



Standard Specification for Polyethylene Plastics for Medical Applications¹

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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.

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 Plastics²

D 671 Test Method for Flexural Fatigue of Plastics by Constant-Amplitude-of-Force³

D 695 Test Method for Compressive Properties of Rigid Plastics²

D 747 Test Method for Apparent Bending Modulus of Plastics by Means of a Cantilever Beam²

D 790 Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials²

D 883 Terminology 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 1898 Practice for Sampling of Plastics⁴

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 Spectrophotometry⁵

D 4976 Specification for Polyethylene Plastics Molding and Extrusion Materials⁶

F 619 Practice for Extraction of Medical Plastics⁷

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices⁷

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 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)**.⁸

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.

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 *Annual Book of ASTM Standards*, Vol 08.01.

³ Discontinued; See 2001 *Annual Book of ASTM Standards*, Vol 08.01.

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

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

⁶ *Annual Book of ASTM Standards*, Vol 08.03.

⁷ *Annual Book of ASTM Standards*, Vol 13.01.

⁸ The boldface numbers in parentheses refer to the list of references at the end of this standard.