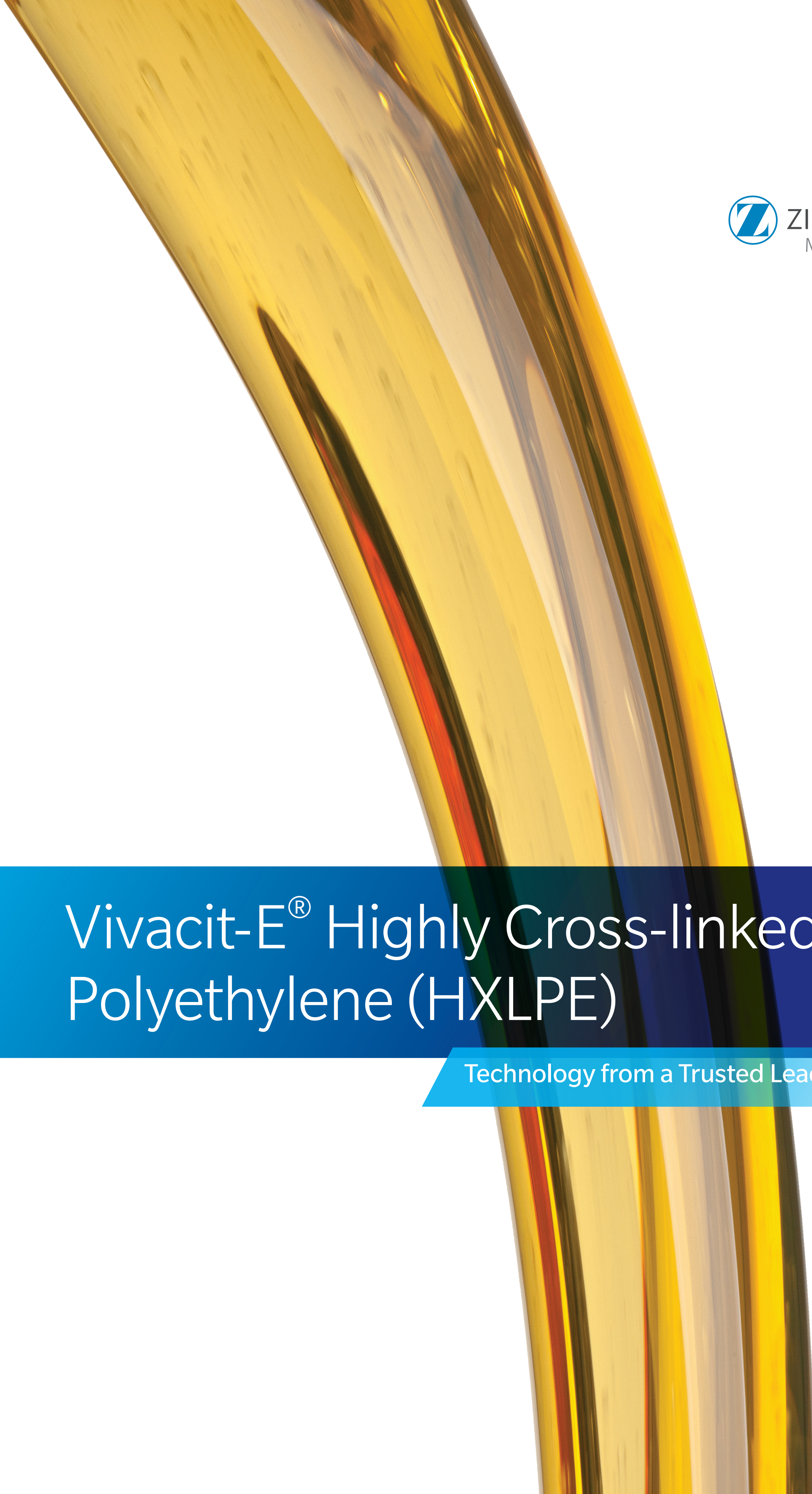
ZIMMER BIOMET
Moving You Forward.™



Vivacit-E® Highly Cross-linked Polyethylene (HXLPE)

Technology from a Trusted Leader

VIVACIT-E HXLPE:

DESIGNED FOR **LONG-TERM PERFORMANCE**

Choosing the right polyethylene for use in joint replacement could mean the difference between long-term performance and the premature need for revision surgery.

