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OIC VARIABLE ANGLE SMALL FRAGMENT LOCKING PLATE SYSTEM

INDICATIONS FOR USE

The OIC Variable Angle Small Fragment Locking 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

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 and excessive bending, which may cause stress concentrations leading to failure.

The OIC Small Fragment Variable Angle Locking Plate System has not been tested for heating or migration or evaluated for safety and compatibility in the MR environment.

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

New products must be carefully cleaned before initial sterilization. Trained personnel must perform cleaning (manual and/or machine cleaning, ultrasound treatment, etc.) along with maintenance and mechanical inspection prior to initial sterilization.

Exact compliance with the equipment manufacturers' user instructions and recommendations for chemical detergents is required.

STERILIZATION METHODS

Pre-vacuum autoclave Minimum Temperature:
270° F (132° C) for 4 minutes
Minimum Dry Time: 30 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.

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.

CAUTIONS

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

Please note that resterilizing a single use device (SUD) which comes into contact with human blood or tissue constitutes reprocessing & that reprocessing can only be performed by an authorized third-party reprocessor who has received 510(k) clearance for such.

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

THE ORTHOPAEDIC IMPLANT COMPANY

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