silony® SPINE

FDA CLEARED*

MULTILEVEL* • SINGLE LEVEL • AUTOGRAFT • ALLOGRAFT

STALIF® M Portfolio

No Profile® Anterior Lumbar Integrated Interbody™ Systems

TECHNIQUE & PRODUCT GUIDE

35+ YEARS OF CLINICAL SUCCESS SINCE 1988

*Not All Products Available in All Markets

STALIF® M Portfolio

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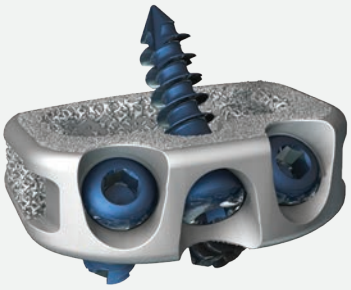
STALIF M *Portfolio*

The **STALIF M** Portfolio is a comprehensive set of instruments and implants designed to support an anterior approach to the lumbar spine. The **STALIF M** portfolio No Profile® implant designs are engineered to conform to patient anatomy, simplify surgery, enhance stability, and maximize opportunities for fusion.

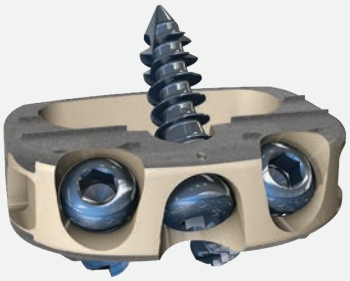
STALIF M portfolio Integrated Interbody™ lumbar fusion devices are designed to achieve immediate load-sharing and segmental stability. Innovative implant design complemented by unique cancellous screws co-function during the healing process to form an "integrated" fusion construct that is highly stable. Laboratory evaluations have repeatedly shown that the **STALIF M** product family attains equivalent biomechanical performance to anterior plate and cage technologies, as well as anterior cage and posterior pedicle screw constructs.[1]

STALIF M portfolio implants are provided in 3 state of the art material options, including **FLX®** (Flexible Lucent MatriX 3D-Printed titanium FUSE-THRU® trabecular scaffold), **Ti-ACTIVE™** (microporous texturized titanium surface), and PEEK (poly-ether-ether-ketone). Unlike other stand-alone implants, **STALIF®** devices are manufactured according to a specific biomechanical design rationale. This rationale was established with the original **STALIF** device introduced over 35 years ago. Through its multiple product iterations, **STALIF** has remained consistent and steadfast with the original design rationale.



STALIF M FLX Implants

STALIF M 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.



STALIF M Ti Implants

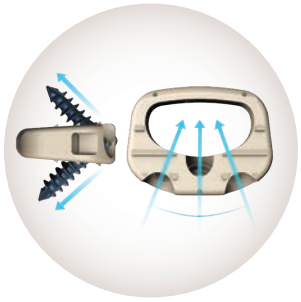
STALIF M-Ti is an innovative, titanium-surfaced, PEEK Integrated Interbody device design that blends the benefits of titanium and PEEK integrated interbody devices. PEEK has superior visualization properties and a modulus of elasticity that is similar to that of cortical bone while titanium is cell-friendly and enables human mesenchymal stem cells to adhere to the surface and proliferate.

The **Ti-ACTIVE** surface topography is designed to provide enhanced cellular attachment and proliferation vs rougher titanium surfaces, enhancing opportunities for fusion.

STALIF *Design Rationale*

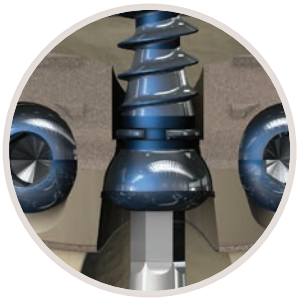
RATIONALE #1

Achieve Stable Fixation of the Motion Segment for Superior Biomechanics



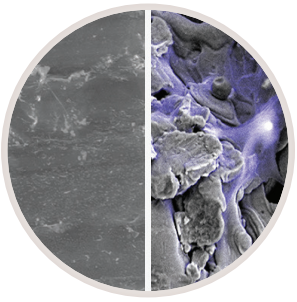
Optimized Screw Trajectories

- 3-screw design utilizes a midline convergence pattern in conjunction with an optimal horizontal inclination.
- Screw trajectories are intended to reduce incidence of backout and increase expulsion resistance.



Anti Back-Out (ABO®) Technology

- Titanium split ring Anti Back-Out (ABO) feature provides increased resistance to screw back-out without compromising the biomechanical principles of the Integrated Interbody construct.



Material Innovations

Ti-ACTIVE

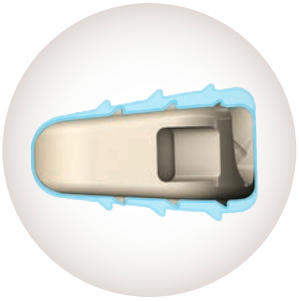
- Texturized surface topography provides 20x the roughness of machine finished PEEK providing enhanced stability upon implantation.
- 3-dimensional surface profile designed to provide enhanced cellular attachment and proliferation vs rougher titanium surfaces, with 2x the cellular attachment of courser titanium surfaces and 20x the cellular proliferation of other titanium surfaces.[2,3]

FLX

- **FLX** FUSE-THRU trabecular scaffold designed to allow for bony in-growth, on-growth, and thru-growth.

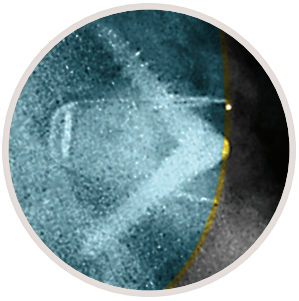
RATIONALE #2

Restore Sagittal Balance, Disc Height, & Lordosis



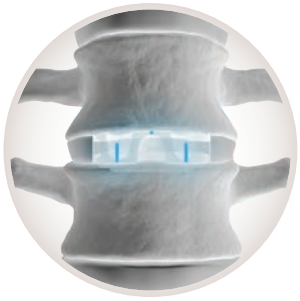
Multiple Footprints & Configurations

- Available in multiple footprint and height configurations.
- Lordotic profiles ranging from 8° to 20° to aid in sagittal balance restoration.



No Profile® Device

- "No Profile" design allows the device to seat within the confines of the disc space.
- **STALIF** maintains axial forces within the anterior aspect of the spine rather than creating a pressure moment outside of the spine.

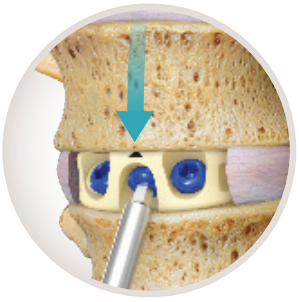


Anatomical Design

- Anatomical shape that is designed to sit on the apophyseal ring and better fill the disc space.

RATIONALE #3

Enhance Opportunities for Fusion

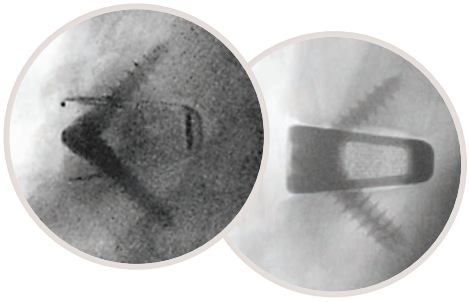


Compressive Lag Fixation

- Cancellous screws produce a lag effect between the vertebral body and the implanted device.
- Following Wolff's Law, the lag effect provides constant compressive forces against the implant and graft material to promote fusion.

Large Graft Window

- The large graft area, combined with an anatomical footprint and load-sharing design, affords the best opportunity for fusion.



Radiolucent Advantage

- Implants afford accurate post-operative assessment of fusion development.
- The **Ti-ACTIVE** surface allows for radiographic visualization of the graft-endplate contact.
- The **FLX** matrix enhances visualization of fusion post-operatively vs solid titanium devices

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.
- Do not use excessive force when introducing and positioning the implant within the intervertebral body space to avoid damaging the implant.
- Instrumentation provided with the implants must be used in accordance with the approved surgical technique.
- 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.
- Should not be used with components of any other system or manufacturer.
- Do not use titanium with stainless steel in the same construct. Premature device failure and/or infection in the patient may occur.
- Based on fatigue testing results, when using the **STALIF M** / **STALIF M-Ti** / **STALIF M FLX** system, the physician / surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may have an impact on the performance of this system.

Case Preparation

Required Sets

The following instrument sets are required for the **STALIF M** portfolio implants surgical technique.

- CAS01068 **STALIF M Gen 1 Instrument Set**
- CAS01069 **STALIF M Trials Set**
- CAS01687 **STALIF M Gen 1 Disc Prep Set**

OR

- STM-INST **STALIF M Instrument Set**
- CAS01069 **STALIF M Trials Set**
- DPS-INST **Anterior Lumbar Disc Prep Set**

Note: See Appendix for set contents and layout.

Additionally Available Instruments

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

Quick Reference Guide

The **STALIF M** Quick Reference Guide (LBL575), **STALIF M-Ti** Quick Reference Guide (LBL573), and **STALIF M FLX** Quick Reference Guide (LBL574), contain an abundance of information about implant offerings, sizes, and measurements and it is recommended to bring one into every case.

Surgical Technique

Approach

STALIF M portfolio implants are designed for use with a standard anterior approach to the spine. **STALIF M FLX**, **STALIF M-Ti**, and **STALIF M** all follow the same surgical technique.

The surgeon has a choice of three different material configurations (**FLX**, **Ti-ACTIVE**, PEEK), four different device heights (11, 13, 15, and 17mm*) with four lordotic angles (8°, 12°, 16°, and 20°) and five medial-lateral footprints (30, 33, 36, 39, and 42mm). Heights and depths vary based on footprint.

Devices and screws are supplied sterile and individually packaged.

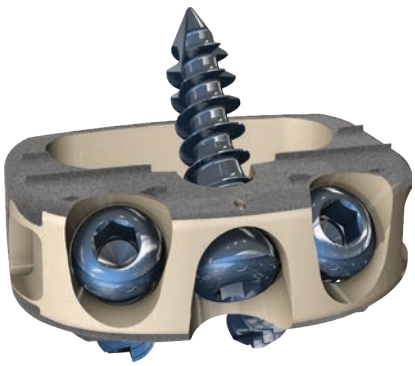
* Additional implant sizes and instruments may be available by request. Call customer service for availability.

