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.

CONTRAINDICATIONS
1.  Spinal or thoracic, anterior or posterior, patients.
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.

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 implants 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 incautious 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.

1.  Care must be taken to achieve the appropriate contour with as few bends as possible. Repeated bending of titanium increases the risk of fracture.
2.  Sharp angles and small bending radii must be avoided to reduce the risk of device breakage.
3.  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.
4.  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.
5.  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. (NOTICE: if using the Sterinacl’s 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.

<p>| Depth of Bone Where |</p>
<table>
<thead>
<tr>
<th>Plate will be Placed</th>
<th>Recommended Screw Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.0-6.0mm</td>
<td>7.0mm</td>
</tr>
<tr>
<td>6.0-7.0 mm</td>
<td>8.0 mm</td>
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<tr>
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<tr>
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</tr>
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<td>16.0-17.0 mm</td>
<td>18.0 mm</td>
</tr>
<tr>
<td>18.0 mm or deeper</td>
<td>20.0 mm</td>
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Paireding 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.

CONTRAINDICATIONS
1.  Spinal or thoracic, anterior or posterior, patients.
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Paireding 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

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, 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 may 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 alcohol, mercury, active chlorine, chloride, 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 phosphoric 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 (VIA 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 matted 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

<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 deionized (DI) water rinse with optional lubricant (64-66°C / 146-150°F)</td>
</tr>
<tr>
<td>9</td>
<td>7 to 30 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>12 minute thermal rinse (80-93°C / 176-200°F)</td>
</tr>
<tr>
<td>6</td>
<td>10 second deionized (DI) water rinse at 93°C</td>
</tr>
<tr>
<td>7</td>
<td>40 minute hot air drying at 110°C</td>
</tr>
</tbody>
</table>

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

- 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>

Drying times vary according to load size and should be increased for larger loads.

For appropriate education and training within the scope of the activities which they are involved in the handling and use of this product.

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.

Table 3 – Recommended Steam Sterilization Parameters for the United States

<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>Prevacuum</td>
<td>134°C / 273°F</td>
<td>3 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.

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

<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>Prevacuum (SAL)</td>
<td>134°C / 273°F</td>
<td>18 Minutes</td>
<td>30 Minutes</td>
<td>30 Minutes</td>
</tr>
</tbody>
</table>

Drying times vary according to load size and should be increased for larger loads.

This cycle is not to be used for the inactivation of prions.

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.

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