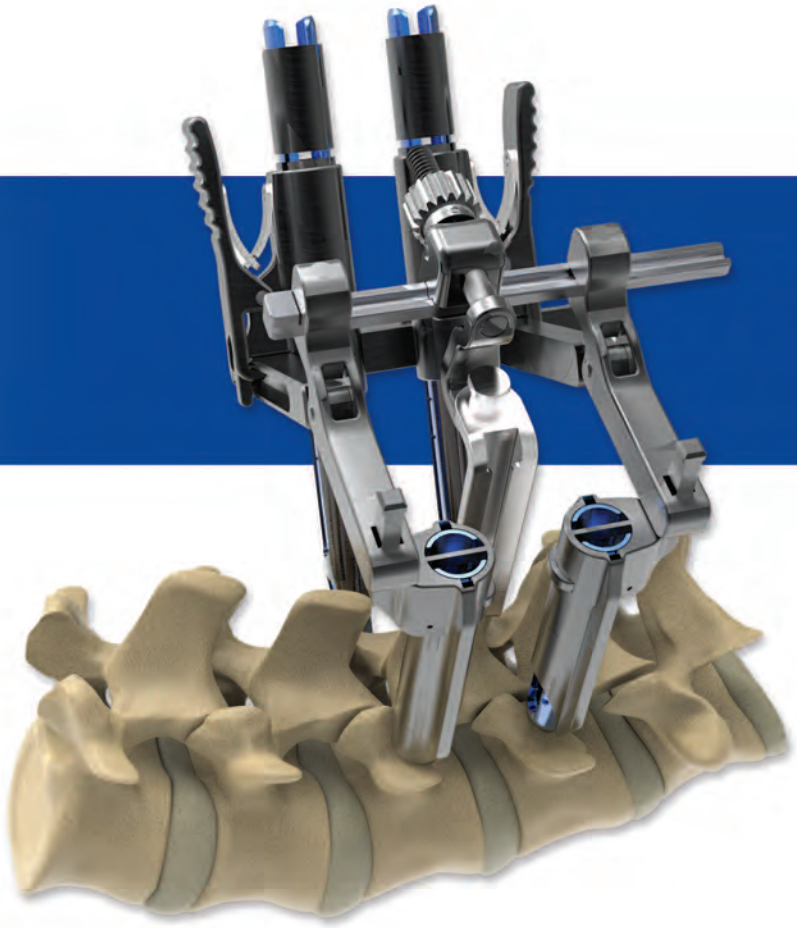
PRECISION SPINE®



MD-MAX™ ULIF

MINIMALLY DISRUPTIVE-MAXIMUM ACCESS SYSTEM

Surgical Technique

FEATURING EXTENDED TAB PEDICLE SCREW

Table of Contents

MD-Max™ *ULIF* System Overview

The MD-Max™ *ULIF* (Universal Lumbar Interbody Fusion) system is a minimally invasive retractor access system that is centered on the philosophy of a minimally disruptive, muscle sparing approach to the spine. The system preserves the posterior stabilizer (multifidus) of the spine that is affected in the classic open approach.

The MD-Max *ULIF* System can be utilized for single and multi-level fusions. It allows the surgeon to address all of the pathology by enabling a decompression from a unilateral approach, with a contralateral distraction of the spine via contralateral towers. This allows for even distraction of the disc space on both sides, thereby opening up both neuroforamen symmetrically. Further, if the surgeon desires to approach the spine from an ipsilateral approach, all pathology can be addressed both contralaterally and ipsilaterally from one side only and if contralateral decompression is desired without notification, the system allows for direct contralateral decompression. Most importantly, this approach and system allows the surgeon to perform all tasks that would be done through the classic open approach but using a minimally disruptive muscle sparing approach.

Indications

The SureLOK SLC Extended Tab 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 (pseudoarthrosis).

The SureLOK SLC Extended Tab 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; pseudoarthrosis; and failed previous fusion.

Please refer to SureLOK *SLC* Extended Tab Instructions For Use (IFU) (LBL-IFU-017) for complete system description, indications, and warnings.

System Features

Set Configuration

Access Instruments

74182-01M	Pedicle Access Needle (PAN) "Jamshidi" (Trocar - Dia. 2.4mm, Needle Dia. 2mm)
74182-02M	Trocar and beveled stylet

Retractor Instruments and Implants

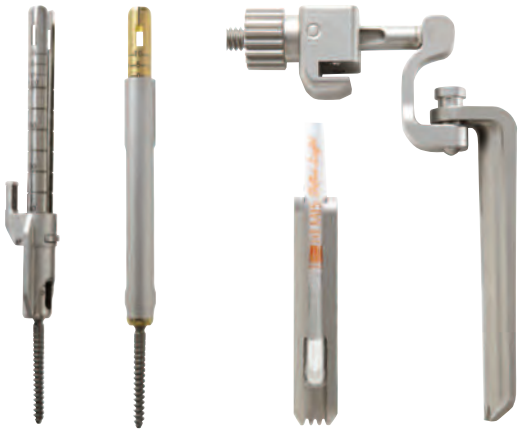
43-8000-CA	MD-Max™ Instrument Kit
43-8500-CA	MD-Max Implant Kit
43-5000	Light Source
OM1242	MIS Ortho-Light Box of 5 Surgical Illuminators

