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Standard Specification for Polyetherketoneetherketoneketone (PEKEKK) Resins for Surgical Implant Applications¹

This standard is issued under the fixed designation F1876; 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.

^{ε1} NOTE—Table 2 was editorially corrected in June 2003.

1. Scope

1.1 This specification covers polyetherketoneetherketoneketone (PEKEKK) resins in virgin forms as supplied by a vendor, such as flakes, pellets, blocks, and so forth. It provides requirements and associated test methods for these thermoplastics when they are to be used in the manufacturing of intracorporeal devices, such as surgical implants or components of surgical or dental devices.

1.2 As with any material, some characteristics may be altered by the processing techniques, such as molding, extrusion, machining, assembly, sterilization, and so forth required for the production of a specific part or device; therefore, properties of fabricated forms of these resins should be evaluated using test methods that are appropriate to assure safety and efficacy as agreed upon by the vendor, purchaser, and regulating bodies.

1.3 The properties included in this specification are those applicable for PEKEKK resins only. Fabricated forms, material or forms containing colorants, fillers, processing aids, or other additives, as well as polymer blends that contain PEKEKK, are not covered by this specification.

1.4 This specification is designed to recommend physical, chemical, and biological test methods to establish a reasonable level of confidence concerning the performance of virgin PEKEKK resins for use in medical devices. The properties listed should be considered in selecting material according to the specific end-use requirements.

1.5 *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.*

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. Referenced Documents

2.1 ASTM Standards:²

- D149 Test Method for Dielectric Breakdown Voltage and Dielectric Strength of Solid Electrical Insulating Materials at Commercial Power Frequencies
- D256 Test Methods for Determining the Izod Pendulum Impact Resistance of Plastics
- D570 Test Method for Water Absorption of Plastics
- D638 Test Method for Tensile Properties of Plastics
- D648 Test Method for Deflection Temperature of Plastics Under Flexural Load in the Edgewise Position
- D695 Test Method for Compressive Properties of Rigid Plastics
- D696 Test Method for Coefficient of Linear Thermal Expansion of Plastics Between -30°C and 30°C with a Vitreous Silica Dilatometer
- D790 Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials
- D792 Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement
- D955 Test Method of Measuring Shrinkage from Mold Dimensions of Thermoplastics
- D1238 Test Method for Melt Flow Rates of Thermoplastics by Extrusion Plastometer
- D1505 Test Method for Density of Plastics by the Density-Gradient Technique
- D1898 Practice for Sampling of Plastics
- D3417 Test Method for Enthalpies of Fusion and Crystallization of Polymers by Differential Scanning Calorimetry (DSC)³
- D3418 Test Method for Transition Temperatures and Enthalpies of Fusion and Crystallization of Polymers by

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

³ Withdrawn. The last approved version of this historical standard is referenced on www.astm.org.

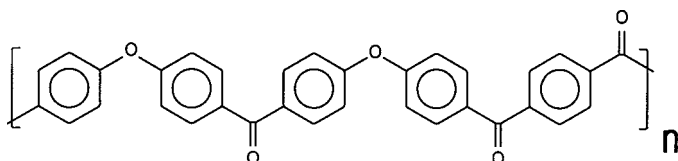


FIG. 1 Chemical Structure of PEKEKK

Differential Scanning Calorimetry

D4000 Classification System for Specifying Plastic Materials

F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices

2.2 ISO Standards:

ISO 1628/1 Plastics—Guidelines for the Standardization of Methods for Determination of Viscosity Number and Limiting Viscosity Number of Polymers in Dilute Solution—Part 1: General Conditions⁶

ISO 1133 Plastics—Determination of the Melt Mass-Flow Rate (MFR) and the Melt Volume-Flow Rate (MVR) of Thermoplastics⁶

ISO 10993 Biological Evaluation of Medical Devices, Parts 1–12⁴

2.3 Other Documents:

FDA Regulation CFR 177.1580⁵

United States Pharmacopeia, Vol XXI, or latest edition⁶

3. Terminology

3.1 Definitions of Terms Specific to This Standard:

3.1.1 *fabricated forms, n*—those items into which the virgin forms may be converted. These forms include shapes and forms produced by means of machining, extruding, and compression molding virgin forms into a subsequent entity, for example, rods, slabs, sheets, film, complex shaped parts and devices.