1. Devices Shown with Three Available Material Choices

STALIF M FLX

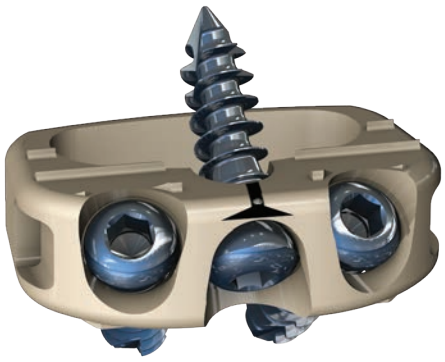
FLX WITH
FUSE-THRU™

STALIF M Ti



PEEK WITH
Ti ACTIVE™

STALIF M



WITH
PEEK

tech TIP *Material choices include 3D-printed titanium (**FLX**), PEEK with a microporous titanium surface (**Ti-ACTIVE**), and machine finished PEEK.*

Discectomy & Endplate Preparation

The anterior longitudinal ligament and annulus should be incised as close to the bony surfaces as possible to enable a thorough discectomy to be performed and allow for the **STALIF M/Ti/FLX** to be positioned on the apophyseal ring of the vertebral bodies. Use of any of the optionally provided or otherwise available disc prep instruments to remove disc material from the intervertebral space to enable trialing.

During the discectomy, particular care must be taken to fully remove the disc material from the posterolateral corners.

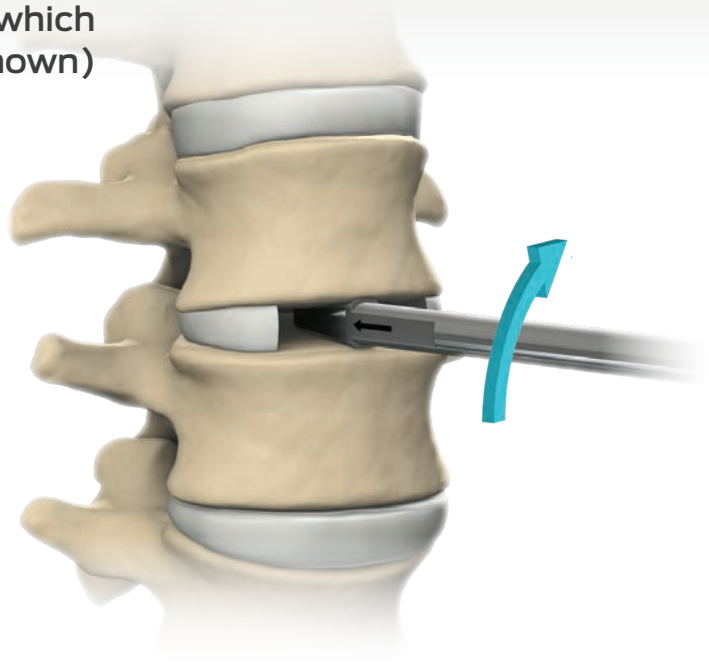
Paddle Distractors can be used to progressively distract the disc space sequentially **(Figure 2)** to mobilize the soft tissue, re-tension the annulus and allow for the appropriately sized device to be selected.

Once the discectomy is complete, use a 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.

Paddle Distractors
IN207 (7mm), IN208 (9mm), IN209 (11mm), IN210 (13mm), IN337 (15mm), IN338 (17mm)

Detachable Paddle Distractors & Handle
IN1459 (7mm), IN1461 (9mm), IN1463 (11mm), IN1465 (13mm), IN1467 (15mm), IN1469 (17mm), IN889 (Handle)

2. Demonstrating the Paddle Distractor which is inserted, then rotated, by 90° (as shown)



please NOTE *Take care to fully remove the nucleus material from the posterolateral corners.*

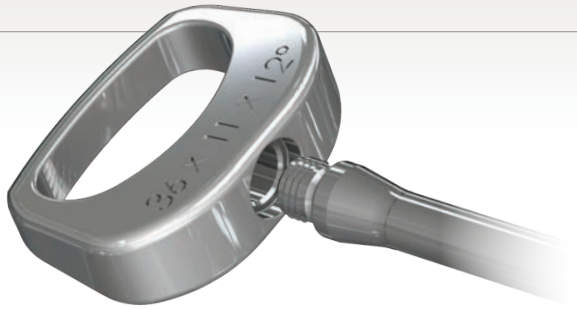
Surgical Technique (continued)

Trialing

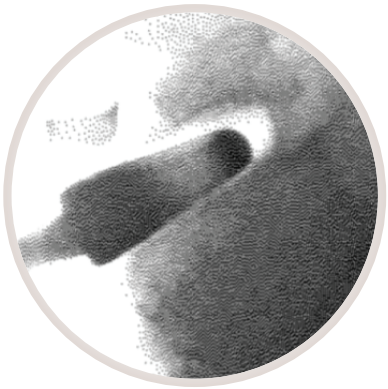
Once the disc space has been prepared, mount the **STALIF M** trial sizers onto the threaded handles **(Figure 3)** to determine the correct device with respect to anterior/posterior (A/P) depth, width, height and lordotic angle **(Figure 4)**. It is recommended to start with an 11mm tall by 12° trial in the desired width as this has the smallest anterior and posterior height combination. To select proper implant fit and fill, use intraoperative A/P fluoroscopy images to visualize the trial sizer **(Figure 4)**. The trial should be flush with the anterior edge of the vertebral body. To ensure proper implant selection, the trial must achieve a tight fit. It is recommended to select the largest footprint that can safely be implanted to optimize the load transfer across the apophyseal ring.

Trial Handle
IN224/1

3. Straight Handle with Trial



4. Trial Sizing



Posterior Gaping:
Reduce Lordosis or Increase Height

Space Behind Trial:
Increase Footprint

Good Fit

please NOTE *For STALIF M FLX, trial must have a tight fit within disc space to limit implant movement during screw insertion*

To remove the trial, use the slotted mallet to apply upward impaction on the trial handle shaft until the trial is free from the disc space.

Note that **STALIF M-Ti** implants may require increased insertion forces compared to the trial due to the surface roughness of the implant (see "Tech Tip" below). **STALIF M FLX** has similar handling characteristics to the PEEK **STALIF M** devices.

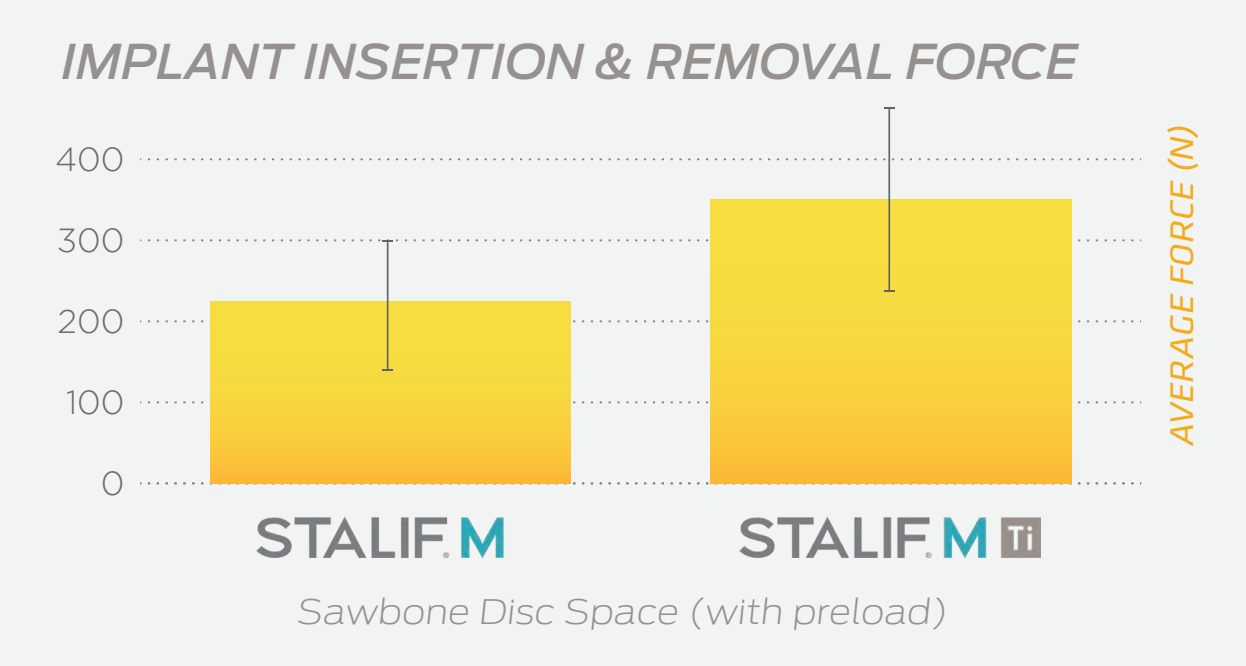
Trials

MT331108, MT331112, MT331308, MT331312, MT331316, MT331508, MT331512, MT331516, MT331712, MT331716, MT361108, MT361112, MT361308, MT361312, MT361316, MT361508, MT361512, MT361516, MT361708, MT361712, MT361716, MT391108, MT391112, MT391308, MT391312, MT391316, MT391508, MT391512, MT391516, MT391712, MT391716

tech TIP

Ti-ACTIVE surfaced implants require increased insertion force. See graph below. (Note: Testing was performed without screws.)

Imaging should be performed to verify proper trial sizer fit. Please select the largest device footprint that can safely be implanted to optimize the load transfer across the apophyseal ring.



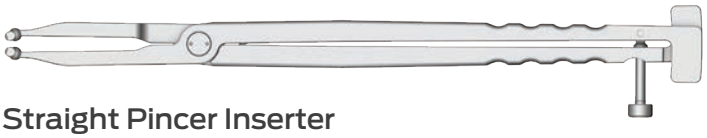
Surgical Technique (continued)

Device Insertion

Prepare the inserter for device attachment by rotating the tensioning knob fully counterclockwise **(Figure 5)**. The indicator below the tensioning knob should be next to "Release." Attach the selected device to the inserter **(Figure 6)** and secure the device by rotating the tensioning knob clockwise **(Figure 7)**. The indicator below the tensioning knob should be next to "Capture" and the implant should be securely attached to the inserter.

