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Anterior Lumbar Stand Alone System

Surgical Technique



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Surgical Technique



Table of Contents

Implant Description and & Profiles	I
Positioning	1
Disectomy & Endplate Preparation	2
Trial Sizing	3
Implant Insertion & Placement	4
Screw Preparation	5
Screw Insertion	6
Rotary Locking Mechanism	7
Implant Removal & Implant Revision	8
Instruments & Implants	9



Lumbar Stand Alone Implant Profile

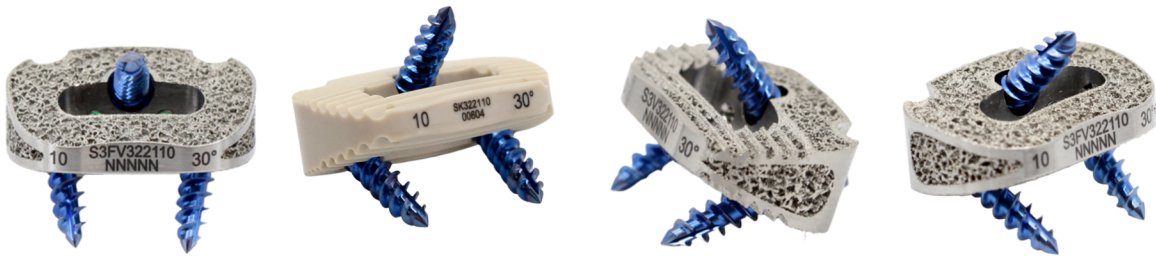
Surgical Technique

Description

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

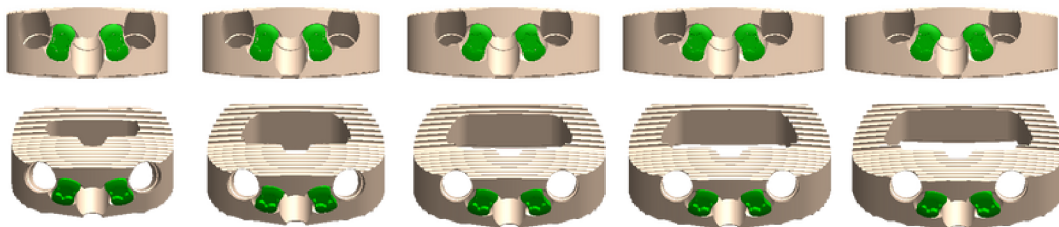
Screws Options

Diameters	Lengths	Types
4.5, 5.0, 5.5, 6.0 mm	20, 25, 30, 35, 40 mm	Self-Drilling, Self-Tapping Fixed & Variable



Lumbar Stand Alone Implant Profiles

Width x Depth	Height (2mm)	Lordosis
32 x 21mm	10-20mm	6, 12, 18, 24 & 30 °
35 x 25mm	10-20mm	6, 12, 18, 24 & 30 °
38 x 26mm	10-20mm	6, 12, 18, 24 & 30 °
40 x 27mm	10-20mm	6, 12, 18, 24 & 30 °
42 x 28mm	10-20mm	6, 12, 18, 24 & 30 °



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).

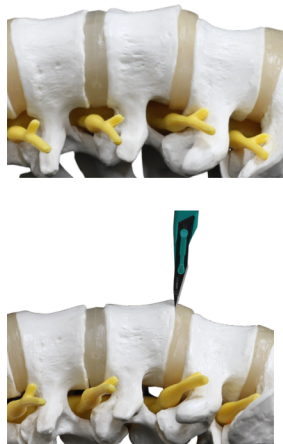


Figure 2

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 ring curettes (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 not provided in the Eminent Spine Surgical Instruments.



Figure 3



Figure 4



Figure 5



Figure 6

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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.



Figure 7

Note:

Remove the superior & inferior osteophytes with a 5mm 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.

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 8), and rotate 90 Degrees to distract the disc space (Figure 9). Verify the wedge distraction position using AP and Lateral Fluoroscopy. Depth markers are also visible to confirm the desired implant depth (Figure 8 & 9).



