyaxial Screw Driver**
- Backs out an implanted Screw to adjust the height of the Screw head tulip to allow for Rod placement
- Part Number - PSSTPS

**Rod Bender**
- Contours Rod to meet the required needs of the construct
- Part Number - PSSRB

**Rod Pusher**
- Assists in manipulation and seating of the Rod within the Screw head tulip
- Part Number - PSSRP
**Rod Fork**
- Assists in manipulation and seating of the Rod within the Screw head tulip
- Part Number - SL-9002

**Rod Persuader**
- Assists in manipulation and seating of the Rod within the Screw head tulip
- Part Number - 09-9009

**Dual Locking Cap Screw Inserter**
- Places Locking Cap over Rod in the Screw head tulip (Not used for definitive tightening)
- Part Number - PSSDCS

**T-Handle Locking Cap Screw Inserter**
- Places Locking Cap over Rod in the Screw head tulip (Not used for definitive tightening)
- Part Number - PSSCS
Compressor
- Utilized to compress implants axially along the Rod
- Part Number - PSSCP

Distractor
- Utilized to distract implants axially along the Rod
- Part Number - PSSDT

Torque Driver
- Used for definitive tightening of the Locking Cap to the construct
- Part Number - PSSTD

Anti-Torque Wrench
- Provides counter-torque leverage while torquing the Locking Cap
- Part Number - 00-9020

Cross-Link Screwdriver
- Tightens the Cross-Link to the Rod
- Part Number - PSSCLS

Cross-Link Round Hex Screwdriver
- Locks the center hex on the Cross-Link
- Part Number - PSSCLR
1. Preoperative Planning:
   a. 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. (Figure 1)
   b. Use a Blunt Tipped Probe 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 to confirm the integrity of the pedicle wall has not been violated. (Figure 3)
   d. If tapping is preferred, the appropriate tap 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 Straight Handle Ratchet Wrench or the T-Handle Ratchet Wrench.
   e. Repeat the preparation procedure for each pedicle that has been identified for instrumentation.
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.

b. The Polyaxial Screw Driver is attached to either the Straight Handle Ratchet or T-Handle Ratchet (Figure 5).
   i. The Blue Ratchet Handle should be towards the floor and the plunger should be facing the ceiling.
   ii. Depress the plunger towards the Blue Handle and insert the Polyaxial Screw Driver. 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 should be towards the floor and the hex tip of the Polyaxial Screw Driver 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. The Polyaxial Screw should be fully seated on the Driver assembly before the Screw Head Locking Sleeve of the Driver 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 flush with the convex portion of the Driver. (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.
d. The Polyaxial Screw is now inserted into the appropriate pedicle identified for instrumentation with this screw diameter and length. (Figure 9)

e. Repeat the procedure for Polyaxial Screw insertion in each pedicle identified for instrumentation

   Note: Do not depress the plunger on the Driver Assembly during Screw insertion (Figure 9).
   Note: Do not release the Locking Coupler while inserting the Screw.

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

      Note: Repeated bending can weaken the Rod.

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

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

Option 1
The Anti-torque Wrench or the Rod Pusher 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 can be secured to the implant with the T-Handle Cap Screwdriver. (Figure 13)

Option 2
The Rod Fork 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 lever 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 can be secured to the implant with the T-Handle Cap Screwdriver. (Figure 13)

Option 3
The Rod Persuader 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 can be secured to the implant with the T-Handle Cap Screwdriver. (Figure 13)
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 and the Torque Driver. (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 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 turning clockwise. (Figure 19)

2. To remove the SureLOK™ Pedicle Screw System follow the surgical technique application in reverse order.
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