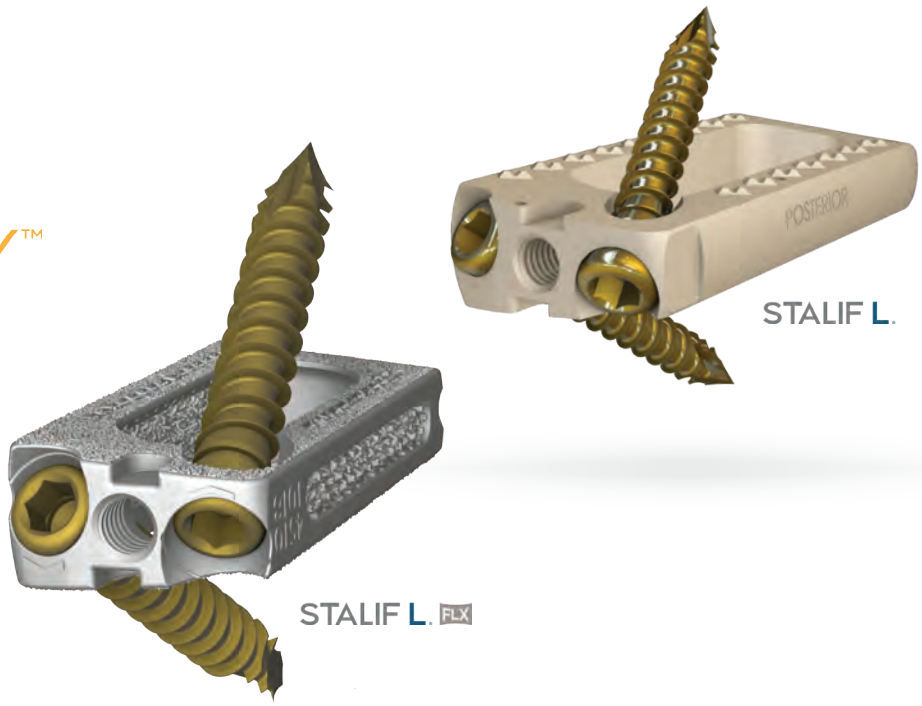
silony® SPINE

# STALIF L. Portfolio

No Profile® Lateral Lumbar Integrated Interbody™ System

## TECHNIQUE & PRODUCT GUIDE

*featuring*
**INTEGRATED**
*INTERBODY™*
*Technology*



STALIF L®

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# STALIF L *Portfolio*

The **STALIF L** Portfolio offers a comprehensive set of instruments and implants designed to support a direct lateral approach to the lumbar spine. The direct lateral approach (also known as XLIF, DLIF, or LLIF) is a minimally invasive, transpsoas approach that is muscle sparing and avoids direct retraction of the anterior vessels and posterior nervous structures.

## Access Options

Silony Spine provides three retractor options to provide direct minimally invasive access to the operative level while allowing for fluoroscopic visualization. Please contact Customer Service for more detailed information on options and availability.

- In'Tech Lateral Retractor System & Disposable Neuromonitoring Kit

  Pre-assembled body with 3 attachable blades, 4th blade option, blade stabilization broaches & disc shim, reusable light cables, disposable light mats, additional instruments (targeting tool, dual ended Penfield, bipolar, long suction tube, bayonet knife handle)

- Koros Lateral Retractor System & Disposable Dilation and Neuromonitoring Kit

  Pre-assembled 4-blade ring system, three-step clover dilation, blade stabilization pins & disc shim, reusable light cables, additional instruments (Penfield #4, nerve root retractors, bipolar, long suction tubes, bayonet knife handle)

- Thompson Lateral Retractor System & Disposable Neuromonitoring Kit

  Modular system allows 2, 3, or 4 blades, two-step clover dilation, blade stabilization pins, and reusable light cables

## Disc Prep Instruments

A variety of straight and angled discectomy instruments are provided to assist in removal of disc material, including endplate elevators, curettes, disc shavers, pituitary and kerrison rongeurs, a rasp, and a long knife handle.

## STALIF L Portfolio Implants

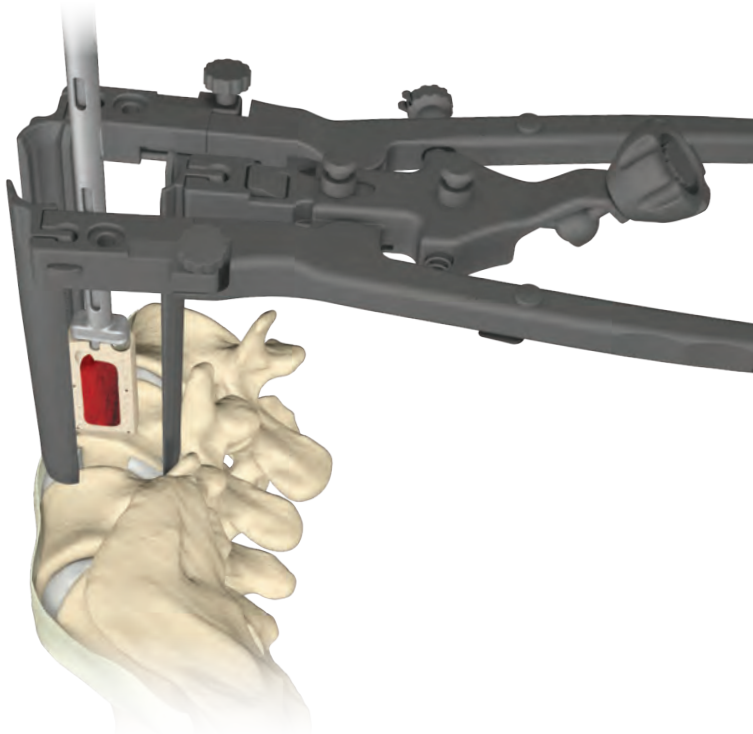
- No Profile® Integrated Interbody™ device with Compressive Lag Screw Fixation for stability
- Parallel and lordotic options to restore sagittal alignment and lumbar lordosis
- 3 medial-lateral footprints (45-55mm) and 4 cage heights (8-14mm) match patient anatomy
- Bulleted nose eases insertion
- Large central graft cavity increases opportunities for fusion through the implant
- Cancellous lag fixation screws with Anti Back-Out (ABO®) technology enhance implant stability
- All implants and screws provided sterile
- Available in 2 state of the art material options: PEEK (poly-ether-ether-ketone) and **FLX** (3D-printed porous titanium)

STALIF L.

STALIF L. FLX

## STALIF L. FLX Implants

**STALIF L FLX** implants are the next evolution in **STALIF** devices. These 3D-printed porous titanium Integrated Interbody devices feature a combination of solid and porous, radiolucent FUSE-THRU® titanium sections which reduce mechanical stiffness and improve visibility compared to solid titanium implants. The proprietary FUSE-THRU trabecular scaffold is modeled to allow for bony in-growth, on-growth, and thru-growth.



## Indications for Use

Refer to the IFU for indications for use and contraindications.

## Warnings & Precautions

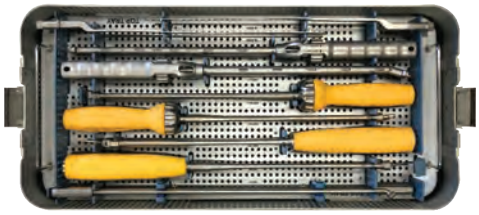
- Patients with previous spinal surgery at the levels to be treated may not experience the same clinical outcomes as those without a previous surgery.
- Selection of an appropriately sized device for the patient is important and increases the likelihood of a satisfactory outcome.
- The implantation of the intervertebral body fusion device should be performed only by experienced spinal surgeons with specific training in the use of this type of device.
- Do not use if the package is damaged or opened. Contents may not be sterile.
- Do not use if current date exceeds label expiry date.
- Do not re-sterilize sterile implants.
- Instrumentation provided with the implants must be used in accordance with the approved surgical technique.
- Do not use excessive force when introducing and positioning the implant within the inter-vertebral body space to avoid damaging the implant.
- Re-usable surgical instruments must be re-sterilized prior to next use.
- Do not reuse the device even if the device shows no external signs of damage. Internal stresses from previous use may cause early failure.
- When using the **STALIF L** Portfolio devices, the physician /surgeon should consider the height of the patient vertebral bodies in the selection of **STALIF L** screw lengths, particularly in contiguous level use.

# *Case Preparation*

## Required Sets

The following instrument sets are required for the **STALIF L** / **STALIF L FLX** surgical technique.

- STL-INST-xxx **STALIF** Lateral Instrument Set
- STL-TRL-xxx **STALIF** Lateral Modular Trials Set
- STL-DPS-xxx **STALIF** Lateral Disc Prep Set



**STALIF** Lateral Instrument Set
STL-INST-xxx

**STALIF** Lateral Modular Trials Set
STL-TRL-xxx

**STALIF** Lateral Disc Prep Set
STL-DPS-xxx

# Case Preparation (continued)

## MIS Retractor Options & Neuromonitoring

The following optional retractor systems and neuromonitoring kits are available for the **STALIF L** surgical technique.

- IN914-01 and IN914-02 In'Tech Lateral Retractor System & S06ITM231 Disposable Nerve Monitoring Probe; optional S06ITM308 Disposable Light Mat Surgical Illuminator
- 7332-65 Koros Lateral Retractor System & 7332-99D Disposable Dilation and Neuromonitoring Kit; optional 7332-77S XL Dilator Tube
- TLRT1 & TLRT2 Thompson Lateral Retractor System & 302427-000-275 Disposable Monopolar Direct Nerve Stimulator Probe or 302775-200 Disposable Multi-stage Lead-wire; optional LLS-2000 light source

**In'Tech Lateral Retractor System**
IN914-01-XX & IN914-02-XX

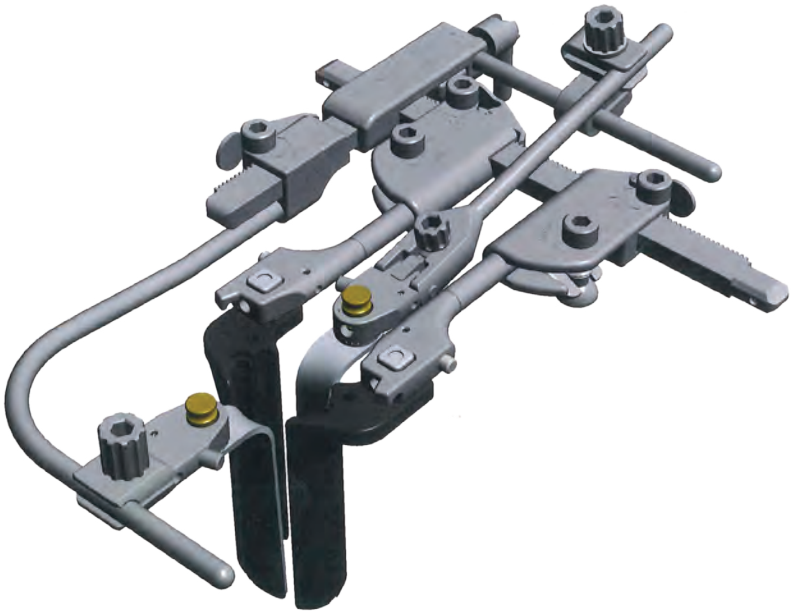

**Koros Lateral Retractor System**
7332-65-XXX

## Additionally Available Instruments

Some instruments are available by special request (see appendix). Please contact Customer Service for availability.

## Quick Reference Guide

The **STALIF L** Quick Reference Guide (LBL593) and **STALIF L FLX** Quick Reference Guide (LBL541) contain an abundance of information about implant offerings, sizes, and measurements and it is recommended to bring one into every case.



**Thompson Lateral Retractor System**
TLRT1-XXX & TLRT2-XXX

# *Surgical Technique*

## Patient Positioning

Correct patient positioning is critical for success. **STALIF L** Portfolio implants are designed for use with a lateral approach to the spine, and the patient should be positioned to enable a direct lateral approach to the disc space.

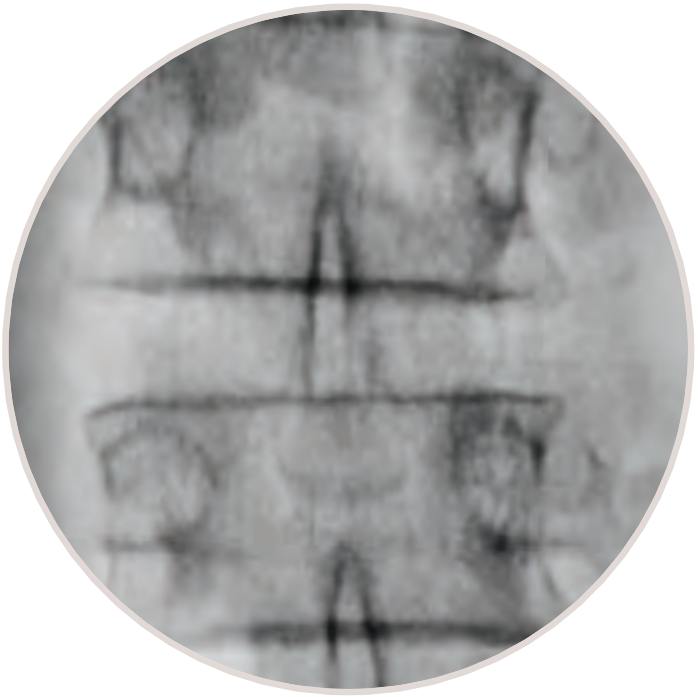
The patient is placed in a lateral decubitus position. When patient anatomy allows, it is recommended that the patient be positioned on their right side for a left side approach (right lateral decubitus approach), because of the relatively anterior position of the vasculature on the left side.