Vivacit-E HXLPE is specifically designed to maximize performance through a proprietary process providing exceptional oxidative stability, ultra-low wear, and improved mechanical strength, from a manufacturer with a trusted clinical heritage. [2, 3, 7, 9; 11–16]

Exceptional Oxidative Stability [1–3]

Oxidation is a primary degradation mechanism of polyethylene that can lead to osteolysis and implant failure.[4, 22, 23, 44] The vitamin E in Vivacit-E HXLPE is a powerful antioxidant that continuously quenches harmful free radicals to prevent oxidative degradation.[1]

Ultra-low Wear [5–7; 35]

Osteolysis induced by wear particles has been recognized as one of the major causes of long-term failure in total joint replacements. Vivacit-E HXLPE is cross-linked to an equivalent of 10 MRad with warm electron beam (e-beam) irradiation, resulting in an ultra-low wear HXLPE that has been tested out to 100 million cycles (Mc) in a 40 mm hip wear simulator test.[8]

Improved Mechanical Strength[2, 3, 9, 10]

Mixing an active antioxidant into the polyethylene and avoiding remelting increase the strength of Vivacit-E HXLPE. The antioxidant actively quenches free radicals, eliminating the need for remelting. Long term, Vivacit-E HXLPE's material strength has been shown to be stable even after extreme lengths of accelerated aging.[1]

Trusted Clinical Heritage

Zimmer Biomet knows how to make polyethylene. In rigorous testing, our technology outperforms other highly cross-linked and conventional polyethylenes—performing well *in vivo* for various, long-term clinical follow-up durations out to 15+ years.[11–16] Vivacit-E HXLPE builds on our heritage of over 40 years of excellence to make us a trusted leader in polyethylene manufacturing.

Laboratory testing is not necessarily indicative of clinical performance.

THE CONNECTION BETWEEN OXIDATION AND POLYETHYLENE PERFORMANCE

First introduced in the 1990s, highly cross-linked polyethylene (HXLPE) has demonstrated promising wear properties through the first decade of *in vivo* use.[19] Studies, however, have shown the potential for *in vivo* oxidation, which can affect long-term performance.[4; 20–23; 36]

To maximize polyethylene performance, Zimmer Biomet has addressed the issue of *in vivo* oxidation with a proprietary method of grafting (locking) vitamin E to HXLPE. Our method effectively inhibits the oxidation that starts as a reaction in the human body between naturally present oxygen and the free radicals that come from cyclic load, the irradiation/cross-linking manufacturing process, and lipid absorption.[2, 10; 24–34, 60]

The Bottom Line

There are two methods of neutralizing free radicals in polyethylene: passive stabilization and active stabilization.

Annealing and remelting are processes that can reduce free radicals, but they can do nothing to prevent oxidation once the component is implanted. These processes are considered passive methods of stabilizing free radicals.[36, 37, 45, 46]

Incorporating vitamin E, a natural antioxidant, into the polymer matrix is an active method of dealing with free radicals. Through this process, vitamin E remains in the polyethylene and continuously quenches free radicals, thus inhibiting oxidation in the body and providing wear resistance.[3]

Vivacit-E HXLPE PROCESS

- Blend GUR 1020 Resin with Vitamin E
- Compression Molding
- Warm E-Beam Irradiation
- Machine into Components
- Packaging
- Terminal Sterilization

WHAT MAKES VIVACIT-E UNIQUE:

Warm E-Beam Technology: The Best Way to Incorporate an Antioxidant

Zimmer Biomet is the only global manufacturer in the industry to use warm electron beam (e-beam) irradiation. Using e-beam irradiation with warmer temperatures allows for increased cross-linking (cross-link density) and increased grafting of vitamin E.[43] This process is a significant improvement for wear resistance and oxidative stability,[28] two of the critical performance characteristics of polyethylene.

Cold Gamma vs. Zimmer Biomet's Warm E-Beam

Other global manufacturers use cold gamma to irradiate and cross-link their antioxidant HXLPEs. Cold gamma delivers significantly less wear resistance because of less efficient cross-linking.[28, 38]

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NOT ALL POLYETHYLENES ARE CREATED EQUAL

The formulation of polyethylene is complex. While one step can help with one material characteristic, it can compromise another.

