



Standard Guide for Assessing Microstructure of Polymeric Scaffolds for Use in Tissue-Engineered Medical Products¹

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1. Scope

1.1 This guide covers an overview of test methods that may be used to obtain information relating to the dimensions of pores, the pore size distribution, the degree of porosity, interconnectivity, and measures of permeability for porous materials used as polymeric scaffolds in the development and manufacture of tissue-engineered medical products (TEMPs). This information is key to optimizing the structure for a particular application, developing robust manufacturing routes, and providing reliable quality control data.

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

1.3 *This guide 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 to determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 ASTM Standards:²

[D2873 Test Method for Interior Porosity of Poly\(Vinyl Chloride\) \(PVC\) Resins by Mercury Intrusion Porosimetry](#) (Withdrawn 2003)³

[D4404 Test Method for Determination of Pore Volume and Pore Volume Distribution of Soil and Rock by Mercury Intrusion Porosimetry](#)

[E128 Test Method for Maximum Pore Diameter and Permeability of Rigid Porous Filters for Laboratory Use](#)

[E1294 Test Method for Pore Size Characteristics of Mem-](#)

[brane Filters Using Automated Liquid Porosimeter](#) (Withdrawn 2008)³

[E1441 Guide for Computed Tomography \(CT\) Imaging](#)

[F316 Test Methods for Pore Size Characteristics of Membrane Filters by Bubble Point and Mean Flow Pore Test](#)

[F2150 Guide for Characterization and Testing of Biomaterial Scaffolds Used in Tissue-Engineered Medical Products](#)

[F2603 Guide for Interpreting Images of Polymeric Tissue Scaffolds](#)

3. Terminology

3.1 Definitions:

3.1.1 *bioactive agent, n*—any molecular component in, on, or within the interstices of a device that is intended to elicit a desired tissue or cell response.

3.1.1.1 *Discussion*—Growth factors and antibiotics are typical examples of bioactive agents. Device structural components or degradation byproducts that evoke limited localized bioactivity are not bioactive agents.

3.1.2 *blind (end)-pore, n*—a pore that is in contact with an exposed internal or external surface through a single orifice smaller than the pore's depth.

3.1.3 *closed cell, n*—a void isolated within a solid, lacking any connectivity with an external surface. Synonym: *closed pore*

3.1.4 *hydrogel, n*—a water-based open network of polymer chains that are cross-linked either chemically or through crystalline junctions or by specific ionic interactions.

3.1.5 *macropore/macroporosity* (life sciences), *n*—a structure (including void spaces) sized to allow substantially unrestricted passage of chemicals, biomolecules, viruses, bacteria, and mammalian cells. In implants with interconnecting pores, macroporosity provides dimensions that allow for ready tissue penetration and microvascularization after implantation. Includes materials that contain voids with the potential to be observable to the naked eye ($>100\ \mu\text{m}$).

3.1.6 *micropore/microporosity* (life sciences), *n*—a structure (including void spaces) sized to allow substantially unrestricted passage of chemicals, biomolecules, and viruses while sized to control or moderate the passage of bacteria, mammalian cells, and/or tissue. Includes materials with typical pore

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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 The last approved version of this historical standard is referenced on www.astm.org.