Fluoroscopy is used to find a direct lateral position. The C-arm is positioned at 0º (vertical) for lateral imaging or 90º (horizontal) for A/P imaging, and adjustments are made to the patient and/or table as needed to obtain a direct lateral approach to the first operative level.

When positioned correctly, endplates at the operative level will be superimposed in both A/P and Lateral fluoro views **(Figures 1 & 2)**. In the lateral view, the facet joints should be overlapped and the posterior cortex should be clearly outlined **(Figure 1)**. In the A/P view, the spinous processes should be clearly outlined in the midline of the vertebral bodies above and below the operative level, and the pedicles should be symmetrical **(Figure 2)**.

### 1. Proper Patient Positioning Verified with Lateral Fluoroscopy

### 2. Proper Patient Positioning Verified with A/P Fluoroscopy



Once the direct lateral position has been determined, the patient should be secured to the table with surgical tape. Often, the patient is taped across the chest, across the hip, from the hip across the knee to the table, and from the table across the knee across the ankle and back to the table **(Figure 3)**. Tape should be placed directly on the patient's skin and should be taut; care should be taken to cover sensitive areas with a towel prior to taping.

It is important to make sure that the patient is adequately secured to the table as many table manipulations may be necessary in order to obtain perfect lateral approach positioning at each level. The table may need to be flexed and/or a bolster may be placed beneath patient to increase the hip to rib distance. Caution should be used when flexing the table as over-flexing can result in stretch injury to the psoas.

Once the patient is secured to the table, lateral positioning is confirmed on a level-by-level basis, starting with the first operative level. Utilize x-ray along with a k-wire or targeting tool to mark the disc position and obtain a direct lateral approach. Again, the C-arm should be positioned at 0º (vertical) for lateral imaging or 90º (horizontal) for A/P imaging. The table may be flexed/rotated to obtain direct lateral access **(Figure 4)**. Once the direct lateral position for the first operative level has been obtained, the patient should be draped for the surgery.

## 3. Proper Patient Positioning and Taping Demonstrated


## 4. Flexing the Table to Obtain Direct Lateral Access

**tech TIP** *When imaging for patient positioning, it is recommended to start with an AP image to determine midline, as once this positioning is correct the lateral imaging is often already in proper alignment.*

## *Surgical Technique (continued)*

### Approach

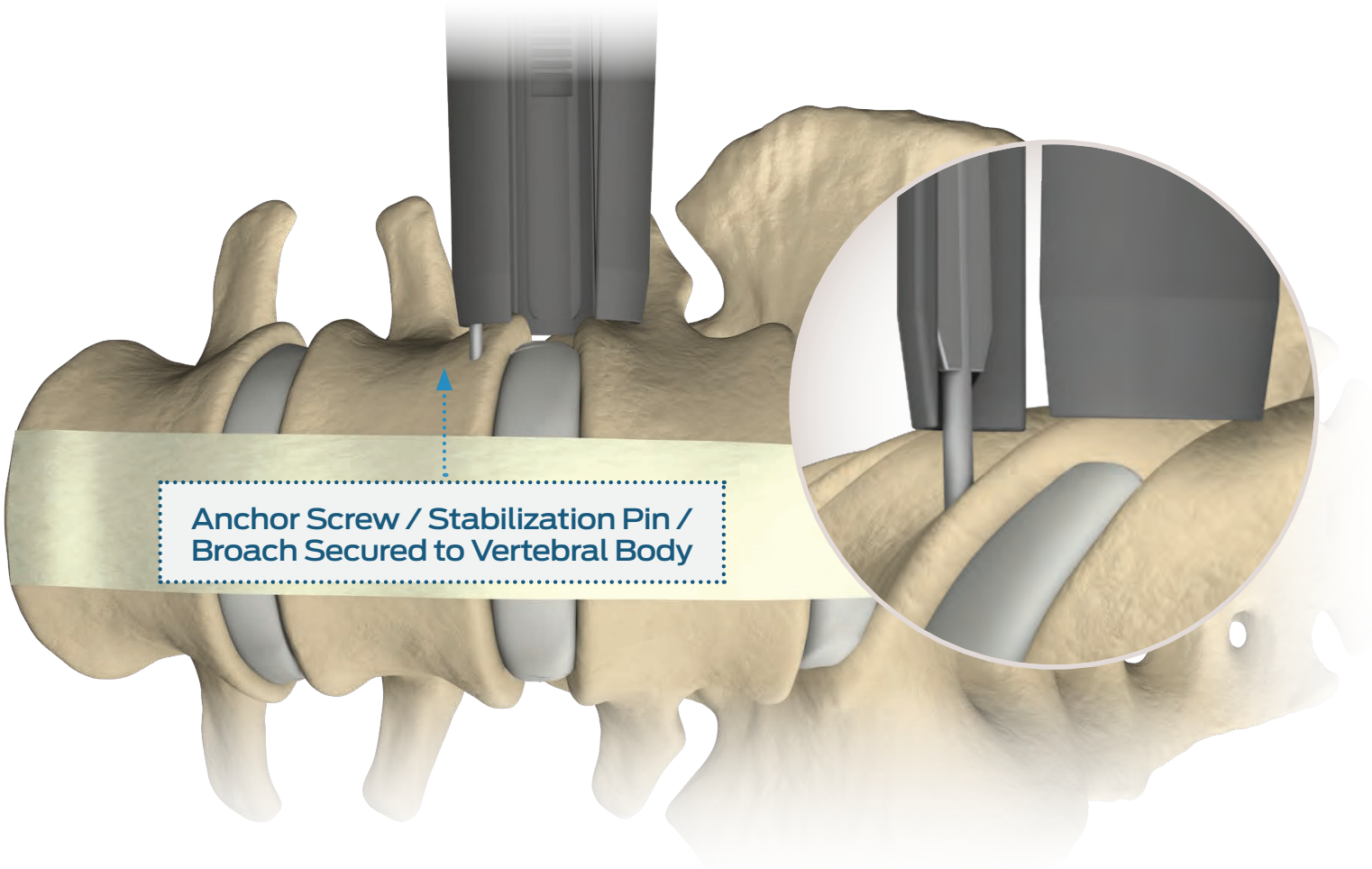
**STALIF L** Portfolio implants are designed for use with a lateral approach to the spine. The patient should be positioned to enable a direct lateral approach to the disc space. To ensure accuracy of approach, the disc is typically targeted slightly anterior of the mid-point.

### Retractor Insertion

The chosen retractor should be inserted according to the applicable retractor technique guide. Retractor blades should be distracted and toed as necessary to enable an appropriate discectomy to be performed and to enable insertion of a 22mm width cage.

Once the appropriate retraction is achieved, the retractor may be temporarily secured to the spine. Depending on the retractor system, an anchor screw / stabilization pin / broach or disc shim may be used. If securing the retractor to the vertebral body, it is recommended that the blade be secured to the vertebral body away from the endplate to limit interference with screw insertion tools **(Figure 5)**.

### 5. In'Tech Retractor with Optional Broach for Added Retractor Stability



## Discectomy and Endplate Preparation

Use any of the disc prep instruments to remove disc material from the intervertebral space to enable trialing.

**STALIF L** PEEK implants are available in a 22mm width; **STALIF L FLX** implants are available in both 18mm and 22mm widths.

An appropriate amount of disc material should be removed to enable insertion of the selected cage. Disc material should be cleared to create a clear lateral pathway through the disc annulus on both sides. It is recommended to leave both the anterior longitudinal ligament (ALL) and posterior longitudinal ligament (PLL) intact.

Once the discectomy is complete, use the rasp or curettes to expose bleeding bone. Care should be taken to only remove the superficial cartilaginous layers of the endplate. Note that excessive removal of subchondral bone may weaken the endplate, and removal of the entire endplate may later lead to segmental instability and implant subsidence.

**Shavers**
IN697 (8mm), IN698 (10mm), IN699 (12mm), IN700 (14mm)

**Box Cutters**
IN903 (6mm), IN904 (8mm), IN905 (10mm)

**Endplate Elevators**
IN838/1 (17mm), IN686/1 (20mm)

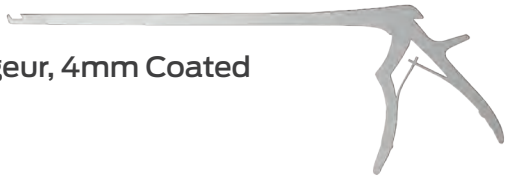
**Forward Angled Endplate Elevator, 13mm**
IN1044/1

**Reverse Angled Endplate Elevator, 13mm**
IN1045/1

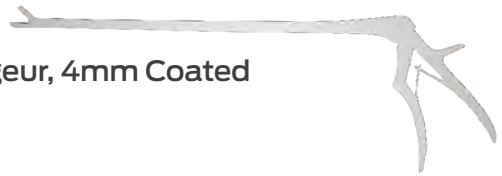
**Rasp**
IN706/1

**Rasp, Bent, 15º**
IN1081

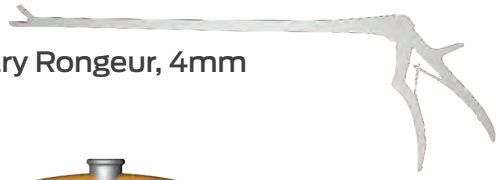
**Knife Handle, 12”**
IN848



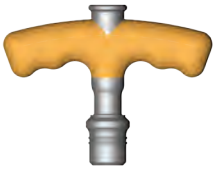
**Kerrison Rongeur, 4mm Coated**
IN710



**Pituitary Rongeur, 4mm Coated**
IN712



**Curved Pituitary Rongeur, 4mm**
IN1043/1



**T-Handle**
IN435/1

**Angled Curettes**
IN685/1 (5mm x 7mm), IN694/1 (3mm x 5mm)

**Teardrop Curette**
IN683 (11mm x 4mm)

**Teardrop Curette, 15º Angle**
IN1077 (11mm x 4mm)

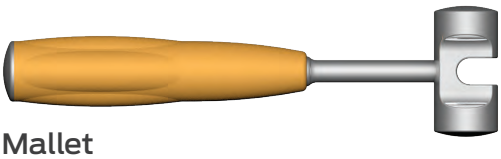
# *Surgical Technique (continued)*

## Trialing

Once the disc has been appropriately prepared, **STALIF L** Portfolio trial sizers are used with the Modular Trial Handle to determine the correct implant size with respect to medial-lateral length and height. There are trials specific to 18mm **FLX** implants, 22mm **FLX** implants, and 22mm PEEK implants, starting at 8mm in height. Starter trials (dilators) are available in 18mm and 22mm to sequentially dilate collapsed disc spaces open, starting at 5mm in height.

To assemble the Modular Starter Trials or Modular Trials to the Modular Trial Shaft, orient the flat side of the Trial/Trial Sizer with the flat face of the T-handle feature of the Trial Shaft **(Figure 6)**.

When using the Modular Trial Shaft, Angled, along with a lordotic (10º or 12º) Modular Trial, care must be taken to also orient the anterior face of the trial for the approach. Hold the Angled Trial Shaft so that the tip of the shaft is angled toward the ceiling **(Figure 7)**; for a left-side up approach, the anterior



**Mallet**
IN228/1

**Slap Hammer**
IN507/2

**Modular Trial Handle**
IN1350

**Modular Trial Shaft, Straight**
IN1414

**Modular Trial Shaft, Angled**
IN1337/1

**Modular Starter Trials (Dilators)**
IN1219/1 (0º x 5mm x 18mm wide),
IN1220/1 (0º x 6mm x 18mm wide),
IN1221/1 (0º x 7mm x 18mm wide),
IN1222/1 (0º x 5mm x 22mm wide),
IN1223/1 (0º x 6mm x 22mm wide),
IN1224/1 (0º x 7mm x 22mm wide)

**Modular Trials**
**FLX**:
IN1134/1 (0º x 8mm x 18mm wide),
IN1136/1 (0º x 10mm x 18mm wide),
IN1138/1 (0º x 12mm x 18mm wide),
IN1145/1 (10º x 10mm x 18mm wide),
IN1147/1 (12º x 12mm x 18mm wide),
IN1149/1 (12º x 14mm x 18mm wide),
IN1151/1 (0º x 8mm x 22mm wide),
IN1144/1 (10º x 10mm x 22mm wide),
IN1167/1 (12º x 12mm x 22mm wide),
IN1169/1 (12º x 14mm x 22mm wide)

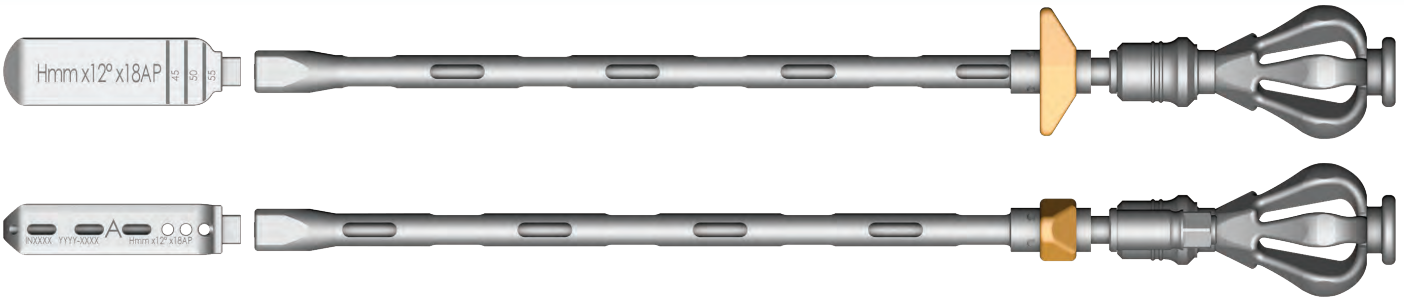
PEEK:
IN1550 (0º x 8mm x 22mm wide),
IN1551 (0º x 10mm x 22mm wide),
IN1552 (0º x 12mm x 22mm wide),
IN1553 (10º x 10mm x 22mm wide),
IN1554 (12º x 12mm x 22mm wide),
IN1555 (12º x 14mm x 22mm wide)

face of the lordotic trial should face left, and for a right-side up approach the anterior face of the lordotic trial should face right **(Figure 7)**.

