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Durasul,® Prolong,® Longevity® and Vivacit-E® are registered trademarks of Zimmer, Inc.

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EXp™ is a trademark of StelKast, Inc.

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One Surgeon. One Patient.®

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E1® Antioxidant
Infused Technology

BIOMET®

E1® Antioxidant Infused Technology

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 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.

Why Choose **E1® Technology?**

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, knee and shoulder bearings that actually **prevent oxidative degradation** of the polyethylene.*

*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, are you confident your polyethylene is giving you enough?

Remelted Products:‡

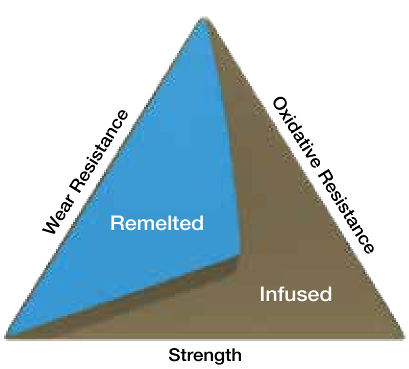
- DePuy XLK,[3] Marathon®[3] or AltrX®
- Smith and Nephew XLPE[3]
- Zimmer Durasul,®[3] Prolong®[3] and Longevity®[2,3,5]

Annealed and Sequentially Annealed Products:‡

- Stryker X3®[12] and Crossfire®[11]

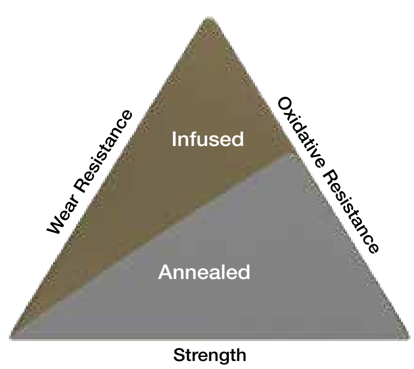
Blended Antioxidant Products:‡

- DePuy AOX®[17]
- Zimmer Vivacit-E®[8]
- DJO E+[16]
- StelKast EXp™
- Corin ECIMA®
- Mathys Vitamys®



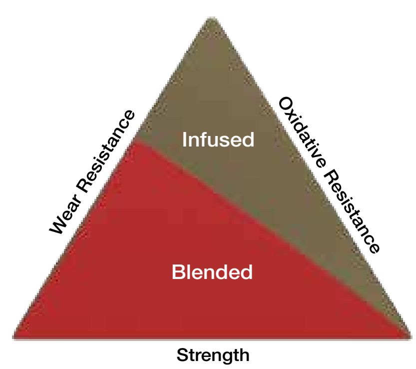
Characteristics of Remelted Polyethylene

- Wear resistant[1]
- Decreased strength[2]
- Limited oxidation resistance[9,10]†



Characteristics of Annealed Polyethylene

- Wear resistant[1]
- Maintains strength[11,12]†
- Limited oxidation resistance[3,13,14]†



Characteristics of Blended Polyethylene

- Decreased wear resistance[7]†
- Maintains strength[1]†
- Increased oxidation resistance[15,16]†

† *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?

E1® Antioxidant Infused Technology

Leading with a legacy of innovative polyethylene

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 to:

1979

Introduce a compression molded tibial component

1995

Develop ArCom® barrier packaging with Argon to protect against on the shelf oxidation

1993

Manufacture polyethylene completely in-house from powder to final product (1979 – knees, 1993 – hips)

1979

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

2005

2007

Introduce antioxidant infused technology in polyethylene acetabular bearings

2012

Introduce antioxidant infused technology in polyethylene humeral bearings

Introduce antioxidant infused technology in polyethylene tibial bearings

2008

E1® Antioxidant Infused Technology

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 years[19]

98.8%
Survivorship at 15 years[20]

100%
Survivorship at 11 years[21]

95%
Survivorship at 11 years[22]

97%
Survivorship at 10 years[23]

99%
Survivorship at 5 years[24]

ArCom® THA Published Survivorship

100%
Survivorship at 5 years[25]

98%
Survivorship at 6.5 years[26]

97.9%
Survivorship at 8.5 years[27] †

100%
Survivorship at 5.7 years[13]

98%
Survivorship at 12–16 years[14]

100%
Survivorship at 9 years[28]

† *In vitro* data. Laboratory testing is not necessarily indicative of clinical performance.

