Designation: F755 – 19

Standard Specification for Selection of Porous Polyethylene for Use in Surgical Implants[1]

This standard is issued under the fixed designation F755; 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 the properties and test methods for porous high-density-polyethylene (HDPE) and porous ultra-high-molecular-weight-polyethylene (UHMWPE) intended for use in surgical implants. The porous polyethylene may be used as a free-standing product or as a coating on a substrate in non-loaded applications.

1.2 Materials covered by this standard can have a broad range of mechanical and morphological properties depending on the starting material and fabrication processes. Therefore no attempt has been made to standardize the properties, and the requirements for a specific application are not within the scope of this standard.

1.3 Evaluation of the tissue response to a porous polyethylene must be completed. Guidance in establishing biocompatibility may be found in the list of references.

1.4 Clinical experience and animal studies have shown that tissue will grow into the open pores of porous polyethylene. The tissue ingrowth into the pores may facilitate the establishment of implant fixation.

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

1.6 *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:*[2]

D638 Test Method for Tensile Properties of Plastics

D732 Test Method for Shear Strength of Plastics by Punch Tool

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

D883 Terminology Relating to Plastics

D1238 Test Method for Melt Flow Rates of Thermoplastics by Extrusion Plastometer

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

D1621 Test Method for Compressive Properties of Rigid Cellular Plastics

D1623 Test Method for Tensile and Tensile Adhesion Properties of Rigid Cellular Plastics

D1898 Practice for Sampling of Plastics (Withdrawn 1998)[3]

D2238 Test Methods for Absorbance of Polyethylene Due to Methyl Groups at 1378 cm^{-1}

E562 Test Method for Determining Volume Fraction by Systematic Manual Point Count

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

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] 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.

F2450 Guide for Assessing Microstructure of Polymeric Scaffolds for Use in Tissue-Engineered Medical Products

2.2 *ISO Standards:*[4]

ISO 10993-1 Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing Within a Risk Management Process

2.3 *Other Documents:*

Code of Federal Regulations Title 21, Paragraph 177.1520 Olefin Polymers[5]

U.S. FDA Guidance Document Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing Within a Risk Management Process"[6]

3. Significance and Use

3.1 Porous polyethylene is a matrix of substantially open cells, interconnected to form multidirectional paths. Performance of these structures, including tissue ingrowth, depends upon the biocompatibility of the polymer, average pore and interstitial opening diameters (ordinarily referred to as average pore size) in conjunction with void volume (referred to as pore volume or percent porosity).

3.2 This specification is applicable to all surgical implant devices in which a porous polyethylene is used. In applications where the use of a porous polyethylene has not been established, the mechanical and physical characteristics required shall be determined by appropriate testing. The required pore size, pore volume, and mechanical properties shall be specified.

4. Raw Material Requirements

4.1 The polyethylene plastic shall consist of basic polymers made with ethylene as essentially the sole monomer as defined in Terminology D883.

4.2 HDPE shall exhibit a density of not less than 0.941 g/cm^3 when tested in accordance with Test Method D1505.

4.3 UHMWPE shall conform to those sections of Specification F648 that apply to base resin.

4.4 The raw materials shall contain no dirt or other foreign matter which will cause the end product to fail to meet the product requirement specified in 5.2. Specification F648 provides a method that may be used to assess the cleanliness of polyethylene resins for surgical implant applications.

4.5 HDPE resin shall conform to all parts of CFR Title 21, Paragraph 177.1520 which apply to polyethylene.

4.6 The polymer shall be characterized by determining the infrared absorption spectrum. An acceptable procedure may be found in Test Methods D2238.

4.7 The polymer shall be characterized by one or more of the following test methods:

4.7.1 The polymer shall be characterized by determining the melt point range and rate of melt by thermal analysis.

4.7.2 The compositional characteristics of the polymer shall be analyzed by thermogravimetric analysis.

4.7.3 The flow rate of high density polyethylene shall be determined in accordance with Test Method D1238.

5. Product Requirements

5.1 The biocompatibility of porous polyethylene materials and implant devices made from them shall be determined in accordance with ISO 10993-1 or Practice F748, unless otherwise agreed upon between the supplier, the customer, and regulating bodies. Additional information on biocompatibility evaluation and test selection is given in the U.S. FDA guidance document on the use of ISO 10993-1. It is intended that biocompatibility be established on the finished product by the appropriate procedures depending on the application, after it has gone through all processing steps including sterilization.

5.2 The surface of the porous polyethylene shall not contain particles of residue or loose particles of plastic of a diameter greater than 300 µm. The concentration of particles visible at 8× magnification shall not be greater than 10 particles/400 cm^2.

5.3 The level of extractables found in the porous product when tested in accordance with 4.5 shall not increase from that found in the raw material.

5.4 The porous product shall be inspected under 8× magnification to ensure that the surface porosity is open.

5.5 The average pore size shall be specified by vendor-user agreement and shall be held to within 20 % of the nominal value unless the end-use application requires less deviation.

5.6 Porous product quality and uniformity shall be ensured by the appropriate test methods as specified by vendor-user agreement and listed in Section 6.

6. Test Methods

Note 1—The shape and end use of the porous product influence which tests are appropriate. For example, it is impossible to perform a bubble point analysis on a total ossicular replacement, while mercury intrusion porosimetry provides acceptable results. Mechanical test methods should employ loading that is relevant to the intended application.

6.1 All mechanical and physical tests shall be sampled as required in Practice D1898. Samples shall be representative of the finished product after it has gone through all processing steps.

6.1.1 Vended product shall be tested in the condition that it is supplied to the user, typically prior to sterilization.

6.2 Average pore size shall be established by appropriate test methods such as are described in Guide F2450.

6.3 Average pore volume shall be established using one of the following methods:

6.3.1 Pore volume can be approximated by measurement of the weight of a non-solvent saturant of known gravity and relating its volume to the matrix volume.

6.3.2 Pore volume can be estimated by optical microscopy as described in Test Method E562.

[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] Available from the U.S. FDA, https://www.fda.gov/regulatory-information/search-fda-guidance-documents.