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Revision I
Date: 2014-10



Biomet Hip Hydroxyapatite Joint Replacement Prostheses

ATTENTION OPERATING SURGEON

DESCRIPTION

Biomet manufactures a variety of porous coated hip joint replacement prostheses for non-cemented use in skeletally mature patients undergoing primary and revision hip replacement surgery. Hip joint replacement components include: femoral stems, femoral heads, acetabular shells, and acetabular liners. Components are available in a variety of designs and size ranges intended for primary applications. Specialty components are available including: acetabular screws, centering sleeves, and canal plugs.

MATERIALS

Femoral Stems	CoCrMo Alloy or Titanium Alloy
Femoral Heads	CoCrMo Alloy
Acetabular Shells	Titanium Alloy
Acetabular Liners	Ultra-High Molecular Weight Polyethylene (UHMWPE)
Acetabular Screws	Titanium Alloy
Centering Sleeves	Polymethylmethacrylate (PMMA)
Canal Plugs	UHMWPE
Porous Coating	Titanium Alloy
Hydroxyapatite (HA) Coating	Calcium Phosphate

INDICATIONS

1. Noninflammatory degenerative joint disease including osteoarthritis and a vascular necrosis.
2. Rheumatoid arthritis
3. Correction of functional deformity
4. Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision procedures where other treatment or devices have failed.

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 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. Use clean gloves when handling implants. The Hydroxyapatite Coating on the prosthetic device should only be handled while wearing surgical gloves. 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 and instruments, prior to performing surgery.

1. Use Biomet femoral and modular head component with appropriate matching "Type I Taper" or "Type II Taper".
2. Firmly seat modular head components to prevent dissociation. Thoroughly clean and dry taper prior to attachment of the modular head component to avoid crevice corrosion and improper seating.
3. Acetabular screws are to be fully seated to assure stable fixation and to avoid interference with the acetabular liner component.
4. Prior to seating the liner into the shell component, all surgical debris (tissue fragments, etc.) must be removed from the interior of the shell component, as debris may inhibit the locking mechanism from engaging and securing the liner into the shell component.
5. Perforation entirely through the pelvic bone with dome fixation screws or rim screws is to be completely avoided. Caution is to be used when determining and selecting the length of screws to be used, as perforation through the pelvic bone with screws that are too long can cause damage to body structures (blood vessels, etc.) located on the interior side of the pelvis.
6. Tight fixation of all non-cemented components at the time of surgery is critical to the success of the procedure. Each component must properly press fit into the host bone which necessitates precise operative technique and the use of specified instruments. Bone stock of adequate quality must be present and appraised at the time of surgery.
7. Complete preclosure cleaning and removal of metallic debris and other surgical debris at the implant site is critical to minimize wear of the implant articular surfaces.
8. 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 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 and warned of general surgical risks, possible adverse effects as listed in advance, 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 level, 3) a good nutritional state of the patient, and 4) the patient must have reached full skeletal maturity.

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. Prior to surgery, 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.
- 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 or migration of the implants can occur due to loss of fixation, trauma, malalignment, bone resorption, and 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) Intraoperative or postoperative bone fracture and/or postoperative pain.

MRI INFORMATION

Biomet Hip Joint Replacement Prostheses 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. Do not resterilize. Single Use Only. Do Not Reuse. 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.

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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.



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



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

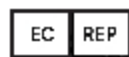


Batch code



FLAMMABLE

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