Figure 8



Figure 9

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Surgical Technique

Step 2 : Continued

A set of Disc Shavers, Trials, and Rasps are available in the Eminent Spine Anterior Lumbar Interbody system. They are not provide in the set, but available upon request. The instruments are in one piece and do not allow for "play" between the handle and the shaft (Figure 10).

Use the Disc Shavers in a controlled manner to distract the disc space (Figure 11) and to clean the lateral portion of the disc. Multiple sizes are available.



Figure 10

Note:

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



Figure 11



Use a Trial spacer to properly reconstitute the desired disc space height (Figure 12). 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 13). Repeat this several times to ensure the endplates are compacted and roughened. The rasp provide the endplates for proper preparation & aids in the creation of bleeding subchondral bone to help promote bone fusion.



Figure 12



Figure 13

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Surgical Technique

Step 3 : Trial Sizing

Attach the desired Trial to the Driver of the Trial Inserter (Figure 14) by turning the Shaft of the Inserter clockwise. Gently impact the Trial into the disc space to determine the correct size of the implant (Figure 15). 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. There should be no gap between the trial and the vertebral body.

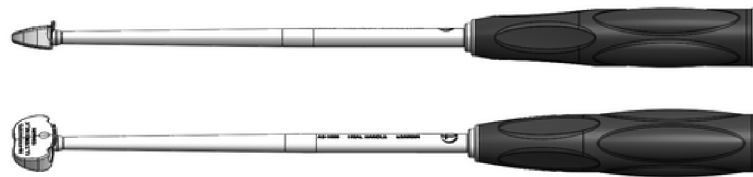


Figure 14



Figure 15

Note:

The Trial heads are offered with (Figure 16) and without Blocking Tabs (Figure 17) on the Anterior edge to prevent the Trial from going too far posterior. The Blocking Tab allows for the implant to be flush with the Anterior aspect of the Vertebral body.

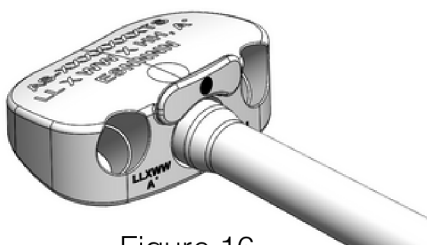


Figure 16

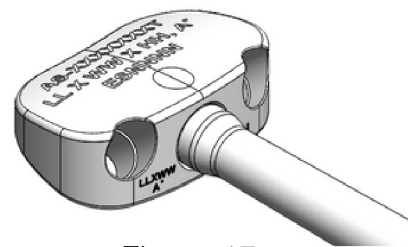


Figure 17

The Surgeon can elect to drill through the holes of the trial heads for the upcoming permanent implant, or remove the Trial head and proceed to the next step. The Trials correspond to the Final implant size. Reattach the Driver to the Trial head and remove the Trial.

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 and rotate the knob at the proximal end of the handle to tighten the implant (Figure 18, 19, & 20).

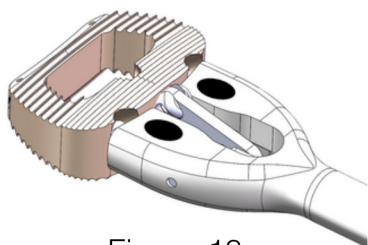


Figure 18



Figure 19



Figure 20

Place the implant into the corresponding footprint on the Graft Packing Block (Figure 21). Fill the chamber of the implant with bone and impact the bone with the Bone Tamp. Impacting the bone graft ensures proper dense bone packing in the implant.



Figure 21

Insert the implant into the disc space, and light impaction may be needed to fully insert the implant (Figure 22). The implant should be placed flush or recessed 1-2 mm relative to the adjacent Vertebral bodies (Figure 23). 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.



Figure 22



Figure 23

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Surgical Technique

Step 5 : Screw Preparation

A variety of instruments are available based on the Surgeon's preference. Screw hole options are the Drill Fixed Angle, Fixed Awl, Straight Spring Awl, Jointed Awl, or Ball Pivot Awl (Figure 24, 25, 26, 27, & 28).



