



Designation: F2097 – 20

Standard Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products¹

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1. Scope

1.1 This guide provides directions for the design and evaluation of primary flexible packages for medical products. The package materials must be selected appropriately for manufacturing process, end use, and the product being packaged.

1.2 This guide provides a compendium of test methods, practices, and procedures. Specific individual test methods must be selected based on the pertinent characteristics of the specific product to be packaged and the purpose for testing, research and development, or compliance. Not all test methods will be applicable.

1.3 This guide does not address acceptability criteria, which need to be determined jointly by the package producer and the medical products manufacturer.

1.4 This guide does not assess the product to be packaged or the sterilization method to be used.

1.5 The units cited in the referenced standard should be used.

1.6 *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.*

2. Referenced Documents

2.1 *ASTM Standards:*²

D374 Test Methods for Thickness of Solid Electrical Insulation (Metric) D0374_D0374M

D589 Test Method for Opacity of Paper (15° Diffuse Illu-

minant A, 89 % Reflectance Backing and Paper Backing) (Withdrawn 2010)³

D638 Test Method for Tensile Properties of Plastics

D645/D645M Test Method for Thickness of Paper and Paperboard (Withdrawn 2010)³

D685 Practice for Conditioning Paper and Paper Products for Testing

D726 Test Method for Resistance of Nonporous Paper to Passage of Air (Withdrawn 2009)³

D882 Test Method for Tensile Properties of Thin Plastic Sheeting

D1003 Test Method for Haze and Luminous Transmittance of Transparent Plastics

D1251 Test Method for Water Vapor Permeability of Packages by Cycle Method (Withdrawn 1999)³

D1434 Test Method for Determining Gas Permeability Characteristics of Plastic Film and Sheeting

D1709 Test Methods for Impact Resistance of Plastic Film by the Free-Falling Dart Method

D1777 Test Method for Thickness of Textile Materials

D1894 Test Method for Static and Kinetic Coefficients of Friction of Plastic Film and Sheeting

D1922 Test Method for Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method

D1938 Test Method for Tear-Propagation Resistance (Trouser Tear) of Plastic Film and Thin Sheeting by a Single-Tear Method

D2019 Test Method for Dirt in Paper and Paperboard (Withdrawn 2010)³

D2457 Test Method for Specular Gloss of Plastic Films and Solid Plastics

D3078 Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission

D3079 Test Method for Water Vapor Transmission of Flexible Heat-Sealed Packages for Dry Products (Withdrawn 2018)³

D3335 Test Method for Low Concentrations of Lead, Cadmium, and Cobalt in Paint by Atomic Absorption Spectroscopy

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 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 The last approved version of this historical standard is referenced on www.astm.org.

