Biomet Orthopedics
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01-50-1236
Revision C
Date: 2014-10

Biomet Freedom Constrained Femoral Heads

ATTENTION OPERATING SURGEON

DESCRIPTION
The Biomet Freedom Constrained Femoral heads are intended for use only in situations where the patient has a high risk of dislocation due to a previous history, severe joint laxity, and/or palsy of surrounding musculature. The heads are designed to be used in conjunction with compatible Biomet modular shells and Freedom constrained liners. Size 36 Freedom heads are compatible with G7 Freedom Constrained Liners, Biomet Ringloc Freedom Constrained Liners, or Biomet Freedom Constrained All-Poly Cups. (NOTE: Where available, Size 32 Freedom heads are compatible only with Biomet G7 Freedom Constrained Liners.) The heads are designed to be used with either a Biomet Type 1 or Type 12/14 femoral taper/stem. Components are intended for both primary and/or revision applications.

MATERIALS
Femoral Modular Heads Co-Cr-Mo

INDICATIONS
The Biomet Freedom Modular Femoral Head is indicated for use as a component of a total hip prosthesis in primary and revision patients at high risk of dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intra-operative instability, and for whom all other options to constrained acetabular components have been considered.

CONTRAINDICATIONS
1. Bone or musculature compromised by disease, infection, or prior implantation that cannot provide adequate support or fixation for the prosthesis.
2. Any active or suspected infection in or about the hip.
3. Skeletal immaturity.

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, and 7) vascular insufficiency, muscular atrophy, or neuromuscular disease.

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, including the retaining ring of the liner. Please see the Biomet Freedom Constrained System surgical technique for the recommended positioning of constrained components. 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. Do not modify implants. The surgeon is to be thoroughly familiar with the implants, instruments, and surgical techniques prior to performing surgery. Closed reduction of a dislocation of a constrained hip may be possible. Patients should be made aware that treatment of device dislocation may require additional surgery.

1. Use appropriate compatible Biomet Type 1 Taper or 12/14 Taper.
2. Tapers must be dry.
3. Correct handling of implants is extremely important. Do not modify implants. Do not notch or bend implants. Notches or scratches put in the implant during the course of surgery may contribute to breakage.
4. Care should be taken to ensure proper head orientation with the etched line being placed in the most superior position. Improper head orientation can increase the likelihood of disassociation from the liner during normal activities.
5. The Biomet Freedom Constrained Femoral Heads operate only with The Biomet Freedom Constrained Liners. For further information contact Biomet.
6. Anatomical alignment is critical to the success of the procedure. Failure to achieve proper anatomical alignment may result in impingement, reduction in the range of motion and excessive wear, or failure of the retaining ring.
7. The femoral head can disassociate from the constrained liner if the head is moved into the plane of insertion while pulling stress is being placed on the extremity.

While the Biomet Freedom Constrained System is intended for use in treating chronic dislocation, the device will not correct joint laxity, palsy, malalignment, or other causes of dislocation. If problems causing dislocation are not corrected, undue stress will be placed upon the device, which will result in excess wear of the implants, including the retaining ring and may cause failure.

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.

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 level, 3) a good nutritional state of the patient, and 4) the patient must have reached full skeletal maturity.

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 limitation 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 in advance and warned of general surgical risks, possible adverse effects as listed, and to follow the instructions of the treating physician including follow-up visits.

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

Device is single use only. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. 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. Do not treat patients with implants that have been, even momentarily, placed in a different patient.

Do not reuse implantable devices.

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.

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. Further, there has been a report dated March 2010, titled "Advice from the CSD Expert Advisory Group on the biological effects of metal wear debris generated from hip implants," regarding an association between articulating surfaces of: 1) CoCrMo alloy on CoCrMo alloy, 2) CoCrMo alloy on polyethylene, and 3) Titanium alloy on polyethylene in hip replacements and increased genotoxicity. This report, however, did not assess either the clinical relevance of the data or make any definite conclusions as to which metal ions or interactions between metal ions or particulate metals might be responsible for the observed data. The report further cautioned that an association does not necessarily mean a causal relationship, and that any potentially increased risk associated with metal ions needs to be balanced against the benefits resulting from hip replacement. 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, bone resorption, or excessive 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 and improper positioning. 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. Trochanteric avulsion or non-union as a result of excess muscular tension, early weight bearing, or inadequate reattachment.
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. Postoperative bone fracture and pain.

MRI INFORMATION

The Biomet Freedom Constrained Femoral Heads 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 dose of 25 kGy – 40 kGy of gamma radiation. Single Use Only. Do Not Reuse. Do not resterilize. Do not use any component from an opened or damaged package. 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 this device can be directed to Attn: Regulatory Dept., 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.

EC REP Authorized Representative: Biomet, U.K., Ltd.
Waterton Industrial Estate,
Bridgend
CF31 3XA U.K.

CE 0086

Symbol Legend

 Manufacturer

 Date of manufacture

 Do not reuse

 Do not resterilize

 Caution, see instructions for use

 Consult instructions for use

 Sterilized using ethylene oxide

 Sterilized using irradiation

 Sterile

 Sterilized using aseptic processing techniques

 Sterilized using steam or dry heat

 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 Damaged)

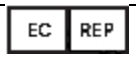
 Use by date

 WEEE device

 Catalogue number

 Batch code

 Flammable

 Authorized representative in the European Community