- Free radicals in HXLPEs can be reduced via passive stabilization by thermally processing below the melt temperature (annealing, including sequentially), which retains the initial strength of the material; however, doing so comes at the expense of oxidative stability due to the incomplete removal of free radicals.[38]
- Conversely, free radicals in HXLPEs can be eliminated via passive stabilization by thermally processing above the melt temperature (remelting); however, doing so comes at the expense of initial strength and toughness.[38]
- Actively stabilized, blended antioxidant HXLPEs that are cold (gamma) irradiated solve the *in vivo* oxidation problem but sacrifice wear resistance of the material.[38]
- Actively stabilized, blended antioxidant HXLPEs that are warm (e-beam) irradiated solve the oxidation problem with NO COMPROMISE of the material's strength and wear resistance.[38]

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How Is Your Polyethylene Performing?

	Cross-linking Process	Oxidative Stabilization Method	Exceptional Oxidative Stability due to Antioxidant[38]	Improved Mechanical Strength[38]	Ultra-low Wear[38]
HXLPE (Thermally Processed)					
X3® (Stryker)[38,53]	Gamma	Annealed	None	May change over time	May change over time
XLPE (S & N)[38,52]	Gamma	Remelted	None	Poor	May change over time
ALTRX® (DePuy)[38,51]	Gamma	Remelted	None	Poor	May change over time
HXLPE (with Antioxidants)					
AOX™ (DePuy)[38,54]	Gamma	Antioxidant	Strong	Strong	Moderate
HXLPE (with Antioxidants and Warm E-Beam)					
Vivacit-E® HXLPE[38]	Warm E-Beam	Antioxidant	Strong	Strong	Strong
MXLPE (moderated highlight cross-linked)					
Marathon (DePuy)[38,39]	Gamma	Remelted	None	Poor	Moderate

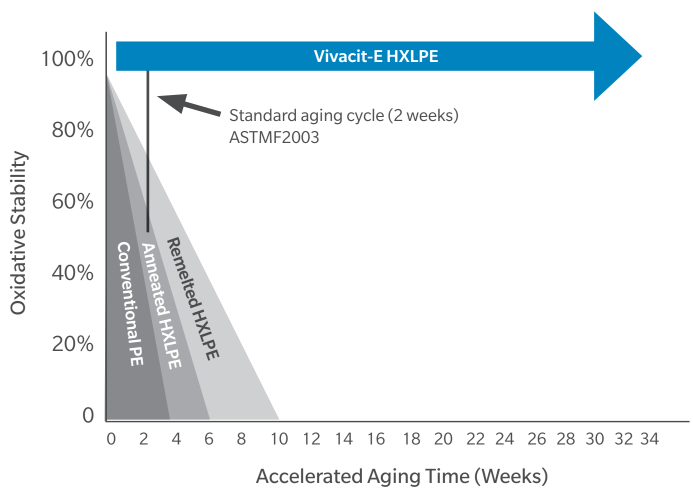
Tested Material Characteristics	✓ Strong	Ø Moderate	✕ Poor	(!) May change over time	None

Harnessing the Antioxidant Power of Vitamin E

Oxidation of polyethylene leads to a decline in mechanical strength and an increase in wear over time.[4, 22, 23, 38] Vitamin E is a powerful natural antioxidant that is used within Vivacit-E HXLPE to protect it from oxidizing within the body. Our polyethylene quenches harmful free radicals to prevent oxidation and maintains its wear resistance and mechanical strength.

Exceptional Oxidative Stability

After accelerated aging for 33 weeks—more than 16 times longer than the industry standard—Vivacit-E HXLPE showed no sign of oxidation or significant changes in mechanical properties.[3]



Vivacit-E HXLPE retained mechanical strength and showed no oxidation after 33 weeks of accelerated aging

Laboratory testing is not necessarily indicative of clinical performance.

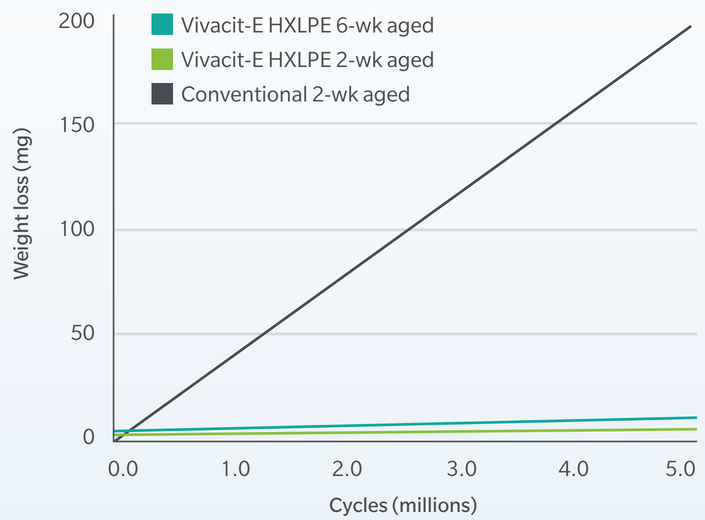
Ultra-low Wear

Vivacit-E HXLPE's wear performance is maintained even after accelerated oxidation aging.[5] Wear testing showed no statistically significant difference between both 2-week and 6-week extreme-aged Vivacit-E groups.[5]

