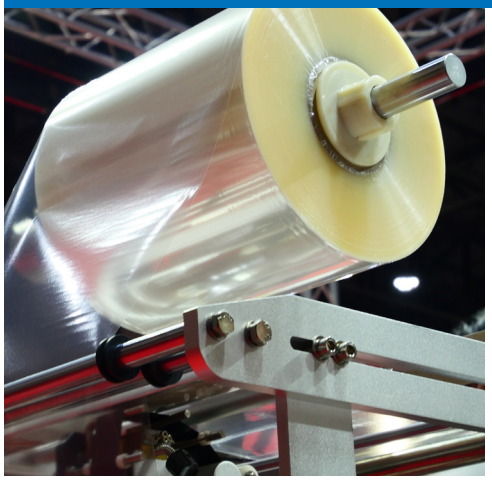
A Guide to Writing Rollstock Specifications

An SPMC White Paper



INSIDE

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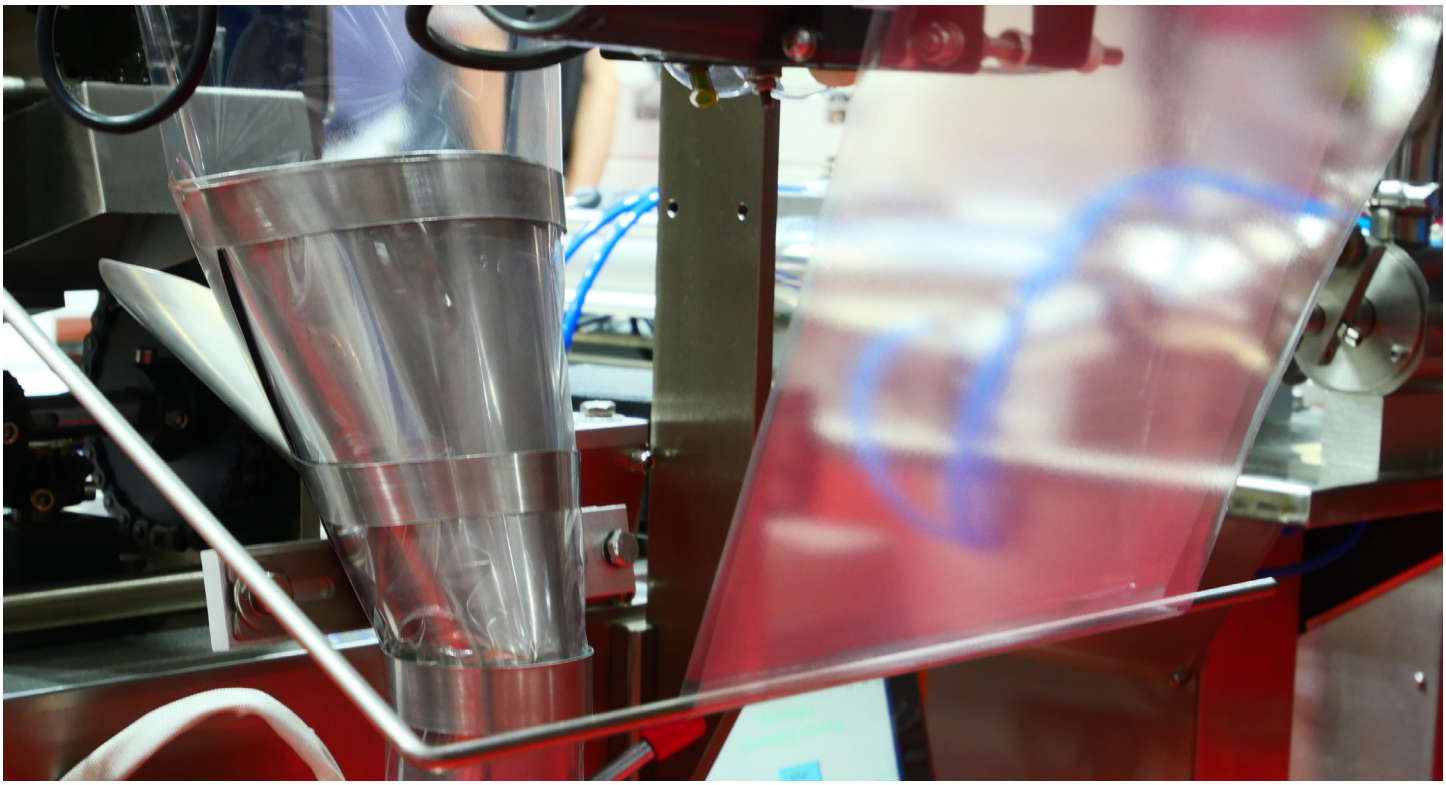


