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WARNINGS AND PRECAUTIONS FOR THE USE OF THE STERNALOCK® 360 STERNAL CLOSURE SYSTEM

ATTENTION OPERATING SURGEON

DESCRIPTION

Biomet Microfixation manufactures and distributes the SternaLock® 360 Sternal Closure System. Each system component is comprised of rigid fixation and cerclage technologies to approximate the sternal halves, provide bone compression, and rigidly fixate bone in one device.

IMPLANT MATERIALS:

Commercially Pure Titanium
Titanium 6Al 4V Alloy
Parylene-C

INSTRUMENT MATERIALS:

Ultem® Polyetherimide (PEI)
Titanium 6Al 4V Alloy
Stainless Steel

INDICATIONS

The SternaLock® 360 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, to promote fusion. The system is intended for use in patients with normal and/or poor bone quality.

CONTRAINDICATIONS

1. Active infection
2. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation.
3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.

POSSIBLE ADVERSE EFFECTS

1. Poor bone formation, Osteoporosis, Osteolysis, Osteomyelitis, inhibited revascularization, or infection can cause loosening, bending, cracking or fracture of the device.
2. Nonunion or delayed union which may lead to breakage of the implant.
3. Migration, bending, fracture or loosening of the implant.
4. Metal sensitivity, or allergic reaction to a foreign body.
5. Decrease in bone density due to stress shielding.
6. Bleeding, pain, discomfort, abnormal sensation, or palpability due to the presence of the device.
7. Increased fibrous tissue response around the fracture site and/or the implant.
8. Necrosis of bone.
9. Inadequate healing.
10. Injury to, or impingement upon, the internal mammary artery and intercostal vessel and nerve bundles.
11. 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.

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.

WARNINGS

Internal fixation devices aid the surgeon in the alignment and stabilization of bone in the anterior chest wall for fixation of fractures and reconstructive procedures in patients with normal and poor bone quality (including, but not limited to, diagnosis of osteoporosis or osteopenia). While these devices are generally successful in attaining these goals, they cannot be expected to replace normal healthy bone or withstand the unsupported stress placed upon the device by full load bearing. Internal fixation devices are internal splints, or load sharing devices that align the fracture until normal healing occurs. If there is delayed union, nonunion, or incomplete healing of bone, the implant can be expected to bend, break, or fail. Therefore, it is important that immobilization of the fracture site be maintained until firm bony union (confirmed by clinical and radiographic examination) is established. The size and shape of bones and soft tissue place limitation on the size and strength of implants. Surgical implants are subject to repeated stresses in use, which can result in fatigue fracture. Factors such as the patient's activity level, limited blood supply, insufficient quantity or quality of bone, active or latent infection and adherence to load bearing instructions may have an effect on the performance of the implant. The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant, but also must be aware of the mechanical and metallurgical aspects of the surgical implants.

1. 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).
2. Correct handling of implants is extremely important. Implants should be modified only when necessary. Modifications or excessive contouring of implants may weaken the implant and contribute to breakage. Notches or scratches put in the implant during the course of surgery may contribute to breakage.
3. Intraoperative fracture or weakening of the device can occur if excessive force (torque) is applied.
4. Implants may be removed after fracture or other bony non-union has healed. Implants can loosen, fracture, corrode, migrate, or cause pain. 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. 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.
5. Adequately instruct the patient. Postoperative care is important. The patient's ability and willingness to follow instruction is one of the most important aspects of

successful management of fracture or other non-union. Patients with senility, mental illness, alcoholism, or drug abuse may be at higher risk of device failure since these patients may ignore instructions and activity restrictions. The patient is to be instructed in the use of external supports and braces that are intended to immobilize the site of the fracture or other non-union and limit load bearing. The patient is to be made fully aware and warned that the device does not replace normal healthy bone, and that the device can break, bend or be damaged as a result of stress, activity, load bearing or inadequate bone healing. The patient is to be made aware and warned of general surgical risks, complications, possible adverse effects, and to follow the instructions of the treating physician. The patient is to be advised of the need for regular postoperative follow-up examination as long as the device remains implanted.

