

**01-50-0966**

**Revision E**

**Date: 2014-01**



## **ArComXL Highly Crosslinked Polyethylene Liners**

### **ATTENTION OPERATING SURGEON**

#### **DESCRIPTION**

Acetabular liners are composed of UHMWPE and are manufactured into various designs and sizes. The acetabular liners are utilized with other hip prostheses as part of a total joint system. Total hip joint prostheses include: femoral stems, femoral heads, acetabular shells, and acetabular liners. Components are available in numerous designs and sizes intended for primary and/or revision applications. Specialty components that can be added to the total hip system include: acetabular screws, centering sleeves, and canal plugs.

#### **MATERIALS**

Acetabular Liners ArComXL highly crosslinked Ultra High Molecular Weight Polyethylene (UHMWPE)

#### **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 of previously failed total hip arthroplasty.

Cemented and uncemented applications.

#### **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/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. Do not modify implants. The surgeon is to be thoroughly familiar with the implants and instruments prior to performing surgery. Use clean gloves when handling implants. Laboratory testing indicates that implants subjected to body fluids, surgical

debris and/or fatty tissue have lower adhesion strength to cement than implants handled with clean gloves.

1. Acetabular screws are to be fully seated to assure stable fixation and to avoid interference with the acetabular liner component.
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. Care is to be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentrations, which may lead to failure of the procedure. Complete preclosure cleaning and removal of bone cement debris, metallic debris, and other surgical debris at the implant site is critical to minimize wear of the implant articular surfaces. Implant fracture due to cement failure has been reported.

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, weight gain, and obesity have been implicated with premature failure of the implant 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, 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.

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. 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, malposition, 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.

**MRI INFORMATION**

ArComXL Highly Crosslinked 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**


Prosthetic components are sterilized by exposure to Gas Plasma. Do not resterilize. Single Use Only. Do Not Reuse. Do not use any component from an opened or damaged package. Do not use implants past 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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