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**WARNINGS AND PRECAUTIONS FOR THE
USE OF THE BIOMET MICROFIXATION
RIBFIX™ ADVANTAGE SYSTEM**

ATTENTION OPERATING SURGEON

DESCRIPTION

The RibFix Advantage System consists of bridges (with locking posts) and locking caps for the thoracoscopic fixation and stabilization of ribs.

IMPLANT MATERIAL:

These implants are manufactured from titanium and titanium alloys.

INDICATIONS

The RibFix Advantage System is indicated for the fixation, stabilization, and fusion of rib fractures and osteotomies of normal and osteoporotic bone.

CONTRAINDICATIONS

The RibFix Advantage system is contraindicated for:

1. Use in patients with latent or active infection, sepsis, and/or device material sensitivity.
2. Use in patients who are unwilling or incapable of following postoperative care instructions.
3. This device is not intended for locking post attachment or fixation to the clavicle or spine.

POSSIBLE ADVERSE EFFECTS

Possible adverse effects or complications include, but are not limited to, the following:

- Nonunion or delayed union which can lead to breakage of the implant.
- Metal sensitivity, or allergic reaction to a foreign body.
- Limb shortening due to compression of the fracture or bone resorption.
- Decrease in bone density.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Nerve damage due to surgical trauma.
- Necrosis of bone.
- Vascular changes.

WARNINGS

Correct selection of the implant is extremely important. The potential for success of fracture fixation is increased by the selection of the proper size, shape and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size and strength of implants. Metallic internal fixation devices cannot withstand activity levels and/or loads equal to those placed on normal healthy bone **as these devices are not designed to withstand the unsupported stress of full weight-bearing or load-bearing.**

- **These devices can break when subjected to the increased loading associated with delayed union or nonunion.** Internal fixation appliances are load sharing devices which hold a fracture in alignment until healing occurs. If healing is delayed, or does not occur, the implant could eventually break due to metal fatigue. Load produced by weight-bearing and activity levels will dictate the longevity of the implant. The patient should understand that stress on an implant can involve more than weight-bearing. In the absence of solid bony union, the weight of the limb alone, muscular forces associated with moving a limb, or repeated stresses of apparent relatively small magnitude, can result in failure of the implant. Notches or scratches put in the implant during the course of surgery may also contribute to breakage.
- **Corrosion.** Implanting metals and alloys in the human body subjects them to an aggressive chemical environment of salts, acids, and proteins, which can cause corrosion. Dissimilar metals in contact with each other can accelerate the corrosion process due to galvanic corrosion effects. Additionally, mixing of implant components from different manufacturers is not recommended, for metallurgical, mechanical and functional reasons.
- Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of implant breakage.
- This device is not intended for highly comminuted fractures.
- Any large hematoma or swelling/edema may impede visibility and/or identification of fracture. Draining may be required to facilitate visibility of the fracture.
- Draining may be required to facilitate visibility of the fracture. If adhesions or swelling are present and to ensure proper bridge fixation, removal of some soft tissue using thoracoscopic instrumentation may be needed where the resulting soft tissue volume would prevent the tips of the bridge scallops from contacting the underside of the rib.
- Bridge scallop tips must contact underside of rib.
- This system requires the surgeon to be skilled in video assisted thoracoscopic surgery (VATS).

PRECAUTIONS

Surgical implants must never be reused. An explanted metal implant must never be re-implanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

• **Correct handling of the implant is extremely important.** Contouring of metallic implants should be avoided where possible. If contouring is necessary, or allowed by design, the surgeon should avoid sharp bends, reverse bends, or bending the device at a locking post hole. The operating surgeon should avoid any notching or scratching of the device when contouring it. These factors may produce internal stresses which may become the focal point for eventual breakage of the implant.

• **Removal after fracture healing.** Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a fracture has healed, particularly in young, active patients. While the surgeon must make the final decision on implant removal, we recommend that whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished. Implant removal should be followed by adequate postoperative management to avoid re-fracture.

