



EMINENT
— SPINE —

LLIF System

Surgical Technique Manual



— Eminent Spine —



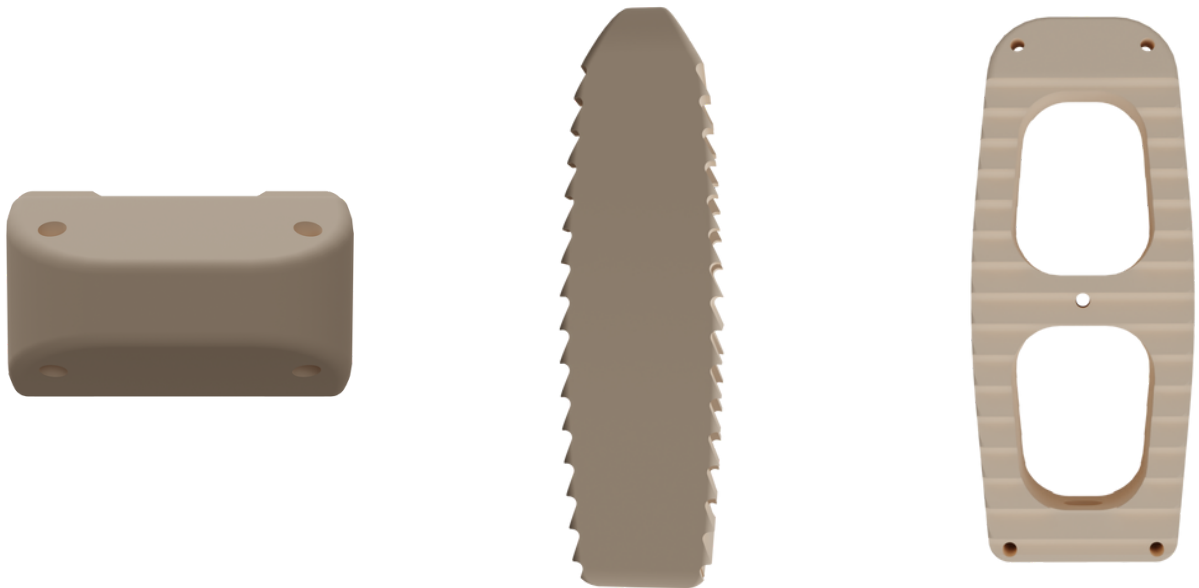
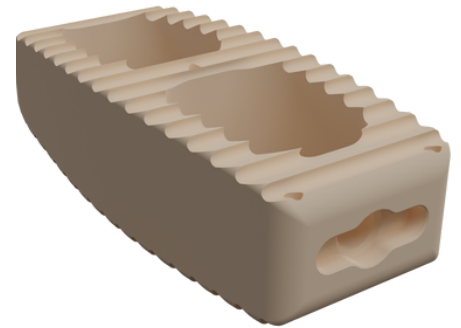
LLIF System

Surgical Technique



Description:

- Aggressive teeth to resist migration
- Tapered nose allows for ease of insertion
- Lordosis allows for ease of insertion and self distraction
- Large central opening for maximum bone graft material
- 3 Material Options:
 - PEEK Optima
 - Machined Titanium
 - 3D Printed Titanium* coming April 2021



LLIF Implant Profiles

| Width x Depth | Height (2mm) | Lordosis |
|--------------------|--------------|-----------|
| 18 x 45, 50 & 55mm | 8 - 16mm | 0 Degrees |
| 22 x 45, 50 & 55mm | 8 - 16mm | 0 Degrees |
| 18 x 45, 50 & 55mm | 10 - 16mm | 8 Degrees |
| 22 x 45, 50 & 55mm | 10 - 16mm | 8 Degrees |

