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Standard Specification for Implantable Polytetrafluoroethylene (PTFE) Sheet, Tube, and Rod Shapes Fabricated from Granular Molding Powders[1]

This standard is issued under the fixed designation F754; 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.

This standard has been approved for use by agencies of the U.S. Department of Defense.

1. Scope

1.1 This specification describes the physical, chemical, and mechanical performance requirements for polytetrafluoroethylene (PTFE) pre-fabricated by compression molding or extrusion into sheet, tube, and rod shapes which may be used for implant products.

1.2 PTFE is a high molecular weight straight chain member of the generic class of perfluorocarbon (containing only the elements fluorine and carbon) polymers.

1.3 Perfluorocarbon high polymers exhibit extraordinary thermal and chemical stability and do not require stabilizing additives of any kind.

1.4 This specification applies to primarily void-free molded or extruded PTFE shapes formed from granular molding powders. This specification does not apply to shapes formed from "fine powder" resins by lubricated paste extrusion, which includes expanded PTFE.

1.5 This specification does not apply to specific surgical implant products, including their packaging, sterilization, or material boicompatibility and/or suitability for a particular end-use application.

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

1.7 *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]

D1710 Specification for Extruded Polytetrafluoroethylene (PTFE) Rod, Heavy Walled Tubing and Basic Shapes

D3294 Specification for Polytetrafluoroethylene (PTFE) Resin Molded Sheet and Molded Basic Shapes

D4894 Specification for Polytetrafluoroethylene (PTFE) Granular Molding and Ram Extrusion Materials

E1994 Practice for Use of Process Oriented AOQL and LTPD Sampling Plans

2.2 *AAMI Standards:*[3]

AAMI STBK9–1 Sterilization—Part 1: Sterilization in Health Care Facilities

AAMI STBK9–2 Sterilization—Part 2: Sterilization Equipment

AAMI STBK9–3 Sterilization—Part 3: Industrial Process Control

2.3 *ANSI Standards:*[4]

ANSI/ISO/ASQ Q9000 Quality Management Systems—Fundamentals and Vocabulary

ANSI/ISO/ASQ Q9001 Quality Management Systems—Requirements

2.4 *ISO Standards:*[4]

ISO 10993 Biological Evaluation of Medical Devices

[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 Association for the Advancement of Medical Instrumentation (AAMI), 1110 N. Glebe Rd., Suite 220, Arlington, VA 22201–4795.

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

2.5 *U. S. Code of Federal Regulations:*[5]
21 CFR 820 Quality System Regulation

2.6 *U. S. Pharmacopeia (USP) Standards:*[6]
USP30/NF25 <1211> Sterilization and Sterility Assurance of Compendial Articles

3. Significance and Use

3.1 Fabricated PTFE meeting the requirements of this specification can be expected to exhibit consistent and reproducible chemical, physical, and biological properties.

3.1.1 This specification provides an analytic method to extract organic contaminants from fabricated configurations, which includes a limit to the presence of residual adulterants, additives, or processing aids.

3.1.2 This specification addresses the characteristics of virgin raw granular molding powders obtained from resin manufacturers and used for producing implant configurations.

4. Physical Property Requirements

4.1 *Molding and Extrusion Powders:*

4.1.1 *PTFE Polymer*—Granular molding and extrusion powders used for fabrication of implant configurations shall be virgin product and shall conform to Specification D4894.

4.2 *PTFE Standard Shapes:*

4.2.1 Standard shapes, such as molded sheet, rod, and/or tube utilized in implants, shall have been prepared from virgin molding or extrusion materials which meet the provisions of 4.1.1.

4.2.2 PTFE molded sheet shall comply with Type I, Grade I, Class A requirements in Specification D3294.

4.2.3 PTFE rod and/or tube in the final implant shape shall comply with Type I, Grade I, Class D specifications in Specification D1710. Material purchased for conversion into a final implant shape may meet Classes A, B, C, or D.

4.2.4 The final implant manufacturer shall determine if the specified dimensions and mechanical properties of the supplier-provided and/or as-converted sheet, rod, and/or tube are appropriate for the intended implant application. Additional material property data (such as fatigue life, wear, and abrasion resistance) may also be necessary to assure suitability, dependent on the implant application.

4.3 *Surface Contamination*—The surface of a fabricated shape shall not contain particles or residue of a diameter greater than 300 µm. The concentration of visible particles under 8× magnification shall not be greater than 10 particles per 400 cm^2.

4.4 Physical properties for other than standard shapes are not encompassed by this specification and must be addressed by appropriate performance standards for given configurations.

5. Chemical Property Requirements

5.1 *Carbon Tetrachloride Extraction*—The supplier-provided or as-converted final PTFE implant shapes shall be sampled in accordance with Practice E1994 (or equivalent standard guidance) and extracted with carbon tetrachloride by the method described in Annex A1.

5.1.1 *Extractable Hydrocarbons*—The absence of extractable hydrocarbons shall be demonstrated by infrared analysis of the carbon tetrachloride extract using the methodology and acceptance criteria described in Annex A1.

5.1.2 *Appearance*—A sample shall be examined under daylight conditions with the naked eye immediately following carbon tetrachloride extraction as described in Annex A1. This sample while still wet with carbon tetrachloride shall not be apparently changed in size or consistency. When dried for 4 h in a 100°C air-circulating oven, the appearance of the extracted polymer sample shall be unchanged as compared to an unextracted specimen.

5.2 *Extraction with Distilled Water*—Final PTFE implant shapes sampled from stock shall be extracted with distilled water by the methodology described in Annex A2.

5.2.1 *Extractable Electrolytes*—The resistivity of the water as measured by a resistivity conductivity meter shall be greater than 0.05 MΩ·cm.

5.2.2 *Appearance*—When examined by unaided vision in daylight, the appearance of PTFE sampled from stock immediately following water extraction shall be unchanged except for being obviously wet with water. When dried for 4 h at 100°C in an air-circulating oven the appearance shall be unchanged from pre-extraction appearance.

6. Manufacturing Control, Sterilization, and Biocompatibility

6.1 Any final implant product needs to be manufactured under an acceptable level of control and provided both in sterile form and with a level of biocompatibility suitable for the final implant application.

6.2 Acceptable levels of manufacturing control are likely to be required for commercial distribution. General guidelines for achieving acceptable levels of manufacturing quality control may be found in the following standards:

6.2.1 United States Code of Federal Regulations (CFR), 21 CFR 820.

6.2.2 ANSI/ISO/ASQ Q9000—Provides fundamentals for quality management systems as described in the ISO 9000 family (informative); and specifies quality management terms and their definitions (normative).

6.2.3 ANSI/ISO/ASQ Q9001—Presents requirements for a quality management system. The application of this guide can be used by an organization to demonstrate its capability to meet customer requirements for products or services, and for assessment of that capability by internal and external parties.

6.3 A summary of most common sterilization methods, testing, and quality assurance can be found in USP30/NF25 <1211>. AAMI maintains a 3-volume set of sterilization standards and recommended practices containing 46 different standards: AAMI STBK9–1, AAMI STBK9–2, and AAMI STBK9–3.

[5] Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401, http://www.access.gpo.gov.

[6] Available from U.S. Pharmacopeia (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852-1790, or through http://www.usp.org/products/USPNF/. The standards will be listed by appropriate USP citation number. Succeeding USP editions alternately may be referenced.