



Medical Device Packaging: Mastery of Design, Sterile Defense, and Compliance

Optimal Protection, Functionality, and Regulatory
Adherence for Effective Medical Packaging

Introduction

Medical device packaging isn't just about encasing a product - it's an intricate balance of design, sterile barrier defense, and regulatory adherence. This white paper expands on the nuances of creating a robust medical device packaging strategy, emphasizing its purpose in safeguarding products and facilitating ease-of-use. Central to this is the critical role of the sterile barrier system, serving as the first line of defense against contaminants and pathogens.

The following is a comprehensive overview of medical device packaging and includes detailed breakout sections on:

- Packaging Design and Purpose
- The Significance of Sterile Barriers in Packaging Design
- Sterile Barrier Testing Methodologies
- A Deeper Dive into Medical Packaging Standards

Industry professionals will find this guide to be an invaluable resource for their own medical device packaging solutions and efforts, and help to ensure the highest standards of safety, functionality, and compliance to build trust within the medical community and among its beneficiaries.



Packaging Design and Purpose

The foundational purpose of your packaging goes above and beyond mere aesthetics; it serves as the cornerstone of a well-conceived design strategy. The objective is to strike a balanced equilibrium among three critical variables: material protection, user-friendliness, and cost-efficiency. By conducting a rigorous analysis of the specific needs and functional demands of your device, you can architect a packaging design that is not only tailor-made but also achieves unparalleled security and success.

We often guide our clients through a series of key considerations, which form the building blocks for a cohesive and effective packaging strategy:

- Dimensional specifications of the device
- Composition and weight
- Regulatory compliance imperatives
- Compatibility with sterilization methods
- Ambient conditions: Temperature and humidity
- Essential layering
- Recommended storage conditions and environmental factors
- Logistics and distribution channels
- Labeling protocols

By giving due attention to these critical elements, you position yourself to create a packaging design that aligns seamlessly with the functional and regulatory requirements of your device, thereby ensuring its safety, usability, and commercial viability.

The Significance of Sterile Barriers in Packaging Design

The sterile barrier system stands as the most critical component in your medical device's packaging architecture. Serving as the initial shield against contaminants and pathogens, this element is pivotal in maintaining the sterility of your device throughout its distribution journey. Packaging commonly comprises multiple layers, each with distinct roles: Primary packaging offers direct contact and immediate defense against microbial invasion, secondary packaging adds an extra layer of protection, and tertiary packaging facilitates bulk shipping and storage.

Proper primary and secondary packaging minimize internal movement of a device or additional packaging elements, which is necessary to prevent movement-related abrasions or punctures that place the sterile barrier system at risk and compromise sterile integrity for the end user.

There are several different package design strategies to mitigate such risks, including:

- Using abrasion-resistant materials
- Incorporating cushion elements
- Using form-fitting designs

Validation testing should be performed to simulate external and internal stresses and confirm the sterile barrier's ability to effectively maintain device sterility from production to point-of-use. It is imperative to be familiar with ISO 11607-1:2019, "Requirements for Materials, Sterile Barrier Systems, and Packaging Systems" which outlines why validation of the sterile barrier is essential not only for compliance with regulatory norms but also for identifying potential vulnerabilities in your packaging design, thereby reducing risks of compromised sterility, and supporting both device and patient safety.

Sterile Barrier Testing Methodologies

ASTM F1886: Visual Inspection Test

This test offers an initial evaluation of the sterile barrier's integrity by conducting a meticulous visual inspection. Applicable to both rigid and flexible packaging types, this method requires transparency in at least one section where the seal is visible. Beyond the seal, the test checks for pinhole defects.

ASTM F88: Peel Strength Test

Primarily aimed at flexible barrier materials, the peel strength test quantifies the seal's resilience by measuring the force required for its separation. The test can also be extended to examine the bonding between flexible and rigid materials.

ASTM F1140: Burst Test and Creep Test

The burst test examines a package's capacity to withstand internal pressurization, essentially stressing the packaging until failure. The creep test, another segment under ASTM F1140, sustains a specific internal pressure for a predetermined duration or until package failure occurs. These tests are particularly relevant for flexible packaging of varying dimensions and seal configurations.

ASTM F1929: Dye Penetration Test

This test involves the application of a dye penetrant solution along the seal edges and inspects for leakage after a specified time. Three application methodologies can be employed: injection, edge dip, and eyedropper, making it especially useful for porous medical packaging.

ASTM F2096: Bubble Emission Test

In this method, the packaging is submerged underwater. The presence of a continuous stream of bubbles indicates a compromised sterile barrier. This test provides a straightforward yet effective way to identify any breaches in the packaging system.

