



**SURGICAL
TECHNIQUE**

PRECISION SPINE
SURELOK™ MIS
PERCUTANEOUS SCREW SYSTEM **3L**



PRECISION SPINE®
Discover the Difference



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SureLOK™ MIS 3L OVERVIEW

The SureLOK MIS 3L is a low profile, percutaneous screw system. The system features an extended tab tulip with 20mm of controlled rod reduction. The screw has a triple lead, proximally tapered thread that greatly enhances delivery. This reduces fatigue and minimizes OR time without compromising screw purchase. In addition, the open tulip design, 30° of rod angulation and rod tip eases rod insertion. The system also offers multiple sleeve options to allow for aggressive tulip manipulation, rod reduction and compression and distraction techniques.

DEVICE DESCRIPTION

The **SureLOK MIS 3L** Percutaneous Screw System is a top-loading, multiple component, posterior spinal fixation system which consists of cannulated pedicle screws, straight and pre-curved rods, and locking cap screws. All of the components are available in a variety of sizes to match more closely the patient's anatomy. The **SureLOK MIS 3L** Percutaneous Screw System is suitable for the following procedures: open, mini-open, percutaneous MIS approach, or a combination of any during the same procedure. All implantable components are made from medical grade titanium or titanium alloy described by such standards as ASTM F136 or ISO 5832-3. All components are supplied clean and "NON-STERILE".

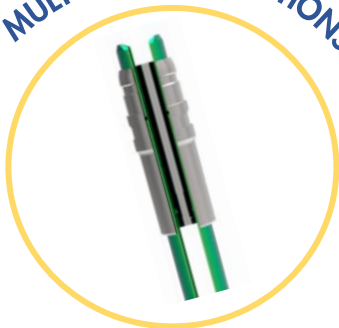
INDICATIONS

The **SureLOK MIS 3L** Percutaneous 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 (pseudarthrosis).

The **SureLOK MIS 3L** Percutaneous 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; pseudarthrosis; and failed previous fusion.

Please refer to package insert (LBL-IFU-026) for complete system description, indications and warnings.

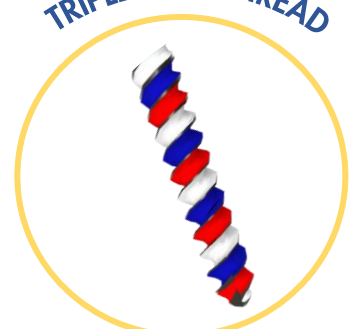
MULTIPLE SLEEVE OPTIONS



AGGRESSIVE SCREW TIP



TRIPLE LEAD THREAD



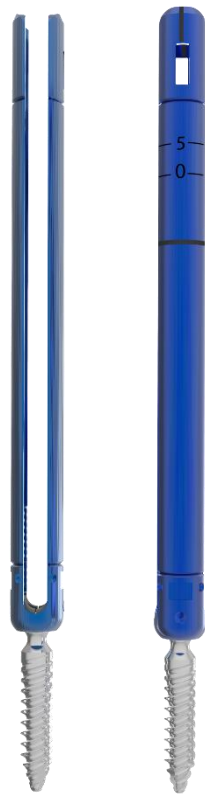
SureLOK™ MIS 3L OVERVIEW

150mm Integrated Extension Tab features a low profile outer diameter (12.7mm) allowing for a smaller incision to minimize muscle disruption

Open Tab Design provides maximum visualization and eases rod placement

Polyaxial Screws offer 30° of angulation in all planes for intraoperative flexibility

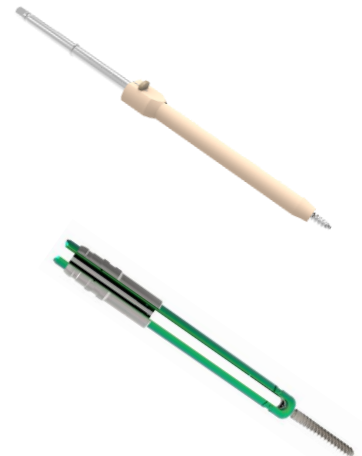
Integrated Reduction Threads provide 20mm of controlled rod reduction



Dilator/Awl/Tap is completed with one instrument

Extended Tab Rings provide maximum rigidity for rod manipulation

Internal Rod Reducer allows for 50mm of controlled rod reduction



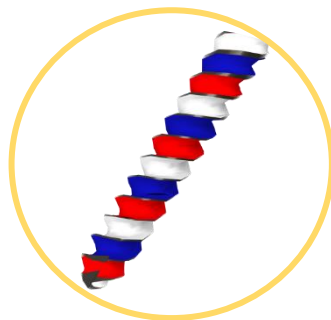
Compressor/Distractor is powerful, precise and effective



Triple Lead Thread allows for efficient screw delivery

Proximal Tapered Thread design increases bone screw interface, enhancing pull-out strength

Aggressive Self Drilling, Self Tapping Screw Tip optimizes screw engagement



Center and Side Load Inserters

meet varying surgical techniques and provides a strong rod interface for secure insertion

Center Load Inserter



Side Load Inserter



SureLOK™ MIS 3L SYSTEM OVERVIEW

SCREW DIMENSIONS

- Diameters
 - 5.5mm (Gold)
 - 6.5mm (Green)
 - 7.5mm (Blue)
 - 8.5mm (Bronze)
- Lengths
 - 35 – 55mm (5mm increments)

ROD DIMENSIONS

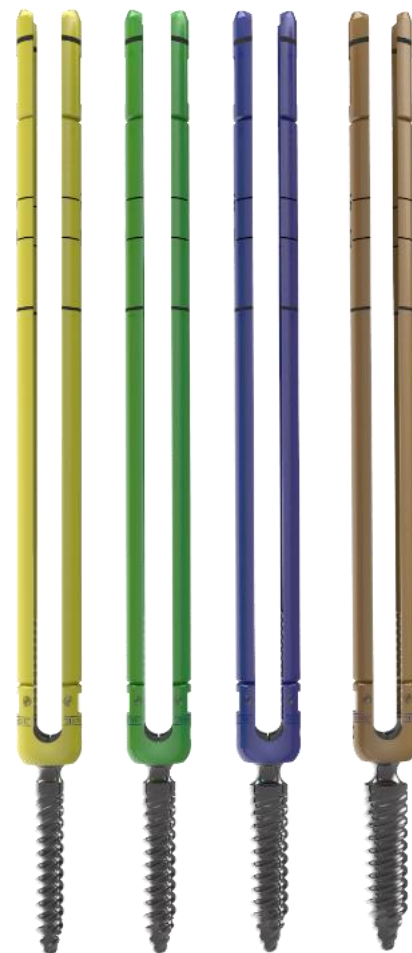
- Lordotic
 - 35 – 80mm (5mm increments)
 - 90 – 110mm (10mm increments)
- Straight
 - 35 – 80mm (5mm increments)
 - 90 – 150mm (10mm increments)

IMPLANT SETS

- 63-8600-CA-01
 - 6.5 & 7.5mm Diameter Screws, **Center Load Lordotic Rods** and Cap Screws
- 63-8700-CA-01
 - 5.5 & 8.5mm Diameter Screws and **Center Load Straight Rods**
- 63-8600-CA-02
 - 6.5 & 7.5mm Diameter Screws, **Side Load Lordotic Rods** and Cap Screws
- 63-8700-CA-02
 - 5.5 & 8.5mm Diameter Screws and **Side Load Straight Rods**

INSTRUMENT SETS

- Either instrument set (**63-8300-CA-01** or **63-8300-CA-02**) may be utilized for implantation of MIS Screws. However the 01 & 02 Implant and Instrument sets must match.
- 63-8300-CA-01 Center Load Instruments
- 63-8300-CA-02 Side Load Instruments



DISPOSABLES

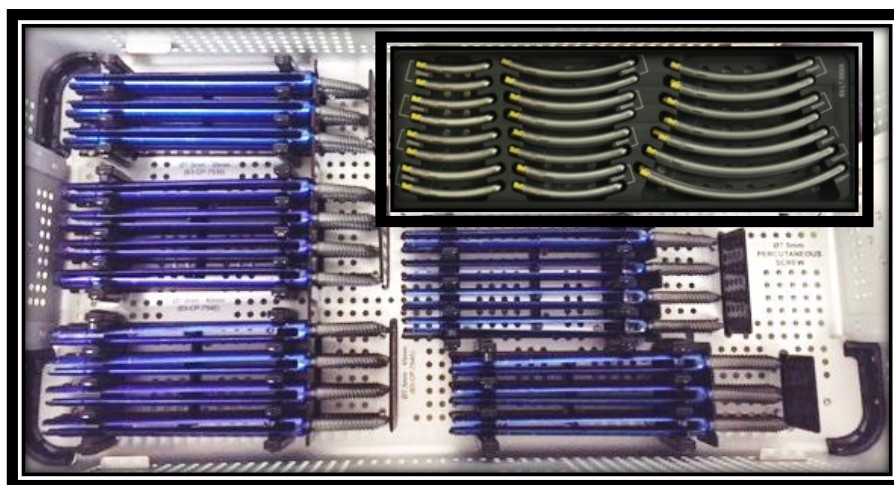
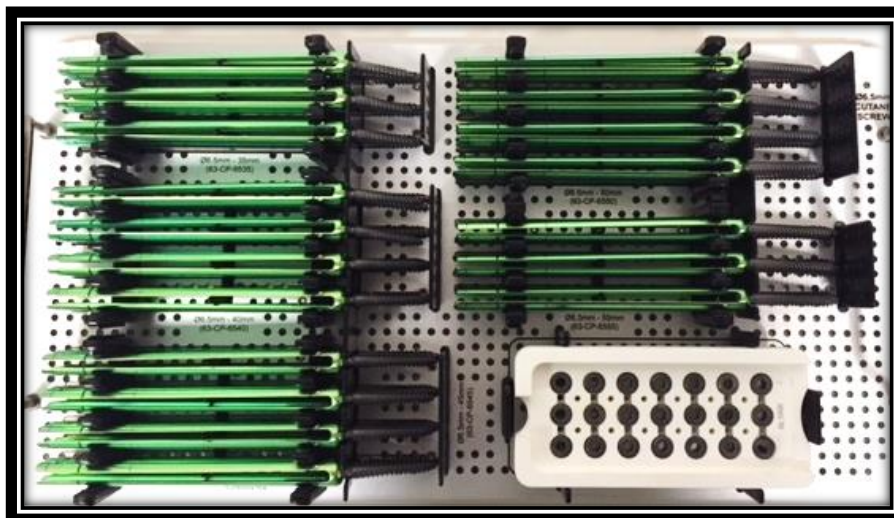
Part #	Description
74174-01M *	Jamshidi Needle 8ga x 6in. Trocar and Bevel Tip Stylets
74066-15M *	Jamshidi Needle 11ga x 4.5in. Trocar Stylet Tip
74182-01M *	Jamshidi Needle 13ga x 4.5in. Trocar Stylet Tip
74182-02M *	Jamshidi Needle 13ga x 4.5in Trocar and Bevel Tip Stylets

