



Designation: F2559/F2559M – 21

Standard Guide for Writing a Specification for Sterilizable Peel Pouches¹

This standard is issued under the fixed designation F2559/F2559M; 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 defines the requirements and considerations for flexible peel pouches with one open, unsealed end that are intended to be sterilized containing medical devices. These are also known as preformed sterile barrier systems.

1.2 Pouch styles are categorized as chevron, header, and corner peel. These pouches are typically manufactured by heat sealing, or in some cases, by cohesive cold sealing. The sealing bond is intended to be peeled open to aseptically dispense the contents.

1.3 Pouch materials may be either porous, nonporous, or any combination of the two.

1.4 This guide addresses some critical printing requirements on the pouch.

1.5 The values stated in either SI units or inch-pound units are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values from the two systems may result in non-conformance with the standard.

1.6 *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.*

1.7 *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 F02 on Primary Barrier Packaging and is the direct responsibility of Subcommittee F02.50 on Package Design and Development.

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2. Referenced Documents

2.1 ASTM Standards:²

E122 Practice for Calculating Sample Size to Estimate, With Specified Precision, the Average for a Characteristic of a Lot or Process

F17 Terminology Relating to Primary Barrier Packaging

F88 Test Method for Seal Strength of Flexible Barrier Materials

F1140 Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages

F1886 Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

F2054 Test Method for Burst Testing of Flexible Package Seals Using Internal Air Pressurization Within Restraining Plates

F2097 Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products

F2203 Test Method for Linear Measurement Using Precision Steel Rule

F2250 Practice for Evaluation of Chemical Resistance of Printed Inks and Coatings on Flexible Packaging Materials

F2475 Guide for Biocompatibility Evaluation of Medical Device Packaging Materials

2.2 TAPPI Standards:³

T213 Dirt in Pulp – Chart Method

T437 Dirt in Paper and Paperboard

T564 Transparent Chart for the Estimation of Defect Size

2.3 ISO Standards:⁴

ISO 11607-1 Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems, and packaging systems

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.

³ Available from Technical Association of the Pulp and Paper Industry (TAPPI), 15 Technology Parkway South, Norcross, GA 30092, <http://www.tappi.org>.

⁴ Available from International Organization for Standardization (ISO), ISO Central Secretariat, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, <https://www.iso.org>.

ISO 11607-2 Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing, and assembly processes

3. Terminology

3.1 *Definitions*—For definitions and terms used in this guide, see Terminology F17.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *pouch, n*—a flexible package constructed of one or more materials sealed together to form a preformed sterile barrier system. When purchased, one end or side is open to allow for product loading and final sealing.

3.2.2 *specification, n*—an explicit set of requirements to be satisfied by a material, product, system, or service. Examples of specifications include, but are not limited to, requirements for; physical, mechanical, or chemical properties, and safety, quality, or performance criteria. A specification identifies the test methods for determining whether each of the requirements is satisfied.⁵

4. Summary

4.1 This guide provides guidance for writing a peel pouch material specification. Materials, method of manufacture, physical properties, performance requirements, dimensioning, appearance, and printing are all issues that need to be addressed in a peel pouch specification. Appropriate requirements and test methods are suggested for preparing a specification.

5. Significance and Use

5.1 Medical device peel pouches are universally used by the industry and produced by a myriad of suppliers. They may be constructed of many different materials including films, foils, paper, nonwovens such as Tyvek, and combinations thereof. However, even with the diversity of materials, there are still basic requirements that all pouches should exhibit. Above all, the pouches must contain and protect the device while maintaining sterility during all physical handling.

5.2 Pouch requirements may be divided into two categories, initial pouch and material qualification, and routine production and receipt requirements to ensure the purchaser receives exactly what is ordered. While all requirements should be included in the written specification, initial qualification tests may only be needed prior to the first order. Routine production and receipt requirements should be adhered to on every order. Initial qualification requirements are indicated within each clause, where applicable.

5.3 This guide provides an understanding of the requirements needed for the manufacture, purchase, and acceptance of a preformed peelable pouch. Appropriate test methods for compliance are also cited.

NOTE 1—All test methods for a particular requirement may not be cited due to specific or unique circumstances. For additional guidance on applicable methods, refer to Guide F2097.

