

ORTEMIZ SMALL / MINI FRAGMENT PLATE SYSTEM INDICATIONS FOR USE

The ORTEMIZ Small / Mini Fragment Plate System is indicated for the fixation of fractures, mal-unions, non-unions or osteotomies for the clavicle, humerus, radius, ulna, metacarpal, tibia, fibula, malleolus and metatarsal.

CONTRAINDICATION

1. Sensitivity to implant material
2. Active or latent infection
3. Osteoporosis
4. Insufficient quantity or quality of bone/soft tissue
5. Conditions which tend to retard healing such as, blood supply limitations, previous infections, etc.
6. Insufficient quantity or quality of bone to permit stabilization of the fracture complex and/or fusion of the joints.
7. Conditions that restrict the patient's ability or willingness to follow postoperative instructions during the healing process.
8. Cases with malignant primary or metastatic tumors which preclude adequate bone support or screw fixations unless supplemental fixation or stabilization methods are utilized.

WARNINGS AND PRECAUTIONS

For safe and effective use of this implant, the surgeon must be thoroughly familiar with the implant, the method of application, instruments, and the recommended surgical technique for this device. The device is not designed to withstand the stress of weight bearing, load bearing, or excessive activity. Device breakage or damage can occur when the implant is subjected to increased loading associated with delayed union, nonunion, or incomplete healing. Improper insertion of the device during implantation can increase the possibility of loosening and migration. The patient must be cautioned, preferably in writing, about the use, limitation, and possible adverse effects of this implant including the possibility of the device failing as a result of loose fixation, stress, excessive activity, or weight bearing or loading bearing, particularly if

the implant experiences increased loads due to delayed union, nonunion, or incomplete healing. The patient must be warned that failure to follow postoperative care instructions can cause the implant and/or treatment to fail. Osteoporotic patients are also at risk for loss of fixation and construct failure due to the poor quality of their bone.

Once applied, the implant should never be reused. Although it may appear undamaged, previous stresses may have created imperfections that could reduce its service life.

Even with anatomic reduction, lack of fracture gap and appropriate construct creation, initial weight bearing restrictions are indicated. In order to prevent loss of correction and premature plate failure, it is recommended that partial weight bearing be instituted for 6-12 weeks followed by advancement to full weight bearing only when radiographs confirm significant callus and bony healing.

Instruments shall be inspected for wear or damage prior to usage.

Protect implant appliances against scratching and nicking, which may cause stress concentrations leading to failure. Plate shape should only be altered using the provided bending and cutting instruments. When bending plates, care should be taken to avoid repeated bending at a single site along the plate.

In no case should an implant be sharply bent, notched, gouged, reamed, or scratched.

The ORTEMIZ Small / Mini Fragment Plate System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of ORTEMIZ Small / Mini Fragment Plate System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

The system is to be used only in skeletally mature adult patients.

ADVERSE EFFECTS

Fracture of the implant due to excessive activity, prolonged loading upon the device, incomplete healing, or excessive force exerted on the implant during insertion. Implant migration and/or loosening.

Metal sensitivity or histological or allergic reaction resulting from implantation of a foreign material.

Pain, discomfort, or abnormal sensations due to the presence of an implant.

Nerve damage resulting from surgical trauma.

Necrosis of bone or bone resorption. Necrosis of tissue or inadequate healing.

CLEANING INSTRUCTIONS

Implants, components and sterilization trays are supplied non-sterile and must be thoroughly cleaned and sterilized prior to surgery. For non-sterile trauma implants remove all original packaging and labeling inserts prior to cleaning and sterilization. New implants and instruments must be thoroughly cleaned before initial sterilization. Trained personnel must perform the cleaning outlined in the Cleaning of Instruments and Sterilization Tray, Automated Washer section of this instruction sheet prior to initial sterilization. Exact compliance with the equipment manufacturers' user instructions and recommendations for chemical detergents is required.

LIMITS ON REPROCESSING:

Repeated processing cycles that include ultrasonic, mechanical washing and sterilization have minimal effects on ORTEMIZ implants and instruments. Implants and instruments should be inspected for damage such as corrosion, scratches, notches, debris, visible wear, discoloration or residue. Damaged implants and instruments should be discarded.

CLEANING OF INSTRUMENTS AND STERILIZATION TRAY

1. Within a maximum of two (2) hours after use, remove visible soil using absorbent paper wipes. Rinse with warm (>45°C) tap water for two (2) minutes. Flush cannulated devices thoroughly to prevent the drying of soil and/or debris to the inside.
2. If cleaning must be delayed, place instruments in a covered container with appropriate detergent (Enzol® Enzymatic Detergent or equivalent) to delay drying.
3. Disassemble device, if possible, prior to cleaning. Detailed instructions for assembling and disassembling the instruments are contained in the surgical technique guide.
4. Tap water used for cleaning and rinsing will meet the characteristics for potable water in AAMI TIR34. Reverse osmosis water or distilled water will meet the characteristics

listed in AAMI TIR34.

