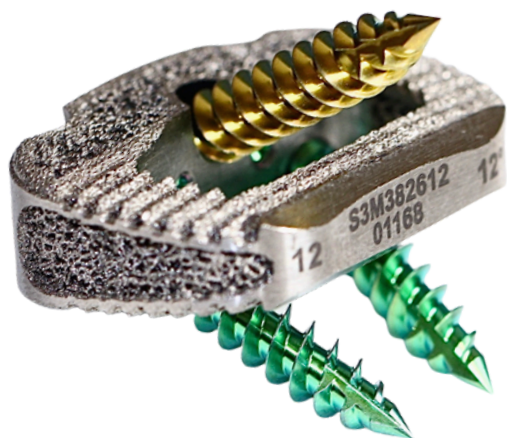




EMINENT
SPINE

Anterior Lumbar Stand-Alone Surgical Technique



Eminent Spine



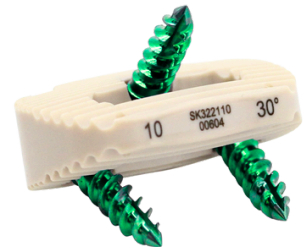
Anterior Lumbar Stand-Alone System

Surgical Technique



Product Features

- Aggressive teeth to resist migration
- 3D Titanium Anterior Surface with and without teeth
- Large central opening for maximum bone graft material
- Lordosis nose, lordosis and rounded edges allows for ease of insertion
- 2 Material Options:
 - 3D Titanium



*PEEK (upon request)

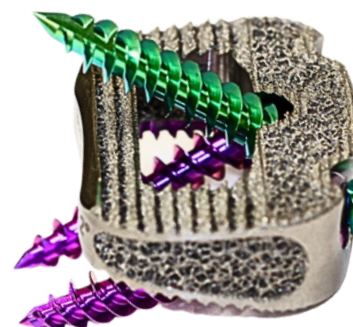
Implant Profiles

PROFILE	HEIGHT (2mm)	LORDOSIS
32mm X 21mm	10mm-20mm	12°, 18°
35mm X 25mm	10mm-20mm	12°, 18°
35mm X 25mm	12mm-20mm	6°
38mm X 26mm	10mm-20mm	12°, 18°
*35mm X 25mm	12mm-20mm	12°
*38mm X 26mm	*Flat Series	



Anterior Lumbar Stand-Alone System

Surgical Technique



Screw Options

Self-Drilling, Self-Tapping

Variable

DIAMETERS

4.5, 5.0, 5.5, 6.0mm

LENGTHS

20, 25, 30, 35mm



10°



40°

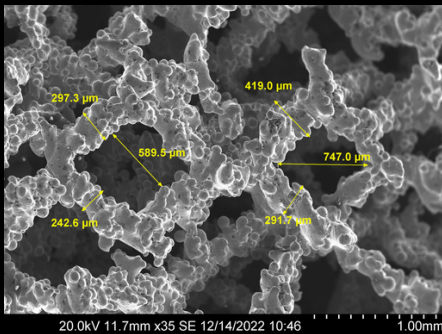
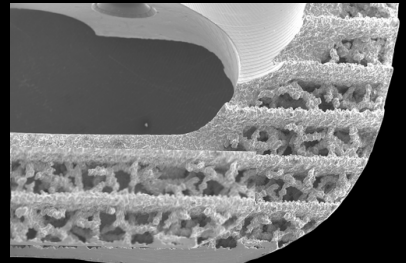
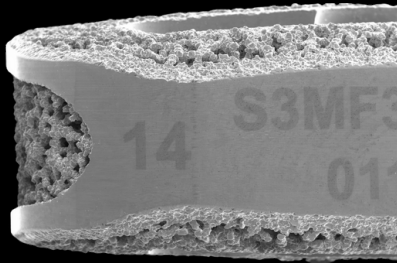
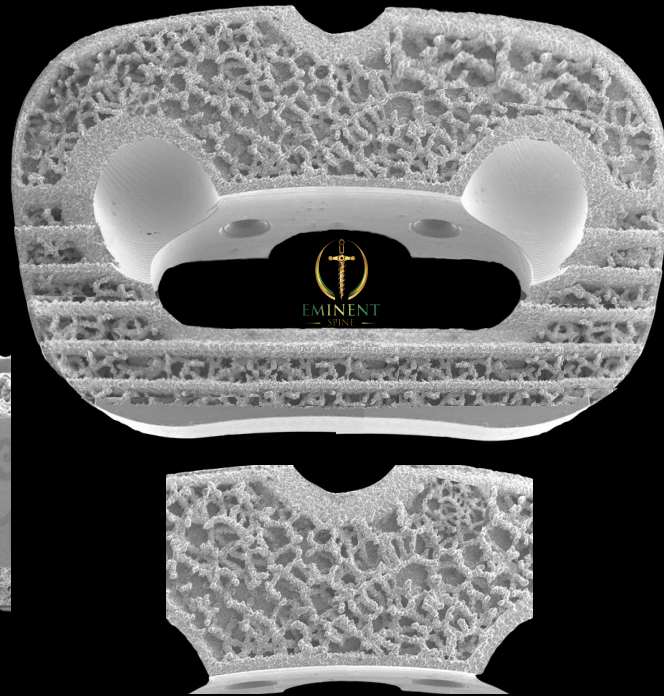


- 10° medial screw convergence
- 40° cranial / caudal screw angulation
- Variable screws have 8° conical rotation

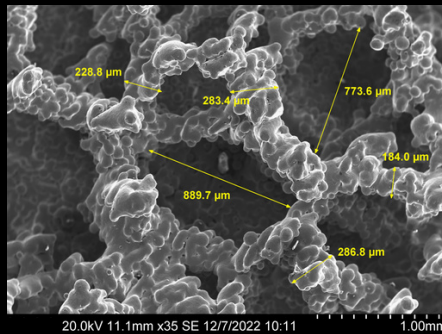
T20 Screw Driver for **Both** Screws and Locking Tabs.