E1® 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.[11,29,30]

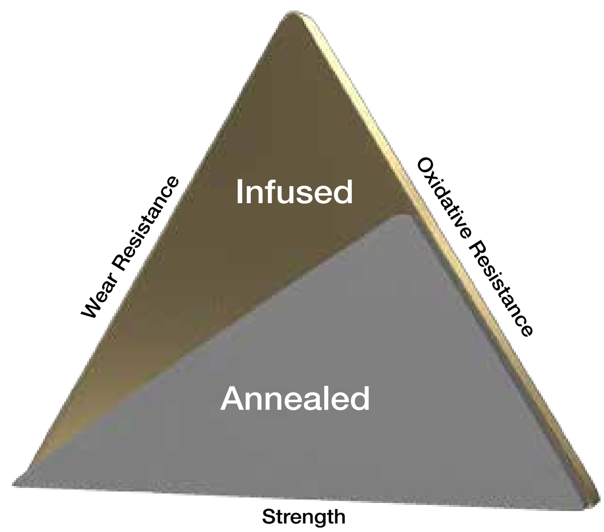
Annealed and Sequentially Annealed Polyethylenes

Evaluation of Oxidation and Fatigue Damage of Retrieved Crossfire Polyethylene Acetabular Cups Currier, B., *et al. JBJS.* 89: 2023–29, 2007.[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."*

Early indications of Oxidative Degradation in Retrieved Annealed UHMWPE Bearings Resembles Gamma Sterilized Materials.[6] Reinitz, S., *et al.* ORS. Paper 0307. 2012.[12†]

- *"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] showed significant decreases in crosslink density compared to the never implanted control, with decreases from 8–17.5 percent."*



† *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[2,3] and has also exhibited decreased tensile and fatigue strengths,[33–35] which can present clinically in the form of cracking and fracture.[29,31,32]

Remelted Polyethylenes

Rim Cracking of the Cross-Linked Longevity Polyethylene Acetabular Liner after Total Hip Arthroplasty. Tower, S., *et al. JBJS.* 89:2212–7, 2007.[2]

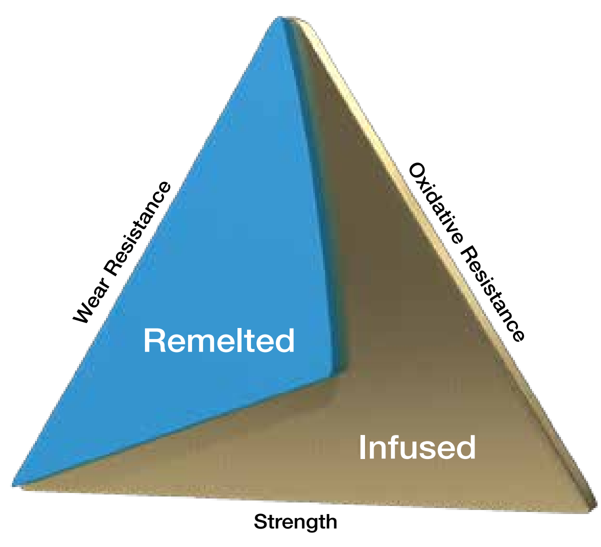
- *"The retrieved liners demonstrated burnishing, scratching, abrasion and creep that in most cases were rated as moderate..."*
- *"All of the liners showed severe cracking or failure at the rim..."*
- *"The calculated toughness of Longevity® is decreased by half compared with non-cross-linked reference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

In Vivo Oxidation in Remelted Highly Cross-Linked Retrievals.[3] Currier, B., *JBJS.* 92:2409–18, 2010.[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.[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."*



E1® Antioxidant Infused Technology

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,"[36] 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.[6,15,16†]