Manual Cleaning:

1. Rinse soiled device under running cold (<45°C) tap water for a minimum of two minutes. Use a soft bristled brush to assist in the removal of visible soil and debris.
2. 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.
3. Rinse device with cold (<45°C) tap water for a minimum of two minutes. Use a syringe, pipette, or water jet to flush lumens, channels and other hard to reach areas.
4. Manually clean device for a minimum of five minutes in a freshly prepared neutral pH enzymatic cleaner or detergent solution. Use a soft bristled brush to remove soil and debris. Actuate joints, handles and other moveable device features to expose all areas to the detergent solution.
5. Rinse device thoroughly with cold (<45°C) reverse osmosis water or distilled 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 devices.

Automated Cleaning:

1. Pre-Treatment is required for any instrument(s) heavily soiled and/or containing visible dried organic material: Add one (1) ounce of Enzol® (or equivalent) to one (1) gallon of cold (<45°C) tap water. Using a soft bristle brush, clean the instrument thoroughly, paying particular attention to rough surfaces and features where soil may be impacted or shielded from the cleaning process. Rinse in warm (>45°C) running tap water until all traces of cleaning solution are removed. Visually inspect for any remaining soil and repeat the above steps if there is visible contamination. Allow to dry.
2. Ultrasonic Clean (if required): Add one (1) ounce of Enzol (or equivalent) and one (1) gallon of warm (>45°C) tap water to an ultrasonic cleaner. Completely submerge instruments and sonicate for ten (10) minutes.
3. Ultrasonic Rinse: To remove the detergent, thoroughly rinse each instrument with cold (<45°C) reverse osmosis water or distilled water including all holes and cannulations. Inspect each instrument for evidence of visual debris. Repeat the sonication and rinse if needed.
4. Automated Washer: Place instrument(s) in an automated washer (e.g. Steris Reliance® 444 Washer/Disinfector or equivalent). Load instruments such that contact is avoided and articulating instruments are in the open position.

Automated Cleaning Parameters

Step	Time mm:ss	Minimum Temp °C	Cleaning Agent
Enzymatic Wash	04:00	49 °C Tap Water	Steris Prolystica 2X Concentrate (or equivalent) (1/8 oz./gal)
Wash	02:00	65.5°C Tap Water	Steris Prolystica 2X Concentrate Alkalkine Cleaner (or equivalent) (1/8 oz./gal)
Rinse	02:00	70°C	Reverse osmosis water or distilled water.
Dry	15:00	80°C	Not Applicable

INSPECTION

After cleaning, visually inspect each instrument and tray for evidence of visual debris to ensure that there is no contamination visible. If the instrument is not visually clean repeat the cleaning process. If instruments are wet, use a lint-free wipe to dry.

STERILIZATION METHODS

Pre-vacuum autoclave
Temperature: 270° F (132° C) for 4 minutes
Minimum Dry Time: 20 minutes

- Please consider your sterilization equipment manufacturer's written instructions for the specific sterilizer and load configuration used.
- Follow current AORN "Recommended Practices for Sterilization in Perioperative Practice Settings" and ANSI/AAMI ST79: 2006 "Comprehensive guide to steam sterilization and sterility assurance in health care facilities".
- Flash sterilization is not recommended, but if used, should only be performed according to requirements of ANSI/AAMI ST79: 2006 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- The devices should be sterilized using an FDA cleared wrap indicated for these sterilization cycles.
- Do not stack trays during sterilization.

STORAGE INSTRUCTIONS

Store in a cool dry place and keep away from direct sunlight.
Prior to use, inspect product package for signs of tampering or water contamination. Use oldest lots first.

MATERIALS

All implant materials for the ORTEMIZ Small / Mini Fragment Plate System are implant grade Ti6Al4V or Commercially Pure Titanium. These materials are not ferromagnetic, susceptible to aging, nor will steam sterilization have an effect on the materials properties. The instruments are made from stainless steel, aluminum, PEEK, medical grade silicone and phenolic plastic.

DEVICE DESCRIPTION

The ORTEMIZ Small / Mini Fragment Plate System is a device comprised of plates and screws which are used for the internal stabilization of bone fractures. The system consists of titanium plates for the Clavicle, Proximal Humerus, Tibia, Distal Fibula, 1/3 Tubular and compression plates, bone screws and instruments to facilitate implantation.

CAUTIONS

Federal Law (USA) restricts this product to sale by or on the order of a physician or hospital.

Please note that the implants included in this device are classified as a single use device (SUD). If the implant comes into contact with human blood or tissue, it must be discarded and may not be reprocessed or reused.

For more information about products, please visit www.orthoimplantcompany.com or contact Customer Service at (800) 619-2797
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