

**SURGICAL
TECHNIQUE**

PRECISION SPINE
SURELOK™ PC
POSTERIOR CERVICAL SYSTEM



PRECISION SPINE®
Discover the Difference



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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

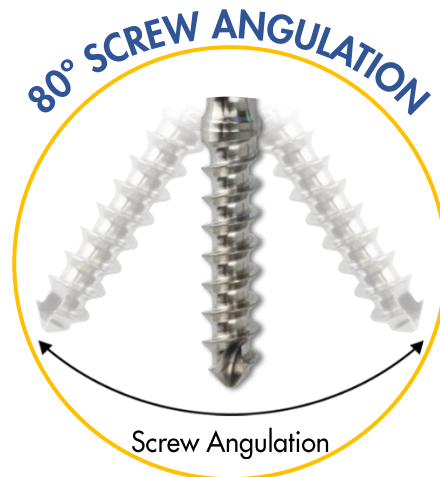
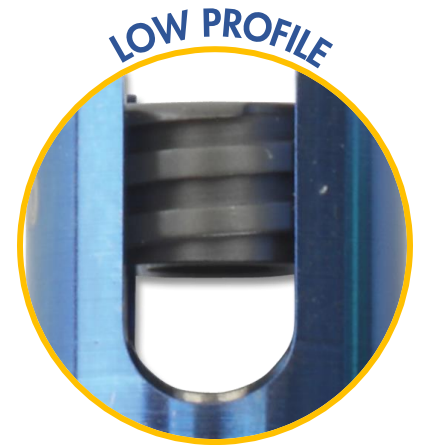
When intended to promote fusion of the cervical spine (C1-C7) in skeletally mature patients, the SureLOK PC Posterior Cervical System is indicated for the following:

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

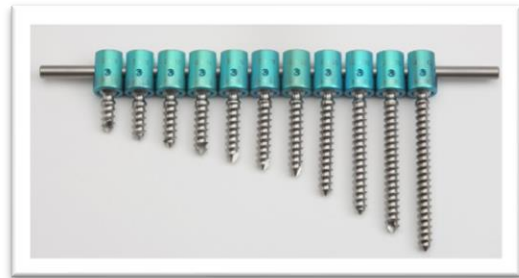
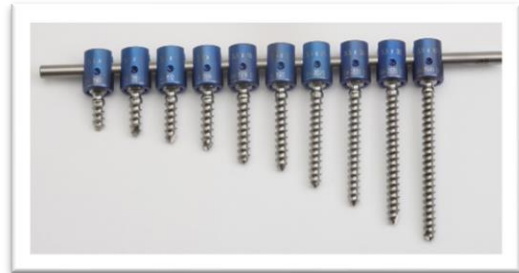
SCREW SELECTION (2.5mm Hex)

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
- 04-1000 Cap Screw, T15



Closed Type

- 3.5mm Rod
- 14 & 25mm lengths
- 04-1000 Cap Screw, T15



IMPLANT FEATURES (Continued)

HOOK SELECTION (T15)

- 04-1000 Cap Screw, T15

Standard Hook

- Size - 5 & 6mm

Right Offset Hook

- Size - 5 & 6mm

Left Offset Hook

- Size - 5 & 6mm



DOMINO SELECTION (T15)

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
- 04-1015-00 Domino Cap Screw, T15



CROSS-LINK SELECTION (T15)

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
- 04-1017-05 Cross Link Cap Screw, T15
- Central Nut, 6mm Hex



CERVICAL CROSS-LINK CAP SCREW (T15)

Replaces Cap Screw when a Cross-Link is used



POLYAXIAL CAP SCREW (T15)

Locks Screw to Rod



INSTRUMENTS

BONE AWL

Marks the entry point of the Screw

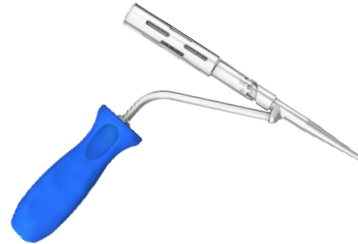
- Part Number – 04-9044
- 2.2mm x 4mm Tip Length



DRILL GUIDE (Adjustable)