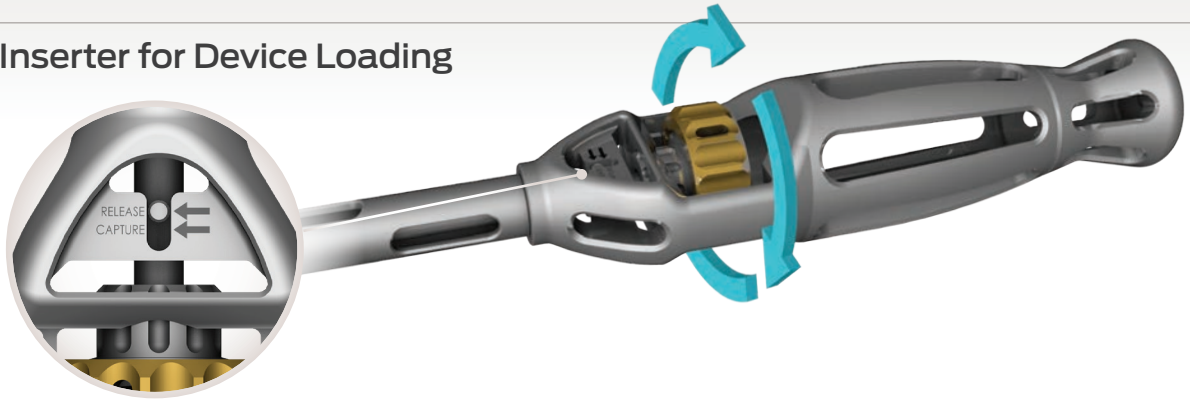
An alternate inserter, the Straight Pincer Inserter, engages the outer screw holes and is available by request; please contact Customer Service for availability.

Inserter
IN566/1 or IN566/2

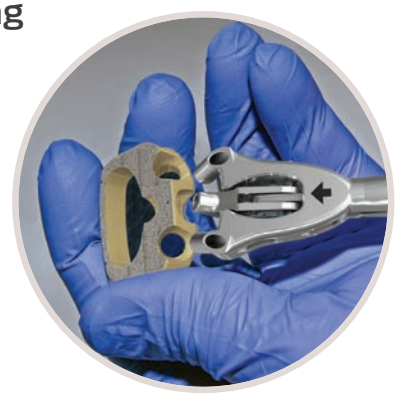


Straight Pincer Inserter
(Additionally Available for Gen 1 Sets)
IN913

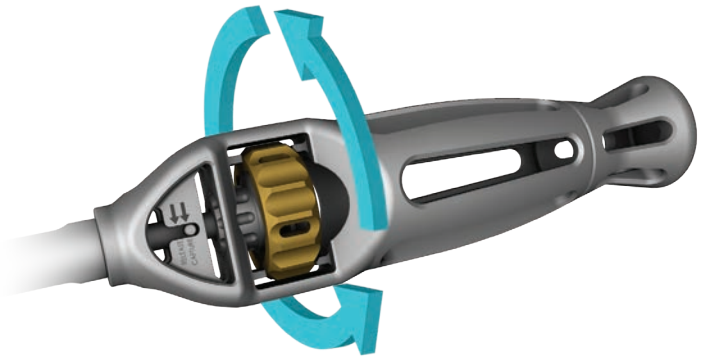
5. Preparing Inserter for Device Loading



6. Securing Device



7. Turning Tensioning Knob Clockwise



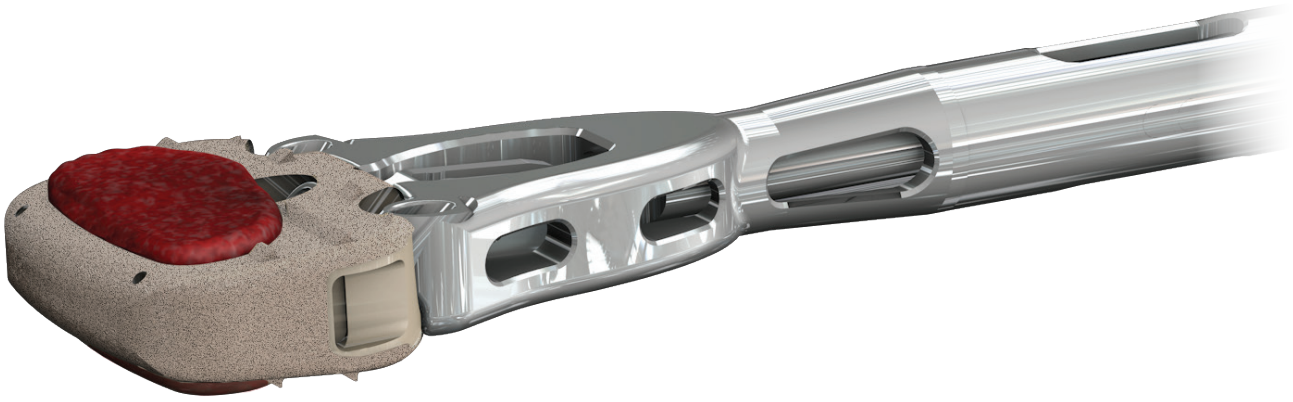
tech TIP *Once the Tensioning Knob has been tightened, check to verify a snug fit between the device and Inserter.*

Insert and pack autograft and/or allograft into the central cavity of the implant. It is recommended that the cavity be packed 2mm proud both superiorly and inferiorly to assure optimal graft/endplate contact **(Figure 8)**.

STALIF M-Ti Device (Anterior View)

STALIF M FLX Device (Anterior View)

8. Device Packed with Graft Material



Surgical Technique (continued)

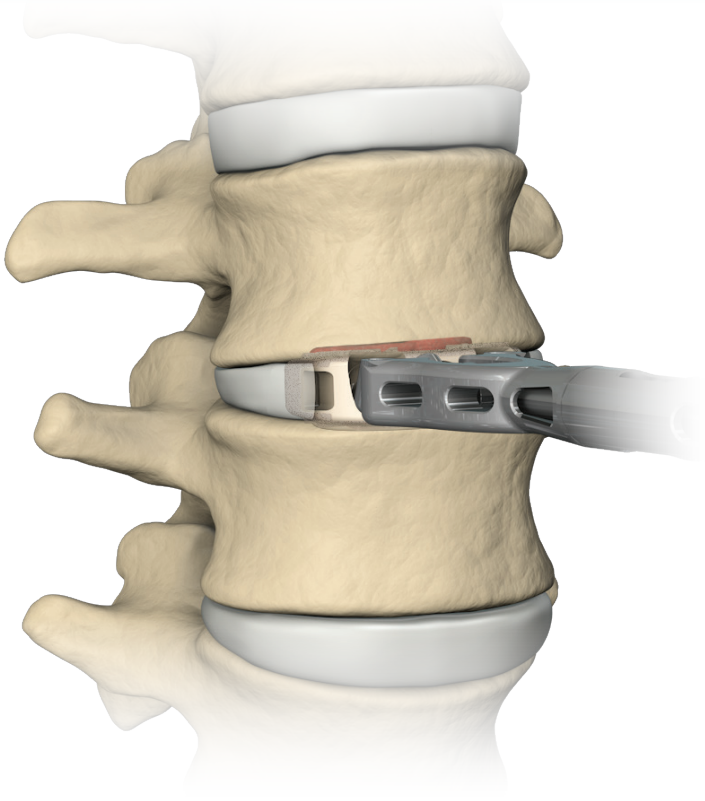
Insert the **STALIF M** portfolio implant into the disc space using the Inserter **(Figure 9)**. The implant may be placed with one screw cephalad or one screw caudal. The arrow on the inserter tip points to the vertebral body that the single screw will be placed into **(Figure 10)**.

Inserter
IN566/1 or IN566/2

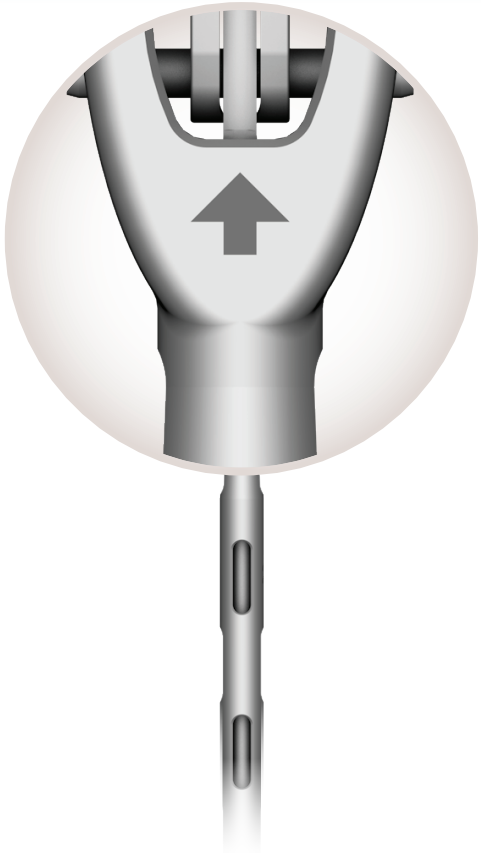
Trial Handle
IN224/1

Tamp
IN156/1

9. Inserting the Device



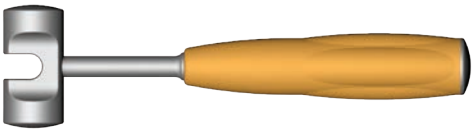
10. Indicator Arrow on Inserter Tip



Note that when using implants in contiguous levels, to avoid potential stress concentrations, the implants must be placed in the same orientation such that the single screw points in the same direction (i.e. single screw caudal in each level) **(Figure 11)**.

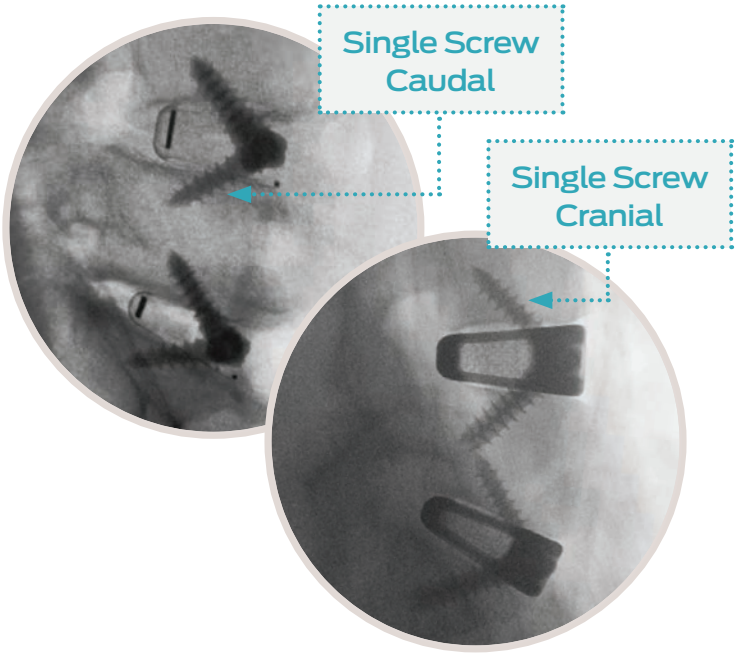
The slotted mallet can be used to impact the strike surface of the inserter to advance the implant into the disc space.

