EXACTECH | **HIP** Technical Monograph



Patented Massachusetts General Hospital Technology

Developed by Massachusetts General Hospital (MGH) in association with Cambridge Polymer Group, the foremost leaders in polyethylene technology, the Alteon[®] XLE is a highly crosslinked, vitamin E material engineered for improved wear properties⁵, superior oxidation resistance², and optimized mechanical strength.^{1-3, 5, 8, 10} By virtue of its proprietary vitamin E binding process, coupled with a 10Mrad gamma irradiation dose and unique compressive mechanical annealing procedure, Alteon XLE represents one of the most advanced and compelling polymer technologies in orthopedics.

Patented Manufacturing Process

Developed by Massachusetts General Hospital in conjunction with Cambridge Polymer Group.³



Turn compression molded, vitamin E blended UHMWPE to bar stock



10Mrad gamma irradiation



Computercontrolled preheat



Compress 2:1 under heat & cool



Recover at

sub-melt

temperature



Precision machining

Superior Oxidative Stability

Blending the vitamin E prior to consolidation allows the antioxidant to distribute uniformly throughout the material. Subsequent gamma crosslinking bonds the vitamin E molecules onto the polyethylene chains, and in combination with the compressive mechanical annealing procedure, greatly reduces measured free radical content.^{3,9} The cumulative result is a material with high oxidative stability² and low potential for surface oxidation.³

Surface Oxidation Testing: Alteon XLE Hip Polyethylene³



Improved Wear Resistance

A patented gamma irradiation and mechanical annealing process, tailored to the vitamin E content, is used to achieve the desired crosslink density. An irradiation dose of 10 Megarad (Mrad) or 100 KiloGray (kGy) is imparted to the material prior to final gamma sterilization. This highly crosslinked polyethylene yields a reduced wear rate compared to conventional polyethylene.⁵

Optimized Mechanical Strength

Unlike remelted polymers, the proprietary XLE polyethylene mechanical annealing process quenches free radicals below the melt temperature, which maintains the crosslink density and provides enhanced mechanical strength over conventional polyethylene.⁹

*TEST PARAMETERS: Exactech XLE [3]: Test parameters: 40mm diameter CoCr head; 4.4mm thick liner; 5 million cycles; 90% bovine serum; 1.1Hz; 2XN peak load; Wear rate: Slope of the linear regression for corrected mass change in the steady-state cycles Conventional UHIMWPE [2]: Test parameters: Not specified 10Mrd irradiated and melted UHIMWPE [2,4]: Test parameters: 46mm head; 3mm thick liner; 11 million cycles; 100% bovine serum; 3.3kN peak load; Wear rate: Slope of the linear regression for corrected UHIMWPE [5]: Test parameters: 36mm CoCr head; 4.9mm thick liner; 5 million cycles; 100% bovine serum; 2Hz, 3KN peak load; Wear rate: Slope of the linear regression for corrected mass change over the full number of cycles 10Mrd irradiated, vitamin E diffused UHIMVPE [5]: Test parameters: 36mm CoCr head; 4.9mm thick liner; 5 million cycles; 100% bovine serum; 2Hz, 3KN peak load; Wear rate: Slope of the linear regression for corrected mass change over the full number of cycles

Hip Simulator Wear Rate*





Ultimate Tensile Strength*

REFERENCES

- Oral, E, Muratoglu, O, "The effects of high dose irradiation on the cross-linking of vitamin E-blended ultrahigh molecular weight polyethylene," *Biomaterials 29 (2008) 3557-3560*
- 2. Oral, E, Muratoglu, O, "Vitamin E diffused, highly crosslinked UHMWPE: a review," Int Orthop. 2011 Feb; 35(2): 215-223
- 3. Data on file at Exactech. TM-2022-0693. Shelf Oxidation Analysis of XLPE Liners.
- Muratoglu OK, Bragdon CR, O'Connor DO, Perinchief RS, Estok DM, Jasty M, Harris WH (2001) Larger diameter femoral heads used in conjunction with a highly cross-linked ultra-high molecular weight polyethylene: A new concept. J Arthroplasty 16(8 Suppl):24 -30
- Oral E, Christensen S, Malhi A, Wannomae K, Muratoglu O (2006) Wear resistance and mechanical properties of highly crosslinked UHMWPE doped with vitamin E. J Arthroplasty 21 (4):580-591
- Muratoglu OK, Bragdon CR, O'Connor DO, Jasty M, Harris WH,Gul R, McGarry F (1999) Unified wear model for highly crosslinked ultra-high molecular weight polyethylenes (UHMWPE). *Biomaterials* 20(16):1463 -1470
- Ries M, Pruitt L (2005) Effect of crosslinking on the microstructure and mechanical properties of ultra-high molecular weight polyethylene. *Clin Orthop Relat Res* 440:149 -156
- Oral E, Wannomae KK, Hawkins NE, Harris WH, Muratoglu OK (2004) a-Tocopherol doped irradiated UHMWPE for high fatigue resistance and low wear. *Biomaterials* 25(24):5515 -5522
- Ebru Oral, Bassem W. Ghali, Orhun K. Muratoglu. "The elimination of free radicals in irradiated UHMWPEs with and without vitamin E stabilization by annealing under pressure." *J Biomed Mater Res B Appl Biomater*. 2011 Apr;97(1):167-74. doi: 10.1002/jbm.b.31799. Epub 2011 Feb 24

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