LATTICE FEATURES

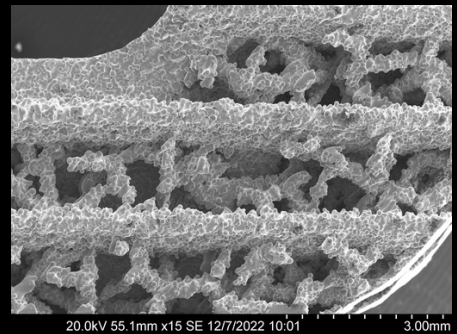
A True Cancellous-Trabecular 3D printed Lattice
Pore sizing ranging from 300-800µm
60% or more porosity



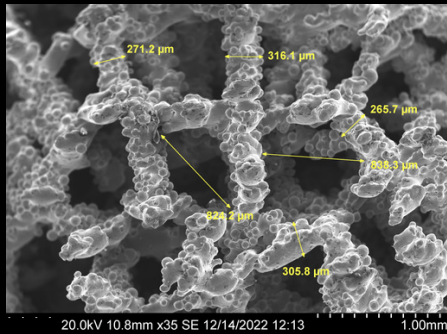
20.0kV 11.7mm x35 SE 12/14/2022 10:46 1.00mm



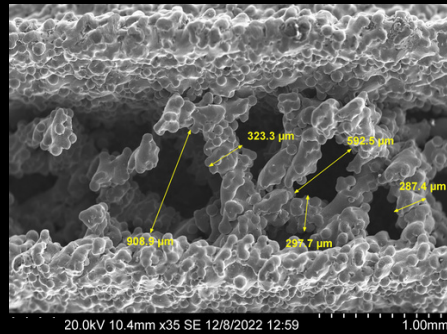
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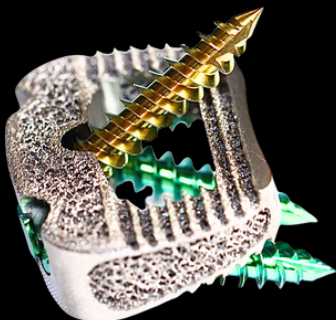
20.0kV 55.1mm x15 SE 12/7/2022 10:01 3.00mm



20.0kV 10.8mm x35 SE 12/14/2022 12:13 1.00mm



20.0kV 10.4mm x35 SE 12/8/2022 12:59 1.00mm



Anterior Lumbar Stand-Alone System

Surgical Technique

Step 1 : Patient Positioning

Place the patient in a supine position. A bump can be placed in the lower back for increased lordosis of the spine. Expose the midline of the correct inter-vertebral disc (Figure 1).



Figure 1

Use a scalpel to incise the annulus and make a rectangular window to outline the disc for resection (Figure 2).



Figure 2



Step 2 : Discectomy & Endplate Preparation

General Anterior Disc Surgical instruments can be used to perform the discectomy. Use pituitary rongeurs to remove disc material (Figure 3). Use chisels (Figure 4), cup curettes (Figure 5), and teardrop curettes (Figure 6) to remove further disc and the cartilaginous layer of the endplates. Those General Instruments are provided upon request.



