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Standard Guide for Assessment of the Ultra High Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic and Spinal Devices[1]

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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 *Units*—The values given in SI units are to be regarded as the 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 and health practices and determine the applicability of regulatory limitations prior to use.*

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
D883 Terminology Relating to Plastics
D1621 Test Method for Compressive Properties of Rigid Cellular 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
E132 Test Method for Poisson's Ratio at Room Temperature
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 Bone
F1714 Guide for Gravimetric Wear Assessment of Prosthetic Hip Designs in Simulator Devices
F1715 Guide for Wear Assessment of Prosthetic Knee Designs in Simulator Devices[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

[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] Withdrawn. The last approved version of this historical standard is referenced on www.astm.org.

F2102 Guide for Evaluating the Extent of Oxidation in Ultra-High-Molecular-Weight Polyethylene Fabricated Forms Intended for Surgical Implants
F2183 Test Method for Small Punch Testing of Ultra-High Molecular Weight Polyethylene Used in 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

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 11542–2 Plastics—Ultra-High-Molecular-Weight-Polyethylene (PE-UHMWPE) Molding and Extrusion Materials. Part 2: Preparation of Test Specimens and Determination of Properties
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 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 Standard:*
21 CFR 58 Good Laboratory Practices Regulations[5]

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 *Definition of Term 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 various 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.

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 should be, therefore, 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.

[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.