A Deeper Dive into Medical Packaging Standards

When dealing with medical products, it's imperative to recognize that their packaging must adhere to a myriad of established standards before gaining the green light for distribution to the end user. This is not just a regional mandate; both the FDA and international regulatory entities underscore the importance of aligning with the ISO 11607 standard titled "Packaging for Terminally Sterilized Medical Devices." This pivotal standard delineates the testing prerequisites vital to ascertain that the sterilized package or device retains its design efficacy throughout its projected lifecycle. More specifically, it guarantees the product's resilience against potential challenges such as sterilization processes, shelf aging, transportation stresses, or storage conditions.

Leading Organizations Defining Packaging Testing Standards:

ANSI - American National Standards Institute

AAMI - Association for the Advancement of Medical Instrumentation

ASTM - American Society for Testing & Materials

ISO - International Organization for Standardization

ISTA - International Safe Transit Association

Key Standard Overview:

ISO 11607-1:2019

Central to medical device packaging is the ISO 11607-1:2019 standard, which stands out as a pivotal guideline for professionals in the field. As an international benchmark, it meticulously sets forth the specifications for materials, sterile barrier systems, and packaging systems. These parameters are crafted to preserve the sterile state of a medical device up to its moment of utilization.

Notably, this standard does not encompass the directives for sterile barrier and packaging systems tailored for aseptically manufactured medical devices. Yet it comprehensively delineates the testing mandates to verify compliance with the standard's prerequisites.

Principal Components of the ISO 11607-1:2019:

- **Packaging Systems:** Must be conceptualized and produced to maintain the sterile barrier's effectiveness and overall integrity throughout the entire distribution journey.
- **Materials:** Vital to the packaging process, materials employed within both the sterile barrier and the encompassing packaging system should be inherently non-toxic and non-pyrogenic. Crucially, they must harmonize with the sterilization techniques utilized for the encapsulated medical device.
- **Sterile Barrier:** This element's design and fabrication should be robust enough to endure the sterilization procedure while concurrently thwarting the intrusion of microorganisms.

By understanding and following the ISO 11607-1:2019 standard, professionals can provide the utmost safety and efficacy of medical device packaging, fostering trust and reliability in the medical community and among end-users.

Other Standards to Review:

ASTM

ASTM International is a leading global standards body that formulates and introduces technical standards for various materials, products, and systems. Predominantly influential in the US, it's recognized as the world's most extensive standards developer. Though the ASTM can't mandate its standards, governments can enforce them. The organization's consensus-driven approach involves numerous global volunteer committees maintaining over 12,000 standards. These include:

- **Standard Specification:** Outlines requirements for a subject.
- **Standard Test Methods:** Details how tests are to be conducted for compliance evaluation.
- **Standard Practice:** Describes operations without producing results.
- **Standard Guidance:** Offers information without endorsing any actions.
- **Standard Classification:** Categorizes based on attributes like origin or properties.

ISTA

The International Safe Transit Association (ISTA) stands as a pioneering authority in package performance testing, having set standards for over six decades. These benchmarks dictate how packages should protect their contents during various stages of transit. Renowned globally, ISTA's methods harness the latest technology and real-world transport data, ensuring alignment with the ISO 11607 standard.

In the modern era, the emphasis on effective and efficient packaging is paramount. Through ISTA's rigorous standards, the industry is steered towards creating resilient and sustainable packaging solutions. By adhering to ISTA's principles, manufacturers not only enhance the integrity of their products but also solidify their brand's reputation, and guarantee safe transit of goods.



Life Science Outsourcing

Bringing Medical Innovations to Life

Life Science Outsourcing is a performance-driven Contract Manufacturing Organization. Our unique model leverages in house end-to-end solutions and service offerings, coupled with deep regulatory knowledge. This allows us to provide the agility and flexibility that customers need to accelerate their go to market launches, while streamlining their supply chain and mitigating risk.

Our core services include: assembly, packaging, medical package testing, sterilization, reagent packaging & design, thermoforming, and resorbables.

Need Assistance?

Life Science Outsourcing is an ISTA-certified packaging test lab (ID ST-2339), delivers comprehensive packaging solutions that adhere to regulatory standards and endure the demands of shipping and distribution. Our testing services include Package Validation Testing, Distribution Simulation Testing, Accelerated Aging & Realtime Aging, among others. Aligned with ISO 11607-1:2019, our services comply with FDA, ISO, EN, and CE Mark requirements. We offer detailed evaluations, bespoke protocols, in-depth results, and extensive final reports.

With over 25 years of experience and 1,800 clients served, our team is equipped to support your medical packaging testing needs, including ISO 11607:201 compliance. We aim to accelerate your growth through our expansive ecosystem of services.

Contact us at info@lso-inc.com for expert assistance.
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