



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

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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 [F2027](#).

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 appro-*

priate safety and health practices and determine the applicability of regulatory requirements prior to use.

2. Referenced Documents

2.1 ASTM Standards:²

- [D412 Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension](#)
- [D570 Test Method for Water Absorption of Plastics](#)
- [D638 Test Method for Tensile Properties of Plastics](#)
- [D648 Test Method for Deflection Temperature of Plastics Under Flexural Load in the Edgewise Position](#)
- [D695 Test Method for Compressive Properties of Rigid Plastics](#)
- [D747 Test Method for Apparent Bending Modulus of Plastics by Means of a Cantilever Beam](#)
- [D790 Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials](#)
- [D792 Test Methods for Density and Specific Gravity \(Relative Density\) of Plastics by Displacement](#)
- [D882 Test Method for Tensile Properties of Thin Plastic Sheet](#)
- [D1042 Test Method for Linear Dimensional Changes of Plastics Caused by Exposure to Heat and Moisture](#)
- [D1238 Test Method for Melt Flow Rates of Thermoplastics by Extrusion Plastometer](#)
- [D1388 Test Method for Stiffness of Fabrics](#)
- [D1621 Test Method for Compressive Properties of Rigid Cellular Plastics](#)
- [D1623 Test Method for Tensile and Tensile Adhesion Properties of Rigid Cellular Plastics](#)
- [D1708 Test Method for Tensile Properties of Plastics by Use of Microtensile Specimens](#)
- [D2857 Practice for Dilute Solution Viscosity of Polymers](#)
- [D2990 Test Methods for Tensile, Compressive, and Flexural Creep and Creep-Rupture of Plastics](#)
- [D3016 Practice for Use of Liquid Exclusion Chromatography Terms and Relationships](#)

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 [F04.42](#) on Biomaterials and Biomolecules for TEMPs.

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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.