pg. 3 - Not tested for MRI

BIOMET MICROFIXATION
1520 Tradeport Drive
Jacksonville, FL 32218-2480 USA
Tel 904-741-4400 FAX 904-741-4500

CE 0086

01-50-1215
Revision: M
Date: 2017-04

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.

DIRECTIONS FOR USE

1. Determine sternal depth measurement to select appropriate screw length*.
2. Contour plates to patient anatomy, if needed.
3. Align plates such that the cuttable cross-sections span the sternotomy line.
4. Confirm approximation of sternal halves.
5. 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	1 L Plate
Body of Sternum	1 vertical X-Plate
Lower Sternum	1 vertical X-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.

***Screw selection:** Measure the sternal depth at each location of expected implant placement. 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.)**

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	18.0mm
18.0mm or deeper	20.0 mm

Pairing the Biomet Microfixation Power Driver with the SternaLock® screws greatly facilitates screw placement and reduces overall closure time. The Power Driver may not fully seat screws. Screws should always be locked in place using a manual screw driver.

BIOMET IMPLANTS IN THE MAGNETIC RESONANCE (MR) ENVIRONMENT: The Biomet Microfixation Sternal Closure System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Biomet Microfixation Sternal Closure System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury. The risks associated with a passive implant in the MR environment are known to include heating, migration, and image artifacts at or near the implant site.

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.
- 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.
- 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.

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 manufacturer's instructions for the hand-piece used with the twist drill must be followed. The manufacturer of the hand-piece 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 AND STERILIZATION
Unless otherwise indicated, instruments are NOT STERILE and must be thoroughly cleaned and sterilized prior to use. Instruments that are not clean may not be effectively sterilized. Automated cleaning using a washer/disinfector alone may not be effective for complex instruments with lumens, cannulations, blind holes, mated surfaces, and other features. **Do not clean soiled instruments while in polymer or metal trays.**

Single-use implants and single-use instruments are for single use only and are not reusable. Single-use implants and single-use instruments that have contacted blood, bone, tissue, or other bodily fluids – even if the device was not used – must not be reprocessed and must be discarded. Single use implants and single use instruments must be cleaned separately from soiled instruments.

The health care facility is responsible to ensure that conditions essential to safe handling and cleaning/disinfection can be achieved. Cleaning should be performed by trained medical personnel. Cleaning agents with low foaming surfactants should be used during manual cleaning procedures to ensure that instruments are visible in the cleaning solution. Manual scrubbing with brushes should always be performed with the instrument below the surface of the cleaning solution to prevent generation of aerosols and splashing which may spread contaminants. Cleaning agents must be completely rinsed from device surfaces to prevent accumulation of detergent residue.

Surgical instruments and instrument cases are susceptible to damage for a variety of reasons including the following: prolonged use; misuse; and rough or improper handling. Care must be taken to avoid compromising the performance of the surgical instruments and instrument cases. To minimize damage and risk of injury, the following should be done:

- Inspect the instrument case and instruments for damage upon receipt and after each use and cleaning. Do not use damaged instruments or instrument cases.
- Only use an instrument for its intended purpose.
- When handling sharp instruments, use extreme caution to avoid injury.
- Alkaline detergents with a pH ≤ 12 may be used to clean stainless steel and polymer instruments; however, it is critical that alkaline cleaning agents are thoroughly neutralized and rinsed from instruments. The use of alkaline cleaning agents

might be corrosive to the surface of aluminum and titanium instruments and produce cosmetic defects in the instruments. Drill bits, reamers, rasps and other cutting instruments should be carefully inspected after processing with alkaline detergents to ensure that cutting edges are fit for use.

- Metal brushes or scouring pads must not be used during manual cleaning procedures. These materials will damage the surface and finish of the instruments. Soft-bristled, nylon brushes and pipe cleaners should be used.
- Do not stack instruments or place heavy instruments on top of delicate devices.
- Saline and cleaning/disinfection agents containing aldehyde, mercury, active chlorine, chloride, bromine, bromide, iodine, or iodide are corrosive and should not be used. Instruments must not be placed or soaked in Ringers Solution.
- Descaling agents that include morpholine should not be used in steam sterilizers. These agents leave residue which can damage polymer instruments over time. Steam Sterilizers should be descaled in accordance with the manufacturer's instructions.
- Polymers used in instrument sets can be sterilized using steam/moist heat. Polymer materials have a limited useful life. If polymer surfaces turn "chalky," show excessive surface damage (e.g. crazing or delamination), or shows excessive distortion or is visibly warped, the instrument should be replaced.
- Most currently available polymers will not withstand conditions in washers/sterilizers that operate at temperatures equal to or greater than 141°C / 285°F, and use live-stream jets as cleaning features. Severe surface damage to polymer instruments may occur under these conditions.
- Stainless steel instruments may be treated with rust removal agents approved for surgical instruments if needed.
- Titanium and titanium alloy devices are especially susceptible to discoloration from steam impurities and detergent residues which form multi-colored surface layers of oxide deposits. Upon repeated sterilization, these oxide layers, while not harmful to the patient, may become dark and obscure graduation marks, item and lot numbers, and other stamped or etched information. Acidic, anti-corrosion agents may be used to remove this discoloration as needed.
- Use of hard water should be avoided. Softened tap water may be used for initial rinsing. Deionized (DI) water should be used for final rinsing to eliminate mineral deposits on instruments.

