Designation: F2026 – 08

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, 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 these polymers should be evaluated using test methods which are appropriate to ensure safety and efficacy as agreed upon by the vendor, purchaser, and regulating bodies.

1.3 The properties included in this specification are those applicable for PEEK polymers only. Indicated properties are for injection molded forms. Fabricated forms, material 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.

1.4 This specification is designed to recommend physical, chemical, and biological test methods to establish a reasonable level of confidence concerning the performance of virgin 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.

1.5 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

D1505 Test Method for Density of Plastics by the Density-Gradient Technique

D1898 Practice for Sampling of Plastics[3]

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 Differential Scanning Calorimetry

D4000 Classification System for Specifying Plastic Materials

[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.

[3] Withdrawn.

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 Conditions[4]

ISO 1133 Plastics—Determination of the Melt Mass-Flow Rate (MFR) and the Melt Volume-Flow Rate (MVR) of Thermoplastics[4]

ISO 10993 Biological Evaluation of Medical Devices, Parts 1-12[4]

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*—the PEEK 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 PEEK polymer as obtained by the synthesizer. It typically will be in the form of pellets or powder. It is the material from which fibers, tubes, rods, slabs, sheets, films, or specific parts and devices are fabricated.

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.

[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
T_g, °C	DSC, 20°C/min, sealed sample, T_g taken on second reheat	125 - 165
T_m, °C	DSC, 20°C/min, sealed sample, T_m taken as max point on reheat exotherm	320 - 360
T_c, °C	DSC, 20°C/min, sealed sample, T_c taken as max point on cooling endotherm	260 - 320
Viscosity	Per 5.3 as agreed	As agreed per 5.1
Infrared Spectrum		
Total heavy metals as lead, max, %	US Pharmacopeia, Test 231	<0.1

5. Properties

5.1 The infrared spectrum[6] of these materials is characteristic of their molecular repeating units. A representative spectrum is listed in Appendix X3. The PEEK polymer shall yield an infrared spectrum, which exhibits major bands only at the wavelengths listed for a standard reference spectrum of that material.

5.1.1 The infrared spectrum, as used in this specification, is to identify the specific type of poly aryl ether ketone (PAEK) present and does not necessarily indicate an acceptable degree of material purity.

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

5.2 The physical and chemical property requirements for the virgin polymer are listed in Table 1. If additional characteristics are necessary because of a specific application, the procedures referenced in 5.6 are recommended, or as agreed upon between the vendor and the purchaser.

5.3 The viscosity requirements will vary depending upon the grade and test method. The method and requirements shall be agreed upon between the vendor and the purchaser.

5.4 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 non-sterilized fabricated forms.

5.5 Test specimens shall be fabricated (machined, injection molded, and so forth) from the virgin polymer, or finished part, in such a way as to effectively represent the material characteristics of the non-sterilized finished part.

5.6 Tests and test procedures shall be such as to ensure a high level of control and characterization of the virgin polymer as received from the supplier. The following are some test methods that may be appropriate: Test Method D149, Test Method D256, Test Method D570, Test Method D638, Test Method D648, Test Method D695, Test method D696, Test Methods D790, Test Methods D792, Test Method D955, Test Method D1238, Test Method D1505, Test Method D3417, Test Method D3418, and Classification System D4000.

6. Sampling

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

7. Biocompatibility

7.1 PEEK has been shown to produce a well-characterized level of biological response following long term clinical use.[7] The results of these studies and the clinical history indicate an

[6] Silverstein, R. M., Bassler, G. C., and Morrill, T. C., *Spectroscopic Identification of Organic Compounds*, 5th ed., John Wiley & Sons, New York, NY.

[7] Kurtz, S.M. and Devine, J.N., "PEEK Biomaterials in Trauma, Orthopedic, and Spinal Implants," *Biomaterials*, Vol 28, No. 32, 2007, pp. 4845-4869.