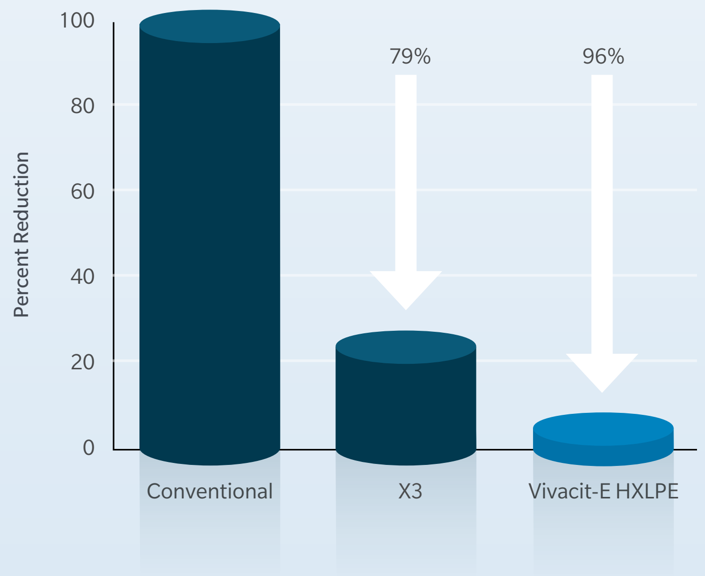
96% Reduction in Wear Compared to Conventional Polyethylene[40]
Compared to other polyethylene formulations, such as Stryker X3 polyethylene and conventional polyethylene, Vivacit-E HXLPE has shown the highest reduction in wear through *in vitro* testing.[40*]

73% Reduction in Wear Compared to Remelted Highly Cross-linked Polyethylene (HXLPE)[40]
Laboratory testing confirmed that Vivacit-E HXLPE not only provides superior wear reduction compared to conventional polyethylene, it also provides unparalleled wear performance over traditional highly cross-linked polyethylene.[40**]

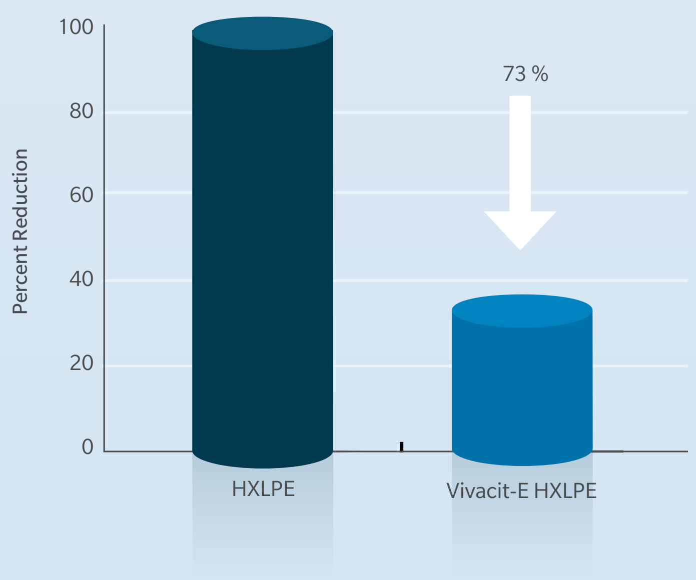
Retention of Wear Properties After Extended Aging



