ortemiz

ORTEMIZ FLEX-FIX™ System

INDICATIONS FOR USE

The ORTEMIZ FLEX-FIX™ System is intended to provide fixation during the healing process following trauma to the Ankle Syndesmosis (Syndesmosis disruption) and as an adjunct in connection with trauma hardware for ankle fractures such as Weber B and C. The device is intended for use in adults.

CONTRAINDICATIONS

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. Conditions that restrict the patient's ability or willingness to follow postoperative instructions during the healing process.
7. Cases with malignant primary or metastatic tumors which preclude adequate bone support or 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 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 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.
Instruments shall be inspected for wear or damage prior to usage.

Protect implant appliances against scratching and nicking and excessive bending, which may cause stress concentrations leading to failure. In no case should an implant be sharply bent, notched, gouged, reamed, scratched or cut.

MRI SAFETY INFORMATION

The ORTEMIZ FLEX-FIX™ 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 FLEX-FIX™ 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.

ADVERSE EFFECTS

Breakage 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.

PACKAGING AND LABELING

Components should only be accepted if received by the hospital or surgeon with the factory packaging and labeling intact. If the sterile barrier has been broken, return the component to The Orthopaedic Implant Company.

STERILIZATION

All components are provided sterile, ethylene oxide gas is used to sterilize the device. Sterile packaged components are supplied in protective sterile barrier packaging. Inspect packages for punctures or other damage prior to surgery. If the sterile barrier has been broken, discard the component.

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

Implant materials for the ORTEMIZ FLEX-FIX™ System are implant grade Titanium alloy per ASTM F136 and a UHMWPE suture. The Titanium alloy is not ferromagnetic, susceptible to aging, nor will sterilization have an effect on the material properties. The instruments are made from stainless steel, aluminum and polycarbonate resin.

DEVICE DESCRIPTION

The ORTEMIZ FLEX-FIX™ System consists of a medial toggle body, lateral button and washer connected by a suture. These implantable components are provided pre-loaded on a deployment handle. The kit also includes a drill bit 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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ortemiz

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