• **Adequately instruct the patient.** Postoperative care and the patient's ability and willingness to follow instructions are two of the most important aspects of successful fracture healing. This is particularly important should the device be used to treat an unstable fracture, such as intertrochanteric or subtrochanteric. The patient must be made aware of the limitations of the implant and that physical activity and full weight bearing or load bearing have been implicated in premature loosening, bending or fracture of internal fixation devices. The patient should understand that a metallic implant is not as strong as a normal, healthy bone and will fracture under normal weight bearing or load bearing in the absence of complete bone healing. Mental or physical impairment which compromises or prevents a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

MR SAFETY INFORMATION:

This device has not been evaluated for safety and compatibility in the MR environment. The device has not been tested for heating, migration, or image artifact in the MR environment. The safety of the RibFix Advantage System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

CLEANING

Cleaning Instruments, Manual

Step	Instructions
1	Disassemble device, if device can be disassembled, prior to cleaning. Refer to technique guide or other supplemental information for specific device disassembly and/or reassembly instructions.
2	Rinse soiled device under running cold tap water for a minimum of two minutes. Use a soft-bristled brush and/or syringes, pipettes and water jet to assist in the removal of gross soil and debris.
3	Soak device in a neutral pH enzymatic cleaner or detergent solution for a minimum of ten minutes. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality and concentration.
4	Rinse device with cold water for a minimum of two minutes. Use a syringe, pipette, or water jet to flush lumens, channels and other hard to reach areas.
5	Manually clean device for a minimum of five minutes in a freshly prepared, newly-made, clean neutral pH enzymatic cleaner or detergent solution. Use a soft-bristled brush to remove soil and debris. Actuate joints, handles and other movable device features to expose all areas to the detergent solution, if applicable.
6	Rinse device thoroughly with AAMI TIR 34 compliant water for a minimum of two minutes. Use a syringe, pipette or water jet to flush lumens and channels. Actuate joints, handles and other moveable device features to rinse thoroughly under running water, if applicable.
7	Visually inspect the device. Repeat steps 2- 6 of the manual cleaning procedure until no visible soil remains on device.
8	Visually inspect device for corrosion, damage such as scratches and notches, debris or discoloration.
9	Perform a final rinse on device using AAMI TIR 34 compliant water.
10	Dry device using a clean, soft, lint-free cloth or clean compressed air.

Cleaning Instruments, Manual and Ultrasonic

Step	Instructions
1	Disassemble device, if device can be disassembled, prior to cleaning. Refer to technique guide or other supplemental information for specific device disassembly and/or reassembly instructions.
2	Rinse soiled device under running cold tap water for a minimum of two minutes. Use a soft-bristled brush and/or syringes, pipettes and water jet to assist in the removal of gross soil and debris.
3	Soak device in a neutral pH enzymatic cleaner or detergent solution for a minimum of ten minutes. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality and concentration.
4	Rinse device with cold water for a minimum of two minutes. Use a syringe, pipette, or water jet to flush lumens, channels and other hard to reach areas.
5	Manually clean device for a minimum of five minutes in a freshly prepared, newly-made, clean neutral pH enzymatic cleaner or detergent solution. Use a soft-bristled brush to remove soil and debris. Actuate joints, handles and other movable device features to expose all areas to the detergent solution, if applicable.
6	Rinse device thoroughly with AAMI TIR 34 compliant water for a minimum of two minutes. Use a syringe, pipette or water jet to flush lumens and channels. Actuate joints, handles and other moveable device features to rinse thoroughly under running water, if applicable.
7	Visually inspect the device. Repeat steps 2- 6 of the manual cleaning procedure until no visible soil remains on device.

Step	Instructions
8	Visually inspect device for corrosion, damage such as scratches and notches, debris or discoloration.
9	Perform a final rinse on device using AAMI TIR 34 compliant water.
Above manual steps must be performed before Ultrasonic Cleaning, Biomet Microfixation does not recommend or support the use of solely an Ultrasonic Process.	
10	Prepare a newly-made, clean neutral pH enzymatic cleaner or detergent solution. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality and concentration.
11	Clean the RibFix Advantage device ultrasonically for a minimum of 15 minutes, using a minimum frequency of 40 KHz.
12	Rinse device thoroughly with water for a minimum of two minutes. Use a syringe, pipette or water jet to flush lumens and channels. Actuate joints, handles and other moveable device features to rinse thoroughly under running water, if applicable.
13	Visually inspect the device. Repeat steps 2-11 until no visible soil remains on device.
14	Perform a final rinse on the device using AAMI TIR 34 compliant water for a minimum of 15 seconds.
15	Dry the device using a clean, soft, lint-free cloth or clean compressed air.

