Biomet Orthopedics
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01-50-0958
Revision O
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Biomet M²a-Magnum and M²a-Magnum Tri-Spike Acetabular Shells & Biomet Selex Modular Head Components

ATTENTION OPERATING SURGEON

DESCRIPTION

The Biomet M²a-Magnum and M²a-Magnum Tri-Spike Acetabular Shells are intended for use in non-cemented primary and revision hip joint replacement procedures, in combination with the Active Articulation hip bearings system*.

The Selex Modular Head Components** are intended for use in primary and revision hip joint replacement procedures in combination with Biomet UHMWPE Polyethylene Acetabular Liners.

MATERIALS

Acetabular Liners	UHMWPE Polyethylene
Active Articulation Bearings	E1, highly cross-linked UHMWPE and α-tocopherol ArComXL, highly cross-linked UHMWPE
Acetabular Shells	Titanium Alloy/CoCrMo Alloy
Femoral Heads	CoCrMo Alloy
Porous Coating	Titanium Alloy

INDICATIONS

1. Noninflammatory degenerative joint disease including osteoarthritis and avascular 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

The components of the Biomet M²a-Magnum and M²a-Magnum Tri-Spike Acetabular Shells are also cleared for diastrophic variant, fracture of the pelvis, fused hip, Legg Perthes, slipped capital epiphysis, subcaptial fractures, and traumatic arthritis indications.

Reference Active Articulation Instruction For Use for appropriate selection, use, and possible adverse effects.

*Where available
**NOT FOR SALE IN CANADA

CONTRAINDICATIONS

Absolute contraindications:

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

Relative contraindications

1. Uncooperative patients or patients with neurologic disorders who are incapable of following directions.
2. Distant foci of infections which may spread to the implant site.
3. Rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram.
4. Osteoporosis.
5. Metabolic disorders which may impair bone formation.
6. Osteomalacia.
7. Vascular insufficiency, muscular atrophy, or neuromuscular disease.
8. Skeletal immaturity.
9. Metal Sensitivity.
10. Patients who are pregnant or may become pregnant.
11. Patients with known moderate to severe renal insufficiency.

WARNINGS

1. Patients should be warned of the impact of excessive loading that can result if the patient is involved in an occupation that includes substantial walking, running, lifting, or excessive muscle loading due to patient weight that place extreme demands on the hip and can result in device failure or dislocation.
2. 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.
3. 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.
4. Malalignment of the components or inaccurate implantation can lead to excessive wear and/or failure of the implant or procedure.
5. Complete preclosure cleaning and removal of surgical debris at the implant site is critical to minimize wear of the implant articular surfaces.
6. Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture and/or excessive wear.
7. Do not modify implants.
8. The surgeon is to be thoroughly familiar with the implants, associated instruments and surgical technique, prior to performing surgery.
9. Use Biomet femoral and modular head component with appropriate matching "Type I Taper", "Type II Taper", or "12/14 Taper".
10. Firmly seat modular head components to reduce the risk of dissociation and/or micro motion. Micro motion may contribute to difficult head removal.
11. Thoroughly clean and dry taper prior to attachment of the modular head component to avoid crevice corrosion and improper seating.
12. Acetabular screws are to be fully seated to assure stable fixation and to avoid interference with the acetabular liner component.
13. 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.
14. 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 in advance of surgery of general surgical risks, possible adverse effects as listed, 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

1. Do not combine components from different manufacturers. This may lead to excessive wear or premature failure of the device.
2. Clinical outcome may be affected by component positioning. Proper placement of the implant should take into consideration individual patient anatomy as well as surgeon preference. The surgical technique sets forth suggested guidelines for placement of the implant including inclination and anteversion.
3. Corrosion is rare but has been reported with the use of dissimilar metals in total hip replacement.
4. Specialized instruments are designed for Biomet joint replacement systems to aid in the accurate implantation of the prosthetic components. The use of instruments from other systems can result in inaccurate fit, incorrect sizing, excessive wear and device failure.
5. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instrument that have experienced extensive use or excessive force, are susceptible to fracture. Surgical instruments should only be used for their intended purpose. It is recommended that surgical instruments are inspected for wear and defects routinely and prior to surgery.
6. Biomet recommends that all instruments be regularly inspected for wear and disfigurement.
7. All trial, packaging, and instrument components must be removed prior to closing the surgical site. Do not implant.
8. Device is single use only. Do not attempt to clean or resterilize this product. After use this product may be a potential biohazard.

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. Foreign body sensitivity. Where suspected, material sensitivity tests are to be made prior to implantation.
4. Pain and/or loss of function.
5. Inadequate range of motion due to improper selection or positioning of components.
6. Undesirable shortening of limb.
7. Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock caused by osteopenia, osteoporosis, bone defects from previous surgery, bone resorption, or while inserting the device.
8. Loosening or migration of the implants can occur due to loss of fixation, trauma, malalignment, malposition, bone resorption, excessive weight, or excessive, unusual and/or awkward movement and /or activity.
9. Periarticular calcification or ossification, with or without impediment of joint mobility.
10. 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.
11. Fatigue fracture of component can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, or excessive weight.
12. Fretting and crevice corrosion can occur at interfaces between components.
13. Wear and/or deformation of articulating surfaces.
14. Trochanteric avulsion or non-union as a result of excess muscular tension, early weight bearing, or inadequate reattachment.
15. 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
16. Postoperative bone fracture and pain.
17. Disassociation of the modular components requiring additional surgery.
18. Fracture of the bone or prosthetic components.
19. Localized progressive bone resorption (osteolysis).
20. Nerve impingement or damage.
21. Vascular disorders or damage (including thrombus).
22. Heterotopic bone formation.
23. Gastrointestinal or genitourinary complications
24. Pulmonary embolism.
25. Death.
26. Myocardial infarction
27. Effusion.
28. Bursitis.
29. Pain, swelling, or the onset of a limp may occur, requiring further evaluation from an orthopedic surgeon.

MRI Information

The devices associated with this IFU 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 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 by or on the order of a physician.

Comments regarding this device can de 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
STERILE EO Sterilized using Ethylene Oxide

STERILE R Sterilized using Irradiation

STERILE Sterile

STERILE A Sterilized using Aseptic Processing Techniques

STERILE 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 Damaged)

Use By

WEEE Device

REF Catalogue Number

LOT Batch Code

FLAMMABLE Flammable

EC REP Authorized Representative in the European Community