



Biomet Orthopedics
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01-50-0990
Revision P
Date: 2014-09



Biomet Orthopaedic Salvage System (OSS)

ATTENTION OPERATING SURGEON

DESCRIPTION

The Biomet Orthopaedic Salvage System (OSS) offers a variety of component options for treatment of patients that require proximal femoral, distal femoral, total femur, or proximal tibial replacements, as well as, resurfacing components for the proximal tibia and distal femur. The Biomet Orthopaedic Salvage System offers the surgeon treatments for patients presenting bone loss and deformity associated with bone tumors resection, trauma, and difficult revision arthroplasty.

MATERIALS

Distal Femoral	CoCrMo Alloy/Titanium Alloy
Proximal Tibial	CoCrMo Alloy/UHMWPE/Titanium Alloy
Proximal Femoral	Titanium Alloy
Proximal Femoral Augment†	Titanium Alloy
Proximal Femoral Bolt†	CoCrMo Alloy
Spiked Washer†	Titanium Alloy
Total Femur Coupling	Titanium Alloy
Total Femur IM Rod	Titanium Alloy
Intramedullary Stem	CoCrMo Alloy /Titanium Alloy
Tibial Bearing	ArCom UHMWPE
Tibial Augments	Titanium Alloy
Tibial Sleeve Augment†	CoCrMo Alloy/Titanium Alloy/Porous Coating
Diaphyseal Component	CoCrMo Alloy/Titanium Alloy / UHMWPE
Diaphyseal Augment†	Titanium Alloy
Patellar Component	UHMWPE/Titanium Alloy/316LVM SS
Locking Screw	Titanium Alloy
Bushing Component	ArCom UHMWPE
Lock Pin	ArCom UHMWPE or CoCrMo Alloy
Yoke	CoCrMo Alloy
Axle	CoCrMo Alloy
Femoral Sleeve Augment	CoCrMo Alloy/Porous coating
Femoral Flange Augment	Titanium Alloy
Porous Coating	Titanium Alloy
Stacking Adapter	Titanium Alloy
Expandable Components	CoCrMo Alloy/Titanium Alloy/UHMWPE/PEEK
AVL Lock Ring	CoCrMo Alloy
Femoral Bumper	ArComXL highly crosslinked Ultra High Molecular Weight Polyethylene (UHMWPE)

† Products are not licensed in Canada

OSS INDICATIONS

1. Painful and disabled joint resulting from avascular necrosis, osteoarthritis, rheumatoid arthritis, or traumatic arthritis.
2. Correction of varus, valgus, or posttraumatic deformity.
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement.
4. Ligament deficiencies.
5. Tumor resections.
6. Treatment of non-unions, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques. *

7. Revision of previously failed total joint arthroplasty.
8. Trauma.

These devices are to be used with bone cement unless composed of OsseoTi (titanium alloy, not licensed in Canada) or a proximal femur is indicated for use (USA).

Biomet OSS Reduced size (RS) components offers a variety of component options for treatment in small adults and adolescents (12-21 years) that require proximal femoral, distal femoral, total femur, or proximal tibial replacement as well as, resurfacing components for the proximal tibia and distal femur (USA).

* Not applicable to Regenerex Ultra Porous Construct titanium knee augment usage (not licensed in Canada), or any other knee component.

COMPRESS 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.

When components of the Orthopaedic Salvage System are used with Biomet's Compress Segmental Femoral Replacement System, the user should refer to the package insert contained with the Compress components for full prescription information.

EXPANDABLE INDICATIONS†

The Biomet Side Access Distal Femoral Expandable offers a treatment option for patients requiring distal femoral replacement who have not yet achieved full skeletal maturity (open epiphysis) or patients who require surgery who have significant residual leg length discrepancy. Indication for use of this device is most commonly tumor resection but could also involve osteoarthritis; rheumatoid arthritis; correction of deformity; and correction or revision of unsuccessful osteotomy, arthrodesis or previous joint replacement.

The devices are single use implants intended for implantation with bone cement or with Biomet Compress.

CONTRAINDICATIONS

Absolute contraindications include: infection, sepsis, and osteomyelitis. Relative contraindications include: 1) uncooperative patient or patient with neurologic disorders who are incapable of following directions, 2) osteoporosis, 3) metabolic disorders which may impair bone formation, 4) osteomalacia, 5) distant foci of infections which may spread to the implant site, 6) rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram, 7) vascular insufficiency, muscular atrophy, or neuromuscular disease.