Fixation Instruments and Implants

21-10910CA	SureLOK™ *SLC* MIS Instruments with Radel Dilators
48-1100-CA	SureLOK *SLC* Extended Tab System Instruments
48-2000-CA	SureLOK *SLC* Extended Tab System Implants

MD-Max System

- Low Profile, Sleek Design
- Allows for Parallel and Multi-Level Distraction
- Enhanced Visualization to Access Corridor
- Intuitive, Easy-to-Assemble Connections
- Breakaway, Extended Tab Screws Allow for Smaller Retractor Blades & Sleeves
- Threaded Medial Blade Assembly Provides Controlled Retraction
- Disposable Lighting Tubes Enhance Visualization



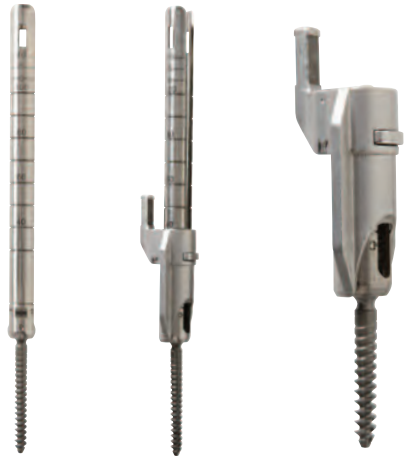
MD-Max™ Screw Features

- Open Tulip design enhances rod insertion
- Breakaway Tabs allow unimpeded access to corridor (10mm increments)
- Additional Tulip Threads provide 20mm reduction

5.5mm Extended Tab Screw Diameter
- Length 35-55mm in 5mm increments

6.5mm Extended Tab Screw Diameter
- Length 35-55mm in 5mm increments

7.5mm Extended Tab Screw Diameter
- Length 35-55mm in 5mm increments



Extended Tab Screw Features

- 150mm Extended Tab allows for low profile, MIS percutaneous placement with 20mm of controlled rod reduction
- Open Tulip design & 30° of angulation eases rod introduction
- Square Thread Locking Cap reduces potential for cross threading
- Proximal tapered thread enhances pull out strength
- Self tapping, self drilling screw tip eases insertion

5.5mm Extended Tab Screw Diameter
- Length 35-55mm in 5mm increments

6.5mm Extended Tab Screw Diameter
- Length 35-55mm in 5mm increments

7.5mm Extended Tab Screw Diameter
- Length 35-55mm in 5mm increments

Percutaneous Rod & Inserter

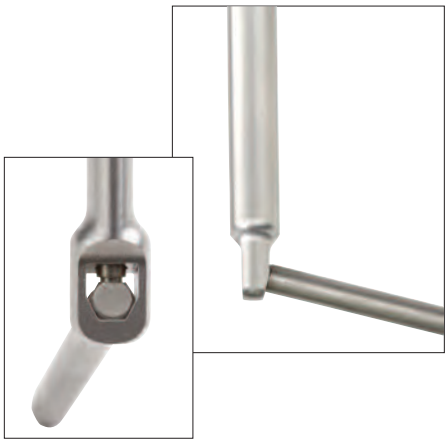
- Easy-to-use percutaneous rod inserter
- Bulleted tip, keyed hex end and 15° rod angle eases rod insertion and release
- Aileron shaped inserter shaft glides easily through the tulips for fast and efficient rod delivery

Curved Rods

- Length 35-75mm in 5mm increments
- Length 80-110mm in 10mm increments

Straight Rods

- Length 100-150mm in 10mm increments

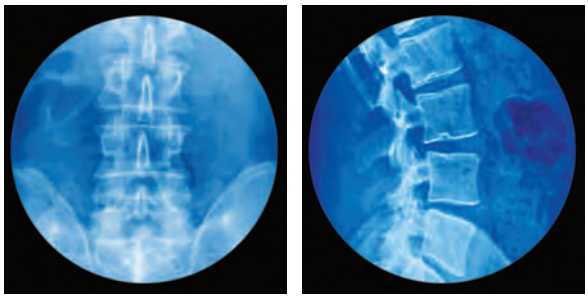


1. Preoperative Setup

The patient is prepped and draped in the usual sterile manner and positioned on a radiolucent operating table in a prone position.

It is recommended that a Jackson Table be used to assist in achieving the proper patient positioning and an unrestricted fluoroscopic view.

Using fluoroscopy, adjust the table so that the C-Arm provides an A/P image when the orbital angle is at 90° and a true lateral image when the orbital angle is at 0° (Figure 1).



