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Standard Guide for Assessment of the Ultra-High Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic and Spinal Devices¹

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1. Scope

1.1 This guide covers general guidelines for the physical, chemical, biocompatibility, mechanical, and preclinical assessments of ultra-high molecular weight polyethylene (UHMWPE) in implantable orthopedic and spinal devices intended to replace a musculoskeletal joint. The UHMWPE components may include knee, hip, shoulder, elbow, ankle, total disc replacement, toe, finger, and wrist joint implant devices. This guide does not cover UHMWPE in fiber or tape forms.

1.2 This guide includes a description and rationale of assessments for the various UHMWPE types and processing conditions. Assessment testing based on physical, chemical, biocompatibility, mechanical, and preclinical analyses are briefly described and referenced. The user should refer to specific test methods for additional details.

1.3 This guide does not attempt to define all of the assessment methods associated with UHMWPE components in orthopedic and spinal devices.

1.4 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.5 *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 Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

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. Referenced Documents

2.1 ASTM Standards:²

- D256 Test Methods for Determining the Izod Pendulum Impact Resistance of Plastics
- D638 Test Method for Tensile Properties of Plastics
- D695 Test Method for Compressive Properties of Rigid Plastics
- D883 Terminology Relating to Plastics
- D2765 Test Methods for Determination of Gel Content and Swell Ratio of Crosslinked Ethylene Plastics
- D4020 Specification for Ultra-High-Molecular-Weight Polyethylene Molding and Extrusion Materials
- E647 Test Method for Measurement of Fatigue Crack Growth Rates
- F619 Practice for Extraction of Medical Plastics
- F648 Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants
- F732 Test Method for Wear Testing of Polymeric Materials Used in Total Joint Prostheses
- 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
- F1714 Guide for Gravimetric Wear Assessment of Prosthetic

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.

Hip Designs in Simulator Devices

- F1715** Guide for Wear Assessment of Prosthetic Knee Designs in Simulator Devices (Withdrawn 2006)³
- F2003** Practice for Accelerated Aging of Ultra-High Molecular Weight Polyethylene after Gamma Irradiation in Air
- F2025** Practice for Gravimetric Measurement of Polymeric Components for Wear Assessment
- 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
- F2423** Guide for Functional, Kinematic, and Wear Assessment of Total Disc Prostheses
- 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
- F2695** Specification for Ultra-High Molecular Weight Polyethylene Powder Blended With Alpha-Tocopherol (Vitamin E) and Fabricated Forms for Surgical Implant Applications
- F2977** Test Method for Small Punch Testing of Polymeric Biomaterials Used in Surgical Implants

2.2 *ISO Standards*:⁴

- ISO 527** Plastics: Determination of Tensile Properties
- ISO 3451-1** Plastics: Determination of Ash Part 1: General Methods
- ISO 5834-1** Implants for Surgery—Ultra High Molecular Weight Polyethylene. Part 1: Powder Form
- ISO 5834-2** Implants for Surgery—Ultra High Molecular Weight Polyethylene. Part 2: Molded Forms
- ISO 10993** Biological Evaluation of Medical Devices
- ISO 14242-1** Implants for Surgery—Wear of Total Hip-Joint Prostheses. Part 1: Loading and Displacement Parameters for Wear-Testing Machines and Corresponding Environmental Conditions for Test
- ISO 14242-2** Implants for Surgery—Wear of Total Hip-Joint Prostheses. Part 2: Methods of Measurement
- ISO 14242-3** Implants for Surgery—Wear of Total Hip-Joint Prostheses. Part 3: Loading and Displacement Parameters for Orbital Bearing Type Wear Testing Machines and Corresponding Environmental Conditions for Test
- ISO 14243-1** Implants for Surgery—Wear of Total Knee-Joint Prostheses. Part 1: Load and Displacement Parameters for Wear-Testing Machines with Load Control and Corresponding Environmental Conditions for Test

- ISO 14243-2** Implants for Surgery—Wear of Total Knee-Joint Prostheses. Part 2: Methods of Measurement
- ISO 14243-3** Implants for Surgery—Wear of Total Knee-Joint Prostheses. Part 3: Loading and Displacement Parameters for Wear-Testing Machines with Displacement Control and Corresponding Environmental Conditions for Test
- ISO 18192-1** Implants for Surgery—Wear of Total Intervertebral Disc Prostheses. Part 1: Loading and Displacement Parameters for Wear Testing and Corresponding Environmental Conditions for Test

2.3 *Federal Standards and Guidance Documents*:

- 21 CFR 58** Good Laboratory Practices Regulations⁵

3. Terminology

3.1 *Definitions*—Additional terminology related to ultra-high molecular weight polyethylene (UHMWPE) and plastics can be found in Terminology **D883** and Specifications **D4020** and **F648** and referenced publications (1-7).⁶

3.2 *Definitions of Terms Specific to This Standard*:

3.2.1 *fabricated form, n*—any bulk shape of UHMWPE fabricated from the virgin polymer powder with or without additives or prior irradiation and used during the process of fabricating surgical implants before packaging and sterilization.

3.2.1.1 *Discussion*—This form results from the application of heat and pressure to the virgin polymer powder, and the material characteristics of this form are subject to the applicable requirements of this guide. In present practice, this includes ram-extruded bars, compression-molded sheets, and direct-molded shapes that are subsequently trimmed.