Figure 3



Figure 4



Figure 5



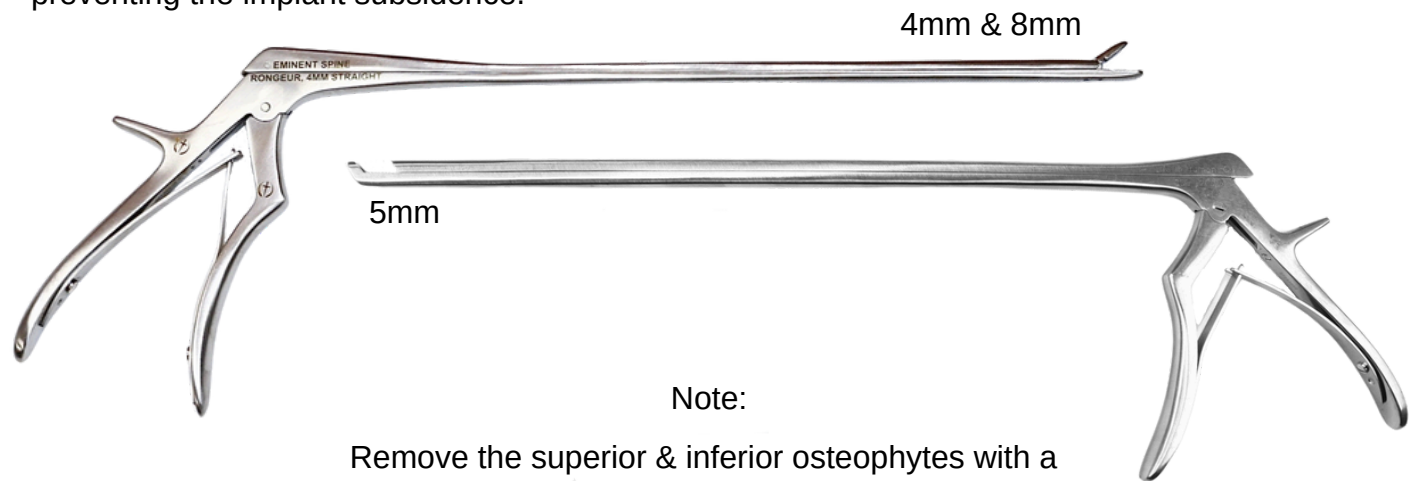
Figure 6

Anterior Lumbar Stand-Alone System

Surgical Technique

Step 2 : Continued

Perform a thorough Discectomy to ensure the posterolateral walls are free of disc material. Remove the non-ossified fibrocartilage, but do not remove too much subchondral bone for preventing the implant subsidence.



Note:

Remove the superior & inferior osteophytes with a 4mm or 8mm straight pituitary or a 5mm kerrison (Figure 7), in order to open up the orifice of the disc space and this will expose the true Anterior Vertebral body surface. Double action rongeurs (5mm or 8mm) may also be used to open up the orifice of the disc space (Figure 8).

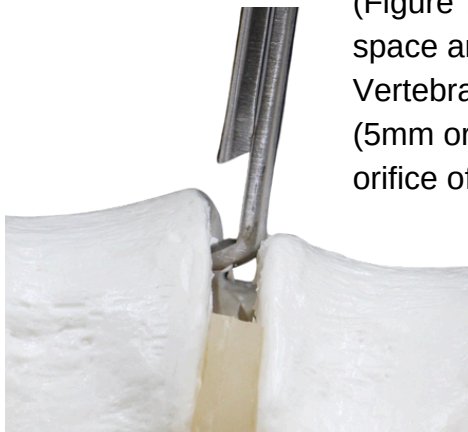


Figure 7

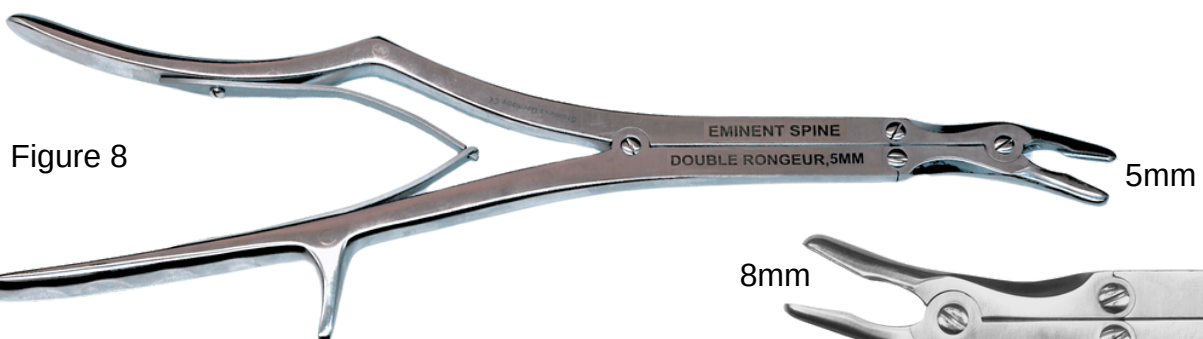
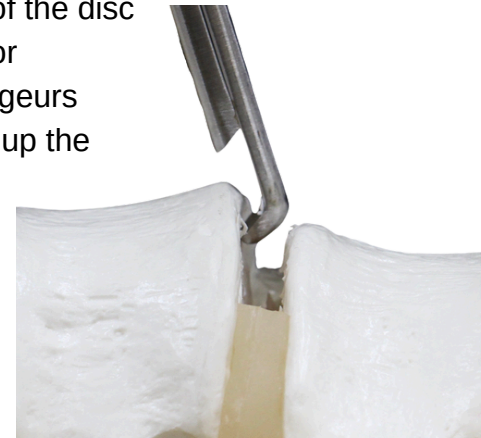


Figure 8

Anterior Lumbar Stand-Alone System

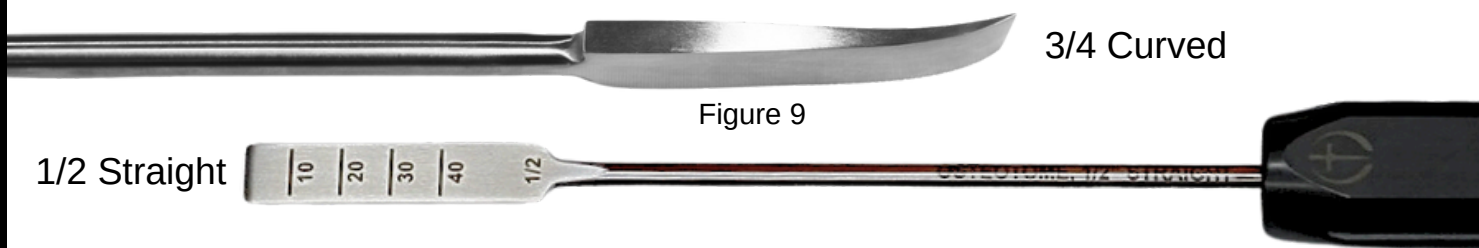
Surgical Technique

Step 2 : Continued

Continue with the Discectomy to ensure the posterolateral walls are free of disc material. Remove the non-ossified fibrocartilage, but do not remove too much subchondral bone for preventing the implant subsidence.