Cleaning and Disinfection

A. Point-of-Use Preparation for Reprocessing
Remove excess body fluids and tissue from instruments with a disposable, non-shedding wipe. Place instruments in a basin of distilled water or in a tray covered with damp towels. DO NOT allow saline, blood, body fluids, tissue, bone fragments, or other organic debris to dry on instruments prior to cleaning. Note: Soaking in proteolytic enzyme solutions or other pre-cleaning solutions facilitates cleaning, especially in instruments with complex features and hard-to-reach areas (e.g. cannulated and tubular designs, etc). These enzymatic solutions as well as enzymatic foam sprays break down protein matter and prevent blood and protein-based materials from drying on instruments. Manufacturer's instructions for preparation and use of the solutions should be explicitly followed. For optimal results, instruments should be cleaned within 30 minutes of use or after removal from solution to minimize the potential for drying prior to cleaning. Used instruments must be transported to the central supply in closed or covered containers to prevent unnecessary contamination risk. Do not place soiled instruments back into the instrument case.

B. Preparation Before Cleaning
Where applicable, multi-component instruments should be disassembled for appropriate cleaning. Care should be exercised to avoid losing small screws and components.

C. Preparation of Cleaning Agents
Neutral pH, enzymatic, and alkaline cleaning agents with low foaming surfactants are recommended. Alkaline agents with pH ≤ 12 may be used in countries where required by law or local ordinance. Alkaline agents should be followed with a neutralizer and/or thorough rinsing. Only agents with proven efficacy (VAH listed, or CE marked, where applicable) should be used. As a large variety of cleaning agents and disinfectants exists around the globe, no specific brand is recommended. It is important to select enzymatic solutions intended for breakdown of blood, body fluids, and tissues.

D. Combination Cleaning and Disinfection Instructions
1. Completely submerge the instruments in an enzyme or alkaline (pH ≤ 12) solution and allow to soak and sonicate for 10 minutes at 40-50 kHz. If using enzymatic cleaning agents, use a soft nylon bristled brush to gently scrub the instrument until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors, and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft nylon bristled brush (i.e. pipe cleaner). Use of a syringe or water jet will improve flushing of difficult to reach areas and closely mated surfaces.
2. Remove instruments from the cleaning solution and rinse in deionized (DI) water for a minimum of 1 minute. Thoroughly and aggressively flush lumens, blind holes, and other difficult-to-reach areas.
3. Place instruments in a suitable washer/disinfector basket and process through a standard instrument washer/disinfector cleaning cycle. Do not clean instruments inside of provided instrument case (where applicable), this may result in stacked instruments not properly cleaned and disinfected. The minimum parameters in Tables 1 and 2 are essential for thorough cleaning and disinfection.

Table 1 – Typical U.S. Automated Washer/Disinfector Cycle for Surgical Instruments

Step	Description
1	2 minute prewash with cold tap water

2	20 second enzyme spray with hot tap water
3	1 minute enzyme soak
4	15 second cold tap water rinse (twice)
5	2 minute detergent wash with hot tap water (64-66°C / 146-150°F)
6	15 second hot tap water rinse
7	2 minute thermal rinse (80-93°C / 176-200°F)
8	10 second deionized (DI) water rinse with optional lubricant (64-66°C / 146-150°F)
9	7 to 30 minute hot air dry (110°C / 240°F)

Table 2 – Typical European Automated Washer/Disinfector Cycle for Surgical Instruments

Step	Description
1	5 minute pre-rinse with cold tap water
2	10 minute alkaline cleaning agent wash at 55°C
3	2 minute rinse with neutralizer
4	1 minute rinse with cold tap water
5	Disinfection at 93°C with hot deionized (DI) water until A_0 3000 is reached (approximately 10 minutes)
6	40 minute hot air drying at 110°C

Sterile Packaging

- The hospital is responsible for in-house procedures for the reassembly, inspection, and packaging of the instruments after they are thoroughly cleaned in a manner that will ensure steam sterilant penetration and adequate drying. Provisions for protection of any sharp or potentially dangerous areas of the instruments should also be recommended by the hospital.

