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WARNINGS AND PRECAUTIONS FOR THE USE OF THE BIOMET MICROFIXATION STERNALOCK® SYSTEM

ATTENTION OPERATING SURGEON

DESCRIPTION

Biomet Microfixation manufactures and distributes the Biomet Microfixation Sternalock® System. It is intended for use in the stabilization and fixation of fractures of the anterior chest wall including sternal fixation following sternotomy and sternal reconstructive surgical procedures to aid in the alignment and stabilization of bone. Instrumentation has been designed specifically for use with this system of implants.

IMPLANT MATERIAL: Commercially Pure Titanium, ASTM F-67
Titanium 6Al 4V Alloy, ASTM F-136

INDICATIONS

The Biomet Microfixation Sternal Closure System is intended for use in the stabilization and fixation of fractures of the anterior chest wall including sternal fixation following sternotomy and sternal reconstructive surgical procedures, to promote fusion.

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. 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. 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. 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 of screws can occur if excessive force (torque) is applied while seating bone screws.
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. Plate position shall not extend across both costal margins. (When plating the sternum, long straight plates should be placed vertically.)

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.

Instruments are available for each implant system to aid in the accurate 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.

BIOMET IMPLANTS IN THE MAGNETIC RESONANCE (MR) ENVIRONMENT: The effects of the MR environment have not been determined for this device. This device has not been tested for heating or migration in the MR environment.

Bone Plates:
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 device breakage.
- 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 fit of the screw head.
- Cutting bone plates may increase the risk of failure of the implant. If the operating surgeon elects to cut a plate, 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.

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.

Twist Drills:
- Twist drills are labeled for single use only.
- When using twist drills, appropriate cooling is necessary to minimize thermal damage to bone tissue. It should be combined with low speed drilling to prevent the risk of bone demineralization and possible loosening of the bone screw and injury to patient.
- The manufacturers instructions for the hand piece used with the twist drill must be followed. The manufacturer of the handpiece may recommend proper speeds to avoid failures such as breakage of the twist drill.
- Excessive force may cause unusual stress conditions and result in breakage or fracture of the device.
- Breakage of twist drills may result in injury to the patient, the user, or third party.

CLEANING
Prior to sterilization, all implants 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. For additional cleaning information, contact Biomet Microfixation Regulatory Affairs department fax 904-741-9425.

STERILITY

Unless supplied sterile, implantable devices must be sterilized prior to surgical use. Unused implants can be re-sterilized. Where specified, do not use implants after expiration date. 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 ^{o} Fahrenheit (132^{o} 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.

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.

STERNALOCK® SURGICAL PROTOCOL

The following procedure is presented to demonstrate the techniques for insertion of the Sternalock® Implants utilized by Jai Raman, MD, MMed FRACS PhD, Director of Adult Cardiac Surgery & Cardiothoracic Surgical Research of University of Chicago.

1. The first step in the successful application of the SternaLock® system is to dissect all soft tissue from the surface of the sternum to allow for complete visualization of the bone. Optimally the soft tissue is dissected to reveal the costal cartilage on both sides of the sternum. Performing this step before the sternotomy decreases the likelihood of off mid-line sternotomy, a potential precursor to dehiscence. This step should also be followed in revision cases where wire is removed due to sternal non-union or for re-operation. In addition to dissecting the soft tissue from the sternum in the revision patient, bony calluses should also be removed from the midline and sternal surface to allow for proper anatomical reduction and plate placement.
2. Complete the intended surgical procedure.
3. Examining the sternum before closure: Closely examine the sternum before anatomical reduction to identify transverse fractures. Marking all transverse fractures before reduction of the sternotomy allows for easy fracture identification after anatomical reduction is performed.
4. Precise sternal depth measurements should also be taken at this time. Measurements should be recorded at the anticipated plate locations before bone reduction to insure the selection of appropriate screws.
5. The sternum should be reduced using the bone reduction forceps found in the SternaLock® Instrument tray. To reduce the sternotomy at the body of the sternum, place the approximating ends of the reduction forceps in the intercostals spaces on either side of the sternum and slowly bring the sternum together. During this process be careful to observe the midline for protruding internal tissue and proper bony alignment. Be careful not to place the reduction forceps in the area of a fracture line. Placing the reduction forceps at the Manubrium and the Xyphoid can attain proper anatomical reduction. Maintain static compression on the sternum by locking the reduction forceps in place. The forceps can be rotated to allow for easy access to all sternal regions.