Note:

Remove the superior & inferior osteophytes with Straight or Curved Chisels and 5mm or 8mm Rongeur (Depending on disc space size), in order to open up the orifice of the disc space and this will expose the true Anterior Vertebral body surface (Figure 9).



*All size osteotomes (3/4, 1/2, 3/8) available in Curved & Straight

Use the Distraction Trials to distract the disc space to restore Lordosis & Neural foraminal height. Insert the Wedge Distractor Nose into the disc space (Figure 10) and rotate 90 Degrees to distract the disc space (Figure 11). Verify the wedge distraction position using AP and Lateral Fluoroscopy. Depth markers are also visible to confirm the desired implant depth.



Figure 10



Figure 11

Anterior Lumbar Stand-Alone System

Surgical Technique

Step 2 : Continued

A set of Disc Shavers, Trials, and Rasps are available in the Eminent Spine Anterior Lumbar Interbody system. The Trials and Rasp are available upon request. The instruments are in one piece and do not allow for "play" between the handle and the shaft (Figure 12).

Use the Disc Shavers in a controlled manner to distract the disc space (Figure 13) and to clean the lateral portion of the disc. Multiple sizes are available.

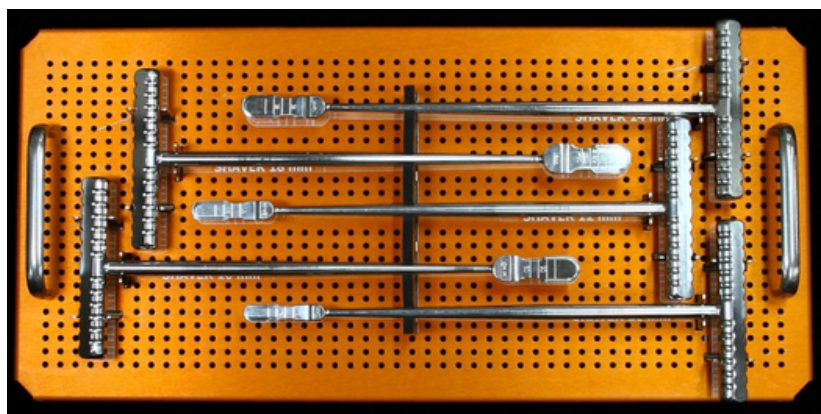


Figure 12

Do not remove excessive subchondral bone; segmental instability could result if too much is removed.



Figure 13

Use a Trial spacer to properly reconstitute the desired disc space height (Figure 14). Rasp the Vertebral Endplates to properly prepare the endplates. Insert the rasp into the disc space and gently tap on the distal end with a mallet (Figure 15). Repeat this several times to ensure the endplates are compacted and roughened. The rasp provides the endplates for proper preparation & aids in the creation of bleeding subchondral bone to help promote bone fusion.



Figure 14

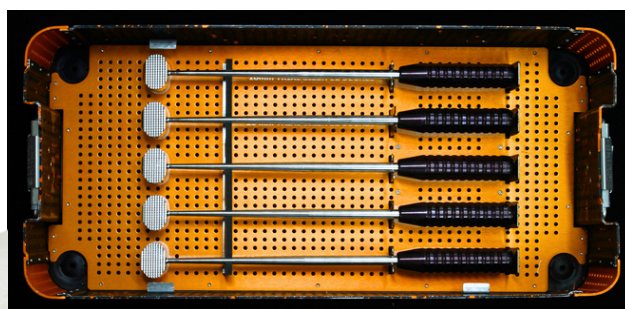


Figure 15

Anterior Lumbar Stand-Alone System

Surgical Technique

Step 3 : Removal Trial Sizing

A set of removable temporary trial heads are available, ranging from 10-18mm. The Trial heads are offered with Blocking Tabs (prevents the Trial from going too far posterior) and without Blocking Tabs on the Anterior edge (Figure 16 and 17). The trial heads are also available as rasps (Figure 18).



Figure 16



Figure 17



Figure 18

Attach the Trial head to the Driver of the Trial Inserter by turning the Shaft of the Inserter clockwise.



Gently impact the Trial into the disc space with Mallet to determine the correct size of the implant.



The DOME of the trial should be centered midline on the AP view.

Anterior Lumbar Stand-Alone System

Surgical Technique

Step 3 : Removal Trial Sizing

Once the final trial size is determined remove the Inserter and obtain AP and Lateral Fluoroscopy images to access the correct sizing of the Implant (Figure 19). The Trial heads pictured below are offered with Blocking Tabs (Safety Stops) which prevent the Trials from going too far posterior.