A. Packaging of Individual Devices
   - Single devices should be packaged in a medical-grade sterilization pouch or wrap which conforms to the recommended specifications for steam sterilization provided in Table 3. Ensure that the pouch or wrap is large enough to contain the device without stressing the seals or tearing the pouch or wrap.
   - The sterilization wrap used should be FDA cleared, where geographically applicable.

B. Packaging Instrument Sets in Rigid Trays and Cases with Lids
   - If an instrument case is provided with the system, implants and instruments may be loaded into their designated locations for sterilization (as applicable). The lid should be secured tightly. If the lid does not close properly, ensure the devices are placed in their appropriate locations and that the instrument case is not over-loaded.
   - Instrument cases may be placed in an approved sterilization container (e.g. Aesculap) with gasketed lids at the user's discretion. Follow the sterilization container manufacturer's instructions for inserting and replacing sterilization filters in sterilization containers.
   - Alternatively, trays and cases with lids may be wrapped in standard medical grade, steam sterilization wrap using the double-wrap method or equivalent.
   - The sterilization wrap or container should be FDA cleared, where geographically applicable.

Sterilization

- Flash (immediate-use) steam sterilization is not recommended.
- Steam sterilizer manufacturer recommendations should always be followed. When steam sterilizing multiple instrument sets in one sterilization cycle, ensure that the manufacturer's maximum load is not exceeded.
- See Table 3 for recommended minimum steam sterilization parameters in the United States that have been validated to provide a 10^{-6} sterility assurance level (SAL). Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in the table.

Table 3 – Recommended Steam Sterilization Parameters for the United States

Cycle Type	Temperature	Exposure Time	Minimum Dry Time[1]	Minimum Cool Time[2]
U.S. Prevacuum	132°C / 270°F	4 Minutes	30 Minutes	30 Minutes

[1]Drying times vary according to load size and should be increased for larger loads.
[2]Cooling times vary according to the type of sterilizer used, device design, temperature and humidity of ambient environment, and type of packaging used.

- See Table 4 for recommended minimum steam sterilization parameters outside the United States that have been validated to provide a 10^{-6} sterility assurance level (SAL). Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in the table.

Table 4 – Recommended Steam Sterilization Parameters for Outside the United States

Cycle Type	Temperature	Exposure Time	Minimum Dry	Minimum Cool

			Time[1]	Time[2]
U.K. Prevacuum	134°C / 273°F	3 Minutes	30 Minutes	30 Minutes
Prevacuum[3,4]	134°C / 273°F	18 Minutes	30 Minutes	30 Minutes

[1]Drying times vary according to load size and should be increased for larger loads.
[2]Cooling times vary according to the type of sterilizer used, device design, temperature and humidity of ambient environment, and type of packaging used.
[3]Disinfection/steam sterilization parameters recommended by the World Health Organization (WHO) for reprocessing instruments where there is concern regarding TSE/CJD contamination.
[4]This cycle is not to be used for the inactivation of prions.

Storage and Shelf Life

- Sterile, packaged devices should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/humidity extremes.
- Care must be exercised to prevent damage to the sterile barrier.
- The health care facility should establish a shelf life for sterilized devices based on the type of sterile wrap or rigid container used and the recommendations of the sterile wrap or rigid container manufacturer.
- Sterile device packages should be carefully examined prior to opening to ensure that package integrity has not been compromised. If a sterile wrap is torn, perforated, shows an evidence of tampering, or has been exposed to moisture, the instrument set must be cleaned, repackaged, and sterilized. If there is any evidence that the lid seal or filters on a sterilization container have been opened or compromised, the sterile filters must be replaced and the instrument set resterilized.

℞ Only **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.

Authorized Representative:
Biomet UK, Ltd.
Waterton Industrial Estate
Bridgend South Wales
CF31 3XA UK
TEL (+44) 1656 655221
FAX (+44) 1656 645454

European Sales Headquarters:
Biomet Microfixation Europe
Toermalijnring 600
3316 LC Dordrecht
Netherlands
Tel. +31 78 629 29 10
Fax +31 78 629 29 12

Emergent Reentry:
If emergent reentry is necessary, the SternaLock® system plates feature a patented 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.

SYMBOLS

 Manufacturer

 Date of Manufacture

 Do Not Reuse

℞ Only Federal Law (USA) restricts this device to sale by or on the order of a physician, dentist or properly licensed practitioner.

 Caution

REF Catalogue Number

Batch Code

Authorized Representative in the European Community