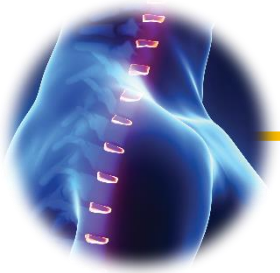


SURGICAL TECHNIQUE

PRECISION SPINE

SURELOK™ PC

POSTERIOR CERVICAL SYSTEM

PRECISION SPINE®

Discover the Difference

Made in the USA

TABLE OF CONTENTS

SureLOK™*PC* Posterior Cervical System

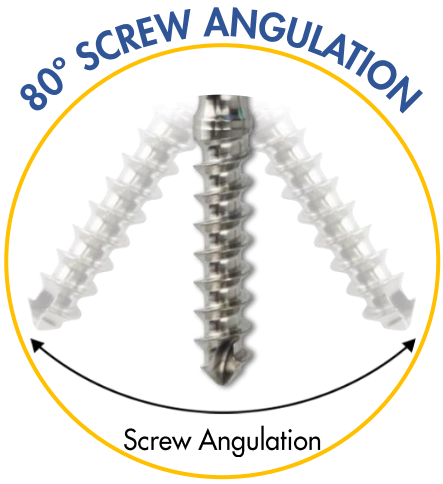
SureLOK™ *PC* Posterior Cervical System

OVERVIEW

The SureLOK™ *PC* is a cervicothoracic system that offers a simple and versatile solution to posterior cervicothoracic fixation. The top loading, low profile polyaxial screw design features 80° of angulation to allow for ease of rod insertion with minimal contouring. The system includes easy to use instrumentation as well as a variety of hook, rod, offset and domino options for the most difficult of cases.

INTRAOPERATIVE FLEXIBILITY

- 80° Screw Angulation
- 3.5mm Screws & 4.0mm Rescue Screws
- Assortment of Lateral Offsets, Hooks, Dominoes, & Transition Rods
- Tulip-to-Tulip Cross-Links Provide 3 Directions of Freedom



INDICATIONS

When intended to promote fusion of the cervical spine (C1-C7) in skeletally mature patients, the SureLOK *PC* Posterior Cervical System is indicated for the following:

1. DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiologic studies)
2. Spondylolisthesis
3. Spinal Stenosis
4. Fracture/Dislocation
5. Revision of previous cervical spine surgery
6. Tumors

The use of polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) for purposes of anchoring the construct. Polyaxial screws are not intended to be placed in the cervical spine.

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical (C1-C7) spine.

Please refer to the SureLOK *PC* Posterior Cervical System Instructions for Use (IFU) (LBL-IFU-008) package insert for complete system description, indications and warnings.

IMPLANT FEATURES

SCREW SELECTION

Diameters
- 3.5mm
- 4.0mm (Rescue)

Lengths
- 8 - 20mm (2mm Increments)
- 25 - 40mm (5mm Increments)

ROD SELECTION

Straight Rods
- 3.5mm
- 20, 30, 40, 50, 60, 70, 80, 90, 100, 120mm

Transition Rods
- 3.5 to 5.5mm
- 500mm

OFFSET SELECTION

Open Type
- 3.5mm Rod
- 14 & 25mm lengths

Closed Type
- 3.5mm Rod
- 14 & 25mm lengths

IMPLANT FEATURES (Continued)

HOOK SELECTION

Standard Hook
- Size - 5 & 6mm

Right Offset Hook
- Size - 5 & 6mm

Left Offset Hook
- Size - 5 & 6mm

DOMINO SELECTION

Straight and Parallel Domino Sizes
- 3.5 x 3.5mm
- 3.5 x 4.5mm
- 3.5 x 5.5mm
- 3.5 x 6.25mm

CROSS-LINK SELECTION

Attaches to Screw Tulip
- 30mm size fits rod spacing of 30-35mm
- 35mm size fits rod spacing of 35-45mm
- 45mm size fits rod spacing of 45-65mm

CROSS-LINK CAP SCREW

Replaces Cap Screw when a Cross-Link is used

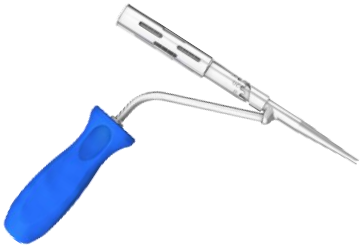
POLYAXIAL CAP SCREW

Locks Screw to Rod

INSTRUMENTS

BONE AWL
Marks the entry point of the Screw
- Part Number – 04-9044

DRILL GUIDE (Adjustable)
Used as a guide for the 2.5mm Drill
- Part Number – 04-9004