A/P Image Lateral Image

Figure 1

2. Pedicle Targeting

a. Using true A/P imaging, place the Targeting Device inline with the spinous processes and draw a center line generously extending beyond the targeted level for intraoperative referencing.

b. Place the Targeting Device transversely across the mid-line of the cephalad pedicles and draw a line again extending generously for intra-operative referencing. Repeat for the caudal pedicles. It is recommended that the surgeon obtains a distinct endplate view above the targeted pedicles.

c. Place the Targeting Device on the lateral border of both ipsilateral and contralateral pedicles and draw a reference line extending generously cephalad and caudal intersecting the transverse lines, establishing incision lines and proper access corridor (Figures 2 and 2a).

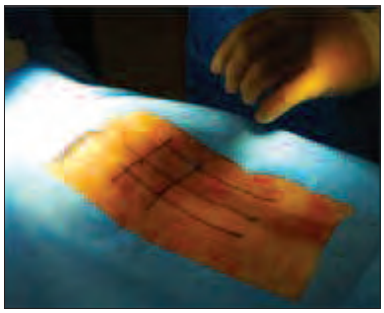
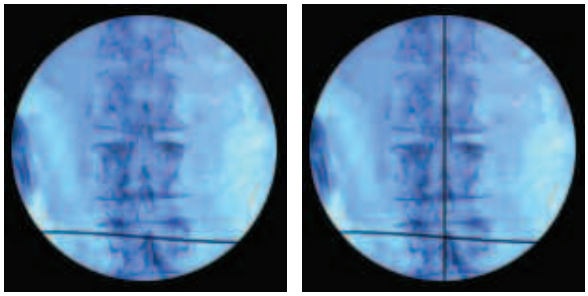


Figure 2



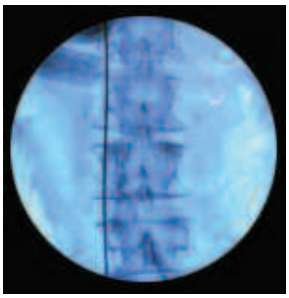


Figure 2a

The entry point is approximately 3-4cm off mid-line, but will change based upon size of patient and location of the multifidus and longissimus interval. A more lateral starting trajectory will help ensure ideal interbody placement across mid-line (Figure 3). The skin incision can be infiltrated with a Marcaine solution, if desired.

a. Make a pedicle-to-pedicle skin incision between the entry point markings on the side where the interbody is being performed (Figure 4). This incision is defined by the pathological distance between pedicles. Once through the skin, use a finger to dissect down to the dorsal lumbar fascia.

b. Incise the dorsal lumbar fascia, making sure to stay in line with the skin incision, approximately one finger width longer than the skin incision on each side. Note: If tissue dilation is difficult, increase the fascial incision. Dissection is then extended bluntly after palpating the interval of the multifidus and longissimus which is easy to identify. Find and palpate the lateral borders of the facets and sweep cephalad-caudal to create a working plane to prevent muscular damage.

3. Guide Wire Introduction

a. Introduce the Drill Guide (43-1543) through the skin incision down to the intersection of the facet and transverse process (Figure 5).

b. Confirm that the appropriate pedicle starting place has been determined using both A/P (Figure 6) and lateral images.

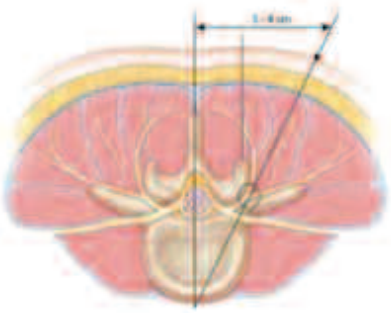


Figure 3

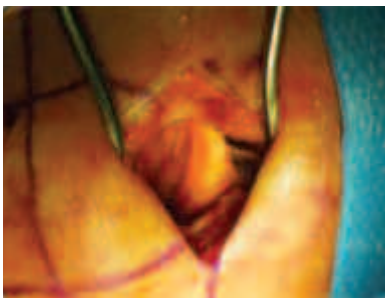


Figure 4

Figure 5

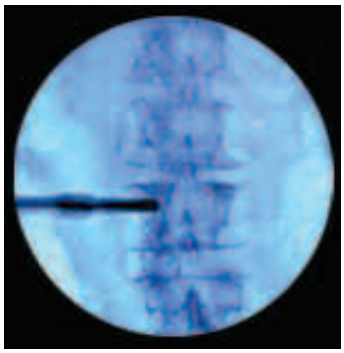


Figure 6

3. Guide Wire Introduction (cont.)

c. Introduce the Drill (43-1545) through the Drill Guide (43-1543) (Figure 7), paying careful attention not to advance past the medial pedicle wall in the A/P view. The drill is designed to be advanced 20mm into the pedicle.

d. Introduce the Guide Wire (48-9016 Nitinol), through the Drill Guide (Figure 8) fixating it into the pedicle. Confirming proper position via fluoro (Figure 9) and then introduce the Guide Wire into the vertebral body. Repeat for additional targeted pedicles.

