Instructions for Use
Eminent Spine LLC Cervical Stand-Alone Fusion System:

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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 Stand-Alone Fusion System implants are available in various heights and geometric footprints to accommodate individual patient anatomy and graft material size. The Cervical Stand-Alone devices are inserted through an anterior cervical approach and packed with autogenous bone graft to facilitate fusion. Serrations on the superior and inferior surfaces of each device grip the endplaces 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 Cervical Stand-Alone System is a stand-alone anterior cervical interbody fusion system indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one or two contiguous disc levels. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. The Cervical Stand-Alone System is used to facilitate intervertebral body fusion in the cervical spine and is placed via an anterior approach at one- or two-disc levels (C2-T1) using autograft bone. Patients should have at least six (6) weeks of non-operative treatment prior to treatment. The Cervical Stand-Alone Interbody Fusion System is intended to be used with the bone screw fixation provided and requires no additional fixation.

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.

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 RESONSANCE 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, migration, or image artifact in the MR environment. The safety of the Cervical Stand-Alone Fusion System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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.

PREOPERATIVE:

1. The surgeon should consider utilizing the Cervical Stand-Alone 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.

INTRAOPERATIVE:

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 Cervical Stand-Alone 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.

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 Cervical Stand-Alone Fusion System may be disassembled for cleaning per instructions provided below.

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

Offset Implant Inserter: 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.

A/O Ratchet Driver: Make sure A/O drills have been disconnected from this driver.

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.

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.	

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:	270ºF (132ºC)
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 dissembled.

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.

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.

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

Symbol Glossary

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 – Indications 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