E1 Antioxidant Infused Technology
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Does polyethylene really matter?**Absolutely.**

Meeting the modern demands of bearing surfaces means achieving the optimal balance of maximized strength, maximized wear resistance and maximized oxidation resistance.

E1 Antioxidant Infused Technology is the only bearing option currently on the market that utilizes a proprietary diffusion process to maximize strength, wear resistance and prevent oxidative degradation of the polyethylene.*

**Only one** company offers a balanced polyethylene maximizing strength, wear resistance and oxidative stability.
The mounting evidence is clear: **oxidation** threatens the longevity of joint replacement.¹-⁷†

Patients are **presenting earlier**, **living longer** and have **higher expectations** than ever before.

Biomet pioneered the **first and only** antioxidant infused hip and knee bearings that actually **prevent oxidative degradation** of the polyethylene.*

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*U.S.-FDA cleared claim. See biomet.com/e1 for complete claim language.
† In vitro data. Laboratory testing is not necessarily indicative of clinical performance.
E1 Antioxidant Infused Technology

Not all polyethylene is created equal

Highly crosslinked polyethylenes that use annealing, sequential annealing and remelting processes cannot maximize strength and wear characteristics while offering oxidative stability. Even polyethylenes that blend antioxidants into the resin have not been shown to achieve this balance.8

With the increasing demands of today’s patients, you should demand more from your polyethylene.

Remelted Products:†
- DePuy XLK3, Marathon®3 or AltrX®
- Smith and Nephew XLPE3
- Zimmer Durasul,® Prolong®3 and Longevity®8,3,5

Annealed and Sequentially Annealed Products:‡
- Stryker X3®12 and Crossfire®11

Blended Antioxidant Products:‡
- DePuy AOX®17
- Zimmer Vivacit-E®88
- DJO E+16
- StelKast Exp™
- Corin ECIMA®
- Mathys Vitamys®

Not all polyethylene is created equal

Characteristics of Remelted Polyethylene
- Wear resistant1
- Decreased strength2
- Limited oxidation resistance9,10†

Characteristics of Annealed Polyethylene
- Wear resistant1
- Maintains strength11,12†
- Limited oxidation resistance3,13,14†

Characteristics of Blended Polyethylene
- Decreased wear resistance7†
- Maintains strength1†
- Increased oxidation resistance15,16†

† In vitro data. Laboratory testing is not necessarily indicative of clinical performance.
‡ These examples are specific to the poly processing technology and are not specific to the referenced studies, unless otherwise cited.
Is your bearing oxidatively stable?
Biomet prides itself on offering surgeons innovative new products, materials and technologies based on sound engineering and science, which has led to Biomet’s rich history of industry firsts in polyethylene development.

**Biomet was the first company in the U.S. to:**

- **1979**: Introduce a compression molded tibial component
- **1993**: Manufacture polyethylene completely in-house from powder to final product (1979 – knees, 1993 – hips)
- **1995**: Develop ArCom barrier packaging with Argon to protect against on the shelf oxidation
Introduce antioxidant infused technology in polyethylene acetabular bearings

Use proprietary mechanical deformation process to create ArCom XL highly crosslinked polyethylene

Introduce antioxidant infused technology in polyethylene tibial bearings
The choice is clear when clinical heritage speaks so loudly

E1 Technology was the first and only antioxidant infused polyethylene designed to truly maximize a bearing’s strength, low-wear characteristics and resistance to oxidation. To accomplish this critical balance, E1 bearings start with a clinically proven, compression molded polyethylene.13,14,19-28**

The results of our compression molded polyethylene speak for themselves.

ArCom TKA Published Survivorship

97.8% Survivorship at 20 years19
98.8% Survivorship at 15 years20
100% Survivorship at 11 years21
95% Survivorship at 11 years22
97% Survivorship at 10 years23
99% Survivorship at 5 years24
ArCom THA Published Survivorship

100% Survivability at 5 years\textsuperscript{13}

98% Survivability at 6.5 years\textsuperscript{16}

97.9% Survivability at 8.5 years\textsuperscript{37}\textsuperscript{†}

100% Survivability at 5.7 years\textsuperscript{13}

98% Survivability at 12-16 years\textsuperscript{14}

100% Survivability at 9 years\textsuperscript{39}

\textsuperscript{†} In vitro data. Laboratory testing is not necessarily indicative of clinical performance.
Antioxidant Infused Technology

The facts are clear...

The process of annealing polyethylene below its melt temperature was designed to retain a bearing’s strength while reducing its potential for oxidation (free radicals).

However, free radicals are still trapped in the polyethylene following the annealing process and have been shown to oxidize in vivo.\textsuperscript{11,29,30}

Annealed and Sequentially Annealed Polyethylenes

Evaluation of Oxidation and Fatigue Damage of Retrieved Crossfire Polyethylene Acetabular Cups
Currier, B., et al. JBJS. 89: 2023–29, 2007.\textsuperscript{11}

- “The relatively rapid oxidation exhibited by these retrieved cups resulted from the free radicals remaining in the polyethylene...”
- “This study of retrieved acetabular cups demonstrated that (remelted) polyethylene oxidizes over time, changing its mechanical properties.”
- “This reduction in mechanical properties can be expected to continue as oxidation increases over time in vivo.”