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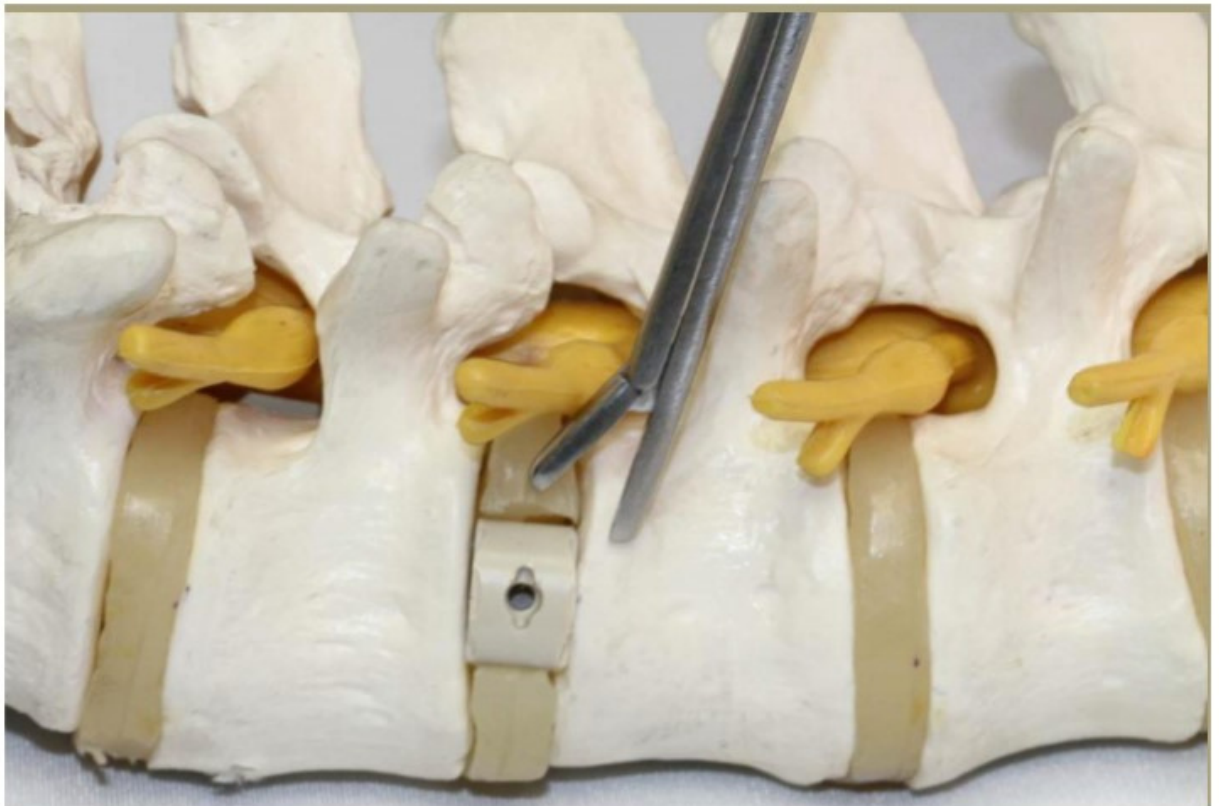
Surgical Technique

Step 1 : Patient Positioning

Place the patient in the prone position. Perform posterior approach to the lumbar spine at the affected disc level.

Step 2 : Perform Discectomy

Start with the discectomy by incising the disc and making a rectangular window. Use curettes & pituitary rongeurs to further remove the disc and the cartilaginous layer of the endplates.



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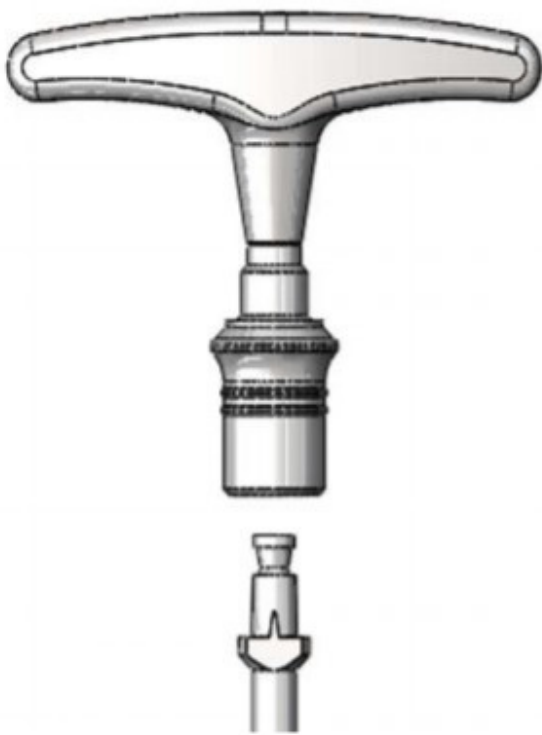
Surgical Technique

