

References

1. Biomet Biomaterials Laboratory 'The revolutionary second generation vitamin E stabilised highlycrosslinked UHMWPE' Jan 2007.
2. Wannomnomae, K. Environmental Stress Cracking of Two-Tocopherol Doped, Irradiated UHMWPEs and Two Contemporary UHMWPEs. Report Provided by the Orthopaedic Biomechanics and Biomaterials Laboratory at Massachusetts General Hospital. January 12, 2007.
3. Bhambri, S. *et al.* The effect of ageing 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. 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.
5. 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.
6. Currier, B.H. *et al.* Crossfire Retrievals—What Can We Learn? Paper No. 1182. ORS. Washington D.C. March 2005.
7. 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.
8. Head, W. *et al.* Mechanical Properties and Clinical Evaluation of Isostatic Molded ArCom™ Polyethylene. SICOT. San Diego, CA. August 2002.
9. 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.
10. Parks, N.L. *et al.* Modular Tibial Insert Micromotion: A Concern with Contemporary Knee Implants. *Clinical Orthopaedics and Related Research*. 356: 10–15, 1998.

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European Central Marketing
Waterton Industrial Estate
Bridgend
South Wales
CF31 3XA
Tel: +44 [0] 1656 655221
Fax: +44 [0] 1656 645454



One Surgeon. One Patient.™



Antioxidant Infused Technology

BIOMET®



Antioxidant Infused Technology

From the pioneers of polyethylene

Uniting the research power of Massachusetts General Hospital with Biomet's polyethylene expertise, E1™ Antioxidant Infused Technology is unlike any other bearing material currently available for joint replacement. It offers:

- **Ultra-low wear¹**
- **Greater strength than first generation remelted HXLPE¹⁻³**
- **True oxidative protection without remelting¹**



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.⁴

2. The annealing process does not fully prevent oxidation.

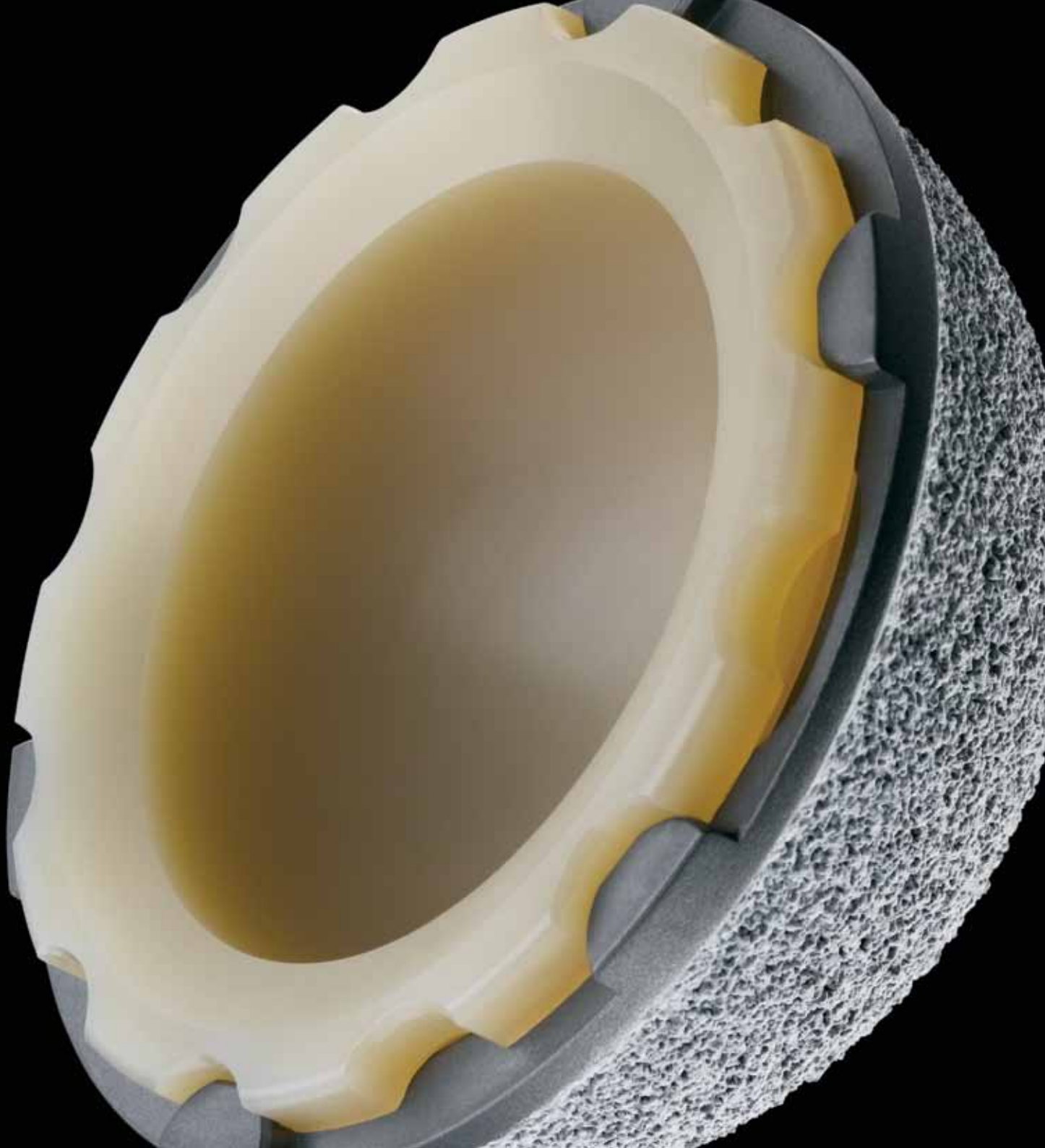
Annealed materials maintain their strength, but this process does not fully eliminate the free radicals in the polyethylene that can cause oxidation.⁵⁻⁷