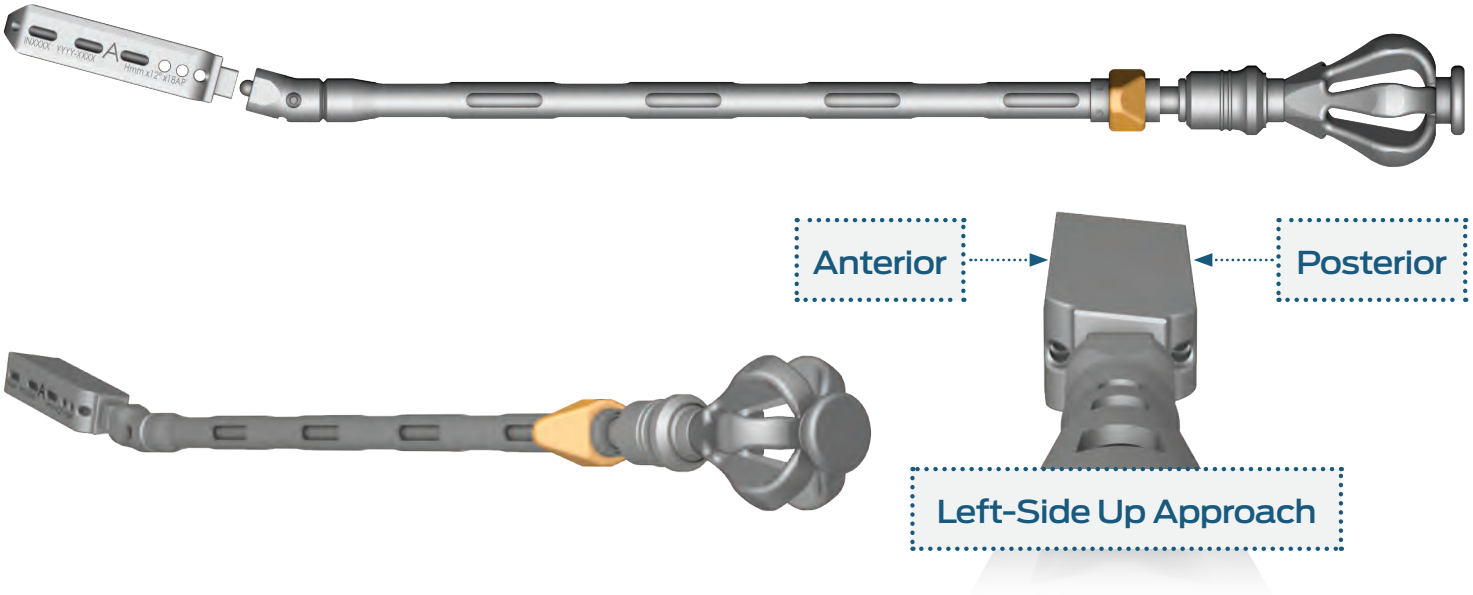
To select proper implant length, use an intraoperative A/P fluoroscopy image to visualize the trial sizer. The indicator holes on the trial sizer indicate implant length (45, 50, or 55mm), and the length corresponding to the hole that aligns with the edge of the vertebral body should be chosen **(Figure 8)**.

When in proper alignment, the indicator holes should appear on x-ray as perfect circles. If desired, the Modular Trial Shaft may be removed for ease of lateral imaging to confirm lateral alignment by rotating the shaft counterclockwise to disengage the shaft from the trial head. In the lateral position, thru-holes on the anterior and posterior sides of the trials will appear as perfect circles when the trial is in proper alignment. Note that the Starter Trials contain indicator grooves instead of indicator holes in the A/P view, that will appear as semi-circles on x-ray, and do not contain thru-holes in the lateral view.

## 6. Modular Trial Assembly with Straight Shaft and Modular Trial Handle




## 7. Modular Trial Assembly with Angled Shaft and Modular Trial Handle

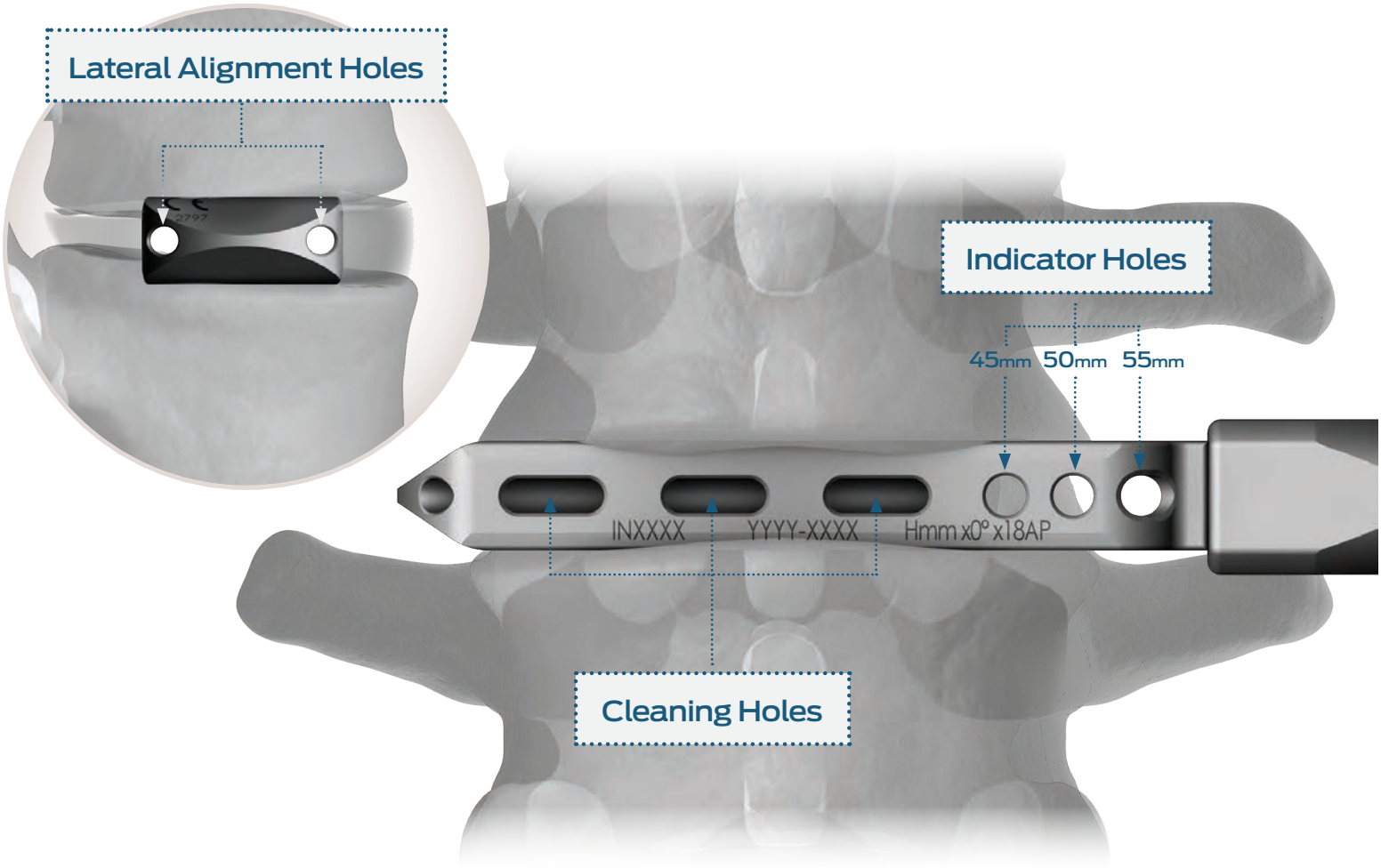


### Trialing (continued)

It is recommended that the largest device footprint possible be safely selected to optimize the load transfer. To ensure proper implant height selection, the trial must achieve a tight fit.

To remove the trial, place the short end of the slap hammer around the Modular Trial Handle slap hammer connection, or alternatively remove the Modular Trial Handle and place the long end of the slap hammer around the end of the trial. Use the slap hammer to apply upward impaction until the trial is free from the disc space.

## 8. Using the Trial to Select Implant Length




**tech TIP** *When using the Modular Trial Shaft, Angled for a left side approach, the anterior face of the trial should face left when the shaft tip is angled towards the ceiling. For a right side approach, the anterior face of the trial should face right.*

*Trial must be tight fit.*

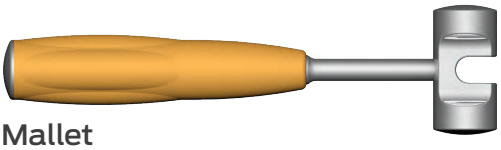
### Implant Insertion

Secure the implant to the **STALIF** Lateral Inserter or **STALIF** Lateral Angled Inserter by rotating the inserter knob clockwise until a hard stop is reached and the face of the implant is flush with the inserter **(Figure 9)**.

If using the **STALIF** Lateral Angled Inserter, ensure that the anterior face of the implant is facing the side of approach when the tip of the inserter is pointed towards the ceiling **(Figure 10)**.

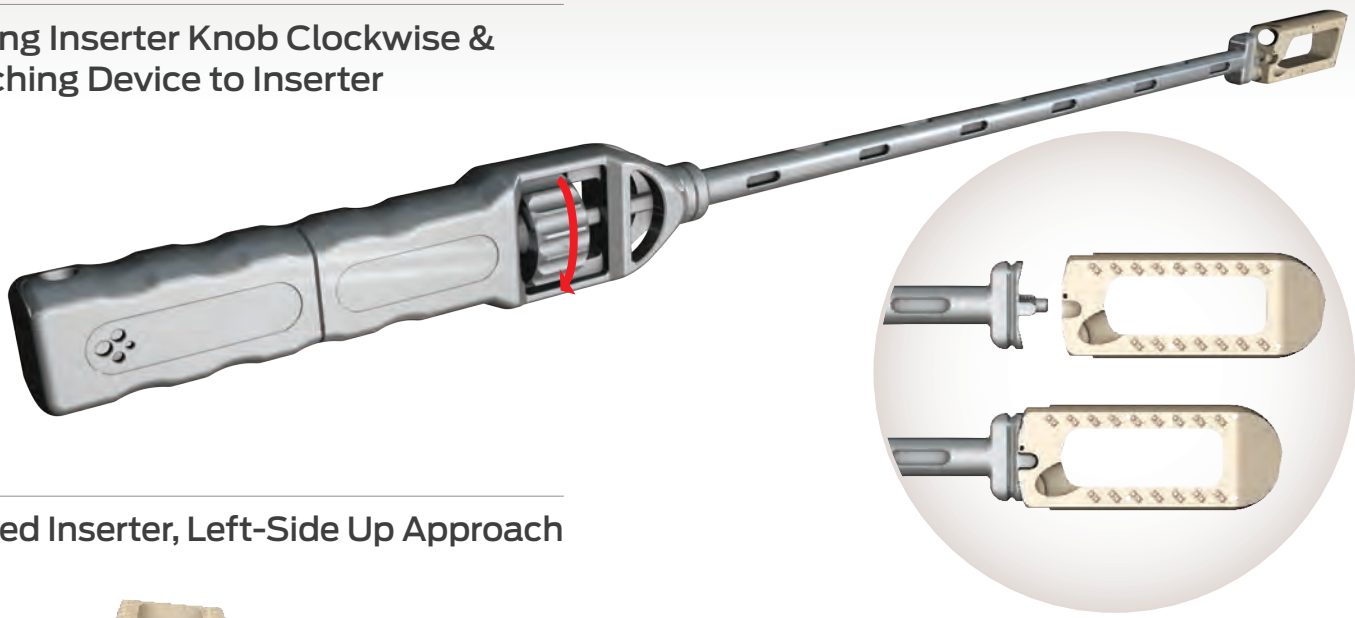
**STALIF** Lateral Inserter
IN968/1

**STALIF** Lateral Angled Inserter
IN1037

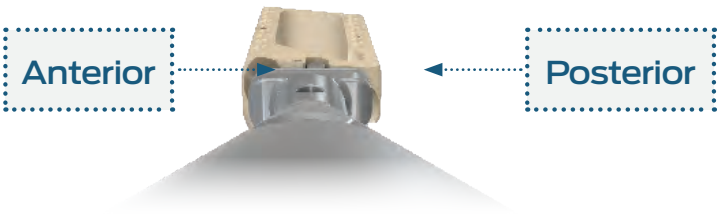


Mallet
IN228/1

## 9. Turning Inserter Knob Clockwise & Attaching Device to Inserter



## 10. Angled Inserter, Left-Side Up Approach




**tech TIP** *When using the Angled Inserter for a left side approach, the anterior face of the implant should face left when the angled tip of the introducer is pointed towards the ceiling. For a right side approach, the anterior face of the implant should face right.*

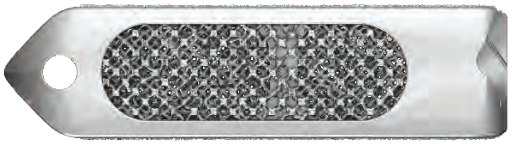
## *Surgical Technique (continued)*

### Implant Insertion (continued)

Insert and pack the appropriate graft material into the **STALIF L** / **STALIF L FLX** implant cavity. It is recommended that the implant cavity be packed 2mm proud both superiorly and inferiorly to assure optimal graft / endplate contact.