- D3420** Test Method for Pendulum Impact Resistance of Plastic Film
- D3718** Test Method for Low Concentrations of Chromium in Paint by Atomic Absorption Spectroscopy
- D3776** Test Methods for Mass Per Unit Area (Weight) of Fabric
- D3985** Test Method for Oxygen Gas Transmission Rate Through Plastic Film and Sheeting Using a Coulometric Sensor
- D4169** Practice for Performance Testing of Shipping Containers and Systems
- D4279** Test Methods for Water Vapor Transmission of Shipping Containers—Constant and Cycle Methods
- D4321** Test Method for Package Yield of Plastic Film
- D4332** Practice for Conditioning Containers, Packages, or Packaging Components for Testing
- D4754** Test Method for Two-Sided Liquid Extraction of Plastic Materials Using FDA Migration Cell
- D5264** Practice for Abrasion Resistance of Printed Materials by the Sutherland Rub Tester
- D7386** Practice for Performance Testing of Packages for Single Parcel Delivery Systems
- E167** Practice for Goniophotometry of Objects and Materials (Withdrawn 2005)³
- E171/E171M** Practice for Conditioning and Testing Flexible Barrier Packaging
- E398** Test Method for Water Vapor Transmission Rate of Sheet Materials Using Dynamic Relative Humidity Measurement
- F17** Terminology Relating to Primary Barrier Packaging
- F88** Test Method for Seal Strength of Flexible Barrier Materials
- F99** Guide for Writing a Specification for Flexible Barrier Rollstock Materials
- F151** Test Method for Residual Solvents in Flexible Barrier Materials (Withdrawn 2004)³
- F372** Test Method for Water Vapor Transmission Rate of Flexible Barrier Materials Using an Infrared Detection Technique (Withdrawn 2009)³
- F392** Practice for Conditioning Flexible Barrier Materials for Flex Durability
- F748** Practice for Selecting Generic Biological Test Methods for Materials and Devices
- F813** Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices
- F895** Test Method for Agar Diffusion Cell Culture Screening for Cytotoxicity
- F904** Test Method for Comparison of Bond Strength or Ply Adhesion of Similar Laminates Made from Flexible Materials
- F1140** Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages
- F1249** Test Method for Water Vapor Transmission Rate Through Plastic Film and Sheeting Using a Modulated Infrared Sensor
- F1306** Test Method for Slow Rate Penetration Resistance of Flexible Barrier Films and Laminates
- F1307** Test Method for Oxygen Transmission Rate Through Dry Packages Using a Coulometric Sensor
- F1608** Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method)
- F1884** Test Methods for Determining Residual Solvents in Packaging Materials
- F1886** Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- F1921** Test Methods for Hot Seal Strength (Hot Tack) of Thermoplastic Polymers and Blends Comprising the Sealing Surfaces of Flexible Webs
- F1927** Test Method for Determination of Oxygen Gas Transmission Rate, Permeability and Permeance at Controlled Relative Humidity Through Barrier Materials Using a Coulometric Detector
- F1929** Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- F1980** Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- F2029** Practices for Making Laboratory Heat Seals for Determination of Heat Sealability of Flexible Barrier Materials as Measured by Seal Strength
- F2054** Test Method for Burst Testing of Flexible Package Seals Using Internal Air Pressurization Within Restraining Plates
- F2095** Test Methods for Pressure Decay Leak Test for Flexible Packages With and Without Restraining Plates
- F2096** Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- F2203** Test Method for Linear Measurement Using Precision Steel Rule
- F2217** Practice for Coating/Adhesive Weight Determination
- F2227** Test Method for Non-Destructive Detection of Leaks in Non-sealed and Empty Packaging Trays by CO₂ Tracer Gas Method
- F2228** Test Method for Non-Destructive Detection of Leaks in Packaging Which Incorporates Porous Barrier Material by CO₂ Tracer Gas Method
- F2250** Practice for Evaluation of Chemical Resistance of Printed Inks and Coatings on Flexible Packaging Materials
- F2251** Test Method for Thickness Measurement of Flexible Packaging Material
- F2252** Practice for Evaluating Ink or Coating Adhesion to Flexible Packaging Materials Using Tape
- F2338** Test Method for Nondestructive Detection of Leaks in Packages by Vacuum Decay Method
- F2391** Test Method for Measuring Package and Seal Integrity Using Helium as the Tracer Gas
- F2475** Guide for Biocompatibility Evaluation of Medical Device Packaging Materials
- F2476** Test Method for the Determination of Carbon Dioxide Gas Transmission Rate (CO₂TR) Through Barrier Materials Using an Infrared Detector
- F2559** Guide for Writing a Specification for Sterilizable Peel Pouches
- F2622** Test Method for Oxygen Gas Transmission Rate Through Plastic Film and Sheeting Using Various Sensors

- F2638** Test Method for Using Aerosol Filtration for Measuring the Performance of Porous Packaging Materials as a Surrogate Microbial Barrier
- F2714** Test Method for Oxygen Headspace Analysis of Packages Using Fluorescent Decay
- F2824** Test Method for Mechanical Seal Strength Testing for Round Cups and Bowl Containers with Flexible Peelable Lids
- F2825** Practice for Climatic Stressing of Packaging Systems for Single Parcel Delivery
- F2981** Test Method for Verifying Nonporous Flexible Barrier Material Resistance to the Passage of Air
- F3004** Test Method for Evaluation of Seal Quality and Integrity Using Airborne Ultrasound
- F3039** Test Method for Detecting Leaks in Nonporous Packaging or Flexible Barrier Materials by Dye Penetration
- F3136** Test Method for Oxygen Gas Transmission Rate through Plastic Film and Sheeting using a Dynamic Accumulation Method
- F3169** Test Method for Leak Detection in Blister Packaging by Vacuum Deflection Method by Laser Measurement
- F3287** Test Method for Nondestructive Detection of Leaks in Packages by Mass Extraction Method
- F3299** Test Method for Water Vapor Transmission Rate Through Plastic Film and Sheeting Using an Electrolytic Detection Sensor (Coulometric P₂O₅ Sensor)
- F3300** Test Method for Abrasion Resistance of Flexible Packaging Films Using a Reciprocating Weighted Stylus
- 2.2 *EN/ISO Standards:*⁴
- ISO 187** Paper, Board and Pulps—Standard Atmosphere for Conditioning and Testing and Procedure for Monitoring the Atmosphere and Conditioning of Samples
- ISO 2556** Plastics—Determination of Gas Transmission Rate of Films and Thin Sheets Under Atmospheric Pressure—Manometric Method
- ISO 5636-5** Paper and Board—Determination of Air Permeance (Medium Range)—Part 5: Gurley Method
- ISO 10993** Biological Evaluation of Medical Devices
- ISO 11607-1** Packaging for Terminally Sterilized Medical Devices, Annex C
- ISO 15105-1** Plastics—Film and Sheeting—Determination of Gas Transmission Rate—Part 1: Differential-Pressure Method
- ISO 15105-2** Plastics—Film and Sheeting—Determination of Gas Transmission Rate—Part 2: Equal-Pressure Method
- 2.3 *Military Specification:*⁵
- Mil Spec 36954C** Bacterial Filtration Efficiency
- 2.4 *TAPPI Standards:*⁶
- TAPPI T 402** Standard Conditioning and Testing Atmospheres for Paper, Board, Pulp Handsheets, and Related Products
- TAPPI T 404** Tensile Breaking Strength and Elongation of Paper and Paperboard
- TAPPI T 425** Opacity of Paper (15/D Geometry, Illuminant A/2 Degrees, 89% Reflectance Backing and Paper Backing)
- TAPPI T 437** Dirt in Paper and Paperboard
- TAPPI T 460** Air Resistance of Paper (Gurley Method)
- TAPPI T 494** Tensile Breaking Properties of Paper and Paperboard (Using Constant Rate of Elongation Apparatus)
- TAPPI T 519** Diffuse Opacity of Paper (D/0 Paper Backing)
- TAPPI T 536** Resistance of Paper to Passage of Air (High Pressure Gurley Method)
- TAPPI T 547** Air Permeance of Paper and Paperboard (Sheffield Method)
- 2.5 *ISTA Procedures:*⁷
- ISTA 3A** Packaged Products for Parcel Delivery System Shipments 70 kg (150 lb) or Less (standard, small, flat, or elongated)
- ISTA 3E** Unitized Loads of Same Product
- ISTA 4AB** Packaged-Products for Shipment in Known Distribution Channels
- ISTA 6-FEDEX-A** FedEx Procedures for Testing Packaged Products Weighing Up to 150 lbs

