



Designation: F 2150 – 01

Standard Guide for Characterization and Testing of Biomaterial Scaffolds Used in Tissue-Engineered Medical Products¹

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 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 as guidance in the selection of appropriate test methods for the generation of a raw material or 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 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.

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 requirements prior to use.*

2. Referenced Documents

2.1 ASTM Standards:

- D 412 Test Methods for Vulcanized Rubber and Thermoplastic Rubbers and Thermoplastic Elastomers—Tension²
- D 570 Test Method for Water Absorption of Plastics³
- D 638 Test Method for Tensile Properties of Plastics³
- D 648 Test Method for Deflection Temperature of Plastics Under Flexural Load in the Edgewise Position³
- D 671 Test Method for Flexural Fatigue of Plastics by

Constant-Amplitude-of-Force³

- D 695 Test Method for Compressive Properties of Rigid Plastics³
- D 747 Test Method for Apparent Bending Modulus of Plastics by Means of a Cantilever Beam³
- D 790 Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials³
- D 792 Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement³
- D 882 Test Method for Tensile Properties of Thin Plastic Sheet³
- D 1042 Test Method for Linear Dimensional Changes of Plastics Under Accelerated Service Conditions³
- D 1238 Test Method for Flow Rates of Thermoplastics by Extrusion Plastometer³
- D 1388 Test Method for Stiffness of Fabrics⁴
- D 1621 Test Method for Compressive Properties of Rigid Cellular Plastics³
- D 1623 Test Method for Tensile and Tensile Adhesion Properties of Rigid Cellular Plastics³
- D 1708 Test Method for Tensile Properties of Plastics by Use of Microtensile Specimens³
- D 1898 Practice for Sampling of Plastics⁵
- D 2857 Practice for Dilute Solution Viscosity of Polymers⁶
- D 2873 Test Method for Interior Porosity of Poly(Vinyl Chloride) (PVC) Resins by Mercury Intrusion Porosimetry⁶
- D 2990 Test Methods for Tensile, Compressive, and Flexural Creep and Creep-Rupture of Plastics⁶
- D 3016 Practice for Use of Liquid Exclusion Chromatography Terms and Relationships⁶
- D 3039/D 3039M Test Method for Tensile Properties of Polymer Matrix Composite Materials⁷
- D 3417 Test Method for Enthalpies of Fusion and Crystallization of Polymers by Differential Scanning Calorimetry (DSC)⁶
- D 3418 Test Method for Transition Temperatures of Polymers by Differential Scanning Calorimetry⁶

¹ This guide is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.43 on Tissue-Engineered Medical Products.

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² *Annual Book of ASTM Standards*, Vol 09.01.

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

⁴ *Annual Book of ASTM Standards*, Vol 07.01.

⁵ Discontinued 1998; see 1997 *Annual Book of ASTM Standards*, Vol 08.01.

⁶ *Annual Book of ASTM Standards*, Vol 08.02.

⁷ *Annual Book of ASTM Standards*, Vol 15.03.