6. Placement of the cerclage should be carefully selected; care should be taken to not place the cerclage band over a transverse fracture as this may lead to loosening of the implant and failure of the device.
7. The device should be implanted only in sternal bone and not fixated across the sternal-manubrial junction, costal cartilage, or cartilagenous bone.
8. Tension should be applied until the bone halves are approximated and visually contacting. Care should be taken to not over-compress the bone halves. Over-compression may lead to bone damage, tearing of surrounding soft-tissue, or damage to the implant leading to failure of the device. Under-compression may lead to poor sternal approximation, reduced implant stability, or nonunion.

PRECAUTIONS

Single use device. Do not reuse implants. 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 reuse instruments that are provided sterile. Instruments are available for each implant system to aid in the implantation of internal fixation devices. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Biomet Microfixation recommends 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.

MR BIOMET IMPLANTS IN THE MAGNETIC RESONANCE (MR) ENVIRONMENT: Non-Clinical testing has demonstrated the SternaLock® 360 Sternal Closure System is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T and 3.0 T
- Maximum spatial gradient field of 3,000 gauss/cm (30 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg (Normal Operating Mode)

Under the scan conditions defined above, a single SternaLock® 360 Sternal Closure device is expected to produce a maximum temperature rise of less than 4°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by a single device extends approximately 1.5 cm from the SternaLock® 360 Sternal Closure device when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

Directions for Use of a Single SternaLock® 360 Device

1. Determine sternal depth measurement to select appropriate screw length.
2. Pass the cerclage band through or around sternal bone.
3. Cut needle from cerclage band using cutters or scissors. Do not twist-off the needle from the band.
4. Insert cerclage band through the locking mechanism/tensioner assembly; the band should be pulled tight with the sternal halves approximated as close as possible.
5. Use tensioner to apply desired amount compression. Refer to the tensioner directions for use below.
6. Contour plates to patient anatomy, if needed.
7. Align plates such that the cuttable cross-sections span the sternotomy line.
8. Confirm approximation of sternal halves.
9. Activate locking mechanism and disengage the tensioner from implant device.
10. Fixate plate to bone with the appropriate length screws. If larger diameter screws are needed, 2.7mm screws are available.

The following is a recommended implant configuration:

Manubrium/1st Intercostal Space	1 Banded Box Plate
Body of Sternum	1 Banded X-Plate
Lower Sternum	1 Banded Box Plate

Configurations with a minimum of 5 cuttable rigid plate sections (the rigid bars or ties that span the sternotomy line) are recommended to close a complete mid-line sternotomy. Configurations may include a combination of SternaLock® 360 devices and SternaLock® Blu plates with cuttable rigid plate sections. Do not use plates without cuttable rigid plate sections to span a sternotomy.

Size Selection for SternaLock® 360 Implant Sets That Include Screws:

- The **SternaLock® 360 Sizer** is provided to facilitate selection of the appropriate implant set for the patient anatomy.
- Using the **SternaLock® 360 Sizer**, measure the thinnest portion of the sternum where a plate will be fixated. The appropriate size is the longest marker (XS, S, M, or L) that does not extend beyond the thickness of the sternal bone. Selection of a size too short may lead to improper fixation of the sternum.

Color and Identifier of Sternum Measurement	Part Number of SternaLock® 360 Implant Set with Screws
YELLOW, XS	74-0010
GREEN, S	74-0012
BLUE, M	74-0014
BLACK, L	74-0016

Size Selection for SternaLock® 360 Implant Sets That Do Not Include Screws (Using the SternaLock® Blu Sizer):

- The **SternaLock® Blu Sizer** is provided to facilitate measurement of sternal depth and may be used to select the appropriate screw length for the patient anatomy.
- Using the **SternaLock® Blu Sizer**, measure the sternum at each location an implant is to be placed, for example:
  Manubrium/1st Intercostal Space
  Body of Sternum
  Lower Sternum
- Select the thinnest portion of the sternum measured to determine the suggested screw length. When measuring, the appropriate size is the longest length that does not extend beyond the thickness of the sternal bone. Selection of a size too short may lead to improper fixation of the sternum.
- Note: When using the **SternaLock® Blu Sizer** to measure sternal depth, 2mm has already been added to the screw length marking on the sizer to account for plate thickness.