Step 3 : Shavers

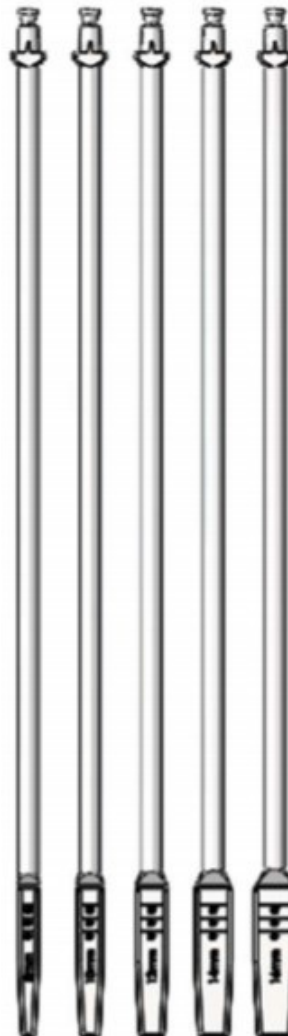
Use the shavers for thorough removal of disc material and cartilaginous tissue from the disc space.

The shavers are individually sized on shafts using a quick connect which allows connection to the T-handle.

Depth markers provide extra safety



Quick attach Hudson adapter T-handle fits all shavers



Shaver sizes
8-16mm

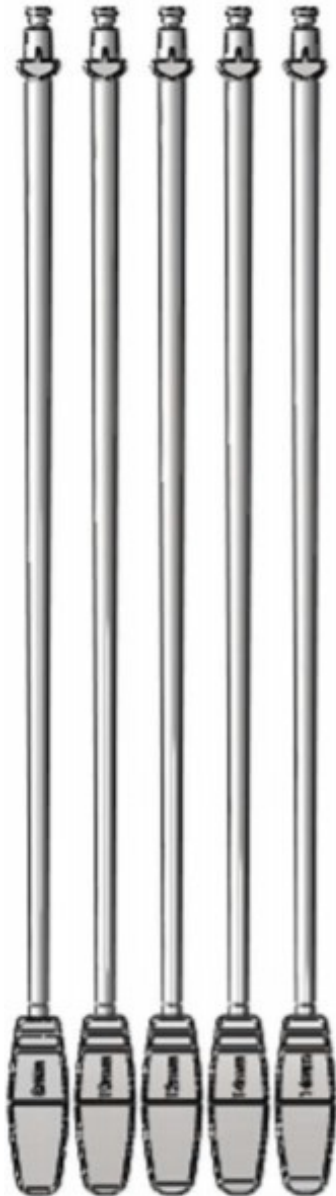


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Step 4 : Trial Sizers

Insert the selected sizer into the disc space to get desired implant height. Correct sizing is critical for the most secure fit.