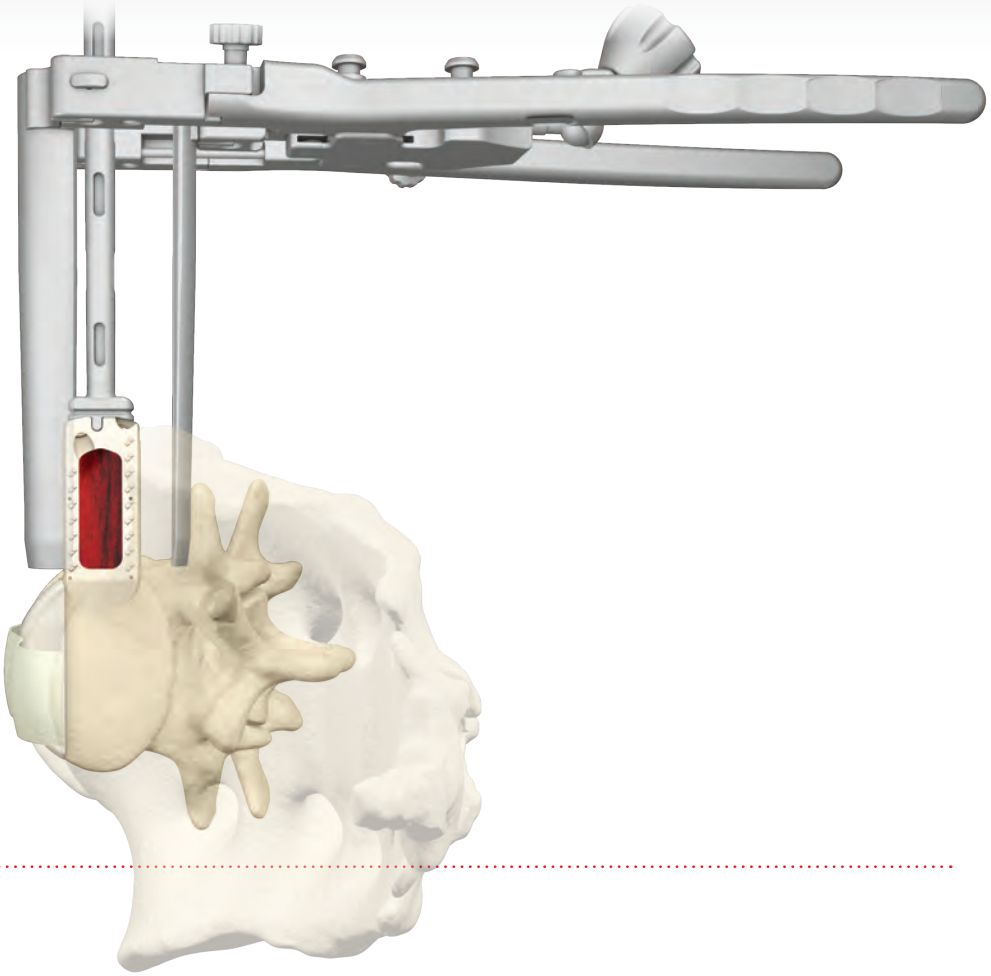
Insert the **STALIF L** / **STALIF L FLX** device into the disc space using the **STALIF** Lateral Inserter or **STALIF** Lateral Angled Inserter **(Figure 11)**. The anterior side of the implant should be facing anteriorly to enable lordosis restoration. Care should be taken to ensure that a direct lateral approach is utilized when inserting the implant.


**STALIF L Device (Anterior View)**



**STALIF L FLX Device (Anterior View)**

### 11. Inserting the Device into the Disc Space



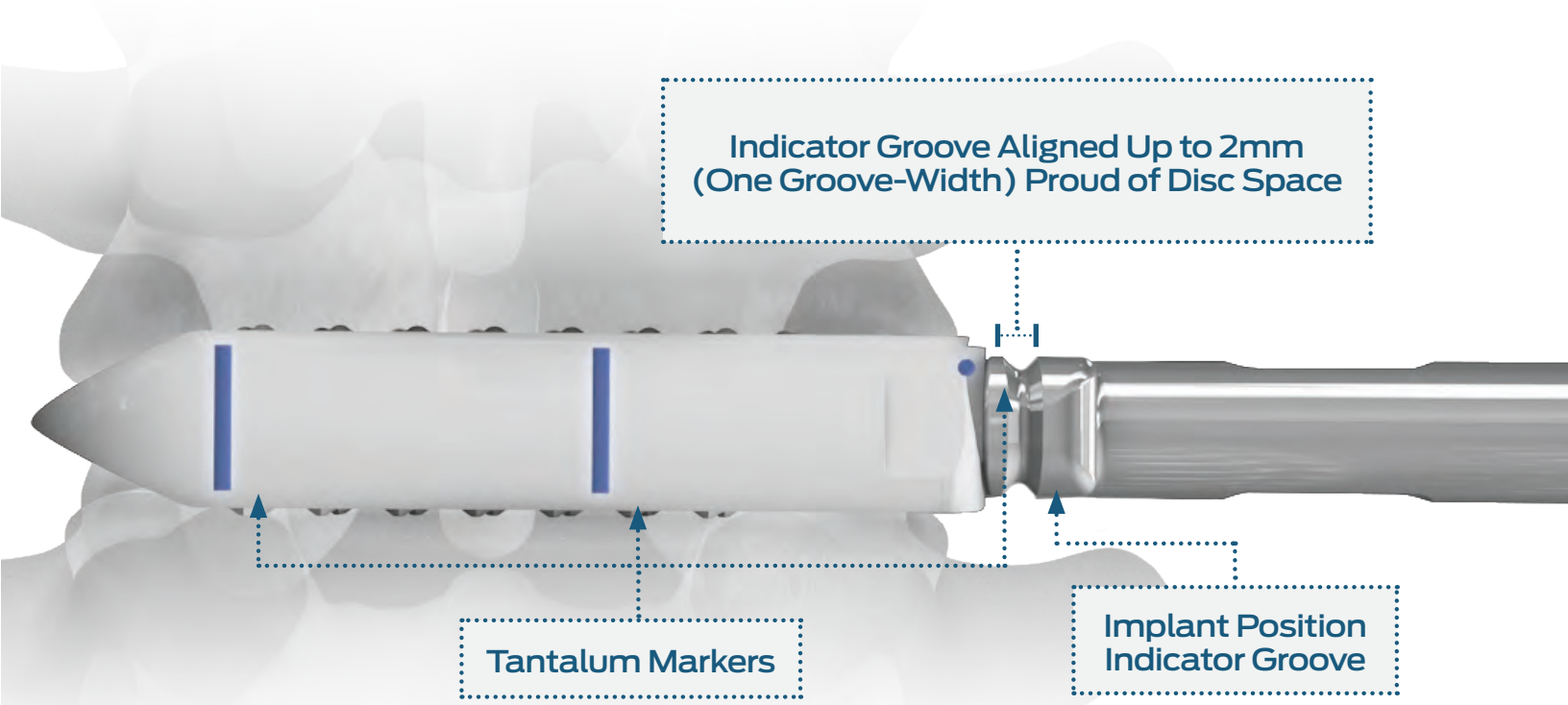
*please* **NOTE** *In'Tech Retractor System Pictured*

Ensure the Inserter positions the device so that the indicator groove on the Inserter is aligned 0mm to 2mm (one groove width) proud of the disc space. Use imaging and the indicator groove on the Inserter to position the implant **(Figure 12)**.

The Indicator Groove should be as close to the disc space as possible without entering the disc space, placing it flush with, or at most 2mm (one groove-width) proud of, the edge of the vertebral body.

For **STALIF L**, tantalum markers are used to radiographically assess device position **(Figure 12)**. For **STALIF L FLX**, the cage profile can be seen radiographically. Use radiographic images to ensure that the **STALIF L** / **STALIF L FLX** implant load-bearing surface is within the confines of the vertebral bodies.

## 12. Initial Device Positioning, Indicator Groove Demonstration & STALIF L Tantalum Markers




**tech TIP** *Indicator Groove should not enter disc space.*

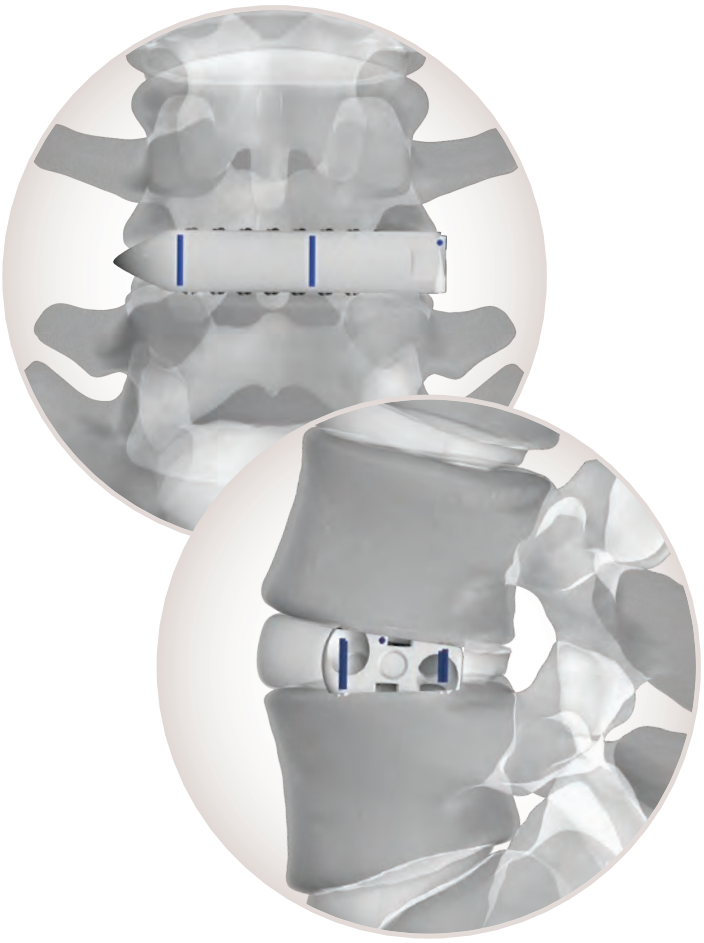
## *Surgical Technique (continued)*

### Implant Insertion (continued)

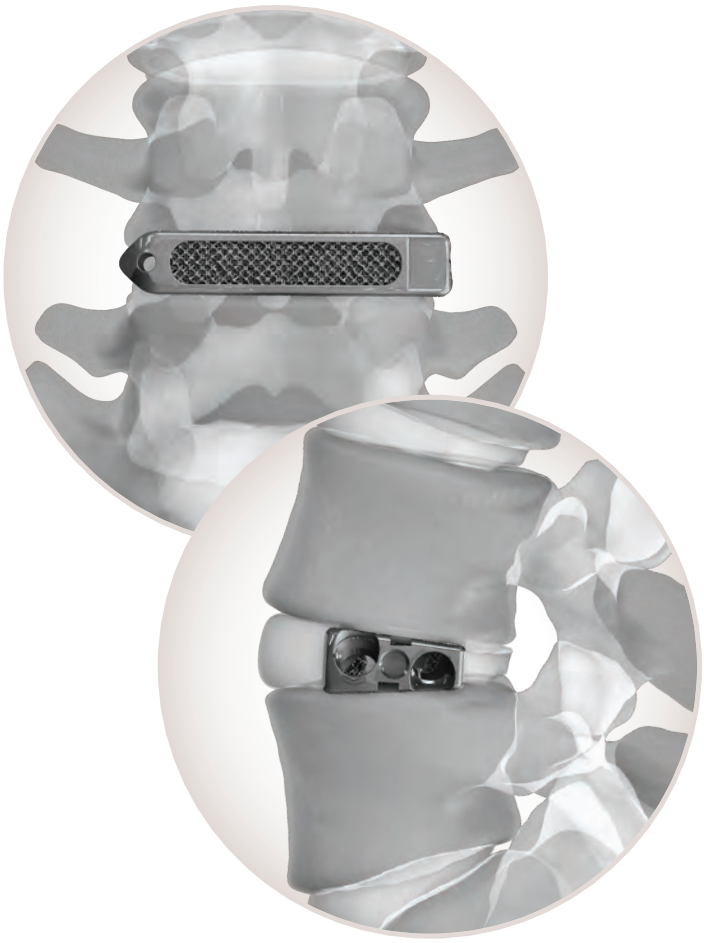
To prevent implant mal-rotation, use A/P and lateral fluoroscopy to verify proper implant alignment. For **STALIF L**, the two marker rods should closely align or superimpose in both A/P and lateral images **(Figure 13)**. For **STALIF L FLX**, the through hole on the nose of the implant should be spherical in an A/P view, and in the lateral view the implant edges should be crisp **(Figure 14)**.

Once the implant is positioned and placement has been confirmed with intraoperative fluoroscopy, release the implant by rotating the inserter knob counter-clockwise until the implant is released then remove the inserter from the surgical site.