5.4 The specification and its requirements should be mutually agreed to by the supplier and purchaser of pouches. This helps ensure that pouches will comply to specified requirements.

5.5 Standards such as ISO 11607-1 and ISO 11607-2 have established criteria for consideration in material testing and for validation. This guide supports the expectations of appropriate materials and package testing occurring within a system of validations supporting demonstration of compliance to ISO 11607-1 and ISO 11607-2.

6. Specification

6.1 *Classification:*

6.1.1 *Style:*

- 6.1.1.1 Chevron pouch (see Fig. 1),
- 6.1.1.2 Corner peel pouch (see Fig. 2), and
- 6.1.1.3 Header bag (see Fig. 3).

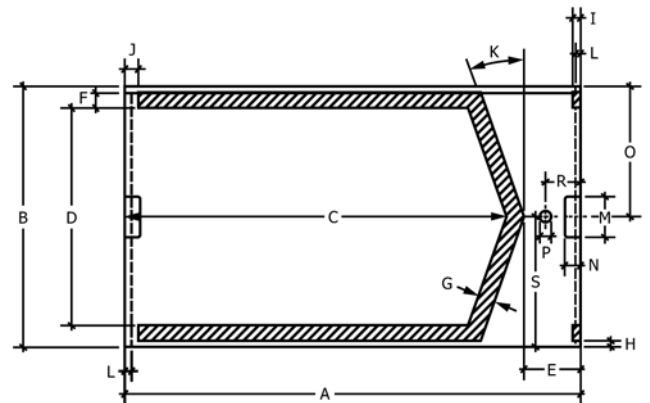
6.2 *Materials and Manufacture:*

6.2.1 Materials used in the construction of medical device peel pouches should be specified as non-toxic, providing a microbial barrier and any other appropriate physical barrier (oxygen, water vapor, light, and so forth), and being compatible with the intended sterilization process. These requirements should be evaluated during the initial package qualification and are not typically performed on a routine production basis.

NOTE 2—There are numerous test methods associated with determining physical and chemical properties of flexible materials used in the fabrication of pouches. Care should be taken in selecting the most appropriate test for the user’s particular application and use. For guidance in determining which methods to use, refer to Guide F2097.

6.2.2 The ability of the materials to demonstrate compliance with predetermined requirements may be addressed by either the certification from raw or component materials supplier or by actual testing performed by the pouch manufacturer in compliance with quality systems. These requirements are often evaluated during the initial package qualification and not typically performed on a routine production basis.

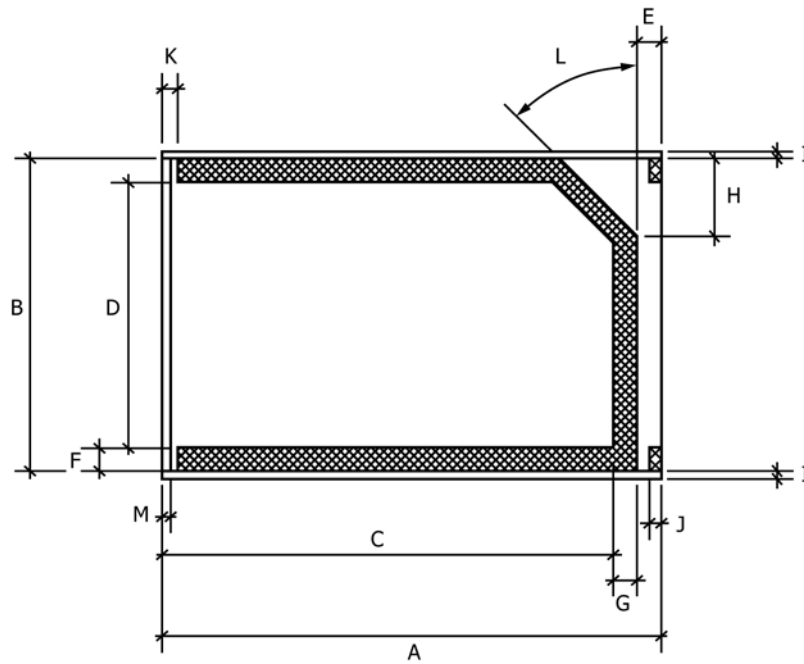
6.2.3 Pouches should be manufactured within a formal quality system.



