Designation: F 1886 – 98

Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection[1]

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:*

F 17 Terminology Relating to Flexible Barrier Materials[2]

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/m^2(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.

NOTE 3—Some packaging materials and adhesives may fluoresce under ultraviolet light. Viewing the seal area in a UV light box will enhance the sealed-to-unsealed area contrast, and provide for easier defect identification.

7.3 Identify and record any part of the seal where channels appear across the entire seal width. Mark the location of the channels.

NOTE 4—All other assessed defects (refer to Appendix X1) should be categorized according to user defined accept/reject criteria. Define the actions to be taken in the event defects are detected during normal production runs.

[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 Packaging.

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[2] *Annual Book of ASTM Standards,* Vol 15.09.

7.4 Record the number and location of channels identified on each package.

NOTE 5—If confirmation of channels or incomplete seal areas in peelable packages is necessary, hand peel such suspected package completely separating the two material components and inspect the seal area of the transferred adhesive for the same incomplete seal attributes as the unopened package. Care should be taken to ensure a smooth continuous peeling motion so as not to cause any extraneous attributes. Heat seals should be cooled to ambient conditions before peeling open to allow for adhesive bonding to the opposite substrate to occur.

In some instances, a channel or unsealed area may be observed only after the package is peeled open. Adhesive transfer is a qualitative measure of a material's ability to release the coating rather than conclusive evidence that the seal has not bee made. It is possible to have continuous seal integrity but fail to give complete transfer. This is because the coating may have a stronger affinity for the substrate on which it is coated rather than the one to which it is sealed. In such cases, an additional physical seal integrity test may be required to confirm if it is an unsealed area.

8. Precision and Bias [3]

8.1 An round robin study was conducted in 1997, which included ten laboratories, four package types, and two different channel sizes randomly produced with 75 µm (0.003 in.) and 125 µm (0.005 in.) diameter wire. The negative control consists of the same type packages produced with no channels. The four different types of medical device packages are:

8.1.1 Open pouch (5 by 7 in.)—clear film/coated paper;

8.1.2 Open pouch (5¼ by 7½ in.)—clear film/uncoated TYVEK[4];

8.1.3 Sealed rigid blister (8½ by 5¼ in.)—blue tinted blister/coated TYVEK; and,

8.1.4 Open end pouch (6 by 8½ in.)—clear film/clear film (clear seal).

8.2 The results of this study are pass or fail; therefore, the data is binomial with an expected average of *np* and an expected variance of *npg* where *n* is the number of samples, *p* is the probability of an incorrect evaluation, and *q* is the probability of a correct evaluation. A statistical analysis of the data by means of a contingency table show significant differences between all factors presented in the tables at a confidence level of better than 99 %. The results are presented in Tables 1-4.

TABLE 1 Percent Incorrect by Laboratory

Lab	Samples Inspected	Incorrect Analysis	Percent (%) Incorrect
1	117	0	0.00
2	117	24	20.51
3	117	5	4.27
4	117	17	14.53
5	117	5	4.27
6	117	12	10.26
7	117	9	7.69
8	117	18	15.38
9	117	26	22.22
10	117	10	8.55

TABLE 2 Percent Incorrect by Material

Material	Samples Inspected	Incorrect Analysis	Percent (%) Incorrect
Film paper	300	14	4.67
Film TYVEK	300	38	12.67
PETG/TYVEK	290	59	20.34
Film/film	280	15	5.36

TABLE 3 Percent Incorrect by Defect Type

Defect Type	Samples Inspected	Incorrect Analysis	Percent (%) Incorrect
No channels	370	20	5.41
75 µm channel	400	83	20.75
125 µm channel	400	23	5.75

TABLE 4 Percent Correct by Material and Defect Type

Material	Defect Type	Samples Inspected	Correct Analysis	Percent (%) Correct
Film/paper	none	100	97	97
	75 µm	100	89	89
	125 µm	100	100	100
Film/TYVEK	none	100	97	97
	75 µm	100	69	69
	125 µm	100	96	96
PETG/TYVEK	none	90	88	98
	75 µm	100	60	60
	125 µM	100	83	83
Film/film	none	80	68	85
	75 µm	100	99	99
	125 µm	100	98	98

9. Keywords

9.1 channels; medical packaging; minimum seal width; spotty seals; sterile package integrity; visual seal inspection

[3] A research report is available from ASTM headquarters. Request RR:F02–1013.

[4] TYVEK is a trademark of Dupont, Wilmington DE.