Position the implant flush or up to 1mm proud of the anterior lip of the vertebral body to ease insertion of screws and allow the lag effect to reduce the device to align with the apophyseal ring. Fluoroscopy should be used to confirm implant placement prior to screw placement **(Figure 12)**.

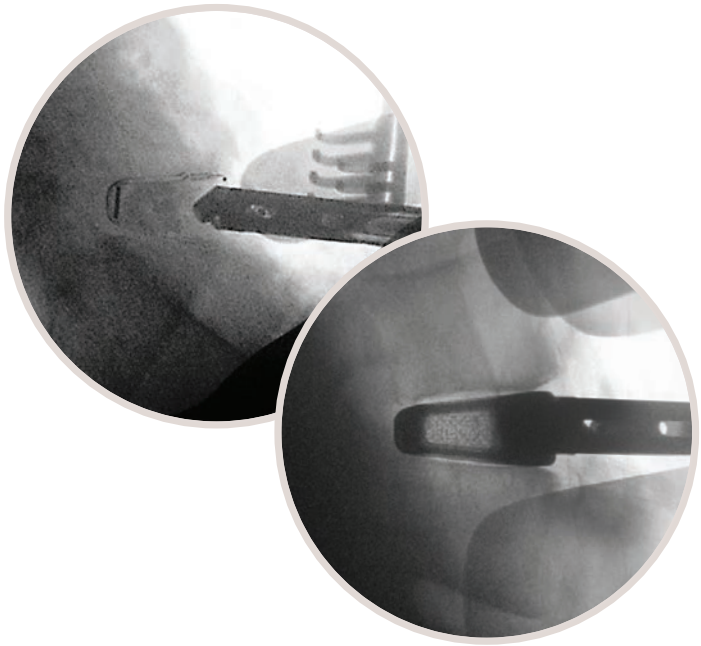


Slotted Mallet
IN228

11. Contiguous Level Placement



12. Lateral Fluoroscopy of Device Insertion



please NOTE *For contiguous levels, the single screws at each level must be pointing the same direction (i.e. single screws cephalad or single screws caudal). To avoid a potential stress concentration, the single screws should never be pointing towards each other. Similarly, the double screws should never be pointing toward each other.*

Surgical Technique (continued)

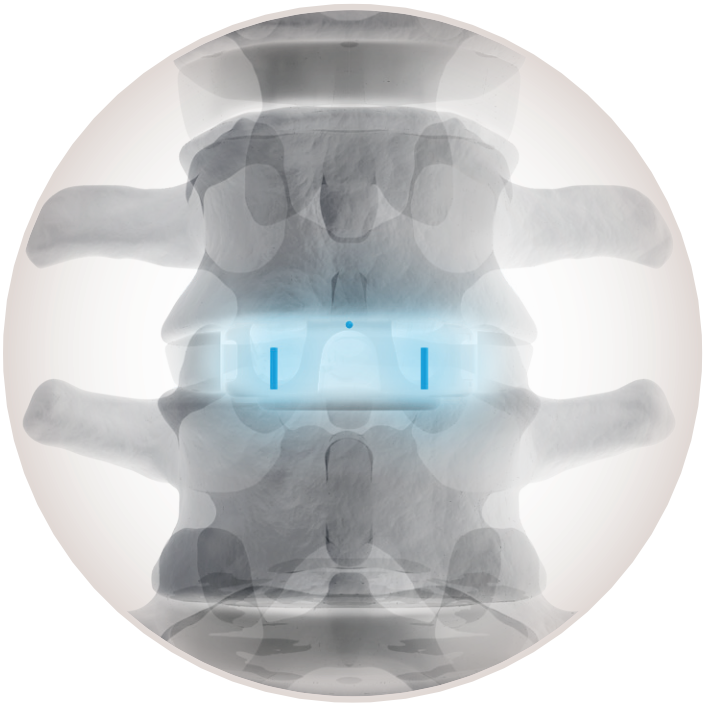
For **STALIF M/Ti** implants, three tantalum markers are used to radiologically assess implant position. There is one tantalum spherical marker to indicate the central anterior margin of the implant. In the anterior view, it should align with the spinous process **(Figure 13)**.

For **STALIF M**, in the lateral view the spherical marker should be flush with the anterior lip of the vertebral body (cage will be 1mm proud of anterior lip of vertebral body).

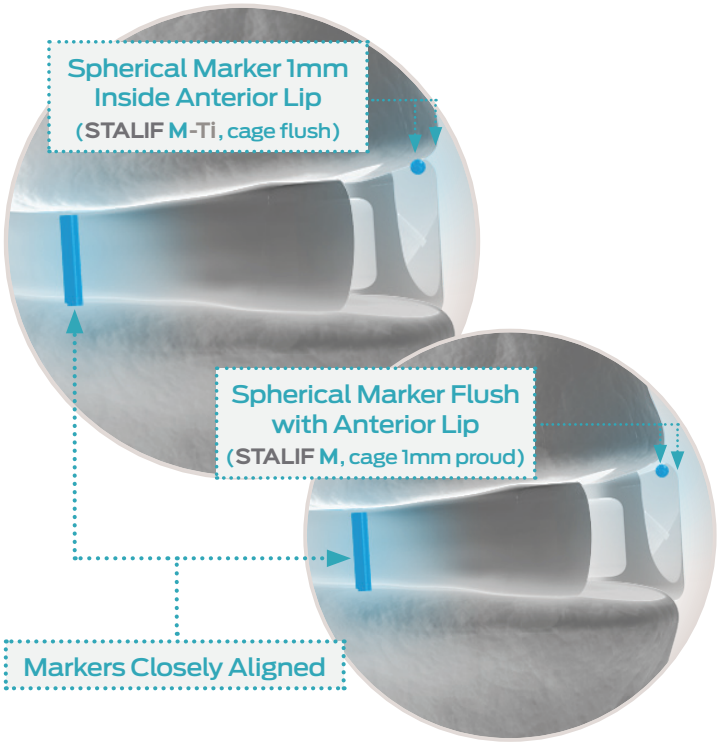
For **STALIF M-Ti**, the spherical marker should be flush with the anterior lip fo the vertebral body (cage will be flush with anterior lip of vertebral body). **(Figure 14)**

There are two tantalum rod markers located on each rounded corner of the posterior portion of the **STALIF M/Ti** implants. In the A/P view the rod markers should be symmetrical to the spherical marker **(Figure 13)**. The posterior rod markers should be closely aligned/superimposed on lateral fluoroscopy **(Figure 14)**.

13. A/P Fluoroscopy to Verify Device & Marker Positioning for STALIF M/Ti



14. Lateral Fluoroscopy to Verify Device & Marker Positioning for STALIF M/Ti



tech TIP *If the two rod markers are not closely aligned, either the x-ray may not be a true lateral or the device may be rotated.*

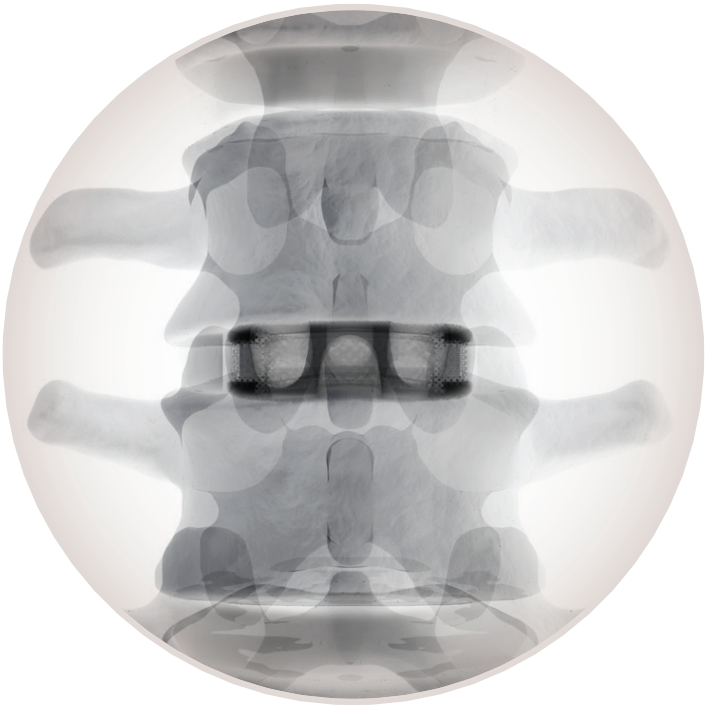
please NOTE **STALIF M** *cages should be placed 1mm proud of the anterior lip of the vertebral body, placing the spherical marker flush with the anterior lip of the VB.*

STALIF M-Ti *cages should be placed flush with the anterior lip of the vertebral body, placing the spherical marker 1mm recessed from the anterior lip of the VB.*

For **STALIF M FLX** implants, the implant profile is visible under fluoroscopy. In the anterior view, the central screw hole should be aligned with the spinous process and the lateral screw holes should be symmetrical to the central screw hole **(Figure 15)**. In the lateral view, the face of the implant should be flush with or at most 1mm proud of the anterior lip of the vertebral body, and the trapezoidal graft window should have crisp edges **(Figure 16)**.

If additional positioning is required, use the tamp attached to the trial handle. Alternatively, the inserter can be reattached to the implant by reversing the steps to secure the device to the inserter prior to repositioning, or the device can be attached to the optional pincer inserter (recommended for **STALIF M-Ti**).