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *barrier requirements, n*—the need to promote or inhibit moisture, gas, or light, or a combination thereof, while maintaining necessary levels of sterility.

3.1.2 *conditioning requirements, n*—exposure to specific temperature, humidity, and time conditions to simulate particular field conditions, mimic the effects of aging, or to minimize the variation in test results.

3.1.3 *distribution simulation, n*—conditioning or stressing of the packaging system, so that its ability to withstand the hazards of handling, distribution, and storage can subsequently be evaluated.

3.1.4 *material and package performance attributes and characteristics requirements, n*—material properties relevant to the ability of the package to protect the product while preserving intended opening for use features.

3.1.5 *package performance, n*—the ability of the packaging system, including the sterile barrier system and protective packaging, to withstand the hazards of handling, distribution and storage as approximated via distribution simulation.

3.1.6 *printed ink requirements, n*—the printed ink properties needed to ensure physical and chemical resistance to degradation.

3.1.7 *processing requirements, n*—the material characteristics needed to ensure the consistent and reliable production of the package.

3.1.8 *safety requirements, n*—safeguard product against contamination and deleterious health effects.

⁴ Available from International Organization for Standardization (ISO), 1 rue de Varembé, Case postale 56, CH-1211, Geneva 20, Switzerland, <http://www.iso.ch>.

⁵ Available from Standardization Documents Order Desk, Bldg. 4 Section D, 700 Robbins Ave., Philadelphia, PA 19111-5094, Attn: NPOPS.

⁶ Available from Technical Association of the Pulp and Paper Industry (TAPPI), 15 Technology Parkway South, Norcross, GA 30092, <http://www.tappi.org>.

⁷ Available from International Safe Transit Association (ISTA), 1400 Abbot Rd., Suite 160, East Lansing, MI 48823-1900, <http://www.ista.org>.

3.1.9 *visibility and appearance requirements, n*—the desired package aesthetics needed to permit or inhibit viewing of the product or to enhance product presentation.

3.2 For other terms used in this guide, see Terminology **F17**.

4. Significance and Use

4.1 This design and evaluation guide describes multiple categories for evaluating flexible medical packages and packaging materials. These include safety, barrier, material and package performance attributes and characteristics, package integrity, visibility and appearance, processing, printed ink, distribution simulation, and conditioning.

4.2 The intent of this design and evaluation guide is to evaluate all cited categories and select those that are applicable. Once the product has been characterized and the sterilization methodology has been defined, there are numerous sets of requirements for any specific package. This design and evaluation guide provides an avenue for assessing these requirements and choosing test methods for both evaluating the package design and monitoring package compliance.

NOTE 1—Many of the standards included in this guide are consensus standards that are recognized by the United States Food and Drug Administration (FDA). Selection and use of a U.S. FDA recognized consensus standard is voluntary and the sole responsibility of the user in determining its applicability. For further information, consult the U.S. FDA Standards and Conformity Assessment Program at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatoryassistance/standards-and-conformity-assessment-program>

4.3 Product characterization shall include mass or weight, geometry (length and width, height, and shape) and product composition.

4.4 All categories must be considered for applicability.

4.5 The Summary of Test Methods for Medical Packaging Design and Evaluation (**Fig. 1**) provides a compact graphical presentation of the test methods referenced in this guide.

4.6 *Test Description and Applicability* (see **Table 1**):

4.6.1 **Table 1** lists the test methods commonly used to evaluate flexible medical packaging. The test methods are used in two phases.

4.6.1.1 *Package Design: Characterization of the Materials and Evaluation of the Resultant Package*—This is referred to as

“R&D Evaluation” in **Table 1**. Testing during this phase is characterized by the generation of quantitative data on the performance of the component materials and the package assembly. These test methods are lengthy, making them inappropriate for the manufacturing environment where rapid response is required for process control. Often, they are expensive and require specialized equipment not readily available at a medical packaging or device manufacturing facility.