Used as a guide for the Adjustable Drills (04-9073-35, 04-9073-40)

- Part Number – 04-9004



14mm FIXED DRILL GUIDE

Used as a guide for the 14mm Fixed Drills (04-9082-35, 04-9082-40)

- Part Number – 04-9081



14mm FIXED DRILLS

Used with Fixed Drill Guide (04-9081)

- 3.5mm - Part Number - 04-9082-35
 - 2.2mm Diameter
- 4.0mm - Part Number - 04-9082-40
 - 2.7mm Diameter

DRILL SHAFT

Used with Adjustable Drill Guide (04-9004)

- 3.5mm - Part Number - 04-9073-35
 - 2.2mm Diameter
- 4.0mm - Part Number - 04-9073-40
 - 2.7mm Diameter



BALL TIP PROBE

Used to check the integrity of Screw's pathway

- 1.6mm 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
- Undersized by 0.5mm



4.0mm TAP

Used to tap the Screw path prior to insertion of 4.0mm Screw

- Part Number – 04-9009-40
- Undersized by 0.5mm



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
- 2.5mm Hex



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
- 3.25mm x 150mm



CAP SCREW INSERTER

Used to insert Cap Screws (not for definitive tightening)

- Part Number – 04-9094
- T15



INSTRUMENTS (continued)

DOUBLE ENDED CAP SCREW INSERTER

Cap inserter that features dual ends

- Part Number – 04-9096
- T15



SCREW ADJUSTMENT DRIVER

Adjusts height of the Polyaxial Screw

- Part Number – 04-9011
- 2.5mm Hex



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 torquing Cap Screw

- Part Number – 04-9083



CROSS-LINK ANTI-TORQUE WRENCH (green handle)

Provides counter-torque leverage while torquing Cross-Link Cap Screw

- Part Number – 04-9084



CAP SCREW TORQUE SHAFT

Used with the Torque Limiting Handle – 04-9023 – to definitively lock Cap Screws, Dominos, and Cross-Link Cap Screws

- Part Number – 04-9097
- T15



INSTRUMENTS (continued)

TORQUE LIMITING HANDLE (blue)

Used with the Cap Screw Torque Shaft – 04-9097 – to definitively lock Cap Screws, Domino Cap Screws, and Cross-Link Cap Screws

