



Standard Guide for Integrity Testing of Porous Barrier Medical Packages¹

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1. Scope

1.1 This guide covers general procedures for conducting controlled tests for determining the integrity of porous barrier medical packages. These procedures are intended to be a guide in determining overall package integrity and are not intended to be used by themselves in determining component material suitability. Material specifications should be written for each component, and a complete battery of tests should be performed to determine its suitability.

1.2 *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:

- D 903 Test Method for Peel or Stripping Strength of Adhesive Bonds²
- D 996 Terminology of Packaging and Distribution Environments³
- D 3078 Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission³
- D 4169 Practice for Performance Testing of Shipping Containers and Systems³
- D 4332 Practice for Conditioning Containers, Packages, or Package Components for Testing³
- E 122 Practice for Choice of Sample Size to Estimate a Measure of Quality for a Lot or Process⁴
- E 515 Test Method for Leaks Using Bubble Emission Techniques⁵
- E 1316 Terminology for Nondestructive Examinations⁵
- F 17 Terminology Relating to Flexible Barrier Materials³
- F 88 Test Method for Seal Strength of Flexible Barrier Materials³
- F 1140 Test Methods for Failure Resistance of Unrestrained and Nonrigid Packages for Medical Applications³

¹ This guide is under the jurisdiction of ASTM Committee F-2 on Flexible Barrier Materials and is the direct responsibility of Subcommittee F02.60 on Medical Packaging.

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² Annual Book of ASTM Standards, Vol 15.06.

³ Annual Book of ASTM Standards, Vol 15.09.

⁴ Annual Book of ASTM Standards, Vol 14.02.

⁵ Annual Book of ASTM Standards, Vol 03.03.

F 1327 Terminology Relating to Barrier Materials for Medical Packaging³

F 1608 Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method)³

F 1886 Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection³

F 1929 Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration³

F 1980 Guide for Accelerated Aging of Sterile Medical Device Packages³

3. Terminology

3.1 Definitions:

3.1.1 Applicable definitions and terminology may be found in Terminologies D 996, E 1316, F 17, and F 1327.

4. Significance and Use

4.1 Maintaining the integrity of a porous barrier medical package is critical to the delivery of a sterile product. This guide provides for the evaluation of the integrity of porous barrier medical packages, using established test methods. Damaged packages, substandard materials, inadequate seals, or a combination thereof, may cause a package to fail during manufacture, sterilization, distribution, storage, or use. When using the tests presented in this guide as part of a qualification test plan, process validation plan, or quality control program, some of the factors to consider are as follows:

4.1.1 *Porosity*—Porous barrier materials are designed to allow for the transmission of gases. Their porosity rates, consistency, uniformity, and the effect that coatings or labels have on their overall porosity can change the uniformity of performance characteristics and results.

4.1.2 *Leaks*—Small leaks may be hard to detect. The effects of the porous barrier material, the product, entrapped air, and the test parameters selected, may be significant and make the detection of small leaks very difficult.

4.1.3 *Physical Handlings*—The number and severity of physical handlings during manufacture, sterilization, and distribution.

4.1.4 *Sealing Process*—The parameters and tolerances such as temperature, dwell time, and pressure.

4.1.5 *Distribution Requirements*.

4.1.6 *Shelf Life Requirement*, utilizing real time or accelerated aging techniques.

4.1.7 *Maintenance of Package Integrity*—The requirements