Designation: F 755 – 99

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

This standard is issued under the fixed designation F 755; 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 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 nonloaded applications..

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

1.3 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 the establishment of implant fixation.

1.4 *This section 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:*

D 638 Test Method for Tensile Properties of Plastics[2]

D 732 Test Method for Shear Strength of Plastics by Punch Tool[2]

D 790 Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials[2]

D 883 Definitions of Terms Relating to Plastics[2]

D 1238 Test Method for Flow Rates of Thermoplastics by Extrusion Plastometer[2]

D 1505 Test Method for Density of Plastics by the Density-Gradient Technique[2]

D 1621 Test Method for Compressive Properties of Rigid Cellular Plastics[2]

D 1623 Test Method for Tensile and Tensile Adhesion Properties of Rigid Cellular Plastics[2]

D 1898 Practice for Sampling of Plastics[2]

D 2238 Test Methods for Absorbance of Polyethylene Due to Methyl Groups at 1378 cm^{-1} [2]

D 2873 Test Method for Interior Porosity of Poly(Vinyl Chloride) (PVC) Resins by Mercury Intrusion Porosimetry[3]

E 562 Practice for Determining Volume Fraction by Systematic Manual Point Count[4]

F 316 Test Method for Pore Size Characteristics of Membrane Filters for Use with Aerospace Fluids[5]

F 469 Practice for Assessment of Compatibility of Nonporous Polymeric Materials for Surgical Implants With Regard to Effect of Materials on Tissue[6]

F 648 Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants[6]

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices[6]

F 763 Practice for Short-Term Screening of Implant Materials[6]

F 981 Practice for Assessment of Compatibility of Biomaterials (Non-porous) for Surgical Implants with Respect to Effect of Materials on Muscle and Bone[6]

2.2 *Other Documents:*

Code of Federal Regulations Title 21, Paragraph 177.1520.

U. S. Pharmacopeia XXIII, 1995

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 in which a porous polyethylene is used. A complete list of end uses has not been established. In those cases where the use of a porous polyethylene has not been established, the mechanical and physical characteristics required shall be determined by proper testing. The pore size, pore volume, and the mechanical properties will be specified in the particular device standard.

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[1] This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.11 on Polymeric Materials.

Current edition approved August 10, 1999. Published September 1999. Originally published as F 755 – 82. Last previous edition F 755 – 98.

[2] *Annual Book of ASTM Standards*, Vol 08.01.

[3] *Annual Book of ASTM Standards*, Vol 08.02.

[4] *Annual Book of ASTM Standards*, Vol 03.01.

[5] Discontinued—See *1995 Annual Book of Standards*, Vol 11.02.

[6] *Annual Book of ASTM Standards*, Vol 13.01.

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 D 883.

4.2 High-density polyethylene shall exhibit a density of not less than 0.941 g/cm^3 when tested in accordance with Test Method D 1505.

4.3 Ultra-high-molecular-weight polyethylene shall conform to those sections of Specification F 648 that apply to base resin.

4.4 Particular 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.

4.5 The polyethylene resin shall conform to all parts of Paragraph 177.1520 of Title 21 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 D 2238.

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 D 1238.

5. Product Requirements

5.1 Until a porous polymer biocompatibility standard is available, porous polyethylene shall be screened by biocompatibility and toxicology tests applicable to its end use. Biological test procedures appropriate to determine biological safety and tissue reactions are described in Practice F 748 and the United States Pharmacopeia which recommends generic biological test methods according to end use applications. Short term screening for implant materials are described in Practice F 763.

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 assure 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 assured 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 dictates which tests are appropriate. For example, it is impossible to perform a bubble point analysis on a total ossicular replacement, while mercury intrusion porosimetry is quite acceptable. A flexural test may be an acceptable nondestructive test where tensile strength tests are destructive.

6.1 All mechanical and physical tests shall be sampled as required in Practice D 1898.

6.2 Average pore size shall be established by appropriate test methods such as is found in Method F 316 or by mercury intrusion porosimetry. Test Method D 2873 is an acceptable method.

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

6.3.1 Pore volume can be measured by mercury intrusion porosimetry. Test Method D 2873 is an acceptable method.

6.3.2 Pore volume can be approximated by measurement of weight of a nonsolvent saturant of known gravity and relating its volume to the matrix volume.

6.3.3 Pore volume can be estimated by optical microscopy as described in Practice E 562.

6.4 The tensile properties shall be determined in accordance with Test Method D 638. Test Method D 1623 may be used as an alternative method.

6.5 The compressive properties shall be determined in accordance with Test Method D 1621.

6.6 The flexural properties shall be determined in accordance with Test Methods D 790.

6.7 The shear properties shall be determined in accordance with Test Method D 732.

7. Certification

7.1 *Vendor of Porous Materials*:

7.1.1 Vendor shall certify that the raw material conforms to Section 4 of this specification.

7.1.2 Vendor shall certify that the porous polyethylene conforms to Section 5 of this specification and is made of the same raw material as has been characterized by Section 4.

7.1.3 Vendor shall certify that the mechanical properties as determined by 6.4-6.7 conform to the vendor-user agreement.

7.1.4 Porosity requirements as determined by 6.2 and 6.3 shall be certified by the vendor to conform to the vendor-user agreement.

7.1.5 Vendor shall specify in the certification report all test methods used.

NOTE 2—Certification is employed since verification would alter or destroy functionality.

8. Keywords

8.1 plastic surgical devices/applications; polyethylene (PE) plastics/surgical implant applications; polymers-surgical applicant

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 The use of some solid polyethylenes in vivo has been well established. Because of their mechanical and physical properties, some porous polyethylenes have also shown considerable promise for many in vivo applications. The list of applications currently being investigated is quite lengthy but, even so, does not exhaust the possibilities. It is to be expected that as applications are developed the properties of the porous polyethylene which are acceptable for a given application will be uniquely specified. This will necessitate the writing of a standard for each end-use product.

X1.2 It is not the purpose of this generic standard to eliminate *a priori* any candidate porous polyethylene. For this reason, it is seen that in some respects the requirements for this are rather broad. The pore size and pore volumes are not specified since they will be a function of the end use and the type of tissue ingrowth desired. The same is true of the mechanical properties. The function of this specificiation is to specify those characteristics and tests to which a material is expected to conform to be used as a surgical implant and to be called porous polyethylene. To this end, the following five areas are addressed: (*1*) raw material requirements; (*2*) limits of impurities and extractables; (*3*) end product property test methods; (*4*) tissue response test methods; and (*5*) responsibilities of vendor certification.

X1.3 Porous polyethylenes which conform to this specification will be safe for selected applications and of a uniform high quality. Those properties which are critical to its being efficacious are the responsibility of an end-use product standard.

X2. BIOCOMPATIBILITY

X2.1 The material covered by this standard has been employed successfully in human implant applications in contact with soft tissue and bone for over a decade. Due to the well characterized level of biological response exhibited by this material, the ultra high molecular weight form (Practice F 648) has been used as a control material in Practice F 981

X2.2 No known surgical implant material has ever been shown to be completely free of adverse reactions in the human body. However, long-term clinical experience of use of this material referred to in this standard has shown that an acceptable level of biological response can be expected, if the material is used in appropriate applications.