- Part Number – 04-9023
- 30 in-lbs



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
- 6mm Hex



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
- 18 in-lbs



UNIVERSAL STRAIGHT HANDLE, AO

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

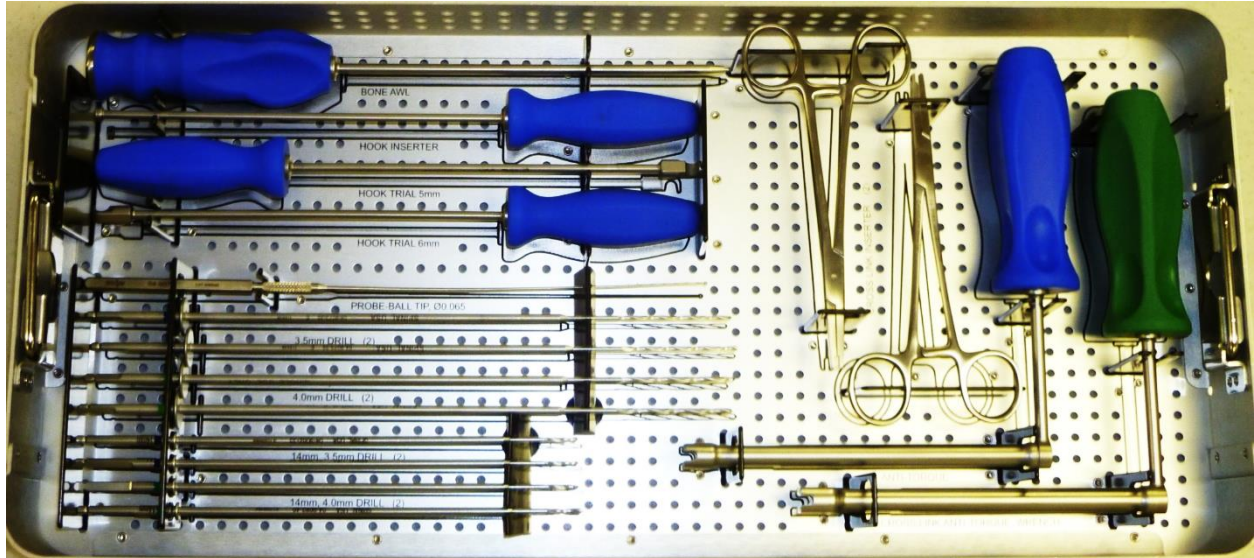
- Part Number – 04-9066



SureLOK PC INSTRUMENT TRAY

04-9201-CA

Top Level

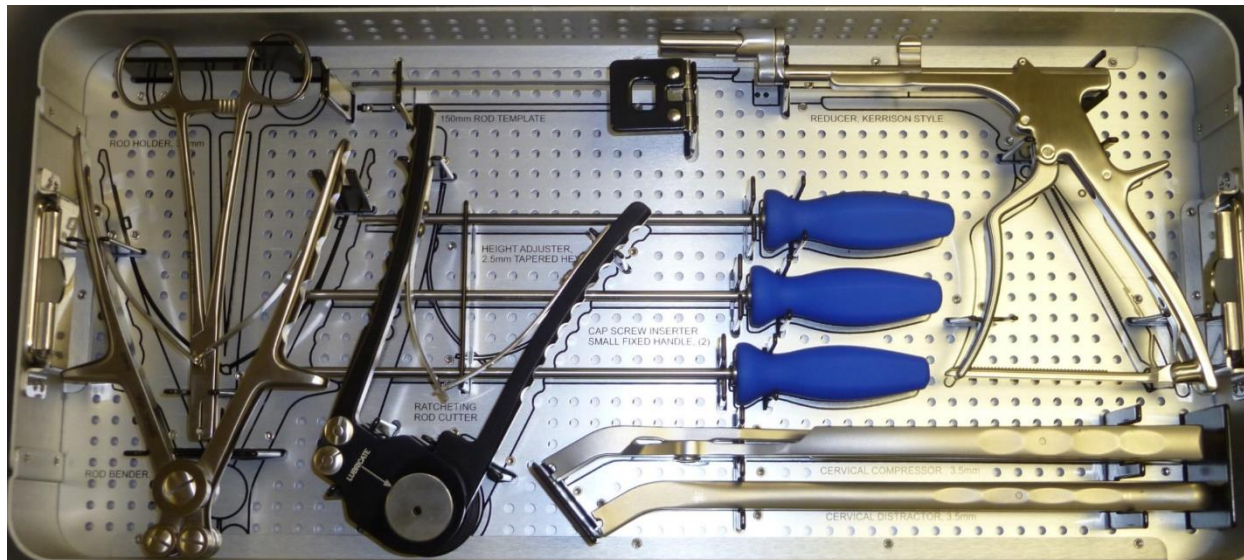


Part Number	Description	Qty
04-9082-35	1.4mm, 3.5mm Drill - (2.2mm Diameter, use small Blue Handle 04-9024)	2
04-9082-40	1.4mm, 4.0mm Drill - (2.7mm Diameter, use small Blue Handle 04-9024)	2
04-9073-35	Drill Shaft 3.5mm - (2.2mm Diameter, use small Blue Handle 04-9024)	2
04-9073-40	Drill Shaft 4.0mm - (2.7mm Diameter, use small Blue Handle 04-9024)	2
04-9074	Ball Tip Probe Curved - (1.6mm Tip)	1
04-9071	6mm Hook Trial	1
04-9070	5mm Hook Trial	1
04-9072	Hook Inserter Tool	1
04-9044	Bone Awl (2.2mm x 4mm Tip Length)	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