Notes: The Drill Guide has a stop allowing 20mm of drill depth. The diameter of the Drill is 3.2mm. The Drill Guide has depth markings to aid in sizing the correct Ipsilateral Blade lengths.

Figure 7

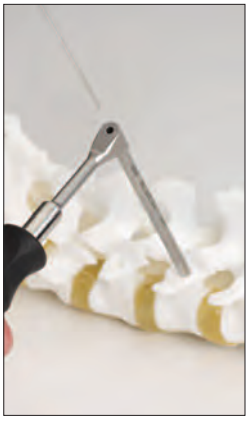


Figure 8

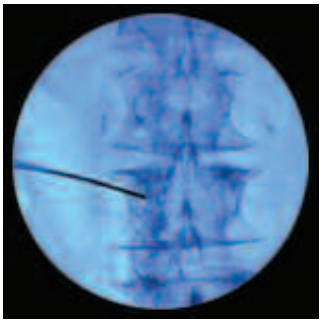


Figure 9

Alternate

Insert the Jamshidi needle (74182-01M) through the skin to the intersection of the facet and transverse process (Figure 10).

Gently advance the needle to engage the trocar tip into the pedicle.

Remove the inner stylet of the Jamshidi needle allowing insertion of the Guide Wire.

Insert the Guide Wire (48-9016 Nitinol or 48-9017 SS) into the Jamshidi needle and advance the Guide Wire beyond the tip of the Jamshidi needle (Figure 11).

Once the Guide Wire is inserted, remove the outer shaft of the Jamshidi needle.

Repeat above for all targeted pedicles.

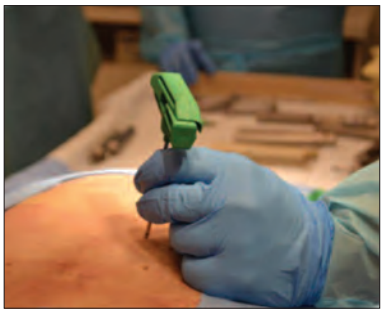


Figure 10

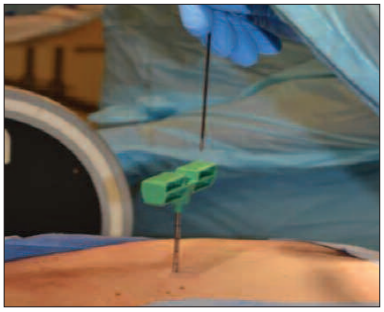


Figure11

4. Tissue Dilation

If not performed on initial exposure, the tissue between the facet joint and the ipsilateral Guide Wires may be released using digital dissection, a cobb, or a curette.

Place the 8mm Dilator (09-9038-08) over the Guide Wire down to the spine (Figure 12) and note the depth markings of the 8mm Dilator in relation to the skin for the selection of the appropriate Ipsilateral Blade and Medial Retractor Blade. Slide the 13mm Dilator (09-9038-13) over the 8mm Dilator to sequentially penetrate and gently dissect soft tissue down to the pedicle (Figure 13).

Figure 12

Figure 13

5. Pedicle Preparation

Remove the 8mm Dilator in preparation for the Cannulated Awl (09-9042) (Figure 14) and/or Tap (09-9033-XX) attached to the Straight handle (PSSRS) or T-Handle (PSSRT). With the 13mm Dilator still in place, prepare the pedicle by placing the Cannulated Awl over the Guide Wire and advance into the pedicle with a twisting motion (Figure 15). Remove the Awl while holding the Guide Wire.

IMPORTANT: Make certain that prior to removing the Awl, the Guide Wire is advanced through the Awl into the vertebral body to prevent it from migrating out.

The Cannulated Modular Taps are concentric with the 13mm Dilator and laser etched with 5mm intervals to help indicate the depth at which the Tap has been inserted, as well as to help determine proper screw length.

Select the appropriate sized Tap, and place over the Guide Wire down to the spine. Insert the Tap into the pedicle (Figure 16). Check pedicle depth with fluoroscopy or read the depth from the 13mm Dilator. Perform this step for all pedicle screws.

NOTE: The diameter of the Taps are .5mm undersized in relation to the screw.

Prior to removing the Tap, make sure that the Guide Wire is advanced through the Tap into the vertebral body to prevent it from migrating out. Grasp the Guide Wire at the skin margin to remove the tap and dilators to prevent wire migration.

Figure 14

Figure 15

Figure 16

6. Screw Insertion

With the pedicle pathway prepared and appropriate screw length and diameter determined, attach the Polyaxial Screw Driver (48-9012) to either the Straight Handle Ratchet (PSSRS) or the T-Handle Ratchet (PSSRT) (Figure 17).

The Ratchet Handle should be towards the floor and the plunger should be facing the ceiling. Depress the plunger toward the Blue Handle and insert the Polyaxial Screw Driver (Figure 18). Confirm that the driver is fully seated in the appropriate handle and will not disengage without depressing the plunger.

