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Standard Specification for Polyethylene Plastics for Medical Applications[1]

This standard is issued under the fixed designation F 639; 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 polyethylene plastics (as defined in Terminology D 883) intended for use in medical device applications involving human tissue contact devices, short-term indwellings of 30 days or less, and fluid transfer devices. The biocompatibility of these materials as a class has not been established. Biocompatibility tests must be conducted on the final product.

1.2 This specification is not applicable to ultra-high molecular weight polyethylenes (UHMWPE) plastics, such as those used in joint implants, and so forth.

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

1.4 *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 and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D 638 Test Method for Tensile Properties of Plastics
D 671 Test Method for Flexural Fatigue of Plastics by Constant-Amplitude-of-Force
D 695 Test Method for Compressive Properties of Rigid Plastics
D 747 Test Method for Apparent Bending Modulus of Plastics by Means of a Cantilever Beam
D 790 Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials
D 883 Terminology Relating to Plastics
D 1238 Test Method for Melt Flow Rates of Thermoplastics by Extrusion Plastometer
D 1505 Test Method for Density of Plastics by the Density-Gradient Technique
D 1898 Practice for Sampling of Plastics
~~D2238 Test Methods for Absorbance of Polyethylene Due to Methyl Groups at 1378 cm^{-1}~~[2]
~~D2576 Test Method for Metals in Water and Waste Water by Atomic Absorption Spectrophotometry~~
~~D4976 Specification for Polyethylene Plastics Molding and Extrusion Materials~~
~~F619 Practice for Extraction of Medical Plastics~~[3]
D 4976 Specification for Polyethylene Plastics Molding and Extrusion Materials
E 117 Method for Spectrographic Analysis of Pig-Lead by the Point-To-Plane Technique[0]
F 748 ~~Practice for Selecting Generic Biological Test Methods for Materials and Devices~~[7] Practice for Selecting Generic Biological Test Methods for Materials and Devices

2.2 *ISO Standard:*

ISO 10993 Biological Evaluation of Medical Devices[4]

3. Significance

3.1 This specification describes polyethylene plastics used in the manufacture of medical devices or components of medical

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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* ~~, Vol 08.01.~~volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Withdrawn.

[4] ~~Discontinued; See 1997 *Annual Book of ASTM Standards* , Vol 08.01.~~

[4] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

devices. The properties listed should be considered in selecting material according to the specific end-use requirements.

4. Classification

4.1 Types of polyethylene plastics molding and extrusion material are described in Specification D 4976.

5. General Requirements

5.1 Polyethylene plastics consist of basic polymers made with ethylene as essentially the sole monomer (as defined in Terminology D 883).

5.2 Polyethylene for use in medical applications shall have a maximum extractable fraction, expressed as weight percent in polymer, in *n*-hexane of 5.5% at 50°C (1). -hexane of 5.5 % at 50°C.[5]

5.3 The formulated compound may contain optional adjuvant substances required in the production of the polymer or in the fabrication or intended use of the end product. The biocompatibility of these adjuvant substances shall be established on the finished compound (see Section 9).

5.4 The formulated compound shall yield a consistent infrared absorption spectrum characteristic of the established formulation.

5.5 Maximum levels and type of extractable metals shall be established in accordance with the intended use of the formulated resin (2) [6](see Appendix X1).

NOTE 1—Appendix X1 is a suggested method for determining extractable metals utilizing the current state-of-the-art methodology. Alternative methods with equal reliability may be used.

5.6 The physical properties of polyethylene plastics may be determined by the methods given in Section 7.

6. Sampling

6.1 The material should be sampled in accordance with standard sampling procedures such as those described in Practice D 1898.

7. Physical Methods

7.1 The following physical test procedures are suggested where applicable to the intended application:

7.1.1 *Density*—Test Method D 1505.

7.1.2 *Melt Flow*—Test Method D 1238.

7.1.3 *Tensile Properties*—Test Method D 638.

7.1.4 *Compressive Properties*—Test Method D 695.

7.1.5 *Stiffness*—Test Method D 747.

7.1.6 *Flexural Fatigue*—Test Method D 671.

7.1.7 *Flexural Properties*—Test Method D 790.

8. Packaging and Labeling

8.1 The product shall be packaged in a suitable container to prevent contamination of contents.

8.2 The material shall be identified, including lot or batch numbers and recommended method of storage.

9. Biocompatibility

9.1 The biological safety of each polyethylene plastic formulation shall be established. Specific biological tests shall be determined in accordance with the intended use. Formulated compounds used in these tests should include all colorants and other additives present in the final product.

9.2 Biological tests are appropriate to determine biological safety and tissue reaction, depending on the end use application. These tests should be conducted when indicated for specific applications. Additional tests may be necessary for certain cases; Practice F 748 and USP Class I–VI Biological Tests (ISO 109933) may be used as guidelines.

9.2.1 Biocompatibility testing should be performed on specimens that have been processed and sterilized using the methods intended for the final device. It should be noted that radiation sterilization of the polyethylene has been shown to cause adverse effects on the properties of the material, such as chain scission and the creation of free radicals that lead to oxidation and subsequent deterioration of mechanical properties.

10. Keywords

10.1 plastic surgical devices/applications; polyethylene (PE) plastics—surgical implant applications; polymers—surgical applications

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[5] Discontinued—See *1980 Annual Book of ASTM Standards* , Part 31.

[5] *Federal Register*, Vol 21, Part 177.1520.

[6] *Annual Book of ASTM Standards*, Vol 08.03. Accuracy in Trace Analysis, NBS Special Publication No. 422, U.S. Government Printing Office, Washington, DC, Catalog No. C-13.10:422.