Figure 24



Figure 25



Figure 26



Figure 27



Figure 28

Insert the fixed (Figure 29) or hinged (Figure 30) drill guide into the implant screw hole (Figure 31). Place the drill or the awl into the drill guide and rotate counterclockwise or impact the awl to create the screw hole (Figure 32). The drills and awls have a positive stop and depth of the screw hole will be 20 mm. When the screw hole is prepared, remove the Drill Guide.



Figure 29



Figure 30

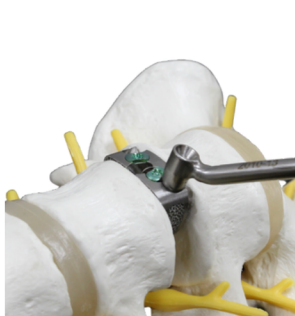


Figure 31



Figure 32



Note:

Be aware that the drill or awl does not move the implant during screw hole preparation.

Anterior Lumbar Stand Alone System

Surgical Technique

Step 6: Screw Insertion

Straight, Jointed, Ball Joint, or Fixed angled screwdrivers are available. Choose the appropriate screw length and diameter and attach the screw onto the distal tip of the screw driver (Figure 33, 34, 35 & 36).

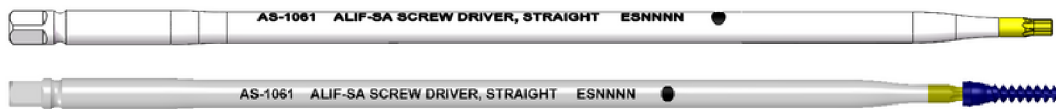


Figure 33



Figure 34



Figure 35

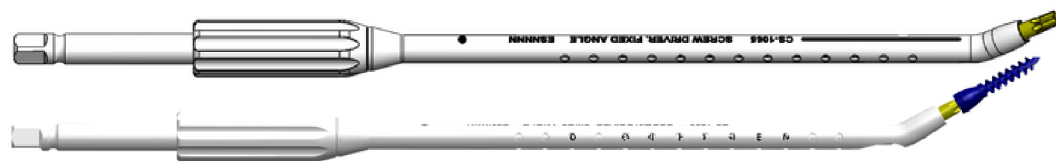


Figure 36

Insert the screw into the screw hole and turn the screwdriver clockwise to insert the screw (Figure 37). 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.

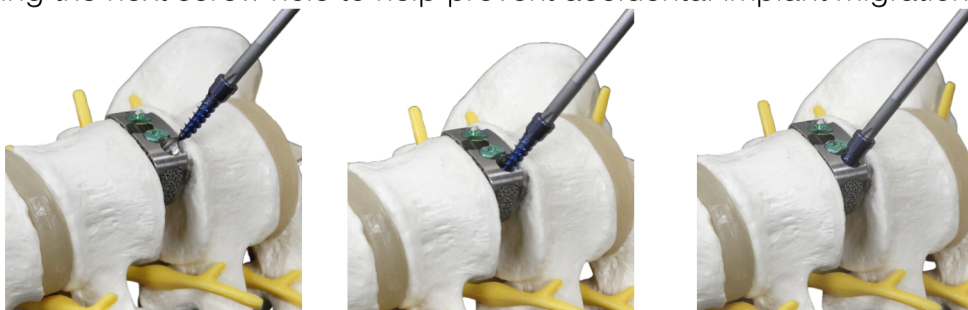


Figure 37

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 38), then turn the Rotary locking tabs clockwise approximately 90 degrees to cover the head of the screws (Figure 39). 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 40).



Figure 38



Figure 39

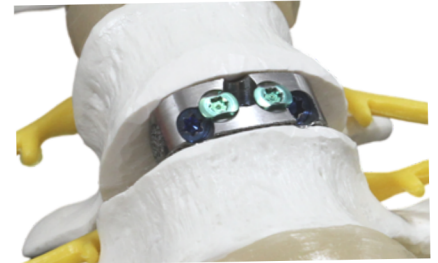


Figure 40

Final Implant Positioning:

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.

