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Standard Specification for ~~Implantable Polytetrafluoroethylene (PTFE) Polymer Fabricated in Sheet, Tube, and Rod Shapes~~ Implantable Polytetrafluoroethylene (PTFE) Sheet, Tube, and Rod Shapes Fabricated from Granular Molding Powders[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).~~

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

~~1.5~~

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:* ~~*D1457Specification for PTFE Molding and Extrusion Materials*~~[2]

D 1710~~Specification for Polytetrafluoroethylene (PTFE) Basic Shapes, Rod, and Heavy-Walled Tubing~~

~~D1898Practice for Sampling of Plastics~~[4] Specification for Extruded Polytetrafluoroethylene (PTFE) Rod, Heavy Walled Tubing and Basic Shapes

~~[1] This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.16 on Biocompatibility.~~

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

[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.

D3293Specification for PTFE Resin Molded Sheet 3294 Specification for Polytetrafluoroethylene (PTFE) Resin Molded Sheet and Molded Basic Shapes
F748Practice for Selecting Generic Biological Test Methods for Materials and DevicesD 4894 Specification for Polytetrafluoroethylene (PTFE) Granular Molding and Ram Extrusion Materials
E 1994 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
2.6 *U. S. Pharmacopeia (USP) Standards:*[6] *F749Practice for Evaluating Material Extracts by Intracutaneous Injection in the Rabbit*[6]
F750Practice for Evaluating Material Extracts by Systemic Injection in the Mouse[6]
F813Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices[6]
F895Test Method for Agar Diffusion Cell Culture Screening for Cytotoxity[6]
F981Practice for Assessment of Compatibility of Biomaterials (Non-porous) for Surgical Implants with Respect to Effect of Materials on Muscle and Bone[6]
USP30/NF25 <1211> Sterilization and Sterility Assurance of Compendial Articles

3. Significance and Use

3.1Fabricated PTFE meeting the requirements of this specification will exhibit consistent and reproducible chemical, physical, and biological properties.
3.1.1This specification ensures the absence of adulterants, additives, or processing aids.
3.1.2This specification ensures the absence of extractable organic contaminants from fabricated configurations.
3.1.3Fabricated configurations satisfying this specification should be compatible with tissue.
3.1.4This 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.
3.2PTFE 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 reaction **(1, 11, 13)** . Therefore, care should be exercised not to construe this specification for applications where particulate debris may be anticipated.
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* :

[3] Annual Book of ASTM Standards, Vol 08.01.
[3] Available from Association for the Advancement of Medical Instrumentation (AAMI), 1110 N. Glebe Rd., Suite 220, Arlington, VA 22201–4795.
[4] Annual Book of ASTM Standards, Vol 08.02.
[4] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.
[5] Annual Book of ASTM Standards, Vol 08.03.
[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] Annual Book of ASTM Standards, Vol 13.01.
[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.