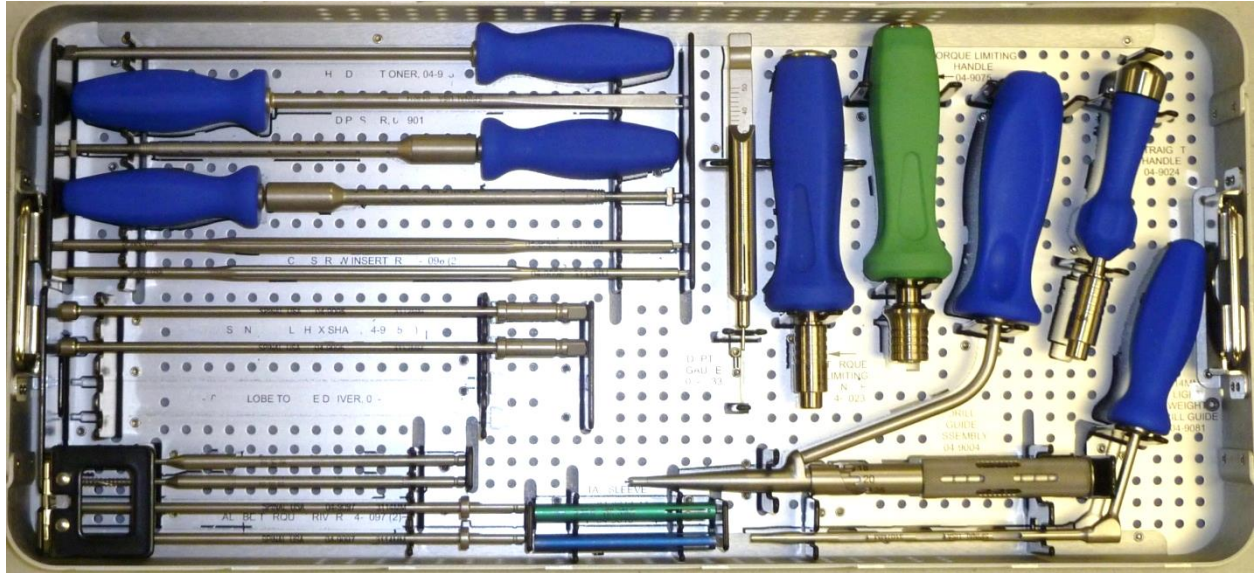


Part Number	Description	Qty
04-9028	Rod Bender 3.5mm	1
04-9029	Rod Holder 3.5mm	1
04-9032	Rod Template 3.25mm x 150mm	1
04-9011	Height Adjuster 2.5mm Hex Tapered Screwdriver - (use w/ Polyaxial Screws)	1
04-9079	Reducer, Kerrison Style	1
04-9036	Compressor - (3.5mm Rod)	1
04-9037	Distractor - (3.5mm Rod)	1
04-9094	Cap Screw Inserter, T15, small fixed handle (use Cap Screw 04-1000)	2
04-9080	Ratcheting Rod Cutter	1

