Designation: F702 – 10

Standard Specification for Polysulfone Resin for Medical Applications[1]

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 appropriate 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.

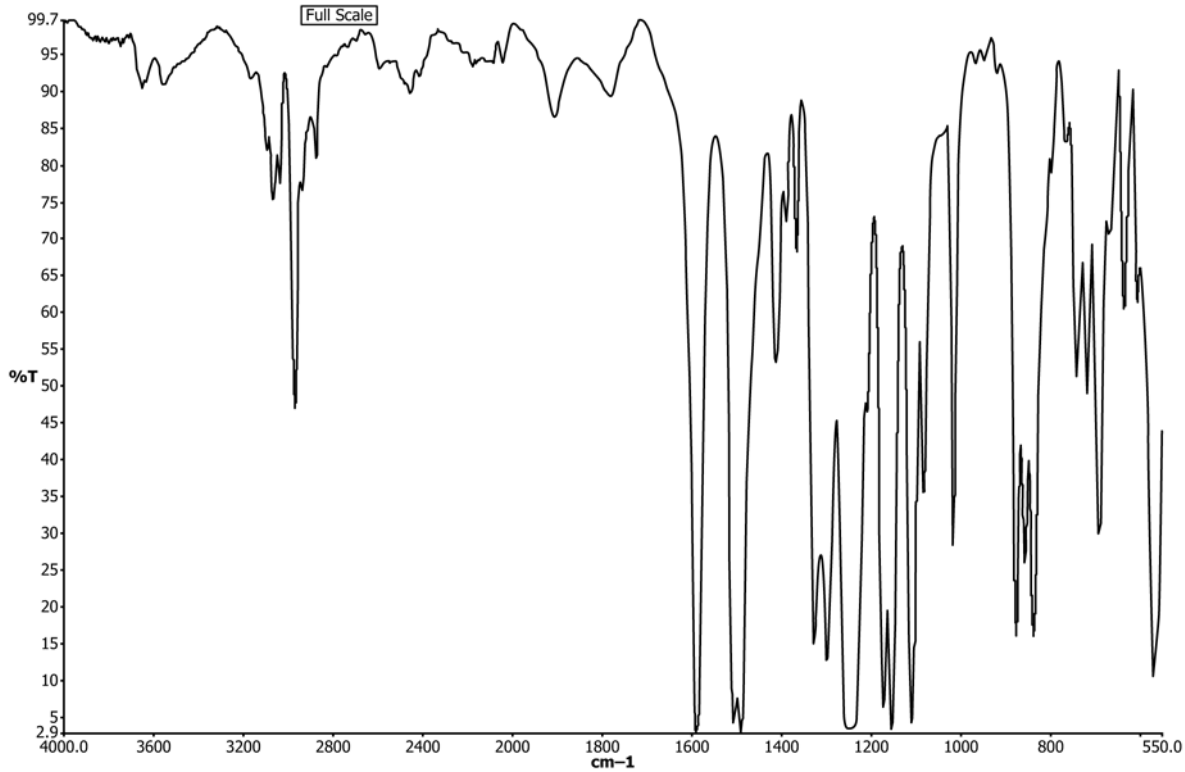


FIG. 1 Polysulfone Infrared Spectrum—Percent Transmittance

4. Classification

4.1 Polysulfone resin may be designated for either implant or non-implant medical applications. Designation of resins for implant applications implies that the resins are manufactured in compliance with relevant aspects of GMP (Good Manufacturing Practices), use of process validation, enhanced controls, testing in a laboratory accredited to ISO 17025, and compliance testing to ISO 10993:5 (cytotoxicity) and ISO 10993:18 (physiochemical testing).

NOTE 1—Implant uses are medical applications implanted in the human body and devices that are in contact with bodily fluids or tissues for greater than 24 h, that is, either prolonged or permanent exposure. Non-implant uses are medical applications in contact with bodily fluids or tissues for 24 h or less, that is, limited exposure.

4.2 Classes and grades of unfilled polysulfone plastics are described in Table SP, Group 1 of Specification D6394. For example, the material designation Specification D6394 SP0112 specifies a material from group 01 (polysulfone), class 1 (general purpose), and grade 2 (5 to 9 melt flow rate grade) with mechanical properties as specified in Table SP of Specification D6394.

5. Properties and Sampling

5.1 Specification D6394 defines a sulfone plastic as an aromatic polymer containing diphenyl sulfone in the backbone of the repeat unit, and polysulfones as a member of sulfone plastics. Specification D6394 and ISO 25137–1 describe the chemical structure for polysulfone resin. The chemical structure for polysulfone is further shown in Appendix X1, and includes benzene rings joined by diphenyl sulfone and ether linkages, and includes a isopropylidene (CH3CH3C) group.

5.2 The polysulfone resin shall yield an infrared transmittance spectrum which exhibits major transmittance bands only at the same wavelengths as appear on the attached reference spectrum (see Fig. 1). The infrared spectrum, as used in this specification, is to identify the polysulfone present and does not necessarily indicate an acceptable degree of material purity. The presence of additional bands in the IR spectrum of a sample may indicate a different sulfone polymer, such as polyether sulfone or polyphenylsulfone, or impurities, or both.

5.3 The properties listed in Table 1 are determined from specimens injection molded in accordance with the resin supplier's process recommendations and per Specification D6394. Additional or different treatments and processing steps (such as extrusion, molding, machining, sterilization, and so forth) may alter the material properties. Table 1 lists typical properties of non-sterilized fabricated forms.

5.4 Sampling shall be statistically adequate to satisfy the requirements of 7.3. The material shall be sampled with commonly accepted sampling procedures or other sampling techniques as agreed upon between the customer and the supplier.