14mm FIXED DRILL GUIDE
- Part Number – 04-9081

14mm FIXED DRILLS
- Part Number – 04-9082-35
- Part Number – 04-9082-40

DRILL SHAFT
Used to prepare pathway in bone for Tap and/or Screw
- 3.5mm - Part Number – 04-9073-35
- 4.0mm – Part Number – 04-9073-40

BALL TIP PROBE
Used to check the integrity of Screw's pathway
- 0.065 Ball Tip – Part Number – 04-9074

DEPTH GAUGE
Used to determine the depth of a Screw hold
- Part Number – 04-9033

INSTRUMENTS (continued)

3.5mm TAP
Used to tap the Screw path prior to insertion of 3.5mm Screw
- Part Number – 04-9009-35

4.0mm TAP
Used to tap the Screw path prior to insertion of 4.0mm Screw
- Part Number – 04-9009-40

TAP SLEEVE
Optional sleeve to protect soft tissue during tapping
- Part Number – 04-9010-35
- Part Number – 04-9010-40 (Green)

POLYAXIAL SCREW DRIVER
Drives the Screw into the prepared Screw pathway
- Part Number – 04-9016

SCREW HEAD POSITIONER
Adjusts orientation of Screw Head Tulip to allow for rod alignment
- Part Number – 04-9034

ROD TEMPLATE
Provides template for Rod bending and length measurements
- Part Number – 04-9032

CAP SCREW INSERTER
Used to insert Cap Screws (not for definitive tightening)
- Part Number – 04-9094

INSTRUMENTS (continued)

DOUBLE ENDED CAP SCREW INSERTER
Cap inserter that features dual ends
- Part Number – 04-9096

SCREW ADJUSTMENT DRIVER
Adjusts height of nut on the Polyaxial Screw
- Part Number – 04-9011

RATCHETING ROD CUTTER
Creates smooth cuts on the Rod
- Part Number – 04-9080

ROD BENDER
Contours Rod to meet the required need of the construct
- Part Number – 04-9028

ROD HOLDER
Holds Rod securely during insertion and positioning
- Part Number – 04-9029

ROD PUSHER
Used for manipulation and seating of Rod within Screw head tulip
- Part Number – 04-9014

INSTRUMENTS (continued)

ROD REDUCER
Used for manipulation and seating of Rod within Screw head tulip
- Part Number – 04-9079

COMPRESSOR
Utilized to compress implants axially along the Rod
- Part Number – 04-9036

DISTRACTOR
Utilized to distract implants axially along the Rod
- Part Number – 04-9037

ANTI-TORQUE WRENCH (blue handle)
Provides counter-torque leverage while torqueing Cap Screw
- Part Number – 04-9083

CROSS-LINK ANTI-TORQUE WRENCH (green handle)
Provides counter-torque leverage while torqueing Cap Screw
- Part Number – 04-9084

CAP SCREW TORQUE SHAFT
Used with the Torque Limiting Handle – 04-9023 – to definitely lock Cap Screws and Cross-Link Cap Screws
- Part Number – 04-9097

INSTRUMENTS (continued)

TORQUE LIMITING HANDLE (blue)
Used with the Cap Screw Torque Shaft – 04-9097 – and Cross-Link Cap Screws to definitively lock Cap Screws
- Part Number – 04-9023

CROSS-LINK TORQUE SHAFT
Used with the Torque Limiting Handle – 04-9075 – to definitively lock the Cross-Link center lock nut
- Part Number – 04-9095

TORQUE LIMITING HANDLE (green)
Used with the Cross-Link Torque Shaft – 04-9095 – to definitively lock Cross-Link center lock nut
- Part Number – 04-9075

