



Standard Specification for Polysulfone Resin for Medical Applications¹

This standard is issued under the fixed designation F702; 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 polysulfone resin (poly(oxy-1,4-phenylenesulfonyl-1,4-phenylene (dimethylmethylene)-1,4-phenylene)) as defined in ISO 25137-1, supplied by a vendor in virgin form (pellets, powder, fabricated forms and so forth) for medical applications. This specification provides requirements and associated test methods for this thermoplastic when it is intended for use in manufacturing medical devices or components of medical devices.

1.2 As with any material, some characteristics may be altered by the processing techniques (such as molding, extrusion, machining, sterilization, and so forth) required for the production of a specific part or device. Therefore, properties of fabricated forms of this resin 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 standard allows for designation of polysulfone resin for all medical applications. The actual extent of performance and suitability for a specific application must be evaluated by the vendor, purchaser, and regulating bodies.

1.4 The properties included in this specification are those applicable for unfilled polysulfone (PSU) polymers with the addition of colorants and processing aids. Indicated properties are for injection molded forms. Forms containing fillers or other additives, as well as polymer blends which contain PSU, or reclaimed materials, are not covered by this specification.

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 concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appro-*

priate safety and health practices and determine the applicability of regulatory limitations prior to use.

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](#)

[D792 Test Methods for Density and Specific Gravity \(Relative Density\) of Plastics by Displacement](#)

[D6394 Specification for Sulfone Plastics \(SP\)](#)

[F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices](#)

2.2 ISO Standards:³

[ISO 10993 Biological Evaluation of Medical Devices](#)

[ISO 17025 General Requirements for the Competence of Testing and Calibration Laboratories](#)

[ISO 25137-1 Plastics—Sulfone Polymer Moulding and Extrusion Materials—Part I: Designation System and Basis for Specifications](#)

3. Significance and Use

3.1 This specification is designed to recommend test methods to establish a reasonable level of confidence concerning the performance of unfilled polysulfone resins for use in medical devices. The properties listed should be considered in selecting material according to specific end-use requirements.

3.2 Polysulfones may be evaluated in implantable medical devices as well as in non-implant medical applications. Polysulfone resins intended for use in implant applications are manufactured with more rigorous use of manufacturing and/or testing controls, to assure consistency of properties, cleanliness and biocompatibility. This is further elaborated in [4.1](#).

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.

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