ADDITIONAL INSTRUMENTS

Part #	Description
PSSRB *	Rod Bender

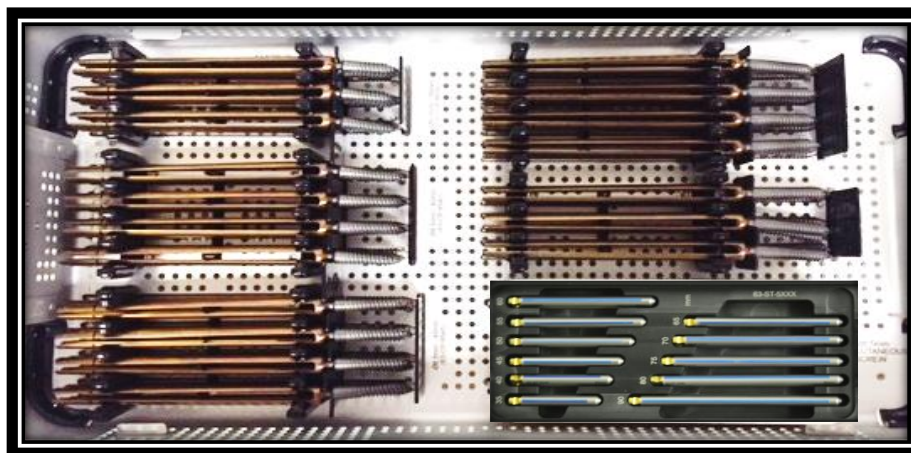
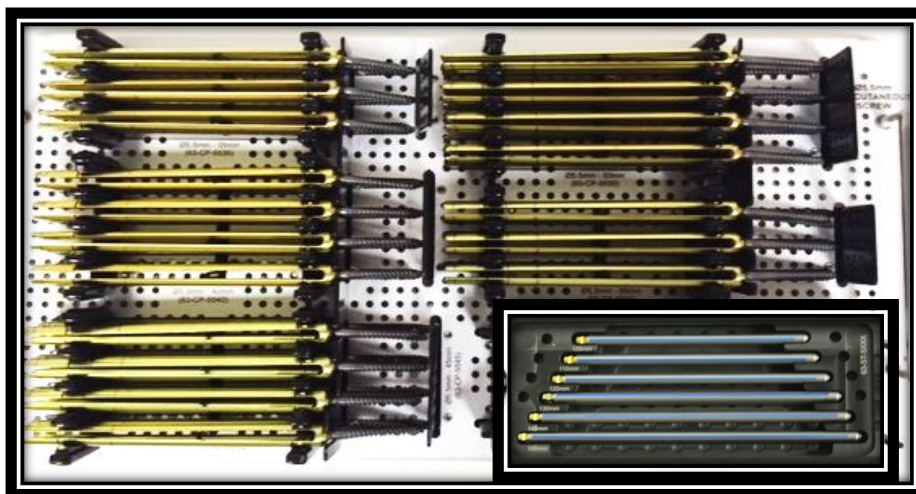
*By request only

SureLOK™ MIS 3L Implant Tray 63-8600-CA-01 (Center Load)



Part #	Description	Qty.	Part #	Description	Qty.
63-CP-6535	MIS 3L Pedicle Screw, 6.5 x 35mm	6	63-LT-5035	Lordotic Ti CL Rod 35mm	4
63-CP-6540	MIS 3L Pedicle Screw, 6.5 x 40mm	8	63-LT-5040	Lordotic Ti CL Rod 40mm	4
63-CP-6545	MIS 3L Pedicle Screw, 6.5 x 45mm	8	63-LT-5045	Lordotic Ti CL Rod 45mm	4
63-CP-6550	MIS 3L Pedicle Screw, 6.5 x 50mm	8	63-LT-5050	Lordotic Ti CL Rod 50mm	4
63-CP-6555	MIS 3L Pedicle Screw, 6.5 x 55mm	6	63-LT-5055	Lordotic Ti CL Rod 55mm	4
63-CP-7535	MIS 3L Pedicle Screw, 7.5 x 35mm	6	63-LT-5060	Lordotic Ti CL Rod 60mm	4
63-CP-7540	MIS 3L Pedicle Screw, 7.5 x 40mm	8	63-LT-5065	Lordotic Ti CL Rod 65mm	4
63-CP-7545	MIS 3L Pedicle Screw, 7.5 x 45mm	8	63-LT-5070	Lordotic Ti CL Rod 70mm	4
63-CP-7550	MIS 3L Pedicle Screw, 7.5 x 50mm	8	63-LT-5075	Lordotic Ti CL Rod 75mm	4
63-CP-7555	MIS 3L Pedicle Screw, 7.5 x 55mm	6	63-LT-5080	Lordotic Ti CL Rod 80mm	4
			63-LT-5090	Lordotic Ti CL Rod 90mm	2
			63-LT-5100	Lordotic Ti CL Rod 100mm	2
			63-LT-5110	Lordotic Ti CL Rod 110mm	2
			SL1000	S-Lok Cap Screw, 4.5mm Hex	21

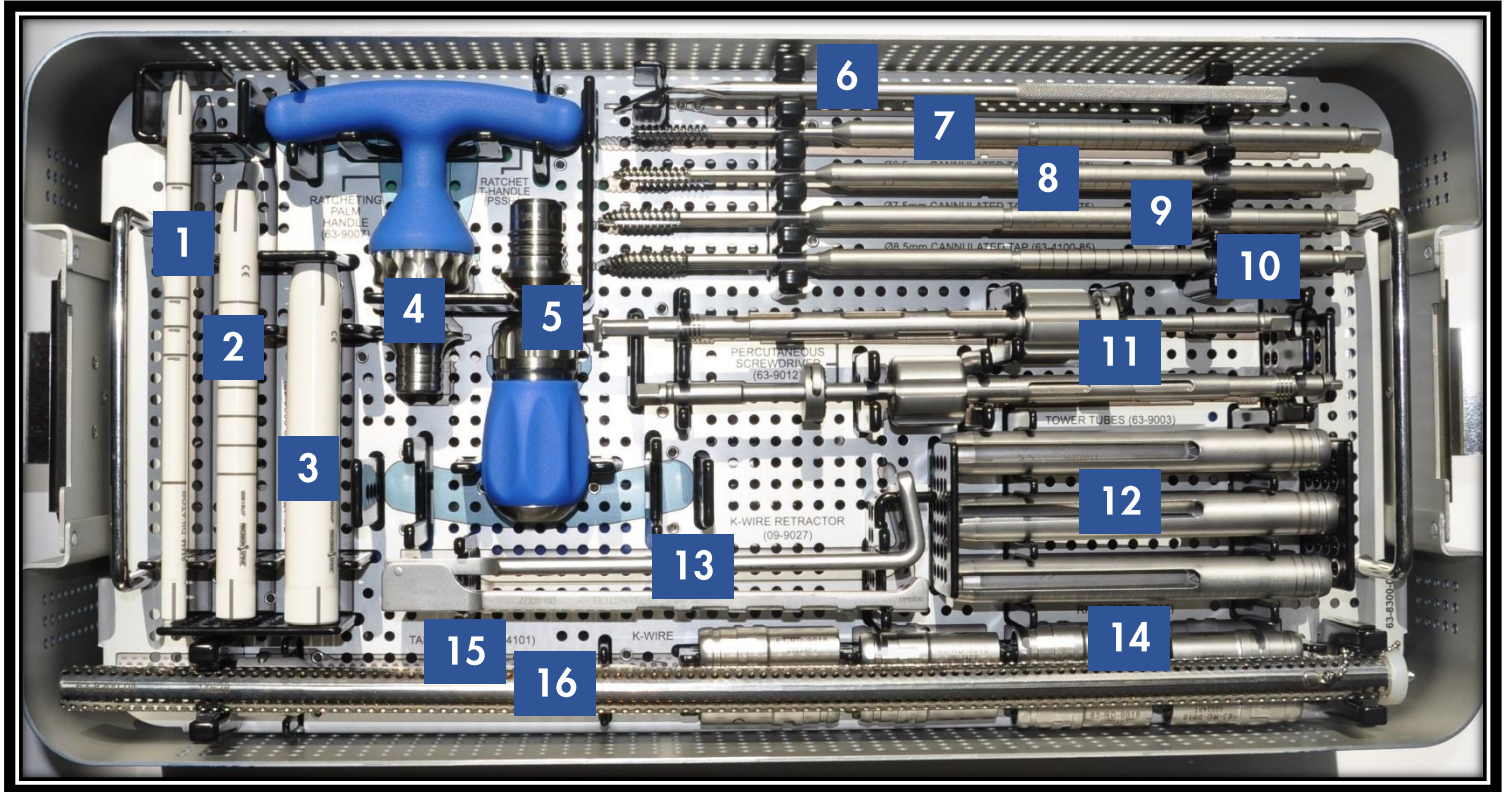
SureLOK™ MIS 3L Implant Tray 63-8700-CA-01 (Center Load)



Part #	Description	Qty.	Part #	Description	Qty.
63-CP-5535	MIS 3L Pedicle Screw, 5.5 x 35mm	6	63-ST-5055	Straight Ti CL Rod 55mm	2
63-CP-5540	MIS 3L Pedicle Screw, 5.5 x 40mm	8	63-ST-5060	Straight Ti CL Rod 60mm	2
63-CP-5545	MIS 3L Pedicle Screw, 5.5 x 45mm	8	63-ST-5065	Straight Ti CL Rod 65mm	2
63-CP-5550	MIS 3L Pedicle Screw, 5.5 x 50mm	8	63-ST-5070	Straight Ti CL Rod 70mm	2
63-CP-5555	MIS 3L Pedicle Screw, 5.5 x 55mm	6	63-ST-5075	Straight Ti CL Rod 75mm	2
63-CP-8535	MIS 3L Pedicle Screw, 8.5 x 35mm	6	63-ST-5080	Straight Ti CL Rod 80mm	2
63-CP-8540	MIS 3L Pedicle Screw, 8.5 x 40mm	8	63-ST-5090	Straight Ti CL Rod 90mm	2
63-CP-8545	MIS 3L Pedicle Screw, 8.5 x 45mm	8	63-ST-5100	Straight Ti CL Rod 100mm	2
63-CP-8550	MIS 3L Pedicle Screw, 8.5 x 50mm	8	63-ST-5110	Straight Ti CL Rod 110mm	2
63-CP-8555	MIS 3L Pedicle Screw, 8.5 x 55mm	6	63-ST-5120	Straight Ti CL Rod 120mm	2
63-ST-5035	Straight Ti CL Rod 35mm	2	63-ST-5130	Straight Ti CL Rod 130mm	2
63-ST-5040	Straight Ti CL Rod 40mm	2	63-ST-5140	Straight Ti CL Rod 140mm	2
63-ST-5045	Straight Ti CL Rod 45mm	2	63-ST-5150	Straight Ti CL Rod 150mm	2
63-ST-5050	Straight Ti CL Rod 50mm	2			

SureLOK™ MIS 3L Instrument Tray 63-8300-CA-01 (Center Load)