Alternate Reduction: The sternum can be reduced with the assistance of appropriate sized Stainless Steel suture at the Xyphoid and Manubrium. Reduction forceps are used in the mid-body of the sternum to ensure full approximation. CAUTION: Putting dissimilar metals and alloys in contact with each other may be detrimental to the patient and/or function of the implant(s).

'The SternaLock® system offers plate options to accommodate anatomical variation. The typical sternum is plated using a four-hole "L" plate on the Manubrium, an eight hole "X" plate in the body of the sternum and an eight-hole "X" plate as inferiorly as possible near the Xyphoid. The "L" and "T" plates are typically used to fixate transverse fractures where the larger shapes are not anatomically appropriate. Place the first "X" plate in the body of the sternum with the cuttable cross-sections running perpendicular to and across the sternotomy line. Care should be taken to keep the plate centered over the sternotomy. The "X" plate can be placed over the sternotomy either lengthwise or across the sternum with four holes on each side of the sternotomy. With the plate positioned on the sternum, check for conformity to the sternal surface. It may be necessary to adapt the plate to provide for better fit to the sternum. However, it is not necessary for the plates to conform perfectly to the sternal surface. Should plate bending be necessary, benders are located in the SternaLock® Instrument tray.

Experience has shown that the following plate configurations are usually standard:

Manubrium	1 L Plate
Body of Sternum	1 vertical X-Plate
Lower Sternum	1 vertical X-Plate

6. Using the measurements recorded during the examination of the sternum, select the appropriate screw length for that location of the plate. Screw length is chosen by adding, **at the most**, 2mm to the full thickness of the selected sternal region. Please refer to the chart below for a summary of suggested screw lengths to use based on measured sternal depth. **(NOTE: If using the Sternalock® Blu Screw Sizer to measure sternal depth, the 2mm maximum length has already been added to the screw length marking on the sizer. Evaluate the size of screw to use accordingly, as appropriate for the patient.)** 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.

Depth of Sternum where Plate will be Placed	Recommended Screw Length
6.0-7.0 mm	8.0 mm
8.0-9.0 mm	10.0 mm
10.0-11.0 mm	12.0 mm
12.0-13.0 mm	14.0 mm
14.0-15.0 mm	16.0 mm
16.0-17.0 mm	18.0 mm
18.0 mm or deeper	20.0 mm

Pairing the Biomet Microfixation Power driver with the SternaLock® screws greatly facilitates screw placement and reduces overall closure time.

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.

Typically one "X" Plate is placed in the body of the sternum first, at that time the reduction forceps may be removed and the remaining plates are placed in the manubrium and xyphoid.

7. Plate options and locations should be chosen to best fit the anatomy of each patient. When plating transverse fractures, take care to avoid placing screws on or near the fracture line. Span the fracture with a plate that appropriately fits the anatomy.

Note: To facilitate emergent reentry, avoid placing non-cuttable portions of the sternal plates over the sternotomy line.

Emergent Reentry:
If emergent reentry is necessary, the SternaLock® system plates feature a patent-pending cuttable section to allow for rapid access to the chest cavity. The SternaLock® plate 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.

Disclaimer: As the manufacturer of the SternaLock® System, Biomet Microfixation does not practice medicine and does not recommend this or any other product or surgical technique for use on a specific patient. The surgeon who performs any sternal closure procedure must determine the appropriate closure method and surgical procedure for each individual patient. The surgical technique portion of this insert is not intended for patients.

SYMBOLS

 Manufacturer

 Date of Manufacture

 Do Not Reuse

 Caution

 Sterilized using Irradiation

 Sterile

 Use By

 Catalogue Number

 Batch Code

 Authorised Representative in the European Community