

## SURGICAL TECHNIQUE



PRECISION SPINE  
**SURELOK<sup>TM</sup>** MIS  
PERCUTANEOUS SCREW SYSTEM **3L**

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# SURELOK™ MIS 3L OVERVIEW

## 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 components are made from medical grade stainless steel, titanium or titanium alloy, which comply with such standards as ASTM F-138, ASTM F-136, ISO5832-1 or ISO5832-3. 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-017) for complete system description, indications and warnings.**



# SURELOK™ MIS 3L SYSTEM FEATURES

## MINIMALLY INVASIVE

- 150mm Extended Tab
- 14mm of controlled rod reduction

## EFFICIENT

- Triple Lead Thread

## SECURE

- Tapered Cortico-Cancellous Thread Form

## SCREW DIMENSIONS

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

## ROD DIMENSIONS

- Lordotic
  - 35 – 80mm (5mm increments)
  - 90 – 110mm (10mm increments)
  - 120 – 150mm (10 mm increments)\*
- Straight
  - 35 – 80mm (5 mm increments)\*
  - 90 – 150mm (10mm increments)

## INSTRUMENT SETS

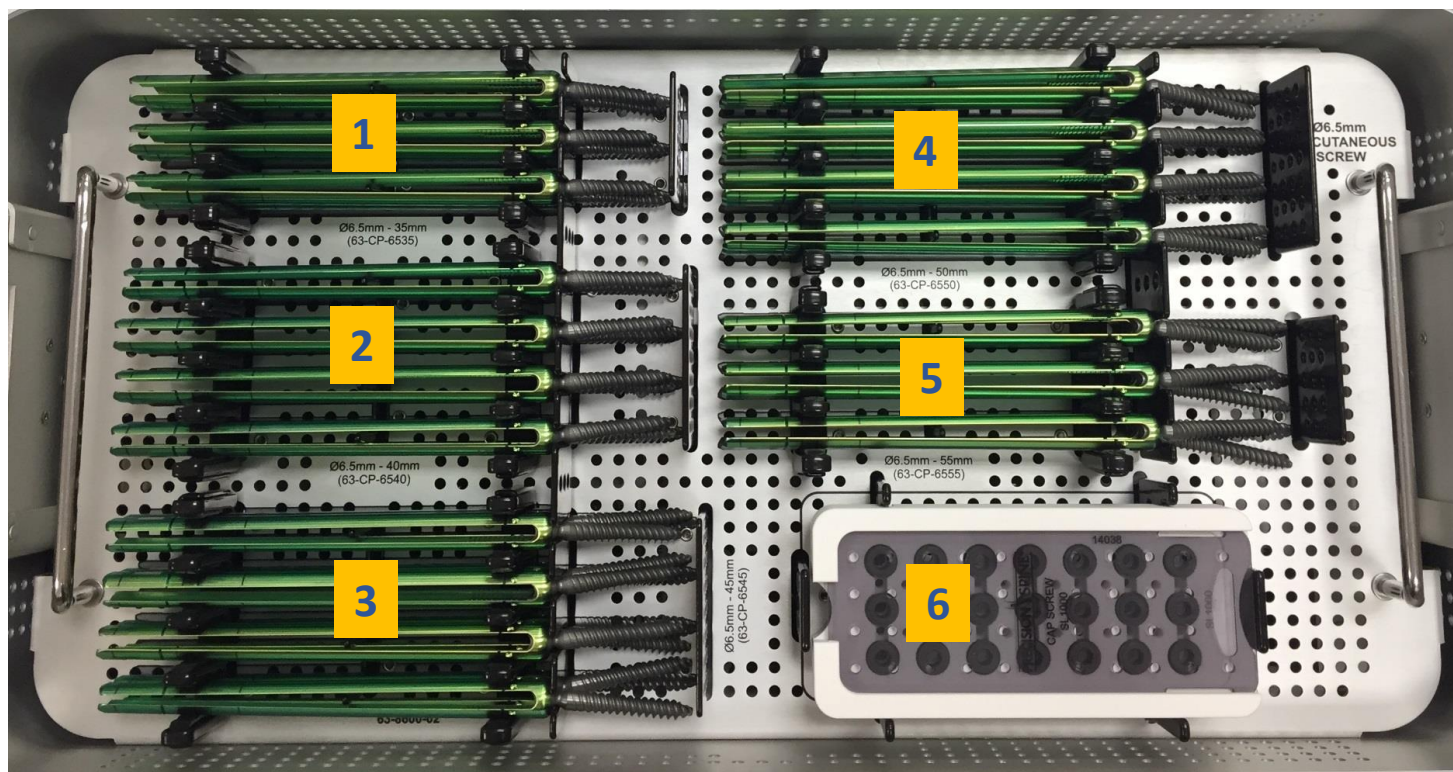
- Either instrument set (63-8100-CA or 63-8200-CA) may be utilized for implantation

\* Available Upon Request



# SURELOK™ MIS 3L – IMPLANTS – TOP TRAY

TRAY NUMBER 63-8600

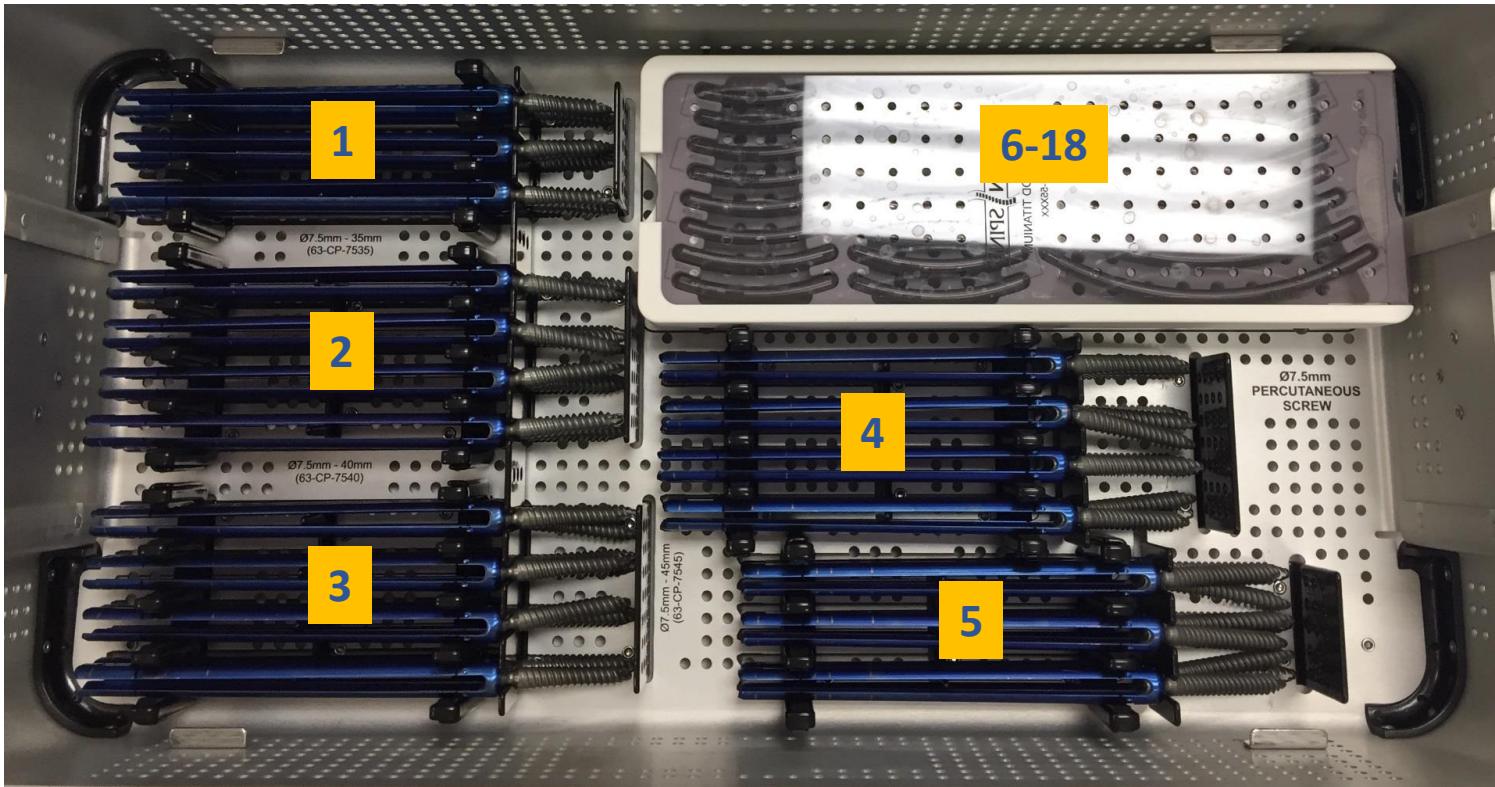


#	Part No.	Description	Qty
1.	63-CP-6535	SureLOK MIS 3L Screw Assembly – 6.5 x 35mm	6
2.	63-CP-6540	SureLOK MIS 3L Screw Assembly – 6.5 x 40mm	8
3.	63-CP-6545	SureLOK MIS 3L Screw Assembly – 6.5 x 45mm	8
4.	63-CP-6550	SureLOK MIS 3L Screw Assembly – 6.5 x 50mm	8
5.	63-CP-6555	SureLOK MIS 3L Screw Assembly – 6.5 x 55mm	6
6.	SL1000	S-LOK Cap Screw	21