Top Level

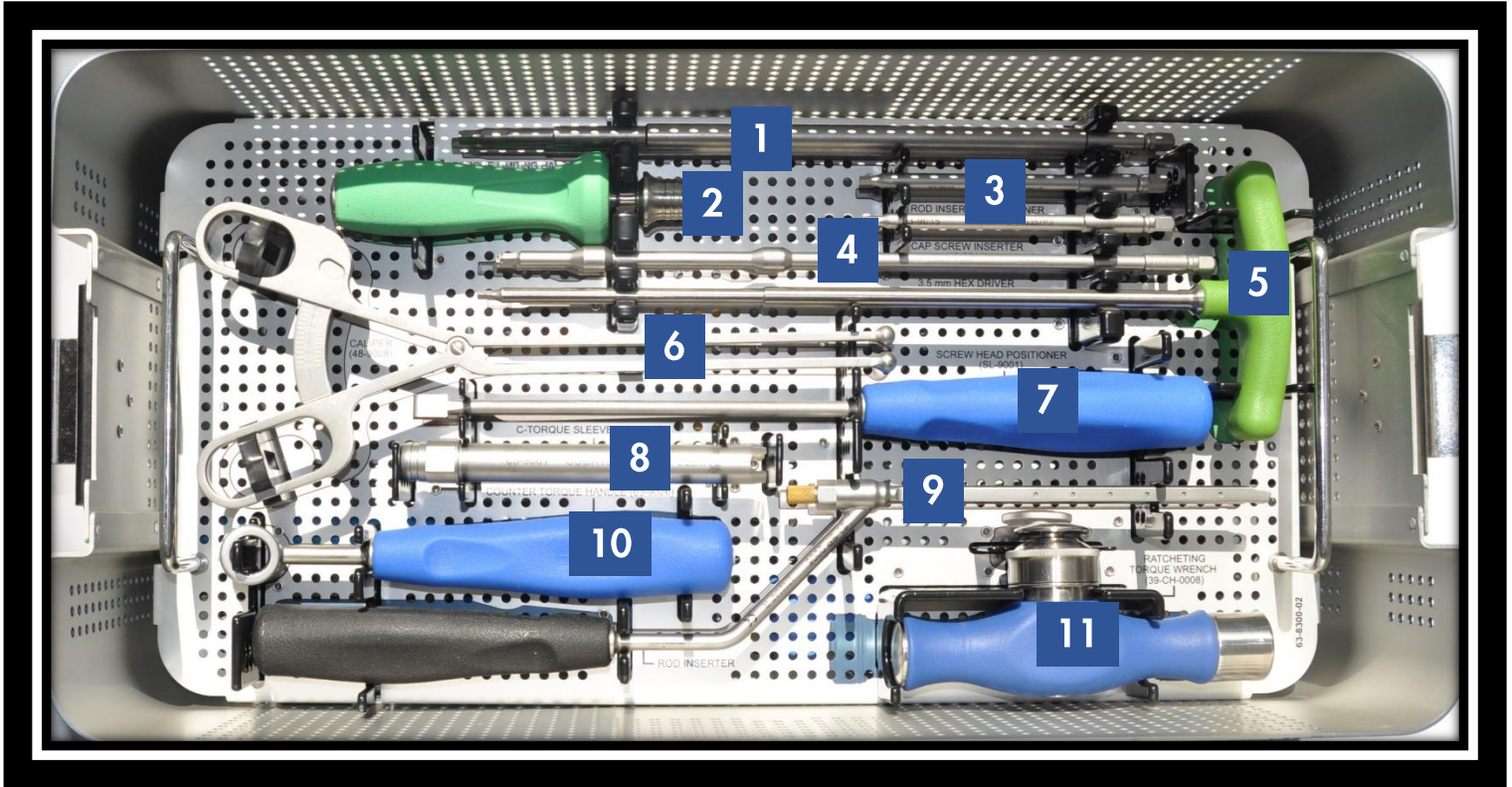


#	Part No.	Description	Qty.
1.	63-9038-08	Dilator, 08mm	1
2.	63-9038-13	Dilator, 13mm	1
3.	63-9038-18	Dilator, 18mm	1
4.	PSSRT	Ratchet T-Handle	1
5.	63-9007	Ratcheting Palm Handle	1
6.	09-9029	Tissue Cutter	1
7.	63-4100-55	Bifurcated Tap, 5.5mm (0.5mm undersized)	1
8.	63-4100-65	Bifurcated Tap, 6.5mm (0.5mm undersized)	1
9.	63-4100-75	Bifurcated Tap, 7.5mm (0.5mm undersized)	1
10.	63-4100-85	Bifurcated Tap, 8.5mm (0.5mm undersized)	1
11.	63-9012	Percutaneous Screwdriver, Short, 3.5mm Hex	2
12.	63-9003	Tower Tubes	6
13.	09-9027	Guide Wire Inserter/Extractor	1
14.	63-RD-9018	Ring (Bottle Cap)	8
15.	63-4101	Tap Dilator	1
16.	HXI-48-0002	18" x 1.6mm K-Wire - Nitinol Trocar/Threaded	*
	HXI-48-0003	18" x 1.6mm K-Wire - Nitinol Blunt/Threaded	10
	HXI-48-0004	18" x 1.6mm K-Wire - SS Trocar/Threaded	*
	HXI-48-0005	18" x 1.6mm K-Wire - SS Blunt/Threaded	*

*Upon Request

SureLOK™ MIS 3L Instrument Tray 63-8300-CA-01 (Center Load)

Middle Level

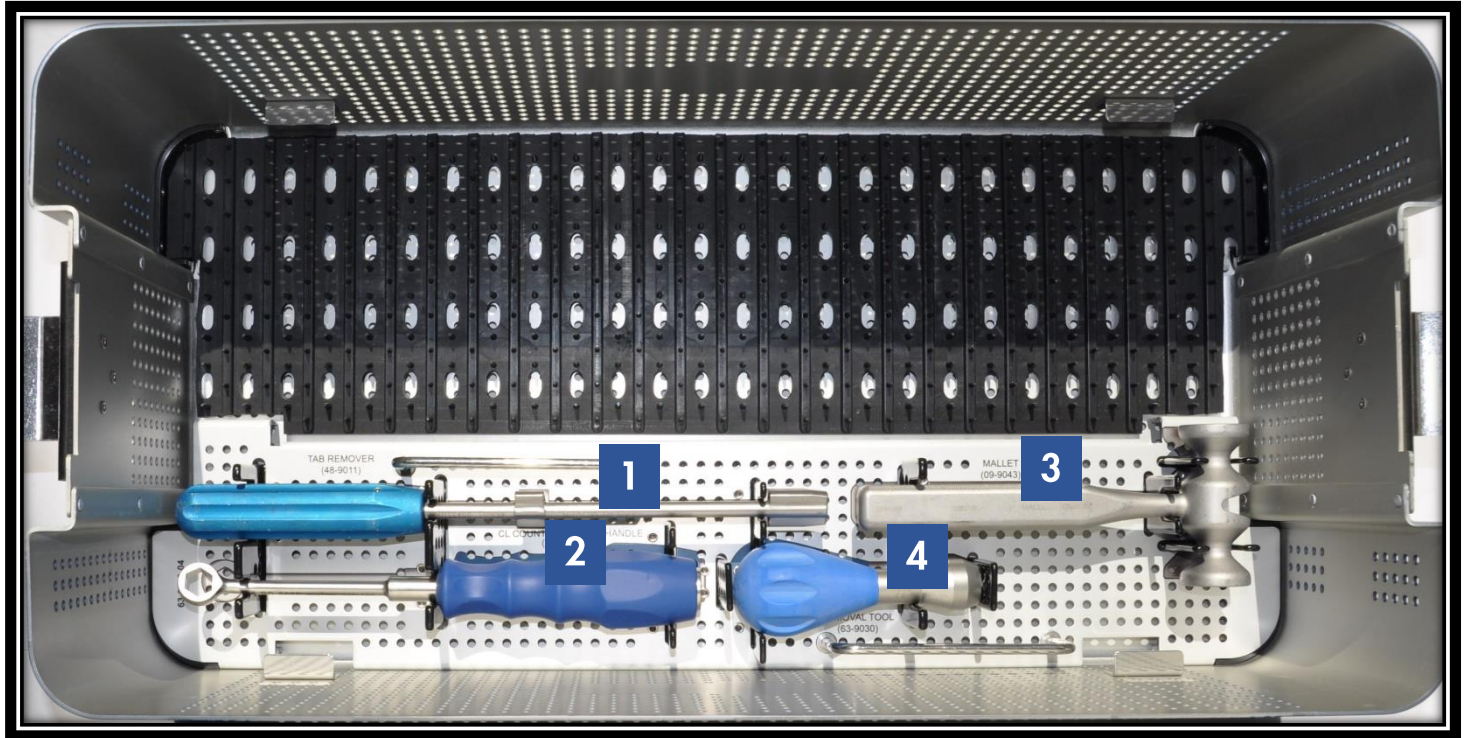


#	Part No.	Description	Qty.
1.	63-9015	Torque Drive Shaft, 4.5mm Hex	1
2.	04-9075	Torque Limiting Handle (Rod Inserter, 18in-lb)	1
3.	63-9035	Rod Inserter Tightener Shaft, 3.5mm Hex	2
4.	48-9014	Cap Screw Inserter, 4.5mm Hex	1
5.	PSSTPS	Screw Height Adjuster, 3.5mm Hex	1
6.	48-9008	Caliper	1
7.	SL-9001	Head Positioner	1
8.	63-9001	Counter Torque, Sleeve	1
9.	63-SP-9005	CL Rod Inserter, (Center Load)	1
10.	63-9026	Counter Torque Handle	1
11.	39-CH-0008	Ratcheting Torque Handle, 106 in-lbs	1

SureLOK™ MIS 3L Instrument Tray

63-8300-CA-01 (Center Load)

Bottom Level



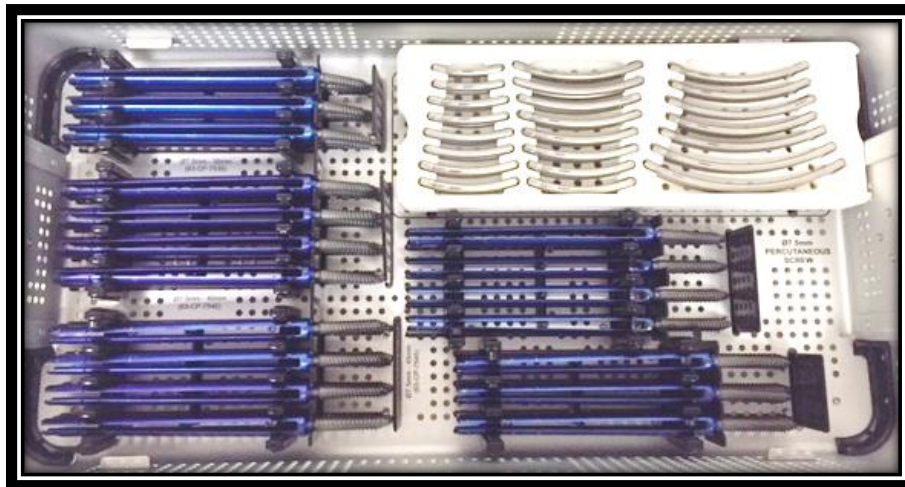
#	Part No.	Description	Qty.
1.	48-9011	Tab Remover	1
2.	63-RD-9005	Counter Torque Handle (for CL Rod Inserter)	1
3.	09-9043	Mallet	1
4.	63-9030	Tower Tube Removal Tool	1

Special Order Only – Not Included in the Standard Tray

Part No.	Description
63-0315	Reduction Driver Handle
63-RD-0312	Reducer Dock
63-RD-0321	Reduction Driver
63-RD-0040	Compression/Distracton Straight Arm A
63-RD-0041	Compression/Distracton Arm B1 (Silver)
63-RD-0042	Compression/Distracton Arm B2 (Gold)