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 Insertor and carefully remove the implant.

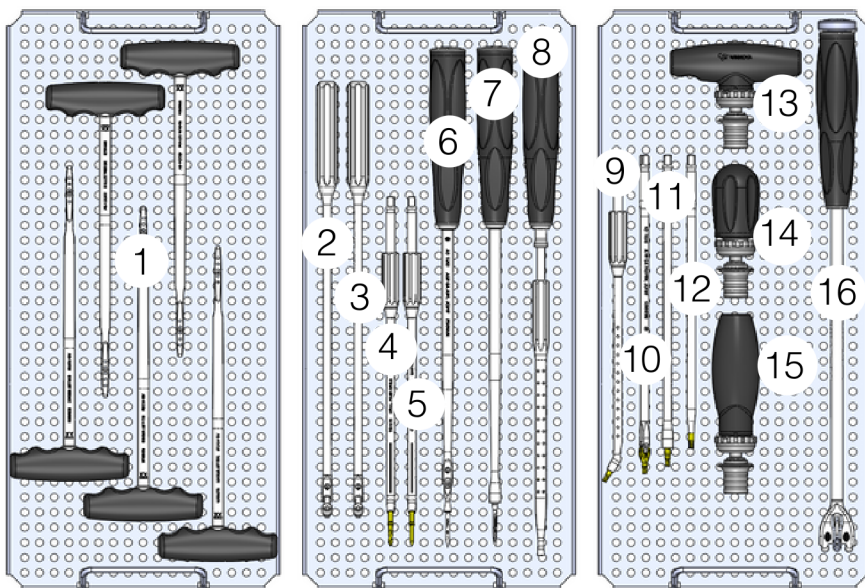
Anterior Lumbar Stand Alone System

Surgical Technique

Anterior Lumbar Stand Alone System Tray

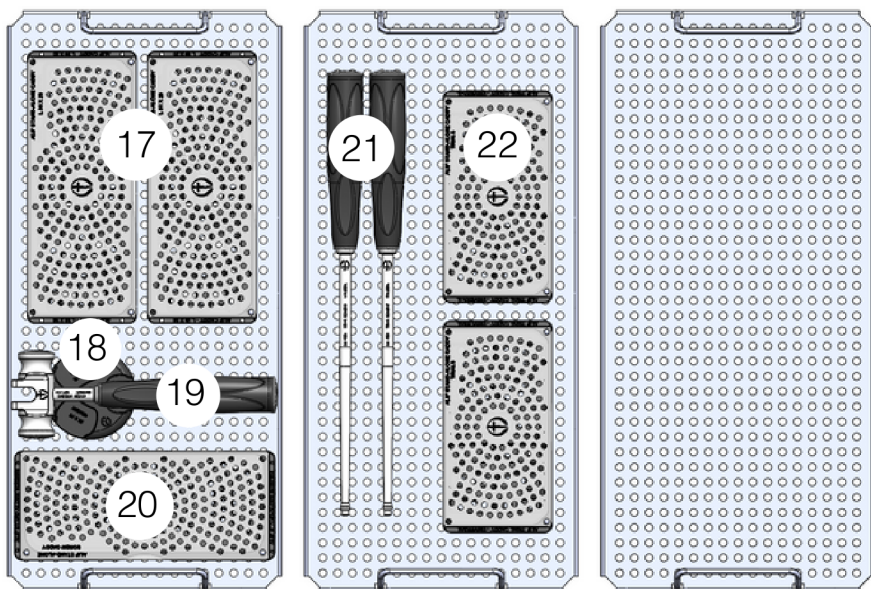
LAYOUT:

1. Lumbar Bullet Wedge Series, 8-20mm
2. Guide, Fixed Angle
3. Guide, Hinged Tip
4. Drill, Fixed Angle
5. Awl, Fixed Angle
6. Awl, Ball Joint
7. Awl, Ball Pivot
8. Spring Awl, Linear
9. Screw Driver - Fixed Angle
10. Screw Driver - Joint
11. Screw Driver - Joint
12. Screw Driver - Straight
13. 1/4 Drive Ratchet, T-Handle
14. 1/4 Drive Ratchet, Palm Handle
15. 1/4 Drive Ratchet, I-Handle
16. Implant Inserter, Straight-I



