

Food and Drug Administration Cleared Claims for E1™ Antioxidant Infused Technology

In order to validate the benefits of E1™ Antioxidant Infused bearings over other polyethylene bearings, Biomet Orthopedics, Inc. submitted laboratory testing results along with several statements, known as claim language, to the Food and Drug Administration (FDA). The FDA returned a response clearing these statements and making Biomet the only orthopedic device manufacturer that offers a bearing that, per the FDA, is able to make the following claims:

Long-Term Material Stability

FDA Cleared Claim: *E1™ Antioxidant Infused Technology prevents oxidative degradation of polyethylene.*¹

Oxidation, like rust on a car, will occur in crosslinked polyethylene bearings if not actively eliminated. This oxidation, or oxidative degradation, can eventually result in higher wear and decreased fracture resistance, potentially shortening the lifetime of the total joint.² E1™ bearings are the only bearing option that contain Vitamin E, a natural antioxidant, which prevents oxidative degradation of E1™ material.³

High Strength

FDA Cleared Claim: *E1™ Antioxidant Infused Technology maintains the mechanical strength of conventional UHMWPE under small punch testing.*¹

FDA Cleared Claim: *E1™ Antioxidant Infused Technology maintains mechanical strength after accelerated aging.*¹

A patient's joints experience high impact forces through even normal daily activities. Maintaining high bearing strength is important and may help prevent fracture and subsequent dislocation of the joint.² Unlike some other polyethylenes, E1™ bearings are not subjected to manufacturing processes, such as remelting, that may weaken the material.^{2,3}

Ultra-Low Wear

The constant motion of a total joint over time can result in the release of polyethylene particles which may ultimately lead to osteolysis or loss of bone,² a reaction most often seen in the hip joint due to its abrasive or "sandpaper" type of wear. Fortunately, the amount of particles released into the joint can be significantly reduced by increasing the wear resistance of polyethylene. Polyethylene bearings available for

use in hip replacement offer varying levels of wear reduction, allowing surgeons to match patients' specific needs. E1™ hip bearings demonstrate wear rates similar to that of metal-on-metal,³ maximizing wear resistance. Additionally, E1™ knee bearings demonstrate wear rates that are 86% less than that of direct compression molded polyethylene,³ the current standard of care in total knees.

The addition of Vitamin E to polyethylene truly differentiates E1™ Antioxidant Infused Technology and allows it to outperform other polyethylenes currently available.³

The complete FDA cleared claim language for E1™ Antioxidant Infused Technology is available at biomet.com/e1. Additionally, a copy of the FDA letter clearing the above claims is available upon request.

Note: Since E1™ Antioxidant Infused Technology is utilized for several different bearing surfaces worldwide, Biomet did not pursue general claim language for reduction of wear.

References

1. FDA Cleared Claim. See biomet.com/e1 for complete claim language.
2. Kurtz, S. UHMWPE Biomaterials Handbook Second Edition, 2009.
3. Data on file at Biomet. Bench test results not necessarily indicative of clinical performance. Laboratory testing.

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