15. A/P Fluoroscopy to Verify Device Positioning for STALIF M FLX



16. Lateral Fluoroscopy to Verify Device Positioning for STALIF M FLX

Surgical Technique (continued)

Screw Placement

Once implant positioning is confirmed, select the appropriate awl and awl guide to create a pilot hole for the center screw **(Figure 17)**. There are three awl options: Straight Guided Punch Awl (with built in awl guide), Ball-Joint Awl, and Universal-Joint Awl; the Ball-Joint and U-Joint awls require the use of the Low Profile Awl Guide. On occasion, to facilitate proper angulation to the screw holes and enable the awl guide to properly seat within the screw aperture, it may be necessary to remove a small portion of the lip of the vertebral body adjacent to the screw hole. The slotted mallet may be used to impact the strike surface of the awl to create the pilot hole. Confirm a 45° awl trajectory using lateral fluoroscopy. Once the pilot hole has been created, remove the awl and awl guide, taking care not to bring the tip of the awl guide near any sensitive structures.

Ball-Joint Awl
IN386

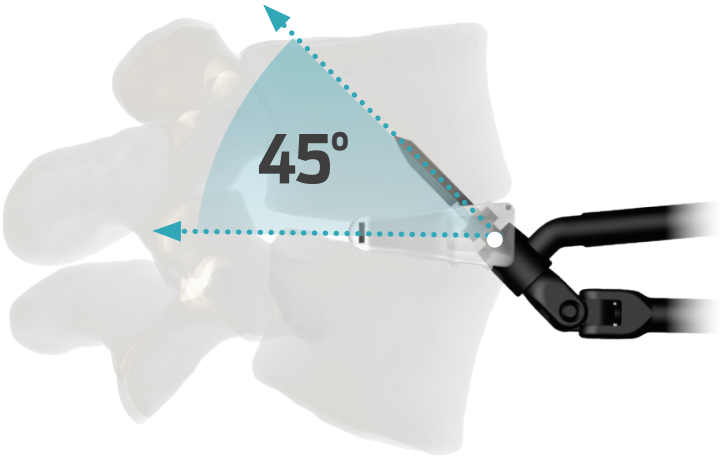
Universal-Joint (UJ) Awl
IN216

Low Profile Awl Guide
IN1430

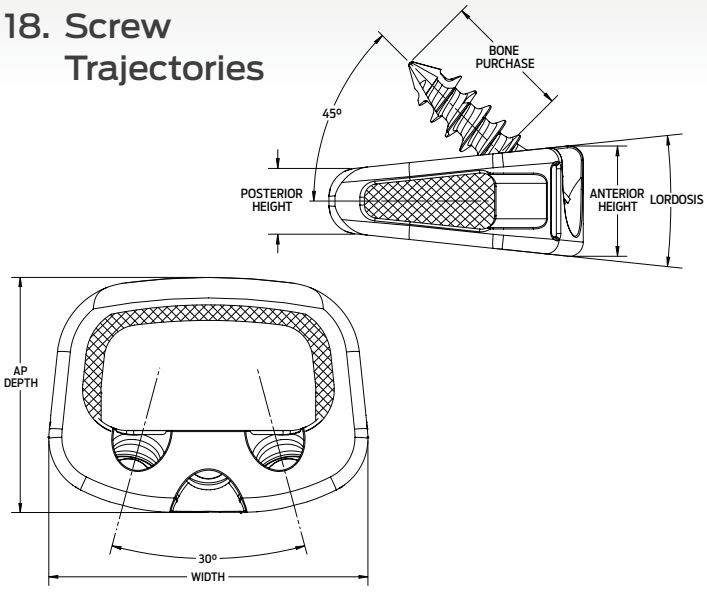
Straight Guided Punch Awl
IN502/2

** Important Note: The IN1430 Low Profile* **STALIF M** *Awl Guide should not be used with an IN217/1 or IN217/2 Long Tip U-Joint Awl as this combination may result in A/P penetration depths that are deeper than the cage.*

17. Confirming 45° Awl Trajectory Using Lateral Fluoroscopy



18. Screw Trajectories



please NOTE *It is critical that the awl guides be used and seated correctly so that the pilot hole is concentric and the screw trajectory optimized. It is also important that only one awl hole is created at a time (a screw should be placed prior to the creation of the next awl hole).*

There are four screwdriver options to choose from for screw insertion: Straight, U-Joint, Ball-Joint, or Fixed Angle. All four drivers use a 3.5mm hex with a self-retention feature to hold the screw. It is recommended to match the screwdriver to the awl used to create the pilot hole. The screw attaches to the screwdriver with a press-fit; due to the self-retention feature bone wax should not be needed.

The **STALIF M** portfolio implants utilize Silony Spine's ABO cancellous screws for optimum compressive lag fixation. The 6.0mm diameter self-tapping, electro-polished ABO screws (code "STM") are provided in color coded lengths of 25mm (blue), and 30mm (green) **(Figure 19)**. A length of 35mm is available by special request. Call customer service for availability. For cages 15mm or taller, a 30mm or longer screw is recommended to maximize bone purchase.

Universal-Joint (UJ) Screwdriver
IN218

Ball-Joint Screwdriver
IN231

Straight Screwdriver
IN225

Fixed Angle Driver
(Additionally Available for Gen 1 Sets)
IN1339

Handle
(Additionally Available for Gen 1 Sets)
IN1458

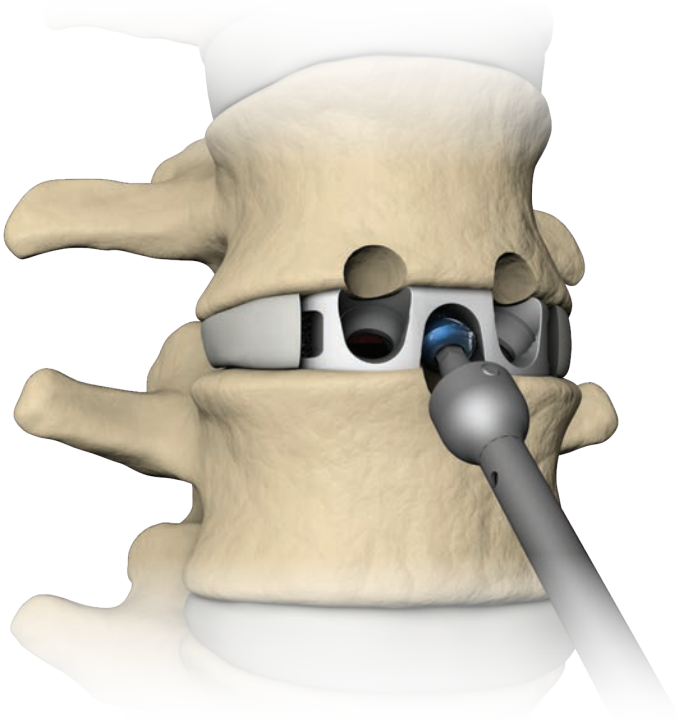
19. 25mm Screw and 30mm Screw Comparison

Surgical Technique (continued)

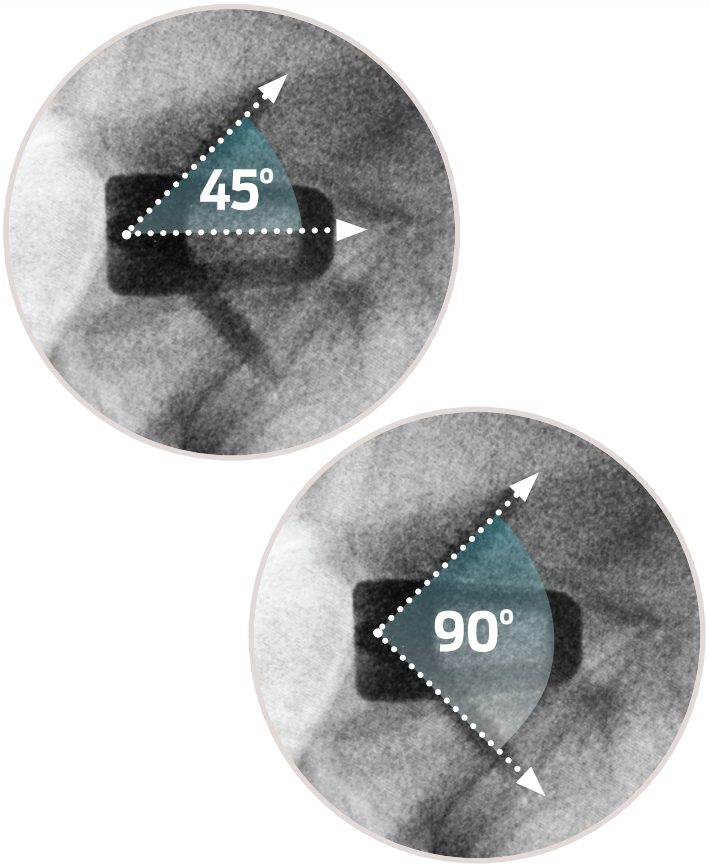
Screw insertion is initiated with the central screw **(Figure 20)**. Load the chosen screw onto the driver and insert the first screw through the center hole where the pilot hole was created. It is recommended to confirm the 45° screw trajectory using lateral fluoroscopy. For **STALIF M**, tighten the screw down 90%; for **STALIF M-Ti/FLX**, tighten the screw down 100%. Repeat the above steps to create an awl hole for the second screw, then place and fully tighten the second screw. The second awl/screw trajectory should be approximately 90° from the center screw.

It is recommended to not overtighten the screw as tactile feel will vary due to varying patient bone quality. Repeat for the third screw, fully tightening the third screw. The third screw should be in alignment with the second screw. For **STALIF M**, final tighten the center screw after the second and third screws have been placed and tightened to maximize compressive fixation.

20. Inserting Screw with Ball-Joint Screwdriver



21. Proper Trajectory



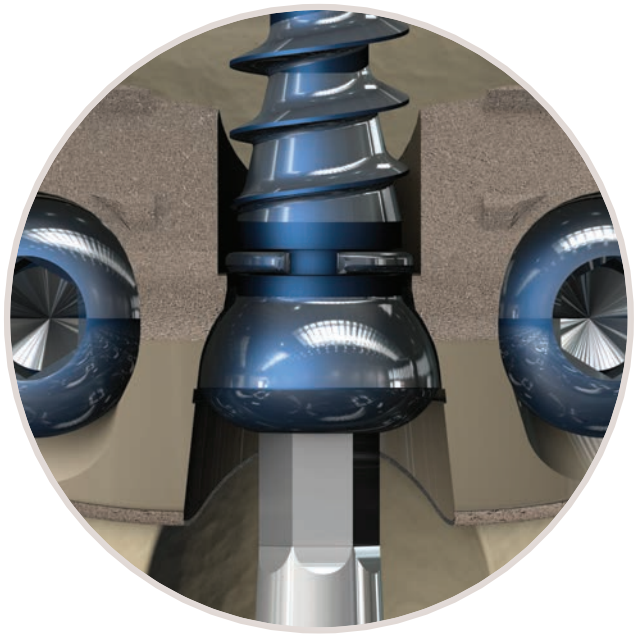
please NOTE *For* **STALIF M** *the screw should not be fully tightened to prevent rotation of the implant until an opposing screw is positioned. For* **STALIF M-Ti/FLX**, *each screw should be fully tightened when placed to enable proper ABO engagement.*

Awl and screw trajectories should be confirmed using lateral fluoroscopy.