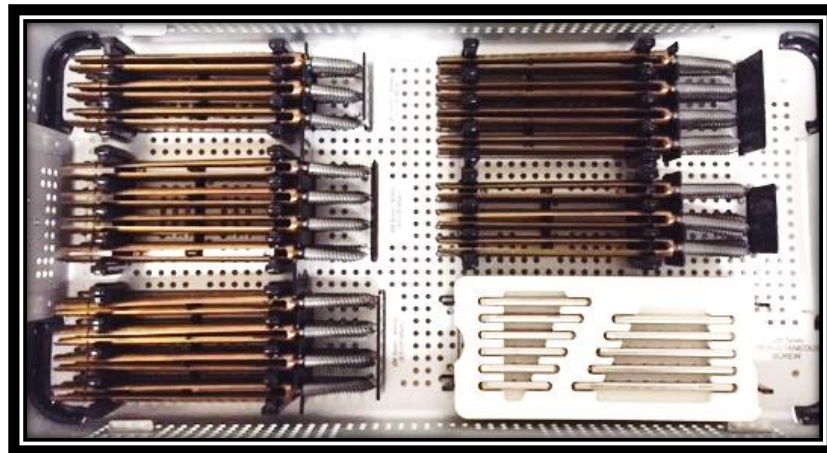
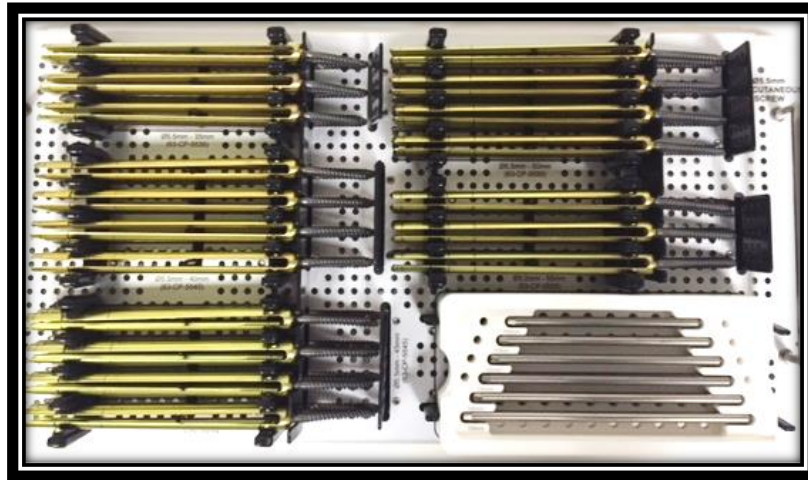


SureLOK™ MIS 3L Implant Tray 63-8600-CA-02 (Side Load)



Part #	Description	Qty.	Part #	Description	Qty.
63-CP-6535	MIS 3L Pedicle Screw, 6.5 x 35mm	6	48-CU-55035	Lordotic Ti SL Rod 35mm	4
63-CP-6540	MIS 3L Pedicle Screw, 6.5 x 40mm	8	48-CU-55040	Lordotic Ti SL Rod 40mm	4
63-CP-6545	MIS 3L Pedicle Screw, 6.5 x 45mm	8	48-CU-55045	Lordotic Ti SL Rod 45mm	4
63-CP-6550	MIS 3L Pedicle Screw, 6.5 x 50mm	8	48-CU-55050	Lordotic Ti SL Rod 50mm	4
63-CP-6555	MIS 3L Pedicle Screw, 6.5 x 55mm	6	48-CU-55055	Lordotic Ti SL Rod 55mm	4
			48-CU-55060	Lordotic Ti SL Rod 60mm	4
63-CP-7535	MIS 3L Pedicle Screw, 7.5 x 35mm	6	48-CU-55065	Lordotic Ti SL Rod 65mm	4
63-CP-7540	MIS 3L Pedicle Screw, 7.5 x 40mm	8	48-CU-55070	Lordotic Ti SL Rod 70mm	4
63-CP-7545	MIS 3L Pedicle Screw, 7.5 x 45mm	8	48-CU-55075	Lordotic Ti SL Rod 75mm	4
63-CP-7550	MIS 3L Pedicle Screw, 7.5 x 50mm	8	48-CU-55080	Lordotic Ti SL Rod 80mm	4
63-CP-7555	MIS 3L Pedicle Screw, 7.5 x 55mm	6	48-CU-55090	Lordotic Ti SL Rod 90mm	2
			48-CU-55100	Lordotic Ti SL Rod 100mm	2
			48-CU-55110	Lordotic Ti SL Rod 110mm	2
			SL1000	S-Lok Cap Screw, 4.5mm Hex	21

SureLOK™ MIS 3L Implant Tray 63-8700-CA-02 (Side Load)

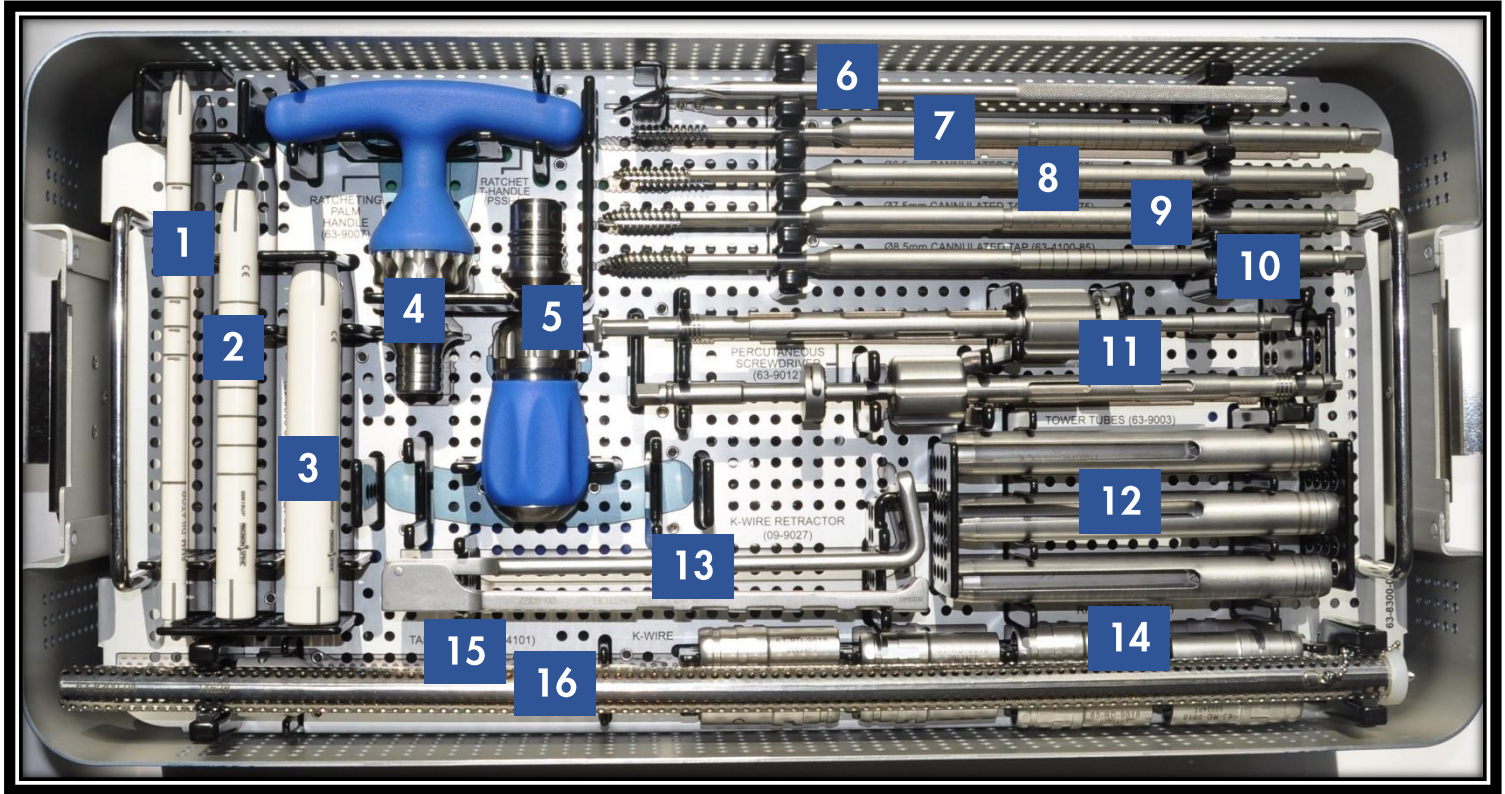


Part #	Description	Qty.	Part #	Description	Qty.
63-CP-5535	MIS 3L Pedicle Screw, 5.5 x 35mm	6	48-ST-55055	Straight Ti SL Rod 55mm	2
63-CP-5540	MIS 3L Pedicle Screw, 5.5 x 40mm	8	48-ST-55060	Straight Ti SL Rod 60mm	2
63-CP-5545	MIS 3L Pedicle Screw, 5.5 x 45mm	8	48-ST-55065	Straight Ti SL Rod 65mm	2
63-CP-5550	MIS 3L Pedicle Screw, 5.5 x 50mm	8	48-ST-55070	Straight Ti SL Rod 70mm	2
63-CP-5555	MIS 3L Pedicle Screw, 5.5 x 55mm	6	48-ST-55075	Straight Ti SL Rod 75mm	2
63-CP-8535	MIS 3L Pedicle Screw, 8.5 x 35mm	6	48-ST-55080	Straight Ti SL Rod 80mm	2
63-CP-8540	MIS 3L Pedicle Screw, 8.5 x 40mm	8	48-ST-55090	Straight Ti SL Rod 90mm	2
63-CP-8545	MIS 3L Pedicle Screw, 8.5 x 45mm	8	48-ST-55100	Straight Ti SL Rod 100mm	2
63-CP-8550	MIS 3L Pedicle Screw, 8.5 x 50mm	8	48-ST-55110	Straight Ti SL Rod 110mm	2
63-CP-8555	MIS 3L Pedicle Screw, 8.5 x 55mm	6	48-ST-55120	Straight Ti SL Rod 120mm	2
48-ST-55035	Straight Ti SL Rod 35mm	2	48-ST-55130	Straight Ti SL Rod 130mm	2
48-ST-55040	Straight Ti SL Rod 40mm	2	48-ST-55140	Straight Ti SL Rod 140mm	2
48-ST-55045	Straight Ti SL Rod 45mm	2	48-ST-55150	Straight Ti SL Rod 150mm	2
48-ST-55050	Straight Ti SL Rod 50mm	2			

SureLOK™ MIS 3L Instrument Tray

63-8300-CA-02 (Side Load)