- “The oxidation rate measured in X3 tibial inserts appears to be higher than the oxidation rate of traditional gamma-sterilized components.”
- “Small punch testing revealed a significant decrease in peak load, ultimate extension and work to failure...”
- “... [X3\textsuperscript{®}] showed significant decreases in crosslink density compared to the never implanted control, with decreases from 8–17.5 percent.”

\textsuperscript{†} In vitro data. Laboratory testing is not necessarily indicative of clinical performance.
Some manufacturers try reducing the oxidation potential of the polyethylene after crosslinking by heating the material above its melt temperature (remelting) to allow free radicals to combine.

While the remelting process was designed to increase the polyethylene’s oxidative stability and maintain its wear properties, remelted polyethylene has still been shown to oxidize in vivo\textsuperscript{2,3} and has also exhibited decreased tensile and fatigue strengths,\textsuperscript{33–35} which can present clinically in the form of cracking and fracture.\textsuperscript{29,31,32}

**Remelted Polyethylenes**


- “The retrieved liners demonstrated burnishing, scratching, abrasion and creep that in most cases were rated as moderate...”
- “All of the liners showed severe cracking or failure at the rim...”
- “The calculated toughness of Longevity is decreased by half compared with non-cross-linked reference polyethylene of the same resin type.”

**In Vivo Oxidation in Remelted Highly Cross-Linked Retrievals.** Currier, B., JBJS. 92:2409–18, 2010.\textsuperscript{3}

- “Oxidation measurements showed measurable oxidation in 22% of the retrieved remelted highly cross-linked liners and inserts after an average of two years in vivo.”
- “Remelted highly cross-linked UHMWPE acetabular and tibial retrievals showed unexpected oxidation.”
- “Maximum oxidation was found to correlate significantly with both in vivo time and total time since implantation.”

**Ex Vivo Stability Loss of Irradiated and Melted Ultra-High Molecular Weight Polyethylene.** Muratoglu, O., et al. JBJS. 92:2809–16, 2010.\textsuperscript{5}

- “Increasing oxidation, increasing crystallinity, and decreasing crosslink density correlated with the duration of ex vivo storage.”
- “…two months of service in vivo changed the irradiated and melted UHMWPE from being oxidatively very stable to being unstable.”
- “Conventional accelerated aging methods that challenge the polymer’s oxidative stability based on pre-existing free radicals need to be reconsidered.”
The facts are clear...

The goal of antioxidant polyethylenes is to address the clear limitations of highly crosslinked polyethylenes. Since vitamin E is “the most abundant and effective chain-breaking antioxidant present in the human body,” it is an attractive choice for increased oxidative stability in bearings.

But how the vitamin E is added to the polyethylene is critical. Simply blending vitamin E into polyethylene has not been shown to maximize wear resistance and keep the polyethylene from oxidizing.

**Blended Antioxidant Polyethylenes**

Effect of Thermal Treatment on the Wear of Radiation-Crosslinked UHMWPE with and without Vitamin E. Wang, A., et al. UHMWPE Meeting, Drexel University, Philadelphia PA, 2011.9†

- “All of the materials without vitamin E had better wear characteristics than [blended] vitamin E containing polyethylene.”

- “This study shows that regardless of thermal treatment, the addition of vitamin E [blended] negatively affects the wear characteristics of polyethylene by at least 40%.”


- “Unstabilized samples exhibited substantial oxidation throughout the surface and bulk with both types of aging.”

- “While vitamin E-stabilized, radiation cross-linked UHMWPEs were all superior to unstabilized samples, irradiated blends showed surface oxidation and subsurface oxidation potential beginning at ten months in real-time aging. In contrast, postirradiation vitamin E-diffused UHMWPEs showed no detectable oxidation and no increase in oxidation potential...”

*U.S. FDA cleared claim. See biomet.com/e1 for complete claim language.
† In vitro data. Laboratory testing is not necessarily indicative of clinical performance.
Only E1 Antioxidant Technology Infused bearings utilize a proprietary diffusion process—the only process that maximizes strength, wear resistance and prevents oxidative degradation of the polyethylene.*

Infused Antioxidant Polyethylenes


- “The low early femoral head penetration with vitamin-E stabilized polyethylene liner is excellent.”
- “This is the longest term documentation of in vivo wear performance of vitamin E stabilized highly cross-linked polyethylene.”


- “Although the sequential processing of SXL [sequentially irradiated and annealed UHMWPE] creates a material with a lower free radical content compared to once-annealed material, it still yields a material prone to oxidation under extreme conditions, raising questions as to the long-term oxidative stability of the material.”
- “The alpha-tocopherol present in E-Poly [E1 Technology] protected it against oxidation during this aggressive environmental stress cracking test.”
- “E-Poly [E1 Technology], protected by alpha-tocopherol, continues to exhibit high oxidation resistance even under adverse conditions.”


