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From the Blog

Sterile Barrier Integrity Testing for Medical Device Systems

May 11th 2026

Sterile barrier systems are designed to maintain the sterility of medical devices throughout storage, transport, and handling until the point of use. The performance of the sterile barrier system directly influences product safety, packaging reliability, and the ability to present the device aseptically within the clinical environment. Packaging systems used for sterile medical devices are exposed to multiple stresses throughout their lifecycle. Sterilization processes, transportation conditions, storage duration, environmental exposure, and repeated handling can all affect packaging integrity. Small defects within seals or packaging materials may compromise sterility without being immediately visible during routine inspection.

Sterile Barrier Integrity Testing is used to evaluate whether packaging systems maintain their protective function under these conditions. These evaluations form part of the broader packaging validation strategy required for terminally sterilized medical devices.

Medistri performs integrity testing and packaging evaluations within its laboratory infrastructure to support medical device manufacturers during packaging development, validation, and routine production activities.

The Role of Integrity Testing in Packaging Validation
Integrity testing is integrated throughout the packaging validation process to evaluate seal quality, material performance, and resistance to physical stress.

Different analytical methods are used depending on the packaging material, sterile barrier design, and intended application. Common integrity evaluations include:

- Visual Inspection, according to ASTM F1886, used to identify visible seal defects or irregularities
- Dye Penetration Testing, according to ASTM F1929 and ASTM F3039, used to detect channel leaks within package seals
- Bubble Emission Testing, according to ASTM F2096, used to identify gross leaks in flexible packaging systems
- Seal Strength Testing, according to ASTM F88, used to evaluate seal tensile performance
- Peel Strength Testing, according to EN 868-5
- Burst Testing, according to ISO 2758, used to evaluate packaging resistance under pressure

These evaluations allow manufacturers to characterize how the sterile barrier system behaves before and after exposure to sterilization, ageing, handling, and transport conditions.

Packaging Configuration and Worst-Case Evaluation
Packaging validation frequently involves multiple product configurations, packaging materials, or sealing conditions. Under these circumstances, identifying the worst-case packaging configuration becomes an important part of the validation strategy.
Comparative testing may therefore be performed across several packaging designs exposed to identical environmental and mechanical conditions. Variables commonly evaluated include:

- Different sterile barrier materials

Why Packaging Integrity Cannot Be Assumed
Sterile barrier systems are often developed using validated materials and qualified sealing processes. However, packaging performance may still vary depending on the product configuration, sterilization process, or distribution environment. Several factors can influence package integrity:

- Sterilization exposure affecting material properties or seal performance
- Multilayer packaging systems influencing flexibility and resistance to stress
- Transportation and handling conditions creating mechanical fatigue
- Product geometry introducing localized pressure points within the package
- Storage conditions affecting long-term packaging stability

A packaging system that performs adequately under laboratory conditions may behave differently after sterilization, accelerated ageing, transport simulation, or long-term storage.

For this reason, packaging validation requires more than visual inspection alone. Integrity testing is used to characterize packaging performance under representative lifecycle conditions and identify defects that may compromise sterile barrier performance.

Integration with Packaging Process Validation
Integrity testing forms part of the broader packaging validation framework established under ISO 11607-1 and ISO 11607-2.
ISO 11607-1 defines requirements related to sterile barrier systems, packaging materials, and packaging system performance. ISO 11607-2 focuses on validation of packaging and sealing processes, ensuring that operational parameters remain controlled and reproducible. Integrity testing supports several elements of this validation framework, including:

- Verification of sterile barrier performance
- Evaluation of seal consistency and packaging robustness
- Assessment of packaging stability throughout shelf life

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- Alternative sealing parameters
- Various packaging geometries
- Multiple load or carton configurations

These studies help identify the packaging configuration most susceptible to integrity failure and support the selection of representative validation conditions.
Worst-case evaluation is particularly important when packaging systems are subjected to aggressive sterilization processes or extended distribution conditions.

Ageing Studies and Lifecycle Simulation
Sterile barrier systems must maintain integrity not only immediately after sterilization, but throughout the entire claimed shelf life of the product. Packaging validation programs therefore commonly integrate both accelerated ageing and real-time ageing studies. Accelerated ageing studies are generally performed according to ASTM F1980 to simulate long-term storage conditions within compressed timeframes. Real-time ageing evaluations are conducted in alignment with ISO 11607-1 requirements and allow manufacturers to confirm packaging performance over actual storage durations. Following ageing exposure, integrity testing is repeated to verify that packaging materials and seals continue to maintain sterile barrier performance. Transport simulation studies may also be incorporated to evaluate the influence of vibration, compression, shock, and repeated handling on package integrity during distribution activities.

From Packaging Development to Routine Production
Packaging systems introduced during product development must eventually transition into controlled routine production environments. Integrity testing therefore continues beyond initial packaging validation and may also support:

- Routine packaging quality monitoring
- Investigation of seal deviations or packaging failures
- Evaluation of packaging changes or material modifications
- Requalification activities following process updates

This ongoing evaluation helps ensure that sterile barrier systems continue to perform consistently throughout commercial manufacturing operations. By combining integrity testing, ageing studies, transport simulation, and packaging process validation, manufacturers can establish documented evidence that sterile barrier systems remain capable of protecting medical devices throughout their intended lifecycle.

Should you fully validate your packaging system or should you simply test one particular characteristic of your packaging, Medistri laboratory is accredited and highly experienced for the most common tests methods provided by the regulatory agencies.

To learn more about Medistri's Sterile Barrier Integrity Testing services, visit on our website here or directly contact our team at contact@medistri.com.

– The Medistri Team

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- Confirmation of packaging resistance following sterilization and transport simulation

These activities are typically integrated within the manufacturer's quality management system in accordance with ISO 13485 and applicable regulatory frameworks such as the Regulation (EU) 2017/745 and the U.S. Food and Drug Administration expectations for sterile medical device packaging.