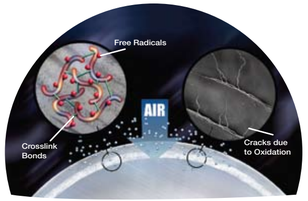
ARCOMXL® POLYETHYLENE

ADDRESSING CHALLENGES OF 1ST GENERATION HXLPE

Building upon the successful clinical heritage of ArCom® Polyethylene, Biomet introduced ArComXL® Polyethylene. Biomet created ArComXL® to address clinical reports showing the following concerns regarding the mechanical and clinical limitations of competitors' 1st generation HXLPE.

Problems with 1st Generation HXLPE

- Lower fatigue strength and increased brittleness[7–10]
- Potential for severe oxidation resulting from certain types of processing methods[11]
- Evidence of premature surface cracking in some short-term retrieval cases[12]



Gamma irradiation increases the level of crosslink bonds in polyethylene. This is beneficial to wear resistance but produces free radicals inside the polyethylene. If left untreated, these free radicals may increase the oxidation potential of polyethylene when exposed to air.

References

1. Data on file at Biomet. Bench test results not necessarily indicative of clinical performance.
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11. Muratoglu, O. *et al*. Effect of Radiation, Heat, and Aging on *In Vitro* Wear Resistance of Polyethylene. *Clinical Orthopaedics and Related Research*. 417, 253–262, 2003.
12. Jasty, M. Crosslinked Poly Podium Presentation. 4th Annual Symposium on Alternative Bearing Surfaces in TJR. Maui, Hawaii, September 2001.

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Form No. BOI0062.1 • REV123107

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BIOMET® ORTHOPEDICS

KNEES • **HIPS** • EXTREMITIES • CEMENT AND ACCESSORIES • PMI • TECHNOLOGY

ARCOMXL® POLYETHYLENE

In laboratory studies, 2nd generation ArComXL® Polyethylene demonstrated:

Low Wear

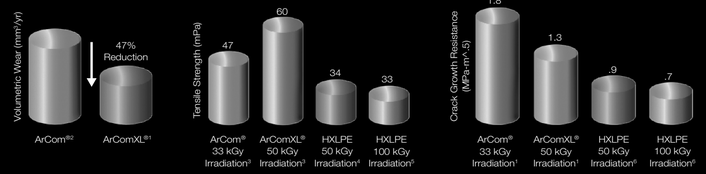
- 47% decrease in volumetric wear rate compared to ArCom® Polyethylene, offering lower potential for osteolysis[1]

High Strength

- 30% increase in ultimate tensile strength over ArCom® Polyethylene, allowing for use with larger femoral heads[1]

No Measureable Oxidation

- No measurable oxidation under accelerated aging[1]



ARCOM® POLYETHYLENE

CLINICALLY PROVEN FOUNDATION

1. Flexible tubes are filled with starting resin and sealed in preparation for water compaction.

2. Isostatic water pressure is applied to the sealed flexible tube, forming the resin into a bar shape.

3. The shaped resin, or "green bar," is now 70% consolidated. Heat and more intense pressure follow for full consolidation.

4. Green bars are packaged in foil pouches and repeatedly flushed with argon gas. Pouches are vacuum sealed.

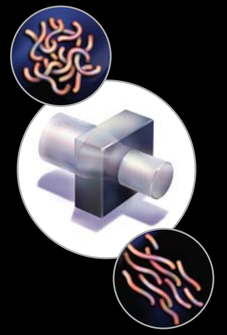
5. The vacuum sealed bars are placed in the hot isostatic compression chamber and subjected to 10 hours of carefully controlled heat and argon gas pressure.

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

7. Pure, consolidated polyethylene barstock is ready to be machined into ArCom® Polyethylene liners or further processed into ArComXL® Polyethylene.

SOLID STATE DEFORMATION PROCESS

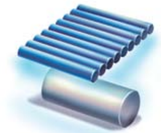
- Enables high levels of crosslinking without sacrificing mechanical strength or increasing oxidation risks
- Quenches residual free radicals, a concern with higher doses of irradiation
- Entire patented process takes place below melting temperature of polyethylene, preserving mechanical strength and maintaining crystallinity[3]



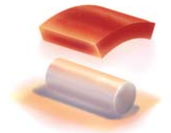
ARCOMXL® POLYETHYLENE

TRUE 2ND GENERATION PROCESSING

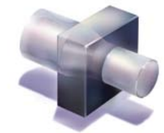
1. ArComXL® Polyethylene begins with ArCom® barstock.



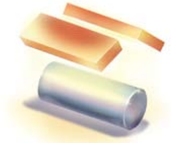
2. 50kGy Gamma Irradiation is utilized to induce crosslinking.



3. Barstock is pre-heated below melting temperature.



4. Solid state deformation quenches free radicals below melting temperature, enabling crosslinking without sacrificing strength or increasing risk of oxidation.



5. Barstock undergoes stress relief processing.

6. ArComXL® barstock is machined into acetabular liners.

7. Gas plasma is utilized for non-energetic sterilization of the finished ArComXL® Polyethylene.