E Poly™
HXLPE



BIOMET®
ORTHOPEDICS



E Poly™
H X L P E

Vitamin E Stabilized HXLPE



From the pioneers of polyethylene

Uniting the research power of Massachusetts General Hospital with Biomet's polyethylene expertise, E-Poly™ vitamin E stabilized highly crosslinked polyethylene (HXLPE) is unlike any other polyethylene currently available for joint replacement. It offers:

- **Ultra-low wear with large femoral heads[1]**
- **Greater strength than first generation remelted HXLPE[1–3]**
- **True oxidative protection without remelting[1]**



Ultra-low wear with large femoral heads

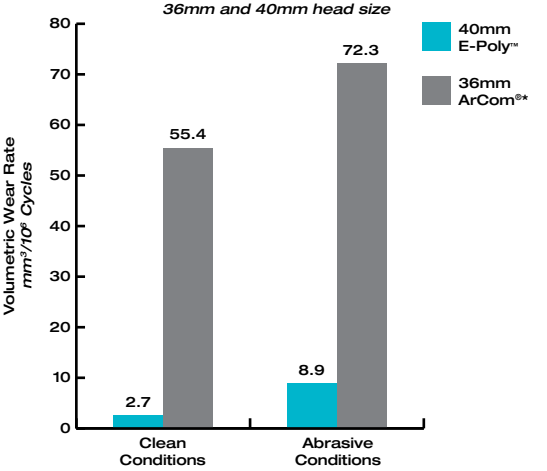
With traditional polyethylene, increasing head size can lead to significant increases in wear.

E-Poly™ HXLPE:

- Can be used with large femoral heads for greater joint stability and ROM
- Employs higher levels of crosslinking for better wear performance
- Demonstrated ultra-low wear rates with large femoral heads; 95 percent wear reduction when comparing 40mm E-Poly™ liners to 36mm ArCom® liners[1]
- Demonstrated ultra-low wear rates with smaller femoral heads; 99 percent wear reduction when compared to the already low wear rate of ArComXL® HXLPE[1]

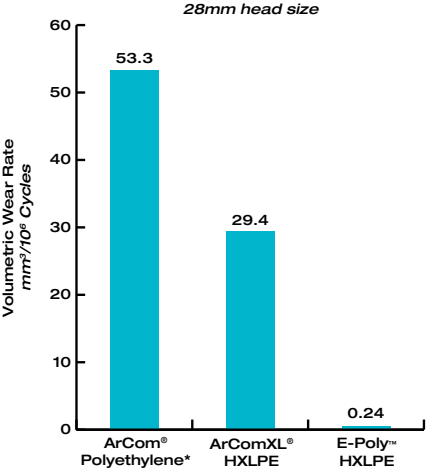
Large Diameter Volumetric Wear[1]

5 million cycles on a hip simulator
36mm and 40mm head size



Small Diameter Volumetric Wear[1]

5 million cycles on a hip simulator
28mm head size

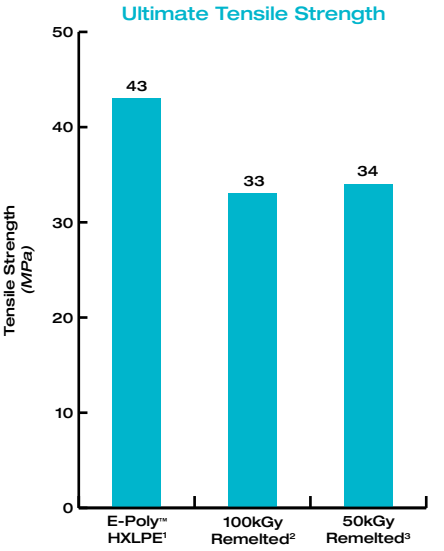


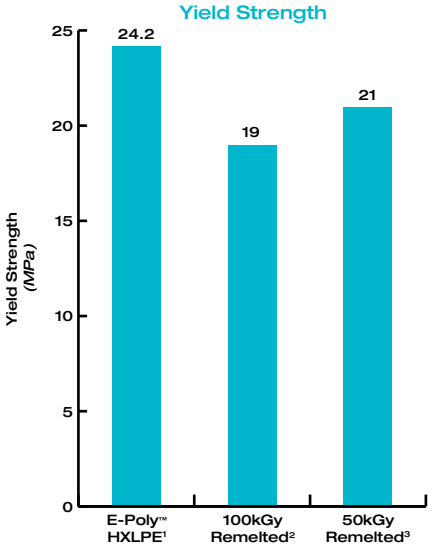
*Clinically proven material[4]



Greater strength than first generation remelted highly crosslinked polyethylene

- Never remelted, E-Poly™ HXLPE maintains its strength
- Fatigue strength greater than first generation remelted highly crosslinked polyethylene[1–3]
- Stronger than sequentially crosslinked and annealed materials after an environmental stress cracking (ESC) study[1]


Ultimate Tensile Strength
Tensile Strength (MPa)
50
40
30
20
10
0
43
33
34
E-Poly™ HXLPE¹
100kGy Remelted²
50kGy Remelted³


Yield Strength
Yield Strength (MPa)
25
20
15
10
5
0
24.2
19
21
E-Poly™ HXLPE¹
100kGy Remelted²
50kGy Remelted³