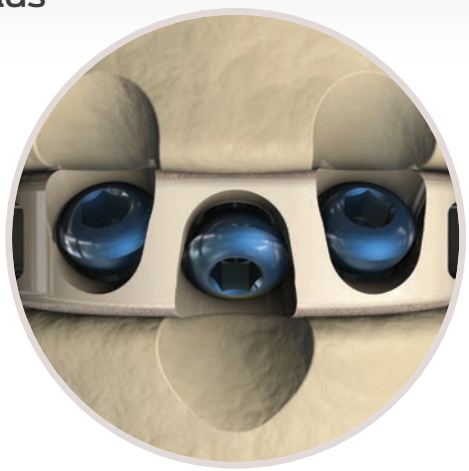
ABO screws feature a titanium split ring **(Figure 22)** which first compresses and then deploys during insertion. Each screw head must be fully seated within the device screw apertures to ensure the ring is properly deployed **(Figures 23 & 24)**.

Bone quality varies between patients, so to optimize the screw lag effect, tactile feel and visualization can be used to determine when the screw heads are correctly seated. Indicator grooves may be visible to the surgeon when the screw heads are correctly seated **(Figure 24)**.

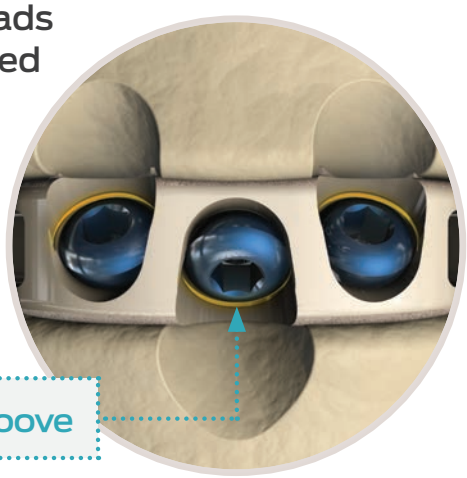
22. Cancellous Screw with ABO® Titanium Split Ring Deployed



23. Screw Heads Not Fully Seated



24. Screw Heads Fully Seated



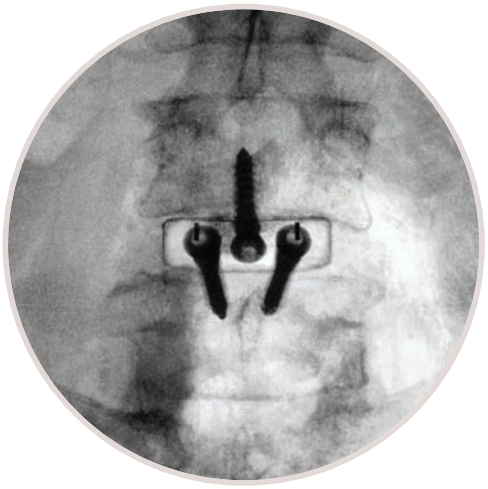
please NOTE *The ABO® titanium split ring is properly deployed when the screw head passes the screw-depth-indicating groove (highlighted in Figure 24).*

Surgical Technique (continued)

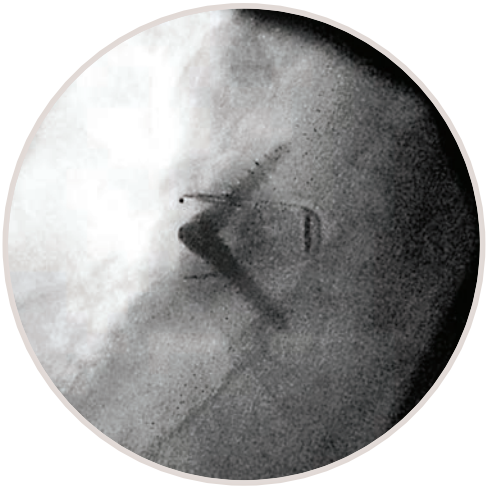
X-Ray Confirmation

Intraoperative fluoroscopy should be taken during and after screw insertion, and prior to closure, to ensure proper positioning **(Figures 25, 26, 27, & 28)**.

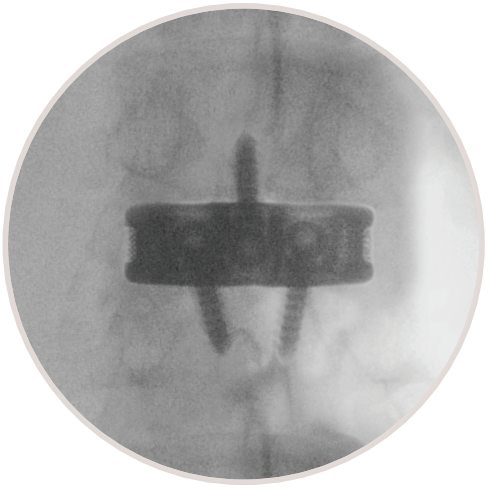
25. A/P Fluoroscopy of STALIF M-Ti Final Positioning



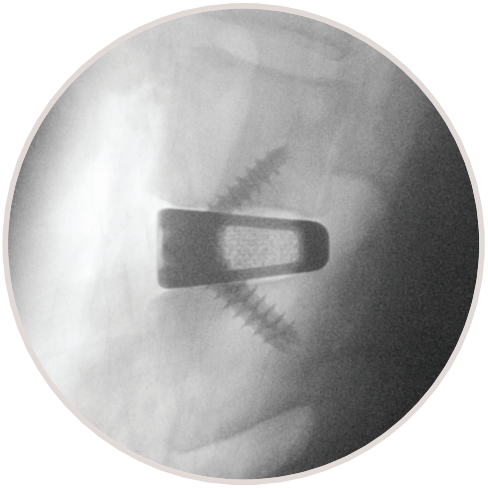
26. Lateral Fluoroscopy of STALIF M-Ti Final Positioning



27. A/P Fluoroscopy of STALIF M FLX Final Positioning

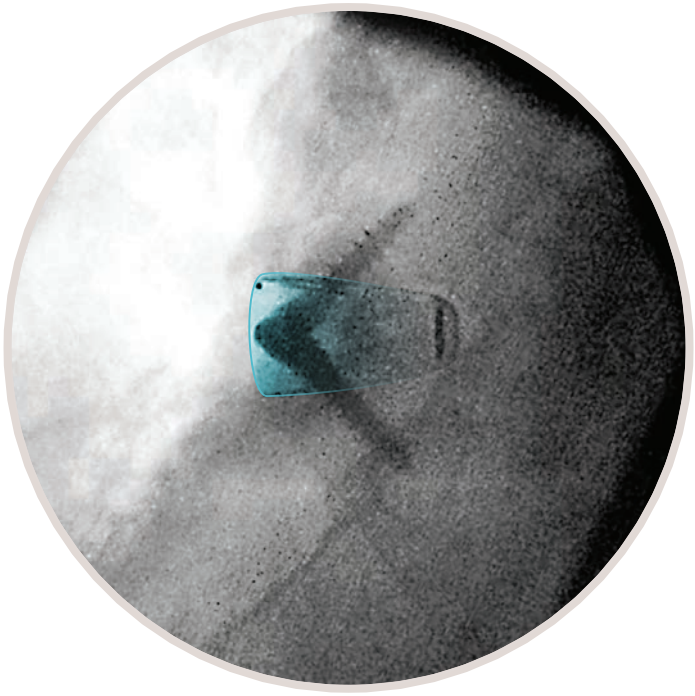


28. Lateral Fluoroscopy of STALIF M FLX Final Positioning

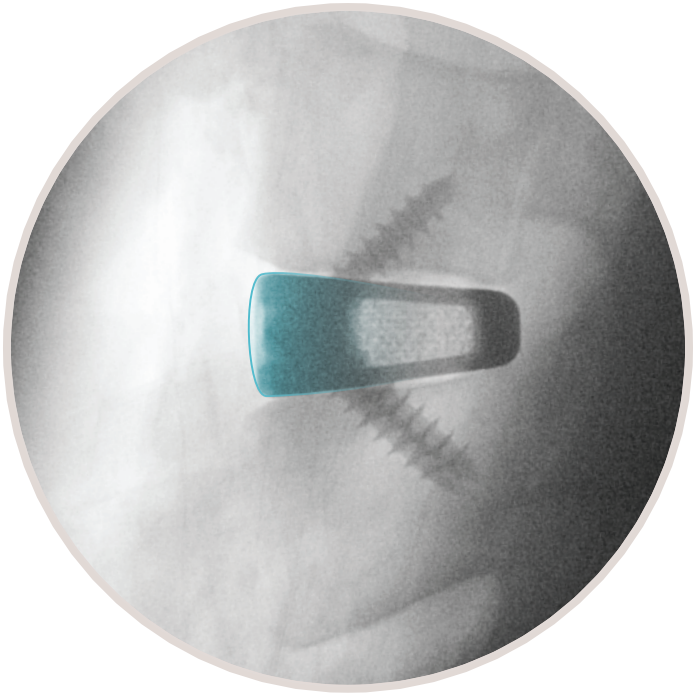


For confirmation that the screws are fully seated and the ABO is engaged, take a lateral fluoroscopy image. For **STALIF M/Ti**, the screw heads should be overlapped and in alignment with the spherical marker, and for **STALIF M-Ti**, the screw heads should be within the confines of the **Ti-ACTIVE** surface **(Figure 29)**. For **STALIF M FLX**, the screw heads should be overlapped and within the confines of the implant **(Figure 30)**.

29. STALIF M-Ti Screw Heads Within Confines of Ti-ACTIVE Surface



30. STALIF M FLX Screw Heads Within Confines of the Implant



Surgical Technique (continued)

Removal / Revision

In the unlikely event that a revision procedure is necessary, the **STALIF M** portfolio construct can be removed by reversing the steps in the surgical procedure. For **STALIF M-Ti/FLX**, a pincer inserter may be necessary for removal to overcome surface friction (contact Customer Service for availability).