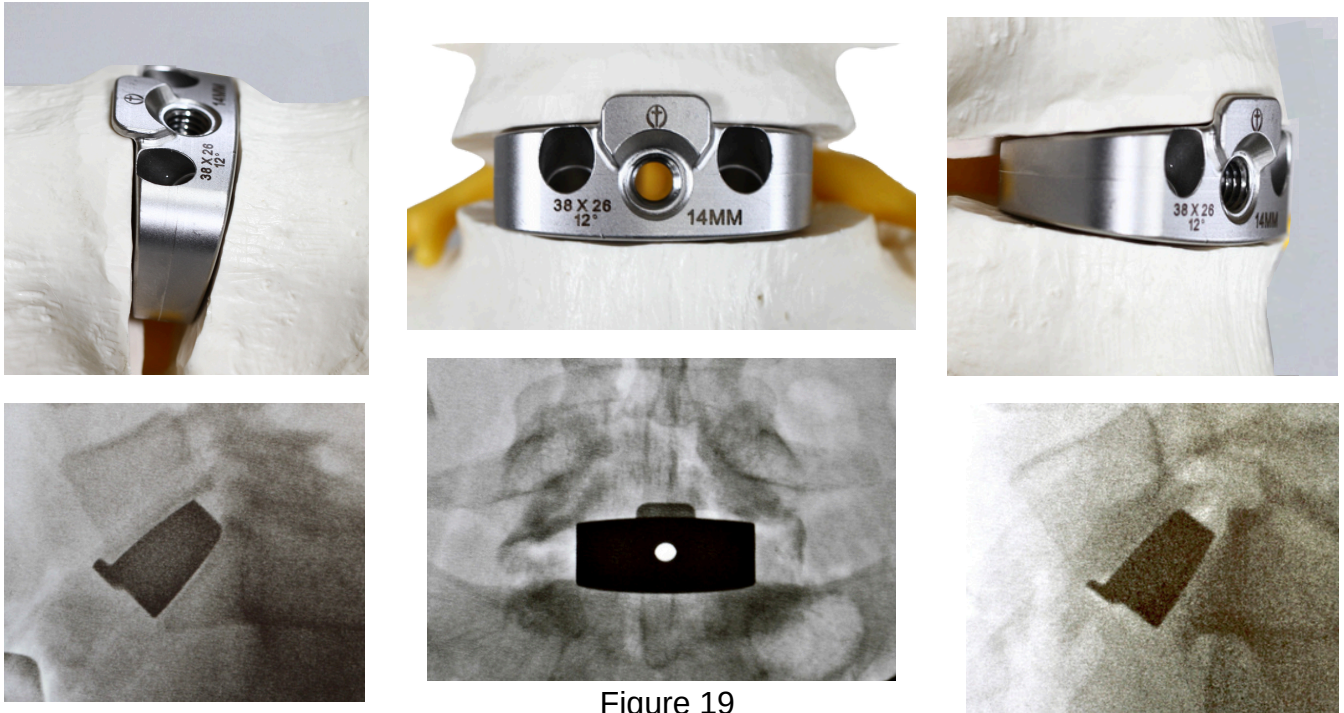
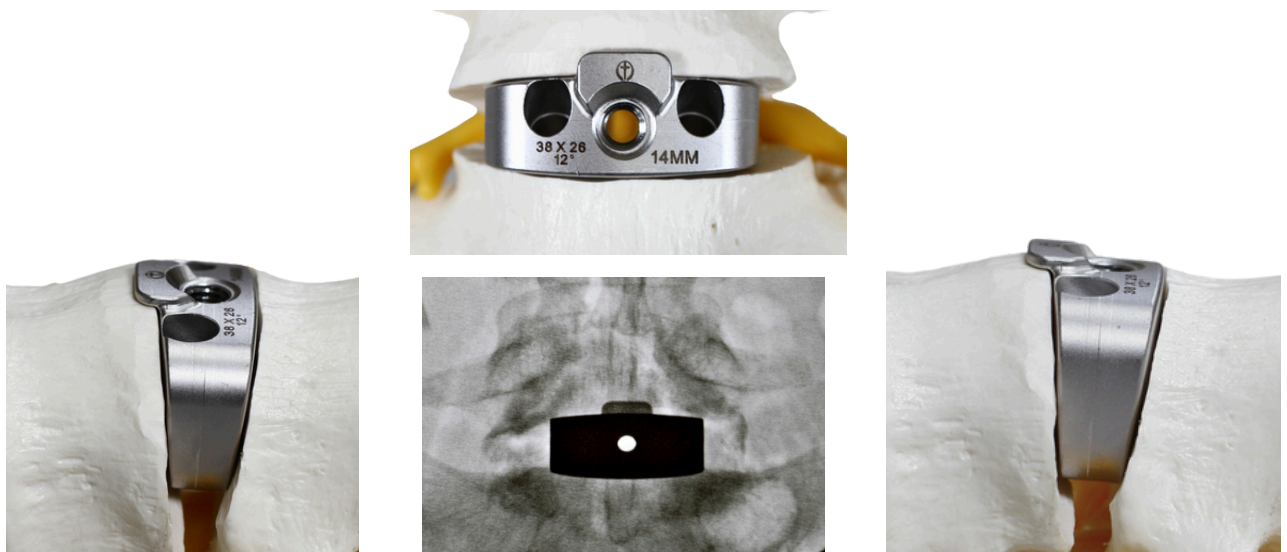


Figure 19

The DOME of the trial should be centered midline on the AP view.
The DOME of the trial is an excellent marker to verify Midline prior to committing to the Final implant