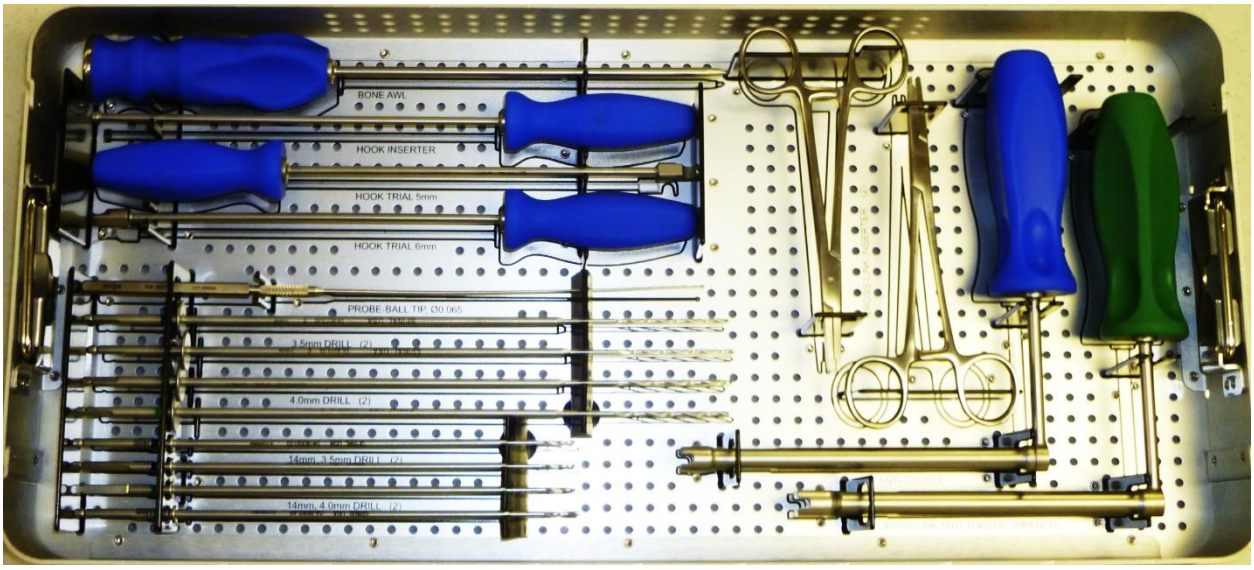
UNIVERSAL STRAIGHT HANDLE
Used with Taps and Drills
- Part Number – 04-9024

HOOK INSERTER
Used to insert Hooks
- Part Number – 04-9072

HOOK TRIAL
Used as a template to determine appropriate Hook selection
- 5mm - Part Number – 04-9070
- 6mm – Part Number – 04-9071

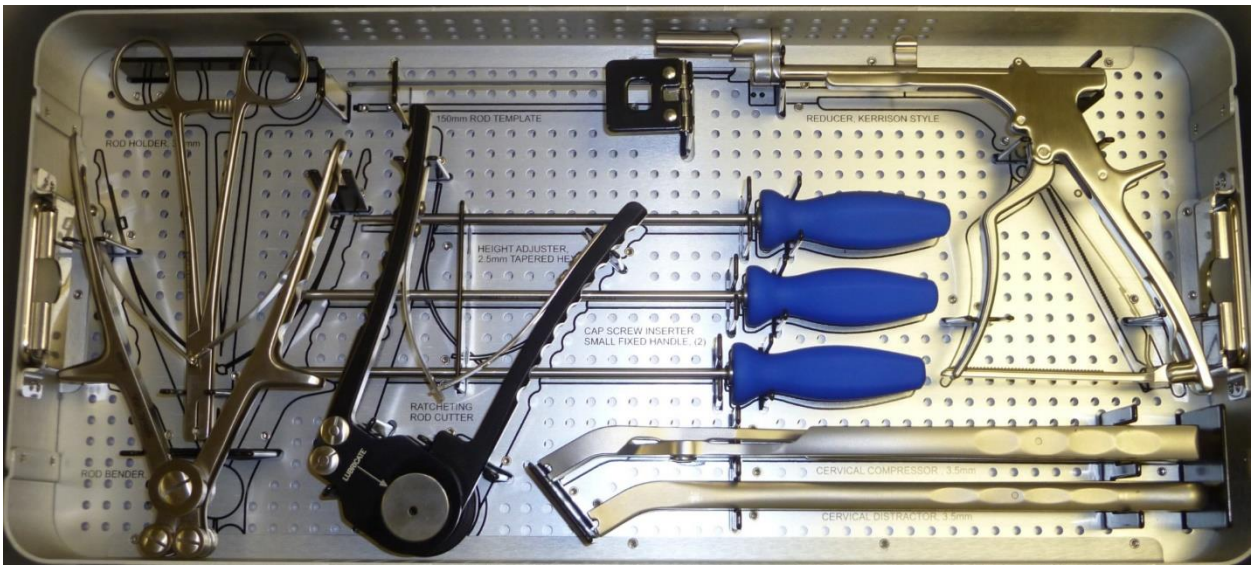
CROSS-LINK INSERTER
Used to position a Cross-Link on the construct
- Part Number – 04-9066

