Designation: F3384 – 21

Standard Specification for Polydioxanone Polymer Resins for Surgical Implants[1]

This standard is issued under the fixed designation F3384; 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 virgin polydioxanone homopolymer resins intended for use in surgical implants.

1.2 Polydioxanone is commonly abbreviated as PDO, and is alternatively referred to as poly(para dioxanone) or poly(ρ-dioxanone) with the acronym PPD. Additionally, it may be referred to as PDS as it is the polymer of composition of PDS suture (Ethicon, Inc.), representing an early and widely used application of polydioxanone polymer.

1.3 This specification covers virgin polydioxanone resins able to be fully solvated at 30 °C by fluorinated solvents such as hexafluoroisopropanol (HFIP) or hexafluoroacetone (HFA).

1.4 Homopolymers of this composition are known to be semi-crystalline. Within this specification, semi-crystallinity within the resin is defined by the presence of a DSC (differential scanning calorimetry) crystalline endotherm peak upon annealing between 105 and 115 °C. While the presence of a crystalline endotherm indicates semi-crystallinity, the percentage and morphology of the crystalline phase are highly dependent on processing, and in particular on the thermal history of the material. Therefore, the thermal properties and percent crystallinity of the virgin polymer resin (with exception of melting temperature) are not necessarily indicative of final product quality.

1.5 This specification addresses material characteristics of the virgin polydioxanone-based resins intended for use in surgical implants and does not apply to packaged and sterilized finished implants fabricated from these materials, nor does it address the characteristics of polydioxanone resins with compounded materials such as dyes, polymeric or ceramic compounds, or any other additives.

1.6 As with any material, some characteristics may be altered by processing techniques (such as molding, extrusion, machining, assembly, 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 independently using appropriate test methods to ensure safety and efficacy.

1.7 Biocompatibility testing is not a requirement since this specification is not intended to cover fabricated devices. While biocompatibility testing of resin may provide an early indication of potential safety, biocompatibility analysis of the final finished device is required to determine safety and suitability for any implant device. Refer to Supplementary Requirement S1 of this standard and Guide F2902 for relevant biocompatibility information.

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

1.9 *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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.10 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D1505 Test Method for Density of Plastics by the Density-Gradient Technique

D2857 Practice for Dilute Solution Viscosity of Polymers

D3418 Test Method for Transition Temperatures and Enthalpies of Fusion and Crystallization of Polymers by Differential Scanning Calorimetry

D4603 Test Method for Determining Inherent Viscosity of Poly(Ethylene Terephthalate) (PET) by Glass Capillary Viscometer

D5296 Test Method for Molecular Weight Averages and

[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.

Molecular Weight Distribution of Polystyrene by High Performance Size-Exclusion Chromatography
E473 Terminology Relating to Thermal Analysis and Rheology
E793 Test Method for Enthalpies of Fusion and Crystallization by Differential Scanning Calorimetry
E794 Test Method for Melting And Crystallization Temperatures By Thermal Analysis
E967 Test Method for Temperature Calibration of Differential Scanning Calorimeters and Differential Thermal Analyzers
E968 Practice for Heat Flow Calibration of Differential Scanning Calorimeters
E1142 Terminology Relating to Thermophysical Properties
E1252 Practice for General Techniques for Obtaining Infrared Spectra for Qualitative Analysis
E1356 Test Method for Assignment of the Glass Transition Temperatures by Differential Scanning Calorimetry
E1994 Practice for Use of Process Oriented AOQL and LTPD Sampling Plans
E2977 Practice for Measuring and Reporting Performance of Fourier-Transform Nuclear Magnetic Resonance (FT-NMR) Spectrometers for Liquid Samples
F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices
F1925 Specification for Semi-Crystalline Poly(lactide) Polymer and Copolymer Resins for Surgical Implants
F2902 Guide for Assessment of Absorbable Polymeric Implants

2.2 *ANSI Standards:*[3]
ANSI/ISO/ASQ 9000:2015 Quality Management Systems—Fundamentals and Vocabulary
ANSI/ISO/ASQ 9001:2015 Quality Management Systems—Requirements
ANSI/ISO/ASQ 13485:2016 Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes

2.3 *Other Documents:*
ICH Q3C International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, Quality Guideline: Impurities: Guideline for Residual Solvents[4]
ICH Q3D International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, Quality Guideline: Guideline for Elemental Impurities[4]
ISO 10993-1 Biological Evaluation of Medical Devices[3]
ISO 11357 Plastics—Differential Scanning Calorimetry (DSC)[3]
ISO 80000-9 Quantities and Units—Part 9: Physical Chemistry and Molecular Physics[3]
21 CFR 820 United States Code of Federal Regulations, Title 21—Food and Drugs Services, Part 820—Quality System Regulation[5]
21 CFR 878.4840 Absorbable Polydioxanone Surgical (PDS) Suture[5]
21 CFR 74.3602 D&C Violet No. 2[5]
FDA Guidance Document Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process' – Guidance for Industry and Food and Drug Administration Staff[6]
USP United States Pharmacopeia, Edition 40[7]
USP <232> Elemental Impurities—Limits[7]
USP <233> Elemental Impurities—Procedures[7]
USP <788> Particulate Contamination[7]
NIST Special Publication SP811 Guide for the Use of the International System of Units (SI)[8]

3. Terminology

3.1 *Definitions:*

3.1.1 *virgin polymer, n*—the initially delivered form of a polymer as synthesized from its monomers and prior to any processing or fabrication into a medical device.

4. Materials and Manufacture

4.1 All raw monomer components and other materials contacting either the raw monomer(s) or resin product shall be of a quality suitable to allow use of such resin in the manufacture of an implantable medical product. Such quality includes adequate control of particles and other potential contaminants that may affect either the toxicity of or the cell response to the as-implanted or degrading final product.

4.2 All polymer manufacturing (including monomer handling, synthesis, pelletization/grinding, and all subsequent handling) shall be undertaken under conditions suitable to allow use of such resin in the manufacture of an implantable medical product.

4.3 Any additional additives, as agreed upon by the manufacturer and customer, shall be of a quality suitable to allow use in the manufacture of an implantable medical product. The presence, analysis, and reporting related to any additives is outside the scope of this standard specification.

4.4 Guidance related to the use of colorants (color additives) may be found through the US-FDA website: https://www.fda.gov/ForIndustry/ColorAdditives.

5. Chemical Composition

5.1 To ensure the attainment of the desired properties, the following tests shall be conducted with the requirements identified in Table 1.

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

[4] Available from ICH Seceretariat, c/o IFPMA, 30 rue de St-Jean, P.O. Box 758, 1211 Geneva 13, Switzerland. Available online at http://www.ich.org/LOB/media/MEDIA423.pdf.

[5] Available from U.S. Government Publishing Office (GPO), 732 N. Capitol St., NW, Washington, DC 20401, http://www.gpo.gov.

[6] Available from U.S. Food and Drug Administration (FDA), 10903 New Hampshire Ave., Silver Spring, MD 20993, http://www.fda.gov.

[7] Available from U.S. Pharmacopeial Convention (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852-1790, http://www.usp.org.

[8] Available from National Institute of Standards and Technology (NIST), 100 Bureau Dr., Stop 1070, Gaithersburg, MD 20899-1070, http://www.nist.gov.