

WARNINGS AND PRECAUTIONS FOR THE USE OF JACE MEDICAL STERNAL CLOSURE SYSTEMS

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

Description

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

Intended Use

The Sternal Closure System is intended for use in the stabilization and fixation of fractures of the sternum, including sternal fixation following sternotomy and sternal reconstructive surgical procedures.

Contraindications

- Active or latent infection, sepsis
- Poor or insufficient quality or quantity of bone, such as osteoporosis
- 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).
- Do not bend the Ratchet Wheel or Shear Bar Plates. Do not make other modifications to the implants or other component parts. This may increase the risk of fracture or separation.
- Contouring/bending should be avoided if possible. If contouring/bending is allowed by design, 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.
- Tension ratchet locking element only enough to obtain bony apposition and stability.

- 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.



- The JACE sternal closure system is MR conditional as defined in ASTM F2503 and is made from non-magnetic titanium alloy. Patients with the sternal closure system may safely undergo MRI under the following conditions:
 - Static field of 3 T or less.
 - Whole body SAR of 2 W/kg or less.
 - Normal mode of the MRI system for both RF and gradients.
 - Maximum spatial gradient in the static field of 30 T/m (3000 Gauss/cm).
 - The part of the body with the sternal closure system should not be in direct contact with the wall of the bore of the MR system. (Electrically insulating padding can be used to avoid contact with the wall.)
- 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.
- Bone Plates: Ensure adequate approximation and alignment of bony anatomy prior to final screw fixation and ratchet tightening.
- Bone Screws: 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.

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 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.



MANUFACTURER:

JACE Medical
3516 Commerce Drive
Warsaw, IN 46580
USA
Ph 574-306-0355
www.jacemed.com

