Biomet Orthopedics, Inc.
P.O. Box 587
56 East Bell Drive
Warsaw, Indiana 46581 USA

01-50-0971
Date: 08/05

Compress® Segmental Femoral Replacement System
Attention Operating Surgeon

DESCRIPTION
The Compress® Segmental Femoral Replacement System is a metallic femoral segmental fixation system intended to replace the resected part of the femur in cases of severe bone loss. The design of the Compress® System allows a compressive load to be applied at the prosthetic implant-bone interface at the time of device insertion. This is accomplished through a spring system built into the stem.

MATERIALS
Titanium Alloy
CoCrMo Alloy
UHMWPE
Stainless Steel
Hydroxyapatite (HA) Coating

INDICATIONS
The Compress® Segmental Femoral Replacement System is indicated for:
1. Correction of revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement.
2. Tumor resections.
3. Revision of previously failed total joint arthroplasty.
4. Trauma.

The Compress® Segmental Femoral Replacement System components are intended for uncemented use.

CONTRAINDICATIONS
1. Active infection.
2. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
3. Patient conditions including vascular insufficiency, insufficient quantity (less than 2.5 mm of cortical thickness) or quality of bone, or latent infections.
4. Pathologic soft tissue conditions or skeletal conditions, which would prevent secure fixation of the device in the bone.

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 excessive wear and/or failure of the implant or procedure. Inadequate preclosure cleaning (removal of surgical debris) can lead to excessive wear. Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture and/or excessive wear. Use clean gloves when handling implants. Do not modify implants. The Hydroxyapatite (HA) coating on the device should only be handled while wearing surgical gloves. The surgeon is to be thoroughly familiar with the implants and instruments, prior to performing surgery and should verify that all articular components are compatible per the accessory component labeling.
1. Firmly seat modular components to prevent disassociation. Thoroughly clean and dry tapers of the modular components to avoid crevice corrosion and improper seating.
2. Malalignment or soft tissue imbalance can place inordinate forces on the components which may cause excessive wear to the associated articulating surfaces. Revision surgery may be required to prevent component failure.
3. Complete preclosure cleaning and removal of metallic debris or other surgical debris at the implant site is critical to minimize wear of the implant articular surfaces.
4. The Compress® Segmental Femoral components, when used for distal femoral replacement, are intended for use only in conjunction with a hinge type knee prosthesis.
5. The force level of the spindle assembly is not intended to be adjusted in the operating room.
6. Remove and dispose of the compression cap after the nut is tightened on the spindle assembly.
7. In order to utilize the optional locking screw with the proximal taper of the intercalary segment, a cap must first be inserted into the end of the spindle before the taper is engaged.
8. Consult the Force Chart in the Surgical Technique to determine the appropriate force level for the spindle.
9. Complete loss of spindle/anchor plug space indicates that the Compress® device has lost compression and revision is warranted to prevent further complications.
10. Loss of spindle/anchor plug space may lead to fracture of the anchor plug traction bar if not revised.

Biomet® joint replacement prostheses provide the surgeon with a means of reducing pain and restoring function 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 reconstruction and the need for protection of the implants from full load bearing until adequate fixation and healing have occurred. Excessive activity, trauma and excessive weight have been implicated with premature failure of the implant by loosening, fracture, and/or wear. Loosening of the implants can result in increased production of wear particles, as well as accelerate damage to bone making successful revision surgery more difficult. 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.

PRECAUTIONS
Patient selection factors to be considered include: 1) need to obtain pain relief and improve function, 2) ability and willingness of the patient to follow instructions, including control of weight and activity levels, and 3) a good nutritional state of the patient.

Specialized instruments are designed for Biomet® joint replacement systems to aid in the accurate implantation of the prosthetic components. The use of instruments or implant components from other systems can result in inaccurate fit, 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, which 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.

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.

POSSIBLE ADVERSE EFFECTS
1. Material 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. Particulate wear debris and discoloration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate a cellular response resulting in osteolysis or osteolysis may be a result of loosening of the implant.
2. Early or late postoperative, infection, and 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 or migration of the implants can occur due to loss of fixation, trauma, malalignment, bone resorption, excessive activity.
5. Undesirable shortening of limb.
6. Dislocation and subluxation due to inadequate fixation and improper positioning. Muscle and fibrous tissue laxity can also contribute to these conditions.
7. Fatigue fracture of component can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, or excessive weight.
8. Fretting and crevice corrosion can occur at interfaces between components.
9. Valgus-varus deformity.
10. Transient peroneal palsy secondary to surgical manipulation and increased joint movement has been reported following knee arthroplasty in patients with severe flexion and valgus deformity.
11. Patellar tendon rupture and ligamentous laxity.
12. Intraoperative or postoperative bone fracture and/or intraoperative pain.

Potential risks associated with the use of the Compress® Segmental Femoral Replacement System include: 1. presence of the Compress® Segmental Femoral Replacement could generate loads at the osteotomy line of a magnitude great enough to induce pressure necrosis in the host bone; 2. loads applied to the transverse fixation pins could potentially cause loosening or migration of the pins through the shaft of the femur causing unpredictable wear of the implant; 3. spring failure resulting in loss of fixation and revision surgery; and, 4. bone resorption that may contribute to deteriorating fixation and loosening and failure of the device.

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

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

Comments regarding this device can be directed to Attn: Regulatory Dept., Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA, Fax: 574-372-1683.

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

CE 0086