Top Level

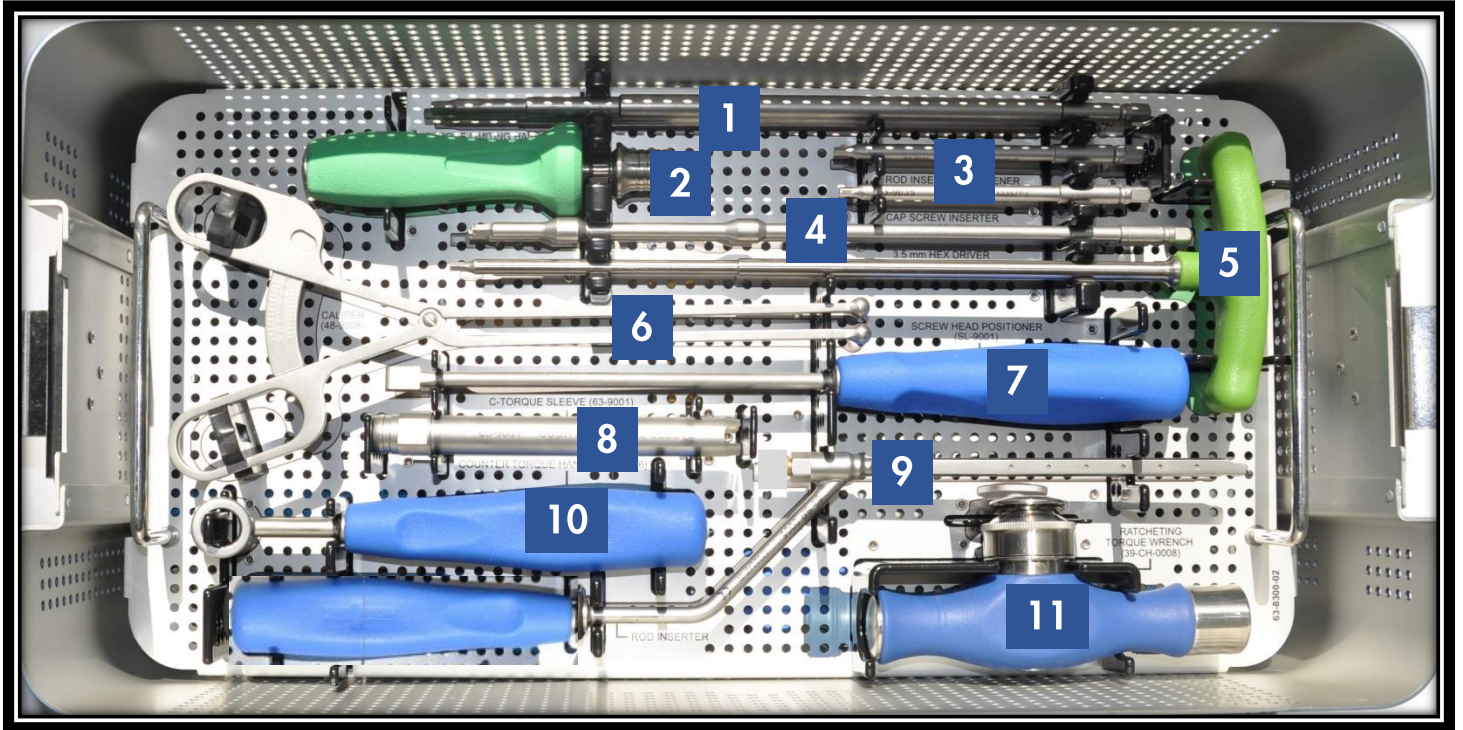


#	Part No.	Description	Qty.
1.	63-9038-08	Dilator, 08mm	1
2.	63-9038-13	Dilator, 13mm	1
3.	63-9038-18	Dilator, 18mm	1
4.	PSSRT	Ratchet T-Handle	1
5.	63-9007	Ratcheting Palm Handle	1
6.	09-9029	Tissue Cutter	1
7.	63-4100-55	Bifurcated Tap, 5.5mm (0.5mm undersized)	1
8.	63-4100-65	Bifurcated Tap, 6.5mm (0.5mm undersized)	1
9.	63-4100-75	Bifurcated Tap, 7.5mm (0.5mm undersized)	1
10.	63-4100-85	Bifurcated Tap, 8.5mm (0.5mm undersized)	1
11.	63-9012	Percutaneous Screwdriver, Short, 3.5mm Hex	2
12.	63-9003	Tower Tubes	6
13.	09-9027	Guide Wire Inserter/Extractor	1
14.	63-RD-9018	Ring (Bottle Cap)	8
15.	63-4101	Tap Dilator	1
16.	HXI-48-0002	18" x 1.6mm K-Wire - Nitinol Trocar/Threaded	*
	HXI-48-0003	18" x 1.6mm K-Wire - Nitinol Blunt/Threaded	10
	HXI-48-0004	18" x 1.6mm K-Wire - SS Trocar/Threaded	*
	HXI-48-0005	18" x 1.6mm K-Wire - SS Blunt/Threaded	*

*Upon Request

SureLOK™ MIS 3L Instrument Tray 63-8300-CA-02 (Side Load)

Middle Level

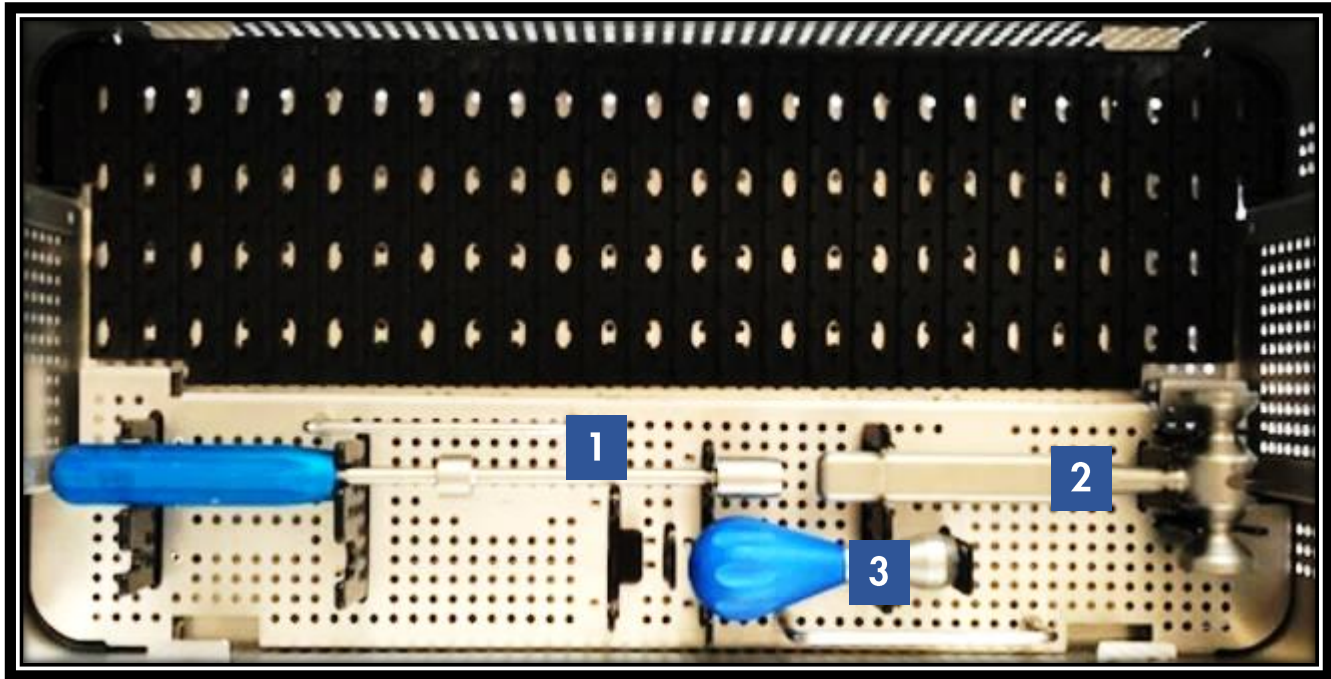


#	Part No.	Description	Qty.
1.	63-9015	Torque Drive Shaft, 4.5mm Hex	1
2.	04-9075	Torque Limiting Handle (Rod Inserter, 18in-lb)	1
3.	63-9035	Rod Inserter Tightener Shaft, 3.5mm Hex	2
4.	48-9014	Cap Screw Inserter, 4.5mm Hex	1
5.	PSSTPS	Screw Height Adjuster, 3.5mm Hex	1
6.	48-9008	Caliper	1
7.	SL-9001	Head Positioner	1
8.	63-9001	Counter Torque, Sleeve	1
9.	63-9005	SL Rod Inserter, Side Load	1
10.	63-9026	Counter Torque Handle	1
11.	39-CH-0008	Ratcheting Torque Handle, 106 in-lbs	1

SureLOK™ MIS 3L Instrument Tray

63-8300-CA-02 (Side Load)

Bottom Level



#	Part No.	Description	Qty.
1.	48-9011	Tab Remover	1
2.	09-9043	Mallet	1
3.	63-9030	Tower Tube Removal Tool	1

Special Order Only – Not Included in the Standard Tray

Part No.	Description
63-0315	Reduction Driver Handle
63-RD-0312	Reducer Dock
63-RD-0321	Reduction Driver
63-RD-0040	Compression/Distracton Straight Arm A
63-RD-0041	Compression/Distracton Arm B1 (Silver)
63-RD-0042	Compression/Distracton Arm B2 (Gold)



SURGICAL TECHNIQUE

1

PATIENT POSITIONING

The patient is positioned prone. The patient is then prepared and draped in a conventional manner. Utilizing anterior/posterior and lateral fluoroscopic imaging and palpation of the patient's appropriate landmarks, the targeted pedicles are located and marked on the patient's skin (Figure 1).

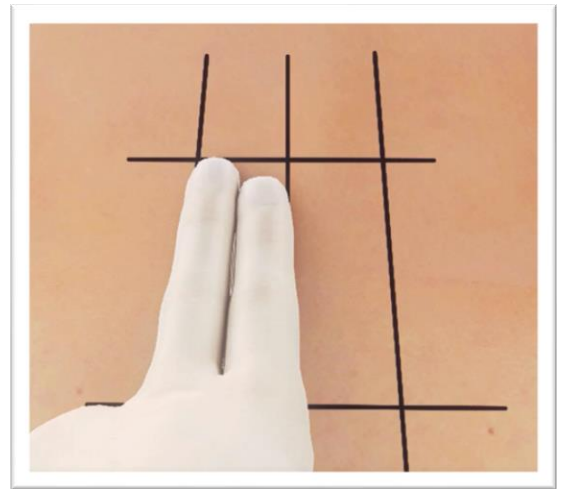


Figure 1

2

SKIN INCISION

A skin incision and fascia release of about 1.5cm is made with a knife blade at the location of the marks on the patient's skin. A Jamshidi is advanced through the skin incision and docked onto the targeted pedicle (Figure 2 & 2a). The placement of the Jamshidi is verified with fluoroscopic imaging.

- 74174-01M * - Jamshidi 8 ga x 6 in. Trocar and Bevel Tip Stylets
- 74066-15M * - Jamshidi 11ga x 4.5 in. Trocar Tip Stylet
- 74182-01M * - Jamshidi 13 ga x 4.5 in. Trocar Tip Stylet
- 74182-02M * - Jamshidi 13 ga x 4.5 in Trocar and Bevel Tip Stylets

Once proper trajectory and docking of the Jamshidi is confirmed, the trocar needle is removed and replaced by the Guide Wire (Figure 3 & 3a).

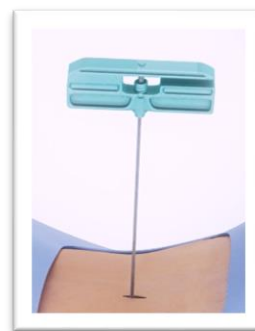


Figure 2

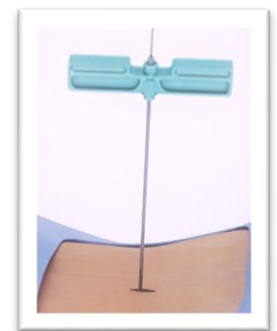


Figure 3

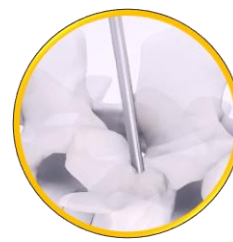


Figure 2a



Figure 3a

Nitinol

- HXI-48-0002 * - Trocar Tip/Threaded 18" x 1.6mm
- HXI-48-0003 - Blunt Tip/Threaded 18" x 1.6mm (Std.)

Stainless Steel

- HXI-48-0004 * - Trocar Tip/Threaded 18" x 1.6mm
- HXI-48-0005 * - Blunt Tip/Threaded 18" x 1.6mm

*By request only

SURGICAL TECHNIQUE

3

PEDICLE PREPARATION

Place the 8mm Dilator (63-9038-08) over the Guide Wire down to the spine (Figure 4 & 4a). Slide the 13mm Dilator (63-9038-13) over the 8mm Dilator to sequentially penetrate and gently dissect soft tissue down to the pedicle (Figure 5). Slide the 18mm Dilator (63-9038-18) (Figure 6).

