



Standard Test Method for Stereological Evaluation of Porous Coatings on Medical Implants¹

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1. Scope

1.1 This test method covers stereological test methods for characterizing the coating thickness, void content, and mean intercept length of various porous coatings adhering to nonporous substrates.

1.2 A method to measure void content and intercept length at distinct levels (“Tissue Interface Gradients”) through the porous coating thickness is outlined in 9.4.

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 determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 ASTM Standards:²

E3 Guide for Preparation of Metallographic Specimens

E883 Guide for Reflected-Light Photomicrography

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *field*—the image of a portion of the working surface upon which measurements are performed.

3.1.2 *intercept*—the point on a measurement grid line projected on a field where the line crosses from solid to void or vice versa.

3.1.3 *measurement grid lines*—an evenly spaced grid of parallel lines all of the same length.

3.1.4 *porous coating*—coating on an implant deliberately applied to contain void regions with the intent of enhancing the fixation of the implant.

3.1.5 *substrate*—the solid material to which the porous coating is attached.

3.1.6 *substrate interface*—the region where the porous coating is attached to the substrate.

3.1.7 *tissue interface*—the surface of the coating that shall have first contact with biological tissue (i.e., the top of the coating).

3.1.8 *working surface*—the ground and polished face of the metallographic mount where the images of the fields are captured.

4. Summary of Test Method

4.1 *Mean Coating Thickness*—Evenly spaced parallel grid lines are oriented perpendicular to the coating-substrate interface on a field. For each gridline, the distance from the coating-substrate interface to the last contact with the porous coating material is measured as the coating thickness. The average of all of the coating thickness measurements obtained from all the measured fields is the mean coating thickness for that coating.

4.2 *Volume Percent Void*—A regular grid of points is superimposed on a field from the working surface. The percentage of points that are in contact with void areas in the coating is the volume percent of void present in that field.

4.3 *Mean Void Intercept Length*—Measurement grid lines are oriented parallel to the substrate interface in a field. The average length of the line segments overlaying the void space is the mean void intercept length for that field. This is a representative measure of the scale, or size, of the pores in a porous structure.

4.4 *Tissue Interface Gradients*—The Volume Percent Void and the Mean Void Intercept Length are characterized in three 200- μ m-thick zones below the Tissue Interface in each field.

5. Significance and Use

5.1 All these test methods are recommended for elementary quantification of the morphological properties of porous coatings bonded to solid substrates.

¹ This test method is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.15 on Material Test Methods.

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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.