Directionally Engineered Highly Crosslinked Polyethylene
For product information, including indications, contraindications, warnings, precautions and potential adverse effects, see the package insert and Biomet’s website.
Building on the long-standing clinical heritage of ArCom® Polyethylene, Biomet is proud to introduce directionally engineered Highly Crosslinked Polyethylene for total hip replacement.
Several years ago, our competitors introduced highly-crosslinked polyethylene (HXLP). Biomet chose not to follow that path. Questions arose regarding the mechanical and clinical properties of HXLP offered by some of our competitors, many of which have been borne out by clinical reports.

1. Lab testing indicated lower fatigue strength and increased brittleness.¹⁻⁴
2. Lab testing indicated the potential for severe oxidation resulting from certain types of processing methods.⁵
3. Short-term retrievals showed evidence of premature surface cracking in some cases.⁶
Before Biomet introduced a new method of processing polyethylene, we wanted to ensure that it would be a true improvement over our own ArCom® polyethylene, addressing the performance questions presented in the literature surrounding other HXLP.

**ArComXL™ 2nd generation HXLP** addresses the concerns associated with 1st generation HXLP by providing:

- High Fatigue Strength
- Extreme Oxidative Stability
- Similar Particle Size to ArCom® Polyethylene
- A Solid Clinical Heritage

Many highly crosslinked polyethylene processing methods lead to mechanical weakening of the material. The patented processing method of ArComXL™ maintains higher resistance to crack propagation than 1st generation HXLPs.
Since 1993, no other attempt at polyethylene improvement has equaled the benefits of isostatic compression molded ArCom® Polyethylene. Many orthopedic surgeons regard ArCom® Polyethylene as the gold standard among modern polyethylene bearings. ArComXL™ is the only highly crosslinked polyethylene built on this clinical heritage. ArComXL™ has demonstrated in laboratory studies a 47%-64% decrease in volumetric wear rate, a 30% increase in ultimate tensile strength, similar wear-particle shape and size, and no measurable oxidation under accelerated aging.15,17

ArCom® Polyethylene

8 Year Clinical Follow-Up
Zero Osteolysis 19

40% Wear Reduction 18
36mm heads available with ArComXL™ liners offer high range of motion and low wear potential.

ArComXL™ Polyethylene

...47–64% Decrease in Volumetric Wear Rate, High Strength, and No Measurable Oxidation.
Step 1: Flexible tubes are filled with starting resin and sealed in preparation for water compaction.

Step 2: Isostatic water pressure is applied to the sealed flexible tube, which forms the resin into a bar shape.

Step 3: The shaped resin, or “green bars,” are now 70% consolidated. Heat and more intense pressure are still required for full consolidation.

Step 4: Green bars are now packaged in foil pouches, repeatedly flushed with argon gas, and a vacuum is drawn on the foil pouches.

Step 5: The vacuum sealed bars are now placed in the hot isostatic compression chamber and are subjected to 10 hours of carefully controlled heat and argon gas pressure.

Step 6: Laser candling inspection is used to ensure that ArCom® bars pass stringent consolidation standards.

Pure, consolidated polyethylene barstock, ready to be machined into ArCom® Polyethylene liners or further processed into ArComXL™ Polyethylene.
Solid State Deformation enables high levels of crosslinking without sacrificing the mechanical strength or increasing the risk of oxidation. Gamma irradiated polyethylene barstock is heated and subjected to the Solid State Deformation process, which quenches residual free radicals, a concern with higher doses of irradiation. The entire process 
takes place below the melt temperature of polyethylene, preserving the mechanical strength. The Solid State Deformation “cannon” (see page 10) quenches residual free radicals through a low heat process which, unlike other 1st generation processes, does not involve melting. This patented process does not decrease the mechanical strength or change the crystallinity of the polyethylene.*
Longitudinal Polymer Orientation (LPO): Directionally Engineered Polyethylene

Solid State Deformation not only assists in quenching free radicals, but also opens the door to a new concept in polyethylene wear reduction:

Longitudinal Polymer Orientation (LPO). As a result of Solid State Deformation, LPO directionally aligns the polymer chains along the longitudinal axis of the polyethylene barstock. This provides the highest level of mechanical strength in the direction that wear occurs.

LPO

- Directionally Orient the Polymer Chains Along the Longitudinal Axis
- Provides High Strength in the Direction of Wear
- Assists in Neutralizing Free Radicals
A Clinical Heritage of Strength, Wear Reduction, and Low Osteolysis

ArComXL™ Polyethylene is the first of the 2nd generation HXLPs to have high mechanical strength and high resistance to oxidation. ArComXL™ also provides a 47 to 64% reduction in volumetric wear rate over ArCom® Polyethylene.15 Extensive independent testing has been conducted on the mechanical strength of the material and the wear particle size, shape, and distribution—all of which are found to be consistent with ArCom® Polyethylene.17

ArComXL™ is built on the strength of ArCom® Polyethylene, which maintains high mechanical strength specifically in the longitudinal axis compared to other highly crosslinked polyethylenes.17, 20, 21

ArComXL™ has similar wear particle shape and size distribution when compared to ArCom® polyethylene with a reduction in the estimated amount of particles in the 0.2 to 0.4 micron range.17 Concerns have been raised about the osteolytic potential of smaller wear particles.9, 10
Acetabular screws are to be fully seated to assure stable fixation and to avoid interference with implants and instruments prior to performing surgery. Components that can be added to the total hip system include: acetabular screws, centering sleeves, and canal plugs.

### Materials

**Acetabular Liners**

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.

### 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 or uncemented applications.

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.

### 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, 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.

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.

