JACE MEDICAL

WARNINGS AND PRECAUTIONS FOR THE USE OF JACE MEDICAL LOW PROFILE STERNAL CLOSURE SYSTEM

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Description

The Low Profile Sternal Closure System consists of plates and accessories designed to provide fixation following sternotomy. Instrumentation has been designed for use specifically with this system of implants.

Implant Materials

The Low Profile Sternal Closure System devices are manufactured from titanium alloy as described by ASTM F136.

Intended Use

The Low Profile Sternal Closure System is indicated for use in the stabilization and fixation of fractures of the chest wall including sternal fixation following sternotomy and sternal reconstructive surgical procedures, trauma, or planned osteotomies.

Contraindications

- Active or latent infection, sepsis
- Poor or insufficient quality or quantity of bone
- Limited blood supply
- Material sensitivity- if suspected, tests should be completed prior to implantation
- Patients unwilling or incapable of following postoperative care instructions
- Any condition not described in the Intended Use

Warnings

- Internal fixation devices aid the surgeon in the alignment and stabilization of bone in the anterior chest wall when a sternotomy is required. Internal fixation devices are internal splints, or load sharing devices that align the fracture until normal healing occurs. These devices cannot be expected to replace normal healthy bone or withstand the unsupported stress placed upon the device by full load bearing. It is important that immobilization of the fracture site be maintained until firm bony union (confirmed by clinical and radiographic examination) is established. If there is delayed union, non-union, onset/ progression of osteoporosis, or incomplete healing of bone; the implant may bend, break, or fail. Surgical implants are subject to repeated stresses in use, which can result in fatigue fracture. Factors such as the patient's activity level and adherence to load bearing instructions affect the service life of the implant.
- These implants are single use devices – do not reuse implants under any circumstances. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been even momentarily placed in a different patient.
- Do not mix implants of dissimilar metals. Implant materials are subject to corrosion. Implanting metals and alloys subjects them to constant changing environments of salts, acids, and alkalis that can cause corrosion. Putting dissimilar metals and alloys in contact with each other may be detrimental to the patient and/or function of the implant(s).
- Contouring/bending should be avoided if possible. Only bend plates in one direction and avoid small radius bends. Do not reverse bend plates or bend through screw holes. Doing so may lead to failure of the device.
- Inspect plates after bending for deformation such as bent screw holes or dents/notches. Do not use plates that contain these deformities as they may lead to failure of the device.
- Do not use if sterile packaging is opened or if the expiration date has passed. Do not use if implant is damaged.
- Intraoperative fracture of screws can occur if excessive force (torque) is applied while seating bone screws.

- Implants can loosen, fracture, corrode, migrate, or cause pain. Implants may be removed after fracture or bony non-union has healed. If an implant remains implanted after complete healing, the implant may cause stress shielding, which may increase the risk of refracture or recurrence of non-union in an active patient. Bone compromising conditions, such as osteoporosis, may increase the risk of implant stress-shielding. The surgeon should weigh the risks versus benefits when deciding whether to remove the implant. Adequate postoperative management to avoid refracture or recurrence of non-union should follow implant removal.
- The device is not designed or intended to withstand sudden dynamic loads associated with accidents or falls.

Precautions

- Instruments are available for the implant system to aid in the accurate implantation of the internal fixation devices. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. It is recommended that all instruments be regularly inspected for wear and disfigurement.
- Surgical instruments must be used only for the device systems for which they are designed. Use of other manufacturer instruments can involve incalculable risks for the implant and instrument, thereby potentially endangering the patient, user, or third party.
- Correct selection of the appropriate implant size is extremely important. Selection of screws which are longer than the depth of the sternum may cause possible impingement on structures internal to chest wall including vessels, pleura and other structures.
- Ensure adequate approximation and alignment of bony anatomy prior to final screw and plate fixation.
- The hexalobe screwdriver which has been designed for this system must always be used to be sure that proper screwdriver/screw head connection is achieved. Incorrect alignment or fit of the screwdriver to the screw head may increase the risk of damage to the implant or screwdriver. Excessive torque can cause the screw to fracture.

MRI Safety Information

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The Low Profile Sternal Closure System components are made from non-magnetic ASTM F136 titanium alloy. Non-clinical testing has demonstrated that the Low Profile Sternal Closure System is MR Conditional. A patient with this device can be safely scanned under the following conditions:

Name/Identification of Device	The Low Profile Sternal Closure System
Nominal Value(s) of Static Magnetic Field [T]	1.5T or 3.0T
Maximum Spatial Field Gradient [T/m and gauss/cm]	30 T/m (3,000 gauss/cm)
Maximum Whole Body SAR [W/kg]	1 W/kg (Normal Operating Mode)
Limits on Scan Duration	1 W/kg whole-body average SAR for up to 15 minutes of continuous RF (a sequence or back-to-back series/scan without breaks) followed by a wait time of 2 minutes for up to 60 minutes.
MR Image Artifact	The presence of this implant may produce an image artifact.
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

The health state of the patient or the presence of other implants may require reduction of the MR limits.

Possible Adverse Effects

- Non-union or delayed union.
- Migration, bending, cracking, fracture or loosening of the implant.
- Metal sensitivity or allergic reaction to a foreign body.
- Decrease in bone density due to stress shielding.
- Pain, discomfort, abnormal sensation or palpability due to the presence of the device.
- Increased fibrous tissue response around the fracture site and/or the implant.
- Necrosis of bone or bone resorption.
- Inadequate healing.

Apart from these adverse effects, there are always possible complications of any surgical procedure such as, but not limited to infection, nerve damage, and pain which may not be related to the implant.

Cleaning and Sterilization

Prior to sterilization, all implants and instruments must be carefully cleaned and inspected. It is important to confirm that implants which are returned for processing from the operating room have not entered the operative site, as they may have been compromised. Implants in the tray which have touched the defect or entered the operative site, should be discarded. Cleaning should be performed by trained medical personnel.

Unless labeled as sterile, the Low Profile Sternal Closure System non-sterile devices must be sterilized prior to surgical use. Steam autoclaving is performed after removal of the protective packaging.

The **JACE Medical Product Care, Cleaning and Sterilization** instructions are available on the JACE Medical website (www.jacemed.com) or by calling customer service at (574) 306-0355.

Operating Surgeons and all personnel involved with handling these products are responsible for attaining appropriate education and training within the scope of the activities which they are involved in the handling and use of this product.

Consult the appropriate JACE Medical Surgical Technique prior to use. Surgical Techniques are available by calling Customer Service at (574) 306-0355.

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