Life Science Outsourcing

Bringing Medical Innovations to Life

Reduce Time to Market and Cut Costs with Pre-Validated Packaging Solutions for Medical Devices

Introduction

Medical device package design can be a complex process that requires significant time and budget investments. Medical device manufacturers have increasingly turned to pre-validated packaging to mitigate such challenges. Pre-validated packaging has become a useful tool with considerable advantages over traditional custom-built packaging and can streamline the packaging process to prevent supply chain issues and deliver products to market faster, with reduced costs and fewer testing requirements.

This white paper will examine pre-validated packaging definitions according to ISO 11607, pre-validated options such as trays and pouches, and explore the many benefits of pre-validated packaging to medical device manufacturers looking for packaging process efficiencies.

I. ISO 11607 and Packaging Definitions

The International Organization for Standardization (ISO) created ISO 11607: Packaging for Terminally Sterilized Medical Devices as an industry standard to specify requirements and test methods for medical device packaging materials, preformed sterile barrier systems and packaging systems to ensure sterile barrier reliability. Packaging must prove resilient enough to withstand various tests, including environmental, distribution, and accelerated aging.

Medical device manufacturers can better strategize packaging priorities and approaches by understanding ISO 11607 packaging terminology that defines the nuances of a packaging system.

DEFINITIONS

Sterile barrier system

The minimal packaging necessary to reduce the risk of microorganism ingress and facilitates aseptic presentation of the sterile contents at the point of use.

Protective packaging

The configuration of materials designed to prevent damage to the sterile barrier system and its contents from the time of their assembly until the point of use.

Preformed sterile barrier system

A sterile barrier system that is partially assembled for filling and final closure or sealing.

Packaging system

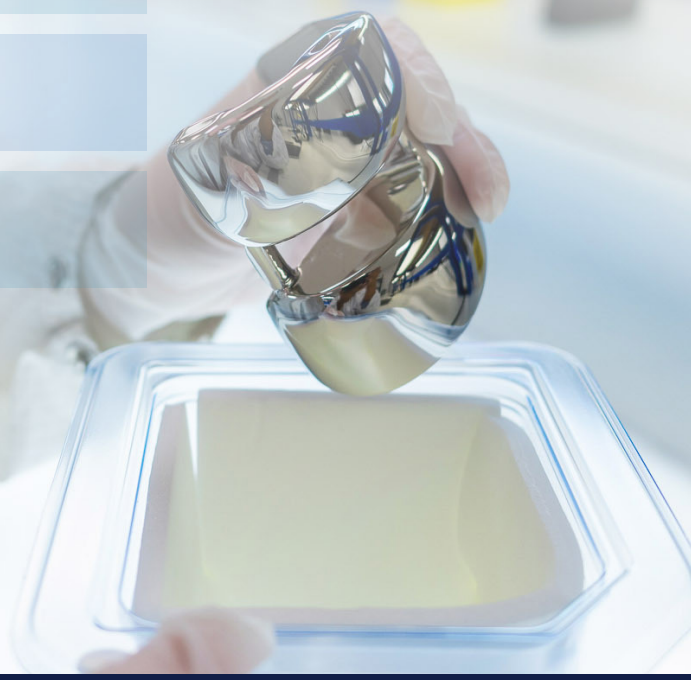
The combination of the sterile barrier system and protective packaging.

A packaging system should be effectively designed to protect the device and the sterile barrier during shipping, handling, and storage. Custom-built packaging can address these issues but has longer development timeliness to meet multiple stringent design requirements and standards. Pre-validated packaging expedites the process by eliminating customization delays.

II. Pre-Validated Packaging Advantages

Pre-validated packaging is an ideal solution over custom packaging, with ready-made industry compliance standards built in. Additionally, pre-validated packaging significantly reduces lead time and costs so common to custom package development and validation by eliminating the need for extensive design, testing, and regulatory approvals:

- Package materials have been selected and documented within a quality system
- Sterile barrier system materials and seals have proven ability to maintain sterility over time
- Completed qualification testing
- Various sterilization methods compatibility
- 5-year shelf-life validation
- Leverages economies of scale
- Prevents supply chain issues or delays
- Has undergone accelerated aging testing

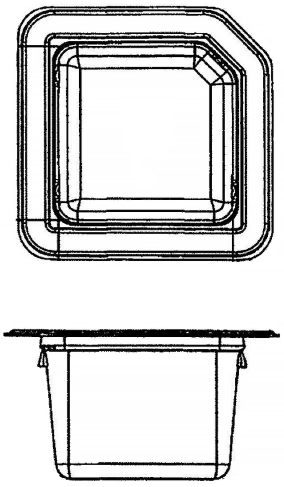


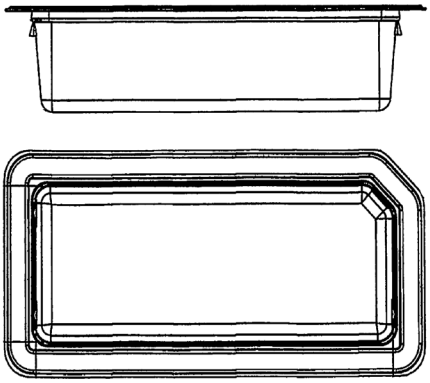
An LSO specialist places an orthopedic implant into a medium-sized pre-validated tray.