Supplemental Fixation

STALIF M portfolio implants are indicated for use as stand-alone devices and do not require supplemental fixation. **STALIF M FLX** devices with lordotic angles greater than or equal to 20° require additional supplemental fixation indicated for use in the lumbar spine.

Tips & Pearls

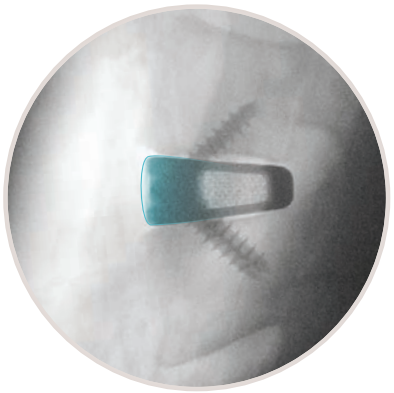
- Refer to quick reference guides.
  - Posterior heights can be used to find "sister sizes" – identify implants that may fit the disc space equally as well as a desired size by matching posterior heights.

For STALIF M PEEK:

- Place PEEK implants 1mm proud of anterior edge of VB.
  - Do not recess.
- Recommend first inserting but not fully seating the center screw until two outer screws are fully secured.
- Caution against over-tightening screws (there is no audible click).
- Confirm screw ABO® engagement with lateral fluoro.
  - Screw heads overlapped and in alignment with anterior spherical marker.

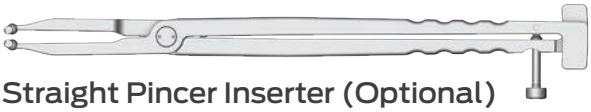
For STALIF M FLX:

- Trial should have a tight fit.
- Place **FLX** implants flush to 1mm proud of anterior edge of VB.
  - Do not recess—implant will lag & handle like PEEK.
- Recommend first inserting & fully seating the center screw.
  - Recommend using lateral fluoroscopy to confirm awl & screw angulation for each screw.
    - Place & fully seat each screw before awling the next screw hole.
  - Caution against over tightening screws (there is no audible click).
    - Confirm screw ABO® engagement with lateral fluoro.
      - Screw heads overlapped and fully contained within confines of implant



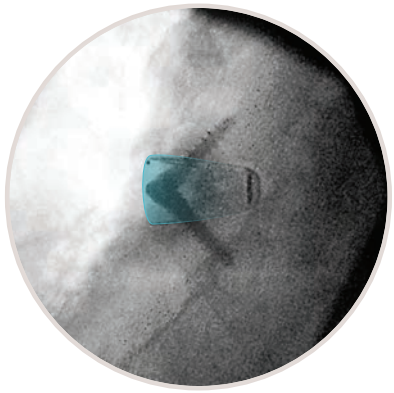
For STALIF M-Ti:

- If the trial is difficult to insert/back out, consider going down 1 height—**Ti-ACTIVE** surface adds up to 0.4mm in total height & has increased friction because of surface topography.
  - Trial should be snug but only take a few impactions to back out.
  - Place implant as midline as possible.
- Adjustment will be difficult due to increased friction from **Ti-ACTIVE** surface.
  - If adjustment is needed, use pincer inserter (recommend requesting pincer for all **Ti-ACTIVE** cases).



Straight Pincer Inserter (Optional)
IN913

- Place **Ti-ACTIVE** implants flush with anterior edge of VB.
  - Do not recess because cage will still lag (just not as much as the PEEK) & will be very difficult to back out.
- Recommend first inserting & fully seating the center screw.
  - Caution against over-tightening screws (there is no audible click).
    - Confirm screw ABO® engagement with lateral fluoro.
  - Screw heads overlapped & in alignment with anterior spherical marker.
- Final confirmation with lateral fluoro.
  - Screw heads overlapped, in alignment with anterior spherical marker, & contained within confines of **Ti-ACTIVE** surface.



APPENDIX:
STALIF M System Instrument Offering

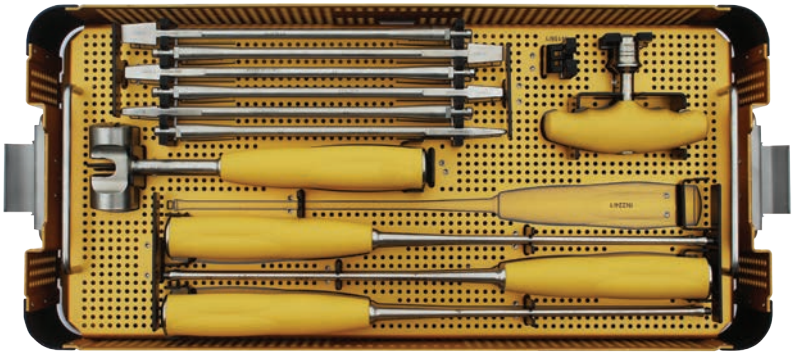
Gen 1 Instrument Set BOM (CAS01068-XXX)

For reference only. Contact Customer Service for latest BOM.

CAS01068	Instrument Tray

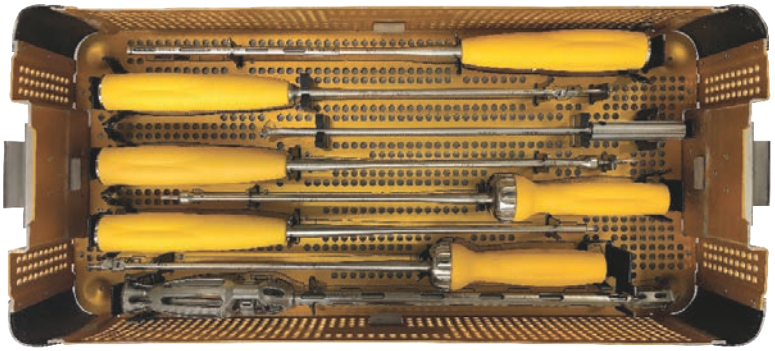
TOP LEVEL

IN382	T-Handle
IN156/1	Tamp
IN207	7mm Paddle Distractor
IN208	9mm Paddle Distractor
IN209	11mm Paddle Distractor
IN210	13mm Paddle Distractor
IN337	15mm Paddle Distractor
IN338	17mm Paddle Distractor
IN228/1	Mallet
IN224/1	Trial/Tamp Handle (3)



BOTTOM LEVEL

IN502/2	Straight Guided Punch Awl
IN216/1	U-Joint Awl
IN1430	Low Profile Awl Guide
IN386	Ball-Joint Awl
IN231/1	Ball-Joint Screw Driver
IN225/1	Straight Screw Driver
IN218/1	U-Joint Screw Driver
IN566/1 or IN566/2	Inserter



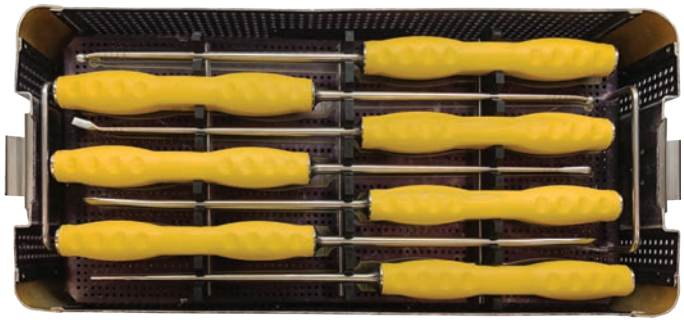
Gen 1 Disc Prep Set BOM (DPS-BAXXX)

For reference only. Contact Customer Service for latest BOM.

CAS01687	Gen 1 STALIF M Disc Prep Instrument Tray

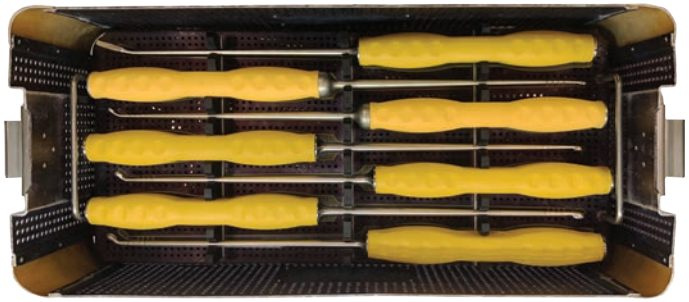
TOP LEVEL

IN675	8mm Ring Curette, Bent 15˚
IN676	6mm Ring Curette, Bent 15˚
IN677	8mm x 20mm Square Curette, Bent 15˚
IN683 | 04A00010	11mm x 4mm Teardrop Curette
IN682	20mm Endplate Elevator
IN886 | IN681 | 09A00005	25mm Endplate Elevator, Slim
IN680 | 09A00012	15mm Osteotome



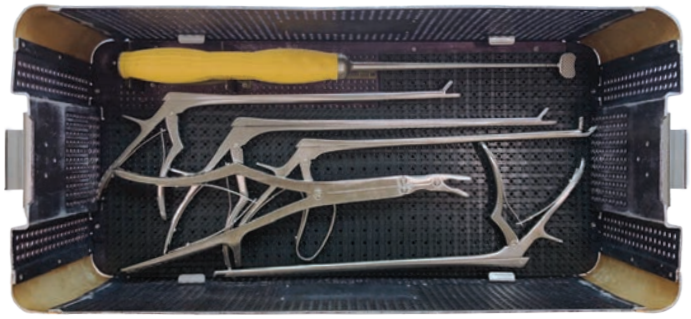
MIDDLE LEVEL

IN678	Rasp, Bent 15°
IN670 | 04A00001	4mm x 6mm Straight Cup Curette
IN679	4mm x 6mm Bent 35° Cup Curette
IN671 | 04A00003	6mm x 8mm Straight Cup Curette
IN672 | 04A00004	6mm x 8mm Bent 35° Cup Curette
IN673 | 04A00005	8mm x 10mm Straight Curette
IN674	8mm x 10mm Bent 35° Curette



BOTTOM LEVEL

IN976	Kidney Shaped Rasp
IN1009 | GY-0001 | 248-1300 | 830-1204-0 | IN710	4mm Kerrison Rongeur, 12”
GY-0005 | 228-9449 | 832-1208-0	8mm Pituitary Rongeur, Straight, 12”
IN1012 | IN712 | GY-0004 | 249-2991 | 873-1304-0	4mm Pituitary Rongeur, Straight, 13”
IN1011 | GY-0003 | 249-6101 | 873-1408-0	Double-Action Rongeur, w/o Teeth, 14 3/8”
IN1010 | GY-0002 | 249-2667 | 831-1206-1	6mm Pituitary Rongeur, Up, 12”



STALIF M *Instrument Set BOM (STM-INST-XXX)*

For reference only. Contact Customer Service for latest BOM.