Revolutionary processing

Utilising 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.⁸
- Through a proprietary manufacturing process, which does not involve remelting, Biomet infuses vitamin E into the highly crosslinked polyethylene to neutralise free radicals.



Ultra-low wear with large femoral heads

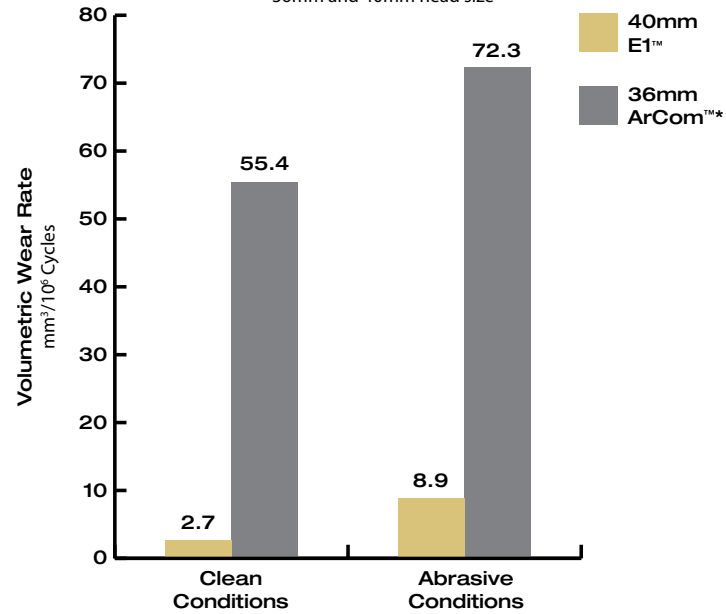
With traditional polyethylene, increasing head size can lead to significant increases in wear.