4.6.1.2 *Package Compliance: Routine Monitoring of Adherence to Specifications*—This is referred to as “Compliance Testing” in **Table 1**. Testing during this phase must be rapid, inexpensive, and readily implemented in a manufacturing environment. The objective is not to develop design data, but to ensure that the design specifications are being met. These test methods do not necessarily make direct measurements of critical values, but detect variations in material, process, or product that are indicative of all critical characteristics.

4.6.2 It is important to note that no individual test method is entirely predictive of final package performance. Filled packages must be evaluated under conditions of use.

4.6.2.1 Distribution simulation is intended to provide a standardized, uniform, and repeatable basis of conditioning or stressing a package system so that the packaging system’s ability to withstand routine distribution can subsequently be evaluated. The damage-producing motions, forces, conditions, and sequences of transport environments are simulated within a laboratory setting. The intended test sequences and intensity levels can be adjusted to address the specifics of the distribution cycle.

4.6.2.2 Performance testing must be conducted to confirm product protection and sterile package integrity in design validation. Confirmation is by means of product testing and package integrity testing. The specific tests used for evaluation will be dependent upon the product and the sterile barrier system. Consideration should be given to evaluating the effects of environmental extremes.

4.7 Once the design of the package and/or packaging materials has been determined, it may be appropriate to create a package and/or material specification. Guides **F99** or **F2559** may provide useful guidance.

