



Standard Guide for Assessment of Surface Texture of Non-Porous Biomaterials in Two Dimensions¹

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1. Scope

1.1 This guide describes some of the more common methods that are available for measuring the topographical features of a surface and provides an overview of the parameters that are used to quantify them. Being able to reliably derive a set of parameters that describe the texture of biomaterial surfaces is a key aspect in the manufacture of safe and effective implantable medical devices that have the potential to trigger an adverse biological reaction in situ.

1.2 This guide is not intended to apply to porous structures with average pore dimensions in excess of approximately 50 nm (0.05 μm).

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

C813 Test Method for Hydrophobic Contamination on Glass by Contact Angle Measurement

F2312 Terminology Relating to Tissue Engineered Medical Products

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

F2664 Guide for Assessing the Attachment of Cells to Biomaterial Surfaces by Physical Methods

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.

2.2 Other Standards:³

ISO 3274 Geometrical Product Specifications (GPS)—Surface Texture: Profile Method—Nominal Characteristics of Contact (Stylus) Instruments

ISO 4287 Geometrical Product Specifications (GPS)—Surface Texture: Profile Method—Terms, Definitions and Surface Texture Parameters

ISO 4288 Geometrical Product Specifications (GPS)—Surface Texture: Profile Method—Rules and Procedures for the Assessment of Surface Texture

ISO 13565–1 Geometrical Product Specifications (GPS)—Surface Texture: Profile Method—Surfaces Having Stratified Functional Properties; Filtering and General Measurement Conditions

3. Terminology

3.1 Definitions of Terms Specific to This Standard:

3.1.1 *biomaterial*, *n*—any substance (other than a drug), synthetic or natural, that can be used as a system or part of a system that treats, augments, or replaces any tissue, organ, or function of the body. **F2664**

3.1.2 *evaluation length*, *ln*, *n*—length in the direction of the *x*-axis used to assess the profile under evaluation.

3.1.2.1 *Discussion*—The evaluation length may contain one or more sampling lengths. **ISO 4287**

3.1.3 *hydrophilic*, *adj*—having a strong affinity for water; wettable.

3.1.3.1 *Discussion*—Hydrophilic surfaces exhibit zero contact angles. **C813**

3.1.4 *hydrophobic*, *adj*—having little affinity for water; nonwetable.

3.1.4.1 *Discussion*—Hydrophobic surfaces exhibit contact angles appreciably greater than zero: generally greater than 45° for the advancing angle. **C813**

3.1.5 *implant*, *n*—a substance or object that is put in the body as a prosthesis, or for treatment or diagnosis. **F2664**

3.1.6 *lay*, *n*—the direction of the predominant surface pattern. **ISO 13565–1**

³ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.