E1™ Antioxidant Infused Technology:

- 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 E1™ liners to 36mm ArCom™ liners¹
- Demonstrated ultra-low wear rates with smaller femoral heads; 99 percent wear reduction when compared to the already low wear rate of ArComXL™ HXLPE¹

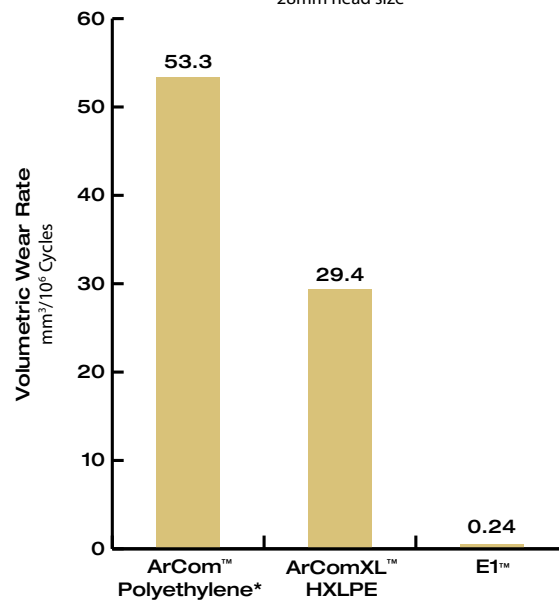
Large Diameter Volumetric Wear¹

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



Small Diameter Volumetric Wear¹

5 million cycles on a hip simulator
28mm head size



*Clinically proven material⁴

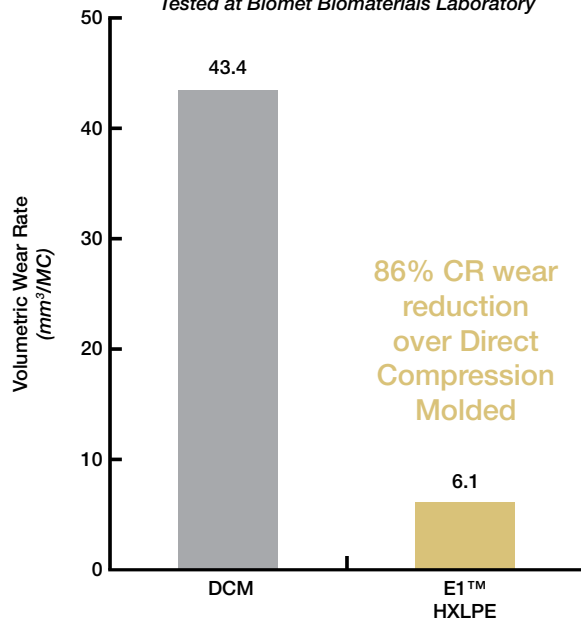
Ultra-low wear with tibial bearings

E1™ Antioxidant Infused Technology:

- Employs higher levels of crosslinking for better wear performance
- Demonstrated ultra-low wear rates with Cruciate Retaining Tibial bearings; 86 percent wear reduction when comparing CR E1™ bearings to CR ArCom™ bearings¹
- Demonstrated ultra-low wear rates with Posterior Stabilised Tibial bearings; 87 percent wear reduction when comparing PS E1™ bearings to PS ArCom™ bearings¹
- E1 Vanguard Tibial Bearings are combined with a compressively loaded tibial locking mechanism, providing proven resistance to micromotion¹⁰
- 3 primary articulations, providing increasing levels of constraint; Cruciate Retaining, Cruciate Retaining Lipped and Posterior Stabilised