# SURELOK™ MIS 3L – IMPLANTS – BOTTOM TRAY

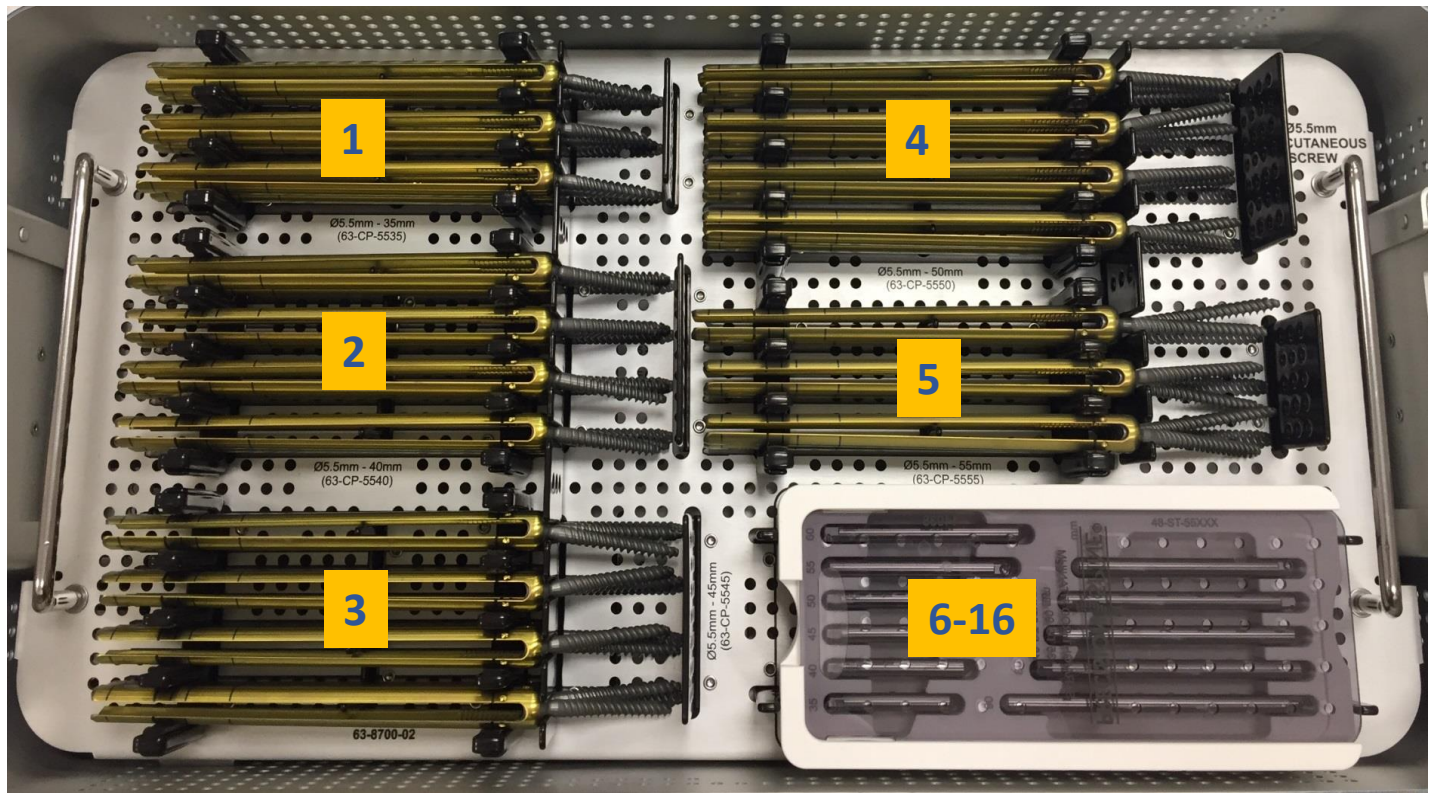
## TRAY NUMBER 63-8600



#	Part No.	Description	Qty
1.	63-CP-7535	SureLOK MIS 3L Screw Assembly – 7.5 x 35mm	6
2.	63-CP-7540	SureLOK MIS 3L Screw Assembly – 7.5 x 40mm	8
3.	63-CP-7545	SureLOK MIS 3L Screw Assembly – 7.5 x 45mm	8
4.	63-CP-7550	SureLOK MIS 3L Screw Assembly – 7.5 x 50mm	8
5.	63-CP-7555	SureLOK MIS 3L Screw Assembly – 7.5 x 55mm	6
6.	48-CU-55035	35mm – Curved Rod (Ti)	4
7.	48-CU-55040	40mm – Curved Rod (Ti)	4
8.	48-CU-55045	45mm – Curved Rod (Ti)	4
9.	48-CU-55050	50mm – Curved Rod (Ti)	4
10.	48-CU-55055	55mm – Curved Rod (Ti)	4
11.	48-CU-55060	60mm – Curved Rod (Ti)	4
12.	48-CU-55065	65mm – Curved Rod (Ti)	4
13.	48-CU-55070	70mm – Curved Rod (Ti)	4
14.	48-CU-55075	75mm – Curved Rod (Ti)	4
15.	48-CU-55080	80mm – Curved Rod (Ti)	4
16.	48-CU-55090	90mm – Curved Rod (Ti)	2
17.	48-CU-550100	100mm – Curved Rod (Ti)	2
18.	48-CU-550110	110mm – Curved Rod (Ti)	2

# SURELOK™ MIS 3L – IMPLANTS – TOP TRAY

TRAY NUMBER 63-8700

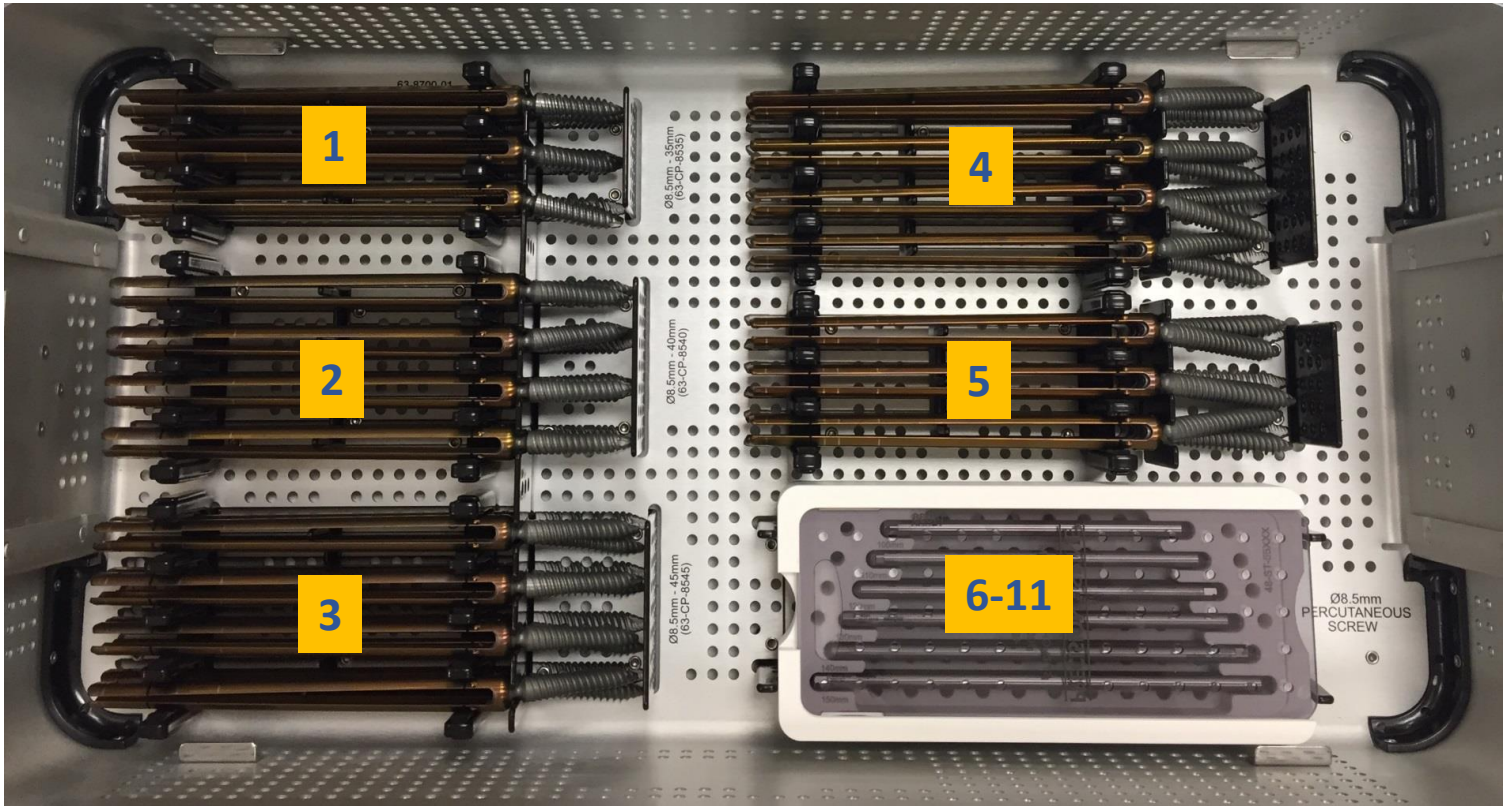


#	Part No.	Description	Qty
1.	63-CP-5535	SureLOK MIS 3L Screw Assembly – 5.5 x 35mm	6
2.	63-CP-5540	SureLOK MIS 3L Screw Assembly – 5.5 x 40mm	8
3.	63-CP-5545	SureLOK MIS 3L Screw Assembly – 5.5 x 45mm	8
4.	63-CP-5550	SureLOK MIS 3L Screw Assembly – 5.5 x 50mm	8
5.	63-CP-5555	SureLOK MIS 3L Screw Assembly – 5.5 x 55mm	6
6.	48-ST-55035	35mm – Straight Rod (Ti)	2
7.	48-ST-55040	40mm – Straight Rod (Ti)	2
8.	48-ST-55045	45mm – Straight Rod (Ti)	2
9.	48-ST-55050	50mm – Straight Rod (Ti)	2
10.	48-ST-55055	55mm – Straight Rod (Ti)	2
11.	48-ST-55060	60mm – Straight Rod (Ti)	2
12.	48-ST-55065	65mm – Straight Rod (Ti)	2
13.	48-ST-55070	70mm – Straight Rod (Ti)	2
14.	48-ST-55075	75mm – Straight Rod (Ti)	2
15.	48-ST-55080	80mm – Straight Rod (Ti)	2
16.	48-ST-55090	90mm – Straight Rod (Ti)	2



