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Lumbar Buttress Plate System

Surgical Technique

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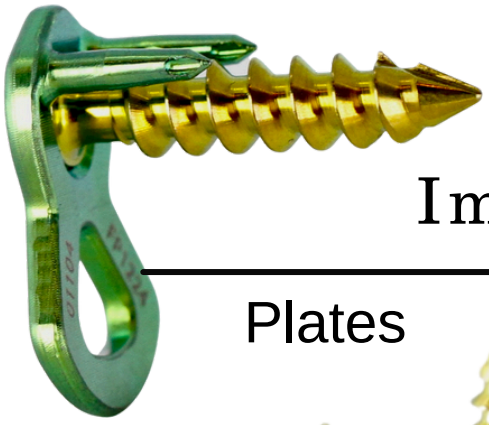
Product Features

Plate:

- Large window for graft visualization
- Smooth contours for vessel protection
- Broad plate span to prevent graft expulsion
- 8 degree lordosis contours to spine, buttress against implant
- 2 Fangs provide rotational stability - Tripod Fixation
- Fangs have self-tapping grooves
- Large graft windows for visual cage confirmation

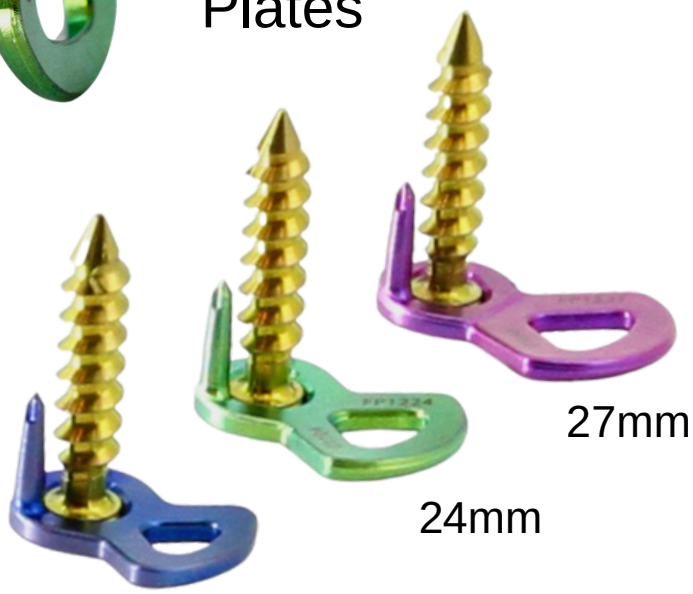
Screws:

- 5.5mm self-tapping screw
- Tri-Lobe patented locking screw technology



Implant Profiles

Plates



Screws

Step 1 : Implant

Follow the ALIF procedure to implant the interbody fusion device (Figure 1).

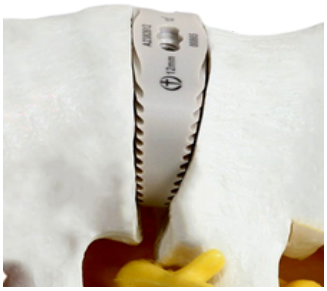


Figure 1

Step 2 : Preparation of Vertebral Body

Remove the anterior osteophytes of the vertebral body by utilizing a 5mm long-handed, straight pituitary (Figure 2).
The anterior osteophytes of the vertebral body should be removed so that the buttress plate will be flush up against the true anterior aspect of the vertebral body (Figure 3).

Figure 2

NOTE:
It is very important to provide a nice, stable flush base for the buttress plate to engage the true vertebral body.