Measurement Shown on SternaLock® Blu Sizer	Recommended SternaLock® Blu Screw Length
8.0mm	8.0mm
10.0mm	10.0mm
12.0mm	12.0mm
14.0mm	14.0mm
16.0mm	16.0mm
18.0mm	18.0mm
20.0mm	20.0mm

Tensioner:

- A tensioner is provided pre-assembled on each implant.
- Directions for use of the tensioner once the cercalge band has been passed through the tensioner and the sternal halves have been approximated as close as possible:

STEP 1: Push thumb lock up to hold initial tension of the band.

STEP 2: Rotate dial clockwise to fully approximate sternal halves.

NOTE: Should tension need to be readjusted during intra-operative placement, rotate dial counter-clockwise to its starting position and push thumb lock down to release tension. Re-approximate by repeating steps 1-2.

STEP 3: Turn the paddle clockwise two full revolutions to lock the device and cut the band.

STEP 4: Place index and middle finger under "T" handle with the tensioner in the palm of your hand and lift up fingers to remove tensioner from the implant.

Note: Discard tensioner after removal from implant. Tensioner cannot be reused.

Rigid Plate Fixation with Cerclage Implant:

- Do not separate the plate from cerclage band prior to or during implantation. Do not implant band without bone plate.
- Bone plates may need to be contoured to the surface of the bone by bending the plates with a bending instrument. Care must be taken to achieve the appropriate contour with as few bends as possible. Repeated bending of titanium increases the risk of fracture.
- Sharp angles and small bending radii must be avoided to reduce the risk of bone plate breakage. Sharp angles must be avoided to reduce the risk of band failure or reduction in locking strength.
- The bending instruments must be used with care because they can cause damage to the implant. The operating surgeon should always inspect the implant after bending for damage which may include dents or deformed screw holes. These defects can lead to breakage of the implant. Deformed screw recesses due to bending may impair the proper locking of the screw head.
- Threaded benders should be held as perpendicular as possible when threading the benders into the plate to prevent damage to bone plate.
- Cutting bone plates after implantation should be avoided as this may damage the implant and increase the risk of failure of the implant. If the operating surgeon elects to cut a plate prior to implantation, care must be taken to cut in such a way to maintain adequate strength, support, and fixation for the intended use. Cutting a plate between the screw holes is a preferred method to maintain strength characteristics. Sharp edges should be smoothed to avoid soft tissue damage or irritation. When cutting a plate, extra care must be taken to prevent the portion being cut from projecting towards the patient, user or third party.
- To facilitate emergent reentry, avoid placing non-cuttable portions of the sternal plates over the sternotomy line.

Bone Screws:

- The screwdriver which has been designed for a particular system of screws 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.
- With the plate in position, place the selected screw by turning clockwise to insert the screw. Be sure to keep the screw as perpendicular as possible to the plate to ensure proper fixation. DO NOT fully seat the first screw at this time; tightening the first screw in each plate will cause the plate to rotate. Pressure should be applied to the plate during the insertion of the screws to assure the plate's full contact with the bony surface. After placing the first screw the remaining screws can be placed and fully seated. Return to the first screw at this time and ensure that it is fully seated into the plate.

- Final tightening must be completed using manual screw driver to ensure locking. Failure to fully lock screws may result in screw loosening.

CLEANING

Accessory instrumentation may be reusable unless specifically stated otherwise in this IFU or on the outer packaging labeling. Prior to sterilization, all instrumentation must be carefully cleaned and inspected. Cleaning should be performed by trained medical personnel.

