Designation: F 754 – 00

Standard Specification for Implantable Polytetrafluoroethylene (PTFE) Polymer Fabricated in Sheet, Tube, and Rod Shapes [1]

This standard is issued under the fixed designation F 754; 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 performance of polytetrafluoroethylene (PTFE) fabricated in sheet, tube, and rod shapes which may be used for surgical implants. PTFE is a member of the generic class of perfluorocarbon (containing only the elements fluorine and carbon) polymers.

1.2 Perfluorocarbon high polymers are solids exhibiting extraordinary thermal and chemical stability. They do not require stabilizing additives of any kind.

1.3 The biological response to PTFE in soft tissue and bone has been well characterized by a history of clinical use and animal studies (**1-9**).[2]

1.4 This specification does not apply to specific surgical implants. Such implants would be subject to appropriate end-use performance standards.

1.5 *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:*

D 1457 Specification for PTFE Molding and Extrusion Materials[3]

D 1710 Specification for Polytetrafluoroethylene (PTFE) Basic Shapes, Rod, and Heavy–Walled Tubing[4]

D 1898 Practice for Sampling of Plastics[4]

D 3293 Specification for PTFE Resin Molded Sheet[5]

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices[6]

F 749 Practice for Evaluating Material Extracts by Intracutaneous Injection in the Rabbit[6]

F 750 Practice for Evaluating Material Extracts by Systemic Injection in the Mouse[6]

F 813 Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices[6]

F 895 Test Method for Agar Diffusion Cell Culture Screening for Cytotoxity[6]

F 981 Practice for Assessment of Compatibility of Biomaterials (Non-porous) for Surgical Implants with Respect to Effect of Materials on Muscle and Bone[6]

3. Significance and Use

3.1 Fabricated PTFE meeting the requirements of this specification will exhibit consistent and reproducible chemical, physical, and biological properties.

3.1.1 This specification ensures the absence of adulterants, additives, or processing aids.

3.1.2 This specification ensures the absence of extractable organic contaminants from fabricated configurations.

3.1.3 Fabricated configurations satisfying this specification should be compatible with tissue.

3.1.4 This specification addresses the characteristics of virgin raw molding powders obtained from resin manufacturers and used for producing implant configurations and of configurations packaged in either nonsterile or sterile states.

3.2 PTFE configurations were first used for implantation in the early 1950's and have served as compatible implants in large numbers of patients since that time with some implant durations beyond 20 years (**1**). Reports of reaction to particulate debris of PTFE in load bearing applications outside of the pressure-velocity (PV) limits for the polymer (**10, 11**) have not been correlated with other biocompatibility assays for this polymer and clinical experience with molding powders or intact implants of this polymer (**1, 12**). The shape and size of wear particles of this polymer and other implanted high polymers have been suggested as factors in elicited tissue

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

[3] *Annual Book of ASTM Standards*, Vol 08.01.

[4] *Annual Book of ASTM Standards*, Vol 08.02.

[5] *Annual Book of ASTM Standards*, Vol 08.03.

[6] *Annual Book of ASTM Standards*, Vol 13.01.

reaction (**1**, **11**, **13**). Therefore, care should be exercised not to construe this specification for applications where particulate debris may be anticipated.

4. Physical Property Requirements

4.1 *Molding and Extrusion Powders*:

4.1.1 *PTFE Polymer*— Molding and extrusion powders used for fabrication of implant configurations shall be virgin product which conform to Specification D 1457.

4.2 *PTFE Standard Shapes*:

4.2.1 Standard shapes such as molded sheet, rod, or tube shall have been prepared from virgin molding or extrusion materials which meet Specification D 1457.

4.2.2 PTFE molded sheet shall comply with Type I, Grade I, Class A requirements in Specification D 3293.

4.2.3 PTFE rod and tube shall comply with Type I, Grade I, Class D specifications in Specification D 1710. Material purchased for conversion into final implant shapes may meet Classes A, B, C, or D by vendor and vendee agreement.

4.3 *Surface Contamination*—The surface of a fabricated shape shall not contain particles of residue of 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*—PTFE sampled in accordance with Practice D 1898, from packaged-for-sale stock shall be 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 should be obtained from packaged-for-sale stock and 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*—PTFE sampled from packaged-for-sale 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. Biocompatibility

6.1 *Extractables Under Simulated and Accelerated In Vivo Exposure*—The polymer sampled from packaged-for-sale stock shall be tested under the general methodology and Practices F 749 and F 750 with specific conditions and criteria described in Annex A3.

6.2 *Acute Biocompatibility Requirements*—The polymer sampled from packaged-for-sale stock shall show no cytopathic effect when evaluated by a tissue culture test using direct contact of specimen with cell layer technique (**13**, **14**) or ASTM Practice F 813 and Test Method F 895.

6.3 *Chronic Biocompatibility Requirements*—Vendor and vendee agreement may utilize the large, long-term and benign animal and clinical history of this generic class of polymer as equivalent to Practice F 748 and Practice F 981 certification.

7. Sterility

7.1 Fabricated configurations of PTFE are thermally stable to indefinite exposure at 200°C. The fabricated polymer shall, after sterilization, pass the USP Sterility Test (**15**). Therefore, primary or repetitive sterilization by reliable steam autoclave technique is suggested. An alternative sterilization technique of using ethylene oxide may be adopted with due consideration for degassing rates for the particular specimen configuration. Sterilization by irradiation may cause molecular degradation of the polymer above certain radiation levels. Depending on the intended use of the implant, this molecular degradation could affect its mechanical and biocompatible properties.

8. Keywords

8.1 high polymer; polymer; polytetrafluoroethylene; PTFE; surgical implant