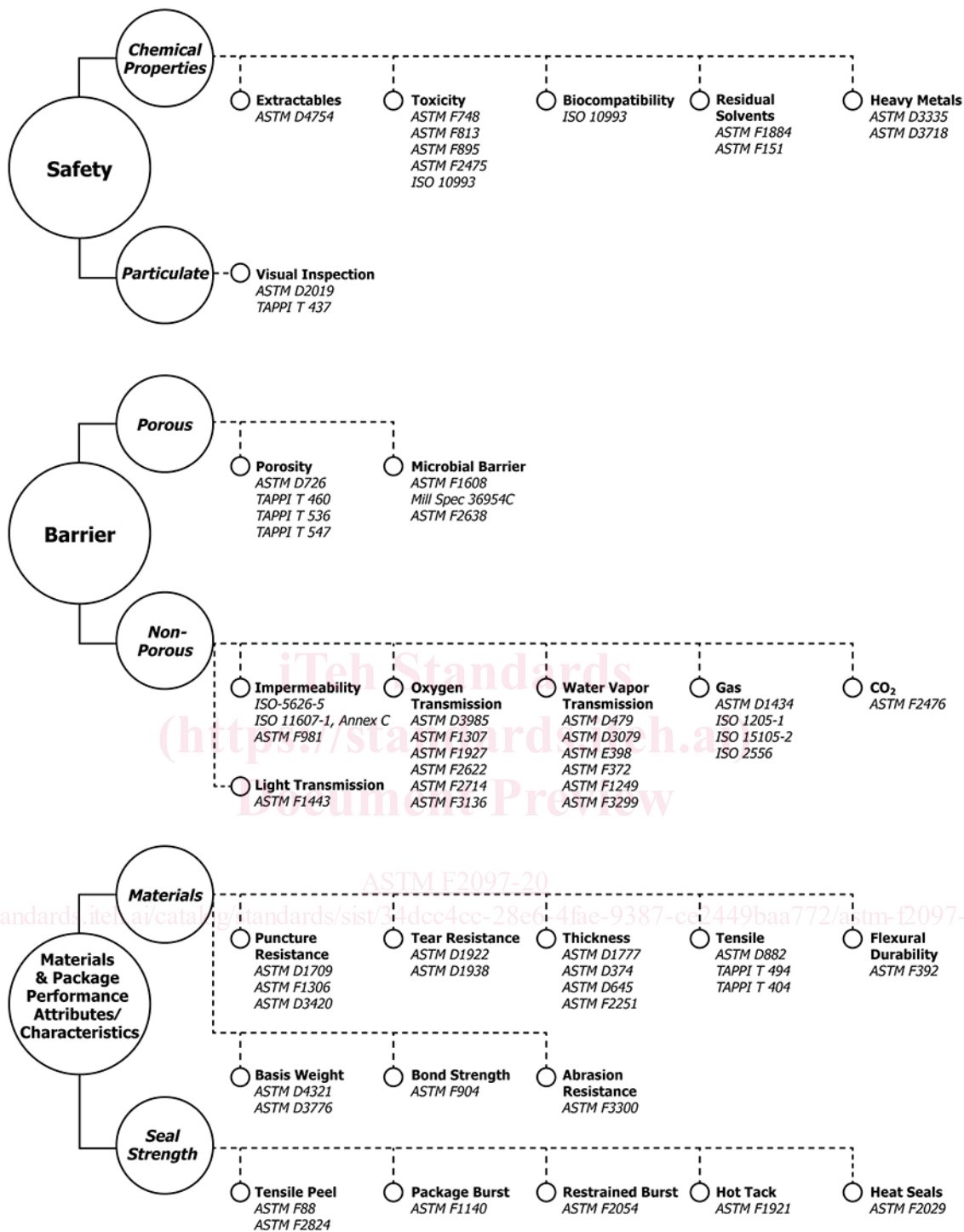


FIG. 1 Summary of Test Methods for Medical Packaging Design and Evaluation

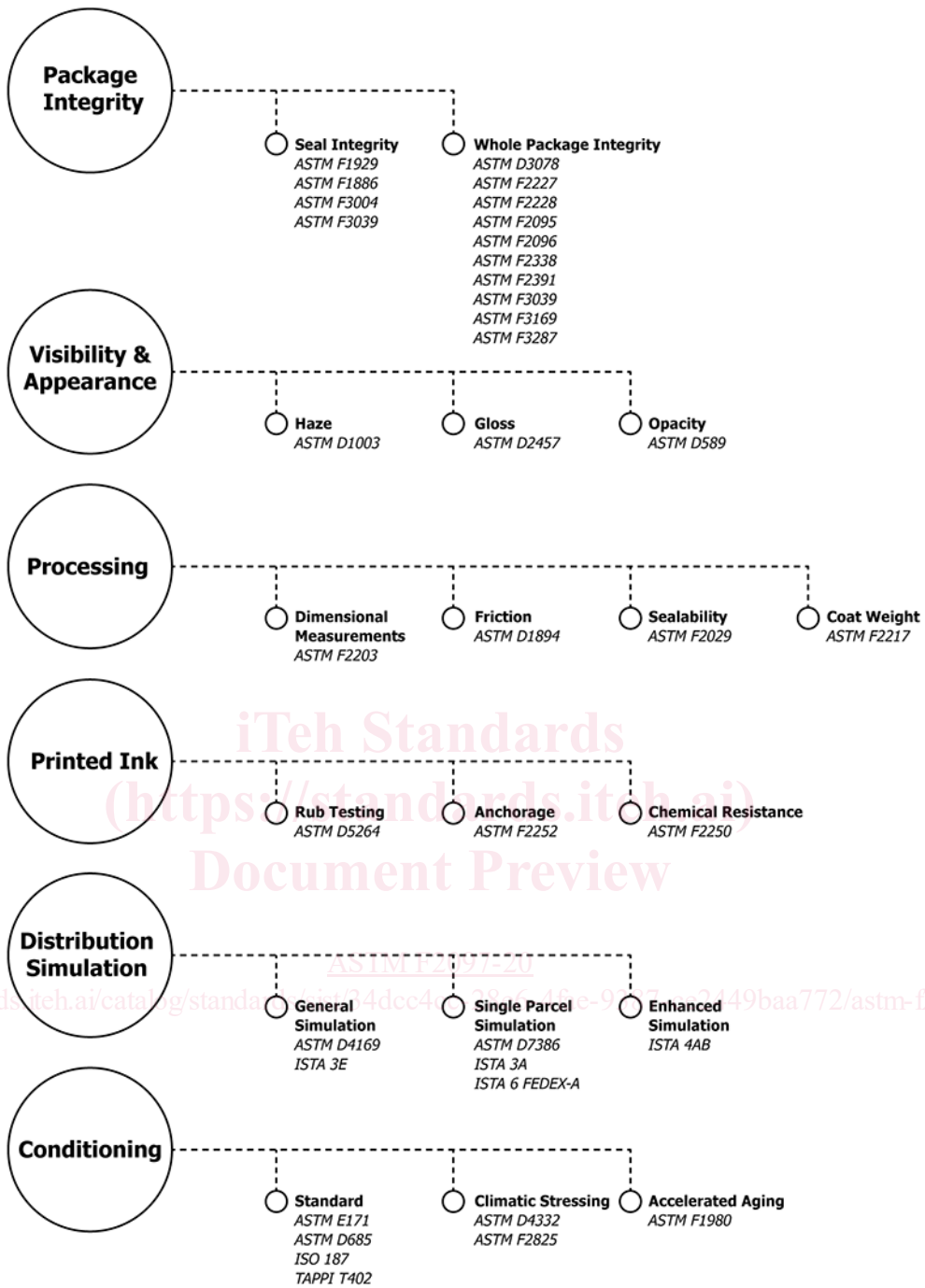


FIG. 1 Summary of Test Methods for Medical Packaging Design and Evaluation (continued)

