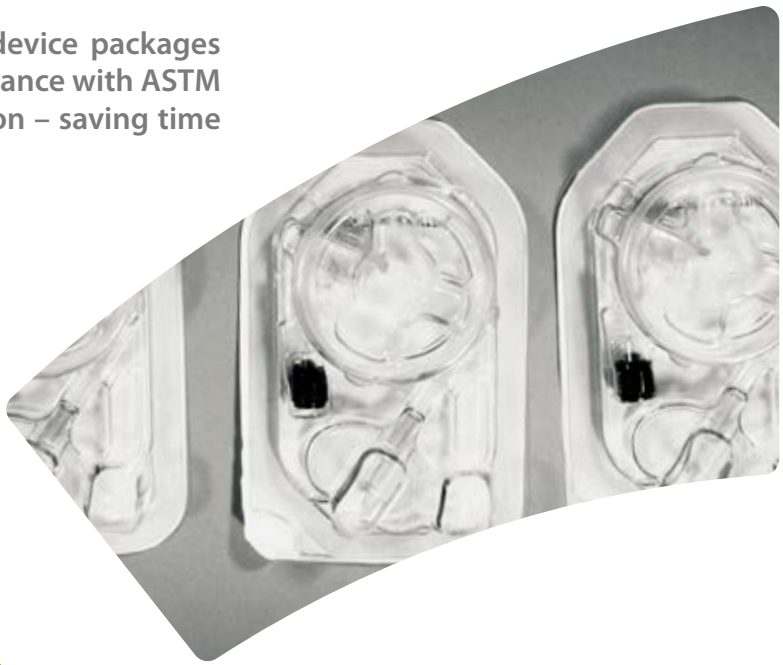
APPLICATION NOTE

TESTING THE SEAL STRENGTH OF POROUS MEDICAL DEVICE PACKAGES

Now porous, sterilized medical device packages can be tested efficiently in compliance with ASTM F2054 without tedious preparation – saving time and lives.



Introduction

After primary packaging, medical devices are sterilized in various ways (e.g., chemically with ethylene oxide (EtO), physically with steam, irradiation). Some of these processes require a portion of the package to be breathable. This is accomplished with gas-porous materials such as medical-grade paper and Tyvek® which allow penetration of sterilant but not microorganisms, and provide excellent seal and peel functionality when properly applied.

ISO Standard 11607-1:2006 *Packaging for terminally sterilized medical devices*[1] specify test methods for materials, preformed sterile barrier systems, sterile barrier systems and packaging systems. Essentially, seal strength and package integrity[2] must be validated to ensure the protective packaging will uphold

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the product's sterile barrier and that it has no channel leaks. The mechanical seal strength must withstand the rigors of production, sterilization, distribution and storage, yet be easily opened by healthcare professionals.

ASTM F88 Standard Test Method for Seal Strength of Flexible Barrier Materials regards opening force, package integrity and the ability to produce consistent seals. However, F88 is limited to testing portions of the packaging material rather than the complete package. The process of cutting a small piece out of the sealing and testing it with a tensile tester must be done for all four (4) sides of a package, meaning 4 samples must be prepared and tested. Moreover, the results do not represent the complete package; a weak sealing point may have been missed.

ASTM F2054 enables accurate testing of the whole package's seal strength (i.e., selectively missing a faulty portion is avoided). If there is a weak point in the package, it will be detected by this method.

Challenge

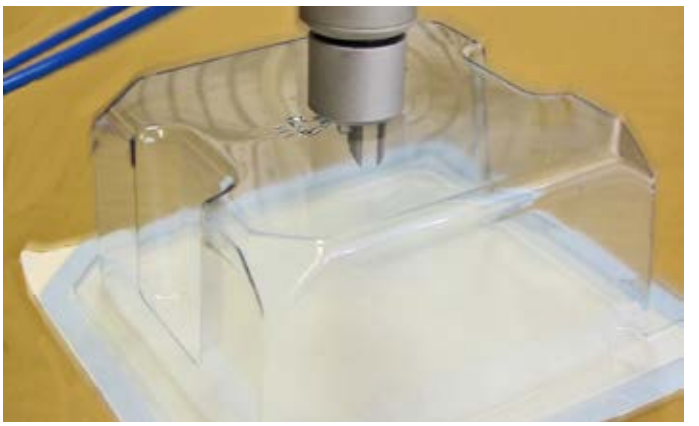
The difficulty in testing the seal burst strength of whole, finished packages containing porous barrier materials is providing sufficient air flow. Air escapes through the porous material faster than it can be supplied into the package to maintain the necessary pressure. Masking or coating could be applied over the porous material but is time-consuming and also requires exacting technique to obtain reliable results.

Solution

With slight modification, an optional high-flow valve and dual needle, the Lippke 4500 system quickly locates the weakest seal area. In lieu of masking or coating the porous area, the high-flow valve pressurizes the porous package enough to compensate the flow/pressure loss through the porous material until the seal bursts. The system's restraining plates ensure uniformity of stress along the package's perimeters, and the specially-designed needles (one for trays and another for pouches) separate pressure 'fill' and 'sense' lines. The internal pressure of the package is increased at a given rate to the point at which the seal bursts, and then empirical data can be analyzed and archived.

Benefits

Now finished, porous, sterilized medical device packages can be efficiently tested for seal burst strength in compliance with ASTM F2054. Bypass time-consuming test sample preparation and increase testing throughput. Generate objective, quantifiable seal strength results for conformance reference, packaging line troubleshooting and trend analysis. Most importantly, achieve a higher standard of quality control to deliver safely-packaged, sterilized medical devices to market while preventing costly recalls and saving lives.



Testing a medical device package using the Lippke 4500 with dual needle.

Footnotes

1. ISO Standard 11607-1:2006. Available from: ISO website: https://www.iso.org/standard/38712.html; Retreived on: September 15, 2017

2. Package Integrity is defined as the physical capability of a given package to protect its contents with the desired level of protection over a defined period of service; for example, as a barrier to physical, microbiological, or chemical challenges. ASTM F17-17, "*Standard Terminology Relating to Primary Barrier Packaging*". Retreived September 1, 2017, from https://www.astm.org/Standards/F17.html

To discuss your unique medical device packaging application or challenges, contact your local MOCON representative.

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