



Designation: F 2026 – 00

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

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1. Scope

1.1 This specification covers polyetheretherketone (PEEK) resins in virgin forms as supplied by a vendor (flakes, pellets, blocks, and so forth). It provides requirements and associated test methods for these thermoplastics when they are to be used in the manufacture of intracorporal 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 resins 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 resins only. Fabricated forms, material or forms containing colorants, fillers, processing aids, or other additives, as well as polymer blends which contain PEEK, 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 resins for use in medical 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 Solid Electrical Insulating Materials

at Commercial Power Frequencies²

D 256 Test Method for Determining the Pendulum Impact Resistance of Notched Specimens 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 -30C and 30C³

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 Molded Plastics³

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 Thermal Analysis⁶

D 4000 Classification System for Specifying Plastic Materials⁶

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

2.2 ISO Standards:

ISO 1628/1 Plastics—Guidelines for the Standardization of Methods for Determination of Viscosity Number and

¹ This specification is under the jurisdiction of ASTM Committee F-4 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 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.