Cleaning Instruments, Manual and Mechanical Washer

Step	Instructions																								
1	Disassemble device, if device can be disassembled, prior to cleaning. Refer to technique guide or other supplemental information for specific device disassembly and/or reassembly instructions.																								
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Above manual steps must be performed before Ultrasonic Cleaning, Biomet Microfixation does not recommend or support the use of solely a Mechanical Washer Process.																									
10	Process in Mechanical Washer using the following Cycle Parameters <table border="1" style="margin-left: 20px;"> <thead> <tr> <th>Cycle</th> <th>Minimum Time (minutes)</th> <th>Minimum Temperature / Water</th> <th>Type of Detergent</th> </tr> </thead> <tbody> <tr> <td>Pre-Wash</td> <td>2</td> <td>Cold tap water</td> <td>N/A</td> </tr> <tr> <td>Wash I</td> <td>2</td> <td>Cold to warm tap water</td> <td>Enzymatic with neutral pH</td> </tr> <tr> <td>Wash II</td> <td>5</td> <td>Warm tap water (>40°C)</td> <td>Detergent with neutral pH</td> </tr> <tr> <td>Rinse</td> <td>2</td> <td>Warm DI or PURW (>40°C)</td> <td>N/A</td> </tr> <tr> <td>Dry</td> <td>40</td> <td>90°C</td> <td>N/A</td> </tr> </tbody> </table>	Cycle	Minimum Time (minutes)	Minimum Temperature / Water	Type of Detergent	Pre-Wash	2	Cold tap water	N/A	Wash I	2	Cold to warm tap water	Enzymatic with neutral pH	Wash II	5	Warm tap water (>40°C)	Detergent with neutral pH	Rinse	2	Warm DI or PURW (>40°C)	N/A	Dry	40	90°C	N/A
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Wash I	2	Cold to warm tap water	Enzymatic with neutral pH																						
Wash II	5	Warm tap water (>40°C)	Detergent with neutral pH																						
Rinse	2	Warm DI or PURW (>40°C)	N/A																						
Dry	40	90°C	N/A																						
11	If a dry cycle is not included in the mechanical washer, dry the device using a clean, soft, lint-free cloth or clean compressed air.																								

Cleaning Implants

Implants are not recommended to be cleaned, however they must be terminally sterilized prior to use, instructions below. Additional cautions must be taken when processing implants:

- o Implants should not be lubricated
- o Implants must be inspected prior to sterilization. Any implant with corrosion, discoloration, scratches, flaws, residue, or debris should be removed.
- o Do not use steel wool or abrasive cleaners.
- o Avoid cross contamination of implants with soiled instruments during transport.

CAUTIONS AND ADDITIONAL INFORMATION

The instructions provided have been validated in a laboratory setting. It is the responsibility of the Hospital to ensure that reprocessing is performed using the appropriate equipment and materials, and that personnel in the reprocessing facility have been adequately trained in order to achieve the desired result. Equipment and processes should be validated and routinely monitored. Any deviation by the processor

from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.

If an implant has been explanted, become contaminated, found to be damaged, or come into direct contact with a patient, implant should be discarded following any hospital protocol and removing contaminated or damaged implants.

Hospital staff must wear appropriate protective equipment (PPE) when processing implants.

STERILIZATION

These devices may be offered STERILE and/or NONSTERILE. The following parameters are for sterilization of the individual nonsterile devices. Individual sterile devices/sets may not be resterilized, a new device/set would be needed. Note: New non-sterile implants do not require cleaning prior to sterilization.

Cycle Type	Sterilization Exposure Time	Sterilization Exposure Temperature	Min Dry Time*
Pre-vacuum	4 minutes	132°C (270°F)	20 minutes

These parameters are validated to sterilize only these devices. The device manufacturer's validated sterilization parameters and the autoclave manufacturer's operating instructions should be followed. The autoclave must be properly installed, maintained, and calibrated. Only legally marketed, FDA cleared sterilization wrap, pouches, or containers should be used by the end-user for packaging terminally sterilized devices. Steam Sterilization is not recommended in any other container other than that provided by Biomet Microfixation.

*Dry times may be highly variable due to the differences in packaging materials (e.g. non-woven wraps), environmental conditions, steam quality, device materials, total mass, sterilizer performance and varying cool down time. The user should employ verifiable methods (e.g. visual inspections) to confirm adequate drying.

Immediate Use Sterilization

Biomet Microfixation does not recommend or support the Immediate Use sterilization method for implant or instruments.

The cleaning and sterilization information is provided in accordance with ANSI/AAMI ST81, AAMI TIR 12, ISO 14937, ANSI/AAMI ST79, AAMI ST77, ANSI/AAMI/ISO 17665.



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.

All trademarks herein are the property of Zimmer Biomet or one of its subsidiaries unless otherwise indicated.

SYMBOLS



Manufacturer



Date of Manufacture



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



Do Not Reuse



Caution



Catalogue Number



Batch Code