INTRODUCTION

ASTM F99, Standard Guide for Writing a Specification for Flexible Barrier Rollstock Materials, was originally approved in 1976, and has been updated and improved since that time. Members of the Technical Committee of the SPMC continue to play a key role in the evolution of that original guide and in bringing it to its present form. The main purpose of ASTM F99 is to assist purchasers of flexible barrier materials, either monolayer or multilayer, in writing appropriate specifications, highlighting areas of consideration that need to be addressed regardless of the diversity of flexible materials available. As section 5.3 of the standard states, "This guide provides an understanding of the requirements needed for the manufacture, purchase, and acceptance of flexible barrier materials." ASTM F99 also makes a clear distinction between requirements for initial qualification of a material "prior to the first order" and those for its use in production and receipt "adhered to on every order."

Within the Specification section, physical properties, application, appearance, roll characteristics, printing and packaging are key topics listed. In this whitepaper, we will highlight certain aspects of the specification that occasionally cause confusion and attempt to provide additional background and clarity to the guidance provided in F99. Not all sections of F99 will be covered in this whitepaper. Readers are encouraged to purchase a copy of the latest revision of F99 for reference.

Thickness

Section 6.2.1 of the standard states that "the total thickness of the flexible barrier material and associated thickness tolerance should be identified." When manufactured, flexible web thickness is typically controlled with in-line thickness scanners. This controls and limits the variation that can impact roll quality and provides the consistency important to subsequent operations and use. In most cases, the total thickness will be measured with mechanical gages to check against expectations. Once a target thickness measurement is known the tolerance and the method of measurement should be determined. Typically, thickness is measured across a web width and averaged to determine a value to compare to the target value. Tolerances should be set to include material and equipment limits and capability, and should be mutually agreed upon with the material supplier.

The ASTM standard F2251 provides a simple step by step method for measuring thickness. Of key importance is the interlab study creating the Precision and Bias statement of the repeatability and reproducibility. These measures performed on flexible materials with different equipment types provide a level of variability to be expected in labs (repeating tests) and from lab to lab (comparing labs).

ASTM F2251 Guidance

ASTM F2251 Standard Test Method for Thickness Measurement interlab study was run in 2001. Members of the SPMC Technical Committee planned and coordinated the study, created test samples of various flexible packaging materials used in the medical device industry, provided lab time with other volunteers for testing and completed the statistical analysis for the Precision and Bias statement.

Materials included: 2 mil PE, 2.5 mil PET/PE, 10 mil EVA/Surlyn/EVA, 4.2 mil Foil lamination, Uncoated Tyvek 1073B, uncoated 42# medical grade paper, 48 ga PET and a calibrated gage for bias testing.

Equipment included benchtop and handheld gauges with a variety of foot sizes.

Roll Width

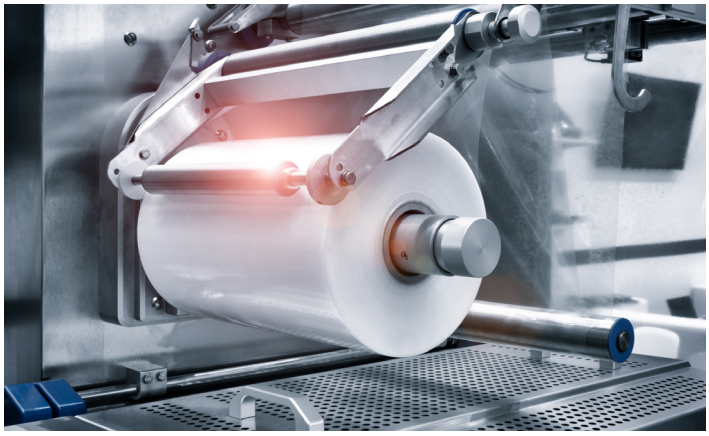
The final slit width of finished rollstock is determined by the final package size (possibly including print repeats), the equipment used to convert the rollstock into a finished package, and trim losses (if any) involved in that process. In most cases, the material supplier will produce the specified material in mill roll or master roll form that is optimized for raw material and equipment efficiency. For instance, a 6" (~152 mm) final width may be produced at 60-62" (1524-1575 mm) and then slit down to 6" prior to product release and shipment.