LAYOUT:

17. Implant Caddy's, Varies
18. Universal Packing Block
19. Mallet
20. Screw Caddy
21. Threaded Trial Handle
22. Trial Caddy



Anterior Lumbar Stand Alone System

Surgical Technique



Instructions for Use
Eminent Spine LLC Standalone ALIF Interbody Fusion System:



Eminent Spine, LLC
2004 Ventura Drive, Suite #100
Plano, TX 75093

System Contents:

- Non-Sterile Implants – Single Use Only
- Non-Sterile Instruments - Reusable

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Carefully read all instructions and be familiar with the surgical technique(s) prior to using this product.

DESCRIPTION and INTENDED USE:

The Standalone ALIF devices are inserted through an anterior lumbar approach and packed with autogenous bone graft to facilitate fusion. Serrations on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebral bodies to aid in expulsion resistance, while screws are inserted through the anterior face of the implant for bone fixation. The device is intended to provide mechanical support to the implanted level until biologic fusion is achieved.

The cages are made from medical grade polyetheretherketone (PEEK) per ASTM F2026 with tantalum per ASTM F560 pins, from titanium alloy Ti-6Al-4V ELI per ASTM F136, or from additively manufactured Ti-6Al-4V per ASTM F3001. The integrated fixation screws and screw anti-backout plate are manufactured from Ti-6Al-4V ELI per ASTM F136.

INDICATIONS:

The Standalone ALIF Interbody Fusion System is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The Eminent Spine Standalone ALIF Interbody Fusion System is a Standalone interbody fusion device intended to be used with screws which accompany the spacers for fixation. Hyperlordotic implants ($\geq 25^\circ$ lordosis) are intended for use with supplemental fixation (e.g. facet screws or posterior fixation). The device is intended for use at either one or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I Spondylolisthesis or retrolisthesis. DDD is defined as a back pain of discogenic with degeneration of the disc confirmed by history and radiographic studies. The device is designed for use with autograft and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft to facilitate fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.



Anterior Lumbar Stand Alone System

Surgical Technique



WARNINGS:

Following are specific warnings, precautions, and adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to spinal fixation devices. General surgical risks should be explained to the patient prior to surgery.

1. Patients with prior spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.
2. **PATIENT SELECTION.** In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:
 - a) A patient may have multiple pain generators due to advanced degeneration of the spine (e.g. intervertebral disc, facets or bony stenosis). These conditions may be present at the index level or adjacent levels. Careful review of the clinical record, including radiographic studies and applicable diagnostic tests, should be performed to make the appropriate diagnosis. Concomitant conditions may reduce the effectiveness of the surgery and this should be discussed with the patient.
 - b) The patient's weight. An overweight or obese patient can produce loads on the device that can lead to failure of the implant or subsidence.
 - c) The patient's occupation or activity. If the patient is involved in an occupation or activity that includes substantial walking, running, lifting or muscle strain, the resultant forces can cause failure of the implant or subsidence.
 - d) Patients that are non-compliant with postoperative guidance may place too much stress on the implant in the early postoperative period and compromise the maturing fusion mass.
 - e) Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used.
 - f) Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

PRECAUTIONS:

1. The implantation of spinal fixation devices should be performed only by experienced surgeons with specific training in the use of such devices. This is a technically demanding procedure presenting a risk of serious injury to the patient.
2. **PROPER SIZING OF THE IMPLANTS IS IMPORTANT.** The surgeon should use trials to determine the appropriate implant to use. The implant should be tall enough to provide segmental distraction and stability. The implant should be wide enough to maintain contact with the cortical rim of the vertebral body else the risk of subsidence may increase.
3. **SURGICAL IMPLANTS MUST NEVER BE REUSED.** An explanted spinal fixation device should never be re-implanted. Even though the device may appear undamaged, it may have small defects and internal stress patterns that may lead to early breakage.
4. **CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT.** The operating surgeon should avoid any notching or scratching of the device during surgery. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.
5. **ADEQUATELY INSTRUCT THE PATIENT.** Postoperative care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the body's response to the implant and how the fusion mass is expected to develop. A patient that is non-compliant with post-operative guidance is particularly at risk during the early postoperative period.



