



Standard Guide for Characterization of Ceramic and Mineral Based Scaffolds used for Tissue-Engineered Medical Products (TEMPs) and as Device for Surgical Implant Applications¹

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1. Scope

1.1 This guidance document covers the chemical, physical, biological, and mechanical characterization requirements for biocompatible mineral- and ceramic-based scaffolds used solely as device or to manufacture tissue-engineered medical products (TEMPs). In this guide, the pure device or the TEMPs product will be referred to as scaffold.

1.2 The test methods contained herein provide guidance on the characterization of the bulk physical, chemical, mechanical, and surface properties of a scaffold construct. These properties may be important for the performance of the scaffold, especially if they affect cell behavior, adhesion, proliferation and differentiation. In addition, these properties may affect the delivery of bioactive agents, the biocompatibility and the bioactivity of the final product.

1.3 This document may be used as guidance in the selection of test methods for the comprehensive characterization of a raw materials, granules, pre-shaped blocks, or an original equipment manufacture (OEM) specification. This guide may also be used to characterize the scaffold component of a finished medical product.

1.4 While a variety of materials can be used to manufacture such scaffolds, the composition of the final scaffold shall contain mineral or ceramic components as its main ingredients.

1.5 This guide assumes that the scaffold is homogeneous in nature. Chemical or physical inhomogeneity or mechanical anisotropy of the scaffold shall be declared in the manufacturer's material and scaffold specification.

1.6 This guide addresses neither the biocompatibility of the scaffold, nor the characterization or release profiles of any biomolecules, cells, drugs, or bioactive agents that are used in combination with the scaffold.

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

1.8 *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:²

C373 Test Method for Water Absorption, Bulk Density, Apparent Porosity, and Apparent Specific Gravity of Fired Whiteware Products

C693 Test Method for Density of Glass by Buoyancy

C729 Test Method for Density of Glass by the Sink-Float Comparator

C830 Test Methods for Apparent Porosity, Liquid Absorption, Apparent Specific Gravity, and Bulk Density of Refractory Shapes by Vacuum Pressure

C1198 Test Method for Dynamic Young's Modulus, Shear Modulus, and Poisson's Ratio for Advanced Ceramics by Sonic Resonance

C1274 Test Method for Advanced Ceramic Specific Surface Area by Physical Adsorption

C1424 Test Method for Monotonic Compressive Strength of Advanced Ceramics at Ambient Temperature

D695 Test Method for Compressive Properties of Rigid Plastics

D1621 Test Method for Compressive Properties of Rigid Cellular Plastics

D4404 Test Method for Determination of Pore Volume and Pore Volume Distribution of Soil and Rock by Mercury Intrusion Porosimetry

D6226 Test Method for Open Cell Content of Rigid Cellular Plastics

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.