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Standard Specification for Polyetheretherketone (PEEK)~~Resins~~ Polymers for Surgical Implant Applications ¹

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1. Scope

1.1 This specification covers polyetheretherketone (PEEK)~~resins~~ polymer in virgin forms as supplied by a vendor (~~flakes, pellets, blocks, (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 ~~resins~~ 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~~resins~~ 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~~resins~~ 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 ~~Solid~~ Electrical Insulating Materials at Commercial Power Frequencies²

¹ This specification is under the jurisdiction of ASTM Committee F-4 F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.11 on Polymeric Materials.

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