Designation: F648 – 21

Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants[1]

This standard is issued under the fixed designation F648; 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 specification covers ultra-high molecular weight polyethylene powder (UHMWPE) and fabricated forms intended for use in surgical implants.

1.2 The requirements of this specification apply to UHMWPE in two forms. One is virgin polymer powder (Section 4). The second is any form fabricated from this powder from which a finished product is subsequently produced (Section 5). This specification addresses material characteristics and does not apply to the packaged and sterilized finished implant.

1.3 The requirements of this specification do not apply to UHMWPE virgin powder or fabricated forms intentionally crosslinked or blended with other additives, for example, antioxidants.

1.4 The biological response to polyethylene in soft tissue and bone has been well characterized by a history of clinical use (**1-3**)[2] and by laboratory studies (**4-6**).

1.5 The values stated in SI units are to be regarded as standard.

1.6 The following precautionary caveat pertains only to the test method portion, Section 7, of this specification: *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.*

1.7 *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:*[3]

D256 Test Methods for Determining the Izod Pendulum Impact Resistance of Plastics

D638 Test Method for Tensile Properties of Plastics

D648 Test Method for Deflection Temperature of Plastics Under Flexural Load in the Edgewise Position

D790 Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials

D792 Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement

D1505 Test Method for Density of Plastics by the Density-Gradient Technique

D1898 Practice for Sampling of Plastics (Withdrawn 1998)[4]

D4020 Specification for Ultra-High-Molecular-Weight Polyethylene Molding and Extrusion Materials

F619 Practice for Extraction of Materials Used in Medical Devices

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

[1] This specification 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] The boldface numbers in parentheses refer to the list of references at the end of this specification.

[3] 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.

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

F2759 Guide for Assessment of the Ultra-High Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic and Spinal Devices

2.2 *ISO Standards:*[5]

ISO 3451-1 Plastics—Determination of Ash, Part 1: General Methods

ISO 11542/2 Plastics—Ultra-High Molecular Weight Polyethylene (UHMWPE) Moulding and Extrusion Materials—Part 2: Preparation of Test Specimens and Determination

ISO 9001 Quality Management Systems—Requirements

ISO 13485 Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

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

3.1.1.1 *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 specification. In present practice, this includes ram-extruded bars or molded blocks from which the final product form is machined, or a molded shape which is subsequently trimmed.

3.1.2 *generic property, n*—that property which is determined solely by the chemical composition and structure of the virgin polymer.

3.1.3 *morphology index (MI), n*—ratio of the total number of Type A and Type B indications (see Annex A2) to the total surface area examined in cm^2.

3.1.4 *Type A non-fused flake, n*—a Type A non-fused flake (A2.4.1 and Fig. A2.1) is an indication visible under conditions described in A2.5.1 that has an essentially complete circumferential black boundary and a white center.

3.1.5 *Type B non-fused flake, n*—a Type B non-fused flake (A2.4.2 and Fig. A2.2) is an indication visible under conditions described in A2.5.1 that has a partially circumferential black boundary that appears to trace out 50 % to 99 % of a flake's perimeter.

3.1.6 *virgin polymer powder, n*—form of UHMWPE as obtained from the powder manufacturer and prior to fabrication into a bulk shape.

4. Virgin UHMWPE Powder Requirements

4.1 *Generic Properties:*

4.1.1 The virgin polymer shall be a homopolymer of ethylene in accordance with Specification D4020.

4.1.2 The resin type and solution viscosity number requirements are listed in Table 1.

4.2 *Nongeneric Properties:*

TABLE 1 Requirements for UHMWPE Powders

Property	Test Method	Requirement		
Resin Type		Type 1	Type 2	Type 3
Viscosity Number, mL/g,	ASTM D4020 (0.02 %)	2000–3200	>3200	>3200
Elongation Stress, (Minimum)	ASTM D4020	0.20	0.42	0.42
Ash, mg/kg, (Maximum)	ISO 3451-1	125	125	300
Extraneous Matter, No. Particles, (Maximum)	4.2.1	3	3	25
Titanium, mg/kg, (Maximum)	7.1.3.1	40	40	150
Aluminum, mg/kg, (Maximum)	7.1.3.1	20	20	100
Calcium, mg/kg, (Maximum)	7.1.3.1	5	5	50
Chlorine, mg/kg, (Maximum)	7.1.3.2	30	30	90

4.2.1 When a 300 g sample is prepared and viewed in accordance with 7.1.2, there shall be no more particles of extraneous matter than that specified in Table 1.

4.2.2 To promote uniformity between different lots of polymer powder, concentration limits for trace elements have been established and are listed in Table 1.

4.2.3 When determined as described in ISO 3451-1, the mean ash of duplicate samples shall not exceed the limits established in Table 1.

4.3 *Quality System Requirements:*

4.3.1 The UHMWPE powder as described in the scope of this specification shall be produced in accordance with an ISO 9001 or ISO 13485 certified Quality Management System.

5. UHMWPE Fabricated Form Requirements

5.1 *Compositional Requirements:*

5.1.1 No stabilizers, antioxidants, or processing aids are to be added to the virgin polymer powder during manufacture of a fabricated form.

