FDA CLEARED CLAIMS[1] FOR E1™ ANTIOXIDANT INFUSED TECHNOLOGY[2]

Claim 1:
E1™ Antioxidant Infused Technology prevents oxidative degradation of polyethylene. Environmental stress crack testing was conducted by cyclically loading GUR1020 and GUR1050 E1™ test specimens in an air atmosphere maintained at 80°C for 5 weeks. Testing was completed per the literature (Nabar, Sean, et al. Transactions of the 54th Annual Meeting of the ORS, Poster No. 1684). E1™ specimens showed no evidence of environmental stress cracking and infrared spectroscopy showed no detectable oxidation in the loaded or unloaded samples (oxidation indices <0.1). E1 samples were machined from either GUR1020 (E1 knee) or GUR1050 (E1 hip) isostatically compression molded UHMWPE crosslinked with 100 kGy gamma irradiation under argon, doped with α-tocopherol, and subsequently gamma sterilized (25-40 kGy) in Argon. *Bench testing is not necessarily indicative of clinical performance.*

Claim 2:
E1™ Antioxidant Infused Technology protects polyethylene from oxidation and cracking during environmental stress crack testing. Environmental stress crack testing was conducted by cyclically loading test specimens in an air atmosphere maintained at 80°C for 5 weeks per the literature (Nabar, Sean, et al. Transactions of the 54th Annual Meeting of the ORS, Poster No. 1684). GUR1050 E1™ specimens ran head to head with GUR1050 gamma sterilized (25-40kGy in argon) polyethylene and sequentially crosslinked and annealed polyethylene (GUR 1050 barstock, 33kGy gamma irradiated in air, annealed at 130C in air and repeated for a total dose of 99kGy and machined into final part geometry). GUR1020 E1™ specimens ran head to head with GUR1050 direct compression molded polyethylene that was gamma sterilized (25-40kGy) in argon. The E1™ material was the only material tested that showed no evidence of environmental stress cracking or fracture and no detectable oxidation (oxidation indices <0.1) in the loaded and unloaded samples using infrared spectroscopy. Both gamma sterilized and sequentially crosslinked and annealed polyethylene showed evidence of increased oxidation and cracking or fracture during environmental stress crack testing. E1 samples were machined from either GUR1020 or GUR1050 isostatically compression molded UHMWPE, crosslinked with 100 kGy gamma irradiation under argon, infused with vitamin E, and subsequently gamma sterilized (25-40 kGy) in Argon. *Bench testing is not necessarily indicative of clinical performance.*

Claim 3:
E1™ Antioxidant Infused Technology maintains the mechanical strength of conventional UHMWPE under small punch testing. Small punch testing per ASTM F2183 was conducted for the E1™ hip material and the E1™ knee material. The E1™ hip material was compared to GUR1050 gamma sterilized in argon isostatic compression molded (ICM) UHMWPE and the E1™ knee material was compared to GUR1050 gamma sterilized (25-40kGy) in argon direct compression molded (DCM) UHMWPE. The ultimate load for the E1™ hip material and the GUR1050 ICM material are 105±5.5N and 75.4±5.3N respectively. The ultimate load for the E1™ knee material and the DCM control material are 97.2±6.4N and 86.6±7.5N respectively. The E1™ materials had ultimate loads greater than that of the ICM and DCM control. These differences were statistically significant ($p<0.001$ for all comparisons). E1 samples were machined from either GUR1020 (E1 knee) or GUR1050 (E1 hip) ICM UHMWPE, crosslinked with 100 kGy gamma irradiation under argon, infused with vitamin E, and subsequently gamma sterilized (25-40 kGy) in Argon. *Bench testing is not necessarily indicative of clinical performance.*

Claim 4 :
E1™ Antioxidant Infused Technology maintains mechanical strength after accelerated aging. There was no significant decrease ($P>0.05$) in ultimate load , ultimate tensile strength, or yield strength after

accelerated aging for either the E1™ hip or the E1™ knee material. Ultimate load was measured by small punch testing per ASTM F2183; ultimate tensile strength and yield strength were measured by tensile testing per ASTM D638; Accelerated aging was performed per ASTM F2003 (70^{o}C and 5 atm of oxygen for 14 days). The ultimate load for the E1™ knee material before and after accelerated aging was 97.2±6.4N and 100.0±5.0N respectively. The ultimate tensile strength for the E1™ knee material before and after accelerated aging was 45.8±1.6 and 46.1±2.9 MPa respectively. The yield strength for the E1™ knee material before and after accelerated aging was 22.6±0.2 and 22.8±0.3 MPa respectively. The ultimate load for the E1™ hip material before and after accelerated aging was 105.0±5.5N and 115.0±3.2N respectively. The ultimate tensile strength for the E1™ hip material before and after accelerated aging was 43±3 and 43±2 MPa respectively. The yield strength for the E1™ hip material before and after accelerated aging was 24.2±0.2 and 24.4±0.2 MPa respectively. E1 samples were machined from either GUR1020 (knee material) or GUR1050 (hip material) isostatically compression molded UHMWPE, crosslinked with 100 kGy gamma irradiation under argon, infused with vitamin E, and subsequently gamma sterilized (25-40 kGy) in Argon. *Bench testing is not necessarily indicative of clinical performance.*

FDA CLEARED CLAIM[3] FOR E1™ KNEE BEARINGS[2]

The Biomet E1™ Vanguard™ tibial bearings had a volumetric wear rate that was 86% less than that of a conventional DCM UHMWPE bearing of the same geometry. The testing was completed on a multi-axis knee simulator under force control (AMTI 6-Station Knee Simulator) for 5 million cycles utilizing walking waveforms presented in ISO 14243-1 and a bovine calf serum solution with a protein concentration around 20g/L. The test specimens were 10x87/91 mm CR bearings coupled with 80 mm CoCr Vanguard™ CR femoral components. The volumetric wear rates of the E-Poly™ tibial bearings and the DCM Conventional tibial bearings were 6.1±0.8 and 43.4±1.5 $mm^3/10^6$ cycles respectively. The Biomet E-Poly™ Vanguard™ tibial bearings tested were identical to final finished product. They were machined from isostatically compression molded UHMWPE crosslinked with 100 kGy gamma irradiation under argon, doped with α-tocopherol, and subsequently gamma sterilized (25-40 kGy) in Argon. *Bench testing is not necessarily indicative of clinical performance.*

1. Cleared through 510(k) K100048

2. Note: ***E1™ Antioxidant Infused Technology may be used interchangeably with any of the following: E1™ Antioxidant Infused Bearings, E1™ Antioxidant Infused Material, E1™ material, E1™ technology, E1™ bearings, E1™ liners, E1™ acetabular liners and E1™ tibial bearings.***

3. Cleared through 510(k) K080528