WARNINGS

Improper selection, placement, positioning, alignment and fixation of the implant components, or absence of, or nonfunctioning quadriceps mechanism 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. 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 surgical technique, implants and instruments prior to performing surgery.

1. Firmly seat modular components to reduce the risk of disassociation.
2. Thoroughly clean and dry tapers of the modular components to minimize the risk of crevice corrosion and improper seating.
3. Malalignment or soft tissue imbalance can place inordinate forces on the components, which may cause excessive wear to the patellar or tibial bearing articulating surfaces. Revision surgery may be required to prevent component failure.

4. Care is to be taken to assure complete support of all parts of the device embedded in bone cement to minimize the risk of stress concentrations, which may lead to failure of the procedure. Complete preclosure cleaning and removal of bone cement debris, metallic debris, and other surgical debris at the implant site is critical to minimize wear of the implant articular surfaces. Implant fracture due to cement failure has been reported.
5. Use Biomet femoral and modular head components with appropriate matching "Type I taper".
6. Total lengths of devices are determined by adding the length of each component together. For example, a distal femur can be replaced with a 5cm diaphyseal segment and a 7cm segmental femoral component for a total of a 12cm replacement.
7. The combined diaphyseal length is not to exceed 23 cm.
8. Expandable devices should not be lengthened more than 1-2cm at one time.
9. Do not utilize more than one diaphyseal augment per individual diaphyseal segment. †
10. Diaphyseal augments can only be utilized with the following segments which have a corresponding external taper (151836, 151837, 151838, 151839, 151840, 151841, 150842, 151843, 151844, 151845, 151846, and 151847). †
11. Adolescents (12-21 year olds) with an open epiphysis, who do not have an expandable device, may require subsequent surgeries to add segments/bodies throughout the growth process. †
12. It is the responsibility of the operating surgeon to determine whether there is adequate initial fixation and stability. Stem extensions are available if additional fixation and stability are needed.
13. Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.

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, 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. 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 and possible adverse effects as listed in advance of surgery, and to follow the instructions of the treating physician including follow-up visits.

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.

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.

PRECAUTIONS

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, 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, prior to surgery. All trial, packaging, and instrument

components must be removed prior to closing the surgical site. Do not implant.

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. Foreign body sensitivity. Where suspected, material sensitivity tests are to be made prior to implantation.
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, or fracture of the implants can occur due to loss of fixation, trauma, malalignment, malposition, bone resorption, and/or excessive, unusual and/or awkward movement and/or activity.
5. Periarticular calcification or ossification, with or without impediment of joint mobility.
6. Inadequate range of motion due to improper selection or positioning of components.
7. Undesirable shortening of limb.
8. Dislocation and subluxation due to inadequate fixation, malalignment, malposition, excessive, unusual and/or awkward movement and/or activity, trauma, weight gain, or obesity. Muscle and fibrous tissue laxity can also contribute to these conditions.
9. Fatigue fracture of component can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, or excessive weight.
10. Fretting and crevice corrosion can occur at interfaces between components.
11. Wear and/or deformation of articulating surfaces.
12. Valgus-varus deformity.
13. Problems of the knee or ankle of the affected limb or contralateral limb aggravated by leg length discrepancy, too much femoral medialization or muscle deficiencies.
14. 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.
15. Patellar tendon rupture and ligamentous laxity.
16. Intraoperative or postoperative bone fracture and/or postoperative pain.
17. Telescopic failure of the Expandable Knee.

MRI INFORMATION

The Biomet Orthopedic Salvage System (OSS) components have not been evaluated for safety and compatibility in the MR environment. The devices have not been tested for heating or migration in the MR environment. The risks associated with a passive implant in an MR environment have been evaluated and are known to include heating, migration, and image artifacts at or near the implant site.

STERILITY

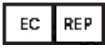
Prosthetic components are sterilized by exposure to a minimum dose of 25 kGy of gamma radiation. Single Use Only – DO NOT REUSE. Do not use from an opened or damaged package. Do not resterilize. Do not use implants after expiration date.

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.

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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
 CF31 3XA, U.K.



Authorized representative in the European Community

Symbol Legend



Manufacturer



Date of manufacture



Do not reuse



Do not resterilize



Caution, see instructions for use



Sterilized using ethylene oxide



Sterilized using irradiation



Sterile



Sterilized using aseptic processing techniques



Sterilized using steam or dry heat



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



Do not use if package is damaged (Pack Damage)



Use by date



WEEE device



Catalogue number



Batch code



FLAMMABLE Flammable