SureLOK PC IMPLANT TRAY

04-9202-CA

Top Level

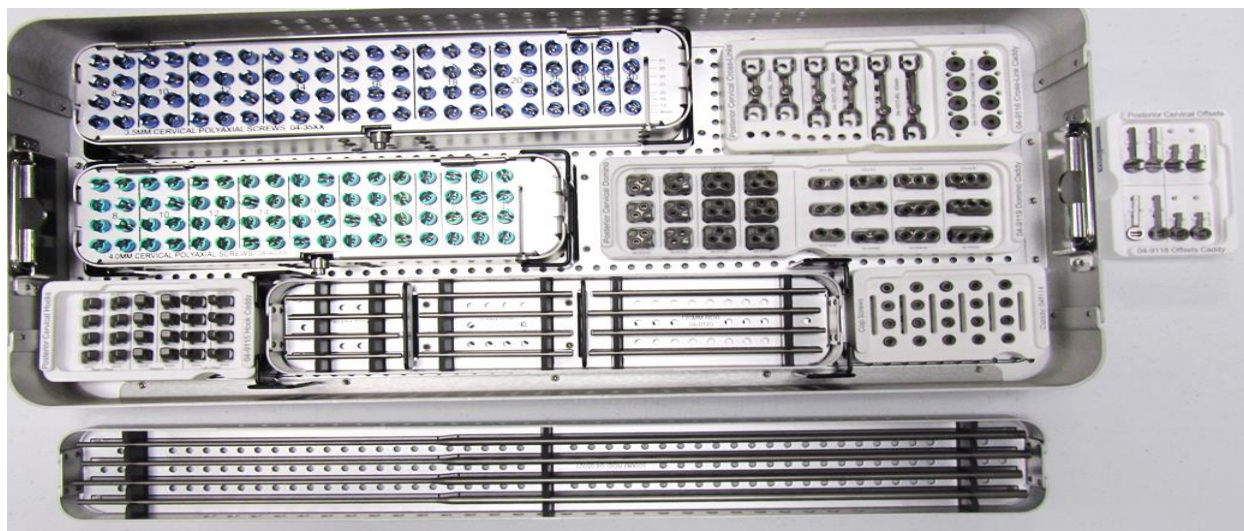


Item Number	Description	Qty
04-9097	T15 Torque Driver Shaft - (use Torque Limiting Blue Handle 04-9023 & Cap Screws 04-1000, 04-1017-05, 04-1015-00)	2
04-9009-35	3.5mm Tap (0.5mm undersized)	1
04-9009-40	4.0mm Tap (0.5mm undersized)	1
04-9095	Cross-Link 6mm Hex Torque Driver Shaft - (use Torque Limiting Green Handle 04-9075)	2
04-9096	Cap Screw Inserter, T15, double ended - (use Cap Screw 04-1000)	2
04-9016	Polyaxial Mini Screwdriver, 2.5mm Hex	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, AO	1
04-9081	14mm Fixed 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	Item Number	Description	Qty
04-3508	3.5mm x 8mm SureLOK PC Screw	8	04-0020	3.5mm x 20mm Rod	4
04-3510	3.5mm x 10mm SureLOK PC Screw	8	04-0030	3.5mm x 30mm Rod	4
04-3512	3.5mm x 12mm SureLOK PC Screw	12	04-0040	3.5mm x 40mm Rod	4
04-3514	3.5mm x 14mm SureLOK PC Screw	12	04-0050	3.5mm x 50mm Rod	4
04-3516	3.5mm x 16mm SureLOK PC Screw	12	04-0060	3.5mm x 60mm Rod	4
04-3518	3.5mm x 18mm SureLOK PC Screw	12	04-0070	3.5mm x 70mm Rod	4
04-3520	3.5mm x 20mm SureLOK PC Screw	8	04-0080	3.5mm x 80mm Rod	4
04-3525	3.5mm x 25mm SureLOK PC Screw	4	04-0090	3.5mm x 90mm Rod	4
04-3530	3.5mm x 30mm SureLOK PC Screw	4	04-0100	3.5mm x 100mm Rod	4
04-3535	3.5mm x 35mm SureLOK PC Screw	4	04-0120	3.5mm x 120mm Rod	4
04-3540	3.5mm x 40mm SureLOK PC Screw	4	04-0240	3.5mm x 240mm Rod	4
			04-0500T	3.5/5.5mm x 500mm - Transition Rod	4
04-4012	4.0mm x 12mm SureLOK PC Screw	8	04-1017-30	30mm Cervical Crosslink	2
04-4014	4.0mm x 14mm SureLOK PC Screw	8	04-1017-35	35mm Cervical Crosslink	2
04-4016	4.0mm x 16mm SureLOK PC Screw	8	04-1017-45	45mm Cervical Crosslink	2
04-4018	4.0mm x 18mm SureLOK PC Screw	8	04-1017-05	Cervical Cross Link Cap Screw, T15	8
04-4020	4.0mm x 20mm SureLOK PC Screw	4			
04-4025	4.0mm x 25mm SureLOK PC Screw	4	04-1015-35	3.5mm x 3.5mm Parallel Domino	3
04-4030	4.0mm x 30mm SureLOK PC Screw	4	04-1015-45	3.5mm x 4.5mm Parallel Domino	3
04-4035	4.0mm x 35mm SureLOK PC Screw	4	04-1015-55	3.5mm x 5.5mm Parallel Domino	3
04-4040	4.0mm x 40mm SureLOK PC Screw	4	04-1015-62	3.5mm x 6.25mm Parallel Domino	3
04-1000	SureLOK PC Cap Screws, T15	20	04-1016-35	3.5mm x 3.5mm Straight Domino	3
04-1013-14	Offset Open 14mm	2	04-1016-45	3.5mm x 4.5mm Straight Domino	3
04-1013-25	Offset Open 25mm	2	04-1016-55	3.5mm x 5.5mm Straight Domino	3
04-1014-14	Offset Closed 14mm	2	04-1016-62	3.5mm x 6.25mm Straight Domino	3
04-1014-25	Offset Closed 25mm	2	04-1015-00	Domino Cap Screw, T15	60