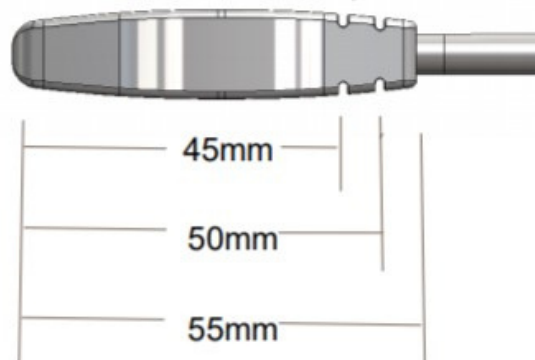


Trial Sizers
8-16mm

Quick attach Hudson
adapter T-handle fits
all shavers



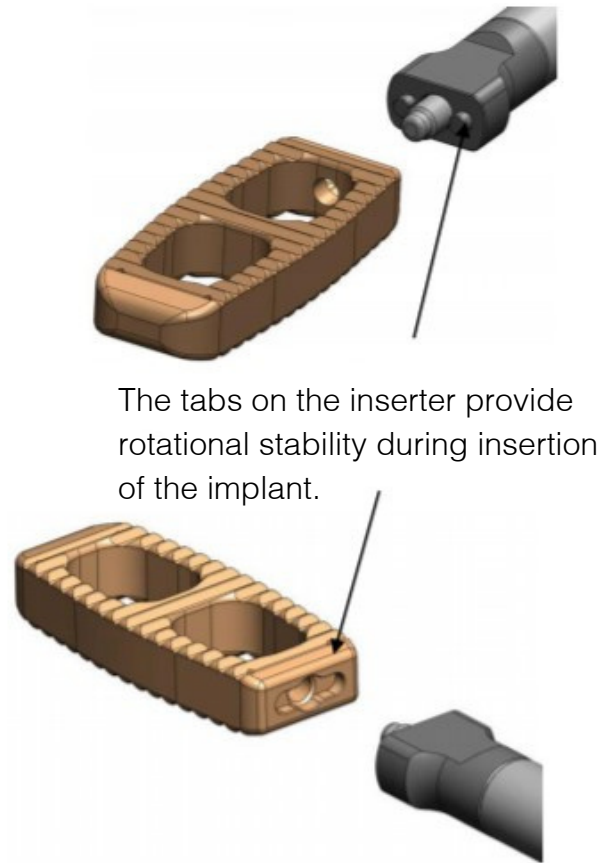
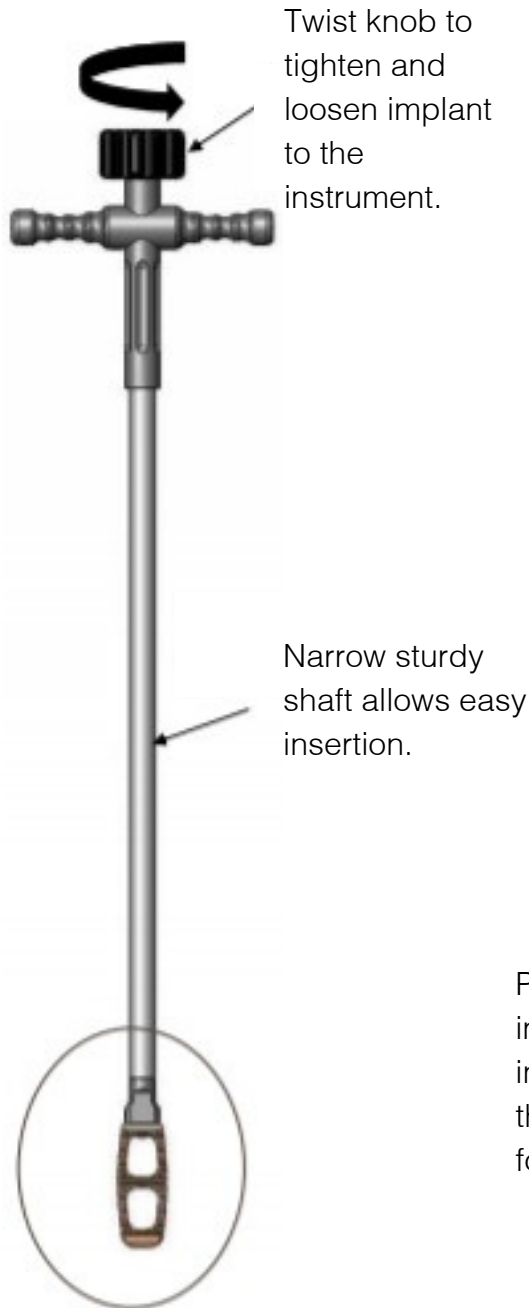
Sizer has depth grooves
seen in X-ray