5.1.2 No stabilizers, antioxidants, or processing aids are to be added to the fabricated form during manufacture of the final implant.

5.2 *Physical Requirements:*

5.2.1 *Foreign Matter Requirements:*

5.2.1.1 When 5000 cm^2 is evaluated according to 7.2.2, there shall be no more than ten particles of extraneous matter visible on the surface when visually inspected by a person with normal or fully corrected vision.

5.2.2 *Morphology Requirements:*

5.2.2.1 When evaluated during the consolidation process validation according to Annex A2, the calculated morphology index (MI) and total surface area examined shall be reported. It is not required to evaluate the morphology index during routine monitoring of a validated manufacturing process because alternative test methods in this standard, such as density and the mechanical properties required in Table 2, already provide reasonable, redundant assurance of successful consolidation.

5.3 *Mechanical Requirements:*

5.3.1 UHMWPE in fabricated form from which implants will be made (after annealing processes, if appropriate) shall meet the requirements listed in Table 2.

5.3.2 The following mechanical tests may be conducted based on agreement between the vendor and purchaser:

5.3.2.1 Deflection temperature, Test Method D648 (1.8 MPa); and flexural modulus, Test Methods D790 (secant, 2 % offset).

[5] Available from International Organization for Standardization (ISO), 1, ch. de la Voie-Creuse, CP 56, CH-1211 Geneva 20, Switzerland, http://www.iso.org.

TABLE 2 Requirements for UHMWPE Fabricated Forms

Property	Test Method	Requirement		
Resin Type		Type 1	Type 2	Type 3
Density, kg/m^3	ASTM D792 or D1505	927–944	927–944[B]	927–944
Tensile Strength, 23 °C, MPa, (Minimum)	ASTM D638, Type IV, 1.5 mm ± 0.5 mm, 5.08 cm/min			
Ultimate		40	40	27
Yield		21	19	19
Elongation, %, (Minimum)[A]	ASTM D638, Type IV, 5.08 cm/min	380	340	250
Izod Impact Strength, kJ/m^2, (Minimum)	Annex A1	126	73	25

[A] Use an extensometer for measuring strain and calculating percent elongation.
[B] For molded shapes as defined in 3.1.1.1, the density requirement is 925 to 944 for Type 2 resin.

5.4 *Quality System Requirements:*

5.4.1 The UHMWPE fabricated forms as described in the scope of this specification shall be produced in accordance with an ISO 9001 or ISO 13485 certified Quality Management System.

6. Sampling

6.1 Where applicable, the requirements of this specification 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.

7. Test Methods

7.1 *UHMWPE Powder:*

7.1.1 Determine the solution viscosity number in accordance with the method given in Specification D4020 at a concentration of 0.02 %.

7.1.2 Determine the amount of extraneous matter by the following procedure as agreed upon by the purchaser and seller.

7.1.2.1 A 300 g sample is divided into four 75 g samples. Place a 75 g sample in each of four 1000 mL Erlenmeyer flasks, add 400 mL isopropyl alcohol, shake 5 min, and let settle for 5 min. Count the total number of particles of extraneous matter in the four flasks.

7.1.2.2 Visually examine (with 20/20 corrected vision if necessary) the four flasks and count the total number of particles of extraneous matter.

7.1.3 Determine the following trace element concentrations by the following methods, or by methods agreed upon by the purchaser and seller.

7.1.3.1 The elements Ti, Al, and Ca may be determined by atomic absorption (AA) or emission spectroscopy (ES); inductively coupled plasma mass spectroscopy (ICP/MS); or inductively coupled plasma spectroscopy (ICP).

7.1.3.2 The element chlorine (Cl) may be determined potentiometrically, titrametrically, by neutron activation analysis, by inductively coupled plasma mass spectroscopy (ICP/MS), or by the oxygen bomb combustion/UV-Vis spectroscopy method.

7.2 *UHMWPE Fabricated Form:*

7.2.1 The requirement that there will be no addition of any stabilizer, antioxidant, or processing aid during fabrication of the fabricated form shall be met by certification of the fabricator.

7.2.2 Determine the amount of extraneous matter by the following procedure.

7.2.2.1 Prepare a number of test specimens from the fabricated form as agreed upon by the purchaser and seller.

7.2.2.2 Visually examine (with 20/20 corrected vision if necessary) a total area of 5000 cm^2 taken from locations within the fabricated form agreed upon by the purchaser and seller.

7.2.3 Determine the density in accordance with Test Methods D792 or D1505.

7.2.4 Determine specific mechanical properties in accordance with the methods listed in Table 2. Mechanical test specimens shall be produced by methods that represent those used to produce the fabricated form.

7.2.5 Unless otherwise specified, the testing described in Table 2 (except for ash) shall be conducted under standard conditions of 23 ± 2 °C after storage of the test specimens for at least 16 h.

8. Biocompatibility

8.1 This material has been shown to produce a well-characterized level of biological response following long-term clinical use in laboratory animals. 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 recommendations of Practice F748 should be considered and testing as described in Practices F619, F749, F756, F763, F813, and F981 as well as Test Method F895.

9. Keywords

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