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# A Guide to Gross Leak Bubble Testing for Medical Device Packaging


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# Introduction

Terminally sterilized medical devices must remain undamaged and sterile throughout transportation and storage until end-use; package design and testing are paramount. Package design and the packaging process are critical to ensure that sterilized medical devices are delivered as required.

The primary function of packaging for terminally sterilized medical devices is to ensure sterility is maintained until its final point of use. As stated in ISO 11607-2:2019, “Packaging for terminally sterilized medical devices should be designed and manufactured to ensure that the medical devices can be sterilized and remain sterile under documented storage and transport conditions until the sterile barrier system is damaged or opened.” Package designs and packaging processes must be controlled and qualified according to regulatory requirements and industry standards, that are listed in ISO 11607. The loss of package integrity could have severe consequences for the manufacturer, which could result in compromised patient safety, costly product recalls, and loss of consumer trust.

Validating a sterile barrier system (SBS) requires several quality-related activities, such as design validation, process validation, and performance testing.

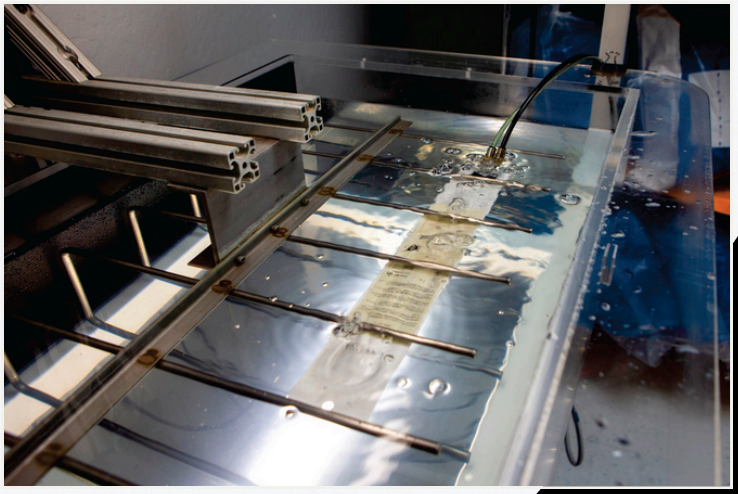
# Package System Performance Testing

Packaging system performance testing is a physical evaluation that proves the existing process offers adequate protection throughout the handling, distribution, and storage stages. It is conducted by simulating the environment and distribution process and evaluating how the sample packages have held up. These are usually conducted using either ASTM or ISTA standards.

Depending on the product's specific distribution environment, the medical device packages are exposed to a series of challenges to simulate what its primary and secondary packaging systems would encounter in the distribution environment.

It's important to note that a risk assessment of any change to the distribution environment, packaging design, materials, process, or specifications will require performance testing to be redone or a justification written to be compliant with relevant regulations.

After the distribution challenge, a few testing methods are available to ensure the SBS remained intact; one of the most crucial package system performance tests is Gross Leak Testing, or “Bubble” Testing.



# What is Gross Leak Bubble Testing?

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Gross Leak or “Bubble” Testing is conducted by submerging a lightly pressurized medical device SBS package under water to visually inspect for a steady stream of bubbles indicating a leak or defect in packaging systems. These primary packages or SBSs undergo Bubble Testing to determine if they have maintained a sterile barrier or if tears, holes, or improper seals have compromised it.

This qualitative method seamlessly uncovers any SBS defects or gross leaks as small as 250 µm (0.010 in) according to ASTM F2096 test. When applied correctly in a package validation test plan, Bubble Testing offers a true advantage by testing the entire SBS and not only the seal.

### The protocol and title is:

ASTM F2096 “Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)”
• Test method sensitivity is down to 250 µm (0.010 in.) for tray and pouch packages

So, what typically causes an SBS to fail? And how do we address and prevent these failures from continuously occurring, affecting the product's safety and efficacy?

# Common Causes of SBS Failure During Gross Leak Testing

**There are various reasons why SBSs fail during Gross Leak Testing. Common occurrences include:**

- Folding or creasing of pouches
- Sharp product edges
- Square corners on backer cards
- Seals that have not been properly validated
- Inappropriate film thickness
- Improper material
- Thin corners in the bottom of a tray
- Unsuitable package design

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Folding or creasing the barrier material is never recommended, as it can cause failure. However, a crease or fold can inadvertently happen to the product packaging during the distribution and handling.

Additionally, it's common practice for manufacturers to leverage existing packaging components for new product packaging, which could force devices to use packaging that is not the optimum size, leading to folding, creasing, or sheet separation.

There are many instances in which an SBS could fail and need to be re-evaluated and redesigned.

## Evaluating for Failure

**Evaluating porous barrier materials following a test failure often involves several steps. To identify if a failure anomaly has occurred during Bubble Leak Testing, follow these suggested approaches:**

### 1 REVIEW PACKAGING MATERIALS

Review the packaging materials that have been chosen. If failures continue, consider changing to a more robust material.

### 2 VISUAL INSPECTION

Conduct a visual inspection of the packaging to look for physical defects or anomalies that might explain how the leak was created, such as folding of the package sharp corners and edges of the product or back card.

