
This standard is issued under the fixed designation F 2150; 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 guide is a resource of currently available test methods for the characterization of the compositional and structural aspects of biomaterial scaffolds used to develop and manufacture tissue-engineered medical products (TEMPs).

1.2 The test methods contained herein guide characterization of the bulk physical, chemical, mechanical, and surface properties of a scaffold construct. Such properties may be important for the success of a TEMP, especially if they affect cell retention, activity and organization, the delivery of bioactive agents, or the biocompatibility and bioactivity within the final product.

1.3 This guide may be used in the selection of appropriate test methods for the generation of an original equipment manufacture (OEM) specification. This guide also may be used to characterize the scaffold component of a finished medical product.

1.4 This guide is intended to be utilized in conjunction with appropriate characterization(s) and evaluation(s) of any raw or starting material(s) utilized in the fabrication of the scaffold, such as described in Guide F 2027.

1.5 This guide addresses natural, synthetic, or combination scaffold materials with or without bioactive agents or biological activity. This guide does not address the characterization or release profiles of any biomolecules, cells, drugs, or bioactive agents that are used in combination with the scaffold. A determination of the suitability of a particular starting material and/or finished scaffold structure to a specific cell type and/or tissue engineering application is essential, but will require additional in vitro and/or in vivo evaluations considered to be outside the scope of this guide.

1.6 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 requirements prior to use.

2. Referenced Documents

2.1 ASTM Standards:

D 412 Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension
D 570 Test Method for Water Absorption of Plastics
D 638 Test Method for Tensile Properties of Plastics
D 648 Test Method for Deflection Temperature of Plastics Under Flexural Load in the Edgewise Position
D 671 Test Method for Flexural Fatigue of Plastics by Constant-Amplitude-of-Force
D 695 Test Method for Compressive Properties of Rigid Plastics
D 747 Test Method for Apparent Bending Modulus of Plastics by Means of a Cantilever Beam
D 790 Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials
D 792 Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement
D 882 Test Method for Tensile Properties of Thin Plastic Sheeting
D 1042 Test Method for Linear Dimensional Changes of Plastics Under Accelerated Service Conditions
D 1238 Test Method for Melt Flow Rates of Thermoplastics by Extrusion Plastometer
D 1388 Test Method for Stiffness of Fabrics
D 1621 Test Method for Compressive Properties Of Rigid Cellular Plastics
D 1623 Test Method for Tensile and Tensile Adhesion Properties of Rigid Cellular Plastics
D 1708 Test Method for Tensile Properties of Plastics by Use of Microtensile Specimens
D 2857 Practice for Dilute Solution Viscosity of Polymers
D 2873 Test Method for Interior Porosity of Poly(Vinyl Chloride) (PVC) Resins by Mercury Intrusion Porosimetry

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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 Withdrawn.
D 2990 Test Methods for Tensile, Compressive, and Flexural Creep and Creep-Rupture of Plastics
D 3016 Practice for Use of Liquid Exclusion Chromatography Terms and Relationships
D 3039/D 3039M Test Method for Tensile Properties of Polymer Matrix Composite Materials
D 3417 Test Method for Enthalpies of Fusion and Crystallization of Polymers by Differential Scanning Calorimetry (DSC)3
D 3418 Test Method for Transition Temperatures and Enthalpies of Fusion and Crystallization of Polymers by Differential Scanning Calorimetry
D 4001 Test Method for Determination of Weight-Average Molecular Weight of Polymers By Light Scattering
D 4404 Test Method for Determination of Pore Volume and Pore Volume Distribution of Soil and Rock by Mercury Intrusion Porosimetry
D 4603 Test Method for Determining Inherent Viscosity of Poly(Ethylene Terephthalate) (PET) by Glass Capillary Viscometer
D 5226 Practice for Dissolving Polymer Materials
D 5296 Test Method for Molecular Weight Averages and Molecular Weight Distribution of Polystyrene by High Performance Size-Exclusion Chromatography
D 5732 Test Method for Stiffness of Nonwoven Fabrics Using the Cantilever Test
D 6125 Test Method for Bending Resistance of Paper and Paperboard (Gurley Type Tester)
D 6474 Test Method for Determining Molecular Weight Distribution and Molecular Weight Averages of Polyolefins by High Temperature Gel Permeation Chromatography
D 6539 Test Method for Measurement of Pneumatic Permeability of Partially Saturated Porous Materials by Flowing Air
D 6579 Practice for Molecular Weight Averages and Molecular Weight Distribution of Hydrocarbon and Terpene Resins by Size-Exclusion Chromatography
E 128 Test Method for Maximum Pore Diameter and Permeability of Rigid Porous Filters for Laboratory Use
E 177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods
E 456 Terminology Relating to Quality and Statistics
E 473 Terminology Relating to Thermal Analysis and Rheology
E 691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method
E 793 Test Method for Enthalpies of Fusion and Crystallization by Differential Scanning Calorimetry
E 794 Test Method for Melting And Crystallization Temperatures By Thermal Analysis
E 967 Test Method for Temperature Calibration of Differential Scanning Calorimeters and Differential Thermal Analyzers
E 968 Practice for Heat Flow Calibration of Differential Scanning Calorimeters
E 996 Practice for Reporting Data in Auger Electron Spectroscopy and X-ray Photoelectron Spectroscopy
E 1078 Guide for Specimen Preparation and Mounting in Surface Analysis
E 1142 Terminology Relating to Thermophysical Properties
E 1294 Test Method for Pore Size Characteristics of Membrane Filters Using Automated Liquid Porosimeter
E 1298 Guide for Determination of Purity, Impurities, and Contaminants in Biological Drug Products
E 1356 Test Method for Assignment of the Glass Transition Temperatures by Differential Scanning Calorimetry
E 1642 Practice for General Techniques of Gas Chromatography Infrared (GC/IR) Analysis
E 1829 Guide for Handling Specimens Prior to Surface Analysis
E 1994 Practice for Use of Process Oriented AOQL and LTPD Sampling Plans
F 151 Test Method for Residual Solvents in Flexible Barrier Materials3
F 316 Test Methods for Pore Size Characteristics of Membrane Filters by Bubble Point and Mean Flow Pore Test
F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices
F 1249 Test Method for Water Vapor Transmission Rate Through Plastic Film and Sheeting Using a Modulated Infrared Sensor
F 1251 Terminology Relating to Polymeric Biomaterials in Medical and Surgical Devices
F 1634 Practice for In-Vitro Environmental Conditioning of Polymer Matrix Composite Materials and Implant Devices
F 1635 Test Method for in vitro Degradation Testing of Hydrolytically Degradable Polymer Resins and Fabricated Forms for Surgical Implants
F 1884 Test Methods for Determining Residual Solvents in Packaging Materials
F 1890 Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
F 1983 Practice for Assessment of Compatibility of Absorbable/Resorbable Biomaterials for Implant Applications
F 2025 Practice for Gravimetric Measurement of Polymeric Components for Wear Assessment
F 2312 Terminology Relating to Tissue Engineered Medical Products
F 2450 Guide for Assessing Microstructure of Polymeric Scaffolds for Use in Tissue Engineered Medical Products
G 120 Practice for Determination of Soluble Residual Contamination by Soxhlet Extraction
2.2 AAMI Standards:4
AAMI STBK9-1 Sterilization—Part 1: Sterilization in Health Care Facilities