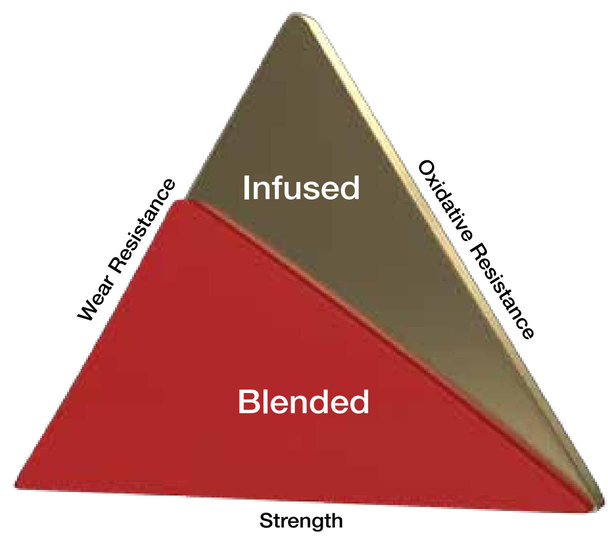
Blended Antioxidant Polyethylenes

Effect of Thermal Treatment on the Wear of Radiation-Crosslinked UHMWPE with and without Vitamin E.[7] Wang, A., *et al.* UHMWPE Meeting, Drexel University, Philadelphia PA. 2011.[9†]

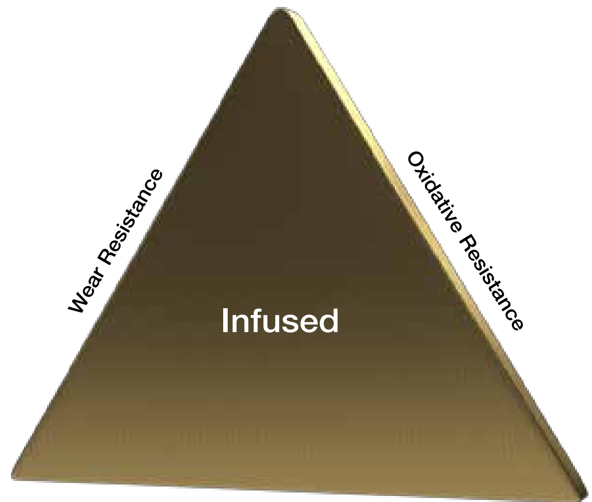
- *"All of the materials without vitamin E had better wear characteristics than [blended] vitamin E containing polyethylene."*
- *"This study shows that regardless of thermal treatment, the addition of vitamin E [blended] negatively affects the wear characterisitcs of polyethylene by at least 40%."*

Comparative Oxidative Stability of alpha-Tocopherol Blended and Diffused UHMWPEs at 3 Years of Real-Time Aging. Rowell, S., *et al. Journal of Orthopedic Research*. 29:773–80, 2011.[16†]

- *"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..."*



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

Three Year RSA Evaluation of the Wear of Vitamin E Stabilized Highly Crosslinked Polyethylene, the Stability of the Regenerex Acetabular Shells, and Femoral Components with 32 mm Heads. Greene, M., *et al.* ORS Annual Meeting. Paper 1071. 2012.[37]

- *"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."*

Comparison of Second Generation Highly Crosslinked Polyethylene Under Adverse Aging Conditions. Nabar, S., *et al.* 54th ORS Meeting. Poster 1684.[7†]

- *"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."*

Vitamin E Diffused, Highly Crosslinked UHMWPE: A Review. Oral, E. and Muratoglu, O. International Orthopaedics (SICOT). Online publication. December 2010.[36†]

- *"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."*

*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

One **Complete** Portfolio

One company provides E1® Antioxidant Infused Technology for knee, hip and shoulder applications, offering surgeons the most advanced[25] bearing options to address multiple indications and the individual needs of their patients.

Knee Bearing

Primary articulations with proprietary 1:1 conformity in coronal plane allow unlimited femoral/tibial sizing options.

Humeral Bearing

E1® humeral bearings, for a reverse shoulder design, offer additional intraoperative options.

Hip Bearing

E1® acetabular liner configurations are available to be used with large femoral heads for optimal joint stability and range of motion.

One Surgeon. One Patient.®

Over 1 million times per year, Biomet helps one surgeon provide personalized care to one patient.

The science and art of medical care is to provide the right solution for each individual patient. This requires clinical mastery, a human connection between the surgeon and the patient, and the right tools for each situation.

At Biomet, we strive to view our work through the eyes of one surgeon and one patient. We treat every solution we provide as if it's meant for a family member.

Our approach to innovation creates real solutions that assist each surgeon in the delivery of durable personalized care to each patient, whether that solution requires a minimally invasive surgical technique, advanced biomaterials or a patient-matched implant.

When one surgeon connects with one patient to provide personalized care, the promise of medicine is fulfilled.

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

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Wear Resistance
Oxidation Resistance
Strength