Remove the 8mm Dilator leaving the 13mm and 18 mm Dilators over the Guide Wire. Select the appropriate sized Tap (63-4100-XX) that matches the screw diameter that will be implanted. Assemble either the Ratcheting Palm Handle (63-9007) or the Ratcheting T-Handle (PSSRT) onto the Tap. Advance the tap assembly over the guide wire and tap the pedicle (Figure 7 & 7a). **The Taps are .5mm undersized. It is not recommended to under tap.**

There are measurements on the Tap to indicate the appropriate screw length. The Dilator must be in contact with the pedicle bone surface to achieve an accurate measurement. After completion of the tapping procedure remove the tap and the 13mm Dilator, leaving the Guide Wire and the 18mm Dilator in place.



Figure 4



Figure 4a



Figure 5



Figure 6



Figure 7



Figure 7a

SURGICAL TECHNIQUE

3

PEDICLE PREPARATION (Optional)

Select the appropriate sized Tap (63-4100-XX) that matches the screw diameter that will be implanted. Assemble either the Ratcheting Palm Handle (63-9007) or the Ratcheting T-Handle (PSSRT) onto the Tap (Figure 8). Insert the Tap into the Tap Dilator (63-4101) while depressing the Release Button (Figure 9). Once the Tap is partially inserted into the dilator, you can take your thumb off the Release Button and advance the Tap until it stops at the zero position. Inspect the tip of the Tap to ensure that it is protruding from the Tap Dilator.

Place the Tap Dilator assembly over the guidewire and advance it through the tissue using a twisting motion (Figure 10). Once the Tap engages the pedicle, depress the release button and begin tapping the pedicle (Figure 11). **The Taps are 0.5mm undersized. It is not recommended to under tap.**

There are measurements on the Tap to indicate the appropriate screw length. The Tap Dilator Sleeve must be in contact with the pedicle surface to achieve an accurate measurement.



Figure 8

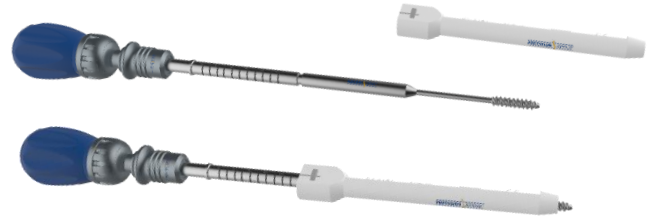


Figure 9

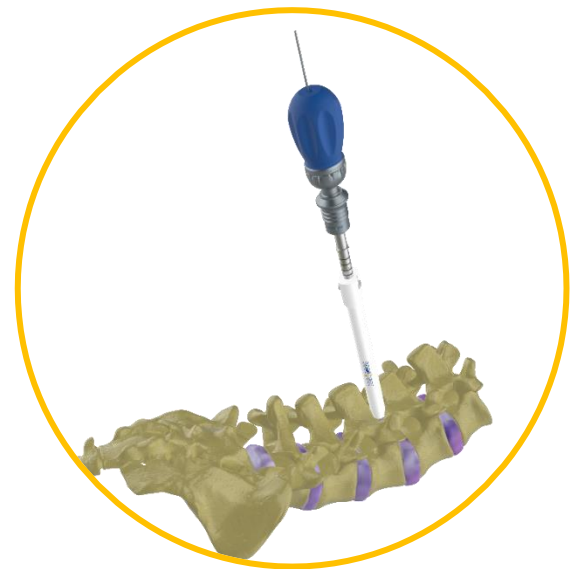


Figure 10

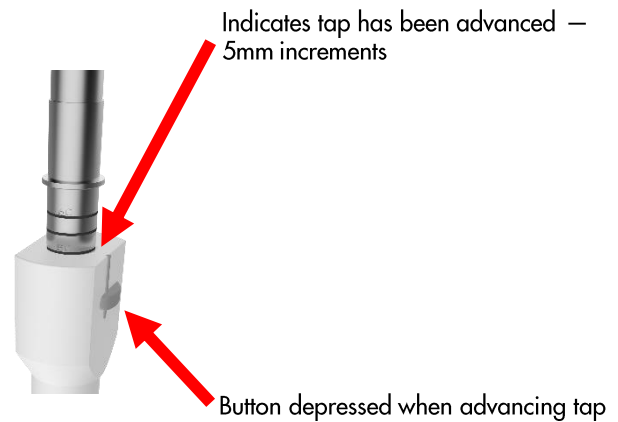


Figure 11

SURGICAL TECHNIQUE

4

DRIVER/SCREW ASSEMBLY

With the pedicle pathway prepared and appropriate screw length and diameter determined, attach the Cannulated Percutaneous Screw Driver (63-9012) to either the Ratcheting Palm Handle (63-9007) or the Ratcheting T-Handle (PSSRT)

The Handle should be towards the floor and the plunger should be facing the ceiling. Depress the plunger towards the Blue Handle and insert the Cannulated Polyaxial Screw Driver. Confirm that the driver is fully seated in the appropriate handle and will not disengage without depressing the plunger.

To provide additional stability to the MIS 3L Extended Tab Tulip, either the Ring (63-9018) or the Tower Tube (63-9003) can be placed over the extended tab tulip.

To insert the Ring, ensure that the arrow on the inside of the Ring is pointing down and is aligned with the opening of the tulip's rod slot. Place the Ring over the tulip and push down until it engages with the detent on the tulip (Figure 12).

To insert the Tower Tube, align the tube's rod slot with the tulip's rod slot and advance the tube until it is fully seated and the tube's inner tabs engage with the proximal window of the tulip (Figure 13).

Attach the Screw Assembly to the Polyaxial Screw Driver (63-9012). 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. Load the hex tip portion of the Polyaxial Screw Driver into the appropriate screw. Ensure that the male hex head of the Driver is fully seated in the female hex of the screw head (Figure 14). This can be verified by attempting to angulate the screw relative to the tulip head.

NOTE:

The Ring (63-RD-9018) and Tower Tube (63-9003) are NOT COMPATIBLE with the 18mm Dilator (63-9038-18).

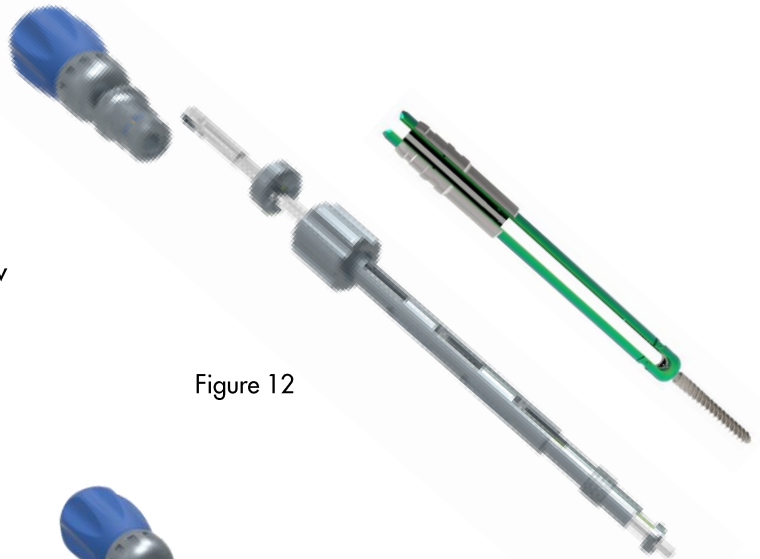


Figure 12

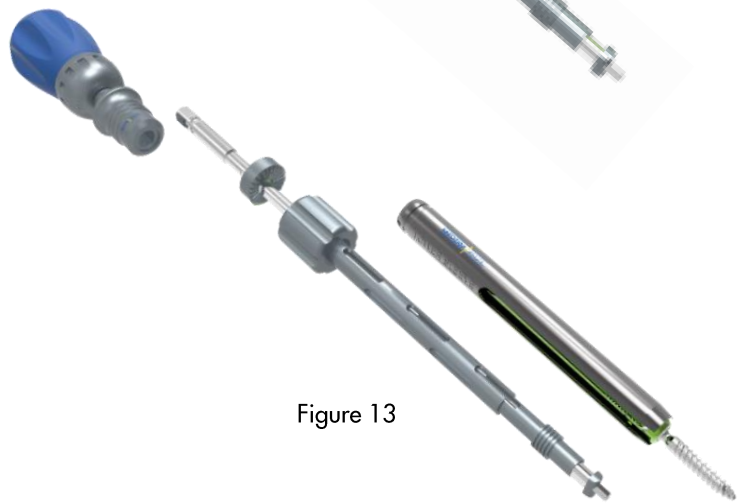


Figure 13



Figure 14

SURGICAL TECHNIQUE

4

DRIVER/SCREW ASSEMBLY (Continued)

With the Screw Driver assembly in the same orientation and the screw head firmly seated on the driver, thread the Screw Driver into the tulip until fully engaged and the rod slot is flush with the convex portion of the driver tip (Figure 15).

Advance the locking coupler until it is flush with the base of the screw driver locking sleeve. Ensure the coupler clicks into position (Figure 16 & 17). The Screw Driver will not disengage from the screw while the locking coupler is in this position.



Figure 15

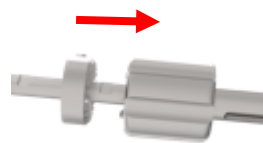


Figure 16



Figure 17

5

SCREW INSERTION

While using fluoroscopic imaging, advance the Screw Inserter assembly over the guide wire, through the pedicle and into the vertebral body (Figure 18).

To implant screws into adjacent level(s), repeat the procedural steps for planning, incision, exposure and pedicle preparation/screw placement as outlined.

NOTE:

The Ring (63-RD-9018) and Tower Tube (63-9003) are NOT COMPATIBLE with the 18mm Dilator (63-9038-18).

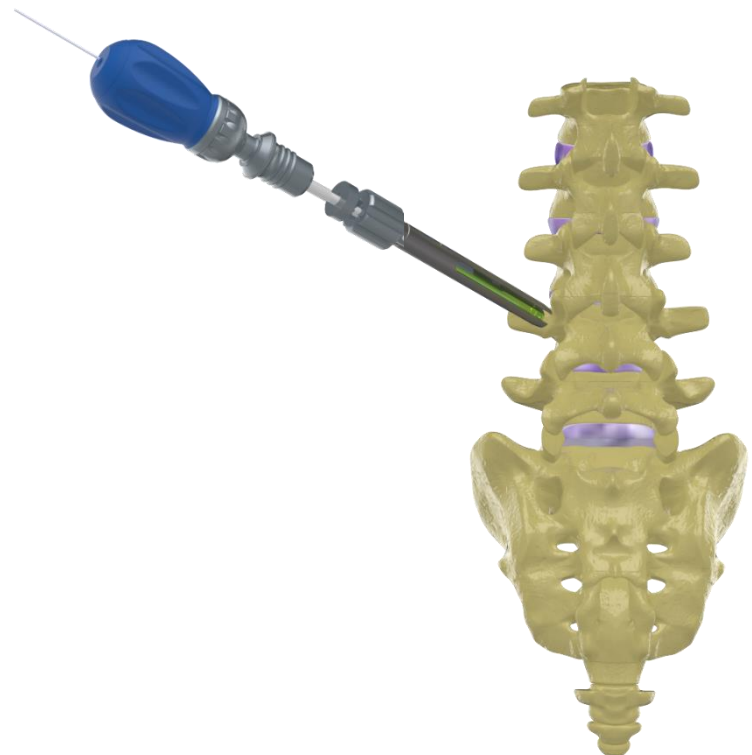


Figure 18

SURGICAL TECHNIQUE

6

GUIDE WIRE REMOVAL

After confirming that the screws are in the proper position, remove the Guide Wire, Screw Driver, and Dilator, leaving the Polyaxial Screws in place (Figure 19).