SureLOK *PC* INSTRUMENT TRAY
04-9201-CA
Top Level



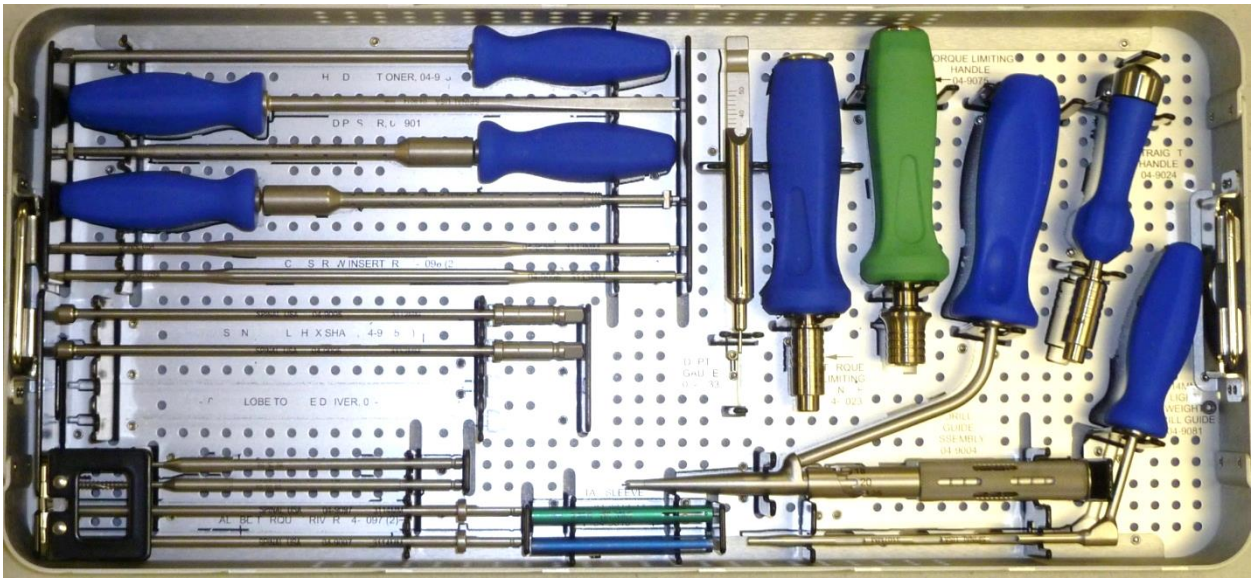
Part Number	Description	Qty
04-9082-35	14mm, 3.5mm Drill - (use small Blue Handle 04-9024)	2
04-9082-40	14mm, 4.0mm Drill - (use small Blue Handle 04-9024)	2
04-9073-35	Drill Shaft 35mm - (use small Blue Handle 04-9024)	2
04-9073-40	Drill Shaft 40mm - (use small Blue Handle 04-9024)	2
04-9074	Ball Tip Probe Curved - (.065mm Tip)	1
04-9071	6mm Hook Trial	1
04-9070	5mm Hook Trial	1
04-9072	Hook Inserter Tool	1
04-9044	Bone Awl	1
04-9066	Cervical Cross Link Inserter	2
04-9083	Anti-Torque Shaft for Polyaxial Cap Screws - (Blue Handle)	1
04-9084	Anti-Torque Shaft for Cross Link - (Green Handle)	1