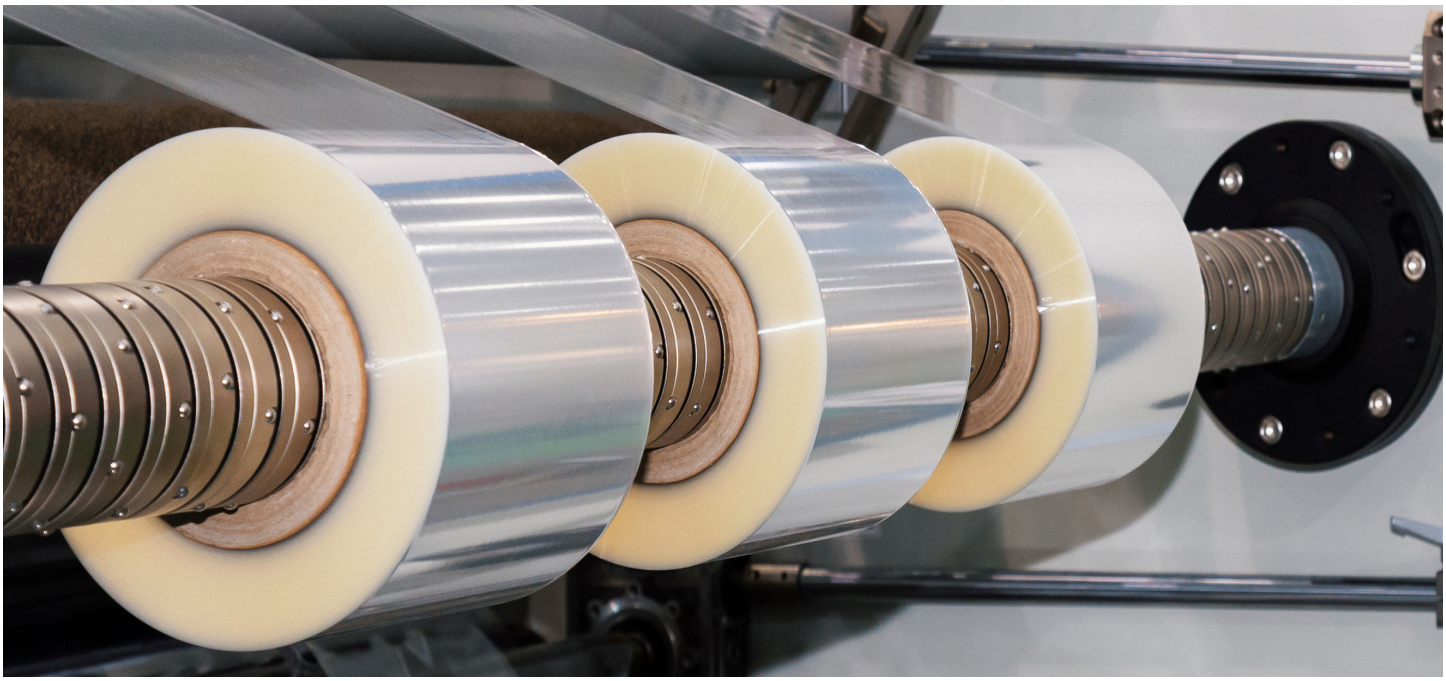
The tolerance required for a final slit roll can be driven by a number of factors. For instance, a thermoforming machine may have a roll width specified for the bottom web that is driven by the distance between the chains that move the film through the equipment and hold it stable during forming. Width tolerances for these applications are often written to allow slightly wider film but not narrower film, as film that is too narrow may not be gripped by the chains.

Other factors that may influence achievable width tolerances include the stiffness of the film, any slight bagginess that might be present in the film, and equipment capabilities in controlling web weave on downstream processing equipment. Film width tolerances of ± 2 mm or ± $^{1}/_{16}$ in are typical in the flexible packaging industry. Tighter tolerances may be achievable for certain materials and applications. However, very tight tolerances may result in a higher final cost for the material, since the set-up required for those tighter tolerances are typically longer, and additional waste may also be incurred. It is important to work closely with your sterile barrier material supplier to develop the appropriate film width specification and tolerance for your specific application.