### 13. Using Fluoroscopy to Verify STALIF L Device Positioning



### 14. Using Fluoroscopy to Verify STALIF L FLX Device Positioning



**tech TIP** *After disengaging the introducer, and prior to screw placement, verify correct implant position with both A/P and lateral imaging.*

*For STALIF L, verify all markers are contained within the disc space. For STALIF L FLX, verify that the flat superior and inferior edges of the implant are contained within the disc space.*

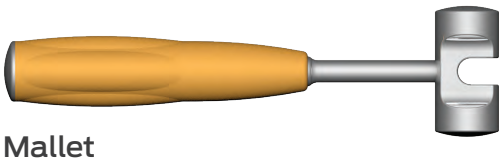
## Screw Placement

The **STALIF L** / **STALIF L FLX** system utilizes Silony Spine's ABO® cancellous screws **(Figure 15)** for optimum compressive lag fixation. **STALIF L** implants utilize either 4.5mm or 5.5mm diameter screws depending on cage height. All **STALIF L FLX** implants use 5.5mm diameter screws, regardless of cage height. The 4.5mm diameter screws should not be used with any **STALIF L FLX** cage.

The 4.5mm and 5.5mm diameter self-tapping, self-drilling ABO® screws are provided in lengths of 30 and 35mm. Refer to the chart below or IFUs LBL024 & LBL025 for restrictions on combination use. ABO® screws feature a titanium split ring **(Figure 16)** which first compresses and then deploys during insertion.

**Ball-Joint Screw Driver (Recommended)**
IN231/1

**U-Joint Screw Driver**
IN218/1

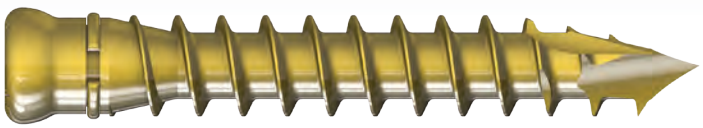


**Mallet**
IN228/1

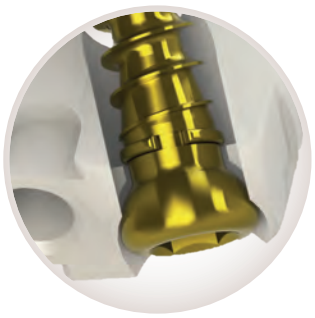
### Restrictions on Screw Diameter According to Cage Height

| Screw Diameter | Restrictions on Use According to Cage Height |
|---|---|
| Ø4.5mm | To be used with 8mm and 10mm height **STALIF L** PEEK cages only |
| Ø5.5mm | To be used with all **STALIF L FLX** cages, and with 12 and 14mm height **STALIF L** PEEK cages only |

### 15. Anti-Backout (ABO®) Screw



### 16. ABO® Titanium Split Ring in Close-Up



**please NOTE**

***The ABO® split rings deploy without audible or tactile feedback. The ring is fully deployed when the screw head is fully seated into the device.***

# Surgical Technique *(continued)*

## Screw Placement (continued)

On occasion, to facilitate proper angulation to the screw holes, it may be necessary to remove a small portion of the lip of the vertebral body adjacent to the screw holes.

If bony endplates are schlerotic, it may be desirable to create optional screw pilot holes utilizing the Ball Joint Awl (recommended) or U-Joint Awl and appropriate Awl Guide. If using the Awl and Awl Guide, care must be taken to ensure that the proper Awl Guide is selected (based on implant height per the screw diameter restrictions chart), and that the Awl Guide is fully seated to ensure optimal pilot hole trajectory.

Insert the **STALIF L** screws with the Screw Driver **(Figure 17)**. For a left side up (right lateral decubitus) approach, the posterior screw trajectory will be cephalad; for a right side up (left lateral decuitus) approach the posterior screw trajectory will be caudal **(Figure 18)**.

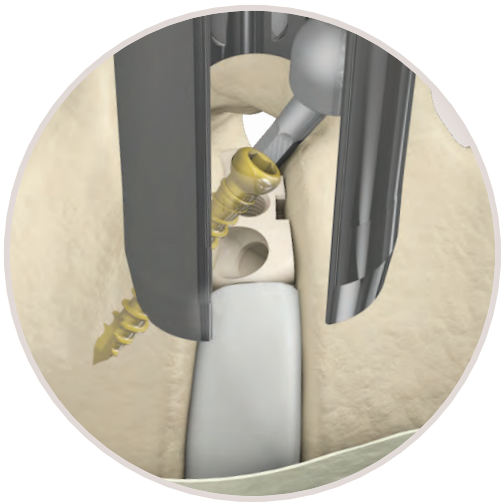
It may be necessary to temporarily distract or tow a distractor blade to enable proper screw angulation. If vertebral body fixation was utilized with any of the retractor blades it may be necessary to disengage the fixation to enable manipulation of the retractor blades. Additionally, it is recommended to remove any flexion from the table prior to placing screws.

**Ball-Joint Awl (Optional)**
IN386

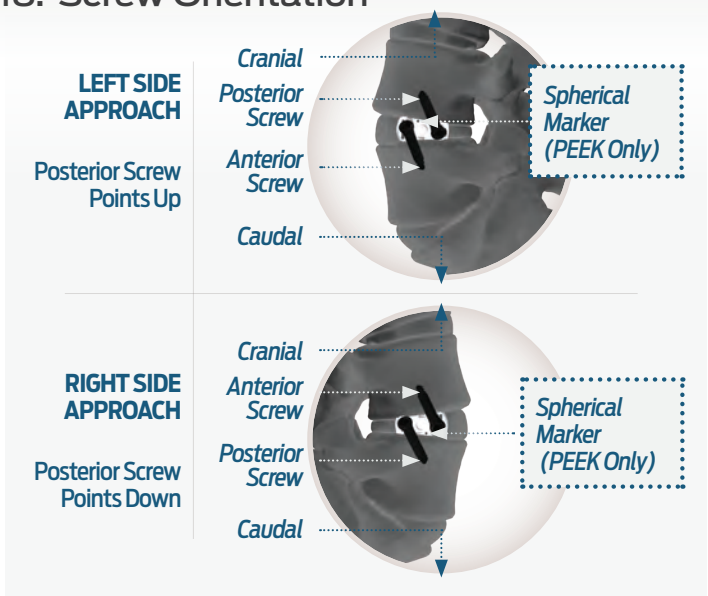
**U-Joint Awl (Optional)**
IN216/1

**Angled Awl Guide (Optional)**
IN527 (4.5mm, for use with 8mm & 10mm PEEK cages only), IN526 (5.5mm, for use with 12mm & 14mm PEEK and all **FLX** cages only)

## 17. Inserting Screw with Ball-Joint Screw Driver



## 18. Screw Orientation




**please NOTE** *It is important if using the Awl Guides, they are seated correctly so that the pilot hole is concentric and the screw trajectory optimized.*

**tech TIP** *For STALIF L PEEK, posterior screw always points toward the vertebral body adjacent to the spherical marker. 35mm screws are recommended (if anatomy allows / safe to do so).*

Once secured, the screws will provide immediate segmental stability and optimal graft / sub-chondral bone contact. **STALIF**® pioneering lag screw technology requires tactile feel to determine when the screws are optimally seated. The degree of screw purchase feedback will vary due to varying patient bone quality.

The heads of each screw must be fully seated.

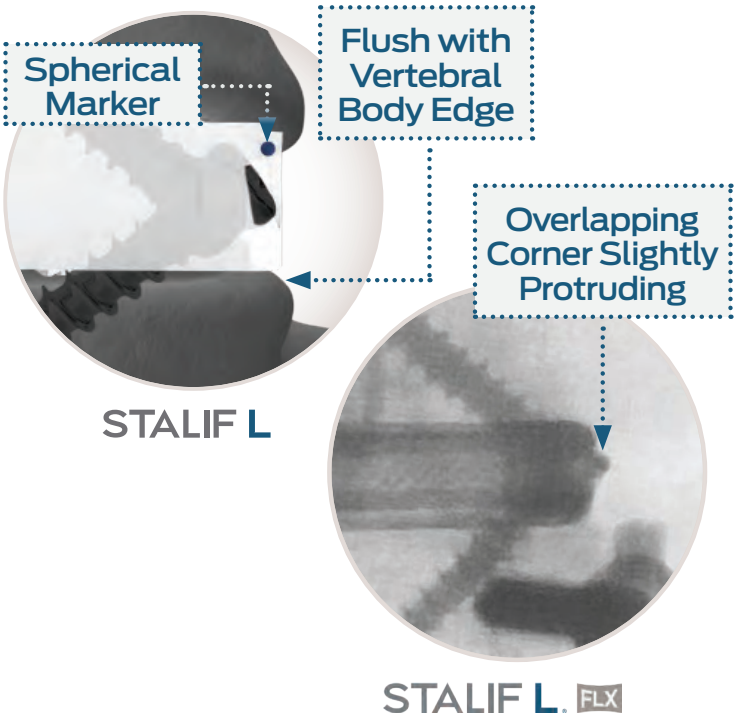
For **STALIF L**, in final position, the lateral spherical marker should align with the edge of the vertebral body or be up to 2mm recessed **(Figure 19)**. Additionally, the screws heads should be directly overlapped, and should be vertically aligned with the lateral spherical marker **(Figure 20)**. All rod and spherical markers should be contained within the confines of the vertebral bodies in both A/P and lateral views.

For **STALIF L FLX**, in final position, the edge of the face of the implant should align with the edge of the vertebral body or be up to 2mm recessed **(Figure 19)**. Additionally, the screws heads should be directly overlapped, with central overlapping corner slightly protruding from the face of the implant **(Figure 20)**. All flat endplate-contacting surfaces should be contained within the confines of the vertebral bodies in both A/P and lateral views.

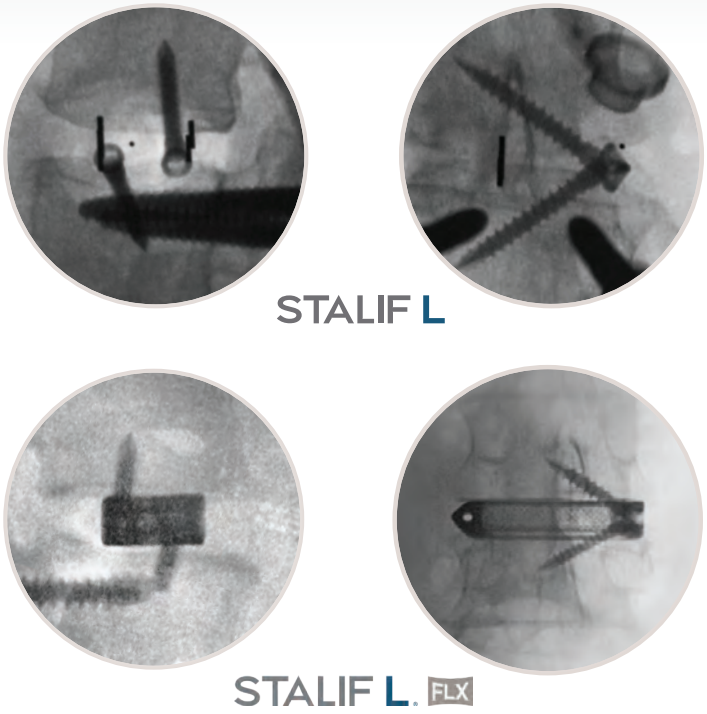
## X-Ray Confirmation

Intraoperative A/P and lateral flouroscopy should be taken during and after screw insertion, and prior to closure, to ensure proper positioning **(Figure 20)**.

## 19. Intraoperative Fluoroscopy with Directly Overlapped Pattern Demonstrated




## 20. Final Device Positioning




**tech TIP** *For STALIF L PEEK, the screw heads will overlap (forming a "duck foot") and will be vertically aligned with the spherical marker when the screws are fully seated. For STALIF L FLX, the screw heads will be overlapped and the overlapping corner will slightly protrude from the face of the implant when the screws are fully seated.*

## *Surgical Technique (continued)*

### Supplemental Fixation

The **STALIF L** Portfolio implants are required to be used with additional supplemental fixation **(Figure 12)**.

### Removal / Revision

The **STALIF L** Portfolio implants can be removed by reversing the steps in the surgical procedure. An additionally available cage removal tool is available for use with **STALIF L** PEEK only (see Additionally Available Instruments). If it is necessary to use the Cage Removal Tool, the cage should be discarded. Please contact Customer Service for availability.

