



Designation: F2565 – 21

Standard Guide for Extensively Irradiation-Crosslinked Ultra-High Molecular Weight Polyethylene Fabricated Forms for Surgical Implant Applications¹

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 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: *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, health, and 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 Recom-*

mendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.

2. Referenced Documents

2.1 ASTM Standards:²

D695 Test Method for Compressive Properties of Rigid Plastics

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

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.

³ The last approved version of this historical standard is referenced on www.astm.org.

F2102 Guide for Evaluating the Extent of Oxidation in Polyethylene Fabricated Forms Intended for Surgical Implants

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 Standard:⁴

ISO 10993-1 Biological Evaluation of Medical Devices—Part 1: Evaluation and testing within a risk management process

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *crosslinking*—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.

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.

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 Specification **F648**.

5.2 *Physical Requirements:*

5.2.1 The manufacture of an extensively crosslinked UHMWPE material may be accomplished many different ways.

⁴ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

TABLE 1 UHMWPE Mechanical and Physical Assessments, Part 1

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

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 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 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 level of biological response following long-term clinical use in humans. The results of these studies and the clinical history indicate an acceptable level of biological

TABLE 2 Mechanical and Physical Assessment, Part 2

Test Description	Method
Small punch ultimate load, N	F2977
Fatigue crack propagation	E647
Swell ratio	D2765 or F2214
Oxidation index (OI), surface oxidation index (SOI)	F2102
and OI Maximum	
t-Vinylene content, trans-vinylene index (TVI) ⁴	F2381

⁴ The relationship between TVI and absorbed dose has not been established for UHMWPE, and there is no acceptance criteria. The FDA Guidance on UHMWPE for Orthopedic Devices (2016) recommends comparison to a predicate. TVI is also useful for establishing the uniformity of dosage.