Anterior Lumbar Stand Alone System

Surgical Technique



CONTRAINDICATIONS:

1. Active systemic infection or infections localized to the site of the proposed implantation are contraindications to implantation.
2. Known sensitivity to PEEK or Titanium alloy 6Al-4V material.
3. Severe osteoporosis is a relative contraindication because it may result in implant subsidence and loss of fixation.
4. Any condition that significantly affects the likelihood of fusion may be a relative contraindication (e.g. cancer, diabetes, osteomalacia, heavy smoker, morbid obesity) and the surgeon must evaluate the relative risks and benefits individually with each patient.
5. Other relative contraindication may include mental illness, drug abuse or alcoholism as these may cause the patient to be non-compliant with post-operative guidance (e.g. bracing and physical therapy).
6. Prior fusion at the levels to be treated.
7. Any condition not described in the indications for use.

POSSIBLE ADVERSE EFFECTS:

1. Non-union, delayed union.
 2. Bending, loosening, disassembly, slippage, and/or fracture of implant.
 3. Allergic reaction to a foreign body.
 4. Infection.
 5. Bone loss and/or bone fracture due to stress shielding.
 6. Pain or discomfort
 7. Loss of proper spinal curvature, correction height and/or reduction.
 8. Loss of neurological function, dural tear, pain, and/or discomfort.
 9. Bone graft fracture, vertebral body fracture or discontinued growth of fusion at, above and/or below the surgery level.
 10. Change in mental status.
 11. Bursitis
 12. Revision Surgery
 13. Paralysis
 14. Erosion of blood vessels due to the proximity of the device, leading to hemorrhage and/or death.
- Note: Additional surgery may be required to correct some of these potential adverse events.

MAGNETIC RESONANCE ENVIRONMENT

The Eminent Spine ALIF Implant has not been evaluated for safety and compatibility in the MR environment. The implant has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Standalone ALIF Fusion System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

MATERIALS:

Standalone ALIF implants are manufactured from either PEEK (Optima LT1 or VESTAKEEP i4R) with Tantalum pins or entirely of Titanium alloy 6Al-4V with no pins. Surgical instruments provided with the implants are manufactured from stainless steel.



Anterior Lumbar Stand Alone System

Surgical Technique



PREOPERATIVE:

1. The surgeon should consider utilizing the Standalone ALIF Fusion System only with those patients that meet the criteria described in the indications.
2. The surgeon should avoid utilizing this device with those patients who meet the criteria described in the listed contraindications.
3. The surgeon should make sure that all implants and instruments are unpacked, sterilized (if not provided sterile), and available prior to surgery.
4. Some implants and all instruments are provided non-sterile and must be cleaned and sterilized prior to use.
5. Implants and instruments should be inspected for surface flaws and scratches and should not be used in the presence thereof. If such instruments will not function optimally, they should be returned to Eminent Spine for replacement.
6. The surgeon should have a complete understanding of the surgical technique, design rationale, indications and contraindications.
7. The surgeon should have a complete understanding of the surgical technique guide.

IINTRAOPERATIVE:

1. The instructions in any available applicable surgical technique manual should be carefully followed.
2. Damage to the nerves will cause loss of neurological functions. Extreme caution should be taken to avoid the spinal cord and nerve roots at all times, especially during endplate preparation, and insertion of the interbody and fixation screws.
3. Careful use of the implants and instruments should be taken. Misuse of the components may cause injury to the patient or operative personnel.
4. Bone graft should be packed inside the device prior to insertion and around the device after insertion. Bone graft must be placed in the area to be fused. The bone graft must extend from the upper to the lower vertebrae to be fused.
5. Notching and scratching of implants should be avoided.
6. The Standalone ALIF Fusion System should be supported by inferior and superior fixation bone screws.

