



Standard Specification for Selection of Porous Polyethylene for Use in Surgical Implants¹

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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 Plastics²
- D 732 Test Method for Shear Strength of Plastics by Punch Tool²
- D 790 Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials²
- D 883 Definitions of Terms Relating to Plastics²
- D 1238 Test Method for Flow Rates of Thermoplastics by Extrusion Plastometer²
- D 1505 Test Method for Density of Plastics by the Density-Gradient Technique²
- D 1621 Test Method for Compressive Properties of Rigid Cellular Plastics²
- D 1623 Test Method for Tensile and Tensile Adhesion Properties of Rigid Cellular Plastics²
- D 1898 Practice for Sampling of Plastics²
- 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 Porosimetry³

E 562 Practice for Determining Volume Fraction by Systematic Manual Point Count⁴

F 316 Test Method for Pore Size Characteristics of Membrane Filters for Use with Aerospace Fluids⁵

F 469 Practice for Assessment of Compatibility of Nonporous Polymeric Materials for Surgical Implants With Regard to Effect of Materials on Tissue⁶

F 648 Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants⁶

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices⁶

F 763 Practice for Short-Term Screening of Implant Materials⁶

F 981 Practice for Assessment of Compatibility of Biomaterials (Non-porous) for Surgical Implants with Respect to Effect of Materials on Muscle and Bone⁶

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.

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.

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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.