6. Inspection

6.1 The resin shall be inspected for particulate foreign matter contamination using the following or equivalent procedure suitable only for transparent material. Specimen plaques 2.67 ± 0.25 mm thick shall be injection molded in accordance with the resin supplier's process recommendation. A sufficient number of plaques shall be made to provide 390 cm^2 of viewing surface, based on one side of the transparent plaques.

TABLE 1 Typical Mechanical Properties of Fabricated Forms

Property	ASTM Test Method	Typical Property Values[A]
Density, g/cm^3	D792	1.24
Izod impact at 22°C of 3.2 mm specimen, J/m of notch	D256	50
Tensile elongation at break, %	D638	50
Tensile modulus of elasticity, MPa	D638	2480
Tensile strength at yield, MPa	D638	70
Heat deflection temperature at 1820 kPa, unannealed, °C	D648	174

[A] Typical property values are tabulated here for reference. Specification limits may be indicated by reference and use of Specification D6394.

The plaques shall be examined visually under fluorescent light using a 2 to 3× magnifier to determine the number of any contaminant specks present. A total level of contamination greater than a count of 12 specks shall be cause for rejection of the material. It may not be possible to evaluate foreign matter contamination by this method for opaque materials.

6.2 More sophisticated methods and/or stricter criteria for evaluating contamination may be agreed to between the supplier and customer, especially for implant applications, including the use of tighter limits on the test procedure described in 6.1.

7. Certification

7.1 Material suitable for medical applications shall be certified to this specification. Additionally, certification shall be as indicated in the material Specification D6394, unless otherwise agreed upon by the supplier and customer.

7.2 Melt Flow Rate alone may be used as the validation property, being the single designated lot acceptance property per subsection 12.2 of Specification D6394. However, as stated in Specification D6394, a periodic check of other designated properties may also be agreed to between the purchaser and supplier, depending on the application. Agreement between the purchaser and supplier may also include testing of other designated properties for validation and certification, depending on the application.

NOTE 2—It is expected that testing for non-implant applications would be minimal and melt flow rate alone may be used for lot validation.

7.3 Certification shall be that the material was manufactured by a process in statistical control, sampled, tested, and inspected in accordance with this specification and that the average values for the lot meet the requirements of the specification.

NOTE 3—The ASTM publication, *Manual on Presentation of Data and Control Chart Analysis*,[4] provides detailed information about statistical process control.

[4] *Manual on Presentation of Data and Control Chart Analysis*, 7th Edition, Stock Number MNL7A, ASTM International.

8. Biocompatibility

8.1 Biocompatibility of PSU polymers and implant devices made using these materials shall be determined in accordance with Practice F748 or the ISO 10993 series, unless otherwise agreed upon between the supplier and the customer and regulating bodies. It is intended that biocompatibility be established on the finished product by the appropriate procedures, after it has gone through all processing steps including sterilization cycles, depending on the application.

8.2 Past applications have indicated that polysulfones are not suitable in load bearing implant applications in contact with biological fluids containing lipids or phospholipids, such as bone marrow, due to susceptibility to environmental stress-cracking and crazing. Asgian et al[5] document a study using bone marrow from the long bones of sheep. Examples of successful implant applications include pacemaker battery housings and infusion ports. Examples of non-implant applications include handles of surgical curettes and heart valve sizers.

8.3 Residual bis-phenol A (BPA) has been implicated as a potential health risk. At present, there is no consensus on the allowable amount of BPA in medical devices, but it is suggested that steps be taken to control and minimize it. For applications in which biocompatibility evaluation would not be appropriate or would not detect potentially harmful levels of BPA, the concentration of BPA should be determined by a valid analytical technique.

9. Keywords

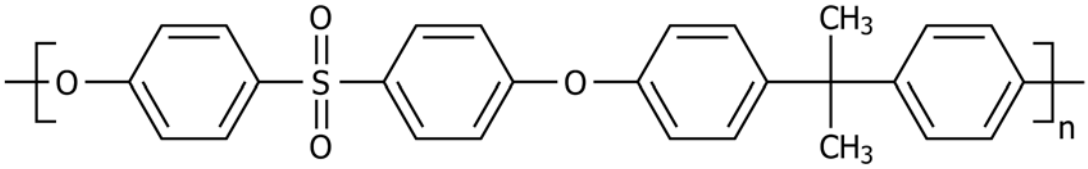
9.1 plastic surgical devices/applications; polymers—surgical applications; polysulfone resins ; unfilled polysulfone (PSU)

[5] Asgian, Gilbertson, Blessing, and Crowninshield, "Environmentally Induced Fracture of Polysulfones in Lipids," *Society for Biomaterials*, 15th Annual Meeting, 1989, pp. 17.

APPENDIXES

(Nonmandatory Information)

X1. CHEMICAL STRUCTURE OF POLYSULFONE



X2. RATIONALE

X2.1 This specification was established to provide guidance in the testing of polysulfone resin intended for use in medical device applications. It recommends test methods for the measurement of chemical, physical, and mechanical properties of unfilled resin. Tests should be selected according to end-use applications. It is intended that biocompatibility be established on the finished product by the appropriate procedures, after it has gone through all processing steps and after all adjuvant substances have been incorporated.

X2.2 Polysulfone resin may be processed by most techniques available for thermoplastic polymers. Medical devices and components of medical devices made of polysulfone may be repeatedly sterilized. Methods used successfully in past applications include steam, ethylene oxide, irradiation, and dry heat sterilization. Actual suitability must be determined by testing suitable for the application.

X2.3 Polysulfones offer practical toughness in a strong inherently transparent polymer, and are available in resin form for injection molding or extrusion, as well as stock shapes for machined components. Polysulfones are available both as transparent and opaque versions, as well as in colored versions.