



Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection¹

This standard is issued under the fixed designation F 1886; 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 test method covers the determination of channels in the package seal down to a width of 75 μm (0.003 in.) with a 60–100 % probability (see Section 8).

1.1.1 The ability to visually detect channel defects in package seals is highly dependent on the size of channel, the degree of contrast from sealed and unsealed areas, the amount and type of adhesive between the two package layers, reflecting light angle, types of material used, the use of magnification, and the inspector's level of training and experience.

1.2 This test method is applicable to flexible and rigid packages with at least one transparent side so that the seal area may be clearly viewed.

1.3 The values stated in SI units are to be regarded as the standard. The values given in parentheses are for information only.

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

F 17 Terminology Relating to Flexible Barrier Materials

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *channel, n*—any unimpaired pathway across the entire width of the intended seal.

3.1.2 *sterile package integrity, n*—property of the package seal and material, which ensures that it presents a microbial barrier. (see also Terminology F 17, *microbiological package integrity*).

4. Summary of Test Method

4.1 This test method provides a qualitative (accept/reject) visual inspection method to evaluate the appearance characteristics of unopened, intact seals in order to determine the presence of defects that may affect the integrity of the package.

5. Significance and Use

5.1 Seal attributes can be linked directly to a number of variables in process parameters, equipment, or material, as well as environmental (room temperature and relative humidity). Visual seal characteristics and defects can provide evidence of sterile package integrity and production sealing problems.

5.2 Visual seal defects often will be the first indication of heat sealing process variation. They also will indicate a lack of, or potential compromise to, package integrity after physical package performance testing.

6. Apparatus

6.1 *Illuminant*, lighting arrangements to give about 540 lumens/m² (50 fc) of white light or daylight on the specimens.

6.2 *Indelible Marking Pen*.

7. Procedure

7.1 Visual acuity shall be such that the inspection of the seal may be performed at a distance of 30 to 45 cm (12 to 18 in.)

NOTE 1—Magnification devices, such as eyeloops, may be used as an analytical tool to characterize identified seal defects.

7.2 Inspect the entire sealed area of the package for completeness and uniformity.

NOTE 2—Different package sizes and shapes may require differing lengths of time to adequately inspect the entire seal perimeter. Any time requirement associated with visual inspection should allow for complete seal inspection without taking too much time to intensely focus on any given area.

¹ This test method is under the jurisdiction of ASTM Committee F02 on Flexible Barrier Materials and is the direct responsibility of Subcommittee F02.60 on Medical Device Packaging.

Current edition approved June 1, 2004. Published June 2004. Originally approved in 1998. Last previous edition approved in 1998 as F 1886 – 98.

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.