InterPlate® LUMBAR TITANIUM PLATE/INTERBODY FUSION DEVICE PACKAGE INSERT

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CAUTION – Federal (or United States) law restricts these devices to sale by or on the order of a physician.

IMPORTANT NOTE TO OPERATING SURGEON

The InterPlate L-Ti is designed to provide biomechanical stabilization as an adjunct to lumbar discectomy and must be used with autograft to facilitate fusion. Spinal fixation should only be undertaken after the surgeon has had hands-on training in this method of spinal fixation and has become thoroughly knowledgeable about spinal anatomy and biomechanics. Correct implant size and proper device orientation are critical. A surgical technique is available containing instructions on the important aspects of this surgical procedure.

Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential adverse effects of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.

Postoperative evaluation of the fusion and implant status is necessary. The surgeon may remove the implant once a solid fusion is obtained. The patient must be informed of the potential of this secondary surgical procedure and the associated risks.

DESCRIPTION

The InterPlate plates, bone screws, and screw covers are fabricated of Ti-6Al-4V titanium alloy per ASTM Standard F136. Various plate sizes are available to accommodate individual patient anatomy and autograft material size. Screw covers are individually matched to the plate size.

STERILIZATION

The InterPlate components are supplied clean and not sterile. All implants and instruments must be cleaned and sterilized prior to surgery. AORN recommended practices for in hospital sterilization should be followed.

Sterilization testing of components has shown the following recommendations for sterilization are effective:

Method:	Steam	Method:	Steam
Cycle:	Gravity	Cycle:	Prevacuum
Temperature:	132°C	Temperature:	132°C
Exposure Time:	25 minutes	Exposure Time:	4 minutes
Minimum Dry Time:	90 minutes	Minimum Dry Time:	60 Minutes
		Preconditioning Pulses:	3

INDICATIONS

The InterPlate is indicated for anterior screw fixation or intervertebral body fusion of the spine in skeletally mature patients. The device system is designed for use with autograft to facilitate fusion. One device is used per intervertebral space.

The InterPlate L System is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is to be used in patients who have had six months of non-operative treatment.

CONTRAINDICATIONS

Use of the InterPlate and spinal fixation surgery are contraindicated when there was recent or local active infection near or at the site of the proposed implantation. Any conditions that preclude the possibility of fusion are relative contraindications. These include but are not limited to: fever, mental illness, alcoholism or drug abuse, osteoporosis or osteopenia, neurotrophic diseases, obesity, pregnancy, foreign body sensitivity, use with components of other systems, unwillingness to restrict activity, reuse of implantable components, or any use not described under INDICATIONS. See also the WARNINGS, PRECAUTIONS AND POTENTIAL RISKS sections of this insert.

The following are specific warnings, precautions and adverse events that should be understood by the surgeon and explained to the patient. These warnings are specific to metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

WARNINGS

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

device component fracture,
loss of fixation,
non-union,
fracture of the vertebra,
neurologic injury, and
vascular or visceral injury.
See the POTENTIAL RISKS section of the package insert for a complete list of potential risks.

PRECAUTIONS

1. **IMPLANT SELECTION**. The potential for the success of the procedure is increased by selecting the correct size of the implant. These devices are not intended to be used as the sole support for the spine.
2. **DELAYED UNION OR NONUNION**. The InterPlate System is designed to assist in providing an adequate biomechanical environment for fusion. It is not intended to be and must not be used as the sole support for the spine. If a delayed union or nonunion occurs the implant may fail due to metal fatigue. Patients should be fully informed of the risk of implant failure.
3. **MIXED METALS**. The InterPlate System is available in titanium alloy. It is imperative that this metal does not come into contact *in vivo* with other dissimilar metals. Accelerated corrosion may occur when two dissimilar metals are in contact within the body environment.
4. **PATIENT SELECTION**. Proper patient selection is critical to the success of the procedure. Only patients who satisfy the criteria set forth under the INDICATIONS section of this document AND who do not have any of the conditions set forth under the CONTRAINDICATIONS section of this document should be considered for spinal fixation surgery using the InterPlate IFD System. In addition, patients who smoke have been shown to have an increased incidence of pseudarthrosis. Based upon the fatigue testing 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.
5. **SINGLE USE ONLY**. These devices are single use only implants and are not to be reused or reimplanted regardless of an apparent undamaged condition.
6. **BENDING**. Bending or other modifications of the InterPlate components are not recommended. Bending will compromise mechanical performance and may adversely affect fit and function of the screw retaining mechanisms.
7. **HANDLING**. Implant components should be handled and stored appropriately to protect them from unintentional damage. The surgeon should avoid introducing notches or scratches into the surfaces as these may induce premature failure of the component.
8. **PATIENT EDUCATION**. Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.

POTENTIAL RISKS

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

1. Bending, fracture or loosening of implant component(s).
2. Nonunion or delayed union.
3. Fracture of the vertebra.
4. Neurological, vascular or visceral injury.
5. Metal sensitivity or allergic reaction to a foreign body.
6. Infection.
7. Decrease in bone density due to stress shielding.
8. Pain, discomfort or abnormal sensations due to the presence of the device.
9. Nerve damage due to surgical trauma.
10. Bursitis.
11. Dural Leak.
12. Paralysis.
13. Death

Patent Numbers: 6,984,234 * 6,235,034 * 8,100,976 * 7,985,255 * 9,278,009 * 9,713,537 B2
Other patents pending and applied for