# SURELOK™ MIS 3L – IMPLANTS – BOTTOM TRAY

## TRAY NUMBER 63-8700

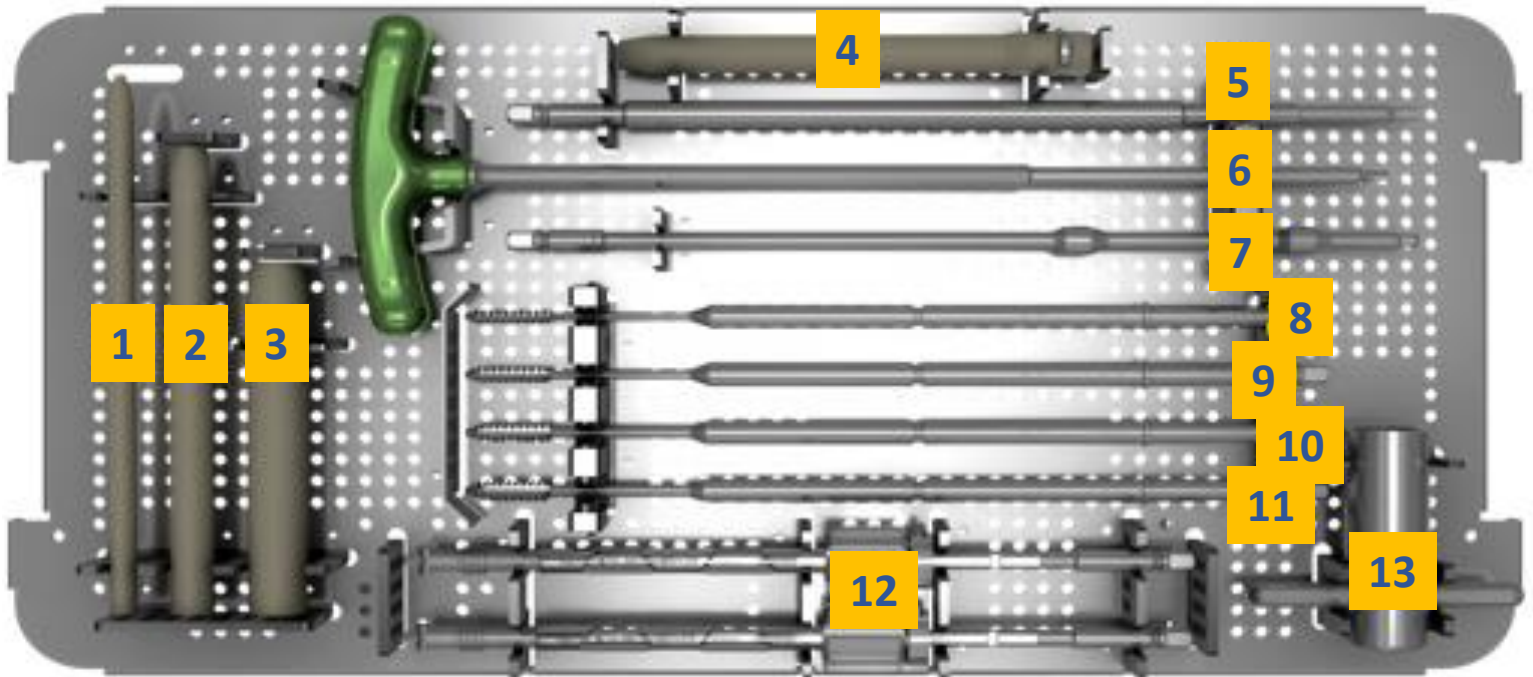


#	Part No.	Description	Qty
1.	63-CP-8535	SureLOK MIS 3L Screw Assembly – 8.5 x 35mm	6
2.	63-CP-8540	SureLOK MIS 3L Screw Assembly – 8.5 x 40mm	8
3.	63-CP-8545	SureLOK MIS 3L Screw Assembly – 8.5 x 45mm	8
4.	63-CP-8550	SureLOK MIS 3L Screw Assembly – 8.5 x 50mm	8
5.	63-CP-8555	SureLOK MIS 3L Screw Assembly – 8.5 x 55mm	6
6.	48-ST-55100	100mm – Straight Rod (Ti)	2
7.	48-ST-55110	110mm – Straight Rod (Ti)	2
8.	48-ST-55120	120mm – Straight Rod (Ti)	2
9.	48-ST-55130	130mm – Straight Rod (Ti)	2
10.	48-ST-55140	140mm – Straight Rod (Ti)	2
11.	48-ST-55150	150mm – Straight Rod (Ti)	2



# SURELOK™ MIS 3L – INSTRUMENTS – TOP TRAY

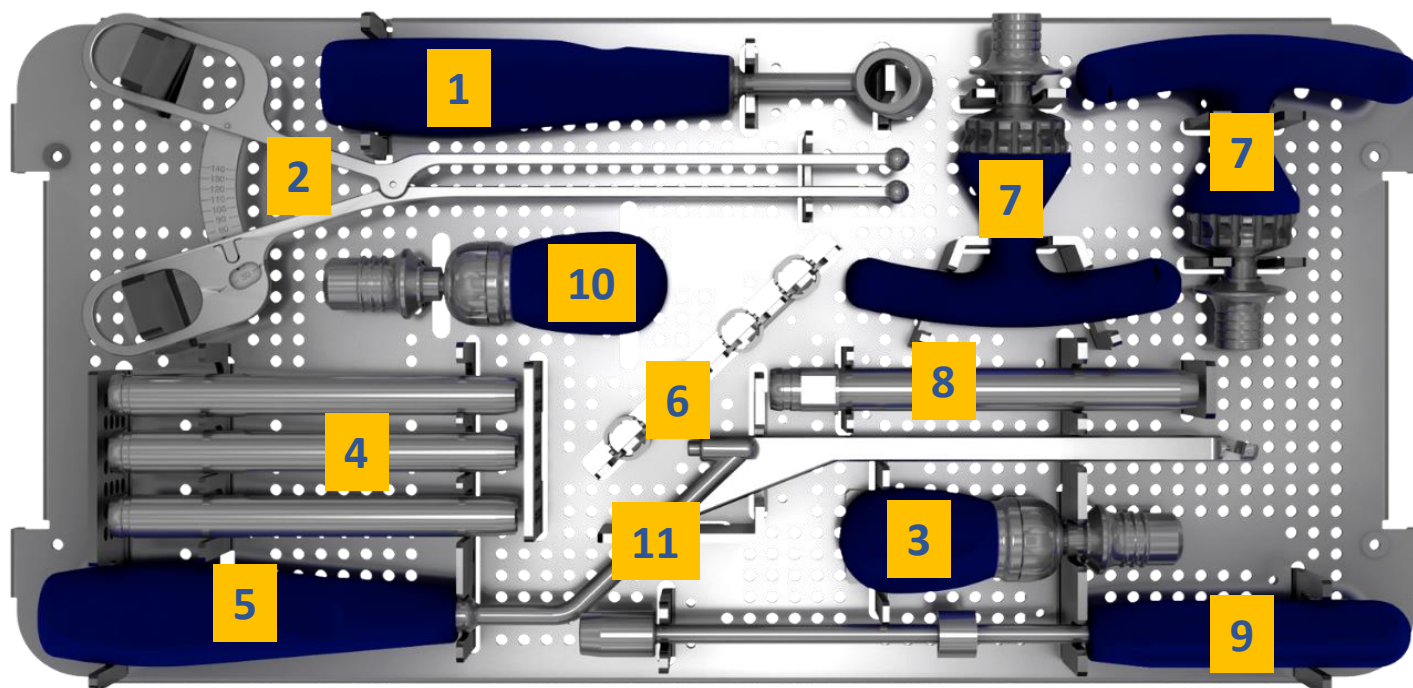
TRAY NUMBER 63-8100-CA



#	Part No.	Description	Qty
1.	63-9038-08	Dilator Radel, 08mm	1
2.	63-9038-13	Dilator Radel, 13mm	1
3.	63-9038-18	Dilator Radel, 18mm	1
4.	63-4101	Tap Dilator	1
5.	63-9015	Torque Drive Shaft	1
6.	PSSTPS	3.5mm Hex Driver (fine tuner)	1
7.	48-9014	Cap Screw Inserter	1
8.	63-4100-55	Bifurcated Tap, 5.5mm	2
9.	63-4100-65	Bifurcated Tap, 6.5mm	2
10.	63-4100-75	Bifurcated Tap, 7.5mm	2
11.	63-4100-85	Bifurcated Tap, 8.5mm	2
12.	63-9012	Percutaneous Screwdriver, Short	2
13.	63-0315	T-Handle, Reduction Tower	1

# SURELOK™ MIS 3L – INSTRUMENTS – MIDDLE TRAY

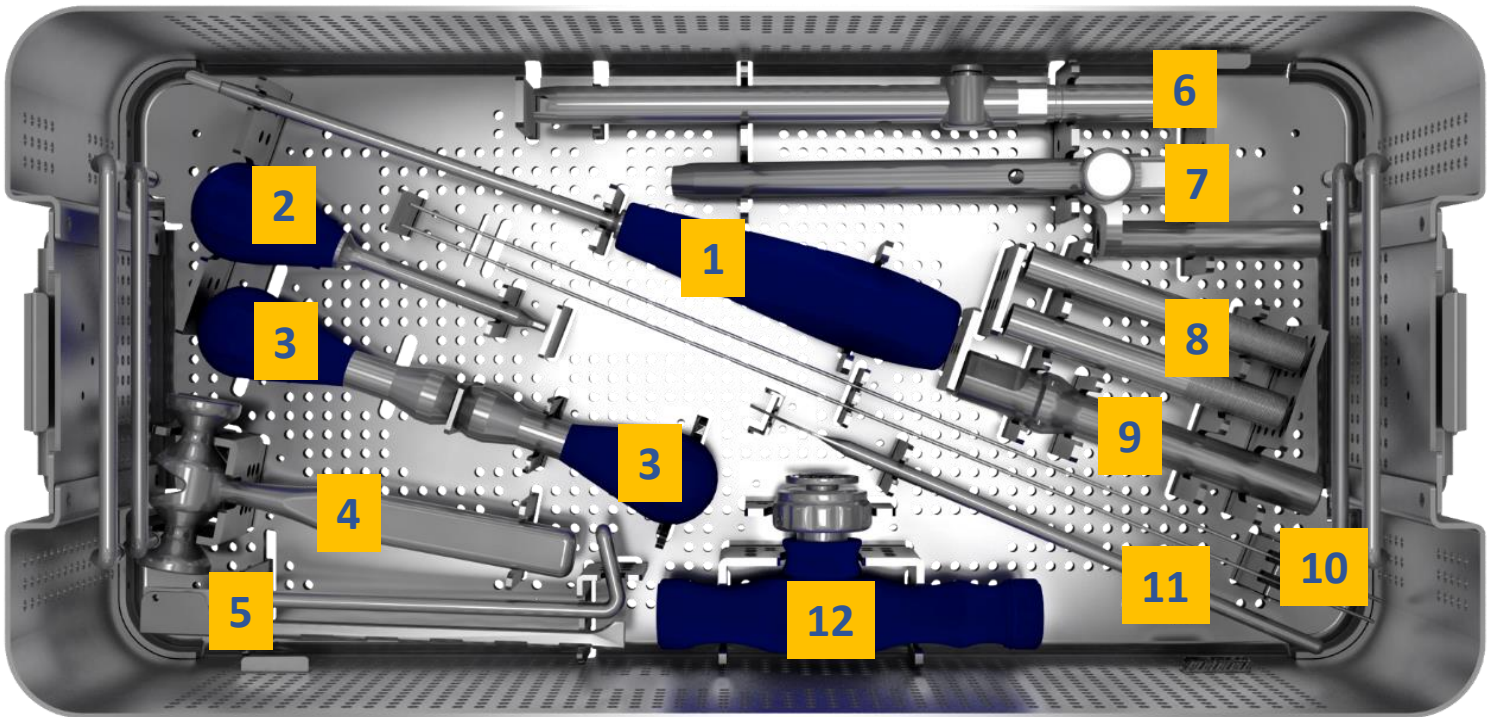
TRAY NUMBER 63-8100-CA



#	Part No.	Description	Qty
1.	63-9026	Counter Torque Handle	1
2.	48-9008	Caliper	1
3.	63-9007	Ratcheting Palm Handle	2
4.	63-9003	Tower Tubes	6
5.	63-9005	Rod Inserter, Side Load	1
6.	63-9018	Bottle Cap	8
7.	PSSRT	Ratchet T-Handle	2
8.	63-9001	C-Torque, Sleeve	1
9.	48-9011	Tab Remover	1
10.	04-9075	Torque Limiting Handle	1
11.	63-9035	Rod Inserter Tightener	2