NOTE 1—Dimension “I” or “J” but not both.

FIG. 1 Chevron Pouch

⁵ In accordance with ASTM International *Form and Style for ASTM Standards*.



NOTE 1—Dimension “J” or “K” but not both.

FIG. 2 Corner Peel

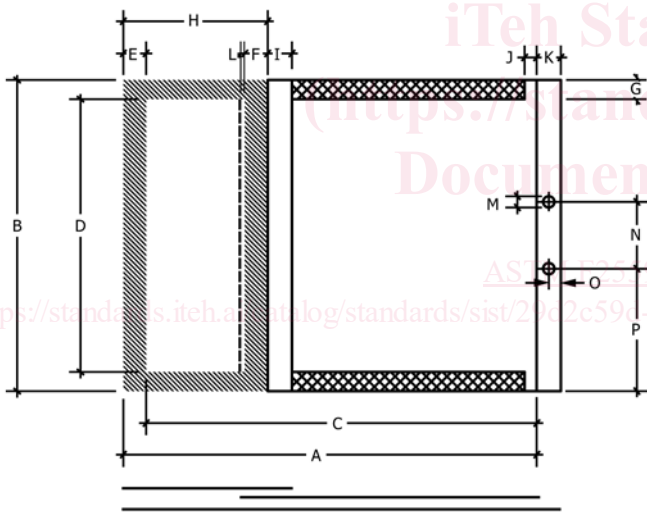


FIG. 3 Header Bag

NOTE 3—Minimum seal strength is typically that which maintains package integrity through the processing, sterilization, handling, and distribution systems. Maximum seal strength is that which, if exceeded, may result in the perception that the pouch is too difficult to open or causes fiber tear or delamination between one or more of the bonded substrates.

6.3.2.1 Seal strength is measured using a tensile test method such as Test Method F88 or burst test using Test Method F2054 or Test Method F1140.

NOTE 4—Burst testing is more commonly used for in-process testing rather than acceptance testing. If burst strength is to be used for in-process control, then concurrent tensile and burst testing should be performed at the time of validation.

6.3.2.2 Test Method F88 indicates three different tail holding techniques for the test sample: (a) unsupported, (b) supported 90° (by hand), and (c) supported 180°. Because the effect of each of these on test results is varied, consistent use of one technique should be negotiated with the supplier and indicated in the specification.

6.3.3 The visual seal appearance either in the intact or peeled state should be specified as continuous around the perimeter of the seal with no skips, channels, or unsealed areas. The seal pattern, which can be solid, ribbed, or grid, should be homogeneous over the entire seal area with no spotty or mottled appearance, which typically indicates an insufficient seal. Refer to Test Method F1886.

6.3.4 Pouch seals should be able to withstand the intended sterilization process(es). This requirement should be evaluated on the filled pouch during the initial package qualification and not typically performed on a routine production basis.

NOTE 5—Some sterilization processes may cause seals to soften and separate, or increase or decrease seal strength.

6.4 Performance Requirements:

6.4.1 Peeled pouch seal characteristics and requirements should be indicated. When seals are peeled open, there should

6.2.4 The process of converting materials into pouches should be validated to demonstrate it is capable of consistently producing a product that complies with predetermined requirements such as dimensions, quality attributes, seal strength and seal integrity.

6.3 Physical Properties:

6.3.1 The critical physical property for a peel pouch is how well the seal is fabricated and how well it will stand up to the stresses of sterilization, distribution, storage, and handling environments.

6.3.2 A seal strength should be specified. This requirement may be a minimum or maximum value, or both, the user has qualified, or it may be an average or range value based on the sealing process capability.

be no visible film fracturing, delamination, or fiber tear, or particulate visually observed in accordance with Test Method **F1886** that presents a risk of contaminating package contents, the sterile field or operating room.

6.4.1.1 Full pouch length if less than 15 cm [6 in.] long.

6.4.1.2 One half ($\frac{1}{2}$) the pouch length if 15 to 45 cm [6 to 18 in.] long.

6.4.1.3 One third ($\frac{1}{3}$) pouch length if greater than 45 cm [18 in.] long.

NOTE 6—Peeling or opening technique, as well as pouch geometry and materials, may affect the visual characteristics of the pouch seal. The peeling technique should be one continuous motion.

