



Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications¹

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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 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:

- D 149 Test Method for Dielectric Breakdown Voltage and Dielectric Strength of Electrical Insulating Materials at Commercial Power Frequencies²
- D 256 Test Method for Determining the Izod Pendulum Impact Resistance of Plastics³
- D 570 Test Method for Water Absorption of Plastics³
- D 621 Test Methods for Deformation of Plastics Under Load⁴
- D 638 Test Method for Tensile Properties of Plastics³
- D 648 Test Method for Deflection Temperature of Plastics Under Flexural Load³
- D 695 Test Method for Compressive Properties of Rigid Plastics³
- D 696 Test Method for Coefficient of Linear Thermal Expansion of Plastics Between -30°C and 30°C with a Vitreous Silica Dilatometer³
- D 790 Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials³
- D 792 Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement³
- D 955 Test Method for Measuring Shrinkage from Mold Dimensions of Thermoplastics³
- D 1238 Test Method for Flow Rates of Thermoplastics by Extrusion Plastometer³
- D 1505 Test Method for Density of Plastics by the Density-Gradient Technique³
- D 1898 Practice for Sampling of Plastics⁵
- D 3417 Test Method for Enthalpies of Fusion and Crystallization of Polymers by Differential Scanning Calorimetry (DSC)⁶
- D 3418 Test Method for Transition Temperatures of Polymers by Differential Scanning Calorimetry⁶
- D 4000 Classification System for Specifying Plastic Materials⁶
- F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices⁷

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² *Annual Book of ASTM Standards*, Vol 10.01.

³ *Annual Book of ASTM Standards*, Vol 08.01.

⁴ Discontinued; see *1993 Annual Book of ASTM Standards*, Vol 08.01.

⁵ Discontinued; see *1997 Annual Book of ASTM Standards*, Vol 08.02.

⁶ *Annual Book of ASTM Standards*, Vol 08.02.

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

F 1579 Specification for Polyaryletherketone (PAEK) Polymers for Surgical Implant Applications⁸

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 Conditions⁹

ISO 1133 Plastics—Determination of the Melt Mass-Flow Rate (MFR) and the Melt Volume-Flow Rate (MVR) of Thermoplastics⁹

ISO 10993 Biological Evaluation of Medical Devices, Parts 1-12⁹

2.3 Other Documents:

United States Pharmacopeia, Vol. XXI, or latest edition¹⁰

Food and Drug Administration, Regulation 21 CFR 177.2415¹¹

3. Terminology

3.1 Definitions of Terms Specific to This Standard:

3.1.1 *fabricated forms*—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*—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*—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 D 4000.

5. Properties

5.1 The PEEK polymers used in medical applications may comply with the Food and Drug Administration (FDA) regulation 21 CFR 177.2415, which covers both wet and dry food contact applications.

5.2 The infrared spectrum¹² 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.

5.2.1 The infrared spectrum, as used in this specification, is to identify the specific type of poly aryl ether ketone (PAEK) present (see Specification F 1579) 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 or impurities, or both.

5.3 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 5.7 are recommended, or as agreed upon between the vendor and the purchaser.

5.4 The viscosity requirements will vary depending upon grade and test method. The method and requirements shall be agreed upon between the vendor and the 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 non-sterilized fabricated forms.

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

5.7 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 D 149, Test Method D 256, Test Method D 570, Test Method D 638, Test Method D 648, Test Method D 695, Test method D 696, Test Methods D 790, Test Methods D 792, Test Method D 955, Test Method D 1238, Test Method D 1505, Test Method D 3417, Test Method D 3418, and Classification System D 4000.

6. Sampling

6.1 The material should be sampled in accordance with the standard sampling procedures, such as those described in

⁸ Annual Book of ASTM Standards, Vol 13.01.

⁹ Available from American National Standards Institute, 25 W. 43rd St., 4th Floor, New York, NY 10036.

¹⁰ Available from U.S. Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852.

¹¹ Available from the Food and Drug Administration, 5600 Fisher Ln., Rockville, MD 20857.

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 5.4 as agreed	As agreed per 5.2
Infrared Spectrum		
Total heavy metals as lead, max, %	US Pharmacopeia, Test 231	<0.1

¹² Silverstein, R. M., Bassler, G. C., and Morrill, T. C., "Spectroscopic Identification of Organic Compounds," 5th ed., John Wiley & Sons, New York, NY.

TABLE 2 Typical Properties of Fabricated Forms

Parameter	ISO Methods and Requirements		ASTM Methods and Requirements	
Density, kg/m ³	ISO 1183	1280 - 1320	ASTM D 1505	1280 - 1320
Tensile Strength, min, MPa, Yield Break	ISO 527, Type 1B, 50 mm/min	90 70	ASTM D 638, Type IV, 5.08 cm/min	90 70
Percent elongation, min, %	ISO 527, Type 1B, 50 mm/min	5	ASTM D 638, Type IV, 5.08 cm/min	5
Flexural Strength, min, MPa	ISO 178	110	ASTM D 790	110
Flexural Modulus, min, GPa	ISO 178	3	ASTM D 790	3
Impact Strength, Notched Izod, min	ISO 180	4 (kJ/m ²)	ASTM D 256, 0.254 cm depth, 0.025 cm radius	50 (J/m)

Practice D 1898, or other sampling techniques unless otherwise agreed upon between the consumer and the supplier.

