Designation: ~~F755 – 99 (Reapproved 2011)~~ 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 and ultra high molecular weight polyethylenes~~ 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~~ free-standing product or as a coating on a substrate in ~~nonloaded~~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 ~~allow for~~ 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 ~~section~~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~~ safety, health, and ~~health~~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}
~~D2873 Test Method for Interior Porosity of Poly(Vinyl Chloride) (PVC) Resins by Mercury Intrusion Porosimetry (Withdrawn 2003)[3]~~

[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.

E562 Test Method for Determining Volume Fraction by Systematic Manual Point Count
F316 Test Methods for Pore Size Characteristics of Membrane Filters by Bubble Point and Mean Flow Pore Test
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
F763 Practice for Short-Term Screening of Implant Materials
F981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Insertion into Bone
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. Pharmacopeia,FDA Guidance Document Vol 23, 1995Use 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 device standards surgical implant devices in which a porous polyethylene is used. A complete list of end uses has not been established. In those cases In applications where the use of a porous polyethylene has not been established, the mechanical and physical characteristics required shall be determined by properappropriate testing. The required pore size, pore volume, and the mechanical properties will be specified in the particular device standard. 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 High-density polyethylene HDPE shall exhibit a density of not less than 0.941 g/cm^3 when tested in accordance with Test Method D1505.

4.3 Ultra-high-molecular-weight polyethylene UHMWPE shall conform to those sections of Specification F648 that apply to base resin.

4.4 Particular 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 The polyethylene HDPE resin shall conform to all parts of Paragraph 177.1520 of Title 21CFR 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 Until a porous polymer biocompatibility standard is available, porous polyethylene shall be screened by biocompatibility and toxicology tests applicable toThe biocompatibility of porous polyethylene materials and implant devices made from them shall be determined in accordance with ISO 10993-1 or Practice F748its end use. Biological test procedures appropriate to determine biological safety and tissue reactions are described in Practices, unless otherwise agreed upon between the supplier, the customer, and regulating bodies. Additional information on biocompatibility evaluation F748 andand test F981 and the United States

[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 U.S. Pharmacopeia (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852-1790, http://www.usp.org.the U.S. FDA, https://www.fda.gov/regulatory-information/search-fda-guidance-documents.