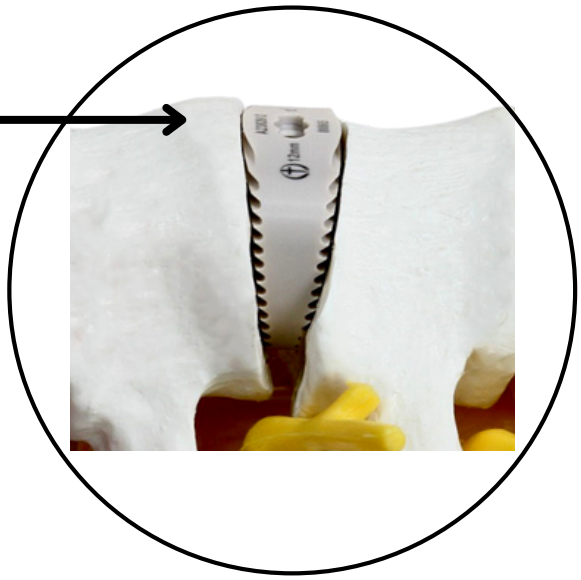
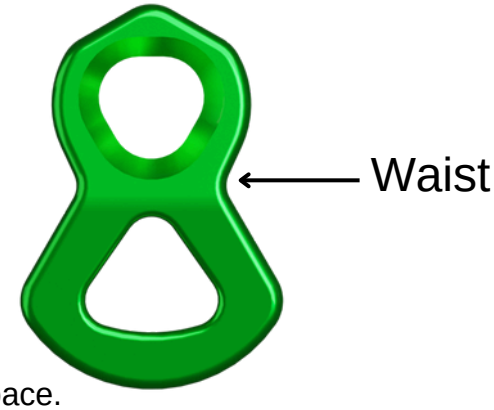


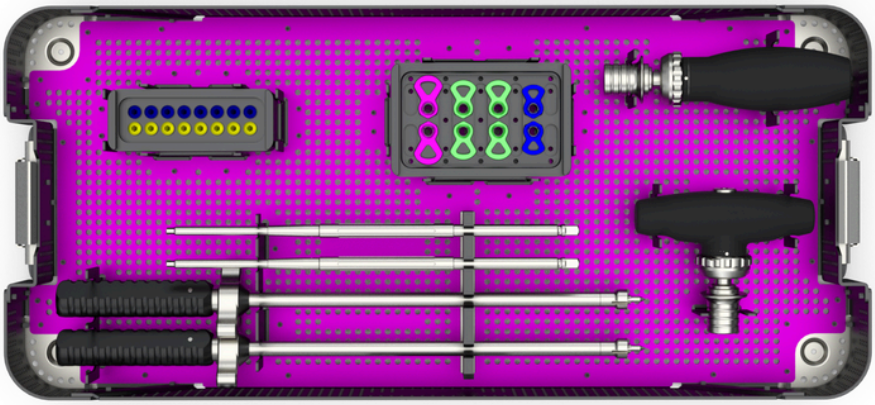
Figure 3

Step 3 : Placement and Sizing

The waist of the buttress plate should be at the superior or inferior vertebral body based on bone anatomy, as well as vascular anatomy.



The buttress plate Tail should overhand 50-80% of the disc space.



There are three sizes: 21mm, 24mm and 27mm (Figure 4).

Figure 4

Step 4 : Loading Implant

Insert the awl into the buttress plate while it is in the caddy. The slit of the awl should be at the 12 o'clock position as it engages the buttress plate (Figure 5). Rotate the awl approximately 30° clockwise; both slits should line up with the base of the origin of the spikes (Figure 6).

Figure 5

Figure 6

Hold the knob at the base of the shaft and rotate the colored handle clockwise until it is snug (Figure 7).

Figure 7

Remove the awl and the buttress plate from the caddy (Figure 8).

Figure 8

Step 5 : Insert and Seat Plate

Mallet the buttress plate into the vertebral body so that the plate sits flush and the spikes are fully engaged into the vertebral body. The spikes provide fixation in the vertebral body and resist rotation of the plate while inserting the screw (Figure 9, 10 11). Once the buttress plate is inserted into the vertebral body, rotate the awl handle counterclockwise to release the buttress plate.