NOTE: If the Guide Wire is deformed or damaged, it should not be re-used.

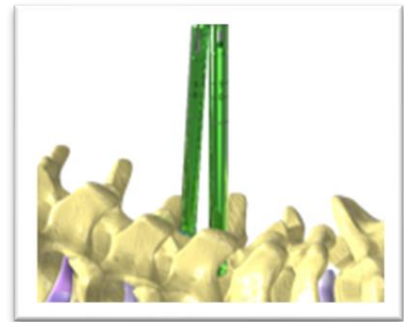


Figure 19

7

ROD SELECTION

If necessary, use the 3.5mm Screw Height Adjuster (PSSTPS) to adjust the height of the tulips to the desired position. Place the distal ends of the Rod Caliper (48-9008) into the extended tab tulip heads and measure the appropriate rod length (Figure 20 & 21). The Rod measurement that is indicated on the Caliper includes the recommended amount of rod overhang for the bulleted and hex ends.

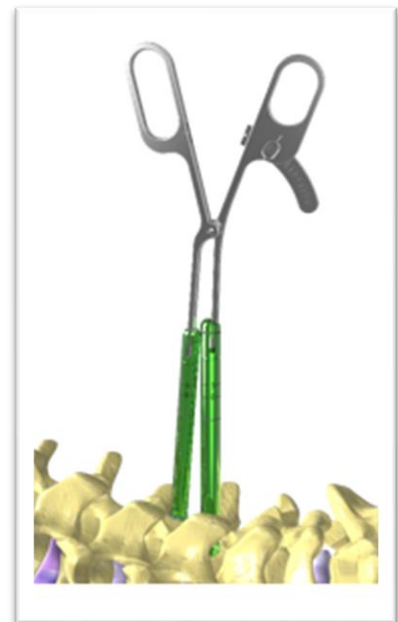


Figure 20



Figure 21

SURGICAL TECHNIQUE

8

ROD INSERTION

Loosen the knob on the Rod Inserter (63-9005 or 63-SP-9005) and insert the distal end of the appropriate rod design and rod length into the distal hex opening of the Inserter (Figure 22 and 22A). Attach the Torque Limiting Handle (04-9075) to the Torque Drive Shaft (63-9035). Secure the rod by tightening the Rod Inserter knob (Figure 23) until an audible click is heard.



Figure 22
Center Load



Figure 22A
Side Load

Figure 23

SURGICAL TECHNIQUE

8

ROD INSERTION

Place the Rod Inserter assembly parallel to the patient, in between the Extended Tab Tulips, and insert the rod into the skin incision. Slowly advance the Rod *in-situ* while arching the Rod Inserter handle cephalad (Figure 24). Confirm proper rod placement via intraoperative fluoroscopy or by placing the 8mm Dilator into the extended tab tulip (Figure 25). If the horizontal etched line on the dilator is above the top of the tulip, then the rod is within the tulip's rod slot.

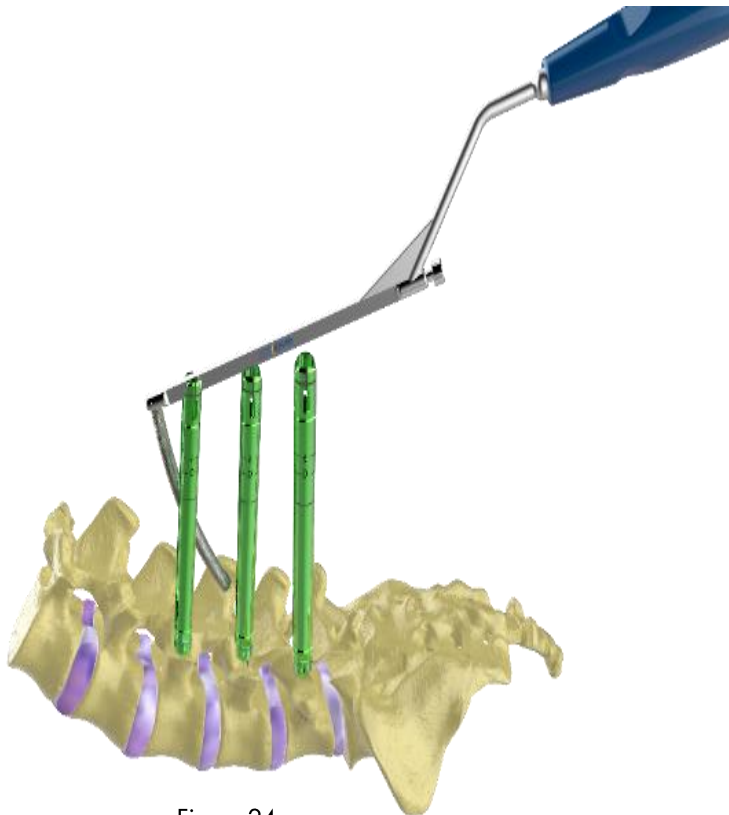


Figure 24



Figure 25

SURGICAL TECHNIQUE

9

CAP SCREW INSERTION

Assemble either the Ratcheting Palm Handle (63-9007) or the Ratcheting T Handle (PSSRT) onto the Cap Screw Inserter (48-9014). Insert the Cap Screw (SL1000) onto the tip of the Cap Screw Inserter (Figure 26). Insert the assembly through the Extended Tab and thread the Cap Screw into the tulip (Figure 27).

NOTE: Excessive force can damage the tip of the Cap Screw Inserter. After Cap Screw insertion, remove the Cap Screw Inserter. Repeat for subsequent screws.

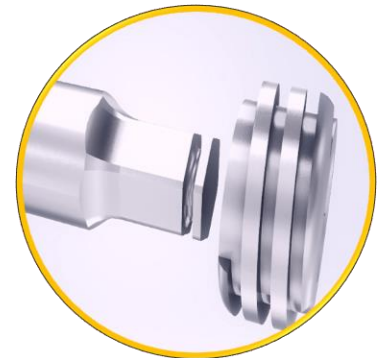


Figure 26

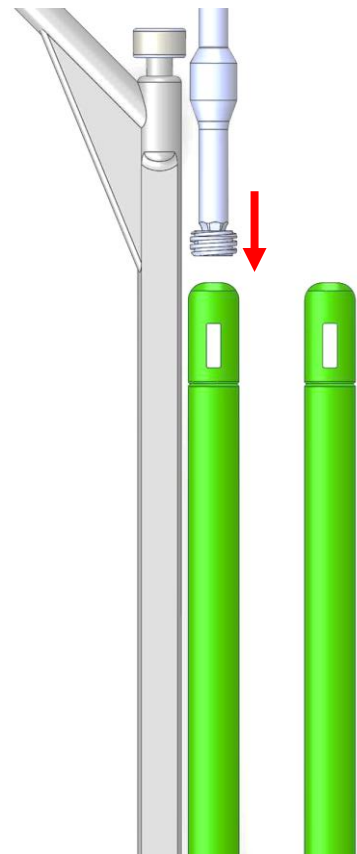


Figure 27

SURGICAL TECHNIQUE

10 ROD REDUCTION (Optional)

If the Tower Tubes (63-9003) are used, remove them from the extended tab tulip. **While pulling upwards on the Tower Tube**, place downward pressure to insert the Tower Tube Removal Tool (63-9030) until it is fully seated (Figure 28 & 28A). Pull up on the removal tool, removing both the Tower Tubes from the extended tab tulip (Figure 28B).

Insert the Ring (63-RD-9018) over the extended tab tulip. Ensure that the arrow on the inside of the Ring is pointing down and is aligned with the opening of the tulip's rod slot. Place the Ring over the tulip and push down until it engages with the detent on the tulip (Figure 29).

Place the Dock (63-RD-0312) over the Ring. Align the side of either the part number or the Precision Spine Logo with the Tab's rod slot and insert the Dock onto the Ring (Figure 31). Turn the Dock ¼ of turn in the Clockwise direction. (Figure 32)



Figure 28

Figure 28A

Figure 28B

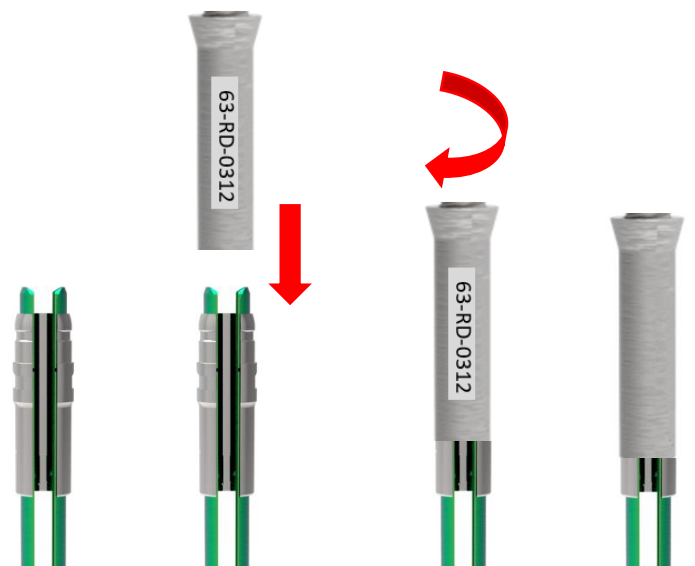


Figure 29

Figure 30

Figure 31

Figure 32

Special Order Only – Not Included in the Standard Tray

Part No.	Description
63-0315	Reduction Driver Handle
63-RD-0312	Reducer Dock
63-RD-0321	Reduction Driver

SURGICAL TECHNIQUE

10 ROD REDUCTION (Optional)

Insert the Locking Cap (SL-1000) onto the distal end of the Reduction Driver (63-RD-0321) (Figure 33)

Pull up on the small internal knob to the top of the upper black line to fully expose the internal shaft (Figure 34)

Insert the Reduction Driver Assembly into the Dock (Figure 35) and turn the large external knob Clockwise to reduce the Rod. When the proximal portion of the Reduction Driver touches the Dock, the Rod is fully reduced in the tulip (Figure 36). The Reduction Driver Handle (63-0315) can be used for additional ease in reducing the rod.

Push down on the small internal knob to ensure that the Cap Screw is seated on the internal threads of the extended tab tulip. Turn the small internal knob Clockwise to drive the Cap Screw (Figure 37). When the small internal knob reaches the distal black line, the Locking Cap is fully seated (Figure 38).

To remove the assembly, lift up on the small internal knob, turn the large external knob a couple of turns, turn the dock Counterclockwise ¼ of a turn and remove the Reduction Driver Assembly.

A maximum of 50mm of controlled rod reduction can be achieved via the Reduction Driver Assembly.



Figure 33



Figure 34



Figure 35



Figure 36



Figure 37



Figure 38

Special Order Only – Not Included in the Standard Tray

Part No.	Description
63-0315	Reduction Driver Handle
63-RD-0312	Reducer Dock
63-RD-0321	Reduction Driver

SURGICAL TECHNIQUE

11

FINAL TIGHTENING

Side Load & Center Load

Verify, under fluoroscopy that the position of the Screws and Rods are acceptable. Assemble the Counter Torque Handle (63-9026) to the Counter Torque Sleeve (63-9001) (Figure 39).

Place the Counter Torque Sleeve Assembly over the Extended Tab until it is fully seated over the Rod (Figure 40)

Assemble the Offset Ratcheting Torque Handle (39-CH-0008) to the Torque Drive Shaft (63-9015).

Insert the Torque Driver Assembly through the Extended Tab and seat the distal end of the driver into the Cap Screw. Turn the Offset Torque-Limiting Handle clockwise until an audible click is heard, verifying the final torque of 106 in-lbs. (Figure 41). Repeat for the remaining screws.

