



Standard Guide for Writing a Specification for Sterilizable Peel Pouches¹

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

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 Flexible Barrier Packaging](#)

¹ This guide is under the jurisdiction of ASTM Committee F02 on Flexible Barrier Packaging and is the direct responsibility of Subcommittee F02.50 on Package Design and Development.

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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.

[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 Medical 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:

[T437 Dirt in Paper and Paperboard](#)³

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.⁴

4. Summary

4.1 This guide provides guidance for writing a peel pouch material specification. Materials, method of manufacture,

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

⁴ In accordance with ASTM International *Form and Style for ASTM Standards*.