

The Powers of Destruction

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Destructive testing of sterile medical packaging has become increasingly crucial to package validation, but OEMs need to continue their education

By: Shana Leonard

The establishment of ISO 11607 for packaging for terminally sterilized medical devices, as well as the subsequent modifications to the standard several years ago, has dramatically altered the role of medical device packaging. "Back in 1997, FDA made it mandatory that a package be designed, evaluated, and produced basically under the same conditions that a device is," says Stephen Franks, executive vice president of testing equipment manufacturer **TM Electronics Inc.** (Boylston, MA; www.tmelectronics.com). "That's become very important to anyone in the industry—to produce a package that's equally as valid as the product that they're making."



TM Electronics's Integra-Pack tester performs both seal strength and leak testing operations, as well as additional common package tests.

As part of this emphasis on package quality, destructive testing methods have become increasingly important to ensuring and proving the safety and efficacy of sterile device packaging. And while packaging industry professionals agree that medical device OEMs have made significant strides in their understanding and development of sterile medical packaging, there are still misconceptions to correct, tips to be learned, and best practices to undertake.

Make It A Priority

As OEMs know, it's typically a long and difficult process to design and develop a medical device. And the intense pressure to bring the product to market as fast as possible is ever present. So why run the risk of unnecessary or costly delays or even redesigns in the late stages of the development cycle?

It may seem like a silly question. But OEMs may not be as concerned with packaging as early in the process as they should be, according to contract package testing labs. Packaging is not always an afterthought anymore, as was often the case prior to ISO 11607 and similar standards; yet, it does not seem to always garner the attention it deserves, packaging professionals profess.

Rather than being an afterthought, packaging should be a forethought, concur contract packaging companies. "Companies need to really step back and bring package engineering into the forefront when they're looking at a particular product so that they can match up the right product with the right type of package," advises Scott Levy, packaging engineer for **DDL Inc.** (Eden Prairie, MN; www.testedandproven.com). The company is a third-party testing facility that helps medical device manufacturers satisfy the regulatory requirements of ISO 11607 through such test methods as accelerated aging, thermal conditioning, package strength, package integrity, and distribution simulation, among others.



Tray sealing at Life Science Outsourcing, Medical Package Testing Div. is followed by in-line leak testing in the facility's cleanroom.

Life Science Outsourcing, Medical Package Testing Div. (LSO; Brea, CA; www.lso-inc.com), which specializes in the sterile package testing of disposable medical devices, also points out that OEMs could benefit from preliminary testing. “Sometimes when we receive a package and do the test, we see immediately that there is a defect; something falls apart or the product does not stay properly in the tray, for example,” says Barry Kazemi, president, LSO. “We try to advise our clients that when there is a decision point—before they do a full validation—for them to send some samples to us so we can go ahead and do some sort of quick or limited test for them. Sometimes these things don’t get done up front and they assume that something’s going to work well and, by the time they come to us, it’s too late.”

Strength vs. Integrity

Although OEM understanding of and emphasis on package quality has come a long way in recent years, package testers agree that there remains in the industry some confusion regarding the difference between the strength of a package and its integrity. “Package strength evaluates the overall strength of the package—the seals that are being made. That’s all it does,” clarifies Levy. “Package integrity validates the efficacy of the sterile barrier, meaning if the package has no voids, holes, channels in it, everything inside that package is still sterile.”

Franks of TM Electronics elaborates, commenting that many OEMs try to achieve one through the other. “Everybody says they want to test the leak integrity of the package, but it doesn’t do any good if the seals are so weak that when the product gets to a customer, the seals are open,” he says.

To safeguard against such a misconception and to promote better, more-convenient testing, TM Electronics has introduced the BT Integra-Pack tester, which performs both seal strength and leak testing operations, as well as additional common package tests. “There are two functions that you want to be sure that you test in the package as part of the 11607 paradigm,” Franks states. “You want to be able to test that the strength of the seals are adequate and, from a production point, where you want them to be in terms of seal strength. And that the packages don’t leak after they’re sealed.” The tester conducts seal strength tests by either filling the package with air until it breaks or bursts, or placing a load on the package and examining whether the seal fails.

Compared with prior generations of the company’s combined leak and seal strength technology and current competing products on the market, the BT Integra-Pack boasts a more-automated operation, according to Franks. Whereas competing testers require the input of certain test parameters associated with the package, the BT Integra-Pack, he says, will test almost any package automatically. He adds that its sophisticated nature allows for manual operation and control of ramp rate, for example, if desired by the user. “So, if you have any special types of packaging or special configurations, it will allow you to do these things manually as well,” Franks says. The tester can work with almost any type of medical packaging, including such popular materials as spun-bonded olefin, commonly known as Tyvek.

Advanced features of the package tester also include input-output functions enabling connectivity to USB printers, PCs, and LANs for sharing data. It can also store virtually unlimited quantities of data owing to its installed Flash memory and can be run remotely. These connectivity and data-collection features facilitate the obtaining and sharing of information required by OEMs and FDA.

Is It the Outside that Counts?

Proper sterile medical device package testing doesn’t end at leak, burst, or accelerated aging testing, however. To ensure that a package can genuinely withstand many of the real-world environments it will encounter, testing labs strongly recommend distribution simulation. Also known as transportation simulation, this technique entails placing the sterile packages in corrugated shippers, replicating the shipping environment in a laboratory, and conducting a series of shock and vibration tests.

“For medical device manufacturers, transportation simulation is probably the most critical element in their validation,” Levy says. “The main reason is they have to ship these samples from Point A to Point B. They want to make sure that once they get from Point A to Point B that the sterile barrier has not been compromised.” The importance of this test method, according to Levy, lies in its repeatability. He points out that if a package experiences a failure, the same conditions can be repeated in the laboratory simulation to ensure that the issue has been corrected.

But despite its agreed-upon importance, this area of testing still has some issues to iron out, it seems. OEMs, for example, have to better define what they deem acceptable in terms of cosmetic defects to the shippers, according to Kazemi. As long as the shipper fulfills its purpose of protecting the interior sterile packaging pouch or tray, it passes the overall simulation test, he explains. However, the shippers may experience slight cosmetic defects from such tests, such as bent corners, or the interior cartons may be slightly compressed. As a result, client expectations can differ from those outlined in testing standards.

“The definition of cosmetic rejects and defects on a distribution simulation is something that requires a little bit more attention,” Kazemi states. “We know the content of your package is safe, sterile, and it passed. But your carton doesn’t look as good. What is your opinion about the cosmetic issues of the carton?” To confirm that LSO and its customers are on the same page, Kazemi notes that the company has begun asking many more questions up front to properly define what is and is not acceptable in terms of cosmetic defects for the client.

“Nobody’s happy when a package fails,” Kazemi concludes. That sentiment is an undeniable fact whether it refers to the inability of a package to meet criteria set forth by packaging standards or the expectations of an OEM.

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