Roll Diameter

The maximum roll diameter or roll length is another parameter that should be specified. Specifying both is not recommended as the roll length is calculated from the maximum roll outer diameter (OD) and might be calculated differently by the supplier based on material thickness variability, roll hardness or other factors. As part of the converting machine documentation, it is common for the equipment supplier to specify the maximum roll diameter and weight the machine unwinds can accommodate. It is advantageous for the MDM to maximize roll size (OD) since roll changes will be minimized at both the MDM and supplier thereby decreasing costs associated with downtime and waste. When determining the maximum roll OD, the weight and size of the rolls vs. the available roll handling equipment should be considered also. Once determined, the supplier will convert this roll OD to a target footage since roll size is measured and controlled by a footage counter at the supplier. The calculated target footage will factor in the material's thickness variability to ensure the maximum OD is not exceeded while maximizing the roll size.



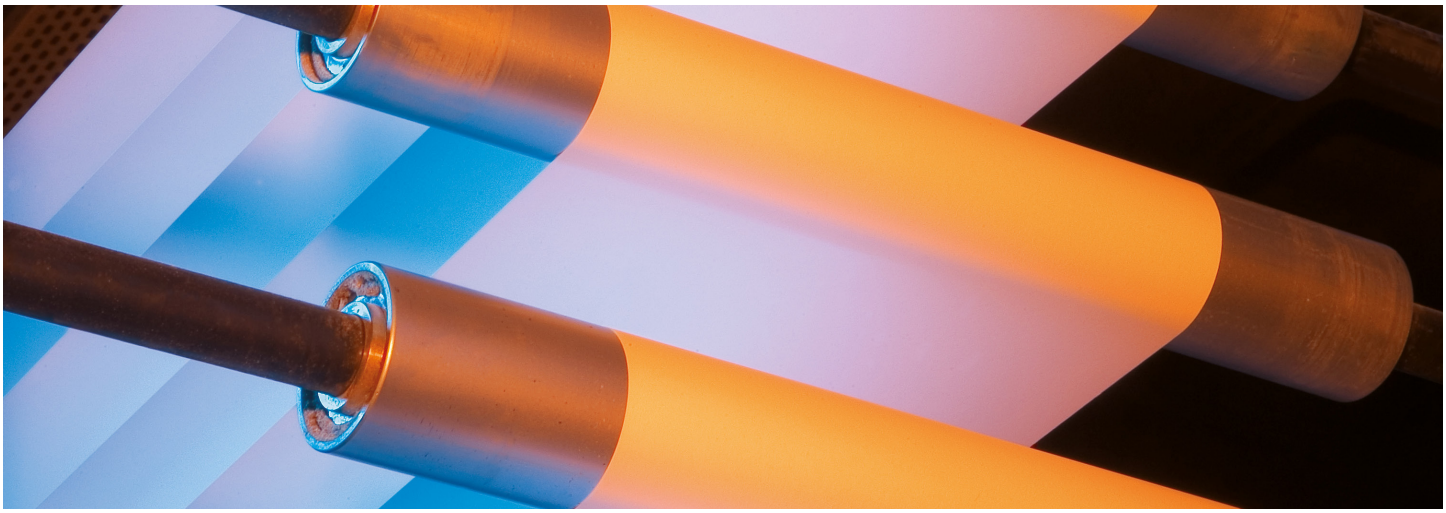


Splices

Section 6.5.4.1 of the guide states "The maximum allowable number of splices per roll should be indicated (typically 2 on rolls less than 300 mm (12 in.), 3 on rolls with an OD of 300 mm (12 in.) to 500 mm (20 in.) and 4 on rolls with an OD of 500 mm (20 in.) or greater)." The standard also indicates that the color, type, and width of the splice tape may be specified, as well as the type of splice to be used (like a two-side butt splice). Most downstream converting equipment is designed to handle rollstock containing splices, since splices are a normal part of flexible barrier material manufacturing. Raw films for lamination, such as oriented polyester and aluminum foil, for example, are rarely the same length. Therefore, a splice will be introduced into the master roll when a new raw material roll is spliced in the lamination process, which will need to be removed at slitting. Additionally, the raw materials rollstock may contain splices from the supplier. Removal of these incoming splices at the final slitting operation creates a break in the film that needs to be spliced together. These considerations, and others, necessitate the splice limits indicated above.

