



Standard Specification for Polyetherketoneketone (PEKK) Polymers for Surgical Implant Applications¹

This standard is issued under the fixed designation F2820; 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 virgin polyetherketoneketone (PEKK) polymer resin as supplied by a vendor (for example, in pellets, powder, and fabricated forms). 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 (for example, molding, extrusion, machining, assembly, and sterilization) 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. With reduced crystallinity, certain polymers have been shown to be more susceptible to environmental stress cracking. Depending upon the implant application, the end user should characterize the material for environmental stress cracking resistance.

1.3 The properties included in this specification are those applicable for PEKK polymers only. Indicated properties are for fabricated forms. Fabricated forms and materials containing colorants, fillers, processing aids, or other additives, as well as polymer blends which contain PEKK, 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 PEKK 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 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.6 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 (Withdrawn 1998)³

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.

Current edition approved April 15, 2012. Published May 2012. DOI: 10.1520/F2820-12.

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