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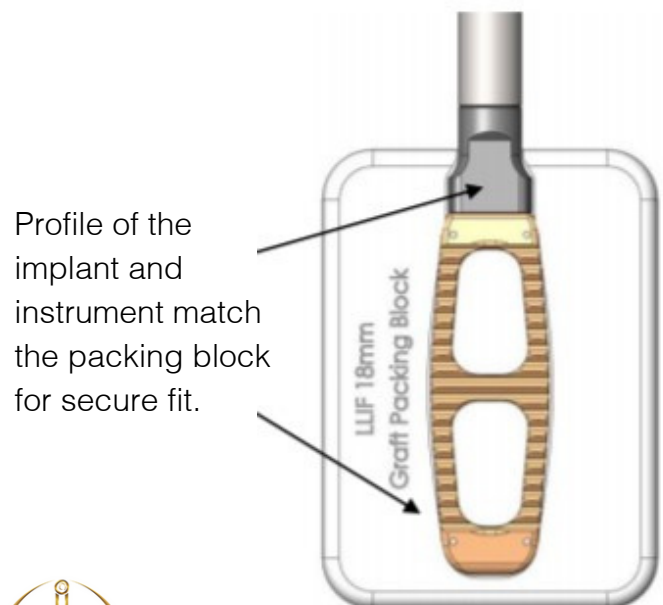
Step 5 : Inserter

Assemble the inserter into the implant. The tabs on the inserter provide rotational stability during insertion of the implant.



Step 6 : Implant Packing

After the correct implant size has been determined, use the graft packing block to fill the pockets with bone.



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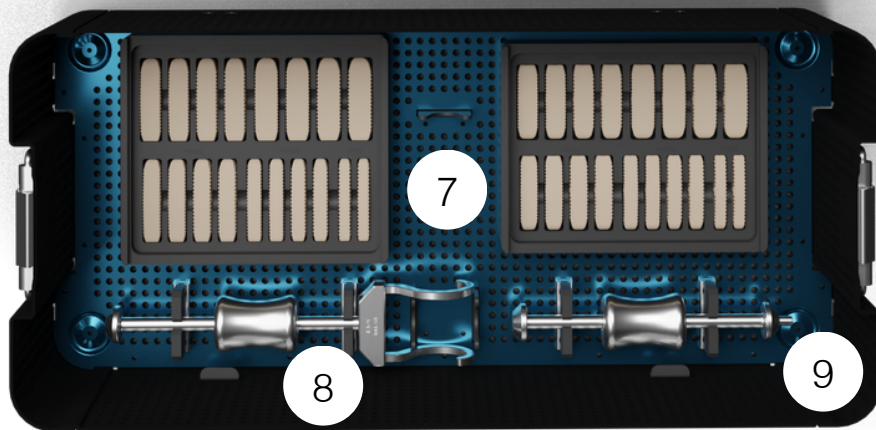
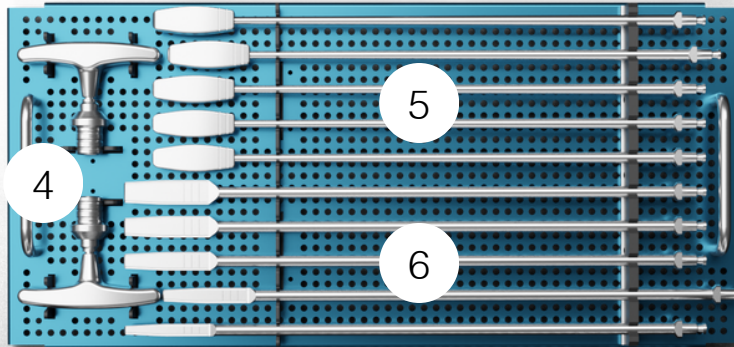
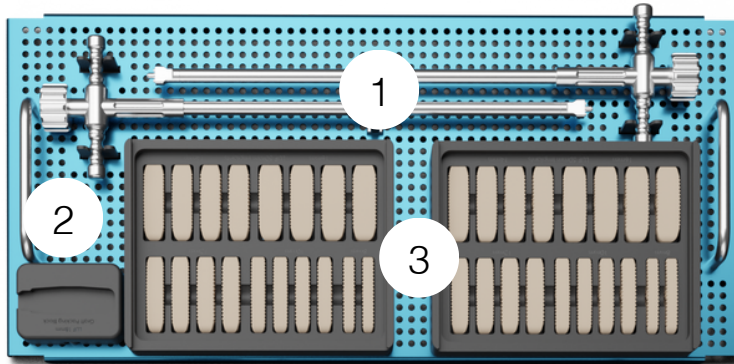
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Step 7 : Implant Position