Core Type | Size | Width

Additional items that need to be specified involve the roll's core. First, the inner diameter (ID) is important to ensure the rolls fit on the unwind shafts or chucks of the converting machine. Common core IDs are 3" and 6" with 3" being the most common. In addition to the core ID, the material type should be specified. Fiber cores are most commonly used in the industry and the most economical. Many of these cores are impregnated with a wax, polymer or adhesive that self-seals the edges after being cut to minimize particulate. In special cases, plastic cores may be specified (e.g., rolls being used in a clean room). Another consideration is the core width or the length the core protrudes from the wound roll. It's not uncommon for a supplier to wind material on a core slightly wider or narrower than the material width. In the case of the core being wider than the material, it should be verified the maximum core width can still be loaded on the unwind. In addition, having the core protrude beyond the material width may result in the material being mis-centered on the machine depending on the design of the unwind. If the unwind cannot adjust the cross-machine position of the material after being loaded, the maximum core protrusion should be specified to ensure the material travels in the desired position of the machine.



Print Repeat

Print repeat (also referred to as cut-off) is a length of one printed package on the roll. In roll-fed processing, this print repeat is the cut or print length corresponding to the circumference of the printing plate cylinder. When a printed rollstock having a registered print repeat pattern is converted (for instance, on a medical device manufacturer's form-fill-seal equipment), the printed image appears in a repeating location on the formed packages. This is normally achieved by the provision of eyemarks or eyespots, which are often printed along the edge of the rollstock. As the printed roll moves across the converting equipment, an electric sensor (eye) on the machine reads the eyemark, controls the web material's position and coordinates the separation, sealing and cutting of the flexible packaging material. The eyemark, therefore, helps identify the location on the web where an individual package needs to be cut. When device packaging engineers are finalizing the print graphics, they must indicate the print repeat length along with the tolerance limits on their artwork specification. This print repeat length is normally measured as the linear distance between the consecutive eyemarks printed on the roll web. ASTM F99 lays out the requirements around specifying print repeat registration and the associated repeat tolerances.

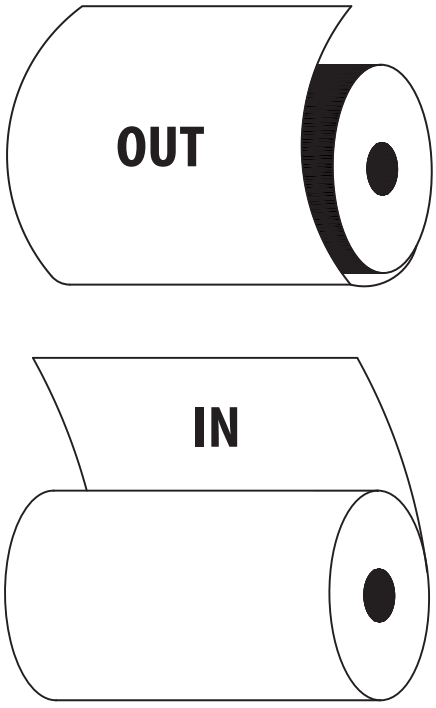
Regarding the specification of the print repeat tolerances, whenever possible, repeat tolerance 'over multiple impressions' is commonly specified. This ensures that all the cut-offs within the print cylinder repeat are within the acceptable specification limit. Sometimes, converting machines require the print repeat on the web to fall within a certain tolerance limit over an integral number of print repeats. As a result, this tolerance limit over multiple impressions must be called out in the specification, depending on the manufacturing requirements of that equipment. It is important that the MDM and the packaging supplier have a mutual agreement over this tolerance specification.

Another important factor for consideration when developing print repeat specifications is the tendency of the flexible packaging materials to stretch under tension. This may apply to the more extensible polymer-based films (ex: PET, PP, Nylon films) rather than more rigid substrates like paper or non-woven materials. Generally, during the roll winding operation, the rolls are wound tight near the core at the beginning of the wind and then the wind tension is gradually decreased as the roll diameter builds. This is known as roll wind taper profile. When extensible materials like films are wound on a roll, the varying tension in the roll may cause the material to undergo stretching to a lesser or greater extent, which may lead to variation in print repeat length. Therefore, tension variability is one of the factors to be considered while drafting print repeat specifications.

