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Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications[1]

This standard is issued under the fixed designation F2026; 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 polyetheretherketone (PEEK) polymer in virgin forms as supplied by a vendor (pellets, powder, fabricated forms, and so forth). It provides requirements and associated test methods for these thermoplastics when they are to be used in the manufacture 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 (molding, extrusion, machining, assembly, sterilization, and so forth) required for the production of a specific part or device. Therefore, properties of fabricated forms of this polymer should be evaluated using test methods which are appropriate to ensure safety and efficacy as agreed upon by the vendor, purchaser, and regulating bodies.~~

1.2 The properties included in this specification are those applicable for PEEK polymers only. Indicated properties are for fabricated forms. Materials or forms containing colorants, fillers, processing aids, or other additives, as well as polymer blends which contain PEEK, or reclaimed materials, are not covered by this specification.

1.3 This specification is designed to recommend physical, chemical, and biological test methods to establish a reasonable level of confidence concerning the performance of virgin PEEK polymers for use in medical implant devices. ~~The properties listed should be considered in selecting material(s) in accordance with the specific end-use requirements.~~

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

1.5 When evaluating material in accordance with this specification, hazardous materials, operations, and equipment may be involved. *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]

~~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~~

[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] 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.

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D1505 Test Method for Density of Plastics by the Density-Gradient Technique
D1898 Practice for Sampling of Plastics (Withdrawn 1998)[3]
~~D3417 Test Method for Enthalpies of Fusion and Crystallization of Polymers by Differential Scanning Calorimetry (DSC) (Withdrawn 2004)[3]~~
D3418 Test Method for Transition Temperatures and Enthalpies of Fusion and Crystallization of Polymers by 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:*[4]
ISO 178 Plastics—Determination of Flexural Properties
ISO 180 Plastics—Determination of Izod Impact Strength
ISO 527 Plastics—Determination of Tensile Properties—Part 1: General Principles
ISO 1183 Plastics—Methods for Determining the Density of Non-cellular Plastics—Part 2: Density Gradient Column Method
ISO 10993 Biological Evaluation of Medical Devices, Parts 1-12
ISO 13485 Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes

2.3 *Other Documents:*
United States Pharmacopeia, Vol. XXI, or latest edition[5]

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 include shapes and forms produced by means of machining, extruding, and compression molding virgin forms into a subsequent entity (for example, fibers, tubes, rods, slabs, sheets, film, or complex shaped parts and devices).

3.1.2 *formulated compound, n*—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~~ the initially delivered form of the polymer as ~~obtained by the synthesizer. It typically will be~~ synthesized from its monomers prior to any processing or fabrication into a medical device. The provided resin is typically in the form of ~~pellets or powder. It~~pellets, granules, or powder and is the material from which fibers, tubes, rods, slabs, sheets, films, or specific parts and devices are fabricated.

iTeh Standards
(https://standards.iteh.ai)
Document Preview
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4. Classification

4.1 The PEEK polymer in the scope of this specification is a pure semicrystalline homopolymer consisting of phenylene rings connected by ether (E) and carbonyl (or ketone, K) groups along the polymer chain (see Appendix X1). Its polymeric structure is defined by the repeating unit EEK.

4.2 Types of PEEK plastics, molding, and extrusion grades are described in Classification System D4000.

[3] The last approved version of this historical standard is referenced on www.astm.org.
[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 U.S. Pharmacopeia (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852-1790, http://www.usp.org.

TABLE 1 Required Properties of Virgin Resin

Parameter	Method	Requirement
Glass Transition Temperature, T_g (°C)	DSC,[A] 20°K/min, sealed sample, T_g taken on second reheat, D3418	125 - 165
Melt Temperature, T_m (°C)	DSC, 20°K/min, sealed sample, T_m taken as max point on reheat endotherm, D3418	320 - 360
Recrystallization Temperature T_c (°C)	DSC, 20°K/min, sealed sample, T_c taken as max point on cooling exotherm, D3418	260 - 320
~~Viscosity~~	~~As agreed per 5.3~~	~~As agreed per 5.3~~
Viscosity	As agreed per 5.4	As agreed per 5.4
~~Infrared Spectrum~~	~~As agreed per 5.1~~	~~As agreed per 5.1~~
Infrared Spectrum	As agreed per 5.2	As agreed per 5.2
Total heavy metals as lead, max, %	US Pharmacopeia, Test 231	<0.1

[A] Differential Scanning Calorimetry (DSC).