



Designation: F3333 – 20

Standard Specification for Chopped Carbon Fiber Reinforced (CFR) Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications¹

This standard is issued under the fixed designation F3333; 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 chopped carbon-fiber reinforced (CFR) polyetheretherketone (PEEK) polymer in pellets, filaments used in additive manufacturing, or fabricated forms. It provides requirements and associated test methods for these thermoplastic composites 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 The properties included in this specification are those applicable for chopped CFR-PEEK compounds and fabricated forms only. Materials or forms containing colorants, fillers other than carbon fibers, processing aids, or other additives, as well as polymer blends which contain PEEK, or reclaimed materials, are not covered by this specification.

1.2.1 This standard does not include continuous carbon-fiber reinforced PEEK composites, which are fabricated using a different process than chopped CFR-PEEK.

1.2.2 This standard can include CFR-PEEK compounds that are fabricated with the use of coupling (sizing) agents. However, when coupling agents are used to improve wetting of the carbon fibers, the biological risk assessments and biocompatibility testing should consider these coupling agents.

1.3 This specification is designed to recommend physical, chemical, and biological test methods to establish a reasonable level of confidence concerning the performance of CFR-PEEK polymers for use in medical implant devices.

1.4 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.5 When evaluating material in accordance with this specification, hazardous materials, operations, and equipment may be involved.

1.6 *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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.

1.7 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*²

- D256 Test Methods for Determining the Izod Pendulum Impact Resistance 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
- 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
- D1505 Test Method for Density of Plastics by the Density-Gradient Technique
- D4000 Classification System for Specifying Plastic Materials
- E1994 Practice for Use of Process Oriented AOQL and LTPD Sampling Plans
- F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices
- F2026 Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications

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.

2.2 ISO Standards:³

- ISO 178 Plastics—Determination of Flexural Properties
- ISO 180 Plastics—Determination of Izod Impact Strength
- ISO 527 Plastics—Determination of Tensile Properties—
Part 1: General Principles
- ISO 1183-1 Plastics—Methods for Determining the Density
of Non-Cellular Plastics—Part 1: Immersion Method,
Liquid Pycnometer Method and Titration Method
- ISO 10993 Biological Evaluation of Medical Devices, Parts
1–12
- ISO 13485 Medical Devices—Quality Management
Systems—Requirements for Regulatory Purposes

3. Terminology

3.1 Definitions of Terms Specific to This Standard:

3.1.1 *compound, n*—material, part, or device fabricated from a virgin form in such a way as to contain intentional or unintentional adjuvant substances.

3.1.2 *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).

3.1.3 *virgin form, n*—the initially delivered form of the polymer as synthesized from its monomers prior to any processing or fabrication into a medical device. The provided resin is typically in the form of pellets, granules, or powder and is the material from which fibers, tubes, rods, slabs, sheets, films, or specific parts and devices are fabricated.

4. Classification

4.1 The CFR-PEEK polymer in the scope of this specification is combination of 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](#)), specified by Specification [F2026](#), and by chopped carbon fibers (see below). The structure of the PEEK polymer is defined by the repeating unit EEK.

4.2 The structure of the chopped carbon fiber is characterized by its route of manufacture (for example, polyacrylonitrile- (PAN-) or Pitch-based), as well as by the median length and diameter of the fibers. The use of sizing agents is permissible provided the resulting CFR-PEEK grade satisfies the biocompatibility requirements of the application (see [7.2](#)).

4.3 The structure of the CFR-PEEK compound is characterized by its volume fraction of fibers.

4.4 Types of PEEK plastics, molding, and extrusion grades are described in Classification [D4000](#).

5. Properties

5.1 The properties listed below shall be considered in selecting material(s) in accordance with the specific end-use requirements.

5.2 The infrared spectrum⁴ of the medical-grade PEEK polymer used in the manufacture of these materials is characteristic of their molecular repeating units. A representative spectrum is listed in Appendix X3 of Specification [F2026](#). The PEEK polymer, specified in Specification [F2026](#), shall yield an infrared spectrum which exhibits major bands only at the wavelengths listed for a standard reference spectrum of that material.

5.3 The physical and chemical property requirements for the virgin polymer are listed in Table 1 of Specification [F2026](#). If additional characteristics are necessary because of a specific application, the procedures referenced in Section 2 of Specification [F2026](#) are recommended, or as agreed upon between the vendor and the purchaser.

5.4 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.

5.5 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

⁴ Silverstein, R. M., Bassler, G. C., and Morrill, T. C., *Spectrometric Identification of Organic Compounds*, 5th Edition, John Wiley & Sons, New York, 1991.

³ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.

TABLE 1 Requirements for Injection-Molded CFR-PEEK Fabricated Forms

Property	Test Method	Requirement	
		Resin Type 1 ^B (PAN)	Resin Type 2 ^B (Pitch)
Density, kg/m ³	ASTM D792 or D1505 ; or ISO 1183	1380–1440	1360–1460
Tensile Strength at Break, 23 °C, MPa, min	ASTM D638 , Type 1, 5 mm/min or ISO 527, Type 1A, 5 mm/min	180	120
Elongation at Break, %, min ^A	ASTM D638 , Type 1, 5 mm/min or ISO 527, Type 1A, 5 mm/min	1.2	1.2
Flexural strength, min, MPa	ASTM D790 or ISO 178	280	180
Flexural modulus, min, GPa	ASTM D790 or ISO 178	16	8
Izod Impact Strength, Notched Izod, min	ISO 180, kJ/m ² (or ASTM D256 0.254 cm depth, 0.025 cm radius, J/m)	6 (59)	4 (^C)

^A Use an extensometer for measuring strain and calculating percent elongation.

^B The properties given in [Table 1](#) are for specific grades of CFR-PEEK having approximately 30 % by weight carbon fiber content.

^C Izod requirements for Type 2 material per Test Method [D256](#) in [Table 1](#) are not available (only the ISO 180 requirements apply).