Wind Direction

In planning for efficient processing of rollstock consider how the web will be unwound from the roll at the final processing step. If the material is unprinted but has a coating or sealant on one side designed to seal to the top of a tray or forming web or to the bottom of a pouch-making heat seal operation, the selection of unwind direction is identified as coating or sealant wound OUT or IN. This would depend on the unwind equipment and process at the final stage of manufacturing the package. This is also referred to as Top (Out) and Bottom (In). (See Figure 1.)

FIGURE 1: Top (Out) and Bottom (In)



When a material is printed, the wind can be a critical component of rollstock specifications. Specifying a print unwind direction ensures a correct feed of web into the intended manufacturing process. If rollstock is to go through multiple unwinds before the final stage of use, select the correct unwind direction for the initial process feed of the web.

FIGURE 2: Printing Wound OUT — Numbered Direction of Print Coming Off the Roll

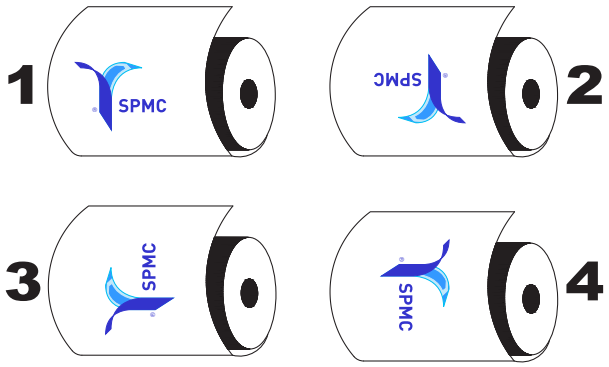
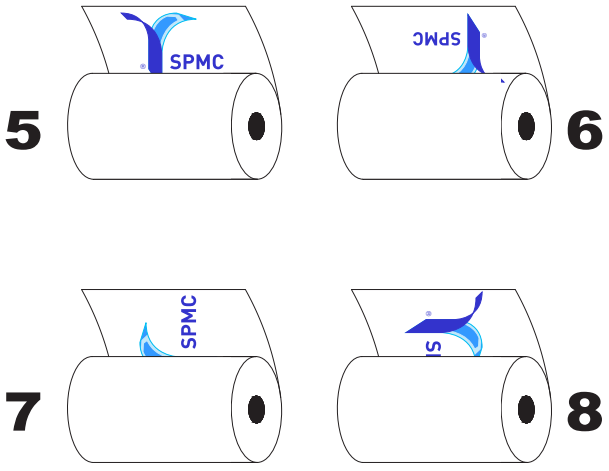
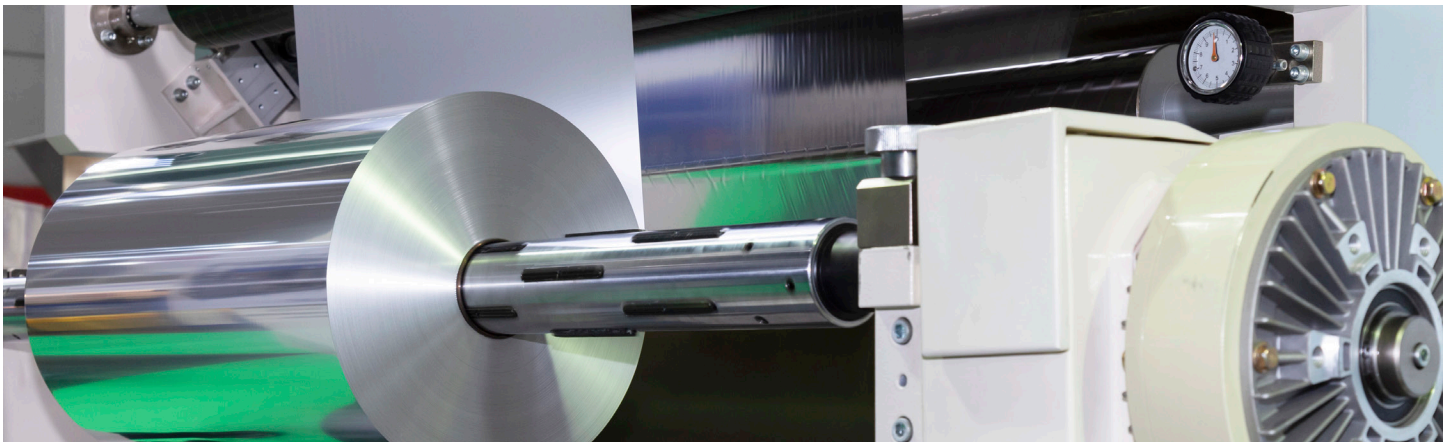