### 3 REVIEW SEALING PARAMETERS

If you have a leak on your in-house seal, you should review your sealing parameters to ensure that your seal has adequate strength to survive the distribution environment. This should have been done during your IQ, OQ, PQ of the sealing equipment using the ASTM F88 standard.

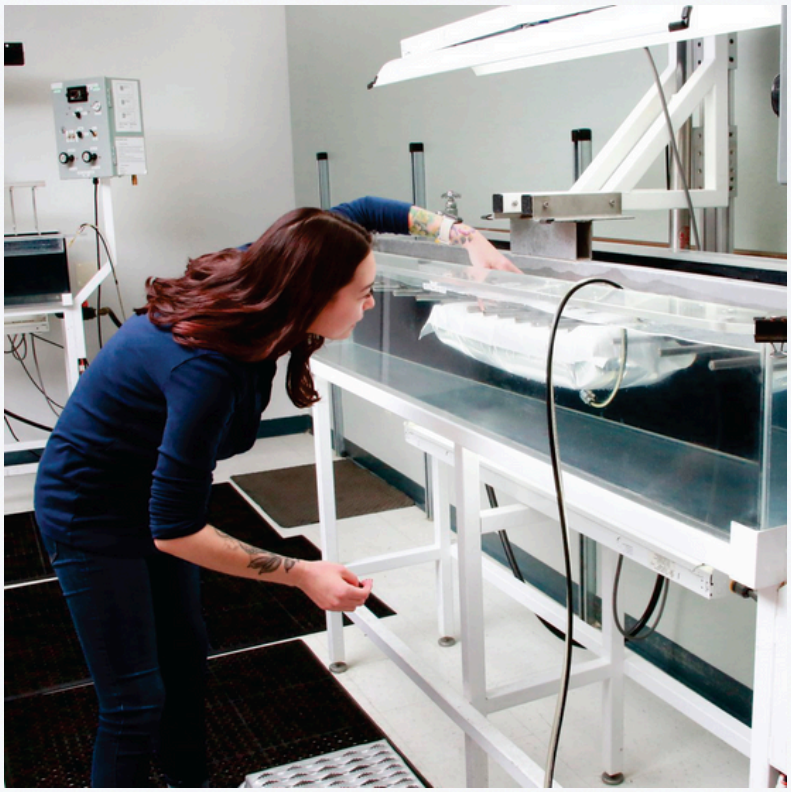
## Why Bubble Testing is Essential

Bubble Testing is the most commonly used method to assess the ability of a package to maintain a sterile barrier since it tests the entire SBS and not only the seal. It is one of the required package integrity tests to ensure a product's sterility, safety, and efficacy until its end-use.

Properly applied in a package validation test plan along with transportation testing, accelerated and real time aging and peel testing, bubble testing has significant advantages over methods such as dye penetration to determine if an SBS has been compromised.

# Partnering with WESTPAK's Dedicated Team of Experts

When finding, trusting, and partnering with laboratory to conduct testing on your SBS, WESTPAK strives to be your ultimate partner for success. Our state-of- the-art equipment, paired with teams of trained and qualified test experts, enables us to uphold our commitment to provide our clients with the most accurate and reliable test data and reports available.



Accreditation is the highest level of competence a laboratory can hold, which is why we are proud to be recognized as an ISTA-certified and ISO 17025 accredited laboratory. WESTPAK is consistently updated on the latest regulatory and test protocol updates. Key members of our technical team serve on ASTM subcommittees and actively participate in shaping many facets of the industry.

Beyond these accolades, what truly sets WESTPAK apart is our integrity, combined with the ability to take on projects of all sizes while maintaining the flexibility and agility required for a customized approach. Armed with years of experience and a robust quality system, WESTPAK is ready to go the extra mile for you.

Are you looking to start with Bubble Leak Testing or other sterile barrier system (SBS) testing methods? Request a quote from our team or call us at 800-830-8021 to get started.

## About WESTPAK

WESTPAK, Inc., a third-party, independent test laboratory specializing in product and package testing solutions, supports speed to market with testing expertise, service, and quality. Its California-based facilities total more than 100,000 square feet of testing and administrative space. Testing is accredited to ISO/IEC 17025 by the American Association for Laboratory Accreditation (A2LA); laboratories are certified by the International Safe Transit Association (ISTA).

## About the Author

**Greg Schwinghammer**

Greg's WESTPAK career began immediately upon graduating with a bachelor's in Packaging Science from San Jose State University in 2001.

Greg has progressed through the ranks by working diligently in all package and product testing phases and capabilities. Internally and within our customer community, Greg is recognized as a go-to expert with solid advice and answers to questions ranging from test protocols to equipment capabilities to product and package design options.

Mr. Schwinghammer represents WESTPAK at ASTM conferences; he is a member of ASTM's D10 Committee for Packaging and F02 for Primary Barrier Packaging. He also has his Packaging Dynamics Professional certification from ISTA.

When not at work, Greg serves as a goalie for a community ice hockey team and enjoys playing golf, hiking, mountain biking, family visits, and time in the Sierra foothills.

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