4 Available from the Association for the Advancement of Medical Instrumentation, 1110 N. Glebe Rd., Suite 220, Arlington, VA 22201-4795.
2.4 British Standards Institute:
EN 1244-1 British Standard—Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices—Part 1: Analysis and Management of Risk
EN 1244-2 British Standard—Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices—Part 2: Controls on Sourcing, Collection, and Handling
EN 1244-3 British Standard—Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices—Part 3: Validation of the Elimination and/or Inactivation of Viruses and Transmissible Agents

2.5 ISO Standards:
ISO 31-8 Physical Chemistry and Molecular Physics—Part 8: Quantities and Units
ISO 1133 Determination of the Melt-Mass Flow Rate (MFR) and the Melt Volume-Flow Rate (MVR) of Thermoplastics
ISO 10993-13 Biological Evaluation of Medical Devices—Part 13: Identification and Quantification of Degradation Products from Polymers
ISO 10993-14 Biological Evaluation of Medical Devices—Part 14: Identification and Quantification of Degradation Products from Ceramics
ISO 10993-15 Biological Evaluation of Medical Devices—Part 15: Identification and Quantification of Degradation Products from Coated and Uncoated Metals and Alloys
ISO 11357-1 Plastics—Differential Scanning Calorimetry (DSC)—Part 1: General Principles
ISO 11357-2 Plastics—Differential Scanning Calorimetry (DSC)—Part 2: Determination of Glass Transition Temperature

2.6 U.S. Code of Federal Regulations:
21 CFR Part 58 Title 21—Food And Drug Administration, Part 58—Good Laboratory Practice For Nonclinical Laboratory Studies
21 CFR Part 820 Title 21—Food and Drugs Services, Part 820—Quality System Regulation

2.7 U.S. Pharmacopeia (USP) Standards:
Source: General Tests and Assays—USP30/NF25, May 1, 2007
2.8 NIST Document:
NIST SP811 Special Publication SP811: Guide for the Use of the International System of Units (SI)

3. Terminology
3.1 Unless provided otherwise in 3.2, terminology shall be in conformance with Terminologies F 1251 and F 2312.
3.2 Definitions:
3.2.1 bioactive agents, n—an any molecular component in, on, or within the interstices of a device that elicits a desired tissue or cell response. Growth factors, antibiotics, and antimicrobials are typical examples of bioactive agents. Device structural components or degradation byproducts that evoke limited localized bioactivity are not included.
3.2.2 pores, n—an inherent or induced network of channels and open spaces within an otherwise solid structure.
3.2.3 porometry, n—the determination of the distribution of pore diameters relative to direction of fluid flow by the displacement of a wetting liquid as a function of pressure.
3.2.4 porosimetry, n—the determination of pore volume and pore size distribution through the use of a nonwetting liquid (typically mercury) intrusion into a porous material as a function of pressure.
3.2.5 porosity, n—property of a solid which contains an inherent or induced network of channels and open spaces. Porosity can be measured by the ratio of pore (void) volume to the apparent (total) volume of a porous material and is commonly expressed as a percentage.

4. Summary of Guide
4.1 The physicochemical and three-dimensional characteristics of the scaffold material are expected to influence the properties of TEMPs. It is the intent of this guide to provide a compendium of materials characterization techniques for properties that may be related directly to the functionality of scaffolds for TEMPs.

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7 Available from U.S. Pharmacopeia, 12601 Twinbrook Pkwy., Rockville, MD 20852, 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.
8 Available from National Institute of Standards and Technology (NIST), 100 Bureau Dr., Stop 1070, Gaithersburg, MD 20899-1070, http://www.nist.gov.