6.5.4.2. only in the medical and surgical aspects of the implant, but must also be aware of the mechanical effect on the performance of the implant. The surgeon must be thoroughly knowledgeable not procedures, trauma, or planned osteotomies. The system may be used in normal and poor bone stabilization and fixation of fractures in the chest wall including sternal reconstructive surgical procedures.

**DESCRIPTION**

Biomet Microfixation manufactures and distributes the Biomet Microfixation RibFix Blu 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 6Al4V Alloy

**INDICATIONS**

The Biomet Microfixation RibFix Blu 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 loss of bone, bone loss or bone breakage. The implant can be expected to bend, break, or fail. Therefore, it is important that immobilization of the fracture site 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 is 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.

**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 is 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 placing the sternum, long straight plates should be placed vertically.)
3. Implant materials are subject to corrosion. Implantaing 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. Intraperiosteal 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 fracture 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 care 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 senile 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 re-use 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 incaulable risks for the implant and instrument, thereby potentially endangering the patient, user, or third party.

**MR SAFETY INFORMATION:**

The safety of the Biomet Microfixation RibFix Blu 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.

<table>
<thead>
<tr>
<th>Depth of Bone Where Plate will be Placed</th>
<th>Recommended Screw Length</th>
<th>Screw Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.0 - 6.0 mm</td>
<td>7.0 mm</td>
<td></td>
</tr>
<tr>
<td>6.0 - 7.0 mm</td>
<td>8.0 mm</td>
<td></td>
</tr>
<tr>
<td>8.0 - 9.0 mm</td>
<td>10.0 mm</td>
<td></td>
</tr>
<tr>
<td>10.0 - 11.0 mm</td>
<td>12.0 mm</td>
<td></td>
</tr>
<tr>
<td>12.0 - 13.0 mm</td>
<td>14.0 mm</td>
<td></td>
</tr>
<tr>
<td>14.0 - 15.0 mm</td>
<td>16.0 mm</td>
<td></td>
</tr>
<tr>
<td>16.0 - 17.0 mm</td>
<td>18.0 mm</td>
<td></td>
</tr>
<tr>
<td>18.0 mm or deeper</td>
<td>20.0 mm</td>
<td></td>
</tr>
</tbody>
</table>

Pairing the Biomet Microfixation Power Driver with the 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.
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 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 AND STERILIZATION

Cleaning and Disinfection

Cleaning agents with low foaming surfactants should be used during manual cleaning/disinfection can be achieved. Cleaning should be performed by trained medical personnel. 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 based on the manufacturer’s instructions. The sterilization wrap used should be FDA cleared, where applicable. 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.

Point-of-Use Preparation for Reprocessing

- 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 surfacants 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, chlorine, 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

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 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

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

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2 minute prewash with cold tap water</td>
</tr>
<tr>
<td>2</td>
<td>20 second enzyme spray with hot tap water</td>
</tr>
<tr>
<td>3</td>
<td>1 minute enzyme soak</td>
</tr>
<tr>
<td>4</td>
<td>15 second cold tap water rinse (twice)</td>
</tr>
<tr>
<td>5</td>
<td>2 minute detergent wash with hot tap water (64-66°C / 146-150°F)</td>
</tr>
<tr>
<td>6</td>
<td>15 second hot tap water rinse</td>
</tr>
<tr>
<td>7</td>
<td>2 minute thermal rinse (80-93°C / 176-200°F)</td>
</tr>
<tr>
<td>8</td>
<td>10 second denoized (DI) water rinse with optional lubricant (64-66°C / 146-150°F)</td>
</tr>
<tr>
<td>9</td>
<td>7 to 10 minute hot air dry (110°C / 240°F)</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5 minute pre-rinse with cold tap water</td>
</tr>
<tr>
<td>2</td>
<td>10 minute alkaline cleaning agent wash at 55°C</td>
</tr>
<tr>
<td>3</td>
<td>2 minute rinse with neutralizer</td>
</tr>
<tr>
<td>4</td>
<td>1 minute rinse with cold tap water</td>
</tr>
<tr>
<td>5</td>
<td>Disinfection at 93°C with hot deinonized (DI) water until A&lt;sub&gt;2&lt;/sub&gt; 3000 is reached (approximately 10 minutes)</td>
</tr>
<tr>
<td>6</td>
<td>40 minute hot air drying at 110°C</td>
</tr>
</tbody>
</table>
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>
<thead>
<tr>
<th>Cycle Type</th>
<th>Temperature</th>
<th>Exposure Time</th>
<th>Minimum Dry Time</th>
<th>Minimum Cool Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. Prevacuum</td>
<td>132°C / 270°F</td>
<td>4 Minutes</td>
<td>30 Minutes</td>
<td>30 Minutes</td>
</tr>
</tbody>
</table>

\(^1\)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>
<thead>
<tr>
<th>Cycle Type</th>
<th>Temperature</th>
<th>Exposure Time</th>
<th>Minimum Dry Time</th>
<th>Minimum Cool Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.K. Prevacuum</td>
<td>134°C / 273°F</td>
<td>3 Minutes</td>
<td>30 Minutes</td>
<td>30 Minutes</td>
</tr>
<tr>
<td>Prevacuum(^*)</td>
<td>134°C / 273°F</td>
<td>18 Minutes</td>
<td>30 Minutes</td>
<td>30 Minutes</td>
</tr>
</tbody>
</table>

\(^*\)Disinfection/steam sterilization parameters recommended by the World Health Organization (WHO) for reprocessing instruments where there is concern regarding TSE/CJD contamination.

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 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.