# SURELOK™ MIS 3L – INSTRUMENTS – BOTTOM TRAY

## TRAY NUMBER 63-8100-CA



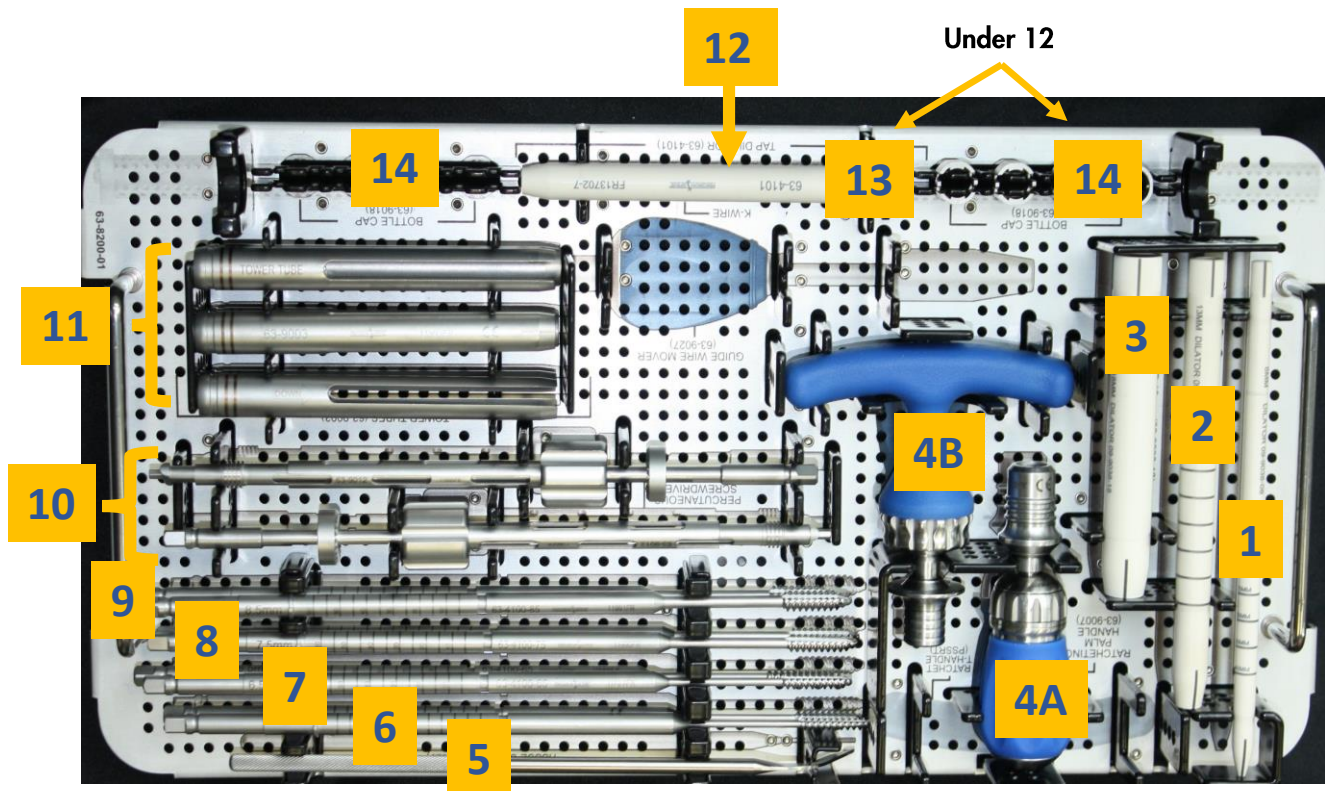
#	Part No.	Description	Qty
1.	SL-9001	Head Positioner	1
2.	63-9035	Rod Inserter Tightener	1
3.	63-9030	Tower Tube Removal Tool	2
4.	09-9043	Mallet	1
5.	09-9027	Guide Wire Inserter/Extractor	1
6.	09-9058	Compression-Distraction Arm-A	1
7.	09-9059	Compression-Distraction Arm-B	1
8.	63-9022	Reducer Extender	2
9.	63-9021	Rod Reducer Sleeve	1
10.	HXI-48-0002	Short K-Wire – Nitinol Trocar/Threaded	0*
	HXI-48-0003	Short K-Wire – Nitinol Blunt/Threaded	10
	HXI-48-0004	Short K-Wire – Stainless Trocar/Threaded	0*
	HXI-48-0005	Short K-Wire – Stainless Blunt/Threaded	0*
11.	09-9029	Tissue Cutter	1
12.	39-CH-0008	Offset Ratcheting Torque Handle (106 in-lbs)	1

\*Special Order



# SURELOK™ MIS 3L – INSTRUMENTS – TOP TRAY

## TRAY NUMBER 63-8200-CA



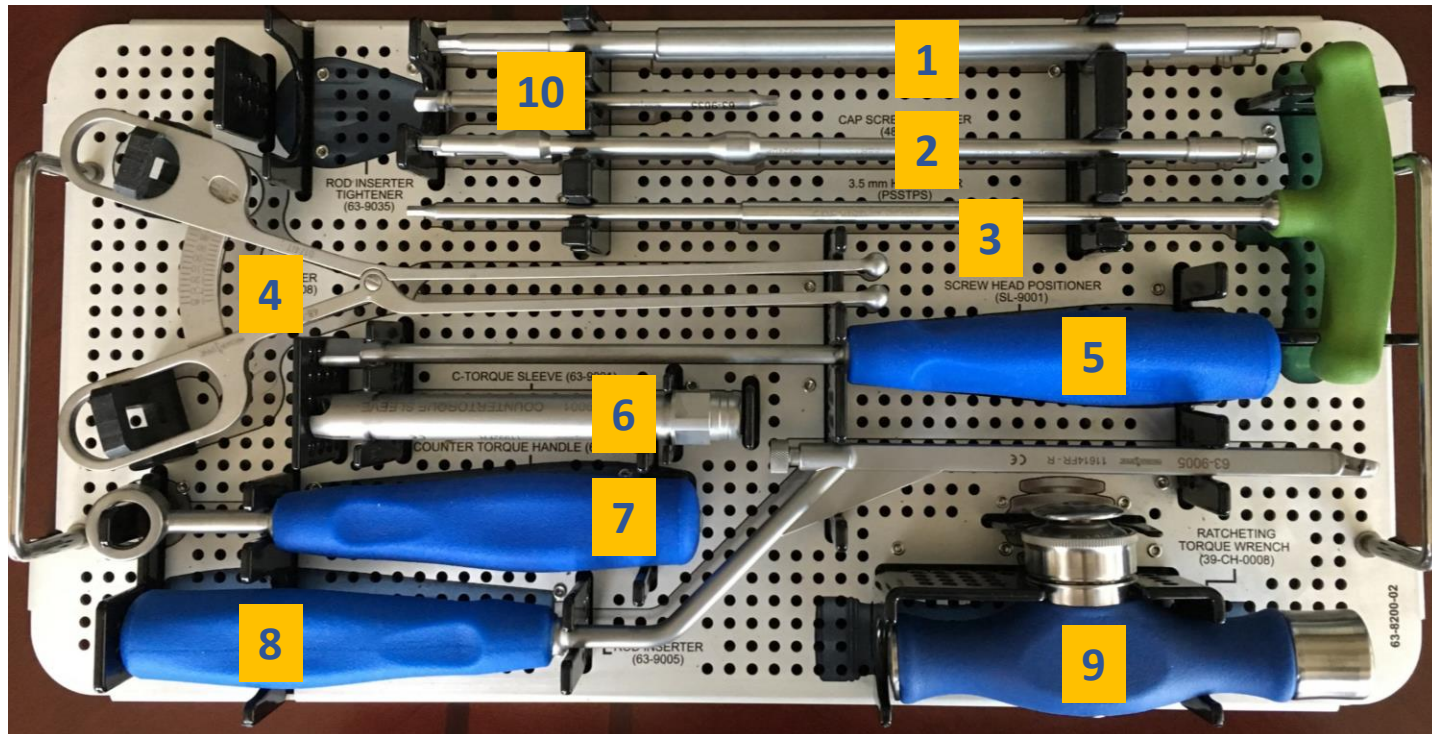
#	Part No.	Description	Qty
1.	63-9038-08	Dilator Radel, 08mm	1
2.	63-9038-13	Dilator Radel, 13mm	1
3.	63-9038-18	Dilator Radel, 18mm	1
4.	63-9007	Ratcheting Palm Handle	2
4B	PSSRT	Ratcheting T-Handle	0**
5.	09-9029	Tissue Cutter	1
6.	63-4100-55	Bifurcated Tap, 5.5mm	2
7.	63-4100-65	Bifurcated Tap, 6.5mm	2
8.	63-4100-75	Bifurcated Tap, 7.5mm	2
9.	63-4100-85	Bifurcated Tap, 8.5mm	2
10.	63-9012	Percutaneous Screwdriver, Short	2
11.	63-9003	Tower Tubes	3
12.	HXI-48-0002	Short K-Wire – Nitinol Trocar/Threaded	0*
	HXI-48-0003	Short K-Wire – Nitinol Blunt/Threaded	10
	HXI-48-0004	Short K-Wire – Stainless Trocar/Threaded	0*
	HXI-48-0005	Short K-Wire – Stainless Blunt/Threaded	0*
13.	63-4101	Tap Dilator	1
14.	63-9018	Bottle Caps	8