Wear Reduction of Highly Cross-linked vs. Conventional Polyethylene



Percent Wear Reduction Compared to HXLPE



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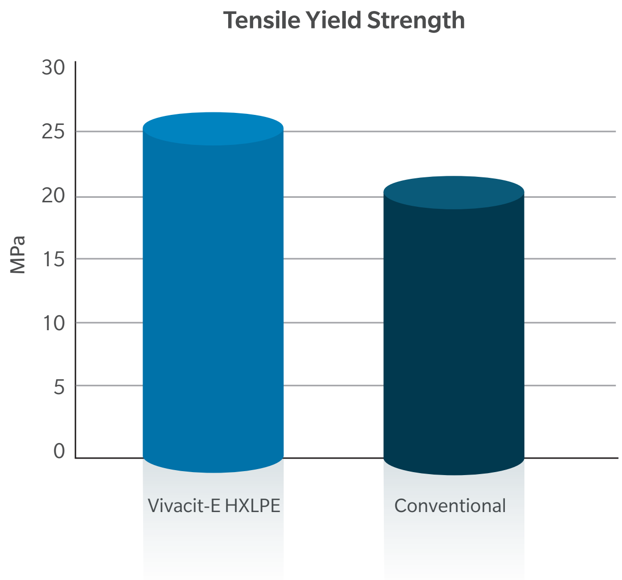
* *The 96% reduction in wear rate applies to articular surfaces of the Vivacit-E HXLPE knee bearing.*

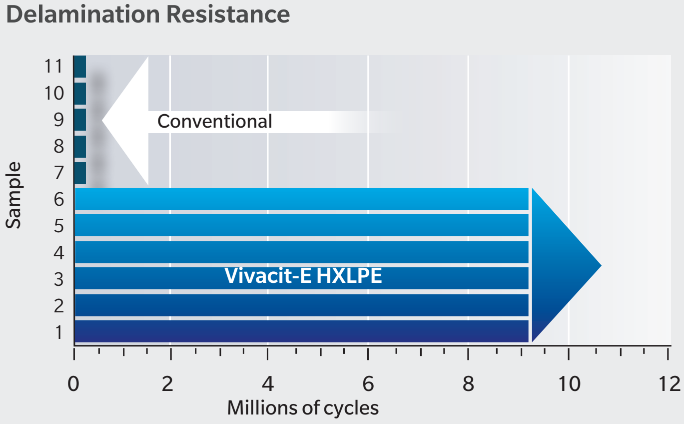
** *The 73% reduction in wear rate applies to articular surfaces of the Vivacit-E HXLPE knee bearing.*

Improved Mechanical Strength

Conventional polyethylene has long been considered the gold standard in mechanical properties.

Vivacit-E HXLPE has demonstrated superior tensile strength over conventional polyethylene due to a warm e-beam irradiation process that grafts vitamin E onto the polyethylene. This process results in Vivacit-E HXLPE retaining its mechanical strength even after long-term aging and oxidation challenges.[2, 3, 9, 43]





Delamination Resistance

High levels of cross-linking combined with the oxidative protection of vitamin E grafting leads to a polyethylene with proven resistance to subsurface fatigue and delamination.[41]

At 9 Mc, NO delamination was observed in Vivacit-E HXLPE, while conventional polyethylene displayed delamination after 0.25 Mc.[8, 42]