TABLE 1 Test Description and Applicability Table

Test Category	Test Method	Usage	Description	Applicability
Safety/Chemical Properties/ Extractables	ASTM D4754	R&D	This test method covers the use of the FDA migration cell in the extraction of components and permits quantitation of individual migrants from plastic materials by suitable extracting liquids, including liquid foods and food-stimulating solvents. This test method provides a two-sided, liquid extraction test for plastic materials that can be formed into film, sheet, or disks.	<p>This test method has been applied to a variety of migrant/polymer systems in contact with numerous foods and food simulants. Though most of the migrants examined were radiolabeled, the use of the FDA cell has been validated for migration studies of unlabeled styrene from polystyrene.</p> <p>This test method has been shown to yield reproducible results under the conditions for migration tests requested by the FDA. However, if the data is to be submitted to the FDA, it is suggested that their guidelines be consulted.</p> <p>Because it employs two-sided extraction, this test method may not be suitable for multilayered plastics intended for single-sided food contact use.</p> <p>The size of the FDA migration cell as described may preclude its use in determining total nonvolatile extractives in some cases.</p>
Safety/Chemical Properties/ Toxicity - Biocompatibility	ASTM F748	R&D	This practice recommends generic biological test methods for materials and devices according to end-use applications. Tests include those performed on materials, end products, and extracts. Rationale and comments on current state of the art are included for all test procedures described. Biological evaluation of materials and devices, and related subjects such as pyrogen testing and batch testing of production lots are also discussed.	<p>The biocompatibility of materials used in single-component or multicomponent medical devices for human use depends to a large degree on the particular nature of the end-use application. It is not possible to specify a set of biocompatibility test methods which will be necessary and sufficient to establish biocompatibility for all materials and applications.</p> <p>While chemical testing for extractable additives and residual monomers or residues from processing aids is necessary for most implant materials, such testing is not included as a part of this practice. The reader is cautioned that the area of materials biocompatibility testing is a rapidly evolving field, and improved methods are evolving rapidly, so this practice is by necessity only a guideline. These test protocols are intended to apply to materials and medical devices for human application.</p>
Safety/Chemical Properties/ Toxicity - Biocompatibility	ASTM F813	R&D	This practice describes a reference method of direct contact cell culture testing that may be used in evaluating the cytotoxic potential of materials for use in the construction of medical materials and devices. This practice may be used either directly to evaluate materials or as a reference against which other cytotoxicity test methods may be compared.	<p>This practice tends to be used less frequently due to the risk of inducing a response from mechanical damage due to direct placement of the sample onto the cell layer. This practice may be suitable for products which have leachates that are not able to diffuse through agar and are not too heavy.</p>

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TABLE 1 *Continued*

Test Category	Test Method	Usage	Description	Applicability
Safety/Chemical Properties/ Toxicity - Biocompatibility	ASTM F895	R&D	<p>The agar diffusion assay is an indirect contact test in which the test material is placed onto an agar layer that protects the cells.</p> <p>This test method is commonly used to evaluate the response of small samples that have at least one flat surface such as elastomeric closures.</p>	<p>This is one of a series of reference test methods for the assessment of cytotoxic potential, employing different techniques. Assessment of cytotoxicity is one of several tests employed in determining the biological response to a material, as recommended in Practice F748.</p> <p>This test method is appropriate for materials in a variety of shapes and for materials that are not necessarily sterile.</p> <p>This test method would be appropriate in situations where the amount of material is limited. For example, small devices or powders could be placed on the agar and the presence of a zone of inhibition of cell growth could be examined. While the agar layer can act as a cushion to protect the cells from the specimen, there may be materials which are sufficiently heavy to compress the agar and prevent diffusion or to cause mechanical damage to the cells.</p> <p>This test method is not appropriate for leachables that are not water soluble because they may not diffuse through agar or agarose and thus not be detected.</p> <p>This test method would not be appropriate for these materials. The L 929 cell line was chosen because it has a significant history of use in assays of this type. This is not intended to imply that its use is preferred; only that the L 929 is an established cell line, well characterized and readily available, that has demonstrated reproducible results in several laboratories.</p>
Safety/Chemical Properties/ Toxicity - Biocompatibility	ASTM F2475	R&D Evaluation	<p>This guide provides information to determine the appropriate testing for biocompatibility of packaging materials used to contain a medical device.</p>	<p>This method applies to packaging for medical devices.</p>
Safety/Chemical Properties/ Toxicity - Biocompatibility	ISO 10993	R&D Evaluation	<p>This entails a series of standards for evaluating the biocompatibility of a medical device prior to clinical study. Part 1 of the standard uses an approach to test selection that is very similar to the Tripartite Guidance.</p>	<p>When selecting the appropriate tests for biological evaluation of a medical device, one must consider the chemical characteristics of device materials and the nature, degree, frequency, and duration of its exposure to the body. Note: FDA has made several modifications to the testing required by ISO 10993–Part 1.</p>

