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WARNINGS AND PRECAUTIONS FOR THE USE OF THE BIOMET MICROFIXATION THORACIC FIXATION SYSTEM

ATTENTION OPERATING SURGEON

DESCRIPTION
Biomet Microfixation manufactures and distributes the Biomet Microfixation Thoracic Fixation System for use in the fixation and stabilization of fractures and osteotomies of the chest wall. Devices include metallic plates and screws to provide rigid fixation of bone. Instrumentation has been designed specifically for use with this system of implants.

IMPLANT MATERIAL:
Commercially Pure Titanium
Titanium 6Al 4V Alloy

INDICATIONS
The Biomet Microfixation Thoracic Fixation System is indicated for use in the stabilization and fixation of fractures in the chest wall including sternal reconstructive surgical procedures, trauma, or planned osteotomies. The system may be used in normal and poor bone to promote union.

CONTRAINDICATIONS
1. Spanning a midline sternotomy.
2. Active infection.
3. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation.
4. 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 bone 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 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. Do not position devices in a manner such that screw attachment or fixation is to the clavicle or spine.
2. Plate position shall not extend across both costal margins. (When plating the sternum, long straight plates should be placed vertically.)
3. 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).
4. 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.
5. Intraoperative fracture of screws can occur if excessive force (torque) is applied while seating bone screws.
6. 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.
7. 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.

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 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 SAFETY INFORMATION: The safety of the Biomet Microfixation Thoracic Fixation System in the MR environment is unknown. High heating may occur at or near the implant site. Other risks associated with a passive implant in the MR environment include device migration and image artifact. Scanning a patient who has this device may result in patient injury.

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.
- Bone plates do not include a cuttable cross-section for emergent re-entry; 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.
- 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.

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.
- 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 bony region. Please refer to the chart below for a summary of suggested screw lengths to use based on measured bone depth. **(NOTE: If using the Sternalock® Blu Screw Sizer to measure bone 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.

Depth of Bone Where Plate will be Placed	Recommended Screw Length
5.0-6.0mm	7.0mm
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

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 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.

DIRECTIONS FOR USE

1. Access fracture/prepare osteotomy
2. Select appropriate plate
3. Cut and/or bend plate to appropriate shape if necessary
4. Select appropriate length screw
5. Reduce fracture/osteotomy
6. Place plate so that a minimum of three screws may be able to be placed on either side of the fracture/osteotomy
7. Place screws

CLEANING

Instrumentation supplied with this system is reusable unless specifically stated otherwise in this IFU or on the outer packaging labeling. Prior to sterilization, all implants and instrumentation must be carefully cleaned and inspected. It is important to confirm that implants which are returned for processing from the operating room have not touched the defect, entered the operative site, or come in contact with a patient's blood or other fluid as they may have been compromised. Compromised implants should be discarded and may not be cleaned and re-sterilized. Cleaning should be performed by trained medical personnel.

The scope of the following cleaning method is to be used prior to implantation for implants that **HAVE NOT BEEN COMPROMISED**, as described above, and for instrumentation, including soiled instrumentation, as applicable. **Compromised implants should be discarded and may not be cleaned and re-sterilized.**

NOTE: **DO NOT ALLOW SOILED INSTRUMENTS TO DRY**

- Immerse or use damp towels with deionized or distilled water to keep soiled instruments moist prior to cleaning.
- For instruments contaminated with blood and body fluids (e.g. protein), use of an enzyme product is recommended to facilitate cleaning.
- Use of a residue free detergent is recommended.
- Mechanical cleaning (i.e. washer-disinfection/washer-decontamination equipment) using equipment designed for medical devices is recommended. Automatic washers/disinfectors should be operated as instructed by the manufacturer.

Cleaning Instructions using an Automatic Washer/Disinfector and Detergent

1. Disassemble reusable instruments from powered hand piece (powered hand pieces not supplied by Biomet Microfixation, Inc.).
2. Pre-rinse by hand
   Remove gross contamination from all soiled instruments under cool to tepid running tap water using an instrument brush to scrub all surfaces of each instrument until visibly clean. Wear protective gloves and goggles during this step.
3. Loading an Instrument Case, if applicable:
   After visually removing gross contamination, the instruments may be placed into a Container/Case. Unused screws are placed into the smaller case, as applicable. The larger surgical instruments should fit into the remaining space so that the lid of the case is easily closed. If the lid of the case will not close, the case is overloaded. Remove excess instrumentation until the case/container closes.

   Warning: Only use the appropriate Biomet Microfixation Container with the Biomet Microfixation System devices being used.

   Pre-wash cycle: optional (if not available, proceed to instruction #4)
   Do not use detergent in this cycle. Pre-wash in deionized or distilled water. *Minimum cycle parameters: 4 minutes at 49°C or 120° F*

4. Wash Cycle
   Use a residue free detergent per manufacturer's instructions. *Minimum cycle parameters: 12 minutes at 49°C or 120°F*
5. Final Rinse/Thermal Disinfect Rinse
   DO NOT USE cleansing agents during this final cycle.
   After the wash cycle, a final rinse cycle using deionized water for a *minimum of 4 minutes at 30°C or 86°F* or a thermal disinfect cycle at an elevated temperature of *85°C or 185°F* should be used.
6. Visual Inspection
   At the end of the cleaning cycle, visually inspect the devices to ensure they are "visually clean". If they are not, repeat cleaning instructions 2-6.

   Warning: Do not, under any condition, reuse implants that entered the operative site. Sterilized unused implants that did not enter the operative site can be cleaned as above and re-sterilized using the steam (autoclave) sterilization parameters below.

   Precaution for reusable trials, instruments and instrument cases:
   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

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° 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.

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

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.

EC REP

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SYMBOLS

 Manufacturer

 Date of Manufacture

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 Do Not Reuse

 Caution

 Catalogue Number

 Batch Code

EC REP Authorized Representative in the European Community