6.5 *Dimensions and Tolerance:*

6.5.1 Dimensions critical to product fit and function should be specified. These typically include, but are not limited to, overall length and width, inside length (to the apex of a chevron pouch) and width, chevron or peel angle, and seal width. Other dimensions should be determined based on individual applications and requirements. Refer to **Fig. 1**, **Fig. 2**, or **Fig. 3**.

6.5.1.1 Linear dimensions should be measured in accordance with Test Method **F2203**.

6.5.1.2 Dimensional tolerances should be in accordance with **Table 1**.

6.6 *Workmanship, Finish, and Appearance:*

NOTE 7—Visual inspection of the pouch and pouch materials should be without magnification under normal lighting conditions at a distance of approximately 30 to 45 cm [12 to 18 in.] and any defects should be noticeable without an extended inspection time. (Refer to Test Method **F1886**.)

6.6.1 Loose foreign matter limits for both inside and outside of the pouch should be specified and negotiated with and agreed to by all parties. Requirements may be established based on the Dirt Estimation Chart in TAPPI T437, T213, or T564.

6.6.2 There should be no wrinkles that could cause channeling through the seal or voids in the seal, and no holes or tears in the pouch.

6.6.3 There should be no scratches or scuffing on the film, if applicable. The degree of scratches or scuffing, if any, should be determined as appropriate for the material used.

6.6.4 Embedded foreign matter limits and gel limitations for each individual component should be established based on the Dirt Estimation Chart in TAPPI T437. Typically, a maximum allowable number of a certain size is specified for a given individual sample area or dimension.

6.6.5 Pouch edges should be smooth and cleanly cut.

6.7 *Printing:*

6.7.1 The printed material should comply with Guide **F2475**. This requirement should be evaluated during the initial package qualification and not typically performed on a routine production basis.

6.7.2 The specification should indicate whether inks on the printed material need to be resistant to water, alcohol, and so forth, and tested in accordance with Practice **F2250**. This requirement should be evaluated during the initial package qualification and not typically performed on a routine production basis.

6.7.3 Ink color should be specified and conform to agreed upon standards.

6.7.4 There should be no missing, incorrect or illegible print.

6.7.5 There should be no smears or smudges from the printing process or print offset or ink pick-off from other pouches.

6.7.6 Placement and location of print should be specified.

NOTE 8—Printing should not be in the seal area. The heat sealing process may be affected by the presence of ink. Additionally, the sealing process may affect the ink or print legibility, or both.

NOTE 9—Extensive coverage of print coating porous material surfaces may result in an unintended change to air permeance.

6.8 *Sampling:*

6.8.1 The number of samples tested should be adequate to be predictive of performance. Caution should be taken when eliminating samples with defects as this can bias results.

6.8.2 See Practice **E122** for guidance on sampling practices.

6.9 *Packaging and Package Marking:*

6.9.1 Pouches should have multiple wraps, such as clean polyethylene (PE) bags, and be packed into a shipping case. Shipping cases should not exceed an agreed upon weight that make the case too heavy to lift and maneuver. Staples should not be used for case closure unless the supplier can adequately protect the pouches from damage by them. Cases should not be stacked so high as to cause damage to the pouches. Cases should be strapped or otherwise secured to pallets so as to prevent shifting, but not so tight as to cause crumpling of the shipping cases.

6.9.2 At a minimum, each case should be marked with the supplier's name, supplier lot number, supplier and/or customer part number and revision if applicable, purchase order number, and quantity.

6.9.3 Any relevant storage conditions or limitations should be marked on the shipping case.

6.10 *Supplementary Requirements:*

6.10.1 Traceability of the materials used in each lot of pouches produced should be maintained back to the direct base material supplier.

6.10.2 The supplier and customer should agree on how changes to materials, processes, or sources of supply will be handled once a pouch product is defined and qualified. This is typically documented as an agreement based upon written approvals.

7. Keywords

7.1 chevron pouch; corner peel pouch; header bag; peel pouch; specification