\* Special Order

\*\* Special Order – Replaces 1 or Both 4A

# SURELOK™ MIS 3L – INSTRUMENTS – MIDDLE TRAY

## TRAY NUMBER 63-8200-CA

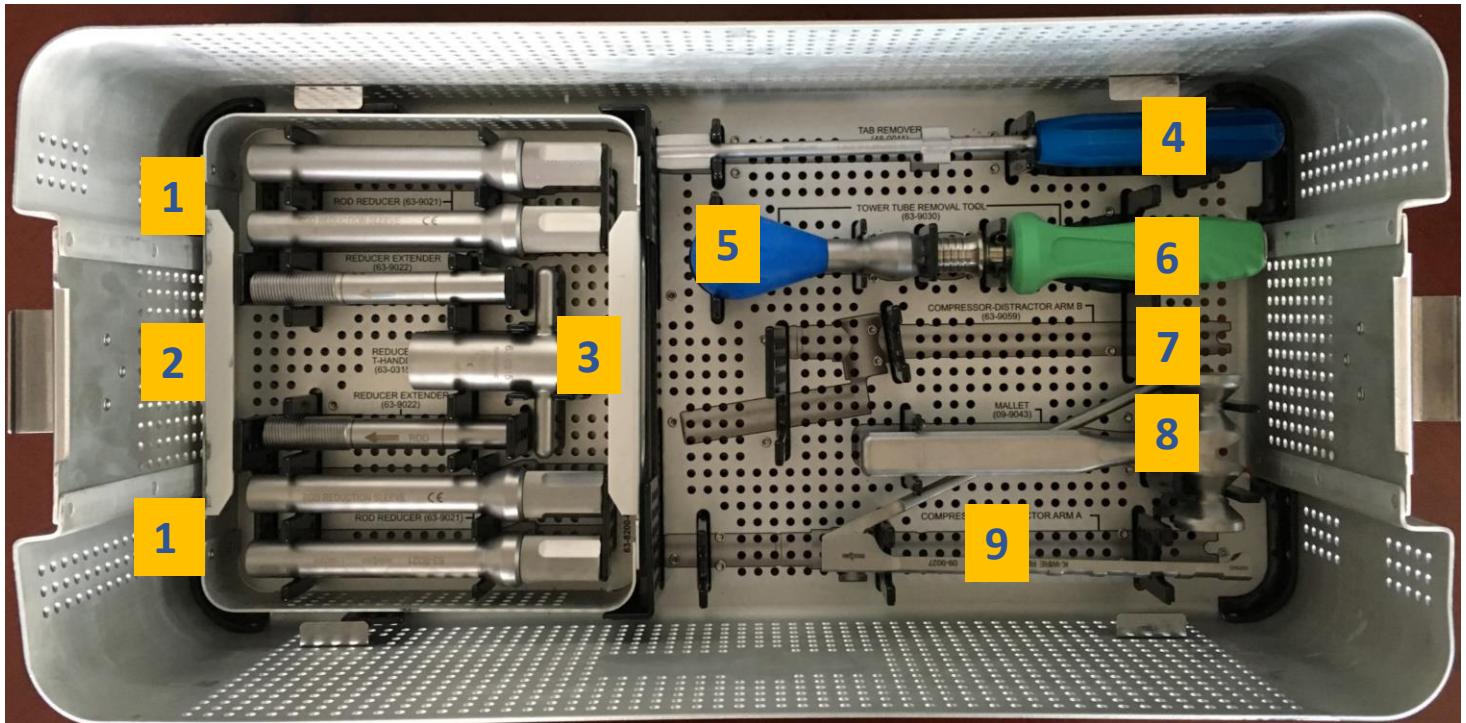


#	Part No.	Description	Qty
1.	63-9015	Torque Drive Shaft	1
2.	48-9014	Cap Screw Tightener	1
3.	PSSTPS	3.5mm Hex Driver (fine tuner)	1
4.	48-9008	Caliper	1
5.	SL-9001	Head Positioner	1
6.	63-9001	C-Torque, Sleeve	1
7.	63-9026	Counter Torque Handle	1
8.	63-9005	Rod Inserter, Side Load	1
9.	39-CH-0008	Offset Ratcheting Torque Handle	1
10.	63-9035	Rod Inserter Tightener Shaft	1



# SURELOK™ MIS 3L – INSTRUMENTS – BOTTOM TRAY

## TRAY NUMBER 63-8200-CA



#	Part No.	Description	Qty
1.	63-9021	Rod Reducer	4
2.	63-9022	Reducer Extender	2
3.	63-0315	T-Handle, Reduction Tower	1
4.	48-9011	Tab Remover	1
5.	63-9030	Tower Tube Removal Tool	2
6.	04-9075	Torque Limiting Handle	1
7.	63-9059	Compressor-Distractor Arm B	1
8.	09-9043	Mallet	1
9.	63-9058	Compressor-Distractor Arm A	1



# 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).

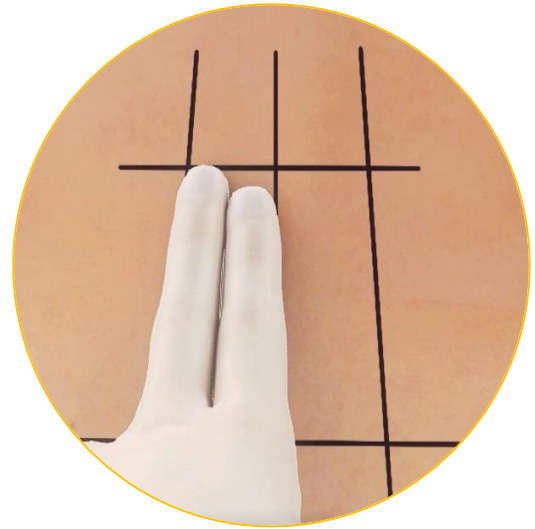


Figure 1

## 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 (74182-01M, 74182-02M, 74174-01M and 74066-15M) is advanced through the skin incision and docked onto the targeted pedicle. The placement of the Jamshidi is verified with fluoroscopic imaging.

Once proper trajectory and docking of the biopsy needle is confirmed, the trocar needle is removed and replaced by the Guide Wire (Figure 2).

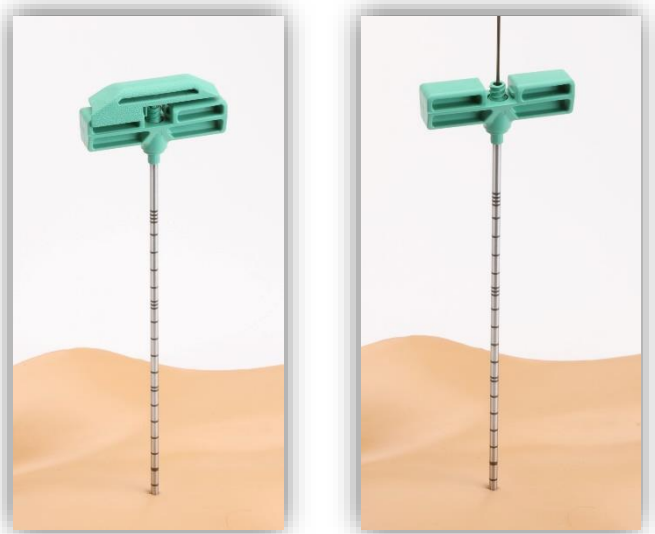


Figure 2

#### Nitinol

HXI-48-0002 - Trocar Tip/Threaded 18 Inch Length

HXI-48-0003 - Blunt Tip/Threaded 18 Inch Length

#### Stainless Steel

HXI-48-004 - Trocar Tip/Threaded 18 Inch Length

HXI-48-005 - Blunt Tip/Threaded 18 Inch Length

# SURGICAL TECHNIQUE

## 3

### PEDICLE PREPARATION

Place the 8mm Dilator (63-9038-08) over the Guide Wire down to the spine. Slide the 13mm Dilator (63-9038-13) over the 8mm Dilator to sequentially penetrate and gently dissect soft tissue down to the pedicle, followed by the 18mm Dilator (63-9038-18) (Figure 3).

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 pedicle (Figure 4). **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.

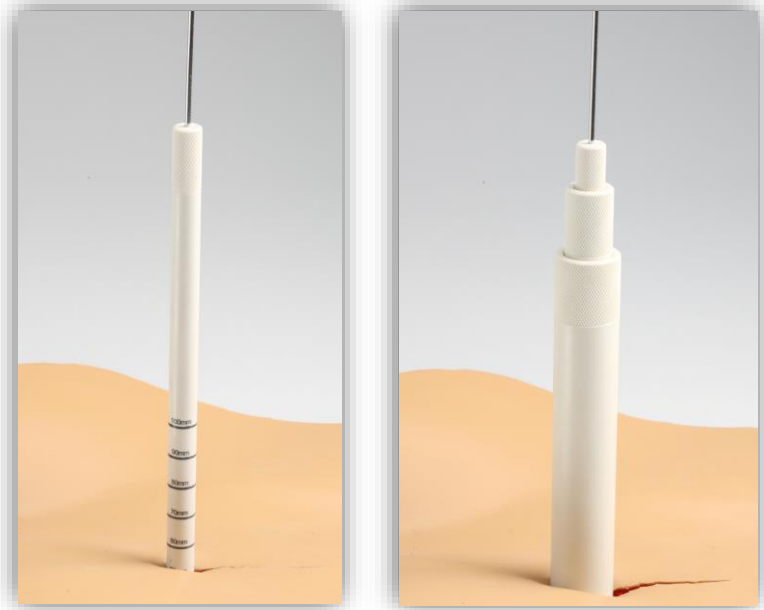


Figure 3



Figure 4

# SURGICAL TECHNIQUE

## 3

### PEDICLE PREPARATION (continued)

Select the appropriate sized Tap 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 5a). Insert the Tap into the Tap Dilator (63-4101) (Figure 5b) while depressing the Release Button (Figure 5c). 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 6). Once the Tap engages the pedicle, depress the release button and begin tapping the pedicle. **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 Tap Dilator Sleeve must be in contact with the pedicle surface to achieve an accurate measurement.