The MD-Max™ Screw (43-7000-XXXX) is now attached to the Polyaxial Screw Driver (Figure 19). 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 chosen for length and diameter (Figure 20). Ensure that the male hex head of the Driver is fully seated in the female hex of the screw head (Figure 21). This can be verified by attempting to angulate the screw relative to the tulip head.

Figure 17

Figure 18

Figure 19

Figure 20

Figure 21

6. Screw Insertion (cont.)

With the driver assembly in the same orientation and the screw held firmly seated on the driver, thread the outer sleeve of the Polyaxial Screw Driver (48-9012) until fully engaged and flush with the convex portion of the driver tip (Figure 22). Depress the tab on the locking coupler (Figure 23) and advance it until it is flush with the base of the screw head locking sleeve and clicks when engaged (Figure 24). The outer sleeve of the Polyaxial Screw Driver will not disengage from the screw while the locking coupler is in this position.


Figure 22

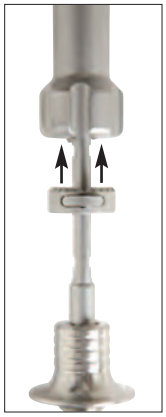


Figure 23


Figure 24

7. Screw Introduction

With the 18mm dilator in place or protecting the paraspinal muscles, place the Polyaxial Screw driver Assembly (48-9012) over the Guide Wire (48-9016 Nitinol) and drive the Screw into the pedicle (Figure 25).

Seat the Screw at the appropriate depth into the pedicle and make sure that there is some movement of the tulip cephalad-caudal and that the Screw has not bound onto the facet.

NOTE: If inserting the screw through the 18mm Dilator (09-9038-18), the Polyaxial Screw driver may bottom out on the Dilator prior to being fully seated. In the event this occurs, the Polyaxial Screw driver and
Dilator can be removed and insertion to the final depth can be accomplished by using the 3.5mm Hex Screwdriver (PSSTPS).

Remove the Guide Wire once the screw is seated in the pedicle to prevent bending or impingement of the wire. To remove the Polyaxial Screw driver from the Screw, depress the tab on the locking coupler of Polyaxial Screw driver and pull up on the coupler (Figure 26). Turn the Screwdriver outer sleeve counter clockwise to unthread the driver from the Screw.

Drive all remaining MD-Max™ screws on the ipsilateral side using the method described (Figure 27).


Figure 25

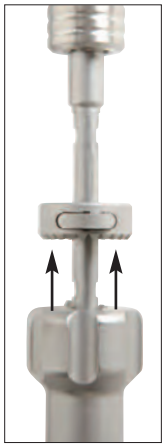


Figure 26


Figure 27

8. Contralateral Screw Introduction

On the contralateral side, the same process to deliver the SureLOK™ *SLC* Extended Tab Screws (Figure 28) is repeated, protecting the muscles, identifying the interval (multifidus-longissimus), proper screw preparation, and insertion of the SureLOK *SLC* Extended Tab Screws (Figures 29 and 29a).

Figure 28

Figure 29

Figure 29a

9. Ipsilateral Blade Introduction

With prior determination, select the appropriate sized Ipsilateral Retractor Blade (43-6100-XXX), depress the sleeve's locking mechanism button, and slide the sleeve over the MD-Max™ Screw down to the base of the tulip (Figures 30 & 30a).

Confirm the Retractor Blade position via a lateral image. Repeat this process for the adjacent level screw.

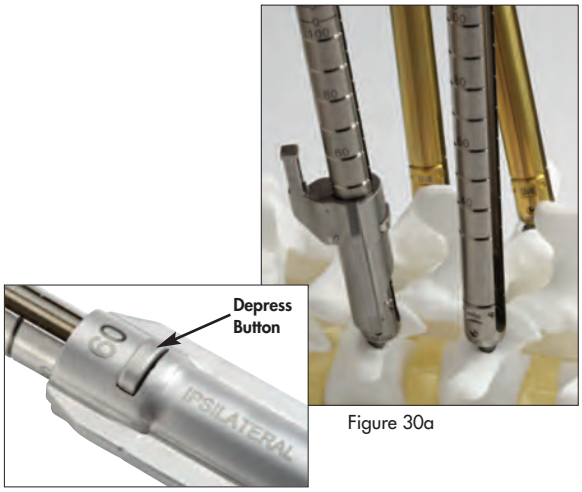


Figure 30a

Figure 30

10. Straight Sleeve Introduction

On the contralateral side, select the Straight Sleeve (48-9003) and slide the Sleeve over the SureLOK™ *SLC* Extended Tab Screw and advance it to the base of the tulip. The proximal portion of the Sleeve will be just below the "0" mark on the Extended Tab (Figure 31). After the Straight Sleeve is seated, slide the Straight Bottle Cap (48-9004) over the SureLOK *SLC* Extended Tab Screw to capture the Straight Sleeve on the Screw.