3.1.2 *formulated compound, n*—PEKEKK materials, parts, or devices fabricated from virgin forms in such a way as to contain intentional or unintentional adjuvant substances.

3.1.3 *virgin forms, n*—that form of the PEKEKK resin as obtained by the synthesizer after removal of residual monomers, solvents, catalysts, and so forth. It typically will be in the form of pellets, chips, or blocks. It is the material from which rods, slabs, sheets, films, or specific parts and devices are fabricated.

4. Classification

4.1 PEKEKK resins in the scope of this specification are pure semicrystalline homopolymers consisting of phenylene rings connected by either (E) and carbonyl (or ketone, K) groups along the polymer chain (see Fig. 1). Their polymeric structures are defined by the repeating unit EKEKK.

4.2 Types of PEKEKK plastics, molding, and extrusion grades are described in Classification **D4000**.

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

⁵ Available from Food and Drug Administration (FDA), 5600 Fishers Ln., Rockville, MD 20857, <http://www.fda.gov>.

⁶ Available from U.S. Pharmacopeia (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852-1790, <http://www.usp.org>.

5. Properties

5.1 PEKEKK resins used in medical applications may comply with the Food and Drug Administration (FDA) Regulation 21 CFR 177.1580, which covers both wet and dry food contact applications.

5.2 The infrared spectrum (**1**)⁷ of these materials is characteristic of their molecular repeating units. A representative spectrum is provided in Fig. 2. The PEKEKK resin shall yield an infrared transmittance spectrum that exhibits major bands only at the wavelengths listed for a standard reference spectrum of that material.

5.2.1 The infrared spectrum, as used herein, is to identify the specific type of PAEK present and does not necessarily indicate an acceptable degree of material purity.

5.2.2 The presence of additional bands in the sample's infrared spectrum compared to that of the reference material may indicate a different PAEK, impurities, or both.

5.3 The physical and chemical property requirements for the virgin resin are listed in Table 1. If additional characteristics are necessary because of a specific application, the procedures referenced in 5.7 are recommended, or as agreed upon by vendor and purchaser.

5.4 The solution viscosity requirements listed in Table 1 may be supplemented, or replaced, by rheological or complex viscosity data as agreed upon by vendor and purchaser.

5.5 The chemical, physical, and mechanical properties of fabricated forms are related to the processes utilized in producing the fabricated form, for example, molding, machining, sterilization, and so forth. Additionally, the properties necessary for a particular device to perform properly will vary from one device type to another. Table 2 lists some typical properties of nonsterilized injection molded material.

5.6 Test specimens shall be fabricated (machined, injection molded, and so forth) from the virgin resin, or finished part, in such a way to effectively represent the material characteristics of the nonsterilized finished part.

5.7 Tests and test procedures shall be such as to assure a high level of control and characterization of the virgin resin as received from the supplier (see Test Methods **D149**, **D256**, **D570**, **D638**, **D648**, **D695**, **D696**, **D790**, **D792**, **D955**, **D1238**, **D1505**, **D3417**, **D3418**, and **D4000**).

6. Sampling

6.1 The material should be sampled in accordance with standard sampling procedures, such as those described in Practice **D1898**, or other sampling techniques unless otherwise agreed upon between consumer and supplier.

7. Biocompatibility

7.1 Biocompatibility of PEKEKK resins and implant devices made using these materials shall be determined in accordance with Practice **F748** or the **ISO 10993** series, unless otherwise agreed upon by packager and consumer, and regulating bodies (**2-5**).

⁷ The boldface numbers in parentheses refer to the list of references at the end of this standard.