



**Biomet Orthopedics**  
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**01-50-1233**

**Revision C**

**Date: 2014-10**



**Biomet G7 Acetabular System  
Polyethylene Acetabular Liners**

**ATTENTION OPERATING SURGEON**

**DESCRIPTION**

The Biomet G7 Acetabular System is a modular acetabular system consisting of a shell (preplugged and packaged with an apical plug), liner and optional screws. The acetabular shell is designed to be used with multiple bearings. Where available, polyethylene liners are manufactured in either ArComXL (UHMWPE) or E1 Antioxidant Infused Technology (UHMWPE and Vitamin E,  $\alpha$ -tocopherol) material. Components are available in numerous designs and sizes intended for primary and/or revision applications.

**MATERIALS**

ArComXL Acetabular Liners	Highly cross-linked Ultra High Molecular Weight Polyethylene (UHMWPE)
E1 Acetabular Liners & E1 G7 Freedom Constrained Liners	E1, highly cross-lined Ultra High Molecular Weight Polyethylene (UHMWPE) and $\alpha$ -tocopherol
Constrained Liner Retaining Ring	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 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 intra-operative 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 is 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/or 7) vascular insufficiency, muscular atrophy, or neuromuscular disease.

**WARNINGS**

Improper selection, placement, positioning, alignment and/or 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. Tapers must be dry.
2. 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.
3. Tight fixation of all non-cemented components at the time of surgery is critical to the success of the procedure. Each component must be fit according to precise operative technique and the use of specified instruments.
4. Acetabular liners should only be used with the Biomet G7 acetabular shells that are currently licensed/cleared for marketing in the country of use.
5. Retaining ring failure and/or disassociation in constrained liners, which may be due to impingement, fatigue, and/or wear, increases the probability of dislocation.
6. Failure or migration of the constrained liner's retaining ring may require additional surgery.
7. The Biomet G7 Freedom Constrained Liner System operates only with the Biomet 36mm Freedom modular head components with +9, +6, +3, standard, -3, and -6mm neck lengths and the 32mm Freedom head where available.
8. 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.
9. Care should be taken with G7 Freedom Constrained Liners to ensure proper head orientation with the etched line being placed in the most superior position. Incorrect head orientation can increase the likelihood of disassociation from the liner during normal activities.
10. The Biomet G7 Freedom Constrained Liner System requires accurate anatomical alignment and careful positioning to prevent impingement with the femoral component.
11. Closed reduction of the Biomet G7 Freedom Constrained Liner System may not be possible. Patients should be made aware that treatment of device dislocation may require additional surgery.

While the Biomet G7 Freedom Constrained Liner 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.

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. Patients should be instructed that significant reduction in the range of motion is inherent to the design characteristics of a G7 Freedom constrained acetabular liner, and that activities that may force the joint to exceed those range of motion limits should be avoided.

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 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.

Specific to Biomet G7 Freedom Constrained Liners:

1. In order to minimize the risks of dislocation and loosening of the shell-acetabular bone or shell-bone cement interface that may occur when using a metallic shell intended for biological fixation or cemented use only, surgeons should consider

providing immediate resistance to tensile forces between the metallic shell and the acetabular bone or bone cement interface through the use of orthopedic bone fixation devices such as bone screws, spikes, screw threads, fins, or other bone fixation devices.

2. Physicians should consider component malposition, component placement, and the effect on range of motion when using modular heads (with sleeves or skirts) and extended liners.
3. Regarding component malposition above, recommendation is to caution physician regarding the malpositioned acetabular components cup and the potential for impingement, 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, malposition, non-union, bone resorption, and/or excessive, unusual and/or awkward movement and/or 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, 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.
9. Fatigue fracture of component can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, and/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.

15. With Biomet G7 Freedom Constrained Liners retaining ring failure or migration which may be due to impingement, fatigue, excessive stress, and/or wear increases the risk of dislocation, and therefore, may require additional surgery.

**MRI INFORMATION**

The Biomet G7 Acetabular System Polyethylene Liners 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**

ArComXL Acetabular Liners

ArComXL components are sterilized by exposure to Gas Plasma.

E1 Acetabular Liners

E1 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.

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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.**



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	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)
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	WEEE device
	Catalogue number
	Batch code
	Flammable
	Authorized representative in the European Community