POSTOPERATIVE MOBILIZATION:

1. The physician's postoperative directions, warnings to the patient and the corresponding patient's compliance are extremely important.
2. Careful management of the load will enable the fusion mass to heal and reduce the likelihood of non-union. Radiographic confirmation of a mature fusion mass may be used as a guide in the lifting of these restrictions.
3. For best possible results, patients should be counseled to avoid lifting, twisting, physical activities, smoking, consuming alcohol, and any other activity that would compromise or delay the healing process.
4. The patient should be warned about the limitation of bending at the point of spinal fusion.
5. The surgeon should instruct the patient regarding the amount and time frame after surgery of any weight bearing activity. The increased risk of bending, dislocation, and/or breakage of the implant devices, as well as an undesired surgical result are consequences of any type of early or excessive weight bearing, vibration motion, fall, jolts, or other movements preventing proper healing and/or fusion.
6. The removed implants should be properly disposed of and are not to be reused under any circumstances.



Anterior Lumbar Stand Alone System

Surgical Technique



CLEANING of INSTRUMENTS and IMPLANTS:

1. Clean all instruments and implants prior to use, and as soon as possible after use. Do not allow blood or debris to dry on the instruments that were used in surgery. If cleaning must be delayed, place instruments that were used in surgery in a covered container with neutral pH detergent or enzymatic solution to delay drying.

2. Loosen and/or disassemble instruments with removable parts. Remove implants (in caddies) from set cases. Failure to disassemble a soiled device may lead to inadequate reprocessing, which poses a risk of infection to patients.

Manual Cleaning Steps for Instruments (Required)

Certain instruments of the Standalone ALIF Fusion System may be disassembled for cleaning per instructions provided below.

Implant Inserters: Turn the outer shaft knob to unthread and completely separate from the inner shaft.

Fixed Angle Drivers: Turn the outer shaft knob to unthread and completely separate from the inner shaft.

Spring Loaded Awl: Turn the outer shaft knob to unthread and completely separate from the inner shaft.

Ratchet Drivers: Make sure instruments have been disconnected from these drivers.

Threaded Trial Drivers: Make sure trial heads have been disconnected from these shafts.

3. Immerse the instruments and implants in a neutral pH detergent or enzymatic solution prepared in accordance with the manufacturer's instructions and soak for 15 minutes.

4. Use a soft-bristle brush and a pipe cleaner to gently clean each instrument and implant (particular attention shall be given to cannulations, holes, and other hard-to-clean areas) until all visible soil has been removed.

5. Rinse the instruments and implants in running water for at least 3 minutes. Thoroughly flush cannulations, holes, and other hard-to-clean areas.

6. After manual cleaning has been completed, load the parts into a suitable automated cleaner and follow the manufacturer's recommended practices. Use only neutral pH enzymatic cleaners and detergents. Avoid excessively acidic or alkaline solutions.



Anterior Lumbar Stand Alone System Surgical Technique

Step	Agent	Minimum Time (mm:ss)
	Instructions	
1. Initial Clean	Enzol Enzymatic Detergent Solution (or equivalent)	10:00
	Add one (1) ounce of Enzol to one (1) gallon of tap water. Soak instruments immediately after use and flush detergent through all channels until evidence of organic material is removed. Soak for a minimum of ten (10) minutes. Use a soft bristle brush (Spectrum™ M-16 or equivalent) to gently remove visible debris. Pay close attention to threads, crevices, lumens and hard to reach areas. If organic material is dried-on, extend soak time and use two (2) ounces of Enzol per one (1) gallon of warm tap water.	
2. Rinse	Deionized water	3:00
	Thoroughly rinse each instrument with deionized water including all channels to remove detergent for a minimum of three (3) minutes.	
3. Inspection	Unaided eye	1:00
	Inspect each instrument for evidence of organic material. Particular attention should be taken to remove all debris from instruments with cannulations, holes, and features that may be shielded from brushing action. Subject instruments to ultrasonic cleaning if organic matter is present after the initial cleaning step.	
4. Ultrasonic Clean (if required)	Enzol Enzymatic Detergent Solution (or equivalent)	10:00
	Prepare a fresh solution by adding one (1) ounce of Enzol and one (1) gallon of warm tap water to a sonication unit (Branson Bransonic® Ultrasonic Cleaner or equivalent). Fully immerse the instruments in the solution and sonicate for a minimum of ten (10) minutes.	
5. Ultrasonic Rinse	Deionized water	3:00
	Thoroughly rinse each instrument with deionized water including all holes and cannulations to remove detergent for a minimum of three (3) minutes.	
6. Inspection	Unaided eye	1:00
	Inspect each instrument for evidence of organic material. Repeat the ultrasonic clean and rinse steps if needed.	