SureLOK *PC* INSTRUMENT TRAY
04-9201-CA
Bottom Level



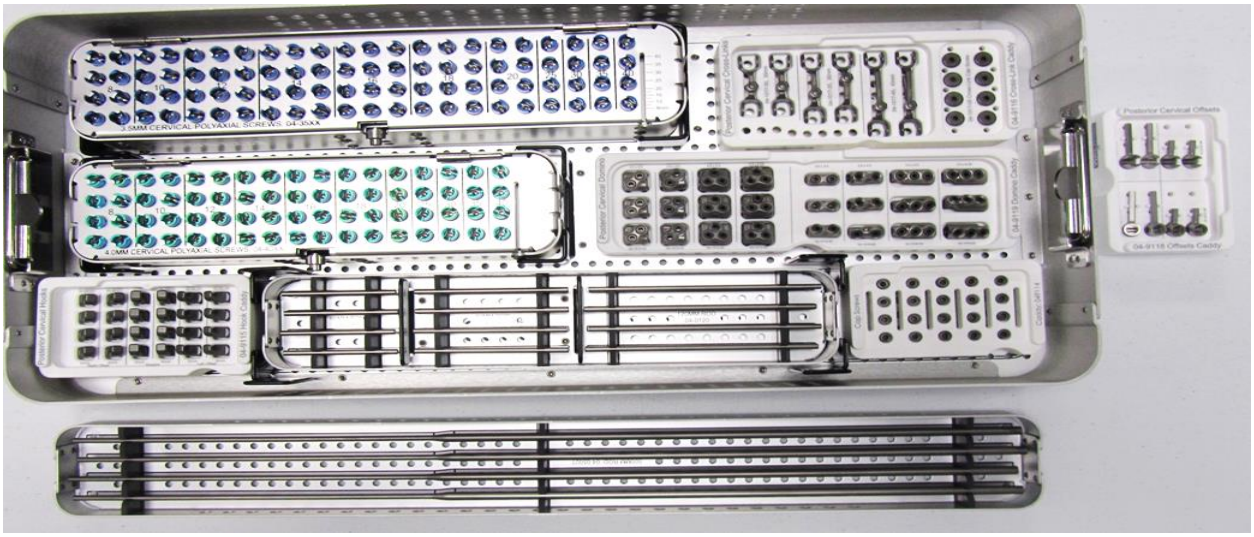
Part Number	Description	Qty
04-9028	Rod Bender 3.5mm	1
04-9029	Rod Holder 3.5mm	1
04-9032	Rod Template 3.25mm x 150mm	1
04-9011	Height Adjuster 2.5mm Tapered Hex Screwdriver - (use w/ Polyaxial Screws)	2
04-9079	Reducer, Kerrison Style	1
04-9036	Compressor - (3.5mm Rod ITM003)	1
04-9037	Distractor - (3.5mm Rod ITM004)	1
04-9094	Cap Screw Inserter, small fixed handle (use Cap Screw 04-1000)	2
04-9080	Ratcheting Rod Cutter - (replaced 04-9027)	1

SureLOK *PC* IMPLANT TRAY
04-9202-CA
Top Level



Item Number	Description	Qty
04-9097	T-15 Hexalobe Torque Driver Shaft - (use Blue Handle 04-9023 & Cap Screw 04-1000)	2
04-9009-35	3.5mm Tap	1
04-9009-40	4.0mm Tap	1
04-9095	Cross-Link Female Hex Torque Driver Shaft - (use Green Handle 04-9075 & Cap Screw 04-1017-05)	2
04-9096	Cap Screw Inserter, double ended - (use Cap Screw 04-1000)	2
04-9016	Polyaxial Mini Screwdriver	2
04-9014	3.5mm Rod Pusher	1
04-9034	Screw Head Positioner Mini	1
04-9033	Depth Gauge 50mm	1
04-9023	Torque Limiting Axial Handle w/ Silicone Grip A-O Connection, 30in-lbs torque - (use Shaft 04-9097)	1
04-9075	Cross-Link Torque Limiting Axial Green Handle, 18in-lbs torque - (use Shaft 04-9095)	1
04-9004	Drill Guide Adjustable	1
04-9024	Universal Straight Handle - (replaced ACP-010)	1
04-9081	14mm Lightweight Drill Guide	1
04-9010-35	Tap Sleeve - (use Tap Shaft 04-9009-35)	1
04-9010-40	Tap Sleeve - (use Tap Shaft 04-9009-40)	1

SureLOK *PC* IMPLANT TRAY
04-9202-CA
Bottom Level



Item Number	Description	Qty
04-0500T	3.5/5.5mm x 500mm - Transition Rod	4
04-05LOH	5mm Left Offset Hook	4
04-05ROH	5mm Right Offset Hook	4
04-05STH	5mm Standard Hook	4
04-06LOH	6mm Left Offset Hook	4
04-06ROH	6mm Right Offset Hook	4
04-06STH	6mm Straight Hook	4
04-4008	4.0mm x 8mm SureLOK PC Screw	8
04-4010	4.0mm x 10mm SureLOK PC Screw	8
04-4012	4.0mm x 12mm SureLOK PC Screw	8
04-4014	4.0mm x 14mm SureLOK PC Screw	8
04-4016	4.0mm x 16mm SureLOK PC Screw	8
04-4018	4.0mm x 18mm SureLOK PC Screw	8
04-4020	4.0mm x 20mm SureLOK PC Screw	4
04-4025	4.0mm x 25mm SureLOK PC Screw	4
04-4030	4.0mm x 30mm SureLOK PC Screw	4
04-4035	4.0mm x 35mm SureLOK PC Screw	4
04-4040	4.0mm x 40mm SureLOK PC Screw	4
04-3508	3.5mm x 8mm SureLOK PC Screw	8
04-3510	3.5mm x 10mm SureLOK PC Screw	8
04-1016-45	3.5mm x 4.5mm Straight Domino	3
04-1016-55	3.5mm x 5.5mm Straight Domino	3
04-1016-62	3.5mm x 6.25mm Straight Domino	3
04-1013-14	Offset Open 14mm	2
04-1013-25	Offset Open 25mm	2
04-1014-14	Offset Closed 14mm	2
04-1014-25	Offset Closed 25mm	2
04-0020	3.5mm x 20mm Rod	4
04-0030	3.5mm x 30mm Rod	4
04-0040	3.5mm x 40mm Rod	4

