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Standard Guide for Extensively Irradiation-Crosslinked Ultra-High Molecular Weight Polyethylene Fabricated Forms for Surgical Implant Applications[1]

This standard is issued under the fixed designation F2565; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This guide covers extensively crosslinked ultra-high molecular weight polyethylene (UHMWPE) materials (fabricated forms) that are produced starting with virgin resin powders and consolidated forms meeting all the requirements of ~~Test Method~~ Specification F648.

1.2 This guide does not cover fabricated forms of ultra-high molecular weight polyethylene which have received only gas plasma, ethylene oxide, or less than 40 kGy ionizing radiation treatments, that is, materials treated only by historical sterilization methods.

1.3 This guide pertains only to UHMWPE materials extensively crosslinked by gamma and electron beam sources of ionizing radiation.

1.4 The specific relationships between these mechanical properties and the *in vivo* performance of a fabricated form have not been determined. While trends are apparent, specific property-polymer structure and polymer-design relationships are not well understood. These mechanical tests are frequently used to evaluate the reproducibility of a fabrication procedure and are applicable for comparative studies of different materials.

1.5 The following precautionary caveat pertains only to the test method portion, Section 5, of this ~~guide.~~guide: *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate ~~safety~~ safety, health, and ~~health~~environmental practices and determine the applicability of regulatory limitations prior to use.*

1.6 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

~~D638 Test Method for Tensile Properties of Plastics~~

D695 Test Method for Compressive Properties of Rigid Plastics

[1] This guide is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.11 on Polymeric Materials.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

D1898 Practice for Sampling of Plastics (Withdrawn 1998)[3]
D2765 Test Methods for Determination of Gel Content and Swell Ratio of Crosslinked Ethylene Plastics
E647 Test Method for Measurement of Fatigue Crack Growth Rates
F619 Practice for Extraction of Materials Used in Medical Devices
F648 Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants
F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices
F749 Practice for Evaluating Material Extracts by Intracutaneous Injection in the Rabbit
F756 Practice for Assessment of Hemolytic Properties of Materials
F763 Practice for Short-Term Screening of Implant Materials
F813 Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices
F895 Test Method for Agar Diffusion Cell Culture Screening for Cytotoxicity
F981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Insertion into Bone
F2003 Practice for Accelerated Aging of Ultra-High Molecular Weight Polyethylene after Gamma Irradiation in Air
F2102 Guide for Evaluating the Extent of Oxidation in Polyethylene Fabricated Forms Intended for Surgical Implants
~~F2183 Test Method for Small Punch Testing of Ultra-High Molecular Weight Polyethylene Used in Surgical Implants (Withdrawn 2017)[3]~~
F2214 Test Method for ***In Situ*** Determination of Network Parameters of Crosslinked Ultra High Molecular Weight Polyethylene (UHMWPE)
F2381 Test Method for Evaluating Trans-Vinylene Yield in Irradiated Ultra-High Molecular Weight Polyethylene Fabricated Forms Intended for Surgical Implants by Infrared Spectroscopy
F2625 Test Method for Measurement of Enthalpy of Fusion, Percent Crystallinity, and Melting Point of Ultra-High-Molecular Weight Polyethylene by Means of Differential Scanning Calorimetry
F2759 Guide for Assessment of the Ultra-High Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic and Spinal Devices
F2977 Test Method for Small Punch Testing of Polymeric Biomaterials Used in Surgical Implants

2.2 *ISO ~~Standards:~~Standard:*[4]
ISO ~~10993~~10993-1 Biological Evaluation of Medical ~~Devices, Parts 1-12~~Devices—Part 1: Evaluation and testing within a risk management process
~~ISO 527 Plastics—Determination of Tensile Properties—Part 1: General Principles~~

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 ~~*fabricated form—*~~*crosslinking*—~~any bulk shape of UHMWPE, fabricated from the virgin polymer powder and used during the process of fabricating surgical implants prior to crosslinking, packaging, and sterilization.~~the process by which ionizing radiation produces chemical bonds between UHMWPE molecules.