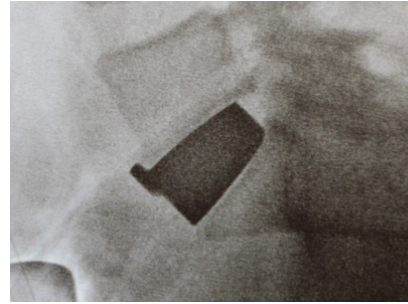
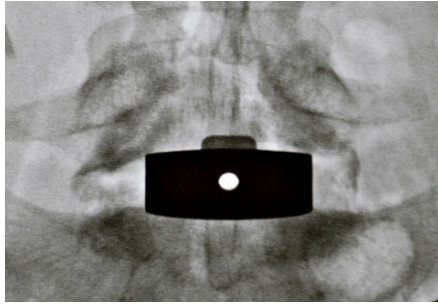


Anterior Lumbar Stand-Alone System

Surgical Technique

Step 3 : Removal Trial Sizing

The DOME of the trial is an excellent marker to verify midline PRIOR to committing to the Final Implant.



The trials are VITAL to determine the correct size of the Width on the AP view and Depth on the lateral view PRIOR to committing to the Final implant. Do not undersize the implant.



Drill through the Trial head.

OPTION: While the trial is flush with the anterior cortex, the Surgeon can elect to drill or awl through the trial heads (Figure 20), to prepare the screw hole. This will minimize the chance of the pushing the implant posteriorly. The screw hole has been prepared, remove the trial and select the implant, and insert it, then place the screws through the implant. Since the screw holes have already been prepared, it should, minimize the implant from being placed too far posteriorly.



Figure 20

Anterior Lumbar Stand-Alone System

Surgical Technique

Step 4 : Implant Insertion

Once the proper size of implant and type has been selected, attach the implant to the inserter (Figures 21, 22) and rotate the knob at the proximal end of the handle to tighten the implant (Figures 23, 24).



Figure 21



Figure 22



Figure 23

The arrows on the inserter indicate the direction of the screws.



Figure 24

Insert the implant into the disc space, and light impaction may be needed to fully insert the implant (Figure 25). The implant should be placed flush or recessed 1-2 mm relative to the adjacent Vertebral bodies (Figure 26). The implant should be aligned in the center of the disc space on the AP view. Use AP and Lateral Fluoroscopy images to verify the implant is centered and not placed too far posteriorly or anteriorly. The implant should not impinge on any neural structures.

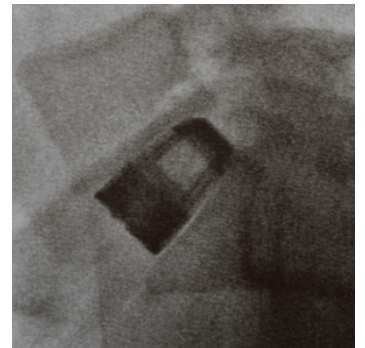
Remove the Inserter by rotating the proximal knob counterclockwise until the Inserter can be removed. It is helpful to lift the handle of the Inserter upward when releasing.



Figure 25



Figure 26



Anterior Lumbar Stand-Alone System

Surgical Technique

Step 5 : Screw Preparation

A variety of instruments are available based on the Surgeon's preference. Screw hole options are the straight and angled awls available in 0°, 30°, 45°, & 60° (Figure 27, 28, 29, & 30).