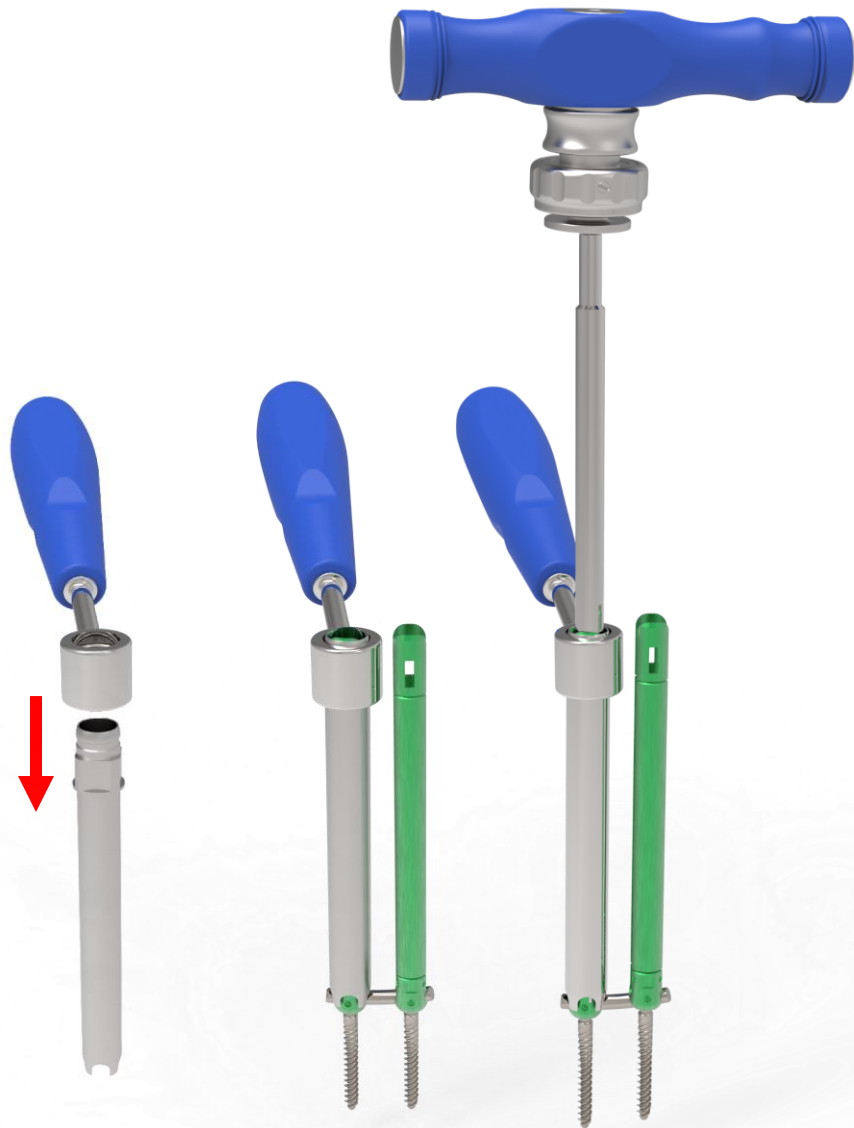


Figure 39

Figure 40

Figure 41

SURGICAL TECHNIQUE

11

FINAL TIGHTENING

Center Load Only

Verify, under fluoroscopy that the position of the Screws and Rods are acceptable. Assemble the Counter Torque Handle (63-RD-9005) to the Center Load Rod Inserter (63-SP-9005) (Figures 42 & 43).

Assemble the Ratcheting Torque Handle (39-CH-0008) to Torque Drive Shaft (63-9015).

Insert the Torque Driver Assembly through the Extended Tab and securely seat the distal end of the driver into the Cap Screw. Turn the Offset Torque-Limiting Handle clockwise until an audible click is heard, verifying the final torque of 106 in-lbs. (Figure 44). Repeat for the remaining screws.

Remove the Rod Inserter from the rod by inserting the Torque Limiting Handle/Driver assembly (04-9075 & 63-9035) into the Rod Inserter knob and turn the assembly counterclockwise a half of a turn to loosen (Figure 45). Remove the Handle/Driver assembly and completely loosen the knurled knob by hand. Remove the Rod Inserter from the rod.

NOTE: If the Gold Knob is turned too far counter clockwise, the Torque Limiting Handle/Driver Assembly will not be able to loosen the Gold Knob. Use the 3.5mm Hex Driver (PSSTPS) to further loosen the Gold Knob (Figure 46).



Figure 42



Figure 43



Figure 44



Figure 45



Figure 46

SURGICAL TECHNIQUE

12

Compression/Distriction (Optional)

With the pedicle screws and rod in place, final tighten the Cap Screw at the end of the construct. It is important to have the Rod Inserter connected and outside of the tulip to ensure that the appropriate screw/rod interface is established (Fig. 47). Ensure that the Cap Screw at the adjacent level is loosely affixed (not tightened).

Slide the Compression/Distriction Straight Arm A (63-RD-0040) over the most cephalad pedicle screw tulip in which the Cap Screw has been tightened (Fig. 48).

Ensure that the Straight Arm is fully seated by viewing the "0" mark on the tulip through the Arm's window (Fig. 49).

NOTE: Compression/Distriction Arm A should always be positioned first.

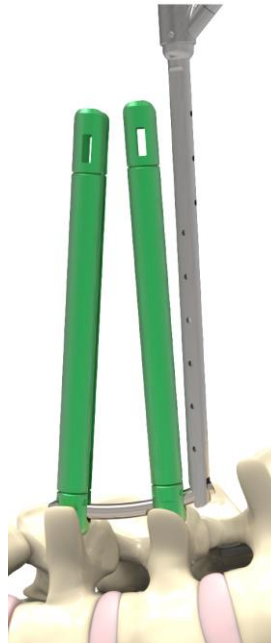


Figure 47



Figure 48

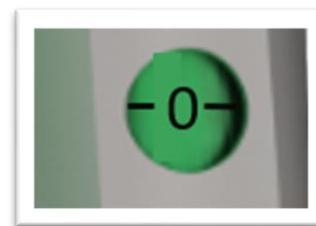


Figure 49

Special Order Only – Not Included in the Standard Tray

Part No.	Description
63-RD-0040	Compression Distriction Straight Arm A
63-RD-0041	Compression/Distriction Arm B1 (Silver)
63-RD-0042	Compression/Distriction Arm B2 (Gold)

SURGICAL TECHNIQUE

12

Compression/Distracton (Optional)

Insert the Torque Drive Shaft (63-9015) into the loosened Locking Cap (Fig. 50), then slide the Compression/Distracton Arm B1 (Silver) (63-RD-0041) or Arm B2 (Gold) (63-RD-0042) over the adjacent tulip (Fig. 51) and connect Arm B's Slot with Straight Arm A's knob (Fig. 52 & 52A).



Figure 50



Figure 51



Figure 52



Figure 52A

Special Order Only – Not Included in the Standard Tray

Part No.	Description
63-RD-0040	Compression Distracton Straight Arm A
63-RD-0041	Compression/Distracton Arm B1 (Silver)
63-RD-0042	Compression/Distracton Arm B2 (Gold)

SURGICAL TECHNIQUE

12

Compression/Distraction (Optional)

To compress, squeeze the two arms together (Fig. 53).
To distract, pull the two arms apart.

Once the position of the screw has been established,
final tighten the adjacent Cap Screw with the Torque
Driver Assembly.

The Counter Torque Handle (63-9026) can also be used
for additional stability by placing it over the hex on the
Silver/Gold Arm.



Figure 53

Special Order Only – Not Included in the Standard Tray

<u>Part No.</u>	<u>Description</u>
63-RD-0040	Compression Distraction Straight Arm A
63-RD-0041	Compression/Distraction Arm B1 (Silver)
63-RD-0042	Compression/Distraction Arm B2 (Gold)

SURGICAL TECHNIQUE

12

L5-S1 Compression/Distracton Arm Orientation

- **ALWAYS** ensure the most cephalad set screw is tightened, then place Compression/Distracton Straight Arm A (63-RD-0040) (Fig. 54) over that screw tower & orient the knob to face the opposite screw tower
- Use the matrix blow to ensure proper selection of the second arm for L5- S1 (Fig. 55)
- Choose the Silver or Gold Arm (63-RD-0041 or 63-RD-0042) based on the side of the patient that is being compressed and the position of the other tower in reference to the Straight Arm.



Figure 54

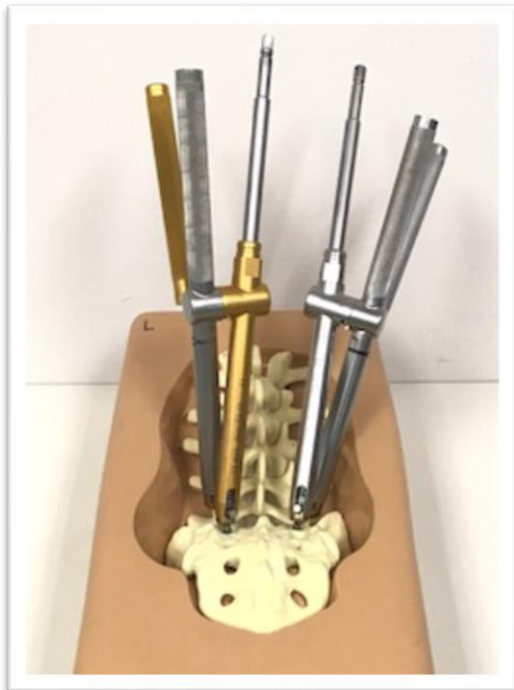


Figure 55

On Patient's
Left Side

On Patient's
Right Side

Caudal screw position
is **Lateral**

Silver Arm

Gold Arm

Caudal screw position
is **Medial**

Gold Arm

Silver Arm

Special Order Only – Not Included in the Standard Tray

Part No.	Description
63-RD-0040	Compression Distracton Straight Arm A
63-RD-0041	Compression Distracton Arm B1 (Silver)
63-RD-0042	Compression Distracton Arm B2 (Gold)

SURGICAL TECHNIQUE

13 REMOVAL OF THE EXTENDED TAB TULIP

Perform a final verification of the Polyaxial Screw and Rod positioning using fluoroscopy. Remove the Counter Torque Assembly. Break off the Extended Tabs of the Polyaxial Screws by inserting the Tab Remover (48-9011) over the Extended Tab until it is fully seated (Figure 56). Rock the Tab Remover in a medial-to-lateral motion until the Extended Tab portion is disassociated from the tulip. Repeat for remaining Polyaxial Screws.

14 IMPLANT REMOVAL

In order to remove the implants, attach the Torque Driver Shaft (63-9015) to the Ratchet T-Handle (PSSRT). Place the Counter Torque Sleeve (63-9001) over the Polyaxial Screw Tulip and down to the rod. Attach the Counter Torque Handle (63-9026) over the Sleeve. Insert the Torque Wrench Assembly through the sleeve, securely into the cap screw, and turn counterclockwise to loosen the Cap Screw. Remove Rods and use the 3.5mm Hex Driver (PSSTPS) to back out the screws from the pedicles.



Figure 56

Indications, Contraindications, Warnings, and Precautions

INDICATIONS:

The **SureLOK MIS 3L** Percutaneous 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 (pseudarthrosis).

The **SureLOK MIS 3L** Percutaneous 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; pseudarthrosis; and failed previous fusion.

PRECAUTIONS:

The **SureLOK MIS 3L** Percutaneous 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 MIS 3L** Percutaneous 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.

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, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). 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.



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