Item Number	Description	Qty
04-3512	3.5mm x 12mm SureLOK PC Screw	12
04-3514	3.5mm x 14mm SureLOK PC Screw	12
04-3516	3.5mm x 16mm SureLOK PC Screw	12
04-3518	3.5mm x 18mm SureLOK PC Screw	12
04-3520	3.5mm x 20mm SureLOK PC Screw	8
04-3525	3.5mm x 25mm SureLOK PC Screw	4
04-3530	3.5mm x 30mm SureLOK PC Screw	4
04-3535	3.5mm x 35mm SureLOK PC Screw	4
04-3540	3.5mm x 40mm SureLOK PC Screw	4
04-1017-30	30mm Cervical Crosslink	2
04-1017-35	35mm Cervical Crosslink	2
04-1017-45	45mm Cervical Crosslink	2
04-1017-05	Cervical Cross Link Cap Screw	8
04-1015-00	Parallel Domino Cap Screw	24
04-1015-35	3.5mm x 3.5mm Parallel Domino	3
04-1015-45	3.5mm x 4.5mm Parallel Domino	3
04-1015-55	3.5mm x 5.5mm Parallel Domino	3
04-1015-62	3.5mm x 6.25mm Parallel Domino	3
04-1016-00	Straight Domino Cap Screw	30
04-1016-35	3.5mm x 3.5mm Straight Domino	3
04-0050	3.5mm x 50mm Rod	4
04-0060	3.5mm x 60mm Rod	4
04-0070	3.5mm x 70mm Rod	4
04-0080	3.5mm x 80mm Rod	4
04-0090	3.5mm x 90mm Rod	4
04-0100	3.5mm x 100mm Rod	4
04-0120	3.5mm x 120mm Rod	4
04-0240	3.5mm x 240mm Rod	4
04-1000	SureLOK PC Cap Screws	20

SURGICAL TECHNIQUE

1 PATIENT POSITIONING/ EXPOSURE

Place the patient in the prone position and secure with the desired sagittal alignment. Drape in the usual manner for posterior cervical spinal fusion. Expose the intended posterior spinal elements to be fused.

2 SKIN INCISION

1. Locate the desired entry point and screw trajectory. Then perforate the cortex with the Bone Awl (04-9044). This helps prevent displacement of the drill bit during initial insertion.

2. Set the Drill Guide (04-9004) to the desired depth by sliding back the sleeve of the Drill Guide. Adjust the position by rotating the sleeve so that the mark on the guide indicates the required depth. Release the sleeve to lock the Drill Guide at the desired depth.

3. Place the distal tip of the Drill Guide in the perforation created by the Awl. Insert the Drill (04-9073-35 for the 3.5mm Screw or 04-9073-40 for the 4.0mm Screw) through the proximal end of the Drill Guide and continue through until the drill tip contacts the vertebrae. Align the Drill Guide to the proper trajectory and advance the Drill to the predetermined depth.

4. Verify the integrity of the pathway with the Ball Tip Probe (04-9074).

5. Verify the depth of the drilled hole with the Depth Gauge (04-9033) and select the appropriate screw length.

Note: A Fixed 14mm Drill Guide (04-9081) is also available. The 14mm 3.5mm Drill (04-9082-35) and 14mm 4.0mm Drill (04-9082-40) are used exclusively with this Drill Guide.


Figure 1


Figure 2A


Figure 2B


Figure 2C


Figure 2D


Figure 2E

SURGICAL TECHNIQUE

2 SKIN INCISION (continued)

6. The SureLOK™ *PC* system Screws are self-tapping. If pre-tapping is desired, connect the appropriate sized Tap (04-9009-35 or 04-9009-40) to the quick-connect Universal Straight Handle (04-9024). Align the Tap with the desired trajectory for Screw insertion and tap to the desired depth.

7. Assemble the proper size and length Polyaxial Screw to the Polyaxial Screw Driver (04-9016) by inserting the hex end of the Driver in the hex hole in the Screw and threading the outer sleeve of the Driver into the tulip head of the Screw. Be certain that the Driver hex is fully seated in the Screw head.