Note: The arrows on the straight sleeve and straight bottle caps point towards each other when correctly assembled

Confirm the Sleeve position via lateral image. Repeat this process for the adjacent level screw.

Figure 31

With Bottle Cap

11. Base Retractor Attachment

Introduce the MD-Max™ Base Retractor (43-6000) onto the engagement post of each Ipsilateral Retractor Blade (43-6100-xxx) (Figures 32 & 32a).

TIP: It may be easier to align the left (stationary) leg of the Retractor first, and then adjust the right (movable) leg while depressing the button distal to the female hex. Align the Screw/Retractor Blade Assemblies such that they line up properly with the affected disc space.

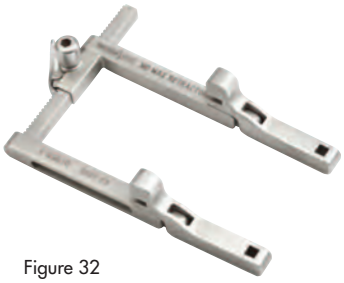


Figure 32

Figure 32a

12. Contralateral Tower Attachment

On the contralateral side, place the Contralateral sleeve (43-6200) (Figures 33 & 33a) over the Straight Sleeves and lock into place on the Base Retractor (Figure 33b).

Push the Retractor Arm towards the ipsilateral side to angle the retractor blades for a TPLIF or PLIF approach.

Figure 33

Figure 33a

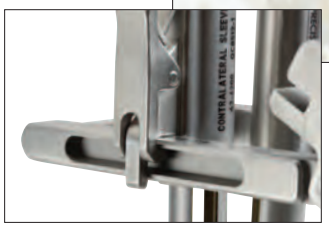


Figure 33b

13. Ipsilateral Screw Tab Removal

Once the Contralateral Towers are secured to the construct, the Extended Tab of the ipsilateral MD-Max™ screws can be removed using the Tab Remover (48-9011).

The Tab Remover is inserted over the individual Extended Tab until flush with the proximal surface of the Ipsilateral Blade.

The Tab Remover is rocked medial/lateral until the Extended Tab disengages from the MD-Max screw (Figures 34 & 34a).

Figure 34

Figure 34a

14. Medial Blade Attachment

Attach the Medial Blade Retractor Assembly (43-2100-00) to the Medial Blade Bar (43-2200-00), and then onto the MD-Max Retractor (Figure 35). Attach the appropriate length Medial Retractor Blade (43-2000-XXX) onto the Medial Blade Retractor Assembly (Figure 36). Turn the knob on the Medial Blade Assembly clockwise to retract the soft tissue and the multifidus muscle medially in order to gain adequate exposure and maintain proper angle of retraction.

Attach the Reusable Light Cable (43-0080) to the Disposable Surgical Illuminator (OM1242) and slide the Disposable Surgical Illuminator down the Medial Blade slot for additional visualization (Figure 37). Attach the Light Cable to the Light Source (43-5000).

Figure 35

Figure 36

Figure 37

15. Facetectomy & Decompression

Identify key anatomy such as the facet joint, pars, and inferior edge of the lamina based on their location relative to the pedicles (Figure 38).

Perform the facetectomy. A burr can be used to thin the remainder of the facet complex, and Kerrison Rongeurs can be used to complete the facetectomy and decompression. The facet joint should be removed to allow for adequate exposure to affected disc space (Figure 39).

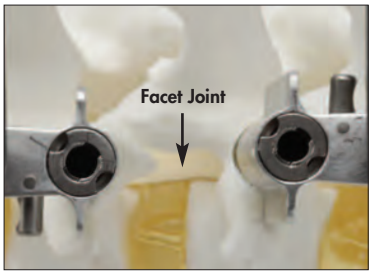


Figure 38

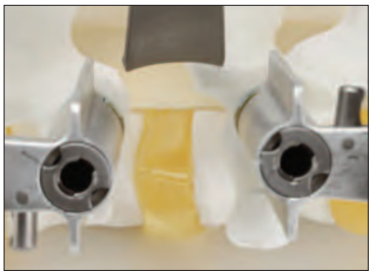


Figure 39

16. Distraction

To distract, attach the Hex Driver (43-1629) to the Torque Limiting T-Handle (43-0552) and insert the Hex Driver into the Base Retractor Hex (Figure 40) and rotate clockwise until the desired amount of distraction is achieved. This will allow simultaneous ipsilateral and contralateral distraction (Figure 41).

Note: Care must be taken to avoid damaging the pedicles during distraction. It is recommended to use the distraction feature initially to tighten the retractor and distract slightly to gain exposure. Once a facetectomy, decompression laminectomy and annulotomy have been performed, increase distraction to open up the disc space further.

Figure 40

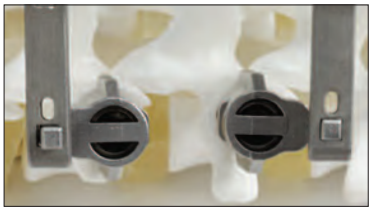


Figure 41

17. Disc Prep/Interbody Insertion

Perform routine discectomy and interbody preparation per surgeon preference.

