



## TECHNICAL TIP

### THE BASICS OF MEDICAL DEVICE PACKAGING

When developing a sterile barrier system for medical devices, there are several aspects that need to be considered in choosing packaging and qualifying your sterile barrier system (SBS).

#### **Material Considerations**

The material and type of SBS should be considered at the beginning of any new development project. Consider the approximate size and weight of the device or system, the sterilization method(s), and the proposed quantity of sterile barriers (single barrier or double barrier) when designing the SBS. Determining your requirements early will help reduce lead times typically associated with packaging design and will allow for early feasibility studies.

#### **Equipment Qualifications**

##### ***IQ (Installation Qualification)***

This testing provides documented evidence that the utilities, safety features and ancillary systems used in the function of the equipment meet the user's specified requirements.

##### ***OQ (Operation Qualification)***

This testing provides documented evidence that the upper and lower limit sealing operating parameters of a piece of equipment provide seals that meet predetermined acceptance criteria for a specific material combination. Engineering studies should be completed prior to the OQ to determine these limits and acceptance criteria.

##### ***PQ (Performance Qualification)***

This testing provides documented evidence that the equipment used to apply a final seal will consistently produce seals that meet predetermined specifications under specified operating conditions. This typically consists of three production runs produced at nominal equipment settings using multiple material lots. Three runs allow for the ability to evaluate variability due to material lots, machine equilibrium, personnel changes, and day-

to-day environment changes.

#### **Package Testing**

##### ***Packaging Distribution***

Prior to receiving regulatory approvals, the SBS must prove that it is capable of withstanding the expected transit life cycle. Package distribution test samples must contain product or representative product (dunnage/simulant) that has been sealed at equipment worst case conditions and sterilized. Expected transit life includes processing, handling, sterilization, transit and warehousing. Typical distribution simulation for medical devices is defined in ASTM D4169 Standard Practice for Performance Testing of Shipping Containers and Systems, DC-13. Testing intensity is determined based on the specific device and system. Final testing after simulation proves strength and integrity of the SBS.

##### ***Aging Studies***

Aging studies must be completed prior to receiving regulatory approvals to prove the SBS is still intact at the end of the labeled shelf life. Testing must verify package strength and integrity after the desired time point(s). Accelerated aging can be completed for regulatory submission, but real time aging samples must run in parallel.

#### **Types of Package Testing**

##### ***Package Integrity Testing***

Package Integrity Testing is important in determining the sterility and the shelf life of a medical device or product. This is done by documenting that the SBS system has no detectable path through, channels or punctures that may allow the introduction of microbes into the system. Examples of package integrity testing include ASTM F1929 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration or ASTM F2096 Standard Test Method of Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test). Visual inspection should also be used to confirm package

### FOR MORE INFORMATION

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integrity. The standard for visual inspection is ASTM F1886/ F1886M Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection.

#### ***Package Strength Testing***

Package Strength Testing shows the force required to separate the two components of the sterile barrier system. Packaging strength is important to show that the package protecting the product is strong enough to contain the product system after distribution or aging. Seal strength also allows the medical device manufacturer to confirm the reproducibility of their sealing process and adherence to design specifications. Examples of package strength testing include ASTM F88/F88M Standard Test Method for Seal Strength of Flexible Barrier Materials or ASTM F1140/F1140M Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages.

When performed together, integrity and strength testing provide documented evidence both qualitatively and quantitatively that the SBS is robust and appropriate to maintain product integrity.

#### **FOR MORE INFORMATION**

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