4. Significance and Use

4.1 This guide aims to provide guidance for a range of assessments and evaluations to aid in preclinical research and device development of various UHMWPE components in orthopedic and spinal devices used for the repair of musculoskeletal disorders.

4.2 This guide includes brief descriptions of various assessments, representative data, processing conditions, and intended use or uses, as well as the qualitative and quantitative analyses of the UHMWPE powder to a finished product component.

4.3 The user is encouraged to use appropriate ASTM International and other standards to conduct the physical, chemical, mechanical, biocompatibility, and preclinical tests on UHMWPE materials, device components, or devices before assessment of an *in vivo* model.

4.4 Assessments of UHMWPE should be performed in accordance with the provisions of 21 CFR 58 where feasible.

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, <http://www.ansi.org>.

⁵ Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401, <http://www.access.gpo.gov>.

⁶ The boldface numbers in parentheses refer to the list of references at the end of this standard.

4.5 Studies to support investigational device exemption (IDE), premarket approval (PMA), or 510K submissions should conform to appropriate Food and Drug Administration (FDA) guidelines for the development of medical devices.

4.6 Assessments with physical, chemical, mechanical, biocompatibility, and preclinical tests on UHMWPE components are not necessarily predictive of human results and therefore should be interpreted cautiously with respect to potential applicability to human conditions. Referenced UHMWPE publications can be found in the References section at the end of this guide for further review.

5. UHMWPE Fabricated Forms and Conditions

5.1 Conventional UHMWPE is manufactured by compression molding or ram extrusion and has not been intentionally cross-linked before terminal sterilization.

5.2 Extensively radiation-cross-linked UHMWPE is manufactured by compression molding or extrusion and irradiated with a dosage higher than 40 kGy of gamma or e-beam radiation for improved wear resistance.

5.3 *Antioxidant (Alpha-Tocopherol)*—Two stabilizing methods for the antioxidant UHMWPE form (Vitamin E-stabilized or alpha-tocopherol) are blending or diffusing. The blending method has the Vitamin E mixed (blended) into the UHMWPE powder before consolidation and radiation cross-linking. The diffusing method has the Vitamin E diffusing into a consolidated UHMWPE form before or after radiation cross-linking. Also, antioxidant UHMWPE could potentially be used without any radiation cross-linking.

5.4 *Thermal Processing*—UHMWPE-fabricated forms undergo at least one or more thermal treatments during the consolidation processes of extrusion or molding, annealing, cross-linking, or after cross-linking. The thermal history should be documented and its effects assessed with mechanical, physical, chemical, and preclinical testing.

5.5 UHMWPE powder is classified as Type 1, 2, or 3. These types have different molecular weights and material properties as defined in Specification F648.

6. UHMWPE Decision Chart (Table 1)

6.1 The assessment chart shown in Table 1 should be performed as indicated on the listed UHMWPE types.

6.2 UHMWPE fabricated form testing should be pursued with samples that are in the final conditions with respect to

annealing, sterilization, aging, and packaging. Assessment parameters should include and be compared to clinically successful UHMWPE materials.

7. Test Methods

7.1 *Virgin UHMWPE Powder*—The tests shown in Table 2 should be conducted on the UHMWPE types designated in Table 1. Alternative tests, such as ones found in ISO 5834–1 and ISO 5834–2, may be considered with documented analysis and rationale.

7.2 *UHMWPE Mechanical and Physical Assessments—Part 1*—The tests shown in Table 3⁷ should be conducted on the UHMWPE types designated in Table 1. Alternative tests may be considered with documented analysis and rationale.

7.3 *Mechanical and Physical Assessment—Part 2*—The tests shown in Table 4⁷ should be conducted on the UHMWPE types designated in Table 1. Alternative tests may be considered, such as electron spin resonance (see X1.1), with documented analysis and rationale.

7.4 *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, and/or shelf-life testing, and functional fatigue loading. Practice F2003 should be considered for determining relative oxidative stability.

7.4.1 *Wear*—See Table 5.

7.4.2 *Functional Device or Material Testing*—UHMWPE implant components have experienced known device failure modes. Examination of known clinical failure modes through functional device or material testing, such as fatigue testing of the post in a posterior-stabilized tibial insert or fatigue-impingement testing of the stem neck and polyethylene liner in a hip implant, should be considered with new UHMWPE processes, material additives, or implant designs.

7.5 *UHMWPE with Antioxidant (Alpha-Tocopherol)*—Commercially available UHMWPEs for implants containing antioxidants are blended or doped with alpha-tocopherol.

⁷ Acceptance criteria have not been established for several of the physical and mechanical properties of consolidated UHMWPE, especially after radiation cross-linking. The 2019 FDA guidance on characterization of UHMWPE used for orthopedic devices suggests comparison to legally marketed predicate devices or to published literature (8). It is also states that several properties should be measured “throughout the sample” to demonstrate uniformity of processing.

TABLE 1 UHMWPE Fabricated Forms and Conditions

Test Method Group	Conventional	Extensively Cross-Linked (Irradiation)	Antioxidant
Virgin powder (7.1)	X	X	X
Mechanical and physical—Part 1 (7.2)	X	X	X
Mechanical and physical—Part 2 (7.3)	X ^A	X	X
Preclinical wear simulation (7.4)	X ^A	X	X
Antioxidant assessment (7.5)			X
Packaging and sterilization rationale (Section 8)	X	X	X
Biocompatibility (Section 9)	X	X	X

^A For materials terminally sterilized by gamma or e-beam irradiation.