

TESTING THE SEAL BURST STRENGTH OF POROUS MEDICAL DEVICE PACKAGES

Efficient testing of porous, sterilized medical device packages in compliance with ASTM F2054

After primary packaging, medical devices must be sterilized; some sterilization processes require a portion of the package to be breathable.

It is necessary to test the seal burst strength of a package to ensure the product remains sterile and protected.



Products such as syringes must be sterilized after primary packaging

Challenges arising from sterilization of packaged medical devices.



Porous materials must be well-sealed to ensure the product remains sterile

After primary packaging, medical devices are sterilized in various ways (e.g., chemically with ethylene oxide, 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®¹ which allow penetration of sterilant but not microorganisms, and provide excellent seal and peel functionality when properly applied.

[ISO Standard 11607-1:2019 Packaging for terminally sterilized medical devices](#) specifies test methods for materials, preformed sterile barrier systems, sterile barrier systems and packaging systems. Essentially, seal burst strength and package integrity must be validated to ensure the protective packaging will uphold the product's sterile barrier and that it has no channel leaks.

CHALLENGES TESTING SEAL BURST STRENGTH OF MEDICAL PACKAGING

Traditional methods for testing seal burst strength are time-consuming and imprecise.

The mechanical seal burst 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](#) addresses 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 seal and testing it with a tensile tester must be done for all four sides of a package, meaning four samples must be prepared and tested. Moreover, the results do not represent the complete package; a weak sealing point may have been missed.

[ASTM F1140/F1140M Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages](#) and [ASTM F2054/F2054M Standard Test Method for Burst Testing of Flexible Package Seals Using Internal Air Pressurization Within Restraining Plates](#) enables accurate testing of the whole package's seal burst strength (i.e., selectively missing a faulty portion is avoided). Any weak points in the package will be detected by this method.

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.

A purpose-built package leak testing system.

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.

Achieve higher quality control standards with the Dansensor® Lippke® 5000.

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 burst 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.

Footnotes:

1. Tyvek is a registered trademark of DuPont



Testing a medical device package using the Lippke 5000 with closed package assembly.

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