Figure 5a



Figure 5b

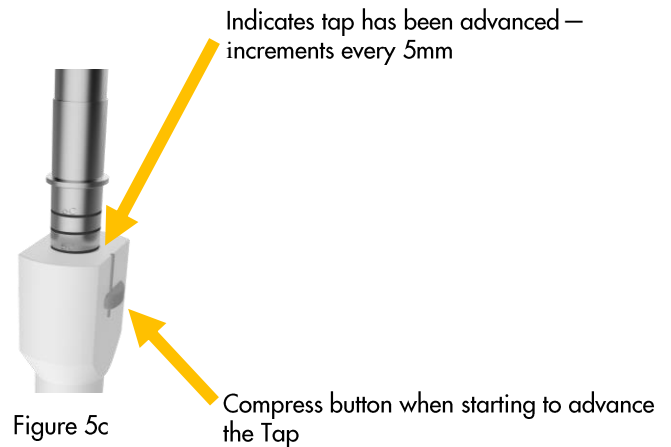


Figure 5c

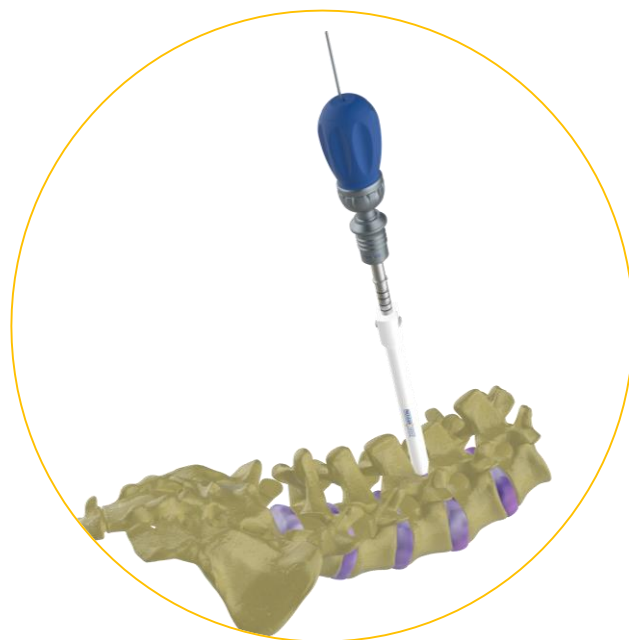


Figure 6



# 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) (Figure 7).

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 Bottle Cap (63-9018) or the Tower Tube (63-9003) can be placed over the extended tab tulip (Figure 7/8).

To insert the Bottle Cap, ensure that the arrow on the Bottle Cap is pointing down and is aligned with the opening of the tulip's rod slot. Place the Bottle Cap over the tulip and push down until it engages with the detent on the tulip.

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.

Attach the Screw to the Screw Driver Assembly (48-9012). 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. This can be verified by attempting to angulate the screw relative to the tulip head (Figure 9).



Figure 7

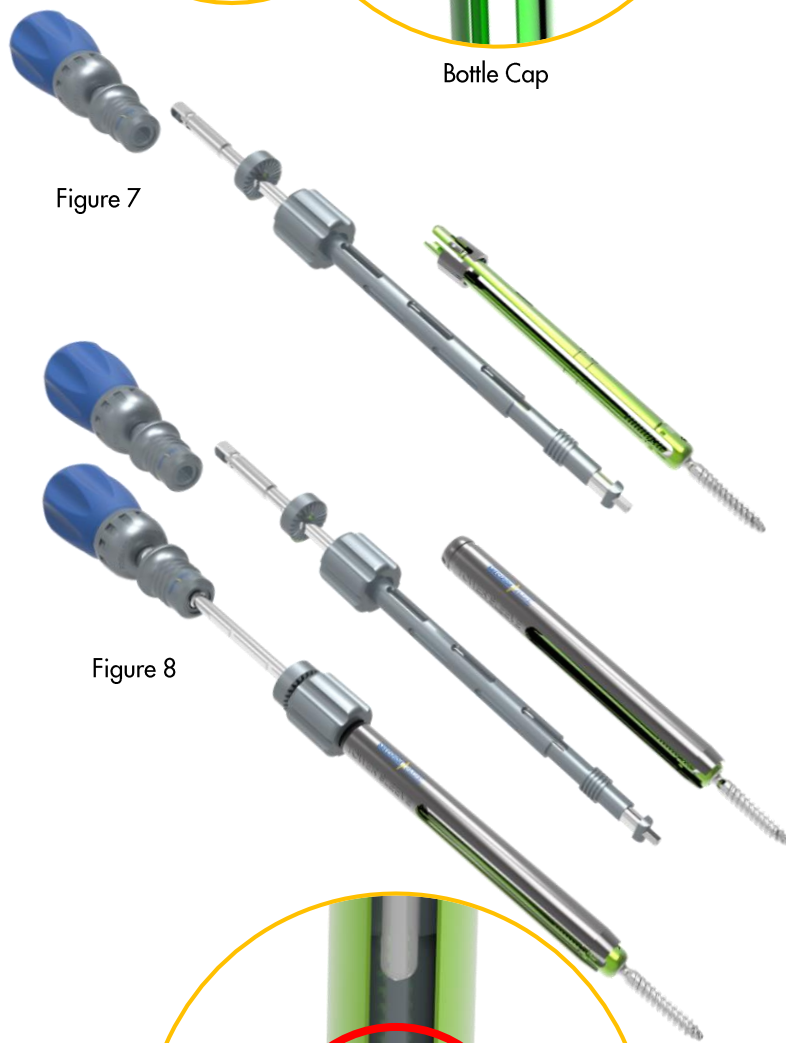


Figure 8



Figure 9

# 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 flush with the convex portion of the driver tip (Figure 10a).

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

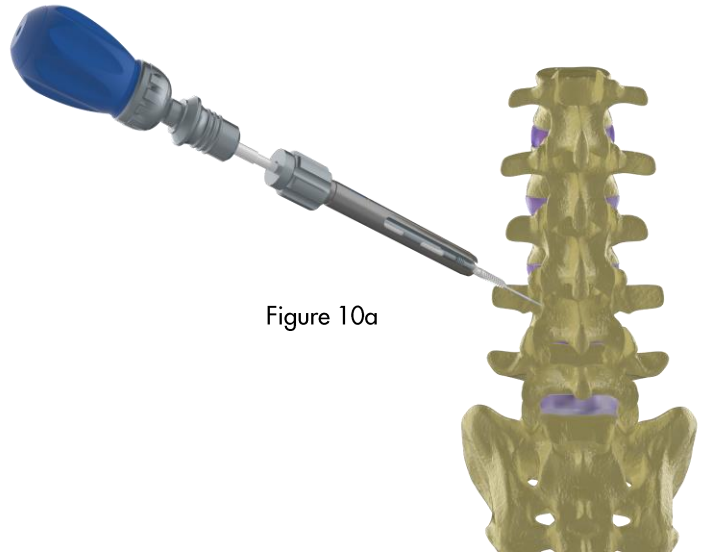


Figure 10a

## 5

### SCREW INSERTION

While using fluoroscopic imaging, advance the Screw Inserter assembly over the guide wire and into the 18mm Dilator, through the pedicle and into the vertebral body (Figure 10b).

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

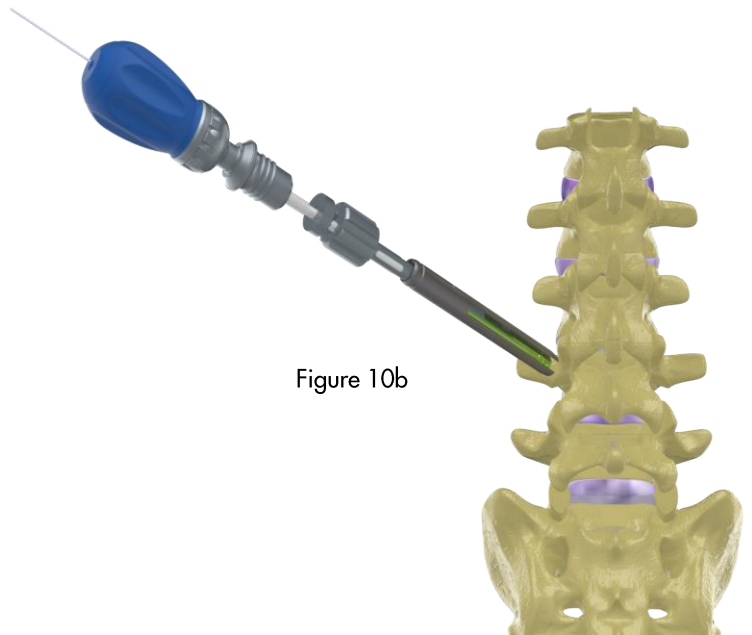


Figure 10b

# SURGICAL TECHNIQUE

## 6

### GUIDE WIRE REMOVAL

After confirming that the screw is in the proper position, remove the Guide Wire, Screw Driver, and Dilator, leaving the Polyaxial Screw in place .

To aid in the removal of the Guide Wire, use the Guide Wire Insert/Extractor (09-9027). Slide the Guide Wire through the cannulated portion of the instrument, grasp the handle to clamp the Guide Wire, and pull the wire out of the pedicle.

**Note: Guide Wire is for Single Use and should not be re-used.**

## 7

### ROD SELECTION

If necessary, use the 3.5mm Hex Polyaxial Screw Driver (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 11a). The Rod measurement that is indicated includes the recommended amount of rod overhang for the bulleted and hex ends (Figure 11b).

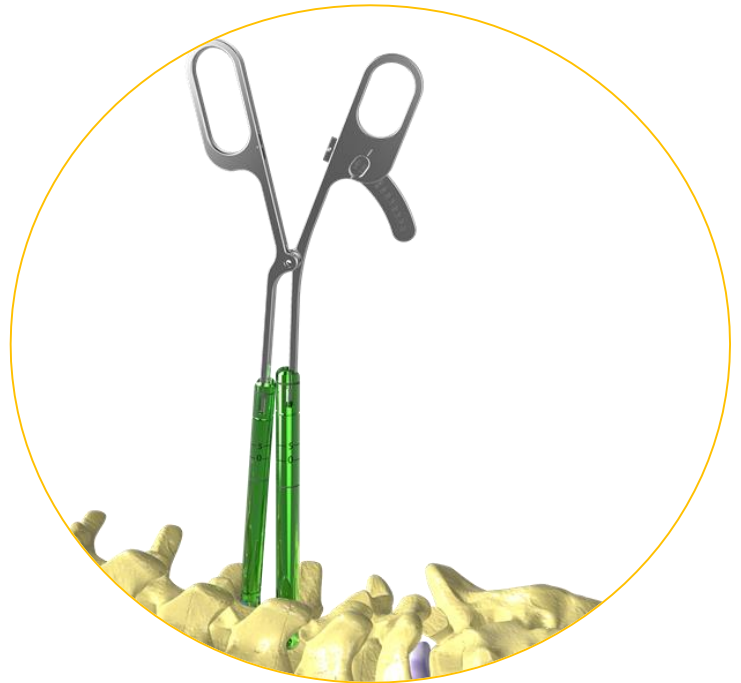


Figure 11a



Figure 11b



# SURGICAL TECHNIQUE

## 8

## ROD INSERTION

Loosen the knob on the Rod Inserter (63-9005) and insert the hex of the appropriate length Rod into the distal hex opening of the Inserter (Figure 12a). Secure the rod by hand tightening the Rod Inserter knob (Figure 12b).

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 13). Confirm proper rod placement via intraoperative fluoroscopy or by placing the 8mm Dilator into the extended tab tulip. 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. Note: The distal end of the Rod Inserter is larger than the Tulip opening and will not pass through the tulip.

