



Standard Guide for Interpreting Images of Polymeric Tissue Scaffolds¹

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1. Scope

1.1 This guide covers the factors that need to be considered in obtaining and interpreting images of tissue scaffolds including technique selection, instrument resolution and image quality, quantification and sample preparation.

1.2 The information in this guide is intended to be applicable to porous polymer-based tissue scaffolds, including naturally derived materials such as collagen. However, some materials (both synthetic and natural) may require unique or varied sample preparation methods that are not specifically covered in this guide.

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

1.4 *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 to determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 ASTM Standards:²

E1919 Guide for Worldwide Published Standards Relating to Particle and Spray Characterization (Withdrawn 2014)³

E2245 Test Method for Residual Strain Measurements of Thin, Reflecting Films Using an Optical Interferometer

F1854 Test Method for Stereological Evaluation of Porous Coatings on Medical Implants

F1877 Practice for Characterization of Particles

F2150 Guide for Characterization and Testing of Biomaterial Scaffolds Used in Tissue-Engineered Medical Products

F2450 Guide for Assessing Microstructure of Polymeric Scaffolds for Use in Tissue-Engineered Medical Products

3. Terminology

3.1 Definitions:

3.1.1 *aliasing, n*—artificial data that originates from an insufficient sampling rate.

3.1.2 *biomaterial, n*—a natural or synthetic material that is suitable for introduction into living tissue especially as part of a medical device, such as an artificial heart valve or joint.

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

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

3.1.5 *feret diameter, n*—the mean value of the distance between pairs of parallel tangents to the periphery of a pore (adapted from Practice **F1877**).

3.1.6 *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.

3.1.7 *irregular, adj*—an irregular pore that cannot be described as round or spherical. A set of reference figures that define the nomenclature are given in **Appendix X2**. (Adapted from Practice **F1877**).

3.1.8 *Nyquist criterion*—a criterion that states that a signal must be sampled at a rate greater than or equal to twice its highest frequency component to avoid aliasing.

3.1.9 *permeability, n*—a measure of fluid, particle, or gas flow through an open pore structure.

3.1.10 *pixel, n*—two-dimensional picture element.

3.1.11 *polymer, n*—a long chain molecule composed of monomers.

3.1.11.1 *Discussion*—A polymer may be a natural or synthetic material.

3.1.11.2 *Discussion*—Examples of polymers include collagen and polycaprolactone.

3.1.12 *pore, n*—a liquid, fluid, or gas-filled externally connecting channel, void, or open space within an otherwise solid or gelatinous material (for example, textile meshes composed

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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.