



Designation: F2952 – 22

Standard Guide for Determining the Mean Darcy Permeability Coefficient for a Porous Tissue Scaffold¹

This standard is issued under the fixed designation F2952; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This guide describes test methods suitable for determining the mean Darcy permeability coefficient for a porous tissue scaffold, which is a measure of the rate at which a fluid, typically air or water, flows through it in response to an applied pressure gradient. This information can be used to optimize the structure of tissue scaffolds, to develop a consistent manufacturing process, and for quality assurance purposes.

1.2 The method is generally nondestructive and non-contaminating.

1.3 The method is not suitable for structures that are easily deformed or damaged. Some experimentation is usually required to assess the suitability of permeability testing for a particular material/structure and to optimize the experimental conditions.

1.4 Measures of permeability should not be considered as definitive metrics of the structure of porous tissue scaffolds and should complement measures obtained by other investigative techniques, for example, scanning electron microscopy, gas flow porometry, and micro-computer X-ray tomography (Guides F2450, F2603, and F3259).

1.5 *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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.6 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

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 TEMP.

Current edition approved April 1, 2022. Published April 2022. Originally approved in 2014. Last previous edition approved in 2014 as F2952 – 14. DOI: 10.1520/F2952-22.

2. Referenced Documents

2.1 ASTM Standards:²

- D737 Test Method for Air Permeability of Textile Fabrics
- D2434 Test Methods for Measurement of Hydraulic Conductivity of Coarse-Grained Soils
- F2450 Guide for Assessing Microstructure of Polymeric Scaffolds for Use in Tissue-Engineered Medical Products
- F2603 Guide for Interpreting Images of Polymeric Tissue Scaffolds
- F3259 Guide for Micro-computed Tomography of Tissue Engineered Scaffolds
- F3510 Guide for Characterizing Fiber-Based Constructs for Tissue-Engineered Medical Products

3. Terminology

3.1 Definitions of Terms Specific to This Standard:

3.1.1 *tortuosity, n* —the ratio of the actual path length through connected pores to the Euclidean distance (shortest linear distance).

4. Significance and Use

4.1 This document describes the basic principles that need to be followed to obtain a mean value of the Darcy permeability coefficient for structures that consist of a series of interconnected voids or pores. The coefficient is a measure of the permeability of the structure to fluid flowing through it that is driven by a pressure gradient created across it.

4.2 The technique is not sensitive to the presence of closed or blind-end pores (Fig. 1).

4.3 Values of the permeability coefficient can be used to compare the consistency of manufactured samples or to determine what the effect of changing one or more manufacturing settings has on permeability. They can also be used to assess the homogeneity and anisotropy of tissue scaffolds. Variability in the permeability coefficient can also be indicative of:

4.3.1 Internal damage within the sample, for example, cracking or permanent deformation.

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.

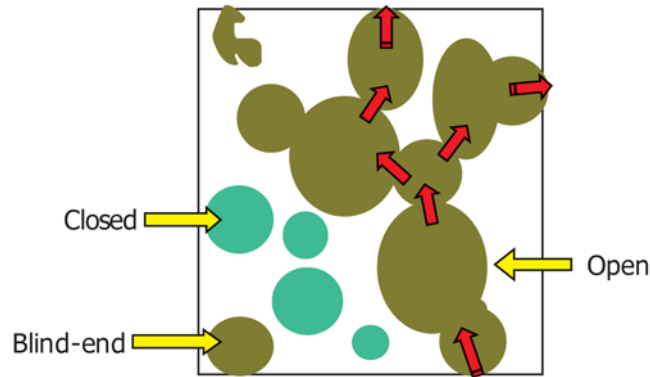


FIG. 1 Schematic of the Different Pores Types Found in Tissue Scaffolds. Fluid Flow Through the Structure is via the Open Pores

4.3.2 The presence of large voids, including trapped air bubbles, within the structure.

4.3.3 Surface effects such as a skin formed during manufacture.

4.3.4 Variable sample geometry.

4.4 This test method is based on the assumption that the flow rate through a given sample subjected to an applied pressure gradient is constant with time.

NOTE 1—If a steady-state flow condition isn't reached, then this could be due to structural damage (that is, crack formation or the porous structure deformed as a result of the force being placed upon it by the fluid flowing through it). Sample deformation in the form of stretching (bowing) can also occur for less resilient structures as a result of high fluid flow rates. This topic is discussed in more detail in Section 7.

4.5 Care should be taken to ensure that hydrophobic materials are fully wetted out when using water or other aqueous-based liquids as permeants.

4.6 Conventionally, the pressure differential created across a sample is measured as a function of both increasing and decreasing flow rates. An alternative approach, which may be practically easier to create, is to apply a range of different pressure differentials across the sample and measure the resultant flow of fluid through it. The hysteresis that occurs during a complete cycle of increasing flow rate followed by a progressive decrease in flow rate can provide an excellent measure of the behavioural consistency of the matrix. Significant hysteresis in the measured pressure differential during increasing and decreasing flow rates can indicate the existence of induced damage in the structure, the fact that the material is behaving viscoelastically, or is suffering from permanent plastic deformation. Some guidance on how to identify which of these factors is responsible for hysteresis is provided in Section 7.

4.7 It is assumed that Darcy's law is valid. This can be established by plotting the volume flow through the specimen against the differential pressure drop across the specimen. This plot should be linear for Darcy's law to apply and a least-squares fit to the data should pass through the origin. It is not uncommon for such plots to be nonlinear which may indicate that the structure does not obey Darcy's law or that the range of pressures applied is too broad. This topic is further discussed in Section 7.

5. Characterization and the Structural Features of Tissue Scaffolds

5.1 Porous tissue scaffolds are typically manufactured from polymers and ceramics and consist of a network of connected voids through which cells, macromolecules such as growth factors, and small molecules such as nutrients and dissolved gases can move (1).³ The material used to create the scaffold may disappear over time, either as a result of enzyme activity or some other degradation processes (for example, hydrolysis). The time-dependent permeability of tissue scaffolds to dissolved gases and solutes is critical to their function, particularly for high levels of cell occupancy due to the demands for oxygen and nutrients as well as the need to remove waste products.

5.2 There are many methods available for characterizing the structural features of scaffolds (Guides F2450 and F3510), but these can be time consuming, expensive to use, and can result in permanent damage or contamination to the scaffold.

5.3 Most investigators report some measure of pore size and an estimate of the scaffold porosity (2, 3). However, there are significant practical issues associated with these measurements. Techniques such as mercury porosimetry and gas flow porometry are used to estimate pore size distributions which typically differ by an order of magnitude due to differences in the underlying physics of the techniques (Guide F2450). Despite the shortfalls of these techniques, both can be used to infer a useful amount of information regarding the structure of the scaffold. Both porosimetry and porometry represent the scaffold structure as a distribution of differently sized parallel-sided pores, that is, the model assumes a simple structure that is equivalent to the more complicated structures usually manufactured where the pores are not parallel-sided and not of uniform diameter.

5.4 Electron and other microscopies are extensively used to image scaffolds, but the data that these techniques produce is often challenging to interpret without some undefinable level of uncertainty (that is, quantifying the dimensions of typically

³ The boldface numbers in parentheses refer to the list of references at the end of this standard.