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

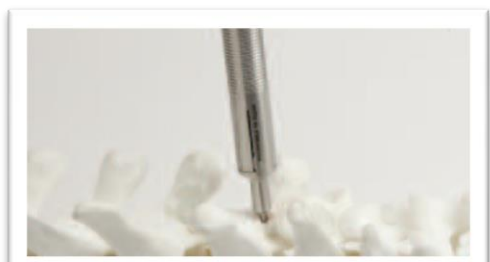


Figure 2E

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.

Note that the Taps are .5mm undersized.

6. Assemble the proper size and length Polyaxial Screw to the Polyaxial Screw Driver (04-9016) by securely 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.
7. Advance the Polyaxial Screw to the desired depth following the path of the tapped hole.
8. 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.

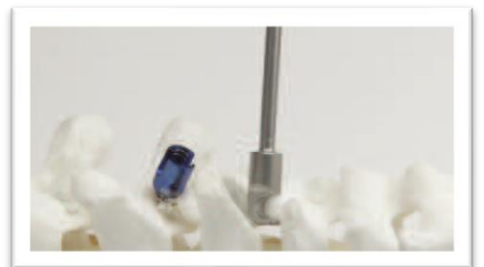


Figure 3A

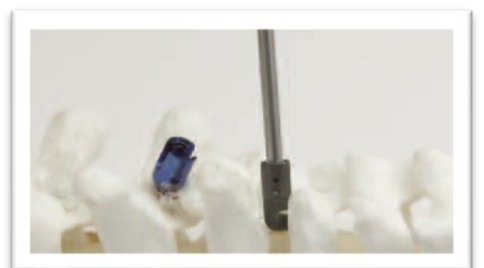


Figure 3B

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.

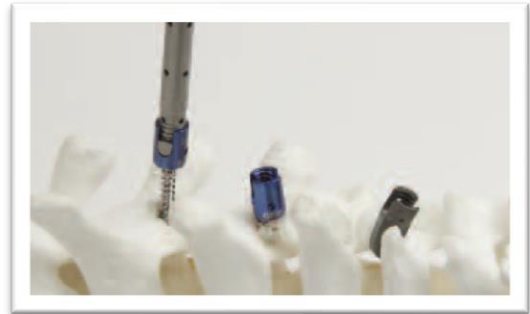


Figure 4A

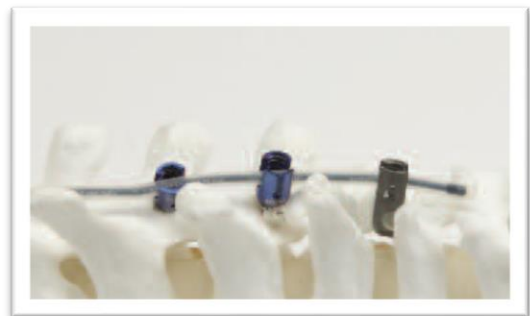


Figure 4B



Figure 4C

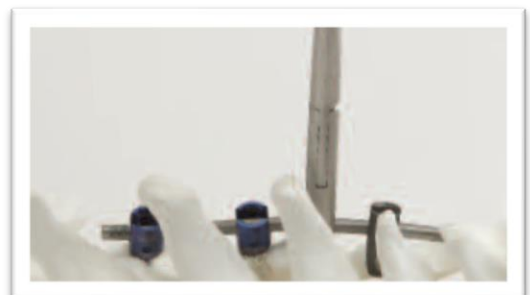


Figure 4D

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.

Once reduction is achieved, insert Cap Screws (04-1000) using the Cap Screw Inserter (04-9094 or 04-9096) and initially tighten by hand.



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).