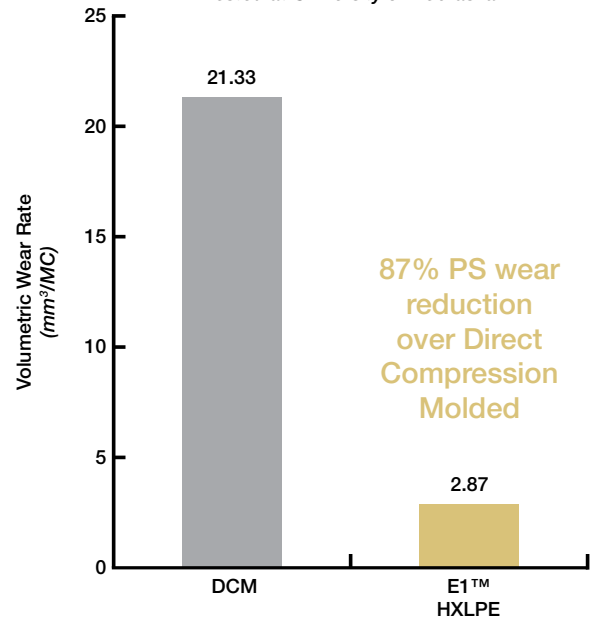
Volumetric Wear Rates of 87/91
Cruciate Retaining (CR) Tibial Bearings¹

Tested at Biomet Biomaterials Laboratory



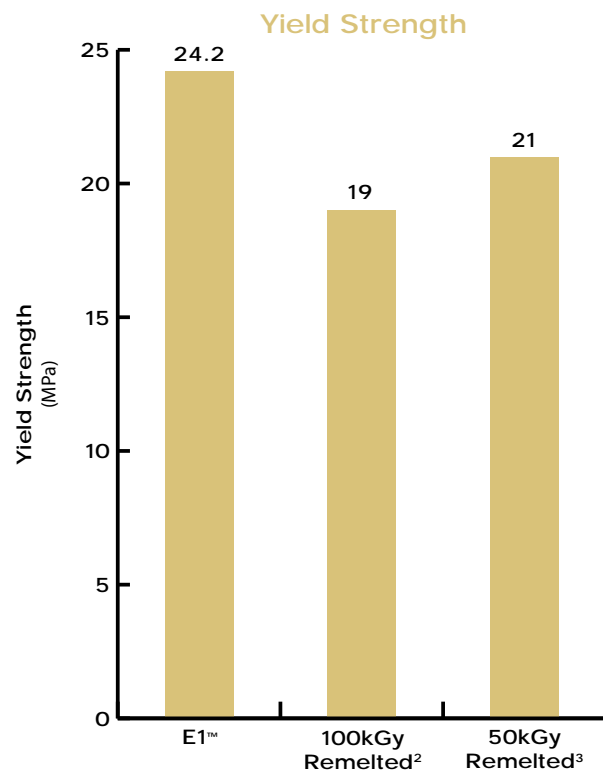
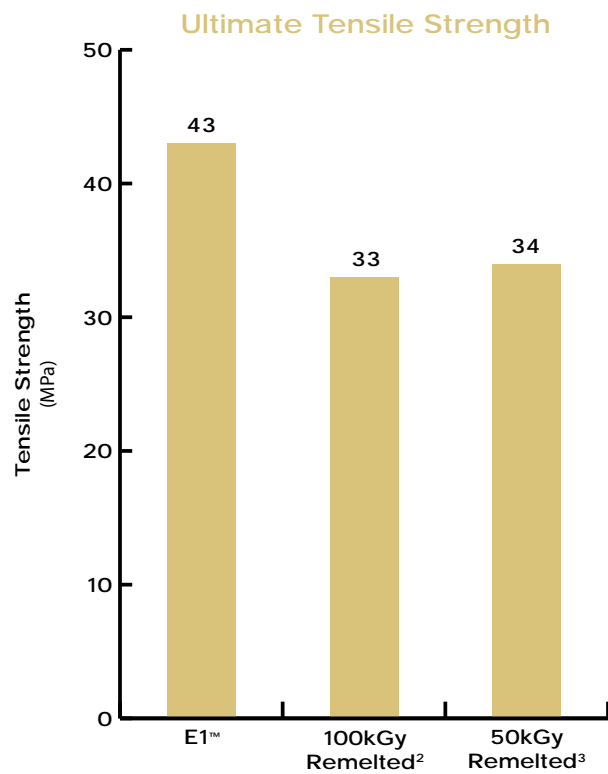
Volumetric Wear Rates of 87/91
Posterior Stabilized (PS) Tibial Bearings¹