## 21. Fluoroscopy Demonstrating the Use of Supplemental Fixation

***please NOTE*** **STALIF L** *Portfolio Implants are required to be used with supplemental fixation*

# *Tips & Pearls*

- Refer to quick reference guides.
- To ensure proper implant height selection, **the trial must achieve a tight fit.**

## For STALIF L PEEK:

- Imaging verification is important
  - During implant insertion, verify that introducer indicator groove is flush to 2mm (one groove-width) proud of disc space
  - Verify proper imaging after disengaging introducer and prior to screw placement, in both A/P and Lateral views—the two sets of marker rods should closely align/superimpose and all markers should be contained within the disc space
- 35mm length screws are recommended
- Screws are self-tapping and self-drilling; awl is optional
- Proper screw combinations must be used
  - **Ø 4.5mm diameter screws for 8mm and 10mm tall cages ONLY**
  - **Ø 5.5mm diameter screws for 12mm and 14mm cages ONLY**
- ABO technology is used
  - Titanium split rings deploy without audible or tactile feedback; ring is fully deployed when the screw head is fully seated into the device
- Confirm ABO is engaged using A/P fluoroscopy → the screw heads should:
  - Be directly overlapped (forming a "duck foot")
  - Be vertically aligned with the spherical marker
- Marker rods should be superimposed under A/P and Lateral fluoroscopy
- In final position:
  - The spherical marker should be aligned with the edge of the vertebral body or recessed up to 2mm
  - All marker rods should be contained within the disc space

## For STALIF L FLX:

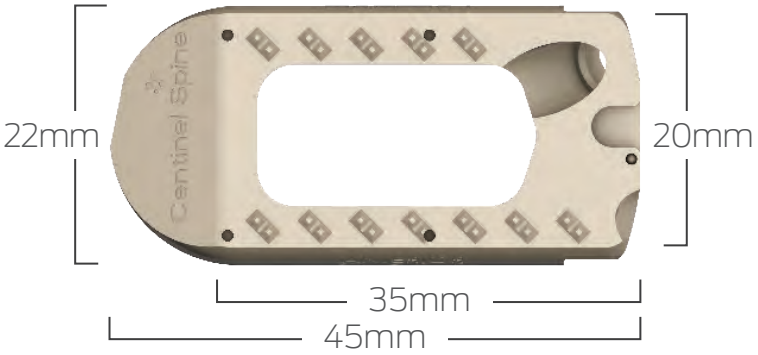
- Imaging verification is important
  - During implant insertion, verify that introducer indicator groove is flush to 2mm (one groove-width) proud of disc space
  - Verify proper imaging after disengaging introducer and prior to screw placement, in the A/P view, the through hole on the nose of the implant should create a circle, and in the Lateral view the implant should have crisp edges
- 35mm length screws are recommended
- Screws are self-tapping and self-drilling; awl is optional
- **Ø 5.5mm diameter screws are used for all STALIF L FLX cages, regardless of cage height**
- ABO technology is used
  - Titanium split rings deploy without audible or tactile feedback; ring is fully deployed when the screw head is fully seated into the device
- Confirm ABO is engaged using A/P fluoroscopy → the screw heads should:
  - Be directly overlapped
  - Have the overlapping corner protrude slightly from the edge of the cage
- The cage should display a clear circle through the nose under A/P fluoroscopy and have crisp edges under Lateral fluoroscopy
- In final position:
  - The face of the cage should be aligned with the edge of the vertebral body or recessed up to 2mm
  - All flat endplate-contacting surfaces should be contained within the confines of the vertebral bodies in both A/P and lateral views

# APPENDIX: STALIF Lateral System Implant & Instrument Offering

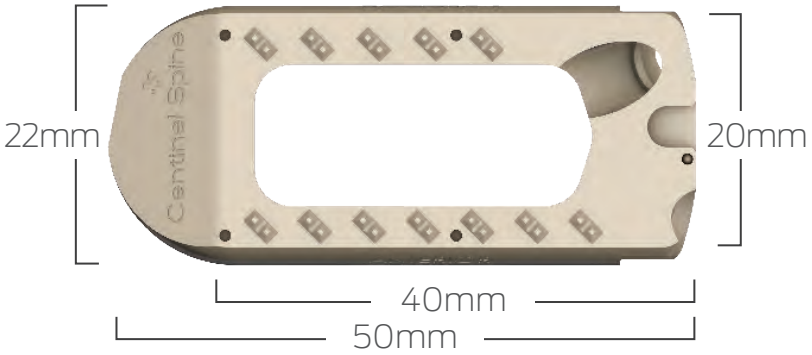
## *Standard Implants & Screws*

### STALIF L PEEK Implants, 22mm A/P

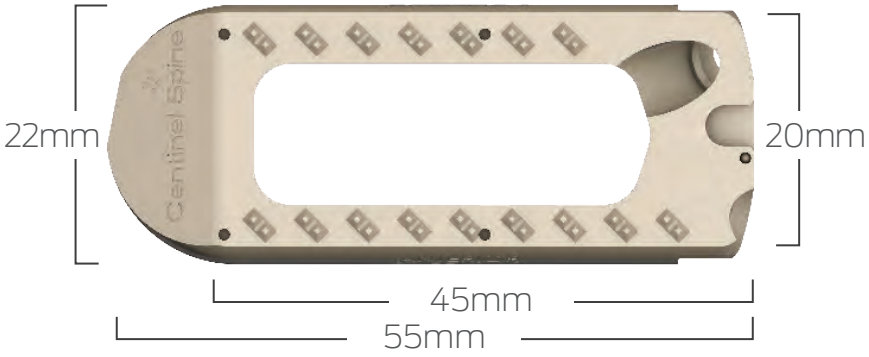
| 45mm Length, Parallel | 45mm Length, Lordotic |
|---|---|
| **STL4508-00** 8mm x 0° | **STL4510-10** 10mm x 10° |
| **STL4510-00** 10mm x 0° | **STL4512-12** 12mm x 12° |
| **STL4512-00** 12mm x 0° | **STL4514-12** 14mm x 12° |




| 50mm Length, Parallel | 50mm Length, Lordotic |
|---|---|
| **STL5008-00** 8mm x 0° | **STL5010-10** 10mm x 10° |
| **STL5010-00** 10mm x 0° | **STL5012-12** 12mm x 12° |
| **STL5012-00** 12mm x 0° | **STL5014-12** 14mm x 12° |

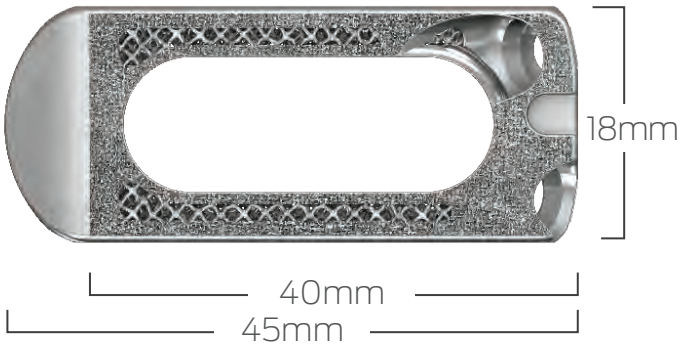


| 55mm Length, Parallel | 55mm Length, Lordotic |
|---|---|
| **STL5508-00** 8mm x 0° | **STL5510-10** 10mm x 10° |
| **STL5510-00** 10mm x 0° | **STL5512-12** 12mm x 12° |
| **STL5512-00** 12mm x 0° | **STL5514-12** 14mm x 12° |




## STALIF L FLX Implants, 18mm A/P

| 45mm Length, Parallel | 45mm Length, Lordotic |
|---|---|
| **SLF450800-18** 8mm x 0° | **SLF451010-18** 10mm x 10° |
| **SLF451000-18** 10mm x 0° | **SLF451212-18** 12mm x 12° |
| **SLF451200-18** 12mm x 0° | **SLF451412-18** 14mm x 12° |




| 50mm Length, Parallel | 50mm Length, Lordotic |
|---|---|
| **SLF500800-18** 8mm x 0° | **SLF501010-18** 10mm x 10° |
| **SLF501000-18** 10mm x 0° | **SLF501212-18** 12mm x 12° |
| **SLF501200-18** 12mm x 0° | **SLF501412-18** 14mm x 12° |

55mm Length, Parallel

**SLF550800-18**
8mm x 0°

**SLF551000-18**
10mm x 0°

**SLF551200-18**
12mm x 0°

55mm Length, Lordotic

**SLF551010-18**
10mm x 10°

**SLF551212-18**
12mm x 12°

**SLF551412-18**
14mm x 12°


## STALIF L FLX Implants, 22mm A/P

45mm Length, Parallel

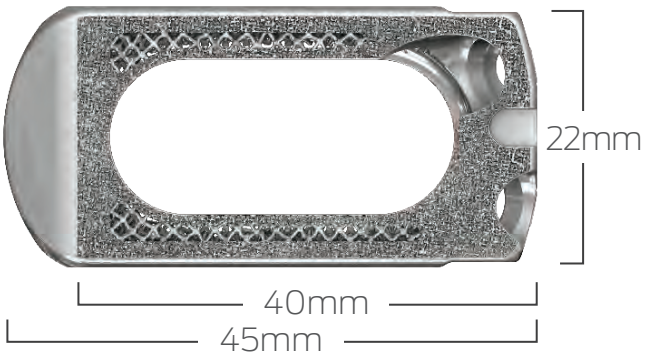
**SLF450800-22**
8mm x 0°

45mm Length, Lordotic

**SLF451010-22**
10mm x 10°

**SLF451212-22**
12mm x 12°

**SLF451412-22**
14mm x 12°




50mm Length, Parallel

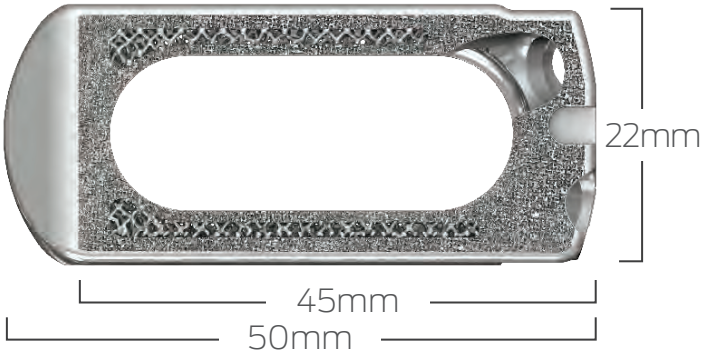
**SLF500800-22**
8mm x 0°

50mm Length, Lordotic

**SLF501010-22**
10mm x 10°

**SLF501212-22**
12mm x 12°

**SLF501412-22**
14mm x 12°



55mm Length, Parallel

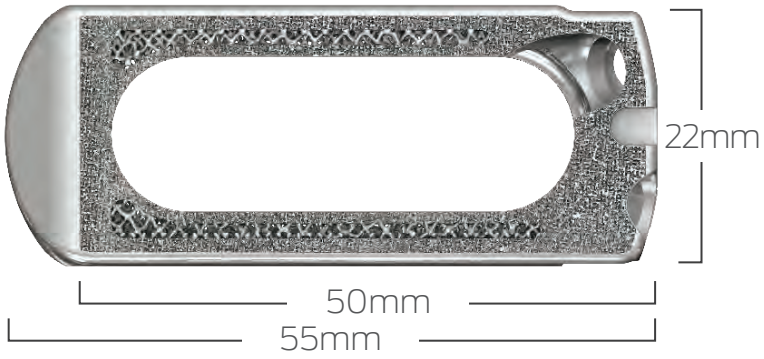
**SLF550800-22**
8mm x 0°

55mm Length, Lordotic

**SLF551010-22**
10mm x 10°

**SLF551212-22**
12mm x 12°

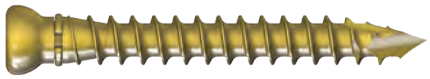
**SLF551412-22**
14mm x 12°



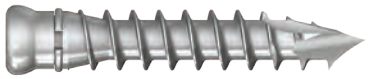

## STALIF L Screws

**STL4530***
Screw, 4.5mm x 30mm

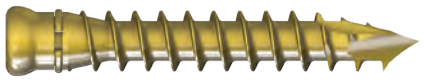
**STL4535***
Screw, 4.5mm x 35mm



**STL5530**
Screw, 5.5mm x 30mm



**STL5535**
Screw, 5.5mm x 35mm



** 4.5mm Diameter Screws are for use with* STALIF L *PEEK 8mm and 10mm tall cages only*

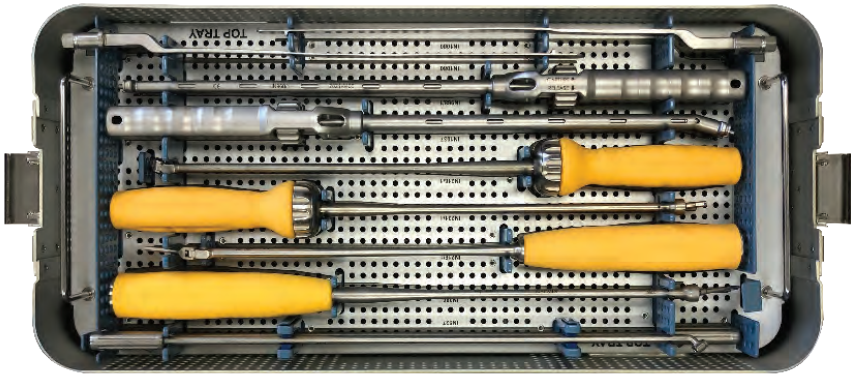
# STALIF *Lateral Standard Instrument Set BOM (STL-INST-XXX)*

*For reference only. Contact Customer Service for latest BOM.*

| | |
|---|---|
| CAS02733 | Instrument Tray |

**ONE LEVEL**

| | |
|---|---|
| IN1080 | Graft Containment Skids (qty. 2) |
| IN968/1 | **STALIF** Lateral inserter |
| IN1037 | **STALIF** Lateral Angled Inserter |
| IN218/1 | U-Joint Screw Driver |
| IN231/1 | Ball-Joint Screw Driver |
| IN216/1 | U-Joint Awl |
| IN386 | Ball-Joint Awl |
| IN526 | 5.5mm **STALIF L**/**L FLX** Angled Awl Guide<br>(For Use with All **STALIF L FLX** Implants, and 12mm & 14mm Height **STALIF L** PEEK Implants Only) |
| IN527 | 4.5mm **STALIF L** PEEK Angled Awl Guide<br>(For Use with All **STALIF L** PEEK 8mm & 10mm Height Implants Only) |



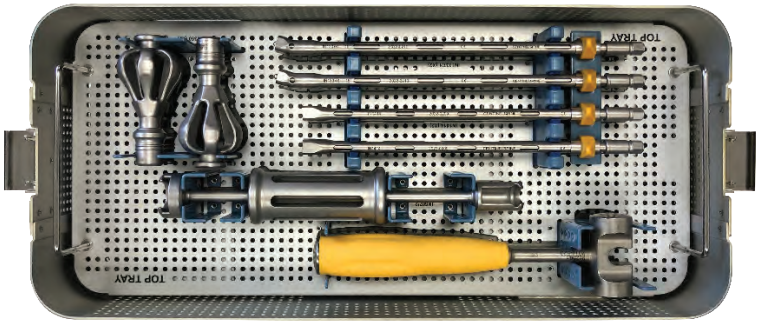
# STALIF *Lateral Modular Trials & Angled Disc Prep Set BOM (STL-TRL-XXX)*