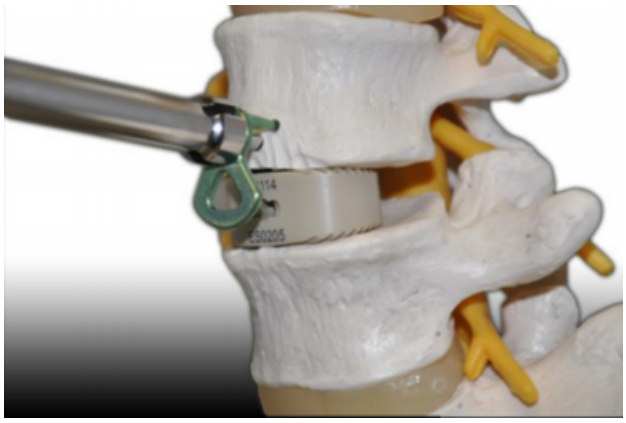


Figure 9

Figure 10

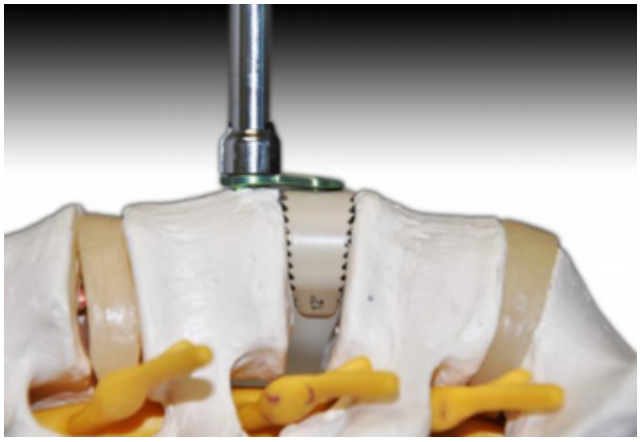


Figure 11

Step 6 : Insert Locking Screw

The awl will create a starting hole for the screw (Figure 12). Insert the self-tapping screw through the hole of the plate. Two lengths of screws are available: 20 and 25mm (Figure 13). It would be appropriate to perform this under lateral fluoroscopy to determine the appropriate screw length.

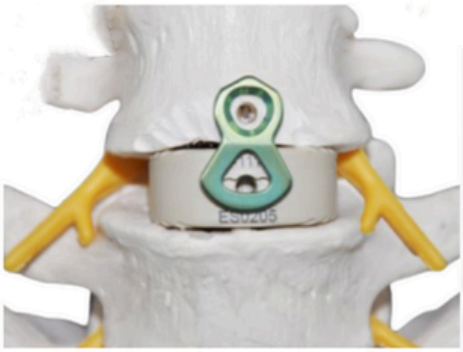
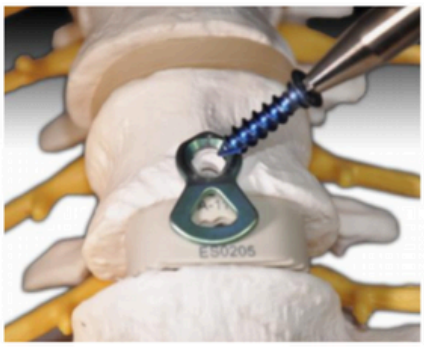


Figure 12

Figure 13

Surgical Pearl - "It is very important to be perpendicular with the screw to the buttress plate so that the locking mechanism will engage (Figure 14, 15). Tighten the screw until it engages the plate. There is typically a tactile feel when the screw is fully seated" (Figure 16).