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TABLE 1 *Continued*

Test Category	Test Method	Usage	Description	Applicability
Safety/Chemical Properties/ Retained Solvents	ASTM F1884	R&D Evaluation Compliance Testing	<p>These test methods cover determination of the amount of residual solvents released from within a packaging material contained in a sealed vial under a given set of time and temperature conditions and is a recommended alternative for Test Method F151.</p> <p>These test methods cover a procedure for quantifying volatile compounds whose identity has been established, and are retained in packaging materials.</p>	<p>These test methods do not address the determination of total retained solvents in a packaging material. Techniques such as multiple headspace extraction can be employed to this end.</p> <p>For purposes of verifying the identity of or identifying unknown volatile compounds, the analyst is encouraged to incorporate techniques such as gas chromatography/mass spectroscopy, gas chromatography/infrared spectroscopy, or other suitable techniques in conjunction with this test method.</p> <p>This is an off-line head space analysis. It is sensitive to technique and sampling equipment resulting in large variations (~25 %) between laboratories.</p> <p>It is a simplified version of Test Method F151 providing about the same level of accuracy. This method differs from Test Method F151 in that it specifies certain conditions. Test Methods F1884, for example, specifies a pre-heat condition of 90 °C for 20 min. Test Method F151 defines a procedure for determining optimum heating time and temperature conditions for the preheat.</p> <p>Because solvents will escape from surface wraps on a roll of film, this test should be performed immediately after manufacturing to provide an indication of solvent levels in the inner wraps of the roll of film.</p>
Safety/Chemical Properties/ Retained Solvents	ASTM F151	R&D Evaluation Compliance Testing	<p>This test method provides an index for comparing the level of solvents retained in flexible barrier materials of the same construction, which result from casting, coating, printing, or laminating operations. This test method does not yield absolute quantitative measurements of solvents retained in flexible barrier materials.</p>	<p>This method is essentially identical to Test Methods F1884 except for a complicated determination of the optimum heating time and temperature for the films in the head space container. There is no improvement in the interlaboratory variation. All other comments under Test Method F1884 apply equally to Test Method F151.</p>
Safety/Chemical Properties/ Heavy Metals	ASTM D3335	R&D Evaluation	<p>This test method covers the determination of lead contents between 0.01 and 5 %, cadmium contents between 50 and 150 ppm (mg/kg), and cobalt contents between 50 and 2000 ppm (mg/kg) present in the nonvolatile portion of liquid coating or contained in dried films by means of atomic absorption.</p>	<p>Higher levels of all three elements can be determined by this test method, provided that appropriate dilutions and adjustments in specimen size and reagent quantities are made. This test method is not applicable to the determination of lead in samples containing antimony pigments (low recoveries are obtained). If lead is present in the sample to be analyzed in the form of an organic lead compound at a concentration greater than 0.1 %, small losses of lead may occur, resulting in slightly poorer precision.</p>
Safety/Chemical Properties/ Heavy Metals	ASTM D3718	R&D Evaluation	<p>This test method covers the determination of the content of chromium (including chromium oxide) in the range from 0.005 to 1.0 % present in the solids of liquid coatings or in dried films obtained from previously coated substrates by means of atomic absorption.</p>	<p>Higher concentrations of chromium can be determined by this test method provided that appropriate dilutions and adjustments in specimen size and reagent quantities are made.</p>

TABLE 1 *Continued*

Test Category	Test Method	Usage	Description	Applicability
Safety/Particulate/ Visual inspection	ASTM D2019	R&D Evaluation	This test method is intended for the numerical estimation of dirt in paper or paperboard in terms of equivalent black area. This test method is satisfactory only for the estimation of visual characteristics and it may be entirely inadequate when nonvisual effects such as grittiness of dirt are of importance. This is ASTM's version of TAPPI T 437. It refers to the TAPPI Dirt Estimation Chart.	This test method can be used to size characteristics other than dirt. Frequently used for estimation of gels, fisheyes, ink splashes, and other visual defects.
Safety/Particulate/ Visual inspection	TAPPI T 437	Compliance testing	This test method is suited for the visual estimation of dirt in paper or paperboard in terms of equivalent black area. Dirt in paper or paperboard is defined as any foreign matter embedded in the sheet, which, when examined by reflected, not transmitted, light has a contrasting color to the rest of the surface and has an equivalent black area of 0.04 mm ² or over.	This test method can be used to size characteristics other than dirt. Frequently used for estimation of gels, fisheyes, ink splashes, and other visual defects.
Barrier/Porous/ Porosity	ASTM D726	R&D Evaluation Compliance Testing	This test method is applicable in papers that permit the passage of up to 25 mL of air/0.785 in. ² in 15 s.	This test method cannot be used in those cases where the paper cannot be clamped securely against surface and edge leakage, such as, crepe or corrugated papers. For testing porous and semiporous paper, refer to TAPPI T 460, and T 536, respectively. Since the three test methods (D726 , T 460, and T 436) do not give the same results, it is recommended that a specific method be agreed upon in specifications covering paper between the seller and the purchaser, and that the test method be chosen to conform to the principle range.
Barrier/Porous/ Porosity	TAPPI T 460	R&D Evaluation Compliance Testing	This test method references the use of a Gurley densometer that measures the amount of time required for a certain volume of air (100 cm ³) to pass through a test specimen of a given area. The air pressure is generated by a gravity-loaded cylinder that captures an air volume within a chamber using a liquid seal. The pressurized volume of air is directed to the clamping gasket ring, which holds the test specimen. Air that passes through an area of the test specimen of 6.4 cm ² (1 in. ²) escapes to atmosphere through the holes in the downstream clamping plate.	The pressure differential used in this test method is 1.22 kPa. The recommended range of time measured is from 5 to 1800 s/100-mL cylinder displacement. For more impermeable materials the time requirements become so excessive that other techniques are preferable. Since this test method measures air passage through the specimen, as well as, leakage across the surface, it is unsuitable for rough-surfaced materials that cannot be securely clamped in the mechanism and may allow significant surface and edge leakage. For measurement of materials at higher pressure (3 kPa) refer to TAPPI T 536. To measure materials at pressures up to 9.85 kPa, TAPPI T 547 references the use of a Sheffield tester which measures the amount of air passing through a material of a given area over a specific time period.
Barrier/Porous/ Porosity	TAPPI T 536	R&D Evaluation Compliance Testing	This test method measures the amount of time required for a certain volume of air to pass through a test specimen of a given size. This test method measures at a higher pressure differential (3 kPa) and is recommended for papers that require 10 or more seconds for 10 mL of air to pass through.	This test method cannot be used in those cases where the paper cannot be clamped securely against surface and edge leakage, such as, crepe or corrugated papers. Since the three test methods (D726 , T 460, and T 536) do not give the same results, it is recommended that a specific test method be agreed upon in specifications covering paper between the seller and the purchaser, and that the test method be chosen to conform to the principle range.

