Biomet Orthopedics
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01-50-1033
Rev. B
Date: 2012-01

OSS Modular Arthrodesis System

ATTENTION OPERATING SURGEON

DESCRIPTION
The OSS Modular Arthrodesis System is intended to aid in the fusion of long bones of the skeletal system when segmental defects are present. Fusion sites include the mid-shaft of long bones, or at the joint between two long bones, i.e. the knee joint.

MATERIALS
Titanium Alloy

INDICATIONS
These devices are intended for use in the replacement of segmental defects of long bone, including midshaft replacement, and arthrodesis of the knee.
Indications include:

1. Treatment of patients who are not candidates for total knee arthroplasty.
2. Irretrievably failed total knee arthroplasty.
3. Limb salvage in oncology surgery.
4. Trauma
5. Any other condition where there is little soft tissue or bony tissue available for support and arthrodesis is the treatment of choice.

These devices are intended for cemented use only.

CONTRAINDICATIONS
1. Active infection.
2. Patient conditions including blood supply limitations.
3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
4. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of the device.

WARNINGS
Improper selection, placement, positioning, alignment and fixation of the implant components may result in unusual stress conditions which may lead to subsequent reduction in the service life of the prosthetic components. Malalignment of the components or inaccurate implantation can lead to failure of the implant or procedure. Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, and/or fatigue fracture. Use clean gloves when handling implants. Laboratory testing indicates that implants subjected to body fluids, surgical debris, or fatty tissue have lower adhesion strength to cement than implants handled with clean gloves. Do not modify implants. The surgeon is to be thoroughly familiar with the implants and instruments prior to performing the surgery.

Patient selection factors to be considered include: the ability and willingness of the patient to follow postoperative care instructions until healing is complete, and a good nutritional state of the patient.

1. Firmly seat modular components to aid in the prevention of disassociation.
2. Thoroughly clean and dry tapers of the modular components to avoid crevice corrosion and improper seating
3. Care is to be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentrations that may lead to failure of the procedure. Implant fracture due to cement failure has been reported.
4. Total lengths of the devices are determined by adding the length of each component together. For example, a 10.5cm defect can be replaced with a 3cm diaphyseal adapter, a 0 degree, 5 degree, or 7 degree central locking collar (6.5cm), and a 1cm diaphyseal adapter.
5. The combined diaphyseal length is not to exceed 23cm.

The OSS Modular Arthrodesis System provides the surgeon with a means of reducing pain and restoring function of the limb for many patients. While these devices are generally successful in attaining these goals they cannot be expected to withstand the activity levels and loads of normal healthy bone and joint tissue.

Accepted practices in postoperative care are important. Failure of the patient to follow postoperative care instructions involving rehabilitation can compromise the success of the procedure. The patient is to be advised of the limitations of the arthrodesis procedure and the need for protection of the implants from full load bearing until adequate fixation and healing have occurred. Excessive, unusual and/or awkward movement and/or activity, trauma, excessive weight, and obesity have been implicated with premature failure of certain implants by loosening, fracture, dislocation, subluxation and/or wear. The patient is to be made aware and warned of general surgical risks, possible adverse effects as listed, and to follow the instructions of the treating physician including follow-up visits.

Do not reuse 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.

Device is single use only. After use, the device may be a potential biohazard. Reuse of devices labeled for single-use may result in product contamination, patient infection and/or failure of the device to perform as intended.

Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.

PRECAUTIONS
Specialized instruments are designed for the OSS modular arthrodesis system to aid in the accurate implantation of the prosthetic components. The use of instruments and/or implant components from other systems can result in inaccurate fit, incorrect sizing, excessive wear and device failure. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments that have experienced extensive use or excessive force are susceptible to fracture. Surgical instruments should only be used for their intended purpose. Biomet recommends that all instruments be regularly inspected for wear and disfigurement.

All trial, packaging, and instrument components must be removed prior to closing the surgical site. Do not implant.

POSSIBLE ADVERSE EFFECTS
1. Metal sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions involving various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain as similar changes may occur as a precursor to or during the healing process. Discoloration from metallic components of the modular arthrodesis implant may be present in adjacent tissue or fluid.
2. Early or late postoperative infection and/or allergic reaction.
3. Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, bone resorption, or while inserting the device.
4. Loosening, migration and/or fracture of the implants can occur due to loss of fixation, trauma, misalignment, bone resorption, and/or excessive activity.
5. Inadequate range of motion of the limb due to improper selection and/or positioning of components.
6. Undesirable shortening of the limb.
7. Fatigue fracture of the components can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, or excessive weight.
8. Fretting or crevice corrosion can occur at interfaces between components.
9. Valgus-varus deformity.

10. Problems of the knee or ankle of the affected limb or contralateral limb aggravated by leg length discrepancy, too much femoral medialization, and/or muscle deficiencies.
11. Transient peroneal palsy secondary to surgical manipulation has been reported.
12. Intraoperative or postoperative bone fracture and/or postoperative pain.

MRI INFORMATION
The OSS Modular Arthrodesis System has not been evaluated for safety and compatibility in the MR Environment. The OSS Modular Arthrodesis System has not been tested for heating or migration in the MR Environment.

STERILITY
Prosthetic components are sterilized by exposure to a minimum dose of 25 kGy of gamma radiation. Do not use from an opened or damaged package. Do not resterilize. Do not use implants after expiration date. Single use only. Do not reuse.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Comments regarding the use of this device can be directed to Attn: Regulatory Affairs, Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA, Fax: 574-372-3968.

CE Mark on the package insert (IFU) is not valid unless there is a CE Mark on the product (description) label.

Authorized Representative: Biomet U.K., Ltd.
Waterton Industrial Estate
Bridgend, South Wales
CF31 3XA UK

CE 0086

Symbol Legend

 Manufacturer

 Date of manufacture

 Do not reuse

 Caution, see instructions for use

Sterilized using ethylene oxide

Sterilized using irradiation

Sterile

Sterilized using aseptic processing techniques

Sterilized using steam or dry heat

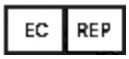
 Use by date

 WEEE device

Catalogue number

Batch code

Flammable



Authorized representative in the European Community