Insert the implant and position it using the inserter in conjunction with the mallet. Obtain AP & Lateral X-rays to ensure the implant position is not too extreme posterior and does not impinge on any neural structure.



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LAYOUT:

1. T-Handle Inserter
2. Graft Packing Block
3. Implant Caddy #1
4. T-Handle, Quick Connect
5. Trials
6. Shavers
7. Implant Caddy #2
8. Slap Hammer, Grab
9. Slap Hammer, Threaded

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Available in Peek, Titanium & 3D Printed Titanium

14 x 12 Profile, Neutral

C141205
C141206
C141207
C141208
C141209
C141210
C141211
C141212

14 x 12 Profile, 6° Lordotic

CL141205
CL141206
CL141207
CL141208
CL141209
CL141210
CL141211
CL141212

15 x 13 Profile, Neutral

C151305
C151306
C151307
C151308
C151309
C151310
C151311
C151312

15 x 13 Profile, 6° Lordotic

CL151305
CL151306
CL151307
CL151308
CL151309
CL151310
CL151311
CL151312

16 x 14 Profile, Neutral

C161405
C161406
C161407
C161408
C161409
C161410
C161411

16 x 14 Profile, 6° Lordotic

CL161405
CL161406
CL161407
CL161408
CL161409
CL161410
CL161411



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IFU



Eminent Spine LLC Cervical Interbody Fusion System:



Eminent Spine LLC
2004 Ventura Drive #100
Plano, TX 75093
Phone: 972-499-3593
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 Cervical device is a rectangular shaped implant, which is available in a parallel or lordotic configuration of various heights. It is hollow to allow for the placement of allograft or autograft bone. There are teeth on the superior and inferior surface of the device to provide increased stability and inhibit movement of the implant.

INDICATIONS:

When used as an intervertebral body fusion device, the implant is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level from the C2-C3 disc to the C7-T1 disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device is designed for use with supplemental fixation and with autograft to facilitate fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage. When used as a vertebral body replacement device, the device is indicated to replace a vertebral body that has been resected or excised (i.e. partial or total vertebrectomy) due to tumor or trauma / fracture. It is intended to be used with autograft or allograft bone.

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 noncompliant 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.

MATERIALS:

Cervical 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.

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.
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.

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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 nonsterile and must be sterilized prior to use. 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: A42013 – 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: A42013 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

- For terminally sterilized devices, only FDA-cleared sterilization barriers (e.g., wraps, pouches, containers) should be used for packaging

POSTOPERATIVE MOBILIZATION:

The surgeon should advise the patient to be careful not to place significant loads on the spine for the first three months after surgery. The surgeon may advise the patient limit their activity or wear a brace. 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.

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.

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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 reimplanted. 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.
6. MAGNETIC RESONANCE ENVIRONMENT. The Eminent Spine® Cervical Implant has not been evaluated for safety and compatibility in the MR environment. The implant has not been tested for heating or migration in the MR environment.


POSSIBLE ADVERSE EFFECTS:

1. Non-union, delayed union.
2. Bending or fracture of implant.
3. Anterior or posterior migration of the implant.
4. Allergic reaction to a foreign body.
5. Infection.
6. Decrease in bone density due to stress shielding.
7. Pain, discomfort, or abnormal sensations due to the presence of the device.

8. Loss of proper spinal curvature, correction height and/or reduction.
9. Vascular and/or nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, and paresthesia.
10. Paralysis.
11. Death.
12. Erosion of blood vessels due to the proximity of the device, leading to hemorrhage and/or death.

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
2004 Ventura Drive
Plano, TX 75093
Phone: 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.

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Notes