FIGURE 3: Printing Wound IN — Numbered Direction of Print Coming Off the Roll





Legibility

Print legibility is one of the critical elements of print requirements for a medical device package including any print graphics, as the key function of this printed content is to effectively communicate vital information to the end user. If the printed content is created in such a way that the information is easy to read and understand, the information pertaining to the packaged product can be interpreted by the end user correctly. Therefore, it is important to make sure that the print is legible and is not missing or incorrect, as per the specification requirement laid out in ASTM F99. Various factors like selection of the font type, font size, letter spacing, and contrast between print color and background can affect the print legibility, as they may have an impact on the user's ability to see, distinguish, and recognize each character and word.

During the print design stage, when the information on the print graphics is being created, the attributes of the packaging materials should also be considered. For instance, printing in the seal area is not recommended unless necessary, because the sealing process may affect the print legibility. Additionally, print in the seal area may also affect the sealability of a material.

During the various stages of package lifecycle, the printed packaging material goes through the stresses of sterilization, handling, distribution, and storage till the point of final use. So, there is a potential for damage to the print and the print legibility due to physical abrasion, scuffing of the text or graphics. Surface printed packaging films are vulnerable to such hazards. As a result, conducting the required print evaluations on the packaging materials is critical in order to demonstrate the ability of the inks to withstand those hazards. The goal is to maintain the print legibility till the point of its final use.

The legibility also needs to be safeguarded from the hazards posed by the exposure to different types of chemicals (acid, alcohol, water etc.) on the printed package during its lifecycle. Sometimes, there could be environments of use that involve wet hands or exposure to chemicals, for example. In such situations, the exposure to chemicals may degrade, soften, smear, or remove the print on the package, in turn, affecting its appearance and legibility. Surface printed web materials can be susceptible to such hazards, as the print surface is directly exposed to the external environment. In such cases, the ability of the printed inks or overprint varnish to withstand chemical exposure must be evaluated. ASTM F2250 (Standard Practice for Evaluation of Chemical Resistance of Printed Inks and Coatings on Flexible Packaging Materials) provides guidance to perform these evaluations. On the other hand, multi-layer laminations are commonly reverse/trap printed. So, as the printed surface is sandwiched between the clear print web and the adjacent web, the direct exposure of the printed side to the outside environment can be avoided.

Barcode readability is another important element as it relates to the print legibility of a package printed with 1D or 2D type barcodes. It can be affected by a variety of factors. Correct placement of barcode, appropriate dimensioning of the barcode symbols (size of the bars, distance between bars, aspect ratio, total symbol size), contrast between barcode color and background, and the printing quality on a variety of substrates are some of those key factors. These are all critical considerations in a barcode print design, as they will determine the ability of the barcode scanner to accurately read and decode the package information.

Summary

ASTM F99 ends with a section on Supplementary Requirements which includes three important points for achieving a high level of assurance in products.

6.8.1 Flexible barrier materials should be manufactured within a formal quality system.

6.8.2 Traceability of the raw materials used to produce each lot of flexible barrier material should be maintained back to the direct base material supplier.

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

The role of these critical points and the work to define requirements for repeatable and continuous quality rollstock serves the overall goal of patient safety.

SPMC Technical Committee and ASTM

The SPMC Technical Committee involvement in ASTM subcommittees has been a proven and longstanding commitment to medical device and packaging industries. Along with other packaging experts from medical device, food and consumer goods, testing laboratories, test device OEMs, logistics companies and others, we have worked to continuously create and improve consensus standards and to educate others in the value of their use.

We encourage others to contact us to suggest ways to improve these methods, to ask questions and to identify gaps in the current packaging standards. Contact us through the FPA site at **www.sterilizationpackaging.org** and post a question in our FAQ area or contact one of our member company contacts directly.

SPMC®

Sterilization Packaging Manufacturers Council

185 Admiral Cochrane Drive, Suite 105 • Annapolis, MD 21401

[tel] 410. 694. 0800 • [fax] 410. 694. 0900

[web] **www.sterilizationpackaging.org** • [email] **info@sterilizationpackaging.org**

[linkedin] **www.linkedin.com/company/sterilization-packaging-manufacturers-council/**

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