CAS02684	**STALIF M** Instrument Tray

TOP LEVEL

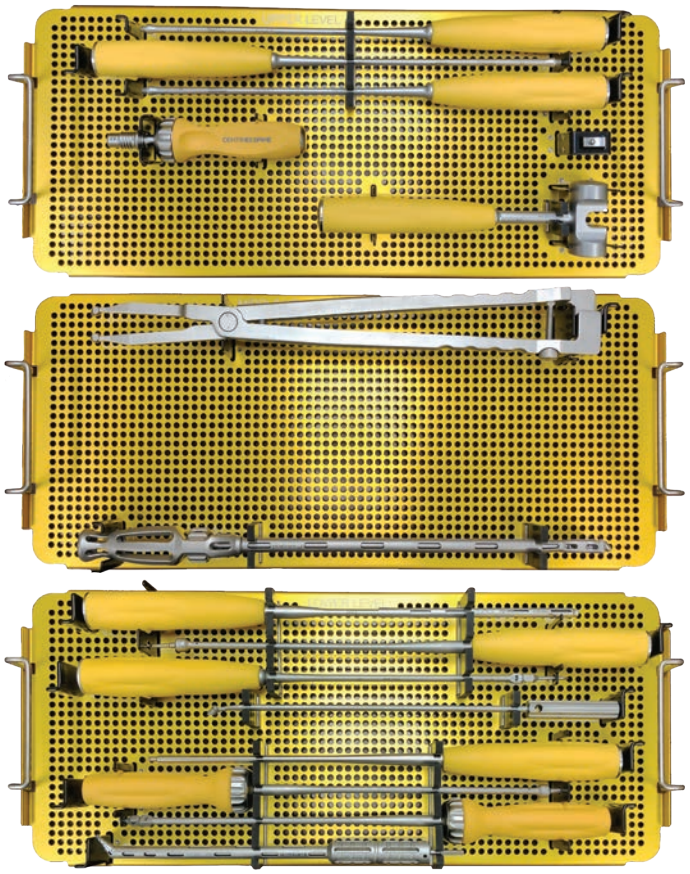
IN675	8mm Ring Curette, Bent 15°
IN224/1	**STALIF M** Trial Handle
IN1458	Lumbar AO Ratchet Handle
IN156/1	**STALIF M** Tamp Head
IN228/1	**STALIF** Lumbar Slotted Mallet

MIDDLE LEVEL

IN913	Straight Pincer Inserter
IN566/2 | IN566 | IN566/1	**STALIF M** Inserter

BOTTOM LEVEL

IN502/2	**STALIF M** Straight Punch Awl
IN386	**STALIF** Lumbar Ball-Joint Awl
IN216/1	**STALIF** Lumbar U-Joint Awl
IN1430	**STALIF M** Awl Guide
IN225/1	**STALIF** Lumbar Straight Screw Driver
IN231/1	**STALIF** Lumbar Ball-Joint Screw Driver
IN218/1	**STALIF** Lumbar U-Joint Screw Driver
IN1339	**STALIF M** 45° Fixed Angle Screwdriver



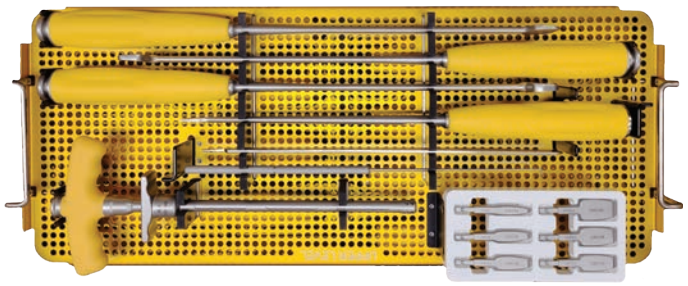
Anterior Lumbar Disc Prep Set (DPS-INST-01-XXX & DPS-INST-02-XXX)

For reference only. Contact Customer Service for latest BOM.

CAS02686-01	Anterior Lumbar Disc Prep Instrument Tray 1 Of 2

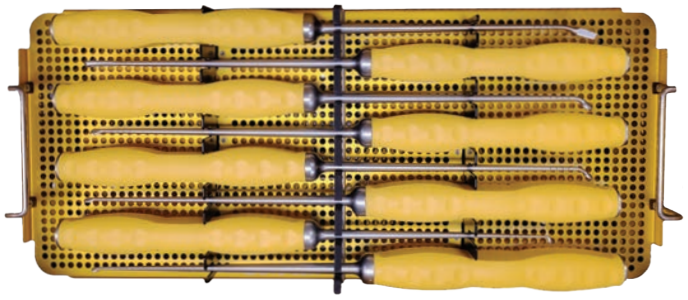
TOP LEVEL

IN1057/1	5mm Trial Dilator
IN1058/1	7mm Trial Dilator
IN1059/1	9mm Trial Dilator
IN1473	Midline Marker 8mm Width 250mm
IN848	12" Knife Handle
IN1480 | 03.605.010	Ball Tip Probe 90 Deg 300mm
IN889	Paddle Distractor Handle
IN1459	Paddle Distractor, 30mm AP - 7mm
IN1461	Paddle Distractor, 30mm AP - 9mm
IN1463	Paddle Distractor, 30mm AP - 11mm
IN1465	Paddle Distractor, 30mm AP - 13mm
IN1467	Paddle Distractor, 30mm AP - 15mm
IN1469	Paddle Distractor, 30mm AP - 17mm



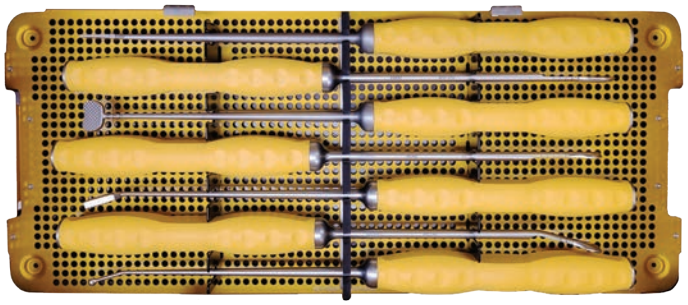
MIDDLE LEVEL

IN677	8mm x 20mm Square Curette, Bent 15°
IN683 | 04A00010	11mm x 4mm Teardrop Curette
IN674	8mm x 10mm Bent 35° Curette
IN673 | 04A00005	8mm x 10mm Straight Curette
IN672 | 04A00004	6mm x 8mm Bent 35° Cup Curette
IN671 | 04A00003	6mm x 8mm Straight Cup Curette
IN1472	Bone Curette-Angled/Oval Head 3.5mm x 4.5mm 430mm
IN670 | 04A00001	4mm x 6mm Straight Cup Curette



BOTTOM LEVEL

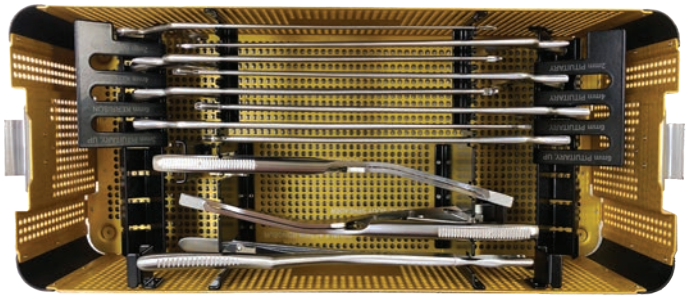
IN680 | 09A00012	15mm Osteotome
IN886	25mm Endplate Elevator, Slim
IN976	Kidney Shaped Rasp
IN682	20mm Endplate Elevator
IN678	Rasp, Bent 15°
IN1120	20mm Endplate Elevator, Slim, 15° Forward Angled
IN676	6mm Ring Curette



CAS02686-02	Anterior Lumbar Disc Prep Instrument Tray 2 Of 2

SINGLE LEVEL

IN1478 | gS 70.6302	40 Deg Up-Biting Laminectomy Punch, 2mm Width/330mm Length
IN1475 | gs68.8535	2mm Pituitary Rongeur
IN1009 | GY-0001 | 248-1300 | 830-1204-0 | IN710	4mm Kerrison Rongeur, 12"
IN1012 | IN712 | GY-0004 | 249-2991 | 873-1304-0	4mm Pituitary Rongeur, Straight, 13"
IN1479 | gS 70.9126 | GY-0006	6mm Kerrison Rongeur, 12"
IN1476 | gS 68.9826 | 03.605.002	Disc Rongeur Straight Without Teeth 6mm Width 330mm
IN1477 | gS 68.9843 | 03.605.000	Disc Rongeur Up-Biting 3mm Width 330mm
IN1010 | GY-0002 | 249-2667 | 831-1206-1	6mm Pituitary Rongeur, Up, 12"
PDL114	Vertebral Body Spreader - Angled
IN1011 | GY-0003 | 249-6101 | 873-1408-0	Double Action Rongeur, W/O Teeth 14 3/8"



Additionally Available Instruments (Special Order)

GY-0006
6mm Kerrison Rongeur

IN913
Straight Pincer Inserter

PDL114
Vertebral Body Spreader, Angled

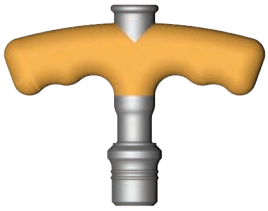
IN887
Fixed Angle Lumbar Screw Remover

IN875
Mini-Axial Quick-Connect Handle (for Fixed Angle Lumbar Screw Remover)

IN221/1
Straight Awl

IN222/1
Straight Awl Guide

IN435/1
T-Handle



IN883
TLIF Revision Hook Tool

IN884
TLIF Revision L Tool

References

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[2] *Yoon, Byung Jo Victor et al. "Optimizing Surface Characteristics For Cell Adhesion And Proliferation On Titanium Plasma Spray Coatings On Polyetheretherketone". The Spine Journal (2016): n. pag. Web. 6 Oct. 2016.*

[3] *Silony Spine Report VAL-2014-010.*

Notes

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