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TABLE 1 *Continued*

Test Category	Test Method	Usage	Description	Applicability
Barrier/Porous/ Porosity	TAPPI T 547	R&D Evaluation Compliance Testing	This method is used to measure the air permeance of a circular area of paper using a pressure differential of approximately 10 kPa (1.5 psig).	In order to accommodate a wide range of paper products, rubber clamping plates are available for five commonly used orifice diameters: 9.5 mm (0.375 in.), 19.1 mm (0.75 in.), 38.1 mm (1.5 in.), 57.2 mm (2.25 in.), and 76.2 mm (3.00 in.). The air flow range for this method is 0 to 3348 mL/min (0 to 400 Sheffield units). Instruments are available with either variable flowmeters (glass tubes with internal tapers and floats) or electronic mass flowmeters.
Barrier/Porous/ Microbial Barrier	ASTM F1608	R&D Evaluation	This test method is used to determine the passage of airborne bacteria through porous materials intended for use in packaging sterile medical devices. This test method is designed to test materials under conditions that result in the detectable passage of bacterial spores through the test material.	A round-robin study was conducted with eleven laboratories participating. Each laboratory tested duplicate samples of six commercially available porous materials to determine the LRV. Materials tested under the standard conditions described in this test method returned average values that range from LRV 1.7 to 4.3. Results of this round-robin study indicate that caution should be used when comparing test data and ranking materials, especially when a small number of sample replicates are used. In addition, further collaborative work should be conducted before this test method would be considered adequate for purposes of setting performance standards.
Barrier/Porous/ Microbial Barrier	ASTM F2638	R&D Evaluation	This test method measures the aerosol filtration performance of porous packaging materials by creating a defined aerosol of 1.0 µm particles and assessing the filtration efficiency of the material using either single or dual particle counters. The intent of this test method is to determine the flow rate through a material at which maximum penetration occurs.	This test method is applicable to porous materials used to package terminally sterilized medical devices. The porous nature of some materials used in sterile packaging applications might preclude evaluation by means of this test method. The maximum penetration point of a particular material could occur at a flow rate that exceeds the flow capacity of the test apparatus. As such, this test method may not be useful for evaluating the maximum penetration point of material with a Bendtsen flow rate above 4000 mL/min as measured by ISO 5636-3.
Barrier/Porous/ Microbial Barrier	Mil Spec 36954C	R&D Evaluation	This test method is performed at high flow rates. The challenge particles are microbial clusters with a mean diameter of 3 µm. Removal of challenge particles is therefore almost entirely by impaction.	Test methods based on this specification are intended to evaluate materials for use in surgical masks. This test method is not applicable for materials intended for low flow rate, barrier applications such as medical packaging where particulate removal is almost exclusively a diffusion mechanism.
Barrier/Non-Porous/ Impermeability	ASTM F2981	R&D Evaluation	This test method provides a means to verify that a flexible barrier material is nonporous by challenging a material with a given volume of air under pressure over a specific time period.	This material challenge is presented in ISO-11607-1, Annex C as a normative test method to demonstrate that a material is nonporous and satisfies the microbial barrier requirements. This test method is not intended to measure the diffusion properties of a material nor to identify or quantify the presence of pin-hole damage to the design that may result in leaks.
Barrier/Non-Porous/ Impermeability	ISO 5636/5, ISO 11607-1, Annex C	R&D Evaluation	Each of these test methods includes the use of a permeability tester to determine the ability of a material to inhibit the passage of air.	These test methods have similar test instruction for impermeability. All reference testing with Gurley Densometer. EN 868-1 includes another permeance tester and a dye penetration test as options.