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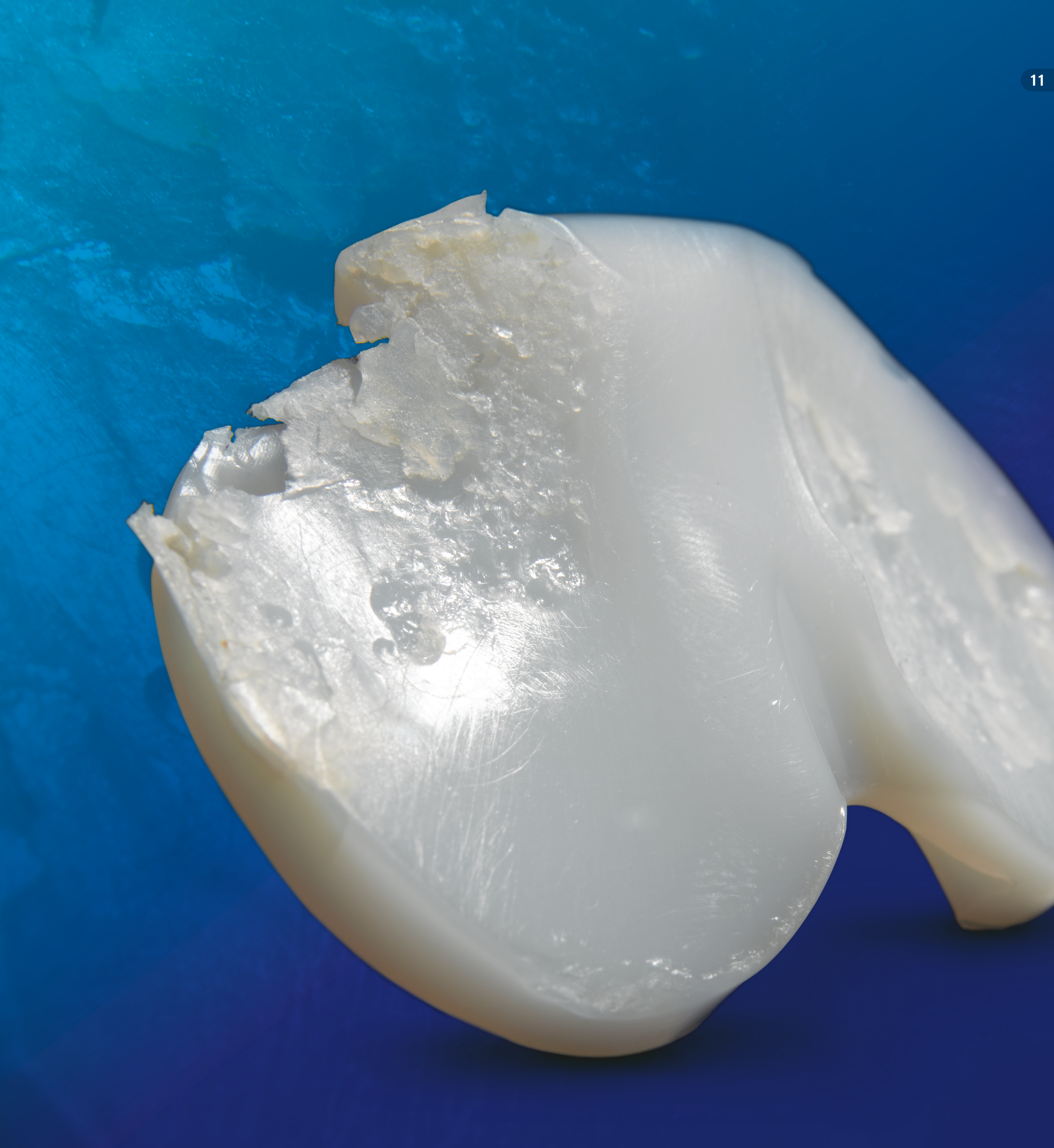


An example of what fatigue damage, subsurface cracking, and delamination can do to polyethylene

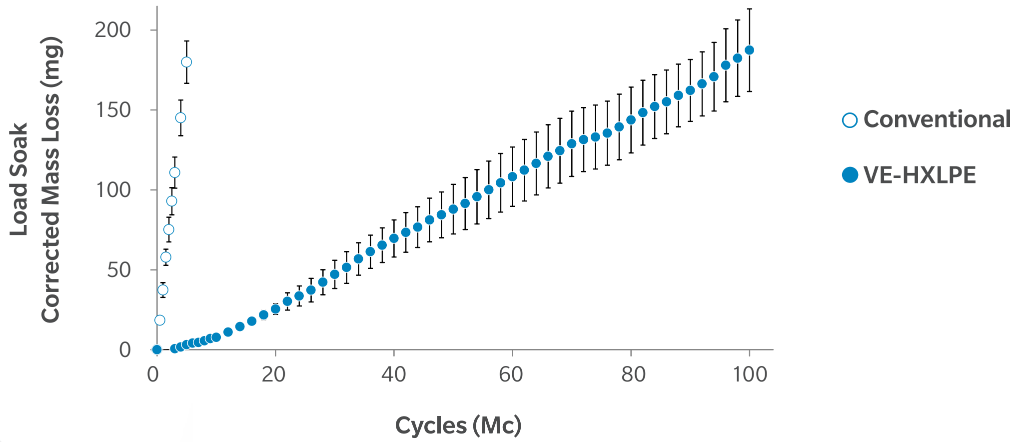
A LIFETIME OF WEAR RESISTANCE[6]

Vivacit-E HXLPE demonstrates 95% wear reduction* at 100 million cycles compared to conventional polyethylene.[6]