SCREW OPTIONS

Self-Drilling, Self-Tapping
Variable

DIAMETERS

4.5, 5.0, 5.5, 6.0mm

LENGTHS

20, 25, 30, 35mm



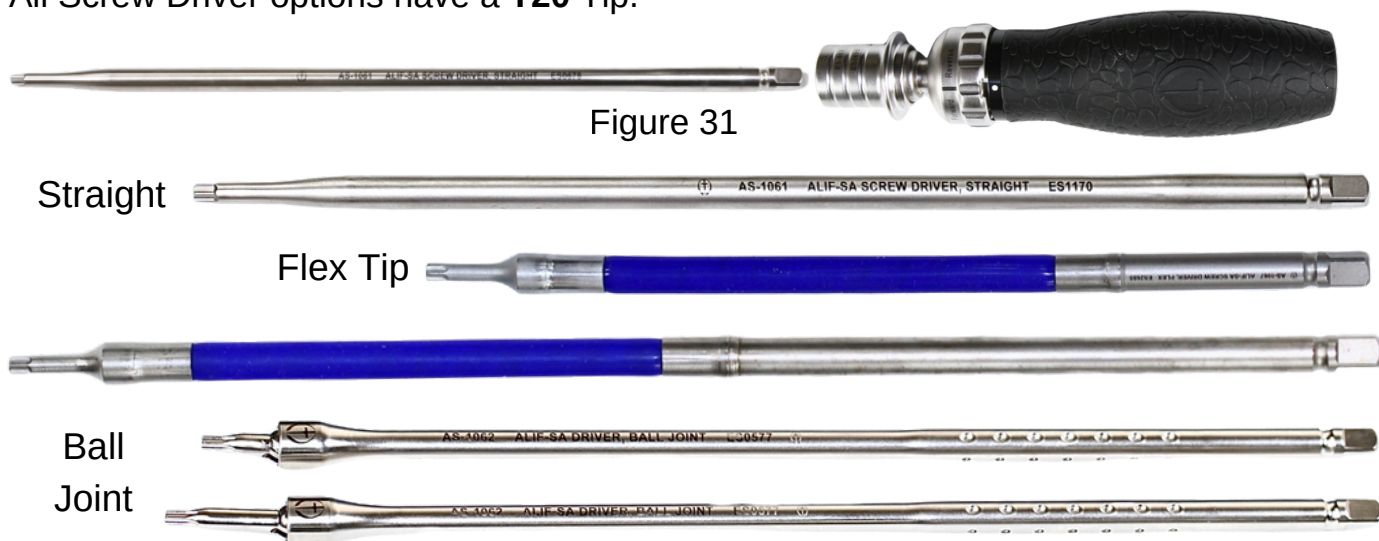
Anterior Lumbar Stand-Alone System

Surgical Technique

Step 6: Screw Insertion

Straight, Flex Tip (Short and Long), and Ball Joint (Short and Long) screw drivers are available (5 total options). Choose the appropriate screw length and diameter and attach the screw onto the distal tip of the screw driver (Figure 31).

All Screw Driver options have a **T20** Tip.



Insert the screw into the screw hole and turn the screwdriver clockwise to insert the screw (Figure 32). Use AP and Lateral Fluoroscopy while inserting the screw to ensure proper screw trajectory and placement. The screws should not breach the posterior vertebral body. All screws must be contained within the Vertebral body. Insert the screw prior to making the next screw hole to help prevent accidental implant migration.



Note:

Figure 32

Do not final tighten the screws until all screws have been inserted. After all screws have been inserted, then sequentially tighten them firmly down.

Anterior Lumbar Stand-Alone System

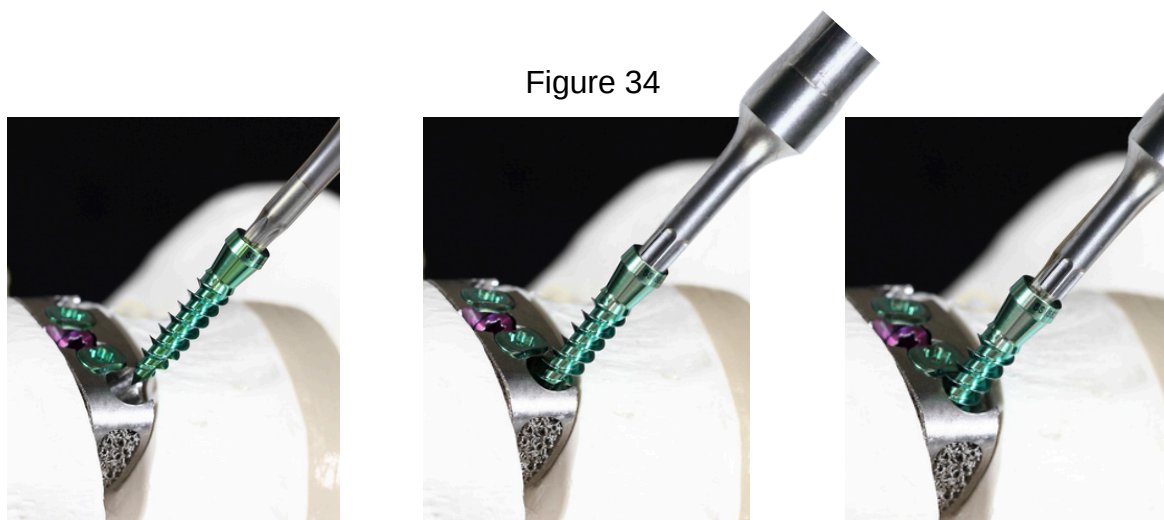
Surgical Technique

Step 6: Screw Insertion (Flex Tip Screw Driver)

Straight, Ball Joint, or Flex Tip screwdrivers are available. Choose the appropriate screw length and diameter and attach the screw onto the distal tip of the screw driver (Figure 33).



Insert the screw into the screw hole and turn the screwdriver clockwise to insert the screw (Figure 34). Use AP and Lateral Fluoroscopy while inserting the screw to ensure proper screw trajectory and placement. The screws should not breach the posterior vertebral body. All screws must be contained within the Vertebral body. Insert the screw prior to making the next screw hole to help prevent accidental implant migration.



Note:

Do not final tighten the screws until all screws have been inserted. After all screws have been inserted, then sequentially tighten them firmly down.

Anterior Lumbar Stand-Alone System

Surgical Technique

Step 6 Cont: Screw Insertion (Ball Joint Screw Driver)

Ball Joint screw drivers are available. The tip of the Ball Joint driver rotates to reach more intense angles, and the hooded shield is rounded to protect from vessel injury. Choose the appropriate screw length and diameter and attach the screw onto the distal tip of the screw driver (Figure 35).

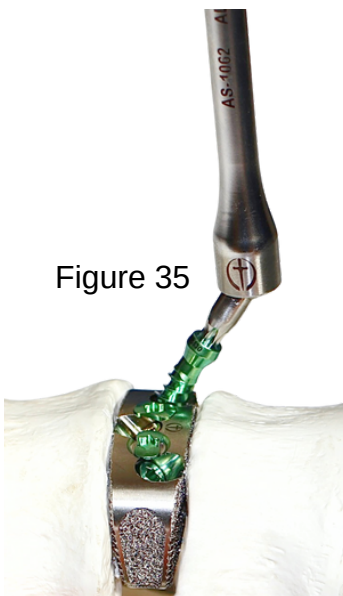
Long Tip



Short Tip



Figure 35



Insert the screw into the screw hole and turn the screwdriver clockwise to insert the screw (Figure 36). Use AP and Lateral Fluoroscopy while inserting the screw to ensure proper screw trajectory and placement. The screws should not breach the posterior vertebral body. All screws must be contained within the Vertebral body. Insert the screw prior to making the next screw hole to help prevent accidental implant migration.