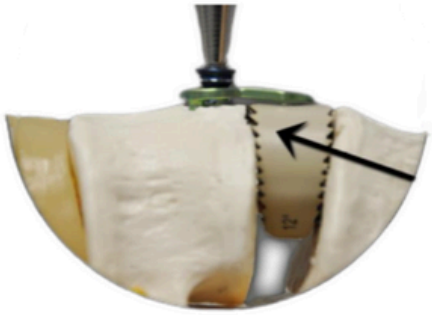


Figure 14

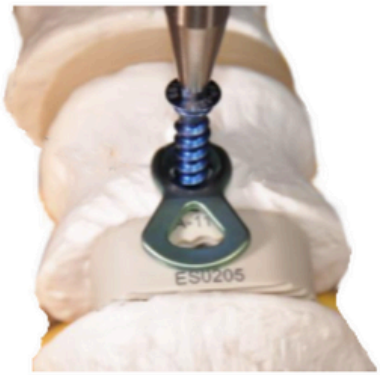


Figure 15

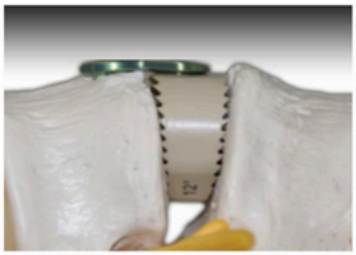
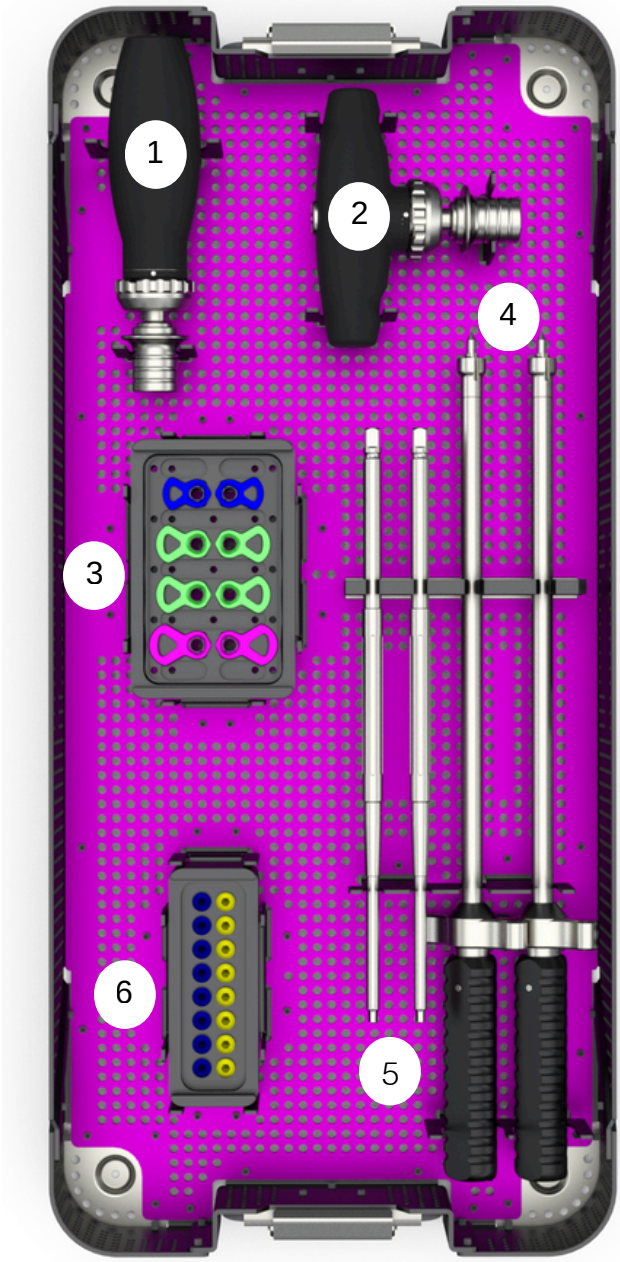


Figure 16

Buttress Plate Tray Layout



1. Straight Ratchet
2. T-Handle Ratchet
3. Implant Caddy with 21, 24 and 27mm implants
4. Two Plate Inserters
5. Two Screwdrivers (1/4 Drive)
6. Screw Caddy with 20 & 25mm screws

Buttress Plate

Part Numbers	Buttress Plate
FP1221	Buttress Plate, 21mm
FP1224	Buttress Plate, 24mm
FP1227	Buttress Plate, 27mm

Buttress Screws

Part Numbers	Buttress Screws
FP1220	Buttress Plate Screw, 20mm
FP1225	Buttress Plate Screw, 25mm

Eminent Spine LLC Buttress Plate System

Eminent Spine LLC
2004 Ventura Drive 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 noncompliant 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 hardto-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 nonsterile and must be sterilized prior to use. 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.
- 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.