3.1.2 *extensively crosslinked UHMWPE*—UHMWPE material that has been subjected to total doses of gamma and/or electron beam ionizing irradiation greater than 40 kGy for the purpose of generating crosslinks within the material.

3.1.3 *fabricated form*—any bulk shape of UHMWPE, fabricated from the virgin polymer powder and used during the process of fabricating surgical implants prior to crosslinking, packaging, and sterilization.

3.1.4 *ionizing radiation*—gamma or high energy electron radiation.

~~3.1.4 *crosslinking*—the process by which ionizing radiation produces chemical bonds between two UHMWPE molecules.~~

4. Sampling

4.1 Where applicable, the requirements of this guide shall be determined for each lot of powder and fabricated form by sampling sizes and procedures according to Practice D1898, or as agreed upon between the purchaser and seller.

[3] The last approved version of this historical standard is referenced on www.astm.org.
[4] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

5. Extensively Crosslinked UHMWPE Fabricated Form Requirements

5.1 *Compositional Requirements:*

5.1.1 The virgin powder and fabricated forms from which the extensively crosslinked material is manufactured shall meet all the requirements of ~~Practice~~Specification F648.

5.2 *Physical Requirements:*

5.2.1 The manufacture of an extensively crosslinked UHMWPE material may be accomplished many different ways. Therefore, each manufacturer of such material(s) has developed its own proprietary method(s) for doing so. The end result of this variation is that some of the mechanical properties of extensively crosslinked materials currently used for orthopaedic implant applications exhibit a wide range of values. When this is coupled with the fact that the limiting value for any specific mechanical property necessary for clinical success is yet unknown, a listing of such data for these materials is currently impractical. It is more useful and practical to describe standard methods suitable for characterizing these materials.

5.2.2 *UHMWPE Mechanical and Physical ~~Assessments—Part~~ Assessments, Part 1*—The tests shown in Table 1 should be conducted on the extensively crosslinked UHMWPE. Alternative tests may be considered with documented analysis and rationale.

5.2.3 *Mechanical and Physical ~~Assessment—Part~~ Assessment, Part 2*—The tests shown in Table 2 should be conducted on the extensively crosslinked UHMWPE. Alternative tests may be considered, such as electron spin resonance (see Appendix X1) with documented analysis and rationale.

5.2.4 *Preclinical Simulation*—Functional testing on the finished UHMWPE component that simulates clinical functions and known failure modes should be considered. Testing that should be considered include creep, accelerated aging, or shelf-life testing, or combinations thereof, functional fatigue loading, and wear as described in Guide F2759. Practice F2003 should be considered for determining relative oxidative stability.

6. Biocompatibility

6.1 This material has been shown to produce a ~~well characterized~~ well-characterized level of biological response following ~~long term~~ long-term clinical use in humans. The results of these studies and the clinical history indicate an acceptable level of biological response in the applications in which the material has been utilized. When new applications of the material, or modification to the material or physical forms of the materials are being contemplated, the applicable parts of ISO 10993 and Practice F748 should be considered and testing considered as described in Practices F619, F749, F756, F763, F813, and F981 as well as Test Method F895.

7. Keywords

7.1 fabricated forms; powdered form; ultra-high molecular weight polyethylene

TABLE 1 UHMWPE Mechanical and Physical Assessments, Part 1

Test Description	Method
~~Tensile Strength~~	~~D638 or ISO 527~~
Tensile Strength	F648
Ultimate	
Yield	
~~Elongation, %~~	~~D638~~
Elongation, %	F648
Izod impact strength, kJ/m^2	F648, Annex A1
~~Elastic modulus~~	~~D638~~
Elastic modulus	F648
Compression modulus, MPa	D695
Density	
Thermal properties	F2625
Percent crystallinity	
Melting temperature	