Biomet Orthopedics
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Revision B
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Biomet G7 Acetabular System
Acetabular Shells and Accessories

ATTENTION OPERATING SURGEON

DESCRIPTION

The Biomet G7 Acetabular System is a modular acetabular system, offering various types of acetabular shell designs.

The G7 Acetabular shells are coated with Porous Plasma Spray (PPS) and are available in either a solid shell design, with an apical plug, or a limited hole pattern with an apical plug. The limited hole design is delivered with pre-plugged screw holes.

The G7 OsseoTi Acetabular shells are available in either a limited hole design with an apical plug or a multi-hole design. The limited hole design is delivered with pre-plugged screw holes.

The acetabular shell is packaged without a liner and the selection of a proper liner is required to complete the acetabular component. The optional G7 acetabular screws are easily identified by their gold color. Although the gold screws are compatible with other Biomet components, only the gold G7 screws may be used with the G7 acetabular system. The acetabular component is designed to be used in conjunction with Biomet® modular heads and femoral stems. Components are available in numerous designs and sizes intended for both primary and/or revision applications.

MATERIALS

G7 & G7 OsseoTi Acetabular Shells	Titanium Alloy
Porous Coating (PPS)	Titanium Alloy
BoneMaster HA (Hydroxyapatite) Coating	Calcium Phosphate
Screw Hole and Apical Hole Plugs	Titanium Alloy
Acetabular Screws	Titanium Alloy

NOTE: The BoneMaster HA coated acetabular shells are not available for sale in the USA.

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 by other techniques.
5. Revision procedures where other treatment or devices have failed.

Porous acetabular shells and femoral stems are indicated for uncemented biological fixation. Non-coated or polyethylene components may be used with mating components that are indicated for either cemented or uncemented use.

Indications for Biomet G7 Freedom Constrained Liners:

The Biomet G7 Freedom Constrained Liner 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 intraoperative instability, and for whom all other options to constrained acetabular components have been considered.

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

Contraindication when shell is used with Biomet G7 Freedom Constrained Liner:

Bone or musculature compromised by disease, infection, or prior implantation that cannot provide adequate support or fixation for the prosthesis.

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. 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. Do not modify implants. The surgeon is to be thoroughly familiar with the implants, instruments and surgical techniques prior to performing surgery.

1. Acetabular screws are to be fully seated to ensure stable fixation and to avoid interference with the acetabular liner component. Only use acetabular screws that are included in the G7 Acetabular System; do not use other Biomet Low-Profile titanium acetabular screws.
2. Tapers must be dry.
3. 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.
4. Perforation entirely through the pelvic bone with dome fixation 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.
5. 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.
6. Acetabular shells should only be used with compatible Biomet acetabular liners that are currently licensed/cleared for marketing in the country of use.
7. Correct handling of implants is extremely important. Do not modify implants. Do not notch or bend implants. Intraoperative fracture of screws can occur if excessive force

(torque) is applied while seating bone screws. Notches or scratches put in the implant during the course of surgery may contribute to breakage.

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 and warned in advance 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.

PRECAUTIONS FOR USE WITH G7 CONSTRAINED LINERS

1. In order to minimize the risks of dislocation and loosening of the shell-acetabular bone interface that may occur when using a metallic shell intended for biological fixation, surgeons should consider providing immediate resistance to tensile forces between the metallic shell and the acetabular bone through the use of bone screws.
2. Physicians should consider component malposition, component placement, and the effect on range of motion when using modular heads and extended liners. Malpostioned acetabular components increase the potential for impingment, premature dislocation and revision.

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, 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 G7 Acetabular System Shells 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.

All trademarks herein are the property of Biomet, Inc. or its subsidiaries unless otherwise indicated.

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

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

Rx 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 date

 WEEE device

REF Catalogue number

LOT Batch code

Flammable

EC REP Authorized representative in the European Community