Tested at University of Nebraska



Greater strength than first generation remelted highly crosslinked polyethylene

- Never remelted, E1™ Antioxidant Infused Technology maintains its strength
- Fatigue strength greater than first generation remelted highly crosslinked polyethylene¹⁻³
- Stronger than sequentially crosslinked and annealed materials after an environmental stress cracking (ESC) study¹

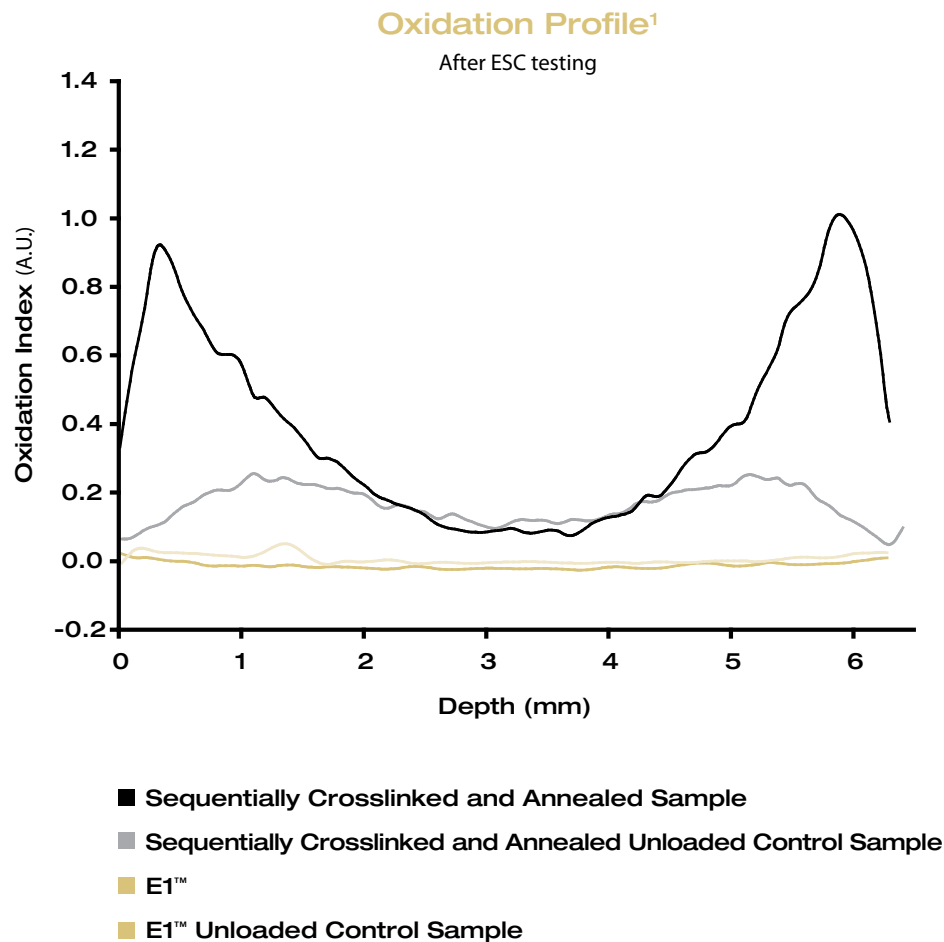


True oxidative protection without remelting

- Infused with vitamin E, a natural antioxidant, to neutralise free radicals
- Greater oxidative protection than sequentially crosslinked and annealed materials after an environmental stress cracking (ESC) study¹
- 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^{1,9}

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-stabilised free radicals in the material and the ability for those free radicals to react with oxygen.



Uniting

Massachusetts General Hospital

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

Biomet Orthopedics LLC

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

