

Eminent Spine LLC Scoliosis Deformity Pedicle Screw 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:

The Eminent Spine Scoliosis Deformity Pedicle System consists of rods, polyaxial screws with set caps, and cross connectors with lock screws. Additionally, the system consists of rod connectors and iliac bolts with their respective locking screws. All of the components are available in a variety of sizes to match more closely to the patient's anatomy. All components are made from titanium alloy per ASTM F136.

INDICATIONS:

The Eminent Spine Scoliosis Deformity Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion as a pedicle screw fixation system (T1-S2/iliac). The system is intended for posterior, pedicle fixation in skeletally mature patients for the treatment of the following acute and chronic instabilities or deformities: degenerative disc disease (DDD) (defined as back pain with discogenic origin with degeneration of the disc confirmed by history and radiographic studies), severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebrae, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, spinal stenosis, scoliosis, kyphosis, lordosis, spinal tumor, pseudoarthrosis and failed previous fusion.

When used for fixation to the ilium, the offset connectors of the Eminent System must be used in conjunction with pedicle screws placed at the S1 or S2 spinal level.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Eminent Spinal Scoliosis Deformity Pedicle Screw System is indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including

idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the Eminent Spine Deformity Pedicle System is intended to treat pediatric patients diagnosed with: spondylolisthesis / spondylolysis, fracture caused by tumor and/or trauma, pseudoarthrosis, and/or failed previous fusion. This system is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

CONTRAINDICATIONS:

1. Active systemic infection or infections localized to the site of the proposed implantation are contraindications to implantation.
2. Known sensitivity to Titanium alloy 6Al-4V per ASTM F136.
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.

MATERIALS:

The implants for pedicle screw systems are manufactured from Titanium alloy 6Al-4V per F136. Surgical instruments provided with the pedicle screw systems 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.

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 LLC representative for a replacement.
4. If corrosion is noted, do not use and contact customer service or your Eminent Spine LLC representative for a replacement.

STERILIZATION:

All implants and instruments are supplied visually clean and non-sterile and must be sterilized prior to use. The following are the recommended sterilization cycles for both systems:

Method:	Steam
Cycle:	Pre-Vacuum
Temperature:	270°F (132°C)
Exposure Time:	4 minutes
Number of Pulses:	4
Drying Time:	
Pedicle Screw	30 minutes
MIS Pedicle Screw	40 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.
- 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. The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar and sacral spine secondary to severe spondylolisthesis (grades 3 or 4) of the L5-S1 vertebrae, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, spinal stenosis, scoliosis, kyphosis, lordosis, spinal tumor and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other condition are unknown.
2. Patients with prior spinal surgery at the levels to be treated may have different clinical outcomes compared to those without previous surgery.
3. **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 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 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.
 - 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 pseudoarthrosis 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. Based upon the fatigue test results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.
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 noncompliant with postoperative guidance is particularly at risk during the early postoperative period.
6. MAGNETIC RESONANCE ENVIRONMENT. The Eminent Spine LLC Pedicle Screw Systems have not been evaluated for safety and compatibility in the MR environment. The Pedicle Screw Systems have not been tested for heating or migration in the MR environment.

POSSIBLE ADVERSE EFFECTS:

1. Nonunion, 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.

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.

Eminent Spine LLC 2024