How Do You Know If a Sterilized Package Remains Sterile?

Major article

Sterility maintenance study: Dynamic evaluation of sterilized rigid containers and wrapped instrument trays to prevent bacterial ingress

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Acknowledgments

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Dunkelberg Study

- 216 rigid sterilization containers obtained in-use inventory of 4 hospitals inspected per facilities policy
- All judged appropriate for maintaining content sterility
- Majority (80%) failed to prevent contamination after sterilization when tested with aerosolized bacteria
- We need to do a better job of inspection, verification, quality assurance
Sterile Packaging Systems (SPSs)

Rigid Containers

Sterilization Wrap
Rigid Containers

• Generally consist of metal or plastic top and bottom
• All models have at least one filter (reusable or disposable) or a valve system
• Vary in size
• Reusable (can exceed 1,000 uses)
Rigid Containers

Vary widely:
✓ Design
✓ Construction
✓ Mechanics
✓ Compatibility with sterilization
Sterilization Wraps

- Woven fabrics
  - Linen or muslin
  - Not moisture resistant
  - Should withstand 50-75 launderings
  - Needs to be inspected for holes per use

- Non-woven fabrics
  - Natural or synthetic fibers
  - Bonded together
  - Act as a filter
  - Needs to be inspected for tears or punctures per use
Polypropylene Sterilization Wrap

- A hydrophobic material often used to wrap around an instrument tray containing surgical tools

- Wrap acts as a filter, allowing penetration of steam from all angles

- Available in many weights/grades

- Disposable
ANSI/AAMI ST77

- Design and performance standard for containment devices
- Voluntary requirements document that provides manufacturer requirements for labeling, sterilization effectiveness, sterilant compatibility and sterility maintenance.
- This standard should be considered flexible and dynamic
4.4.4.1 General Requirements:
The sterile barrier system of the containment device shall maintain sterility until the containment device is opened and the sterile contents are aseptically presented.

5.6 Sterilization
For containment devices with valves or filters, the ability of the valve or filter to allow adequate penetration of the sterilant throughout its useful life shall be determined by demonstrating a 12-log reduction and an SAL of $10^{-6}$. 
5.9.1.1 Sterility Maintenance - General
Compliance with the requirements of 4.4.4 can be verified by performing the sterilization testing of 5.6, exposing the sterile barrier system to the expected stresses of storage, transport, and handling conditions, and then *performing either a whole-package microbial challenge test* (5.9.1.2) or physical integrity tests (5.9.1.3).

*Examples of expected stresses that would be encountered within a health care facility* include movement of containment devices into and out of a sterilizer and onto and off shelving or carts. Additional handling stresses and vehicle vibration should be considered if transport outside the facility is anticipated.
5.9.1.2 Whole-package microbial challenge test:
*The containment device in its sterile barrier system shall be placed inside a chamber and then exposed to a defined aerosol of microorganisms.* Sterility testing of the contents of the containment device for the recovery of the challenge organism shall be performed in accordance with USP.

**ST77 is a Static Test**

In a hospital environment, there is dynamic air movement........
5.9.1.2 Whole-package microbial challenge test:

The containment device in its sterile barrier system shall be placed inside a chamber and then exposed to a defined aerosol of microorganisms. Sterility testing of the contents of the containment device for the recovery of the challenge organism shall be performed in accordance with USP.

- Static test
- SPS’s are exposed to a defined aerosol of microorganisms
- Contamination of packages’ interior is assessed
## Dynamic Air Movement

<table>
<thead>
<tr>
<th>Processing Stage</th>
<th>Environmental Event</th>
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<tbody>
<tr>
<td>Post-sterilization Cool Down</td>
<td>Temperature change causes influx of air into SPS</td>
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<tr>
<td>Storage</td>
<td>Temperature difference from sterilization to storage</td>
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<tr>
<td></td>
<td>Air exchange during storage</td>
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<td>Human traffic</td>
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<td>Opening and closing of doors</td>
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<tr>
<td>Transport</td>
<td>Elevator transport</td>
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<tr>
<td></td>
<td>Movement of SPS’s</td>
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<td></td>
<td>Temperature differences between locations</td>
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</tbody>
</table>
Dynamic Bioaerosol Test Method

- Dynamic test that simulates dynamic air movement in hospitals
- Bacterial challenge (100’s of microbes per liter of air) that better simulates airborne bacterial concentrations in hospitals than previous studies
- Microorganism used was relevant to the hospital environment
Dynamic Bioaerosol Test Method

• Contains multiple fans, vacuum pumps/compressors to simulate dynamic air movement

• Integrated components allow the user to:
  • Regulate and monitor air movement
  • Determine temperature and humidity
  • Determine particle size
  • Determine viable bacterial concentration
Objectives

- Evaluate the performance of rigid containers and sterilization wrapped instrument trays using the dynamic bioaerosol test method.