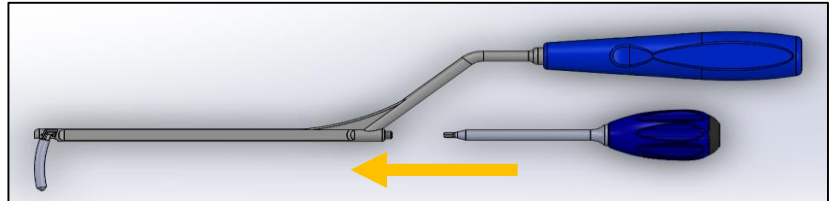


Figure 12a

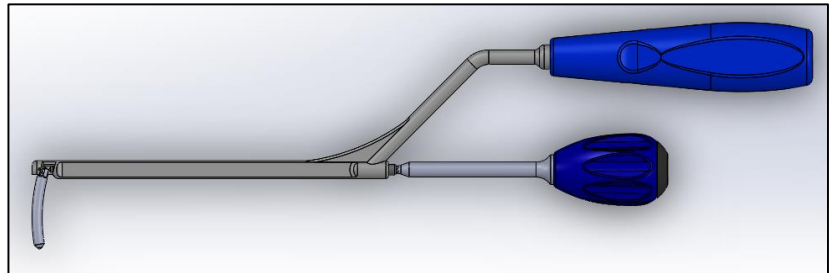


Figure 12b

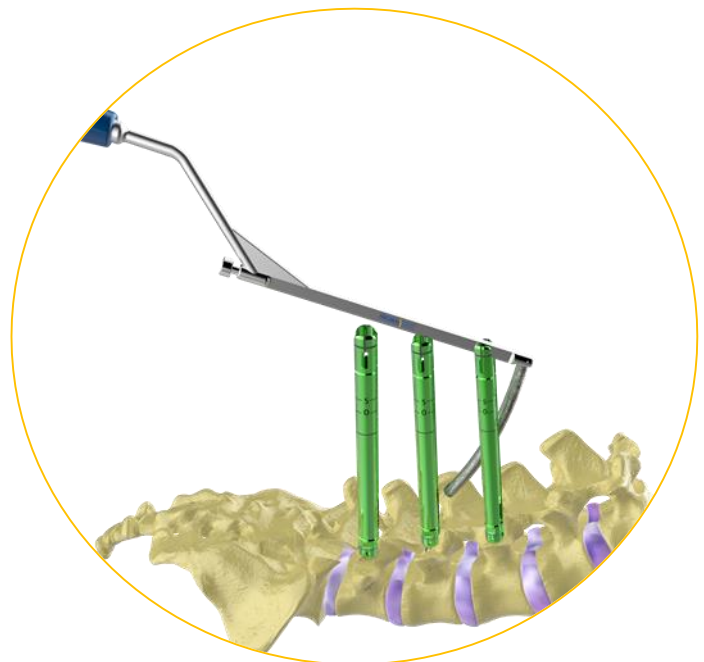


Figure 13

# SURGICAL TECHNIQUE

## 9

### SLEEVE ATTACHMENT

If the Tower Tubes (63-9003) are used, remove them from the extended tab tulip. See Step 12.

## 10

### ROD REDUCTION

Insert the Bottle Cap over the extended tab tulip (Figure 14). Ensure that the arrow on the Bottle Cap is pointing Down and is aligned with the opening of the tulip's rod slot. Place the Bottle Cap over the tulip (Figure 14a) and push down until it engages with the detent on the tulip, then slide it down past the horizontal line etched on the extended tab (Figure 14b).

Slide the Reducer Extender (63-9022) over the extended tab until it locks into place (Figure 114c). Slide the Bottle Cap up until it locks into the extended tab detent. Place the Rod Reduction Sleeve over the Reducer Extender and turn clockwise to reduce the rod (Figure 14d). Insert Set Screw to hold reduction in place.

Reverse steps to remove Reducer.

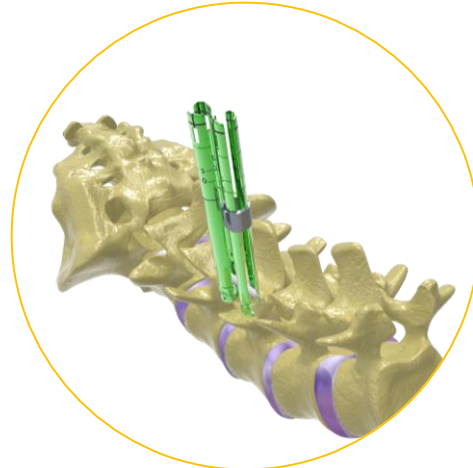


Figure 14



Figure 14a

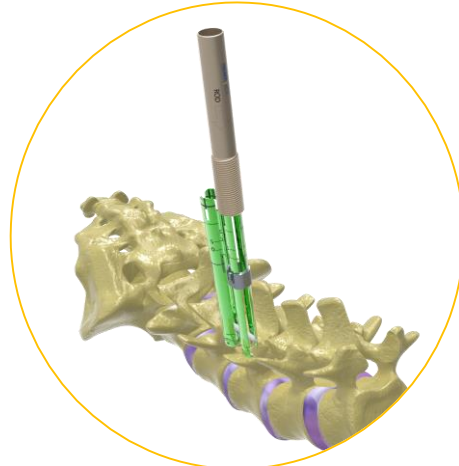


Figure 14b

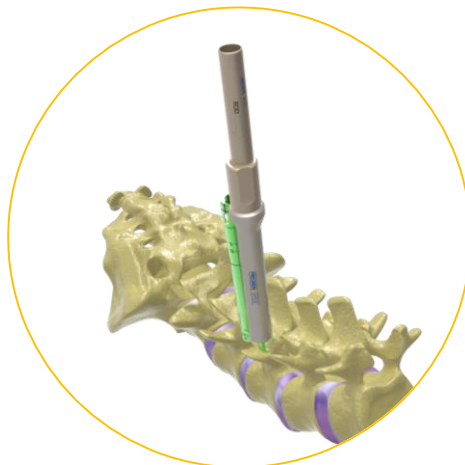


Figure 14c

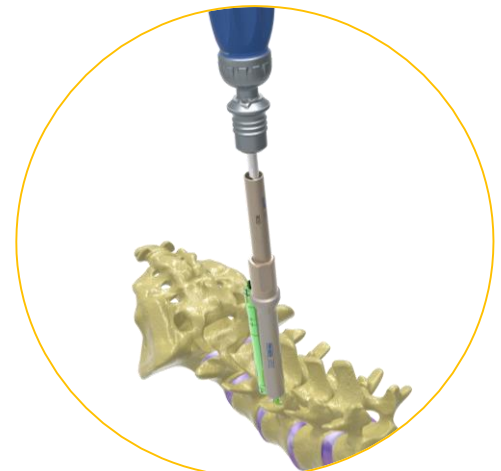


Figure 14d

# SURGICAL TECHNIQUE

## 11

### CAP SCREW INSERTION

Insert the Cap Screw (SL1000) onto the tip of the Cap Screw Inserter (48-9014).

Insert through the Extended Tab and thread the Cap Screw into the tulip.

After Cap Screw insertion, remove the Cap Screw Inserter. Repeat for subsequent screws.



## 12

### TOWER TUBE/BOTTLE CAP REMOVAL

While lifting the Tower Tube, insert the Tower Tube Removal Tool over the Tower Tube until it is fully seated. Pull up on the removal tool, removing both the Tower Tube from the extended tab tulip.

Remove the Bottle Cap by lifting up the Bottle Cap off the extended tab tulip. Pinching the tabs of the tulip will ease removal (Figure 15).

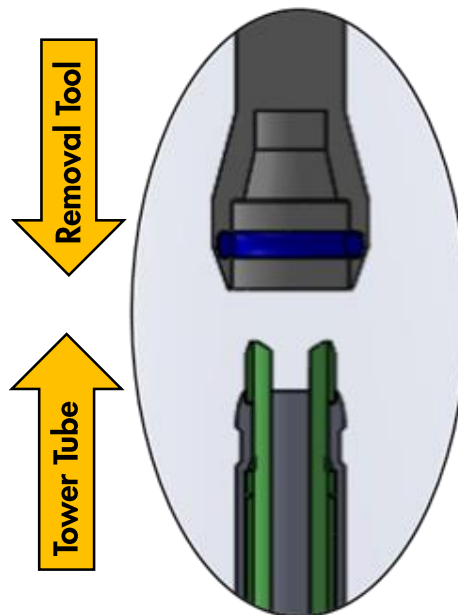


Figure 15

# SURGICAL TECHNIQUE

## 13

## FINAL TIGHTENING

Verify, under fluoroscopy that the position of the Screws and Rods are acceptable.

Assemble the Ratcheting Torque Wrench (39-CH-008) to the Torque Driver Shaft (63-9015).

Place the Counter Torque Sleeve (63-9001) over the Extended Tab until it is fully seated.

Insert the Counter-Torque Handle (63-9026) over the proximal portion of the Counter Torque Sleeve (Figure 16).

Insert the Torque Driver 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. Repeat for the remaining screws.

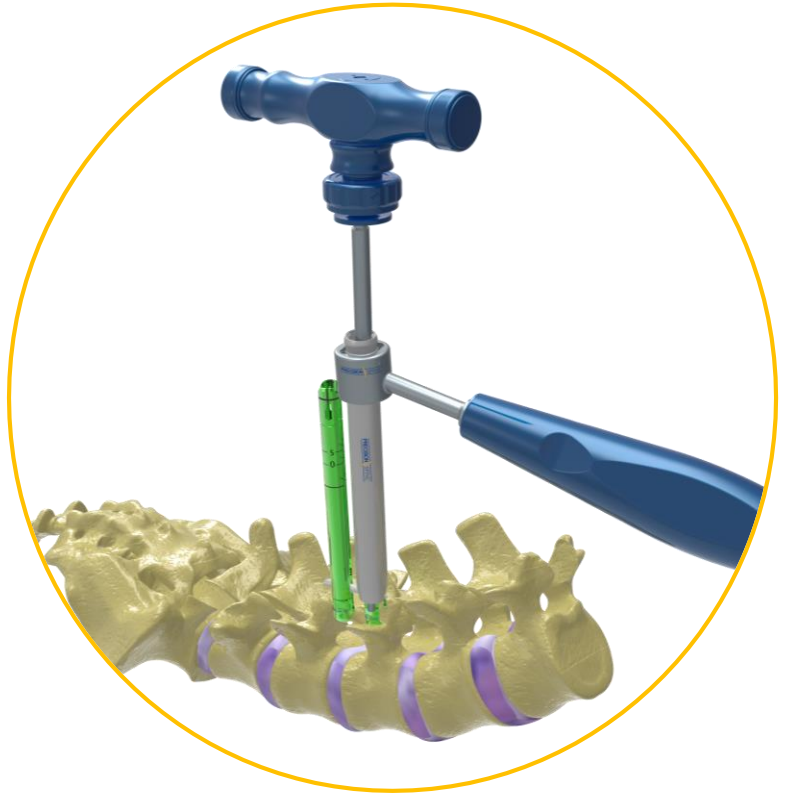


Figure 16



# SURGICAL TECHNIQUE

## 14

### 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 of the screw and rocking the instrument in a medial-to-lateral motion until the Extended Tab portion is disassociated from the pedicle screw. Repeat for remaining Polyaxial Screws (Figure 17).