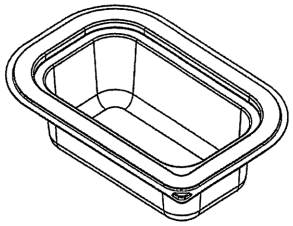
III. Pre-Validated Packaging Options and Benefits

PRE-VALIDATED TRAYS

Pre-validated trays are designed to accommodate a variety of medical devices. They offer robust protection and are often made from high-pressure resistant materials. Their compatibility with many sterilization methods, including ethylene oxide (EtO) or gamma sterilization, allows them to be faster and more reliable path to market.

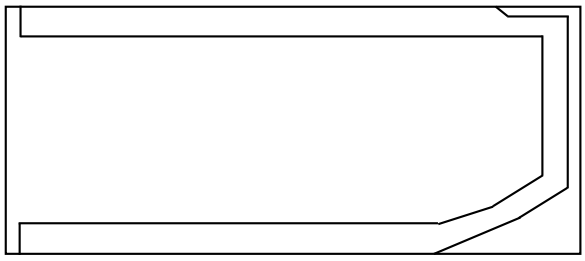




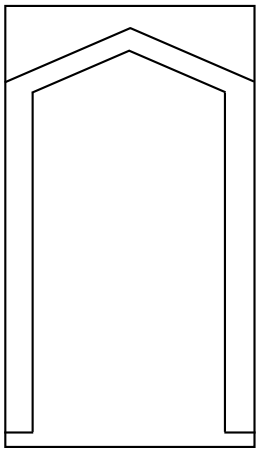


PRE-VALIDATED POUCHES

Pre-validated pouches also provide a flexible, cost-effective packaging option for medical devices of varying sizes. They are available in multiple configurations, such as corner peel and chevron styles, and meet requirements for many sterilization methods. Much like pre-validated trays, pre-validated pouches can also reduce time to market by eliminating many of the extra steps in custom packaging must endure.



LSO Corner Peel Pouch



LSO Chevron Pouch

The benefits of pre-validated pouches and trays directly impact your budget and bottom line in four positive ways:

COST

Pre-validated packaging significantly reduces the cost of materials, design, and labor, making them cost-effective and resource efficient.

TIME

Pre-validated packaging options are ready for immediate use and are market-ready, whereas traditional packaging solutions can delay product launches by 6 to 12 months with their many custom steps and validation requirements.

DESIGN

The established designs of pre-validated packaging have already been tested and validated, eliminating the need for extensive design trials and errors. This allows companies to focus more on innovation, rather than packaging compliance.

TESTING

The amount of testing for pre-validated packaging is significantly reduced because it has already been designed to comply with industry standards and meets all regulatory requirements for sterility and safety over its intended shelf life.

TIMELINE: LSO REDUCES TIME TO MARKET

Using pre-validated packaging saves considerable time in the product packaging process.

Pre-Validated Packaging Timeline: **1-2 months**

1 Concept & Design

LSO has already completed all the necessary design work for the packaging, creating several trays and pouches to meet all your needs.

2 Material Selection and Testing

LSO manufactures its trays using high-pressure resistant PETG and employs high-quality materials such as polyethylene, nylon, Tyvek, and other rigorously tested substances. The same high standards apply to our unit cartons, which are made from solid bleached sulfate.

3 Prototyping and Validation

LSO has already carried out accelerated aging and sealing validation for our pre-validated packaging, saving you a minimum of six months. You only need to conduct a distribution simulation, which can be completed in just a few weeks.

4 Scaling Up Production

Pre-validated packaging capitalizes on economies of scale. Having mass-produced these solutions for years for multiple customers, we have well-established supply chains and redundancy measures in place. There are no lead times!

Traditional Packaging Timeline: **More than a year**

1 Concept & Design *(1-3 months)*

This initial phase focuses on identifying packaging requirements based on the medical device's size, sensitivity, and sterility needs, with design iterations and prototyping used to refine the concept.

2 Material Selection and Testing *(2-4 months)*

Selecting suitable materials is essential for device protection and sterility, ensuring compliance with regulatory standards and suitability for intended use and distribution. This stage involves durability, stability, and compatibility testing.

3 Prototyping and Validation *(3-6 months)*

During this phase, packaging prototypes are created and tested to validate the design and materials through stability, shelf life, and transport simulation tests, ensuring they can withstand real-world conditions.

PACKAGE TESTING	Accelerated Aging *(6 months)*	Sealer Process Validation *(1-2 months)*	Distribution Simulation *(1 month)*

4 Scaling Up and Production *(2-6 months)*

Once the packaging design is finalized and approved, the next step is to scale up production. This involves setting up manufacturing processes, quality control measures, and logistics for distribution.

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?

Medical device manufacturers can leverage the flexibility and reliability of pre-validated packaging options for their devices. They present a strategic advantage with faster, more cost-effective and compliant solutions that guarantee product safety and integrity and can accelerate product launch timelines. Pre-validated packaging has become a popular choice for its undeniable benefits in cost, design, and testing efficiencies.

Get started with pre-validated packaging solutions! Life Science Outsourcing is an industry leader with over 25 years of experience providing medical device packaging solutions that expedite time to market and provide immediate efficiencies and benefits. Contact us today!

ista® CERTIFIED TESTING LABORATORY

LSO West
(714) 672-1090
830 Challenger Street
Brea, CA 92821

LSO East
(603) 692-9955
25 Centre Road
Somersworth, NH 03878