



Device Packaging: Top 10 Mistakes

Packaging is almost as important as the device itself.

Packaging for medical devices plays a key role in safely delivering specialized treatment to patients. Most single-use, sterilized medical devices can be opened with a high degree of confidence that it has remained sterile throughout storage, handling, and transportation.

What makes packaging doubly important is that regulatory authorities recognize the critical nature of sterile barrier or primary package by considering them components or accessories to the medical device. This implies that packaging is almost as important as the device itself. And it is. If a package does not, for instance, keep a pacemaker sterile, patients will be put at risk.

The design and development of packaging has rightfully come under closer scrutiny by international and domestic regulatory agencies. This scrutiny has placed a great deal of emphasis on standardizing package development. Some standardization comes in the form of the international standard [ISO 11607: Packaging for terminally sterilized medical devices](#).

Below are 10 common mistakes that companies make when developing and validating packaging systems for terminally sterilized (inside a closed package) medical devices.

1. Losing sterile integrity

This is the most common defect in medical packaging and can happen from fractured thermoforms along with pinholes, slits, cuts, and tears in pouch packages. These defects come from handling (or mishandling), vibrations during transportation, storage, and impact caused by dropping.

2. Cutting too many corners

Many people in manufacturing are unaware of the need to test their packaging, or the existence of the ISO 11607 standards and the fact that these standards are being used by the FDA and the European Community. So they try to validate the packaging “on the cheap” without using sound, scientific practices. In their haste to get a product to market, companies risk non-compliance with regulations, or worse yet, they risk unknowingly let suspect devices reach patients.

The time to properly validate a full-package system depends on the product’s shelf life and its expiration date. For example, it usually takes three to six months to go from package concept to final qualification for a one-year shelf life. The validation schedule should also allow for unexpected events, such as finding pin holes in the packaging after a test.

3. Not prequalifying package and product for compatibility

A common package development mistake skips the preliminary evaluation and just dives into package validation. Cutting corners to trim time is short-sighted and usually backfires by extending development schedules and increasing overall validation costs because some part of the package fails. That means retests.

A few common prequalification tests that should be used to detect potential design and manufacturing problems include seal strength and integrity tests on manufactured packages. A seal test, for instance, measures the force needed to open a seal.

Such tests point out potential deficiencies in manufacturing and may indicate the production line needing corrective action. This should be done far in advance of testing package performance, such as for transportation, sterilization, or handling. Prequalification tests should also be the basis for establishing targets for process quality control.

Another test used to prequalify package-product compatibility is dynamic testing associated with transportation and handling. A shaker table reproduces the frequencies and amplitudes that the shipping container is likely to experience, for a prescribed duration.

Most sterile medical-device packages do not typically lose sterility simply sitting on a shelf. Failures often stem from events in manufacturing, during shipping to the sterilization facility, or during distribution. Therefore, proposed packages should always undergo a prequalification to isolate potential hazards and determine the package response to each of those hazards.

4. Ignoring the worst-case scenario

It is often difficult to determine which shipping configuration to validate. Should you test just one product in one package? Or four products in a box?

To determine the worst-case scenario, it is necessary to decide the most common shipping configuration before validating the package. In this way, other package configurations of the same or similar products may be covered by one validation.

In fact, a few ISO 11607 guidelines work to device manufacturers' benefit. For example, a provision allows validating families of packaged products rather than individual configurations.

5. Not developing protocols

Before working on a validation, write a protocol. It provides a blueprint for how testing will be done, including its purpose, scope, responsibilities, parameters, production equipment and settings, and acceptance test criteria.

Validation qualifies the materials and processes that make the complete package. If one process is not right, the entire system breaks down and the manufacturer risks harm to patients.

6. Having the wrong sample size

The question 'what is the right sample size for testing' is one of the most daunting to answer. Many factors play a role in determining sample size including what type of test it is (e.g. quantitative/variables or qualitative/attributes); what is the sample population; how many samples are available for testing; what are the economics; and what are the risk factors (e.g. confidence intervals). Most often, the sample size is too small and renders results with no statistical significance.

7. Using the wrong package type/material

Using the wrong package type or material for the product is a package-product compatibility issue, which could have been avoided if pre-qualification of the packaging had been done at an early stage. Some of the typical observations that are prevalent include fracturing of thermoform trays as a result of using the wrong plastic material for the intended product (for instance, if the product mass is too great for the impact resistance of plastic).

This can be avoided for large, massive products by using a high-impact resistant plastic, such as polycarbonate, to reduce the possibility of fracturing during normal distribution and handling. The thermoform design is also critical to ensure that the product is held in place firmly so that a loose product is not jettisoned through the tray lid and fracturing of the plastic doesn't occur from the inside-out.

8. Squeezing oversized pouches into cartons

Pinhole defects in pouches can be reduced by inserting the pouch into a carton without folding, wrinkling or creasing the ends. Pinholes occur at the junctures of the creases and folds when they are vibrated, causing the intersection to be 'worked' or fatigued at the juncture. This effect is exacerbated by making complex folds of the pouch causing a very concentrated point of stress at the juncture of the materials. This can be circumvented by using secondary packages (cartons/shelf boxes) that are large enough to allow insertion of the pouch without folding.

9. Not recognizing Tyvek[®] separation as a false-positive

One phenomenon that was discovered some years ago, but only really came to light when medical device

packages began to be integrity tested routinely using bubble and dye-leak methods, was 'sheet separation' of the porous web of Tyvek®.

In integrity tests, this 'sheet separation' appears as false-positive when the material is bent, folded, or wrinkled. DuPont has proven that this phenomenon does not change the sterile barrier performance of the material and that any leakage of air or dye solution is only along the transverse direction of the material and not between the Tyvek® and poly material, as would be the case in an adhesive (seal) failure. There is no loss of filtration capability when this occurs.

However, when performing these tests, it is incumbent upon the tester to analyze the failure carefully. In some cases, when there is a suspect 'false-positive,' it may be necessary to look at it under high magnification to determine the cause of the leakage.

10. Performing accelerated aging at high test temperatures

In ill-conceived attempts to reduce costs and time, some manufacturers decide to accelerate the shelf life or expiration date studies to unrealistic and indefensible limits, usually by raising the test temperature to a level that causes packages to melt down, warp, or change in other uncharacteristic behaviors. In addition, temperatures over 65°C are indefensible based on the rationale typically used to justify accelerated aging protocols.

Accelerated aging is performed on packaged medical devices to document expiration dates for products. Real time aging can be performed; however, products are often obsolete by the time a three-year expiration date is validated. The FDA does not require expiration dating for products without components with a defined effective life such as batteries, while European Directives imply that all sterile medical devices must have an expiration date. Therefore documented evidence must exist to substantiate those claims.

Temperature selection for the accelerated aging study should avoid unrealistic failure conditions, such as deformation due to melting. This advice is sometimes ignored in the haste to bring products to market faster.

As critical as packaging is, some companies occasionally don't take it seriously, considering it too late in the design cycle, cutting corners, or using inappropriate materials. Avoid these above mistakes and plan well in advance to develop and validate your packaging.

About the Author:

Patrick J. Nolan is the Chief Operating Offer at DDL, Inc, which offers comprehensive package, product and material testing and validation services, designed specifically for the medical device industry.

Patrick has over 27 years of experience in the testing and analysis of packaging and products for shock and vibration hazards inherent in the distribution system. He serves the package testing industry as Chairman for the ASTM committee D-10 on Packaging and is also a member of the AAMI committee to draft a Technical Information Report, which identifies 11607 compliance regulation guidelines.

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