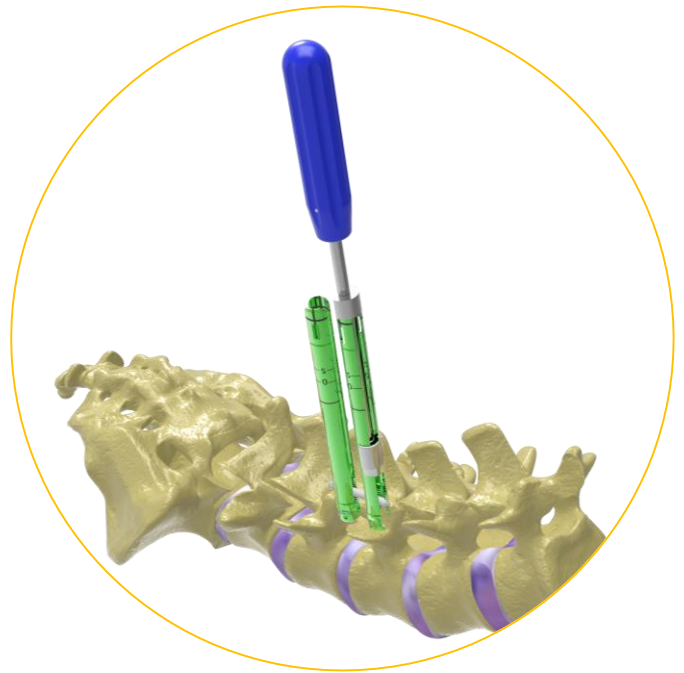


Figure 17

## 15

### IMPLANT REMOVAL

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

# ORDERING INFORMATION — IMPLANTS

PART NUMBER	DESCRIPTION	PART NUMBER	DESCRIPTION
SL1000	Cap Screw	48-ST-55035	35mm Straight Rod
63-CP-5525	Pedicle Screw $\varnothing 5.5 \times 25\text{mm}$	48-ST-55040	40mm Straight Rod
63-CP-5530	Pedicle Screw $\varnothing 5.5 \times 30\text{mm}$	48-ST-55045	45mm Straight Rod
63-CP-5535	Pedicle Screw $\varnothing 5.5 \times 35\text{mm}$	48-ST-55050	50mm Straight Rod
63-CP-5540	Pedicle Screw $\varnothing 5.5 \times 40\text{mm}$	48-ST-55055	55mm Straight Rod
63-CP-5545	Pedicle Screw $\varnothing 5.5 \times 45\text{mm}$	48-ST-55060	60mm Straight Rod
63-CP-5550	Pedicle Screw $\varnothing 5.5 \times 50\text{mm}$	48-ST-55065	65mm Straight Rod
63-CP-5555	Pedicle Screw $\varnothing 5.5 \times 55\text{mm}$	48-ST-55070	70mm Straight Rod
63-CP-5560	Pedicle Screw $\varnothing 5.5 \times 60\text{mm}$	48-ST-55075	75mm Straight Rod
63-CP-6525	Pedicle Screw $\varnothing 6.5 \times 25\text{mm}$	48-ST-55080	80mm Straight Rod
63-CP-6535	Pedicle Screw $\varnothing 6.5 \times 35\text{mm}$	48-ST-55090	90mm Straight Rod
63-CP-6540	Pedicle Screw $\varnothing 6.5 \times 40\text{mm}$	48-ST-55100	100mm Straight Rod
63-CP-6545	Pedicle Screw $\varnothing 6.5 \times 45\text{mm}$	48-ST-55110	110mm Straight Rod
63-CP-6550	Pedicle Screw $\varnothing 6.5 \times 50\text{mm}$	48-ST-55120	120mm Straight Rod
63-CP-6555	Pedicle Screw $\varnothing 6.5 \times 55\text{mm}$	48-ST-55130	130mm Straight Rod
63-CP-6560	Pedicle Screw $\varnothing 6.5 \times 60\text{mm}$	48-ST-55140	140mm Straight Rod
63-CP-7525	Pedicle Screw $\varnothing 7.5 \times 25\text{mm}$	48-ST-55150	150mm Straight Rod
63-CP-7530	Pedicle Screw $\varnothing 7.5 \times 30\text{mm}$	48-CU-55035	35mm Curved Rod
63-CP-7535	Pedicle Screw $\varnothing 7.5 \times 35\text{mm}$	48-CU-55040	40mm Curved Rod
63-CP-7540	Pedicle Screw $\varnothing 7.5 \times 40\text{mm}$	48-CU-55045	45mm Curved Rod
63-CP-7545	Pedicle Screw $\varnothing 7.5 \times 45\text{mm}$	48-CU-55050	50mm Curved Rod
63-CP-7550	Pedicle Screw $\varnothing 7.5 \times 50\text{mm}$	48-CU-55055	55mm Curved Rod
63-CP-7555	Pedicle Screw $\varnothing 7.5 \times 55\text{mm}$	48-CU-55060	60mm Curved Rod
63-CP-7560	Pedicle Screw $\varnothing 7.5 \times 60\text{mm}$	48-CU-55065	65mm Curved Rod
63-CP-8525	Pedicle Screw $\varnothing 8.5 \times 25\text{mm}$	48-CU-55070	70mm Curved Rod
63-CP-8530	Pedicle Screw $\varnothing 8.5 \times 30\text{mm}$	48-CU-55075	75mm Curved Rod
63-CP-8535	Pedicle Screw $\varnothing 8.5 \times 35\text{mm}$	48-CU-55080	80mm Curved Rod
63-CP-8540	Pedicle Screw $\varnothing 8.5 \times 40\text{mm}$	48-CU-55090	90mm Curved Rod
63-CP-8545	Pedicle Screw $\varnothing 8.5 \times 45\text{mm}$	48-CU-55100	100mm Curved Rod
63-CP-8550	Pedicle Screw $\varnothing 8.5 \times 50\text{mm}$	48-CU-55110	110mm Curved Rod
63-CP-8555	Pedicle Screw $\varnothing 8.5 \times 55\text{mm}$	48-CU-55120	120mm Curved Rod
63-CP-8560	Pedicle Screw $\varnothing 8.5 \times 60\text{mm}$	48-CU-55130	130mm Curved Rod
63-CP-8570	Pedicle Screw $\varnothing 8.5 \times 70\text{mm}$	48-CU-55140	140mm Curved Rod
63-CP-8580	Pedicle Screw $\varnothing 8.5 \times 80\text{mm}$	48-CU-55150	150mm Curved Rod
63-CP-8590	Pedicle Screw $\varnothing 8.5 \times 90\text{mm}$		
63-CP-8500	Pedicle Screw $\varnothing 8.5 \times 100\text{mm}$		

# ORDERING INFORMATION — INSTRUMENTS

PART NUMBER	DESCRIPTION	PART NUMBER	DESCRIPTION
04-9075	Torque Limiting Handle	63-9026	Counter Torque Handle
09-9027	K-Wire Retractor	63-9030	Tower Tube Removal Tool
09-9029	Tissue Cutter	63-9035	Rod Inserter Tightener Shaft
09-9043	Mallet	63-9038-08	MIS 3L Serial Dilator, 8mm
39-CH-0008	Offset Ratcheting Torque Handle	63-9038-13	MIS 3L Serial Dilator, 13mm
48-9008	Caliper	63-9038-18	MIS 3L Serial Dilator, 18mm
48-9011	Tab Remover	63-4100-55	Bifurcated Tap, 5.5mm
48-9014	Cap Screw Inserter	63-4100-65	Bifurcated Tap, 6.5mm
63-0315	T-Handle, Reduction Tower	63-4100-75	Bifurcated Tap, 7.5mm
63-9001	C-Torque Sleeve	63-4100-85	Bifurcated Tap, 8.5mm
63-9003	Tower Tube	63-4101	Tap Dilator
63-9005	Rod Inserter, Side Load	HXI-48-0002	K-Wire Nitinol, Trocar/Threaded
63-9007	Handle, Gearshift, ¼ Sq., Ratchet, Cannulated	HXI-48-0003	K-Wire, Nitinol, Blunt/Threaded
63-9012	Percutaneous Screwdriver, Short	HXI-48-0004	K-Wire, S.S. Trocar/Threaded
63-9015	Torque Drive Shaft	HXI-48-0005	K-Wire, S.S. Blunt Threaded
63-9018	Bottle Cap	PSSRT	Ratchet Handle, T
63-9021	Reduction Sleeve	PSSTPS	3.5mm Hex Driver
63-9022	Reducer Extender	SL-9001	Head Positioner
		74174-01m	8G Jamshidi Bevel & Trocar Tip
		74182-01m	11G Jamshidi; Trocar Tip
		74182-02m	13G Jamshidi; Bevel & Trocar Tip
		63-9058	Compressor-Distractor Arm A
		63-9059	Compressor-Distractor Arm B

# INDICATIONS

## APPROVED INDICATIONS

The SureLOK™ MIS 3L Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis).

The SureLOK MIS 3L Pedicle Screw System is also intended for non-cervical pedicle screw fixation for the following indications: severe spondylolisthesis (grades 3 & 4 of the L5-S2 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 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 the Instructions for Use (IFU) (LBL-IFU-017) package insert for complete system description, indications and warnings.

## CONTRAINDICATIONS

The SureLOK MIS 3L System contraindications include, but are not limited to the following:

1. Morbid obesity
2. Mental illness
3. Alcoholism or drug abuse
4. Fever or leukocytes
5. Pregnancy
6. Severe osteopenia
7. Metal insensitivity/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 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 the following:

1. Non-union
2. Fracture of the vertebra
3. Neurological injury
4. Vascular or visceral injury
5. Early or late stage loosening of any or all components
6. Loss of fixation
7. Device component failure
8. Foreign body (allergic) reaction to implants, debris, corrosion products and graft material, including metallosis, straining, tumor formation and/or autoimmune disease
9. Disassembly and/or bending of any or all components
10. Infection
11. Hemorrhage
12. Change in mental status
13. Pressure on the skin from component parts in patients with inadequate tissue coverage of 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 or increase in spinal mobility or function
18. Death

### NOTE:

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



# INDICATIONS (continued)

## 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. 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 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 REUSED.** 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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