Anterior Lumbar Stand Alone System

Surgical Technique



INSPECTION:

1. Carefully inspect each instrument to ensure all visible blood and soil has been removed.
2. Inspect instruments and instrument cases for damage. Check action of moving parts to ensure proper operation, and ensure disassembled instruments readily assemble with mating components.
3. If damage or wear is noted that may compromise the proper function of the instrument or instrument case, do not use and contact customer service or your Eminent Spine representative for a replacement.
4. If corrosion is noted, do not use and contact customer service or your Eminent Spine representative for a replacement.

STERILIZATION:

All implants and instruments are supplied visually clean and non-sterile and must be sterilized prior to use. It is also recommended that system trays be double wrapped using two FDA-cleared wraps prior to sterilization. The following sterilization cycle has been validated:

Method:	Steam
Cycle:	Pre-Vacuum
Temperature:	270°F (132°C)
Exposure Time:	4 minutes
Number of pulses:	4
Dry time:	30 minutes

Implants and instruments should be positioned to allow the steam to come into contact with all surfaces. All jointed instruments should be in the open or unlocked position with ratchets not engaged.

Instruments composed of more than one part or with sliding pieces or removable parts should be disassembled.

Remove all packaging material prior to sterilization. Only sterile implants and instruments should be used in surgery. Cases (including instruments and implants) used in surgery should be cleaned and re-sterilized after surgery. Implants should not be used as templates in surgery. If an unused implant entered the surgical wound it should be cleaned and re-sterilized after surgery.

• Please consider your sterilization equipment manufacturer's written instructions for the specific sterilizer and load configuration used.

• Follow current AORN "Recommended Practices for Sterilization in Perioperative Practice Settings" and ANSI/AAMI ST79: A4 2013 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

- Flash sterilization is not recommended, but if used, should only be performed according to requirements of ANSI/AAMI ST79: A4 2013 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities.



Anterior Lumbar Stand Alone System Surgical Technique



LIMITED WARRANTY:

Eminent Spine LLC products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact Eminent Spine LLC for current information.



Eminent Spine, LLC
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Plano, TX 75093
972-499-3593

For product information or questions pertaining to sales and service, please contact your local sales representative or Eminent Spine LLC customer service.

Eminent Spine LLC 2022



Anterior Lumbar Stand Alone System

Surgical Technique

Symbol	Description	ISO 15223 Reference
	Prescription Required – Federal Law restricts this device to sale by or on the order of a licensed practitioner.	N/A
	Manufacturer - Indicates the medical device manufacturer as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	5.1.1
	Use-by-Date – Indicates the date after which the medical device is not to be used.	5.1.4
	Lot Number – Indicates the manufacture's batch code so that the batch or lot can be identified.	5.1.5
	Reference Number – Indicates manufacture's catalogue number so that the medical device can be identified	5.1.6
	Non-Sterile – Indicates a medical device that has not been subject to a sterilization process.	5.2.7
	Do not re-use - Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	5.4.2
	Consult instructions for use - Indicates the need for the user to consult the instructions for use.	5.4.3
	Caution – Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	5.5.4

Anterior Lumbar Stand Alone System Surgical Technique



NOTES:



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