*For reference only. Contact Customer Service for latest BOM.*

| | |
|---|---|
| **CAS02734** | Instrument Tray |

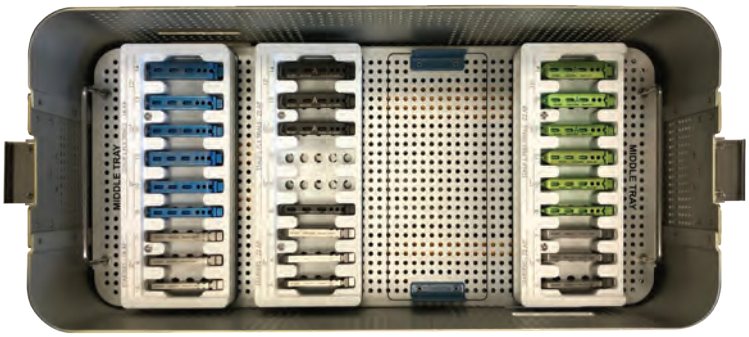
## TOP LEVEL

| | |
|---|---|
| **IN1350** | **STALIF** Lateral Modular Trial Handle (qty.2) |
| **IN1414** | **STALIF** Lateral Modular Trial Shaft, Straight (qty. 2) |
| **IN1337/1** | Stalif Lateral Modular Trial Shaft - Angled (qty. 2) |
| **IN507/2** | Slap Hammer |
| **IN228/1** | Mallet |



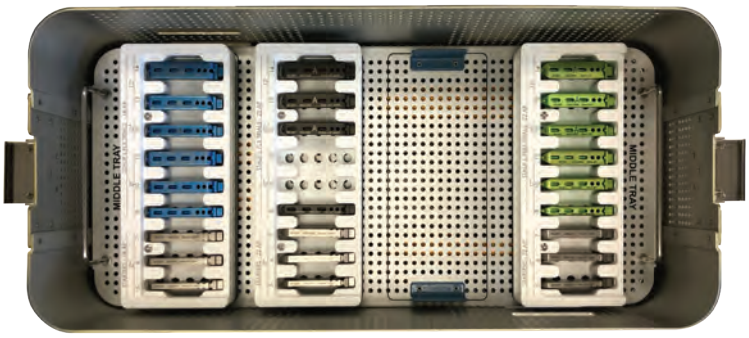
## MIDDLE LEVEL

| | |
|---|---|
| **CAS02729-01** | **STALIF L FLX**<br>**Modular Trials Caddy, 18AP** |
| **IN1219/1** | **STALIF L FLX**, 18mm Starter Trial, 05 x 00º, Modular |
| **IN1220/1** | **STALIF L FLX**, 18mm Starter Trial, 06 x 00º, Modular |
| **IN1221/1** | **STALIF L FLX**, 18mm Starter Trial, 07 x 00º, Modular |
| **IN1134/1** | **STALIF L FLX**, 18mm Trial, 08 x 00º, Modular |
| **IN1136/1** | **STALIF L FLX**, 18mm Trial, 10 x 00º, Modular |
| **IN1138/1** | **STALIF L FLX**, 18mm Trial, 12 x 00º, Modular |
| **IN1145/1** | **STALIF L FLX**, 18mm Trial, 10 x 10º, Modular |
| **IN1147/1** | **STALIF L FLX**, 18mm Trial, 12 x 12º, Modular |
| **IN1149/1** | **STALIF L FLX**, 18mm Trial, 14 x 12º, Modular |



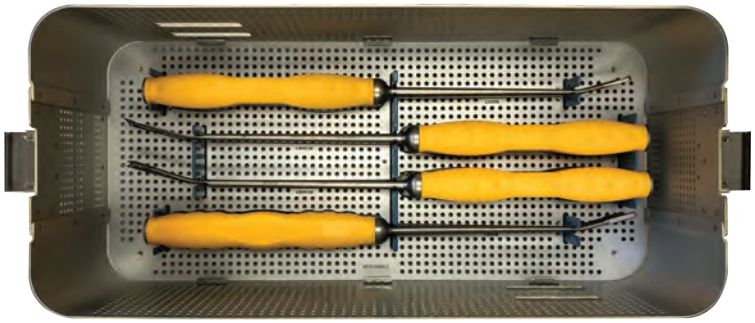
| | |
|---|---|
| **CAS02729-02** | **STALIF L FLX**<br>**Modular Trials Caddy, 22AP** |
| **IN1222/1** | **STALIF L FLX**, 22mm Starter Trial, 05 x 00°, Modular |
| **IN1223/1** | **STALIF L FLX**, 22mm Starter Trial, 06 x 00°, Modular |
| **IN1224/1** | **STALIF L FLX**, 22mm Starter Trial, 07 x 00°, Modular |
| **IN1151/1** | **STALIF L FLX**, 22mm Trial, 08 x 00°, Modular |
| **IN1144/1** | **STALIF L FLX**, 22mm Trial, 10 x 10°, Modular |
| **IN1167/1** | **STALIF L FLX**, 22mm Trial, 12 x 12°, Modular |
| **IN1169/1** | **STALIF L FLX**, 22mm Trial, 14 x 12°, Modular |

| | |
|---|---|
| **CAS02729-03** | **STALIF L PEEK**<br>**Modular Trials Caddy, 22AP** |
| **IN1222/1** | **STALIF L FLX**, 22mm Starter Trial, 05 x 00°, Modular |
| **IN1223/1** | **STALIF L FLX**, 22mm Starter Trial, 06 x 00°, Modular |
| **IN1224/1** | **STALIF L FLX**, 22mm Starter Trial, 07 x 00°, Modular |
| **IN1550** | **STALIF L** PEEK Trial, 08 x 00°, Modular |
| **IN1551** | **STALIF L** PEEK Trial, 10 x 00°, Modular |
| **IN1552** | **STALIF L** PEEK Trial, 12 x 00°, Modular |
| **IN1553** | **STALIF L** PEEK Trial, 10 x 10°, Modular |
| **IN1554** | **STALIF L** PEEK Trial, 12 x 12°, Modular |
| **IN1555** | **STALIF L** PEEK Trial, 14 x 12°, Modular |



## BOTTOM LEVEL

| | |
|---|---|
| **IN1044/1** | Forward Angled Flat Endplate Elevator, 13mm |
| **IN1045/1** | Reverse Angled Flat Endplate Elevator, 13mm |
| **IN1077** | 11mm x 4mm Teardrop Curette, 15° Angle |
| **IN1081** | Rasp, Bent 15° |



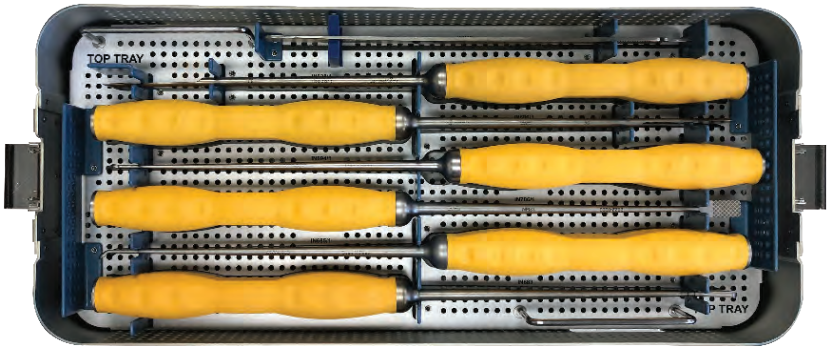
# STALIF *Lateral Disc Prep Set BOM (STL-DPS-XXX)*

*For reference only. Contact Customer Service for latest BOM.*

| | |
|---|---|
| **STL-DPS-XXX** | Instrument Tray |

## TOP LEVEL

| | |
|---|---|
| **IN848** | Knife Handle, 12" |
| **IN838/1** | 17mm Endplate Elevator |
| **IN686/1** | 20mm Endplate Elevator |
| **IN694/1** | 3mm x 5mm Angled Cup Curette |
| **IN706/1** | Rasp |
| **IN685/1** | 5mm x 7mm Angled Cup Curette |
| **IN683** | 11mm x 4mm Teardrop Curette |




## MIDDLE LEVEL

| | |
|---|---|
| **IN697** | 8mm Shaver |
| **IN698** | 10mm Shaver |
| **IN699** | 12mm Shaver |
| **IN700** | 14mm Shaver |
| **IN903** | 6mm Box Cutter |
| **IN904** | 8mm Box Cutter |
| **IN905** | 10mm Box Cutter |
| **IN435/1** | **STALIF** Lateral T-Handle (qty. 2) |

## BOTTOM LEVEL

| | |
|---|---|
| IN712 | 4mm Pituitary Rongeur, Coated |
| IN710 | 4mm Kerrison Rongeur, Coated |
| IN1043/1 | 4mm Pituitary Rongeur, Curved |

## *Additionally Available Instruments (Special Order)*

**IN882**
Cage Removal Tool
(PEEK Only)

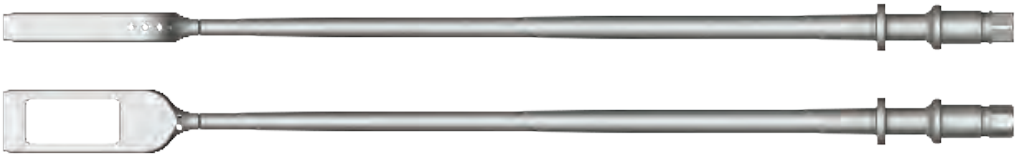
**IN883**
TLIF Revision Hook Tool

**IN884**
TLIF Revision L Tool

**IN432**
Tamp

**IN893**
Shaver, 6mm

**IN905**
Box Cutter, 12mm



**gs36.8563**
Ribbon Retractor,
8” x 1/2”

**gs36.8660**
Ribbon Retractor,
13” x 3/4”

**IN688**
Endplate Elevator, 24mm

**IN689**
Osteotome, 20mm

**IN677**
8mm x 20mm Square Curette, Bent 15º

**IN851**
7mm x 9mm Angled Curette

**7338-05**
Bayonet Knife Handle, 25mm tip

**7218-20 or IN951**
Tear Drop Suction Tube, 260mm

**7042-42i or S06ITM274 or S03-285NS**
Colibri Bipolar Forceps

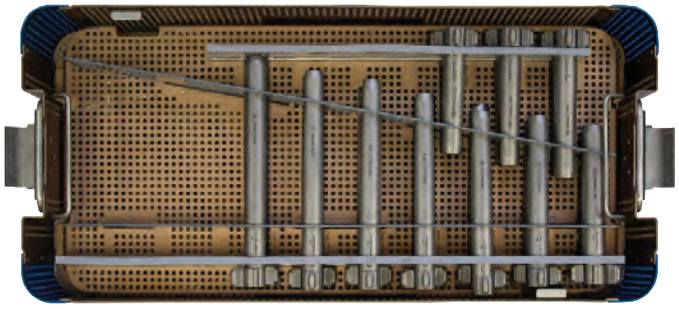
# *In'Tech Lateral Retractor Set BOM (IN914-01-XX & IN914-02-XX)*

*For reference only. Contact Customer Service for latest BOM. Available in the U.S. only.*

| | |
|---|---|
| **IN914-01** | Retractor Set Tray 1 |

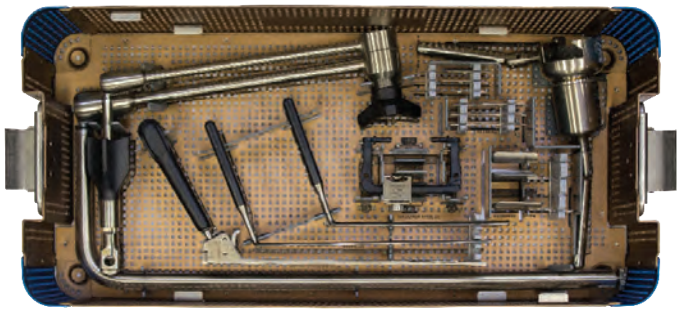
## TOP LEVEL

| | |
|---|---|
| **IN920** | 90mm Blades (Left, Right, Center) |
| **IN921** | 100mm Blades (Left, Right, Center) |
| **IN922** | 110mm Blades (Left, Right, Center) |
| **IN923** | 120mm Blades (Left, Right, Center) |
| **IN924** | 130mm Blades (Left, Right, Center) |
| **IN925** | 140mm Blades (Left, Right, Center) |
| **IN926** | 150mm Blades (Left, Right, Center) |
| **IN927** | 160mm Blades (Left, Right, Center) |
| **IN928** | 170mm Blades (Left, Right, Center) |
| **IN929** | 180mm Blades (Left, Right, Center) |