8. Advance the Polyaxial Screw to the desired depth following the path of the tapped hole.

9. Remove the Polyaxial Screw Driver by rotating the outer sleeve of the driver counterclockwise until the sleeve is no longer attached to the Polyaxial Screw tulip head. The Driver can now be removed. Orient the Polyaxial Screw head using the Screw Head Positioner (04-9034). Insert remaining Screws using the same technique.

Figure 2F

Figure 2G

Figure 2H

3 HOOK PLACEMENT

1. Select the appropriate Hook size and shape based on the desired location and patient anatomy.

2. Attach the Hook Inserter (04-9072) to the Hook and place the Hook under the superior or inferior lamina. The Hook may be positioned in either a cranial or caudal position.

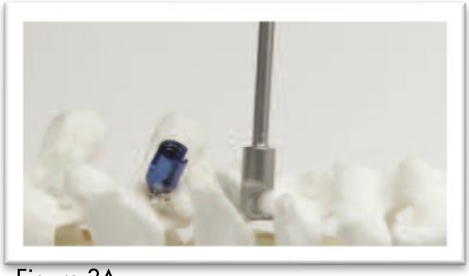


Figure 3A

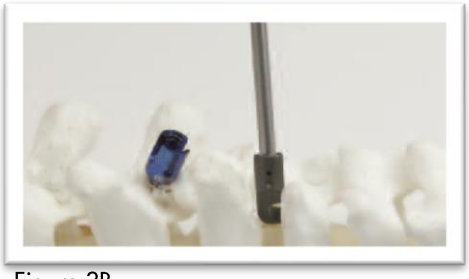


Figure 3B

SURGICAL TECHNIQUE

4 ROD PLACEMENT

1. For additional screw height adjustment, the Screw Adjustment Driver (04-9011) can be used. If required, align the Polyaxial Screw heads using the Screw Head Positioner. (04-9034).

2. The malleable Rod Template (04-9032) can be used as a stencil to aid in creating the required Rod contour.

3. Rods are available in various lengths, however the Ratcheting Rod Cutter (04-9080) can be used to shorten the Rod to the required length.

4. If contouring is desired, use the Rod Bender (04-9028). Place the Rod within the Bender and squeeze handles to achieve desired curvature.

5. Insert the Rod by grasping it with the Rod Holder (04-9029). Place the Rod so that it fits securely within the polyaxial head of the Screw.

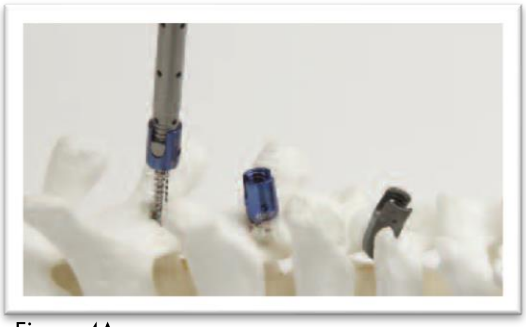


Figure 4A

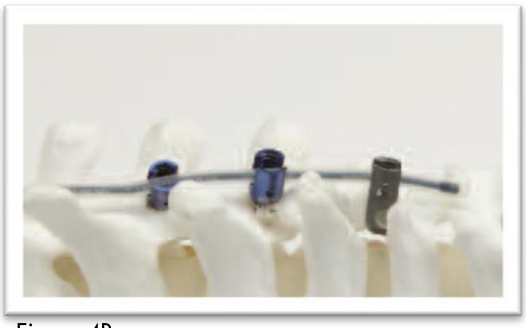


Figure 4B

Figure 4C

Figure 4D

SURGICAL TECHNIQUE

5 ROD REDUCTION

Use the Rod Pusher (04-9014) (Fig. 5A and 5B) or Rod Reducer (04-9079) (Fig. 5C and 5D) to facilitate Rod reduction.

Figure 5A

Figure 5B

Figure 5C

Figure 5D

SURGICAL TECHNIQUE

6 ROD ADJUSTMENT

1. Insert Cap Screws using the Cap Screw Inserter (04-9094) (Figure 6A1) or 04-9096. Alternatively, the Cap Screw can be placed down the barrel of the Anti-Torque Wrench directly onto the Screw (Figure 6A2).

2. Loosen the Locking Cap of the level to be adjusted. Use the Cervical Compressor (04-9036) to achieve compression (Figure 6B1), or the Cervical Distractor (04-9037) to achieve distraction of the construct (Figure 6B2).

3. Final tightening is accomplished by attaching the Cap Screw Torque Shaft (04-9097) to the Torque Limiting Handle (Blue) (04-9023) and then using the Anti-Torque Wrench (04-9083). Torque all Cap Screws on the construct definitively.

