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Designation: F 639 – 98a

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, etc.

1.3 *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:*

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

D 671 Test Method for Flexural Fatigue of Plastics by Constant-Amplitude-of-Force[2]

D 695 Test Method for Compressive Properties of Rigid Plastics[2]

D 747 Test Method for Apparent Bending Modulus of Plastics by Means of a Cantilever Beam[2]

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

D 883 Terminology Relating to Plastics[2]

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

D 1248 Specification for Polyethylene Plastics Molding and Extrusion Materials[2]

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

D 1898 Practice for Sampling of Plastics[2]

D 1928 Practice for Preparation of Compression-Molded Polyethylene Test Sheets and Test Specimens[2]

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

D 2576 Test Method for Metals in Water and Waste Water by Atomic Absorption Spectrophotometry[3]

F 619 Practice for Extraction of Medical Plastics[4]

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices[4]

3. Significance

3.1 This specification describes polyethylene plastics used in the manufacture of medical devices or components of medical 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 1248.

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)**.[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)** (see Appendix X1).

NOTE 1—Appendix X1 is a suggested method for determining extractable metals utilizing the current state-of-the-art methodology. Alternative

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

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

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

[5] The boldface numbers in parentheses refer to the list of references at the end of this standard.

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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 **(3)** may be used as guidelines.

10. Keywords

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

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APPENDIXES

(Nonmandatory Information)

X1. SUGGESTED PRACTICE FOR EXTRACTABLE METALS ANALYSIS OF PLASTIC BY ATOMIC ABSORPTION SPECTROSCOPY

X1.1 Scope

X1.1.1 This practice covers the analysis of extractable metals from plastics intended for use in medical device application.

X1.1.2 Formulated raw materials or finished products may be used.

X1.2 Referenced Documents

X1.2.1 *ASTM Standards*:
D 2576 Test Method for Metals in Water and Waste Water by Atomic Absorption Spectrophotometry[6]
E 117 Method for Spectrographic Analysis of Pig Lead by the Point-to-Plane Technique[7]

X1.3 Significance

X1.3.1 Concentrations of trace metals are measured as extracts in simulated body fluids. The metals concentration in extracts is based on the surface area of the plastic extracted from which the total amount of metal deliverable to the patient may be estimated.

X1.4 Preparation of Specimens

X1.4.1 Use suitable molded test strips of the formulated compound. The total surface area of the specimen to be exposed should be equivalent to 120 cm^2 when the specimen thickness is 0.5 mm or less or 60 cm^2 when the thickness is greater than 0.5 mm. Specimens may be separated from each other by suitable inert spacers to ensure contact with the extraction solvent.

X1.4.2 After the plastic sample has been prepared, extract the specimens using 20 ml of the desired solvent for 72 h at 50°C or 24 h at 70°C, as appropriate for the particular plastic. Then remove the plastic strips and analyze the extract for metals as described in Section X1.5.

X1.5 Preparation of Extract Solution

X1.5.1 Pipet 5.0 ml of the cottonseed oil (CSO) extract into a 10-ml volumetric flask and dilute to volume with hexane. Dilute the CSO atomic absorption standards and controls in the same manner.

X1.5.2 Run the saline eluate directly without dilution.

X1.6 Preparation of Atomic Absorption Standards

X1.6.1 Prepare certified aqueous standard solutions by diluting 1000 ppm of aqueous stock solutions with the 0.9 % saline solution used for extractions. Use the saline solution alone as the blank.

X1.6.2 Prepare the CSO standards by dissolving the appropriate organometallic compound in CSO to give intermediate solutions which are then diluted by volume 1 + 1 with hexane,

[6] *Annual Book of ASTM Standards*, Vol 11.01.
[7] *Annual Book of ASTM Standards*, Vol 03.06.