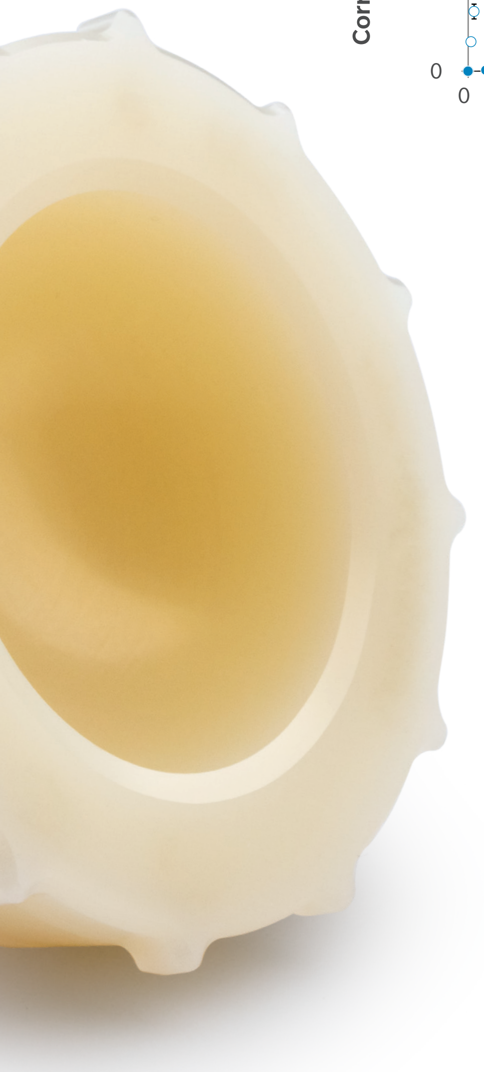
** 95% wear reduction applies to vitamin E-grafted, e-beam-irradiated acetabular bearings.*

Vivacit-E HXLPE: A Real-life Polyethylene Solution for Total Joint Replacement

Vivacit-E HXLPE is laboratory tested to mimic the number of walking steps a patient will typically take during a lifetime following total joint replacement surgery (100 Mc).[8]



Vivacit-E HXLPE hip wear simulator results
for 40 mm hip cups out to 100 million cycles.



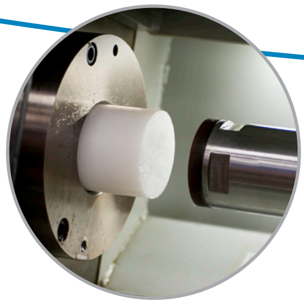
Laboratory testing is not necessarily indicative of clinical performance.

Trusted Clinical Heritage

Vivacit-E HXLPE builds on a heritage of excellence that has made Zimmer Biomet a trusted polyethylene manufacturer. We continue to lead the industry in creating high-performance polyethylene.[4,50,57,58,59,60]

1970s

Direct compression net shape molded conventional polyethylene introduced to provide improved strength compared to ram extrusion manufacturing technique (Knees)[57]



1980s

Bar stock manufacturing introduced for conventional polyethylene to address consolidation and wear properties unique to hip bearing (Hips)

Early 1990s

ArCom® conventional polyethylene enhanced with argon gas packaging to address on-the-shelf oxidation[59]

Late 1990s

Longevity® Remelted Polyethylene introduced to further enhance needed wear, oxidation, and strength properties specific to the mechanics of the hip joint articulation[4]

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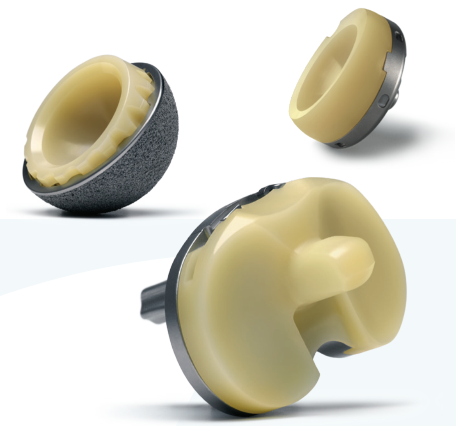
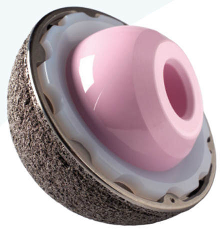
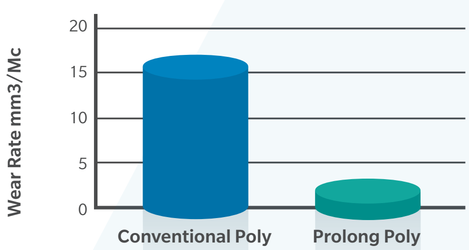




