

Eminent Spine LLC Buttress Plate System



Eminent Spine LLC
2004 VENTURA DR STE 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 Eminent Spine LLC Buttress Plate System consists of a plate and screw. The plate, which is available in three sizes (21mm, 24mm and 27mm), is designed with an 8° bend to conform to the anatomy of the anterior spine to prevent migration or expulsion of allograft or autograft in the thoracolumbar to S1 region. Additionally, the plate features two “fangs” that prevent rotation, and a screw slot for final fixation. The 5.5mm screws are available in 20mm and 25mm lengths.

INDICATIONS:

The Eminent Spine LLC Buttress Plate System, in conjunction with traditional rigid fixation, is intended for use in spinal fusion procedures of the thoracolumbar to S1 spinal region as a means to maintain the

relative position of weak bony tissue such as allografts or autografts. This device is not intended for load bearing applications.

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 material.
3. Patients with greater than Grade I spondylolisthesis, spondylolysis or significant bony defect in the lumbar spine.
4. Patients with a history of abdominal radiation treatment or abdominal vascular graft surgery.
5. Patients who have had previous abdominal surgery with significant vascular scarring.
6. Severe osteoporosis is a relative contraindication because it may result in loss of fixation.
7. 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.
8. 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).

MATERIALS:

The Buttress Plate implants are manufactured from Titanium alloy 6Al-4V. Surgical instruments provided with the Buttress Plate System 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 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 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 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.
- 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.

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.

WARNINGS:

Potential risks identified with the use of this device system, which may require additional surgery, include:

1. Device component fracture.
2. Loss of fixation.
3. Non-union.
4. Fracture of the vertebra.
5. Neurological injury.
6. Vascular or visceral injury

This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

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. 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) 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.
 - b) 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.
 - c) 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.
 - d) Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used.
 - e) Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
3. PROPER SIZING OF THE IMPLANTS IS IMPORTANT. The potential for satisfactory fixation is increased by the selection of the proper size, shape, and design of the implant.
4. 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.
5. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT. Contouring of the metal implants should only be done with proper equipment. It is recommended that contouring be gradual and that great care be used to avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.
6. REMOVAL OF THE IMPLANT AFTER HEALING. Metallic implants can possibly increase the risk of infection, loosen, fracture, corrode,

migrate, cause pain, or stress shield bone even after healing, particularly in young, active patients. The surgeon should carefully weigh the risk versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risk involved with a second surgery.

7. 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 limitations of the implant and follow the post-operative care regimen as instructed by his or her physician.
8. CORRECT PLACEMENT OF ANTERIOR SPINAL IMPLANTS. Due to the proximity of vascular and neurologic structures to the implantation site, there are risks of serious or fatal hemorrhage and risks of neurologic damage with the use of these products. Serious or fatal hemorrhage may occur if the great vessels are eroded or punctured during implantation or are subsequently damaged due to breakage of implants, migration of implants or if pulsatile erosion of the vessels occur because of close apposition of the implants.
9. MAGNETIC RESONANCE ENVIRONMENT. The Eminent Spine® Buttress Plate System has not been evaluated for safety and compatibility in the MR environment. The Buttress Plate System has not been tested for heating or migration in the MR environment.

The Eminent Spine® Buttress Plate is only a temporary implant intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. A successful result is not achieved in every surgical case. Bone grafting must be part of the spinal fusion procedure in which the Buttress Plate System is used.

POSSIBLE ADVERSE EFFECTS:

1. Nonunion, delayed union.
2. Bending or fracture of implant. Loosening of the implant.
3. Metal sensitivity or allergic reaction to a foreign body.
4. Infection, early or late.
5. Decrease in bone density due to stress shielding.
6. Pain, discomfort, or abnormal sensations due to the presence of the device.
7. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness and paraesthesia.
8. Vascular damage could result in catastrophic or fatal bleeding. Malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late postoperative period.
9. Bursitis.
10. Reflex sympathetic dystrophy.
11. Paralysis.
12. Dural tears experienced during surgery could result in the need for further surgery for dural repair, a chronic CSF leak or fistula and possible meningitis.
13. Death.
14. Spinal cord impingement or damage.
15. Fracture of bony structures.
16. Degenerative changes or instability in segments adjacent to fused vertebral levels.
17. Screw back out, possibly leading to implant loosening, and/or reoperation for device removal, non-union, delayed union.

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.

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