Perform placement of interbody per surgeon preference.

18. Rod Placement

With interbody placement completed, disengage the Retractor Assembly and remove. Use the 3.5mm Tapered Hex Driver (PSSTPS) to adjust the height of the screws 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 42). The measurement that is indicated in the Rod Caliper window includes the amount of proper rod distance past the cephalad-caudal ends of the tulip (Figure 43).

Use the appropriate pre-cut rod and introduce it into the tulip using the Rod Holder (PSSRH) (Figure 44), making sure proper sagittal contour is in the correct plane.

Figure 42

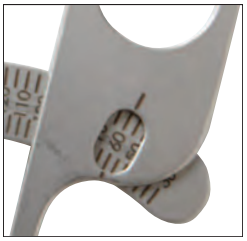


Figure 43

Figure 44

19. Cap Screw Insertion

Insert the Cap Screw (SL1000) onto the tip of the Cap Screw Inserter (48-9014) (Figure 45). The retaining ring will ensure that the Cap Screw is secured to the Inserter. Insert through the Extended Tab (Figure 46) and thread the Cap Screw into the tulip. After Cap Screw insertion, remove the Cap Screw Inserter. Repeat for subsequent screws. Do not use the Inserter to reduce the rod.

Figure 45

Figure 46

20. Final Tightening

Verify under fluoroscopy that the position of the Screws and Rods are acceptable. The Cap Screws (SL-1000) are tightened with the Final Tightener Shaft (PSSTD-Shaft) and the Torque-Limiting Handle (PSSTD - Handle). Place the All-in-One Reduction Sleeve (48-9001) over the Extended Tab, then insert the Counter-Torque Handle (48-9006) over the proximal portion of the All-in-One Reduction Sleeve (Figures 47 & 48). Insert the Final Tightener through the Extended Tab and seat the distal end of the Driver into the Cap Screw (Figure 49). Turn the Offset Torque-Limiting Handle clockwise until an audible click is heard, verifying the final torque of 106 in-lbs. Repeat for remaining screws.

Figure 47

Figure 48

Figure 49

21. Extended Tab Removal

Perform a final verification of the Polyaxial Screw and Rod positioning using fluoroscopy. Remove the Offset Torque-Limiting Handle. Next, 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 Extended Tab portion is disassociated from the Pedicle Screw (Figure 50). Repeat for remaining Polyaxial Screws (Figure 51).

Figure 50

Figure 51

22. Implant Removal

In order to remove the implants, attach the Final Tightener shaft to the Ratcheting T-Handle (PSSRT). Stabilize the construct (Anti-Torque Wrench (00-9020) from standard SureLOK PSS system may be used), then loosen and remove the Cap Screws. Remove Rods. Use the 3.5mm Hex Polyaxial Screw Driver (PSSTPS) to back out the screws from the pedicles.

MD-Max™ *ULIF* System Implants

Item No.	Description
Extended Tab Percutaneous Screw	
43-7000-5535	MD-Max 5.5 x 35mm Percutaneous Screw
43-7000-5540	MD-Max 5.5 x 40mm Percutaneous Screw
43-7000-5545	MD-Max 5.5 x 45mm Percutaneous Screw
43-7000-5550	MD-Max 5.5 x 50 mm Percutaneous Screw
43-7000-5555	MD-Max 5.5 x 55 mm Percutaneous Screw
43-7000-6535	MD-Max 6.5 x 35mm Percutaneous Screw
43-7000-6540	MD-Max 6.5 x 35mm Percutaneous Screw
43-7000-6545	MD-Max 6.5 x 45mm Percutaneous Screw
43-7000-6550	MD-Max 6.5 x 50mm Percutaneous Screw
43-7000-6555	MD-Max 6.5 x 55mm Percutaneous Screw
43-7000-7535	MD-Max 7.5 x 35mm Percutaneous Screw
43-7000-7540	MD-Max 7.5 x 40mm Percutaneous Screw
43-7000-7545	MD-Max 7.5 x 45mm Percutaneous Screw
43-7000-7550	MD-Max 7.5 x 50mm Percutaneous Screw
43-7000-7555	MD-Max 7.5 x 55mm Percutaneous Screw
48-3000-5535	SureLOK™ *SLC* 5.5 x 35mm Percutaneous Screw
48-3000-5540	SureLOK *SLC* 5.5 x 40mm Percutaneous Screw
48-3000-5545	SureLOK *SLC* 5.5 x 45mm Percutaneous Screw
48-3000-5550	SureLOK *SLC* 5.5 x 50mm Percutaneous Screw
48-3000-5555	SureLOK *SLC* 5.5 x 55mm Percutaneous Screw
48-3000-6535	SureLOK *SLC* 6.5 x 35mm Percutaneous Screw
48-3000-6540	SureLOK *SLC* 6.5 x 40mm Percutaneous Screw
48-3000-6545	SureLOK *SLC* 6.5 x 45mm Percutaneous Screw
48-3000-6550	SureLOK *SLC* 6.5 x 50mm Percutaneous Screw
48-3000-6555	SureLOK *SLC* 6.5 x 55mm Percutaneous Screw
48-3000-7535	SureLOK *SLC* 7.5 x 35mm Percutaneous Screw
48-3000-7540	SureLOK *SLC* 7.5 x 40mm Percutaneous Screw
48-3000-7545	SureLOK *SLC* 7.5 x 45mm Percutaneous Screw
48-3000-7550	SureLOK *SLC* 7.5 x 50mm Percutaneous Screw
48-3000-7555	SureLOK *SLC* 7.5 x 55mm Percutaneous Screw
SL1000	Cap Screw