Figure 36



Note:

Do not final tighten the screws until all screws have been inserted. After all screws have been inserted, then sequentially tighten them firmly down.

Anterior Lumbar Stand-Alone System

Surgical Technique

Step 7: Rotary Locking Mechanism

Once all of the screws have been placed into the Vertebral body (Figure 37), then turn the Rotary locking tabs clockwise approximately 90 degrees to cover the head of the screws (Figure 38). Both Visual and Tactile confirmation that the screw heads are covered should be verified by the Surgeon. Both Locking tabs should be horizontal to ensure all 3 screw heads are covered (Figure 39).



Figure 37



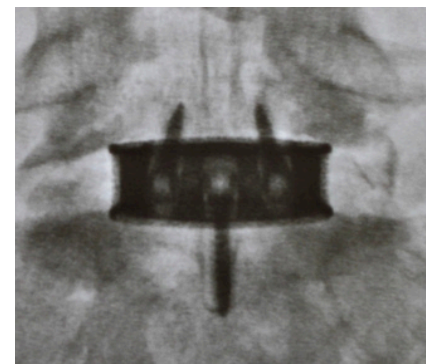
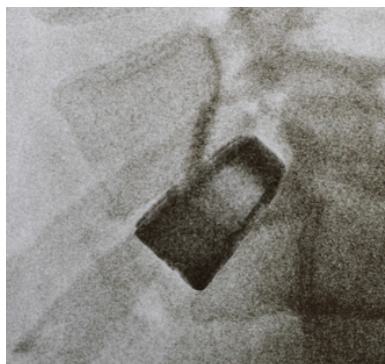
Figure 38

Obtain AP & Lateral Fluoroscopy images to verify correct placement of the implant and screws. Visually inspect the implant and the Locking tabs cover the screw heads.

Final Implant Positioning



Figure 39



Anterior Lumbar Stand-Alone System

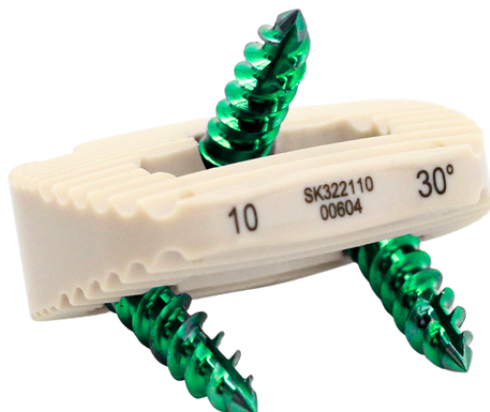
Surgical Technique

Step 8: Implant Removal & Revisions

All implants can be removed by performing the insertion steps in reverse. Rotate the locking mechanism to uncover the screw heads. Attach the screwdriver and rotate the handle counterclockwise until the screw is removed. Proceed to remove the remaining screws. Attach the implant Inserters and carefully remove the implant.



PEEK



3D Titanium



Anterior Lumbar Stand-Alone System Surgical Technique

Anterior Lumbar Stand Alone System Tray



Anterior Lumbar Stand-Alone System

Surgical Technique

Anterior Lumbar Stand Alone System Tray



3D Printed Titanium

Code	Profile	Heights	Material	Lordosis
S3L3525XX	35mm x 25mm	12mm-20mm	3D Titanium	6°
S3M3221XX	32mm x 21mm	10mm-18mm	3D Titanium	12°
S3M3525XX	35mm x 25mm	10mm-20mm	3D Titanium	12°
S3M3826XX	38mm x 26mm	10mm-20mm	3D Titanium	12°
S3H3525XX	35mm x 25mm	12mm-20mm	3D Titanium	18°
*S3MF3525XX	35mm x 25mm	12mm-18mm	3D Titanium	12°
*S3MF3826XX	38mm x 26mm	12mm-18mm	3D Titanium	12°

*** = No Teeth, Flat Series**

PEEK (Upon Request)

Code	Profile	Heights	Material	Lordosis
SA3221XX	32mm x 21mm	10mm-20mm	PEEK	6°, 12°, 18°
SA3525XX	35mm x 25mm	10mm-20mm	PEEK	6°, 12°, 18°
SA3826XX	38mm x 26mm	10mm-20mm	PEEK	6°, 12°, 18°

ALIF Stand-Alone Screws

Code	Diameter	Lengths	Material	Type
SSV45XX	4.50mm	20mm-35mm	Machined Ti	Variable
SSV50XX	5.00mm	20mm-35mm	Machined Ti	Variable
SSV55XX	5.50mm	20mm-35mm	Machined Ti	Variable
SSV60XX	6.00mm	20mm-35mm	Machined Ti	Variable

Code "XX" = Height

Ex: ALIF Stand-Alone - 3D Printed Titanium

Profile: 32mm x 21mm, **Height: 12mm**, Lordosis: 12°

Product Code = S3M322112

Anterior Lumbar Stand Alone System

Notes



EMINENT SPINE

Eminent Spine is dedicated to manufacturing biomechanically sound spinal implants and focusing on surface technology.



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