Place the Anti-torque Wrench over the screw head until it is fully seated over the rod. Insert the Torque Shaft through the Anti-torque Wrench and securely seat the distal end into the Cap Screw. Turn the Torque Limiting Handle clockwise until an audible click is heard, verifying the final torque of 30 in-lbs. Repeat for the remaining screws.

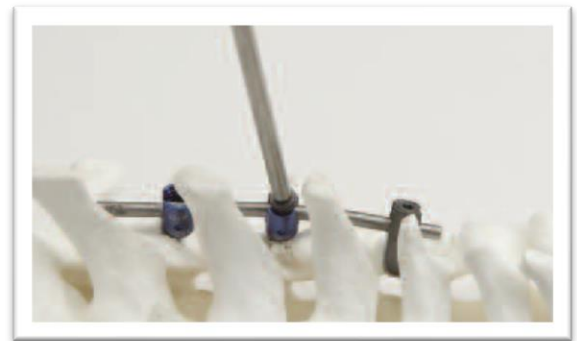


Figure 6A1



Figure 6A2

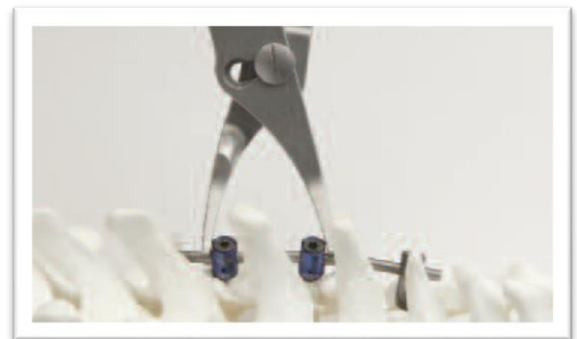


Figure 6B1



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 (04-1017-05) are inserted and definitively tightened using the Cap Screw Torque Shaft (04-9097), Blue Torque Limiting Handle (04-9023) and Green Handle Cross-Link Anti-Torque Wrench (04-9084) (Figure 8).

Securely seat the distal end of the Torque Shaft into the Cross-Link Cap Screw and turn the Torque Limiting Handle clockwise until an audible click is heard, verifying the final torque of 30 in-lbs. Repeat for remaining Cross-Link Cap Screw.

3. The Cross-Link locking nut can now be definitively locked with the Cross-Link Torque Shaft (04-9095) and Green Torque Limiting Handle (04-9075) (Figure 9).

Securely seat the distal end of the Cross-Link Torque Shaft over the center nut of the Cross-Link and turn the Torque Limiting Handle clockwise until an audible click is heard, verifying the final torque of 18 in-lbs.



Figure 7



Figure 8

DOMINOS CAN BE ADDED TO THE CONSTRUCT, IF DESIRED

1. Securely position the selected domino onto the constructs.
2. Once the domino is positioned properly, the Domino Cap Screws (04-1015-00) are definitively tightened using the Cap Screw Torque Shaft (04-9097) and Blue Torque Limiting Handle (04-9023).

Securely seat the distal end of the Torque Shaft into the Domino Cap Screw and turn the Torque Limiting Handle clockwise until an audible click is heard, verifying the final torque of 30 in-lbs. Repeat for remaining Domino Cap Screws.



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. Attach the Cap Screw Torque Shaft (04-9097) to the Universal Straight Handle (04-9024). Apply the Anti-Torque Wrench (04-9083) over the Screw head or Hook to be removed. Insert the Cap Screw Torque Shaft through the Anti-Torque Wrench and securely into the Cap Screw. Turn the Cap Screw Torque Shaft counterclockwise 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 Screw Adjustment Driver (04-9011). Securely insert the driver 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.

Indications, Contraindications, Warnings, and Precautions

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 the 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.

PRECAUTIONS:

Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the **SureLOK PC** Posterior Cervical System. The implantation of the **SureLOK PC** Posterior Cervical System should be performed only by experience spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.

CONTRAINDICATIONS:

The **SureLOK PC** Posterior Cervical System contraindications include, but are not limited to:

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 probably 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 reduction
2. Infection
3. Non-Union or delayed union
4. Foreign body reaction to the 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

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. The use of polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) for the 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 on 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.



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