NOTE: DO NOT ALLOW SOILED INSTRUMENTS TO DRY

1. **Removal of Visible Contamination** – Thoroughly clean instruments until visibly clean, repeating as necessary, prior to initial sterilization and a soon as possible after use. Do not allow soil to dry on the instruments. If cleaning must be delayed, place groups of instruments in a covered container with appropriate detergent or enzymatic solution to delay drying. Wash all instruments whether or not they were used or inadvertently came into contact with blood or saline solution. Visible soil should be removed under running water using a mechanical aid, such as a brush or pipe cleaner. Wear protective gloves and goggles during this step.
2. **Disassembly** – Any complex instrumentation should be disassembled into their individual parts prior to decontamination (if applicable). Particular attention should be taken to remove all debris from all cannulations, crevices, serrations, and obscure holes in the instruments.
3. **Washing/Disinfecting** – It is recommend that the instruments, disassembled as required, be decontaminated using an automatic washer-disinfection unit utilizing thermal disinfection. This should preferably be of the ultrasonic or continuous tunnel process type. The cabinet type is an acceptable alternative if a continuous process machine is not available. Compatible detergents and rinse aids may be used as recommended by the manufacturer of the washer-disinfection unit. These detergents and/or rinse aids, however, should be of neutral or near neutral pH. Excessively acidic or alkaline solutions may corrode aluminum instruments or instrument cases. The following table provides a validated method for cleaning instruments:

Phase	Time (Minutes)	Temperature
Pre-Wash	2:00	35°C (95°F)
Detergent Wash	6:00	70°C (158°F)
Wash	4:00	70°C (158°F)
Rinse (With Purified Water)	2:00	70°C (158°F)
Drying	7:00	115°C (239°F)

Warning: Do not, under any condition, reuse implants that entered the operative site.

Precaution for reusable trials, instruments and instrument cases (if applicable):

DO NOT USE instruments or cases/containers that are disfigured, cracked, corroded, or otherwise damaged. All instruments and cases/containers should be regularly inspected for wear or disfigurement. These should be disposed of appropriately.

Contact Biomet Microfixation Regulatory Affairs department fax 904-741-9425 with any additional questions.

STERILITY

SternaLock® 360 System implants and sterile instruments are supplied sterile by exposure to ethylene oxide (ETO) gas. Do not resterilize. Do not use after expiration date has passed.

Accessory instrumentation must be sterilized prior to surgical use. Individually double wrap all instruments prior to sterilizing. Following is a recommended minimum cycle for steam sterilization that has been validated by Biomet Microfixation under laboratory conditions. Individual users must validate the cleaning and autoclaving procedures used on-site, including the on-site validation of recommended minimum cycle parameters described below.

Pre-vacuumed Steam Sterilization (Hi-VAC) Wrapped:

Time:	Four (4) minutes
Temperature:	270° Fahrenheit (132° Celsius)
Drying Time:	Thirty (30) minutes MINIMUM

Health care personnel bear the ultimate responsibility for ensuring that any packaging method or material, including a reusable rigid container system, is suitable for use in sterilization processing and sterility maintenance in a particular health care facility. Testing should be conducted in the health care facility to assure that conditions essential to sterilization can be achieved. Since Biomet Microfixation is not familiar with individual hospital handling methods, cleaning methods and bioburden, Biomet Microfixation cannot assume responsibility for sterility even though the guideline is followed.

Note to US Customers: FDA cleared sterilizers and wraps are to be used in the sterilization process.

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

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.

Emergent Reentry:

If emergent reentry is necessary, the SternaLock® 360 Sternal Closure System plates feature a patent-pending cuttable section to allow for rapid access to the chest cavity. The SternaLock® 360 plate and cerclage can be cut with most non-scissor type heavy wire cutters found in the operating room or a crash cart.

Should emergent reentry be necessary and no plate cutter is available, place a curved elevator under one side of the sternal plate and lift the plate off of the sternum for removal.

SYMBOLS

 Manufacturer

 Date of Manufacture

 Do Not Reuse

 Caution

Sterilized using Ethylene Oxide

 Use By

Catalog Number

Lot Number

MR Conditional