Item No.	Description
Rods	
48-ST-55100	100mm Straight Rod
48-ST-55110	110mm Straight Rod
48-ST-55120	120mm Straight Rod
48-ST-55130	130mm Straight Rod
48-ST-55140	140mm Straight Rod
48-ST-55150	150mm Straight Rod
48-CU-55035	35mm Curved Rod
48-CU-55040	40mm Curved Rod
48-CU-55045	45mm Curved Rod
48-CU-55050	50mm Curved Rod
48-CU-55055	55mm Curved Rod
48-CU-55060	60mm Curved Rod
48-CU-55065	65mm Curved Rod
48-CU-55070	70mm Curved Rod
48-CU-55075	75mm Curved Rod
48-CU-55080	80mm Curved Rod
48-CU-55090	90mm Curved Rod
48-CU-55100	100mm Curved Rod
48-CU-55110	110mm Curved Rod

MD-Max™ *ULIF* System Instruments

Item No.	Description
43-1543	Drill Guide
43-1545	Drill
48-9016	Nitinol Guide Wire
48-9017	SST Guide Wire*
74182-01M	Jamshidi - Trocar tip*
74182-02M	Jamshidi - Trocar and bevel tip*
09-9038-08	Radel Dilation Tube, 8mm
09-9038-13	Radel Dilation Tube, 13mm
09-9038-18	Radel Dilation Tube, 18mm
09-9038-24	Radel Dilation Tube, 24mm
09-9042	Cannulated Awl
PSSRS	Ratchet Straight
PSSRT	Ratchet T-Handle
09-9033-55	Cannulated Tap (Aggressive), 5.5mm
09-9033-65	Cannulated Tap (Aggressive), 6.5mm
09-9033-75	Cannulated Tap (Aggressive), 7.5mm
48-9012	Percutaneous Screwdriver
09-9027	Guide Wire Retractor
09-9043	MIS Mallet
43-6100-040	Ipsilateral Blade Assembly, 40mm
43-6100-060	Ipsilateral Blade Assembly, 60mm
43-6100-080	Ipsilateral Blade Assembly, 80mm
43-6100-100	Ipsilateral Blade Assembly, 100mm
48-9003	Sleeve, Straight
48-9004	Bottle Cap Straight
43-6000	MD-Max Bilateral Retractor Assembly

Item No.	Description
43-6200	Contralateral Sleeve
43-2200-00	Medial Blade Bar
43-2100-00	Medial Blade Rack Assembly
43-2000-040	Medial Retractor Blade, 40mm
43-2000-050	Medial Retractor Blade, 50mm
43-2000-060	Medial Retractor Blade, 60mm
43-2000-070	Medial Retractor Blade, 70mm
43-2000-080	Medial Retractor Blade, 80mm
43-2000-090	Medial Retractor Blade, 90mm
43-2000-100	Medial Retractor Blade, 100mm
43-2000-110	Medial Retractor Blade, 110mm
43-0080	Reusable Light Cable-Lumitex
OM1242	Disposable Ortholight Surgical Illuminators*
43-0552	Torque Limiting T-Handle
43-1629	Hex Driver
PSSTPS	Tapered Hex Male Fixed T-Handle, 3.5mm
48-9008	Caliper
PSSRH	Rod Holder
48-9005	Rod Inserter
48-9014	Cap Screw Inserter
48-9001	Sleeve, All-in-One
48-9006	Counter Torque Handle
PSSTD Handle	Torque Drive, 106 in-Lbs
PSSTD-Shaft	Torque Drive Shaft
48-9011	Tab Remover
43-5000	Lumitex Light Source*

* Item must be ordered separately

Indications, Contraindications, Warnings, and Precautions

Indications:

The SureLOK SLC Extended Tab 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 (pseudoarthrosis).

The SureLOK SLC Extended Tab 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; pseudoarthrosis; and failed previous fusion.

Precautions:

The SureLOK SLC Extended Tab 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 SLC Extended Tab 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.

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, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). 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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Caution: Federal (USA) law restricts these devices to sale by, or on the order of, a physician.

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