7. Biocompatibility

7.1 Biocompatibility of PEEK polymers and implant devices made using these materials shall be determined in accordance with Practice F 748 or the ISO 10993 series, unless

otherwise agreed upon between the packager and the consumer and regulating bodies.¹³

8. Keywords

8.1 PEEK; polyetheretherketone

¹³ Other useful references for testing biocompatibility of materials include:
 Autian, J., "Toxicological Evaluation of Biomaterials: Primary Acute Toxicity Screening Program," *Journal of Artificial Organs*, Vol 1, No. 1, 1977, p. 53.
 Autian, J., "The New Field of Plastic Toxicological Methods and Results," *CRC Critics Review in Toxicology*, 1973, p. 18.

Homsy, C. A., Ansevin, K. D., O'Brannon, W., Thompson, S. H., Hodge, R., and Estrella, M. E., "Rapid In Vitro Screening of Polymers for Biocompatibility," *Journal of Macromolecular Science Chemistry*, Vol A4, No. 3, May 1970, pp. 615-634.

Rice, R. M., Hegyeli, A. F., Gourlay, S. J., Wade, C. W. R., Dillon, J. G., Jaffe, H., and Kulkarni, R. K., "Biocompatibility Testing for Polymers: In Vitro Studies With In Vivo Correlation," *Journal of Biomedical Materials Research*, Vol 12, 1978, p. 43.

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

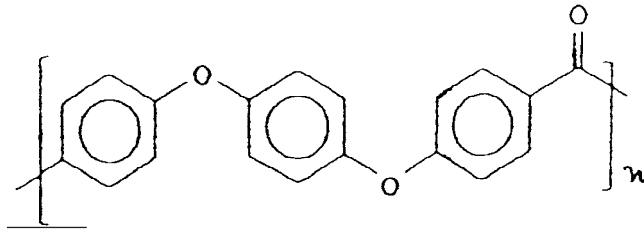
X1.1 The PEEK polymers may be processed by most techniques available for thermoplastic polymers. Medical devices and components of medical devices made of PEEK polymers may be sterilized. Sterilization methods successfully used include steam, ethylene oxide, and irradiation. Repeated sterilization may weaken parts fabricated of any plastic material. The number of times a given part may be sterilized safely without fear of subsequent failure depends on a number of factors including the molecular weight of the polymer and design, fabrication, intended function, and method of sterilization of the device. Therefore, it is imperative that the manufacturer test the device in order to determine the maximum number of sterilization cycles to which it can be safely subjected.

X1.2 The potential to develop a significant level of crys-

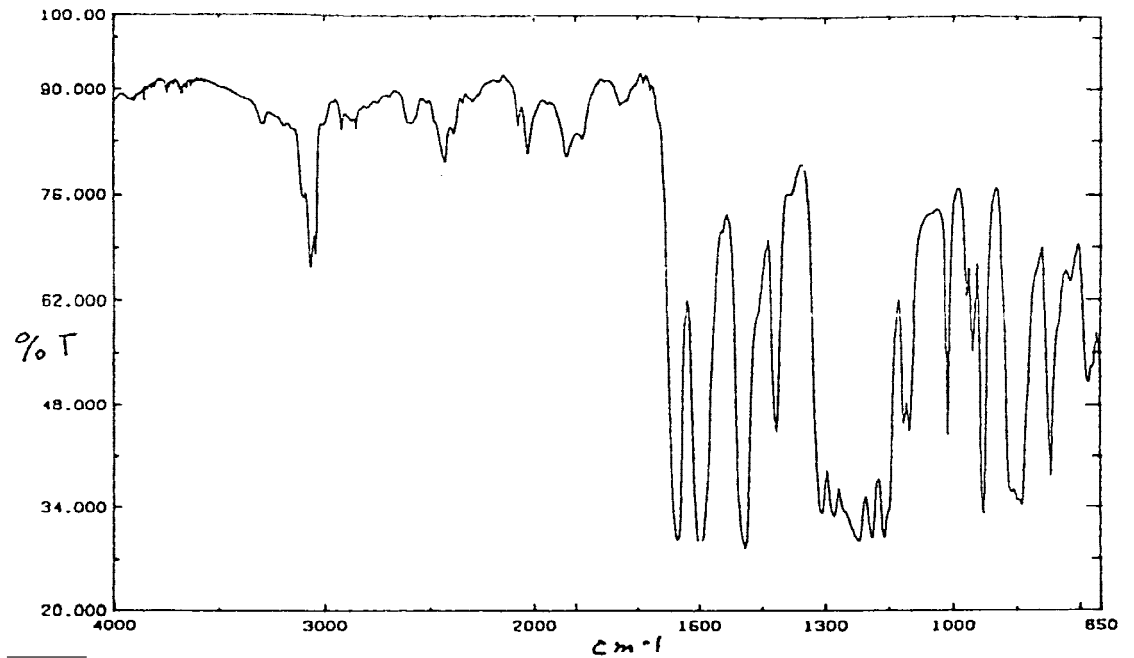
tallinity is an important characteristic of these materials. Performance characteristics are related to the percent crystallinity. Certain additives and processes (for example, excessive cross linking) can limit these materials' ability to crystallize. Therefore, this feature of the polymer and its fabricated form should be evaluated, using appropriate test methods, to ensure efficacy.

X1.3 A formulated compound or fabricated part or device may contain optional adjuvant substances required for the fabrication or intended use of the end product. The biocompatibility of these adjuvant substances, and subsequent formulated compounds, parts, and devices shall be established in accordance with Practice F 748 or the ISO 10993 series.

X2. CHEMICAL STRUCTURE OF PEEK



X3. REPRESENTATIVE INFRARED SPECTRA OF PEEK



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