2004
ArComXL® Thermally and Mechanically Annealed Polyethylene (Hip / Shoulder)[60]

2007
E1 Polyethylene, the first antioxidant polyethylene introduced to industry[58]

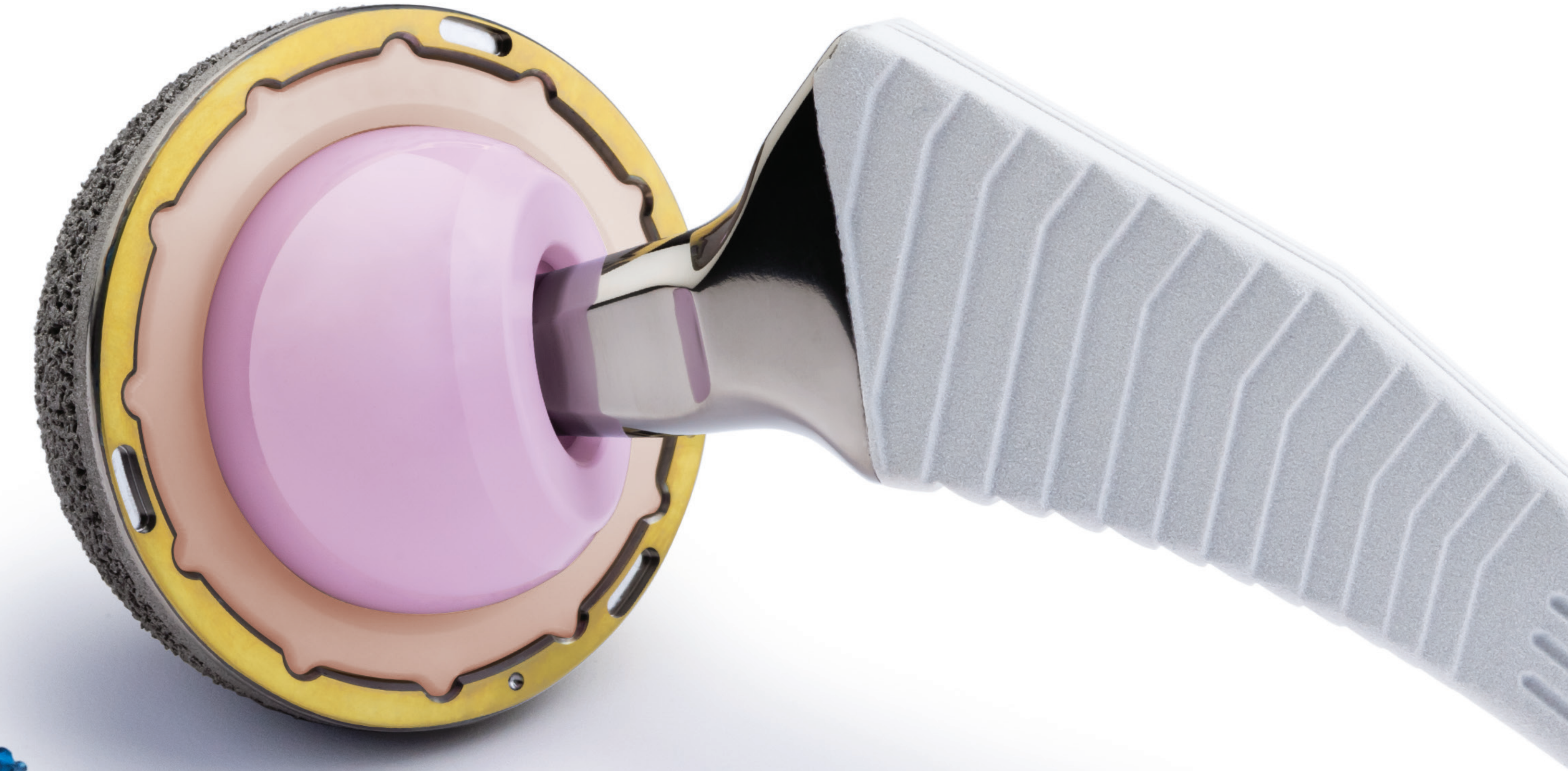
2001
Prolong® Remelted Polyethylene introduced to further enhance needed wear, oxidation, and strength properties specific to the mechanics of the knee joint articulation[50]



Joint simulation wear rates measured during testing for non-cross-linked and cross-linked tibial components[50]

2012
Vivacit-E Antioxidant Warm E-beam Polyethylene Technology introduced to industry (All Bearings)

Laboratory testing is not necessarily indicative of clinical performance.



Complete Portfolio

Our complete portfolio offers vitamin E-blended polyethylene products designed for use in hip, knee, shoulder, and elbow joint replacements. Vivacit-E HXLPE antioxidant technology provides surgeons with advanced liner and bearing options to address the individual needs of their patients.

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