(English) TITANIUM FENESTRATED PLATE

Warning: The FDA has placed labeling limitations on this device.

INDICATIONS FOR USE
The Biomet Titanium Fenestrated Plate is intended to be used as a temporary construct that assists normal healing and is not intended to replace normal body structures. The Titanium Fenestrated Plate is intended to stabilize the spinal operative site during fusion procedures and should be removed after fusion.

The Titanium Fenestrated Plate is attached to the spine posteriorly by means of a Ti cable system. The levels of attachment are T1 to L5.

The Titanium Fenestrated Plate is indicated for the following:
1. Degenerative Disc Disease (as defined by chronic back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).
2. Idiopathic scoliosis.
4. Lordotic deformities of the spine.
5. Vertebral fracture or dislocation.
6. Tumors.
7. Spondylolisthesis.
8. Stenosis.
10. Unsuccessful previous attempts at spinal fusion.

DESCRIPTION OF DEVICE
The Biomet Titanium Fenestrated Plate is a titanium plate containing multiple holes along the length of the plate. The Titanium Fenestrated Plate is intended for use in the thoracolumbar spine from T1-L5. The plate is secured to the posterior spine via a Titanium Cable System. The Titanium Cable System cable is placed through the holes in the Titanium Fenestrated Plate and passed under and around the lamina. The plate and cable(s) are then secured to the spine by using a tensioner/crimper instrument to obtain the appropriate tension level and to secure the cable crimp.

PRODUCT CONFIGURATIONS
The Titanium Fenestrated Plate is made from surgical implant grade titanium alloy as described by ASTM Standard F-136 (Ti 6Al-4V ELI) and is available in lengths of 35mm to 80mm. The number of holes in each plate (seven to sixteen) corresponds to the length of the plate. The Titanium Fenestrated Plate is provided nonsterile and should be cleaned and sterilized prior to use.

INSTRUCTIONS FOR USE
Caution: The Titanium Fenestrated Plate should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. Refer to the Titanium Fenestrated Plate Surgical Technique for complete Instructions For Use.

CONTRAINDICATIONS
Contraindications include, but are not limited to:
1. infection, systemic, spinal or localized;
2. morbid obesity;
3. signs of local inflammation;
4. fever or leukocytosis;
5. metal sensitivity/allergies to the implant materials;
6. any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count;
7. grossly distorted anatomy due to congenital abnormalities;
8. rapid joint disease, bone absorption, osteopenia, and/or osteoporosis (osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft);
9. any case not needing a bone graft and fusion or where fracture healing is not required;
10. any case requiring the mixing of metals from different components;
11. any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition;
12. any case not described in the indications;
13. any patient unwilling to cooperate with the postoperative instructions;
14. any time implant utilization would interfere with anatomical structures or expected physiological performance.

WARNINGS

Warning: This device is not approved for screw attachment. In using metallic surgical implants, the surgeon should be aware of the following:

1. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. The size and shape of the human spine presents limiting restrictions of the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weight bearing.
2. The surgeon must ensure that all necessary implants and instruments are on hand prior to surgery. The device must be handled and stored carefully, protected from damage, including corrosive environments. The implants should be carefully unpacked and inspected for damage prior to use.
3. Correct handling of the implant is extremely important. Contouring of the metal devices is to be avoided.
4. All implants and instruments must be cleaned and sterilized prior to use.
5. Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium implants must NOT be used together.
6. As with all orthopaedic implants, the Titanium Fenestrated Plates should never be reused under any circumstances.
7. Proper implant selection and patient compliance to postoperative precautions will greatly affect surgical outcomes. Patients who smoke have been shown to have an increased incidence of nonunion. Therefore, these patients should be advised of this fact and warned of the potential consequences.
8. Postoperative care is important. The patient should be instructed in the limitations of his/her metallic implant and should be cautioned regarding weight bearing and body stress on the appliance prior to secure bone healing.

PRECAUTIONS

Preoperative:
1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or pre-dispositions such as those addressed in the Contraindications Section should be avoided.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.
4. All components and instruments should be cleaned and sterilized before use.

Intraoperative:
1. Any instruction manuals should be carefully followed.
2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves may occur resulting in a loss of neurological functions.
3. The implant surfaces should not be scratched or notched since such actions may reduce the functional strength of the construct.
4. Bone grafts must be placed in the area to be fused and the graft must be in contact with viable bone.
Postoperative:
1. The physician’s postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.
2. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening or breakage of the components are complications which can occur as a result of excessive or early weight-bearing or excessive muscular activity. The risk of bending, loosening, or breakage of an internal fixation device during post-operative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented, or otherwise unable to use crutches or other such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.
3. To allow maximum chances for a successful surgical result, the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting, twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.
4. The patient should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
5. If a nonunion develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or nonunion of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.
6. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopaedic implants, Titanium Fenestrated Plates should never be reused under any circumstances.

POTENTIAL ADVERSE EFFECTS AND COMPLICATIONS
Possible adverse effects include, but are not limited to:
1. bending, loosening or fracture of the implants or instruments;
2. loss of fixation;
3. sensitivity to a metallic foreign body, including possible tumor formation;
4. skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown and/or wound complications;
5. nonunion or delayed union;
6. infection;
7. nerve or vascular damage due to surgical trauma, including loss of neurological function, dural tears, radiculopathy, paralysis and cerebral spinal fluid leakage;
8. gastrointestinal, urological and/or reproductive system compromise, including sterility, impotency and/or loss of consortium;
9. pain or discomfort;
10. bone loss due to resorption or stress shielding, or bone fracture at, above or below the level of surgery (fracture of the vertebra);
11. hemorrhage of blood vessels and/or hematomas;
12. malalignment of anatomical structures, including loss of proper spinal curvature, correction, reduction and/or height;
13. bursitis;
14. bone graft donor site pain;
15. inability to resume activities of normal daily living;
16. reoperation;
17. death.
STERILIZATION
The Titanium Fenestrated Plate is provided nonsterile. All implants and instruments must be cleaned and sterilized prior to use in a properly functioning, calibrated steam sterilizer. High temperature steam sterilization should be used. All packaging materials must be removed prior to sterilization. The following validated sterilization cycle should be used:

Method: Steam
Cycle: Pre-vacuum
Temperature: 270°F (132°C)
Exposure Time: 8 minutes
Drying Time: 20 minutes

CAUTION
Federal (USA) law restricts these devices to sale by or on the order of a licensed physician.

INFORMATION
For further information, please contact your local Biomet Distributor. In the United States contact Biomet Customer Service at:

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