## BOTTOM LEVEL

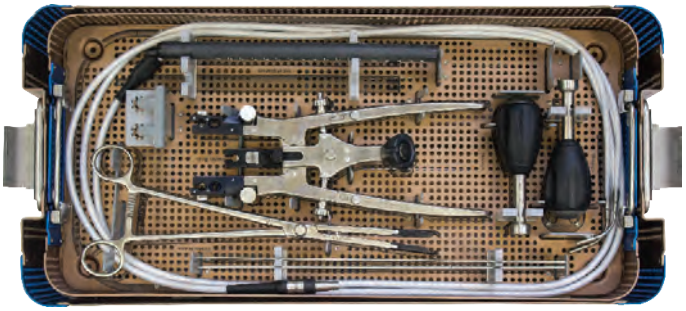
| | |
|---|---|
| **S06ITM288** | Rotative Table Clamp Base |
| **IN961/1** | Table Clamp Arm |
| **IN938** | Shim (qty. 3) |
| **IN939** | Broach (qty.3) |
| **IN933/1** | 4th Blade Attachment, 12-18mm |
| **IN940** | Blade Extension, Center |
| **IN942** | Blade Extension, Unilateral Left |
| **IN943** | Blade Extension, Unilateral Right |
| **IN934** | 4th Blade, 12 x 160mm |
| **IN935** | 4th Blade, 12 x 210mm |
| **IN944** | Shim and Broach Inserter |



| | |
|---|---|
| **IN914-02** | Retractor Set Tray 2 |

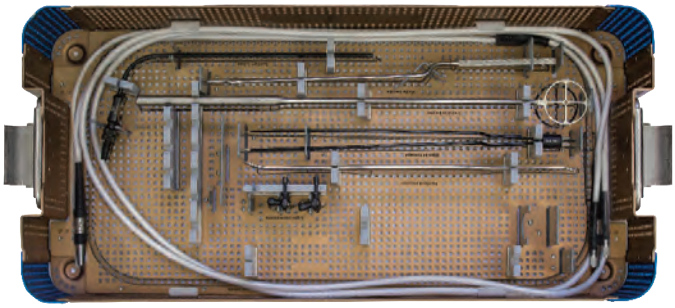
### TOP LEVEL

| | |
|---|---|
| **IN956** | Dilator, 8.5mm |
| **IN957** | Dilator, 14mm |
| **IN915/1** | Retractor Body |
| **IN945/1** | Wrench (qty. 2) |
| **IN955** | Dilator Holder |
| **IN954** | K-Wire (qty. 2) |
| **S06ITM236** | ACMI Light Cable, Reusable |



### BOTTOM LEVEL

| | |
|---|---|
| **IN951** | Suction Tube, 12" (qty. 2) |
| **IN950** | Bayonet Knife Handle |
| **IN948** | Incision Locator |
| **S06ITM274 or S03-285NS** | Bipolar Probe |
| **IN952** | Dual-Ended Penfield |
| **IN958** | Light Connector, Reusable (qty. 2) |
| **S06ITM234** | ACMI Extension Cord (For Light Mat), Reusable |



## In'Tech Disposables

| | |
|---|---|
| **S06ITM231** | Disposable Nerve Monitoring Probe |
| **S06ITM308** | Disposable Light Mat Surgical Illuminator |

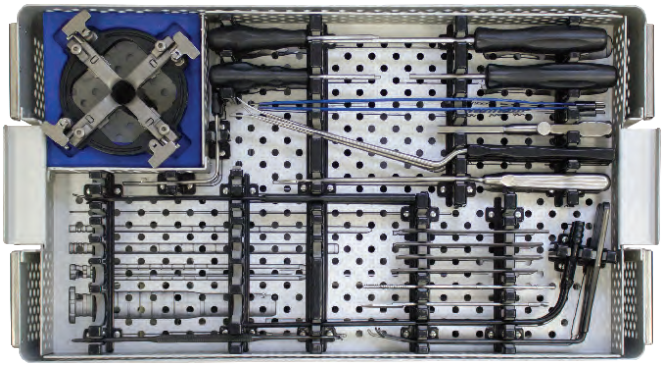
# *Koros Lateral Retractor Set BOM (7332-65-XXX)*

***For reference only. Contact Customer Service for latest BOM. Available in the U.S. only.***

| | |
|---|---|
| **7332-69** | Retractor Set Tray |

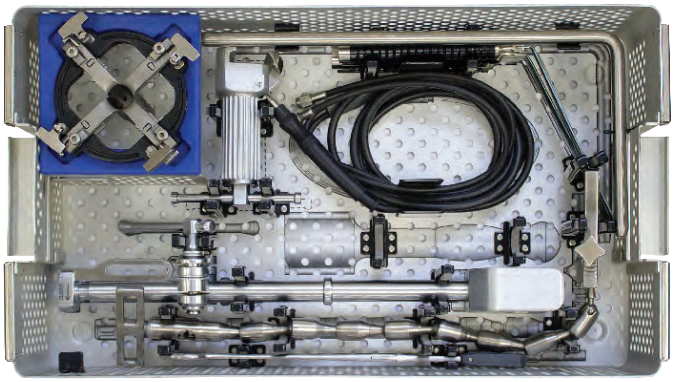
## TOP LEVEL

| | |
|---|---|
| **7332-66** | Clover Retractor Frame |
| **7332-82** | Hex Driver (qty. 2) |
| **7332-81L** | Long Anchor Screw Driver |
| **7332-81** | Short Anchor Screw Driver |
| **7042-42i** | Colibri Bipolar Forceps |
| **7332-87** | Shim Holder |
| **7230-60** | Bayonet Angled Tip Woodson, 190mm |
| **7230-62** | Bayonet Dissector, Down, 190mm |
| **7230-64** | Bayonet Dissector, Up, 190mm |
| **7332-71** | Light Pipe, 3mm Diameter (qty. 2) |
| **7338-05** | Bayonet Knife Handle, 250mm |
| **7332-73S** | K-Wire (qty. 2) |
| **7225-54b** | Long Penfield #4 Dissector, Black (qty. 2) |
| **7332-68** | Clover Fluted Blades (qty. 4) |
| **7332-79** | Anchor Screw, 3mm Diameter (qty. 2) |
| **7332-83** | Titanium Shim |
| **7218-18** | Tear Drop Suction Tube, Black, 260mm (qty. 2) |
| **7332-84** | Blade Adjustor, Black, 190mm (qty. 2) |
| **7233-54** | Weary/Scoville Type Nerve Root Retractor, 6.5mm |
| **7233-56** | Weary/Scoville Type Nerve Root Retractor, 11mm |



## BOTTOM LEVEL

| | |
|---|---|
| **7332-97** | Offset Extension Bar |
| **7233-62** | Ti-Blade Retractor, 9mm x 170mm |
| **7332-91** | Star Table Clamp Base |
| **7332-72** | Double-Ended Light Cord |
| **7332-93** | Multi-Position Table Post |
| **7332-98** | Flex Arm with Clamp |
| **7332-78** | Dilator Holding Clamp |



## Dynamic Flex Arm Table Mount (7332-95)

| | |
|---|---|
| **7332-93** | Multi-Position Table Post |
| **7332-97** | Offset Extension Bar |
| **7332-98** | Flex Arm with Clamp |
| **7332-91** | Star Table Clamp Base |

## Koros Disposable Neuromonitoring Kit (7332-99D)

| | |
|---|---|
| **7332-73D** | Disposable K-Wire |
| **7332-74D** | Disposable Dilator Tube, 5mm |
| **7332-75D** | Disposable Dilator Tube, 9mm |
| **7332-76D** | Disposable Dilator Tube, 16mm |
| **7332-89D** | Disposable Neuro Wire w/ Clip |
| **7332-86D** | Disposable Nerve Stimulator Probe |

## Additional Koros Instruments

| | |
|---|---|
| **7332-77S** | XL Dilator Tube, Disposable |
| **7233-64** | Ti-Blade Retractor, 13mm x 170mm |
| **7233-66** | Ti-Blade Retractor, 18mm x 170mm |

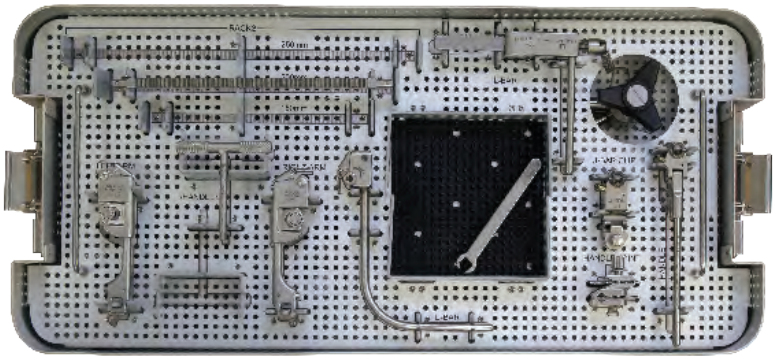
# *Thompson Lateral Retractor Set BOM (TLRT1-XXX & TLRT2-XXX)*

*For reference only. Contact Customer Service for latest BOM. Available in the U.S. only.*

| | |
|---|---|
| **TLRT1** | Retractor Set Tray 1 |

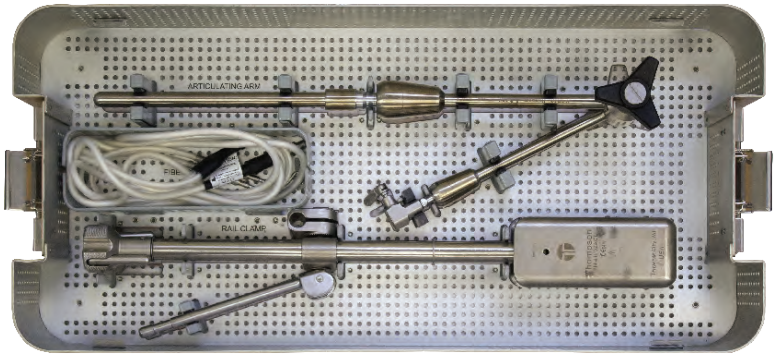
## TOP LEVEL

| | |
|---|---|
| **60010** | Rack, 200mm |
| **47213** | L-Bar |
| **60009** | Left Arm |
| **60020** | T-Handle |
| **60008** | Right Arm |
| **47212** | U-Bar |
| **43032** | Angling Wrench |
| **47205T** | U-Bar Clip |
| **SL45012S** | Handle Joint |
| **SL45002AS** | Handle |



## BOTTOM LEVEL

| | |
|---|---|
| **42138N** | Articluating Arm |
| **40002MISL** | Fiber Optic LED Light Cable, Reusable |
| **41902ACL** | Rail Clamp |



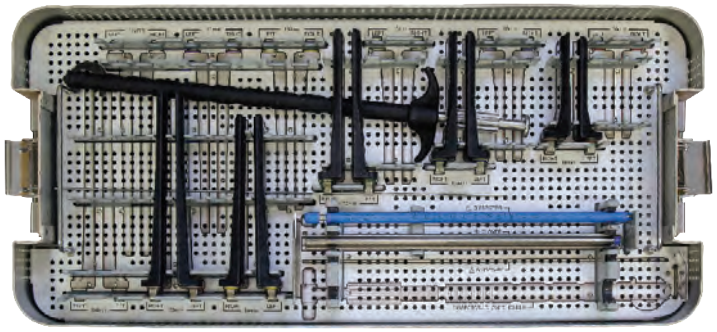

## Thompson Disposables

| | |
|---|---|
| **302427-000-275** | Disposable Monopolar Direct Nerve Stimulator Probe |
| **302775-200** | Disposable Multi-Stage Lead-Wire |

## TLRT2 Retractor Set Tray 2

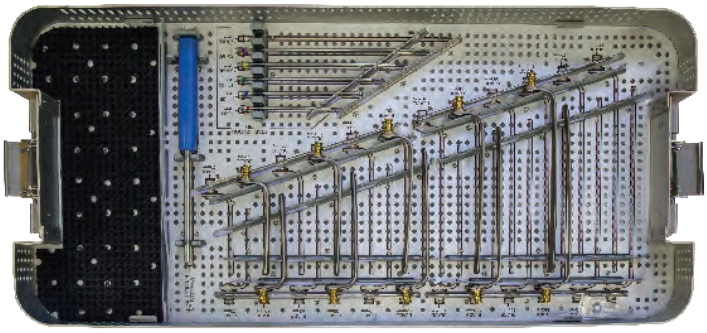
### TOP LEVEL

| | |
|---|---|
| 45817 | Dissector/Clover Holder |
| 45966R | 160mm Caudal/Cephalad Blade, Right (magenta) |
| 45966L | 160mm Caudal/Cephalad Blade, Left (magenta) |
| 45964R | 140mm Caudal/Cephalad Blade, Right (yellow) |
| 45964L | 140mm Caudal/Cephalad Blade, Left (yellow) |
| 45962R | 120mm Caudal/Cephalad Blade, Right (green) |
| 45962L | 120mm Caudal/Cephalad Blade, Left (green) |
| 45960R | 100mm Caudal/Cephalad Blade, Right (blue) |
| 45960L | 100mm Caudal/Cephalad Blade, Left (blue) |
| 45958R | 80mm Caudal/Cephalad Blade, Right (red) |
| 45958L | 80mm Caudal/Cephalad Blade, Left (red) |
| 45805 | Dissector, Coated w/ 2 mm Lumen |
| 45808 | Clover Dilator |
| 64018 | K-Wire (qty. 2) |



### BOTTOM LEVEL

| | |
|---|---|
| 51320 | Stabilization Pin Screw Driver |
| 51315 | 160mm Stabilization Pin (magenta) (qty. 2) |
| 51313 | 140mm Stabilization Pin (yellow) (qty. 2) |
| 51311 | 120mm Stabilization Pin (green) (qty. 2) |
| 51309 | 100mm Stabilization Pin (blue) (qty. 2) |
| 51307 | 80mm Stabilization Pin (red) (qty. 2) |
| SL46738 | 80mm Anterior/Posterior Blade (qty. 2) |
| SL46740 | 100mm Anterior/Posterior Blade (qty. 2) |
| SL46742 | 120mm Anterior/Posterior Blade (qty. 2) |
| SL46744 | 140mm Anterior/Posterior Blade (qty. 2) |
| SL46746 | 160mm Anterior/Posterior Blade (qty. 2) |



### OPTIONAL THOMPSON ACCESSORIES

| | |
|---|---|
| LLS-2000 | LED light source |

# Notes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