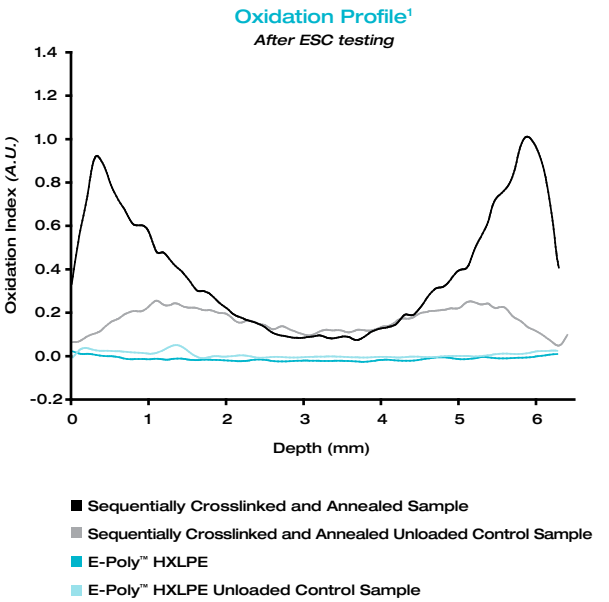


True oxidative protection without remelting

- Infused with vitamin E, a natural antioxidant, to neutralize free radicals
- Greater oxidative protection than sequentially crosslinked and annealed materials after an environmental stress cracking (ESC) study[1]
- Some sequentially crosslinked and annealed samples demonstrated stress cracking and sheared in half close to the end of the ESC test
- Testing showed that vitamin E prevented oxidative degradation of the polyethylene[1,5]

Environmental Stress Cracking Study

Cyclic loading, combined with the *in vivo* environment, may potentially induce cracks in polyethylene. This phenomenon is referred to as environmental stress cracking (ESC). ESC in polyethylene is related to the amount of non-stabilized free radicals in the material and the ability for those free radicals to react with oxygen.





Uniting technology

Massachusetts General Hospital

Material scientists at Massachusetts General Hospital have spent years studying highly cross-linked polyethylene for total joint replacement. Their research has established vitamin E stabilized polyethylene as a technology that has demonstrated increased wear resistance and oxidative stability.[5]

Biomet Orthopedics, Inc.

From the introduction of clinically proven ArCom® polyethylene in 1992, Biomet has maintained a commitment to improve polyethylene technology for joint replacement.



Moving beyond simple wear reduction

First generation highly crosslinked polyethylene has shown significant *in vitro* wear reduction when compared to conventional polyethylene; however, these materials have exhibited two chief limitations:

1. **The remelting process weakens the polyethylene.**
   To prevent oxidation caused by free radicals, a by-product of crosslinking, certain first generation materials remelt the polyethylene, thus reducing its strength.[6]

2. **The annealing process does not fully prevent oxidation.**
   Annealed materials maintain their strength, but this process does not fully eliminate the free radicals in the polyethylene that can cause oxidation.[7–9]



Revolutionary processing

Utilizing technology invented at Massachusetts General Hospital, Biomet engineers developed a unique process to create a revolutionary new polyethylene that would surpass the limitations of first generation highly crosslinked polyethylene.

- The same isostatically compression molded polyethylene barstock as used in clinically proven ArCom® polyethylene is irradiated to induce high levels of crosslinking.[4]

- Through a proprietary manufacturing process, which does not involve remelting, Biomet infuses vitamin E into the highly crosslinked polyethylene to neutralize free radicals.



References:

1. Data on file at Biomet. Bench test results not necessarily indicative of clinical performance.
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3. Bhambri, S. *et al.* The effect of aging on mechanical properties of melt-annealed highly crosslinked UHMWPE. Crosslinked and Thermally Treated Ultra-High Molecular Weight Polyethylene for Joint Replacements. 171–82, 2004.
4. Head, W. *et al.* Mechanical Properties and Clinical Evaluation of Isostatic Molded ArCom Polyethylene. SICOT. San Diego, CA. August 2002.
5. Muratoglu, O. *et al.* Wear Resistance and Mechanical Properties of Highly Cross-Linked, Ultrahigh-Molecular Weight Polyethylene Doped With Vitamin E. *The Journal of Arthroplasty*. 21(4): 580–591, 2006.
6. Halley, D. *et al.* Recurrent Dislocation After Total Hip Replacement with a Large Prosthetic Femoral Head. *Journal of Bone and Joint Surgery.* 86-A(4): 827–30, 2004.
7. Bhattacharyya, S. *et al.* Severe In Vivo Oxidation in a Limited Series of Retrieved Highly-Crosslinked UHMWPE Acetabular Components with Residual Free Radicals. Paper No. 0276. ORS San Francisco, CA. March 2004.
8. Currier, B.H. *et al.* Crossfire Retrievals—What Can We Learn? Paper No. 1182. ORS. Washington D.C. March 2005.
9. Ries, Michael D. Effect of Cross-linking on the Microstructure and Mechanical Properties of Ultra-high Molecular Weight Polyethylene. *Clinical Orthopaedics and Related Research.* (440):149–156, 2005.

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