Figure 6A1

Figure 6A2

Figure 6B1

Figure 6B2

OPTIONAL SURGICAL PROCEDURES

CROSS-LINKS CAN BE ADDED TO THE CONSTRUCT, IF DESIRED

1. The Cross-Link Inserter (04-9066) is used to position a Cross-Link at the desired location on the construct (Figure 7).

2. Once the Cross-Link is positioned, the Cross-Link Cap Screws are inserted and definitively tightened using the Cap Screw Torque Shaft (04-9097), Torque Limiting Handle (04-9023) and Cross-Link Anti-Torque Wrench (04-9084) (Green) (Figure 8).

3. The Cross-Link locking nut can now be definitively locked with the Cross-Link Torque Shaft (04-9095) and Torque Limiting Handle (04-9023) (Figure 9).

Figure 7

Figure 8

Figure 9

SYSTEM REMOVAL

1. If crosslinks are utilized on the implant to be removed, they should be addressed first. Use the Cap Screw Inserter (04-9094) to remove the Cross Link by turning the two Cross Link Cap Screws counter- clockwise until the Cross Link is no longer engaged to the hooks or polyaxial screws to which they were secured. Remove the Cross Link from the construct. Repeat this procedure until all Cross Links have been removed from the construct.

2. Apply the Cannulated Anti-Torque Instrument (04-9008) over the Screw head or Hook to be removed. Insert the Cap Screw Inserter (04-9094) through the Anti-Torque Instrument and into the Cap Screw. Turn the Cap Screw Inserter counter clock-wise until the Cap Screw is disengaged. Remove the Cap Screw from the construct. Repeat this procedure until all Cap Screws have been removed from the construct.

3. The Rod Holder (04-9029) can now be attached to the Rod and used to remove the Rod/Rods from the construct.

4. Hooks are removed from the construct with the Hook Inserter (04-9072). Attach the Hook Inserter to the head of the Hook and turn clockwise to engage the Hook for removal. The Hook should be turned clockwise until it is fully disengaged from the bone. Repeat this procedure until all Hooks have been removed from the construct.

5. Polyaxial Screws are removed from the construct with the Polyaxial Screwdriver (04-9016). Attach the Polyaxial Screwdriver to the head of the Screw and turn counterclockwise to remove the Screw. The Screw should be turned counter-clockwise until it is fully disengaged from the bone. Repeat this procedure until all Screws have been removed from the construct.

CONTRAINDICATIONS & POTENTIAL ADVERSE EFFECTS

CONTRAINDICATIONS

The SureLOK *PC* System contraindications include, but are not limited to the following:

1. Use in the thoracic-lumbar-sacral spine below T3
2. Patients with osteopenia, bone absorption, bone and/or joint disease, deficient soft tissue at the wound site or possibly metal and/or coating intolerance
3. Patients with fever, tumors, elevated white blood count and other medical conditions
4. Obesity
5. Mental illness
6. Pregnancy
7. Local infection or inflammation
8. Any case needing to mix metals from different components
9. Any patient unwilling to cooperate with postoperative instructions
10. All cases not stated in the indications

POTENTIAL ADVERSE EFFECTS

The following potential adverse effects associated with the procedure have been shown to occur with the use of similar spinal systems. All patients considered candidates for fusion should be informed concerning the pathogenesis of their spinal abnormality, the rationale for fusion with instrumentation and the potential adverse effects. The following are potential adverse effects, but not limited to:

1. Loss of proper spinal curvature, correction, height and/or discomfort
2. Infection
3. Non-union or delayed union
4. Foreign body reaction to implants
5. Hemorrhaging
6. Loss of neurological function, dural tear, pain and/or discomfort
7. Bone graft fracture, vertebral body fracture or discontinued growth of fused bone at, above and/or below the surgery level
8. Bending, loosening, fracture, disassembly, slippage and/or migration of all components
9. Pain or discomfort
10. Change in mental status
11. Bursitis
12. Bone loss and/or bone fracture due to stress shielding
13. Inability to resume normal daily activities
14. Revision surgery
15. Death

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

WARNINGS

WARNINGS

The following list contains 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, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other condition is unknown.

2. The use of polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) for purposes of anchoring the construct. Polyaxial screws are not intended to be placed in the cervical spine.

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. 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. These Single Use devices have not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or re-sterilization, after a single patient use. Reuse can potentially compromise device performance and patient safety.

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 pedicle screw systems 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 the performance of the system.

11. 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. This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical spine.

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