Designation: F754 – 08 (Reapproved 2015)

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.

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

2.5 *U. S. Code of Federal Regulations:*[5]

21 CFR 820 Quality System Regulation

[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.

Current edition approved March 1, 2015. Published May 2015. Originally approved in 1983. Last previous edition approved in 2008 as F754 – 08. DOI: 10.1520/F0754-08R15.

[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.

[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.

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.

NOTE 1—Since many fluoropolymers can be readily damaged and/or altered by radiation-based sterilization, significant caution should be undertaken when considering such methods.

[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.

6.4 Finished device biocompatibility can be ascertained through evaluation utilizing the guidelines detailed within ISO 10993.

6.4.1 A brief summary of *in vivo* particulation concerns specific to mechanically loaded PTFE may be found in Appendix X2.

7. Keywords

7.1 perfluorocarbon; polytetrafluoroethylene; PTFE; surgical implant

ANNEXES

(Mandatory Information)

A1. INFRARED ANALYSIS OF HYDROCARBONS EXTRACTABLE IN CARBON TETRACHLORIDE

A1.1 Stir at least 1 g of chopped sample, all of which passes a No. 40 mesh screen, for 30 min with 7-mL of reagent-grade carbon tetrachloride. When decanted, the carbon tetrachloride shall be clear and colorless.

A1.2 Perform infrared analysis of the carbon tetrachloride after placement within a 10 by 10 mm silica quartz UV cuvette (for example, Beckman-Coulter Part No. 580012).

A1.2.1 The requirements of this analysis shall be satisfied when transmission between 3 and 4 μm is essentially 100 % for the reagent grade control and at least 95 % of that of the control scan for carbon tetrachloride in which the chopped sample was stored.

A2. EXTRACTION WITH WATER FOR ELECTROLYTES

A2.1 The specimens shall be cubes or rectangles with no edge dimension greater than 1 cm. The total specimen weight shall be 10 ± 1 g.

A2.2 Place the specimens in a suitable container, such as a 100-cm^3 suction flask, along with 50 mL of distilled water. Store the flask 48 h at ambient temperature.

A2.3 After 48 h, decant the water. The water shall remain clear and colorless. The extractable electrolyte requirements shall be satisfied when the resistivity of the water is greater than 0.05 MΩ·cm.

APPENDIXES

(Nonmandatory Information)

X1. STATEMENT OF RATIONALE

X1.1 This specification was established to provide guidance in the testing of polytetrafluorethylene intended for use in medical device applications. It recommends test methods for the measurement of chemical, physical and mechanical properties of unfabricated and fabricated forms. 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.

X1.2 The scope section of this document defines the term "PTFE" and limits the specific scope of the document to fabricated sheet, tube, and rod shapes. It further makes clear that the specification does not apply to specific surgical implant products that would be subject to appropriate specific end-use performance standards. This section emphasizes the extraordinary chemical and thermal stability and inherent absence of additives in PTFE; these factors are no doubt responsible for the large bibliography of successful implant use for this polymer in the absence of any previous implant grade specification guidance.

X1.3 The significance section sets out the capability of this standard by ensuring consistent and reproducible behavior. X2.1 explains the caution against construing this specification for applications where particulate debris may be anticipated.

X1.4 In 4.1, the specific raw polymer properties consistent with the scope and intent of this specification are defined in

terms of existing ASTM specifications so that the raw polymers will be virgin products providing the highest purity available under current manufacturing technology. Similarly, 4.2 relates the finished shape physical properties consistent with the scope and objectives of this standard specification to existing ASTM specifications for such standard shapes. These requirements would provide the superior properties for such shapes available with current fabrication technology.

X1.5 Section 5 provides appearance and extractable criteria for PTFE-fabricated shapes sampled from stock to establish the absence of extractable organic or electrolytic contaminants that may have contaminated the product during its preparation. A failure would then signal the need for review of the manufacturing process to determine the nature, source, and significance of the contamination.

X2. BIOCOMPATIBILITY

X2.1 PTFE configurations were first used for implantation in the early 1950s and, in numerous applications, have served as compatible implants in large numbers of patients, with some implant durations beyond 20 years (**1**, **2**, **3**).[7] However, use of PTFE in *in vivo* applications with load bearing outside of the pressure-velocity (PV) limits for the polymer may result in significant particulation and extensive adverse effects (**4**, **5**). A brief summary of adverse effects from the historical use of PTFE in the temporomandibular joint application can be found in the document entitled TMJ Implants—A Consumer Informational Update.[8]

X2.2 No known surgical implant material has ever been shown to be completely free of adverse reactions in the human body. However, long term clinical experience of use of specific compositions and formations of this material referred to in this standard has shown that an acceptable level of biological response can be expected, if the material is used in appropriate applications.

[7] The boldface numbers in parentheses refer to the list of references at the end of this specification.

[8] Available from Food and Drug Administration (FDA), Center for Devices and Radiologic Health, 5600 Fishers Ln., Rockville, MD 20857, http://www.fda.gov/cdrh/consumer/tmjupdate.pdf.

REFERENCES

(1) Homsy, C. A., "Biocompatibility of Perfluorinated Polymers and Composites of These Polymers," *Biocompatibility of Clinical Implant Materials*, O.F. Williams, ed., Chap. 3, Vol II, Boca Raton, FL, C.R.C. Press, Inc., 1982, pp 59 –77.

(2) Sanchez, L. A., Snuggs, W. D., Veith, F. J., Marin, M. L., Wengerter, K. R., Panetta, T. F., "Is Surveillance to Detect Failing Polytetrafluoroethylene Bypasses Worthwhile?: Twelve-year Experience with Ninety-One Grafts," *Journal of Vascular Surgery*, Vol 18, 1993, pp. 981–990.

(3) Prager, M., Polterauer, P., Böhmig, H-J., et al, "Collagen Versus Gelatin-coated Dacron Versus Stretch Polytetrafluoroethylene in Abdominal Aortic Bifurcation Graft Surgery: Results of a Seven-year Prospective, Randomized Multicenter Trial," *Surgery*, Vol 130, No. 3, 2001, pp. 408–414.

(4) Charnley, J., "Factors in the Design of an Artificial Hip Joint, Lubrication and Wear in Living and Artificial Human Joints," *Proceedings of the Institute of Mechanical Engineers* , Vol 181, 1966–1967, pp. 104–111.

(5) Swanson, S. A. V., and Freeman, M. A. R., *The Scientific Basis of Joint Replacement*, John Wiley and Sons, New York, N.Y. 1977, pp. 46–85.