Biom 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/or weight gain have been implicated with premature failure of the implant by loosening, fracture, 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.

### Precautions

Specialized instruments are designed for Biom 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, 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 placed in a different patient, even if momentarily.

### 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.
Prosthetic components are sterilized by exposure to one of the following methods:

- Ethylene Oxide Gas (ETO)
- Gas Plasma

Sterility
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- Ethylene Oxide Gas (ETO)
- Gas Plasma

References

15. Data on file at Biomet.
17. Data Submitted for publication (Exponent).
FDA Cleared Claim Statements

Hip Simulator Wear
The Biomet ArComXL™ polyethylene acetabular inserts (Part no.: XL-105933) tested are isostatically compression molded highly crosslinked components (50kGy gamma irradiated under argon) that are sterilized in air by either gas plasma or ethylene oxide. ArComXL™ was compared to identical predicate polyethylene liners (Part No. 12-105893) that were machined from isostatically molded polyethylene that was subsequently gamma sterilized (25-40kGy) in argon. A side by side hip simulator wear test of the two materials showed a 47% reduction in the volumetric wear rate (34.9 opposed to 65.8mm³/10⁷ cycles) for ArComXL™ (ETO sterilized) when compared to the predicate device. All inserts in this study mate with either a 50 or 52mm acetabular shell, have a standard rim, a 32mm inner diameter, and a 4.75mm bearing thickness. Testing was performed under multiaxial hip joint simulation for five (5) million cycles, using a Paul hip load profile with a maximum load of 2.4kN, 32mm CoCr articulating heads, and a bovine calf serum lubricant. The results of in vitro hip wear simulator tests have not been shown to quantitatively predict clinical wear performance.

Abrasive Hip Simulator Wear
The Biomet ArComXL™ polyethylene acetabular inserts (Part No. XL-105933) tested are isostatically compression molded highly crosslinked components (50kGy gamma irradiated under argon) that are sterilized in air by either gas plasma or ethylene oxide. ArComXL™ was compared to identical predicate polyethylene liners (Part No. 12-105893) that were machined from isostatically molded polyethylene that was subsequently gamma sterilized (25-40kGy) in argon. After 5 million cycles of hip simulator wear with no additives, bone cement particulate was added to simulate abrasive conditions for two (2) million cycles. Under abrasive conditions, the Biomet ArComXL™ (ETO sterilized) polyethylene acetabular insert (Part No. XL-105933) showed a 64% reduction in volumetric wear rate (109.8 opposed to 309.0mm³/10⁷ cycles) when compared to the same acetabular inserts fabricated from the predicate polyethylene (Part No. 12-105893). These inserts mate with either a 50 or 52mm acetabular shell, have a standard rim, a 32mm inner diameter, and a 4.75mm bearing thickness. Testing was performed under multiaxial hip joint simulation for two (2) million cycles, using a Paul hip load profile with a maximum load of 2.4kN, 32mm CoCr articulating heads, and a bovine calf serum lubricant. The results of in vitro hip wear simulator tests have not been shown to quantitatively predict clinical wear performance.

Free Radicals
The Biomet ArComXL™ polyethylene material tested is isostatically compression molded, highly crosslinked (50kGy gamma irradiated under argon), and sterilized in air by either gas plasma or ethylene oxide. ArComXL™ was compared to predicate polyethylene material that was machined from isostatically molded polyethylene that was subsequently gamma sterilized (25-40kGy) in argon. The Biomet ArComXL™ (gas plasma sterilized) material showed a 94% reduction in the number of free radicals (0.22x10¹⁴ compared to 3.82x10¹⁰ spins/g) versus the predicate polyethylene material. Testing was performed by an independent laboratory using Electron Spin Resonance (ESR). Results of in vitro free radical testing have not been shown to quantitatively predict oxidation resistance.

Oxidative Stability
The Biomet ArComXL™ polyethylene material tested is isostatically compression molded, highly crosslinked (50kGy gamma irradiated under argon), and sterilized in air by either gas plasma or ethylene oxide. ArComXL™ was compared to predicate polyethylene material that was machined from isostatically molded polyethylene that was subsequently gamma sterilized (25-40kGy) in argon. The Biomet ArComXL™ (gas plasma sterilized) material did not show any measurable oxidation by FTIR (oxidation index less than 0.4 throughout the sample) after accelerated aging per ASTM F2183-02, which is designed to simulate several years of shelf-aging in air. In contrast, when the predicate material was removed from inert packaging (packaging that was vacuum sealed after purging with argon), it did show measurable levels of oxidation after accelerated aging (oxidation index was greater than 1.1 at a depth of 1mm). Further, after accelerated aging the average ultimate load for all three ArComXL™ axes (gas plasma sterilized) remained higher than the peak load (31% higher; 91.8N vs. 70.2N); whereas, the ultimate load for the isotropic predicate material was significantly less than the peak load (44% lower; 42.6N vs. 75.6N) as measured by small punch testing, ASTM F2183-02.

Mechanical Strength
The Biomet ArComXL™ polyethylene material tested is isostatically compression molded, highly crosslinked (50kGy gamma irradiated under argon), and sterilized in air by either gas plasma or ethylene oxide. ArComXL™ was compared to predicate polyethylene material that was machined from isostatically molded polyethylene that was subsequently gamma sterilized (25-40kGy) in argon. The Biomet ArComXL™ (ETO sterilized) material showed a 30% increase in ultimate tensile strength (from 47 MPa to 61 MPa) in the longitudinal axis versus the predicate polyethylene material. The tensile testing was performed per ASTM standard D638-02a using Type 5 tensile specimens.