- Evaluate if duration of use for rigid containers affects barrier properties.
Sterility Maintenance Study

**Rigid Containers**
- Multiple designs and ages were evaluated
- New containers were purchased from multiple vendors
- In-use containers were obtained from: 9 acute care hospitals, 2 teaching hospitals, 1 children’s hospital, 1 ambulatory surgery center, and 1 government hospital throughout the U.S. and Canada

**Sterilization Wrap**
- Three grades of single-use polypropylene wrap from a single manufacturer were evaluated
Hydrophilic polycarbonate membranes (47-mm, 0.4-μm pore size) were used. Membranes were placed in aluminum dishes fixed to the bottom of the containers/trays with heat-resistant tape.
Sterility Maintenance Study – Sterilization Wrap

• Standard envelope method was used to fold the sterilization wrap, unless otherwise directed by manufacturer’s IFUs
Sterility Maintenance Study – Rigid Containers

- Appropriate filters as specified by the manufacturers were secured to the rigid containers
- Sterilization indicators were placed in the containers
- Latches were closed and secured by tamper-evident locks
Sterility Maintenance Study - Sterilization

- SPS’s were placed in sterility maintenance covers and transferred to a local hospital for sterilization.
- Containers were sterilized using standard pre-vacuum cycle (4 minute exposure at 132 °C) followed by a 30 minute drying time.
- Following a 1-1 ½ hour cool down, the SPS’s were placed in new covers and transferred back to ARA’s Bioaerosol and Microbiology Laboratory for evaluation.
Sterility Maintenance Study – Dynamic Bioaerosol Test

- SPS’s were placed in the bioaerosol chamber and simultaneously exposed to a *Micrococcus luteus* (coagulase-negative staphylococci) aerosol and vacuum cycles.
- 100’s of viable bacteria per liter of air were maintained throughout the test.
Sterility Maintenance Study –
Enumeration of Microbial Ingress

• SPS’s were placed in a containment hood and decontaminated using disinfectant wipes

• SPS’s were then placed in a Type II-A2 biological safety cabinet and membranes were aseptically placed on nutrient agar plates
RESULTS

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Results – Level of Bacterial Ingress Based on SPS Type

Enumeration of Microbial Ingress

Rigid Containers \((n = 111)\)
- 18.0%
- 1...
- 22.5%
- 46.8%

Sterilization Wrap \((n = 161)\)
- 100.0%

Legend:
- 0 CFU
- 1-9 CFU
- 10-99 CFU
- ≥100 CFU
Results – **Level of Bacterial Ingress Based on Duration of Use**

![Graph showing bacterial ingress (CFU/container) based on duration of use.](image)
Complexity of Rigid Containers

- New and used rigid containers allowed ingress
- Rigid containers contain many parts, and if they malfunction, it may lead to ingress of bacteria
Rigid Container Failures

- Decay based on duration of use is logical as they would be expected to deteriorate over time
- Gasket material
- Wearing of latches
- Decay in performance of springs
- Mismatching of lids and bottoms
- Denting and deformation of metal parts
Discussion

WRAP

• NO detectable contamination was found
• Devices are simple and used new every

RIGID CONTAINERS

• 72 % of Rigid Containers allowed bacterial ingress
  Rigid containers contain many parts, and if they malfunction, lead to ingress of bacteria.
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Response to Study?

- Not all rigid containers are created equal
- Rigid containers have potential for damage that affects maintaining sterility.
- Risk Assessment of how a facility packages and stores sterile items should be considered.
Rigid Container Failure Demonstration Video

Dollar Bill Seal Check
Rigid Container Failure Demonstration Video

Water Leak Check
What is the Missing Link to a 0% Infection Rate?

Could it be STERILIZATION PACKAGING?

0% Infection Rate
Summary

• Infection prevention primary responsibility of perioperative RNs and your SPD team.

• Sterile instruments key to reducing patient risk

• Appropriate packaging before sterilization assures sterility

• Sterilization packaging systems should
  • Provide effective barrier from microbial penetration
  • Protect from contamination after sterilization