

Biomet® M²a™ Prosthetic Devices

ATTENTION OPERATING SURGEON

DESCRIPTION

The Biomet® Metal-on-Metal Hip Joint Replacement Prosthesis is intended for use in non-cemented primary and revision hip joint replacement procedures. The metal liners are intended for use with specific metal-on-metal femoral articulating heads. The specialized femoral heads and metal-on-metal liners are to be used with Biomet® primary and revision femoral components. Specialized components such as taper adapters are available.

Materials

Femoral Heads	CoCrMo Alloy
One Piece Cup	CoCrMo Alloy
Porous Coating	Titanium Alloy
Taper Adapter	Titanium Alloy

INDICATIONS

1. Non-inflammatory degenerative joint disease including avascular necrosis, diastrophic variant, fracture of the pelvis, fused hip, Legg Perthes, osteoarthritis, slipped capital epiphysis, subcapital fractures, and traumatic arthritis.
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 of previously failed total hip arthroplasty.

CONTRAINDICATIONS

Absolute contraindications include: infection, sepsis, and osteomyelitis. Relative contraindications include: 1) uncooperative patients or patients 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, 8) patients with chronic renal failure, and 9) patients who are pregnant or may become pregnant.

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 may lead to excessive wear and/or failure of the implant or procedure. Inadequate preclosure cleaning (removal of surgical debris) may lead to 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. Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) may 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", "Type II Taper", or "12/14" Taper.
2. Use Biomet® metal-on-metal acetabular liners with specified Biomet® metal-on-metal femoral heads.
3. 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.
4. 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.
5. Perforation entirely through the pelvic bone with 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 may cause damage to body structures (blood vessels, etc.) located on the interior side of the pelvis.
6. Complete preclosure cleaning and removal of surgical debris at the implant site is critical to minimize wear of the implant articular surfaces.

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 activity, trauma and weight have been implicated with premature failure of the implant by loosening, fracture, and/or wear. Loosening of the implants may 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

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.

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 may 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 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.

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 may 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 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. A low incidence of metal hypersensitivity has been reported with failed metal-on-metal implants. The clinical relevance of these findings is unclear, and it is not known whether metal hypersensitivity causes implant failure.
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 may 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 may also contribute to these conditions.
9. Fatigue fracture of component may occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, or excessive weight.
10. Fretting and crevice corrosion may 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.
15. Elevated metal ion levels have been reported with metal-on-metal articulating surfaces. Although mechanical testing demonstrates that metal-on-metal articulating surfaces produce a relatively low amount of particles, the total amount of particulate produced in vivo throughout the service life of the implants remains undetermined. The long-term biological effects of the particulate and metal ions are unknown.

STERILITY

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

Caution: Federal Law (USA) restricts this device to sale, distribution, and use 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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