- “The stabilisation of radiation crosslinked UHMWPEs by the diffusion of the antioxidant vitamin E was developed to obtain oxidation resistance with improved fatigue strength by avoiding post-irradiation melting.”
- “Against accelerated aging and real-time aging in vitro, this material [vitamin E infused polyethylene] showed superior oxidation resistance to UHMWPEs with residual free radicals.”

Does Vitamin E-Stabilized Ultrahigh-Molecular-Weight Polyethylene Address Concerns of Cross-Linked Polyethylene in Total Knee Arthroplasty? Haider, Hani et al. JOA. 27(3):461–9, 2012.38†

- “After accelerated aging, the control material showed elevated oxidation, loss of small-punch mechanical properties, and loss of fatigue-crack propagation resistance.”
- “In contrast, vitamin E-stabilized material [E1 Technology] had minimal changes and exhibited 73% to 86% reduction in wear for both cruciate-retaining and posterior-stabilized TKA designs.”
- “The vitamin E-stabilized material [E1 Technology] exhibited 12% and 541% higher ultimate strength than did the control after 0 and 4 weeks of accelerated aging, respectively.”

Lipid Doping and Aging of Various UHMWPEs. Konsin et al. ORS. Paper 0311. 2012.39†

- “Active protection against oxidation was necessary to protect highly crosslinked polyethylenes against lipid-induced oxidation.”
- “E-PE [vitamin E diffused irradiated UHMWPE] exhibited the greatest oxidative stability out of all the materials tested in this study.”
E1 Tibial Bearings and The Vanguard Complete Knee System

The Vanguard Complete Knee system delivers a clinically proven knee system40-54 offering personalized, cost-effective preoperative planning tools and industry-leading technologies, designed to increase OR efficiency, meet patient demands and extend the life of the implant.

- **Wider Proximal Trochlear Groove**
  Provides excellent patellar tracking regardless of patient’s Q-angle*

- **Increased Wear Reduction**
  E1 tibial bearings exhibited an 87% reduction (PS) in wear over conventional DCM polyethylene (FDA claim)

- **Optimized Tibial-femoral Articulation**
  Increased contact area in high flexion and axial rotation

- **Proven Compressive Locking Mechanism**
  Clinically proven locking mechanism that resists tibial micromotion55

*Within 0-15° of Q-angle
Unmatched Bearing Options

Cruciate Retaining
- 3 degrees posterior slope
- 15 degrees internal/external rotation

Cruciate Retaining Lipped
- Enhanced posterior lip
- 15 degrees internal/external rotation

Anterior Stabilized
- Prominent 10mm anterior lip
- 5mm posterior lip
- 6 degrees internal/external rotation

Posterior Stabilized
- No varus/valgus constraint
- 15 degrees internal/external rotation

Posterior Stabilized Plus
- 2 degrees varus/valgus constraint
- +/- 2 degrees internal/external rotation
E1 Acetabular Options

Biomet has a broad hip bearing portfolio, offering standard, dual-mobility and cemented E1 liner options that provide maximum performance and flexibility to meet the specific needs of each patient.

Exceed ABT Acetabular System

Provides increased dislocation resistance while the fully congruent liner securely locks inside the cup with a locking ring. Anti-rotation tabs prevent the risk of micro-motion.

- **Multi-bearing system:** allows the surgeon to choose between C2A-Delta (ceramic), M²a (metal) and E1 (polyethylene) bearings, creating a patient-specific combination.

- **2 options in 1 shell:** easily converted from a ‘solid’ to a ‘multi-hole’ shell by removing hole blanking plugs. This allows supplementary screw fixation if required.

- **Large diameter bearings:** improved stability limiting the instances of dislocations and impingement, and increasing range of motion.
Avantage Dual Mobility Primary and Revision Acetabular System
Provide low wear and high range of motion to address patients at risk for dislocation.

Exceed ABT E1 Cemented Cups
Offered in flanged, non-flanged and muller design variants that maintain a minimum thickness of cement mantle and reduce the risk of bottoming out.
References

*FDA Cleared Claim. See biomet.com/e1 for complete claim language.

*In vitro data.


43. Biomet Korea Vanguard Study (DS7)
44. Biomet Vanguard DDRP IDE Study (DS9)
45. Biomet UK Vanguard DDRP Study (DS10)
46. Biomet Vanguard Study (DS11)
47. Biomet UK Vanguard Study (DS12)
48. The New England and Wales National Joint Registry Data Extract (DS14)
49. Australian National Joint Registry Annual Report 2010 (DS15)
50. Swedish Knee Arthroplasty Annual Report 2010 (DS16)
51. Biomet France Vanguard Study (DS17)
52. Danish Knee Registry 2010 (DS19)
53. New Zealand National Joint Registry, 11 years
54. Biomet Vanguard DDRP IDE Feasibility (DS21)