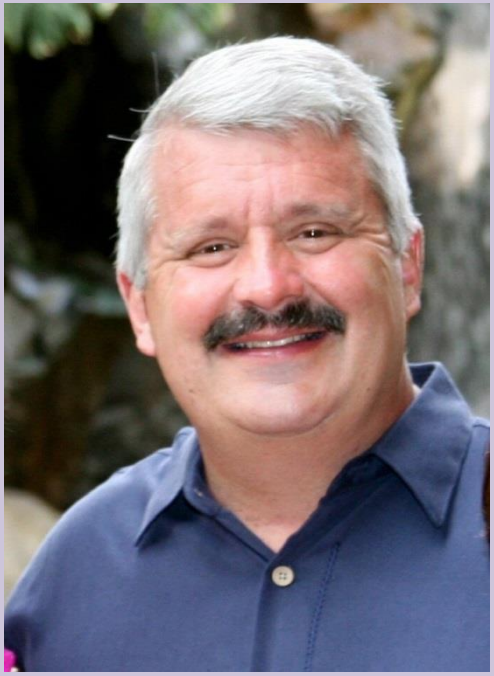
How Do You Know If Your Sterilized Instruments Remain Sterile?

Disclosure

Harry Shaffer is the first author of the sterility maintenance study covered in this presentation and has been compensated by Halyard Health for his expertise in preparing and presenting today's webinar.



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Acknowledgements

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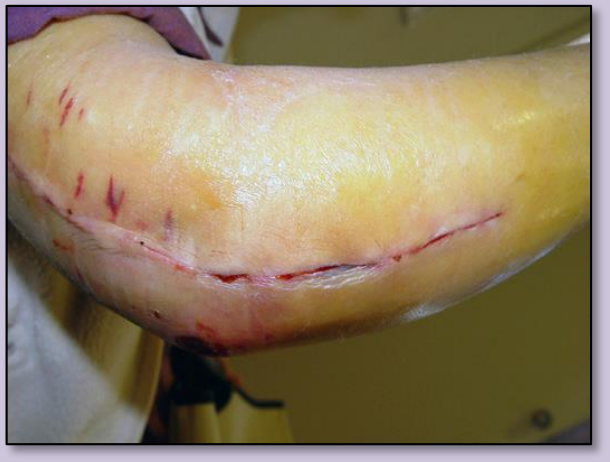
Learning Objectives

- Differentiate four types of rigid sterilization containers used today, including factors that impact their barrier protection.
- Describe the technical aspects of a leading sterilization wrap available for use.
- Discuss components of the AAMI/ANSI ST77 standards related to sterility maintenance testing of sterilization packaging systems.
- Explain the dynamic bioaerosol test method used in the reported study for sterility maintenance testing.
- Discuss the results of a recent sterility maintenance study and the implications for patient care.

Surgical Site Infections

….Approximately 300,000 surgical site infections (SSIs) occur annually in U.S. hospitals, resulting in an estimated 9,000 attributable deaths



Sterile Packaging Systems (SPSs)

Rigid Containers

Sterilization Wrap

Rigid Containers

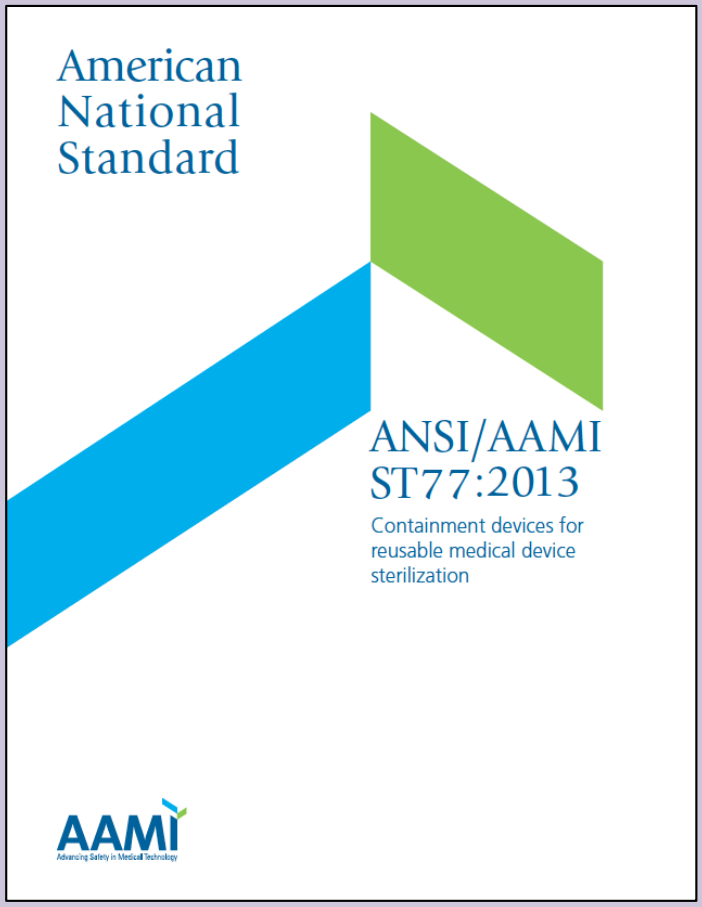
- Generally consists of metal or plastic top and bottom
- All models have at least one filter (reusable or disposable) or a valve system
- Vary in size
- Reusable (can exceed 1,000 uses)

Rigid Sterilization Containers

Vary widely in:

- ✓ Design
- ✓ Construction
- ✓ Mechanics
- ✓ Compatibility with sterilization

ANSI/AAMI ST77



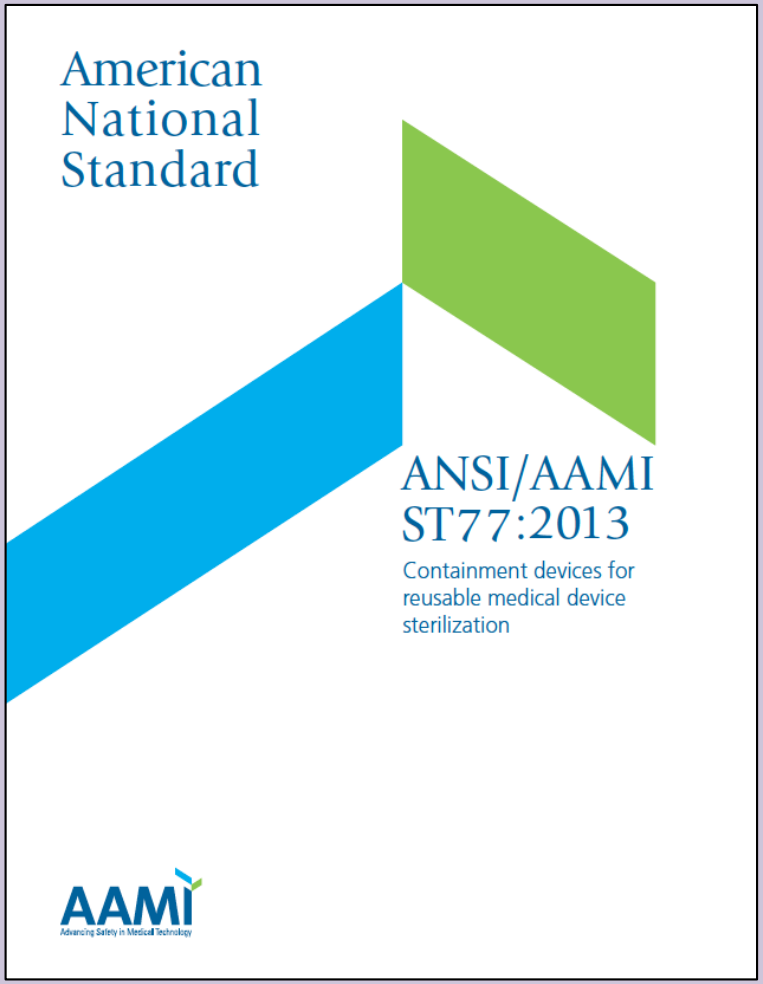
- Design and performance standard for containment devices
- Voluntary requirements document that provides manufacturer requirements
- This standard should be considered flexible and dynamic

Sterilization Wraps

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

- Non-woven fabrics
  - ✓Natural or synthetic fibers
  - ✓Bonded together
  - ✓Act as a filter
  - ✓Need to be inspected for tears or punctures per use

ANSI/AAMI ST77



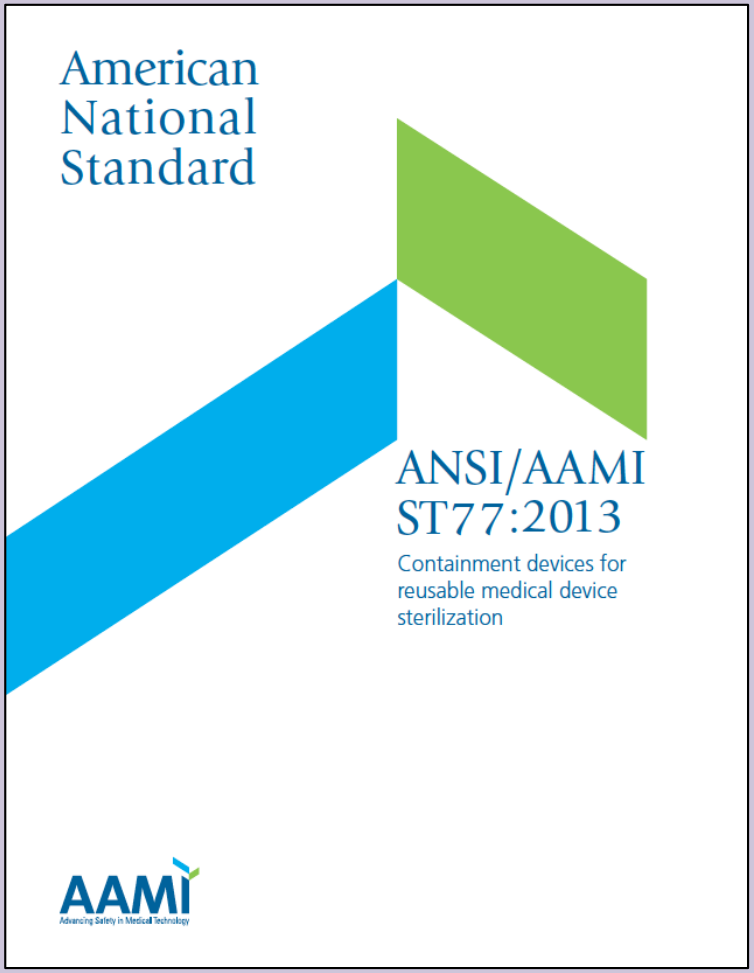
4.4.4.1 General Requirements:
The sterile barrier system of the containment device shall maintain sterility ***until the containment device is opened and the sterile contents are aseptically presented.***

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}.***

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

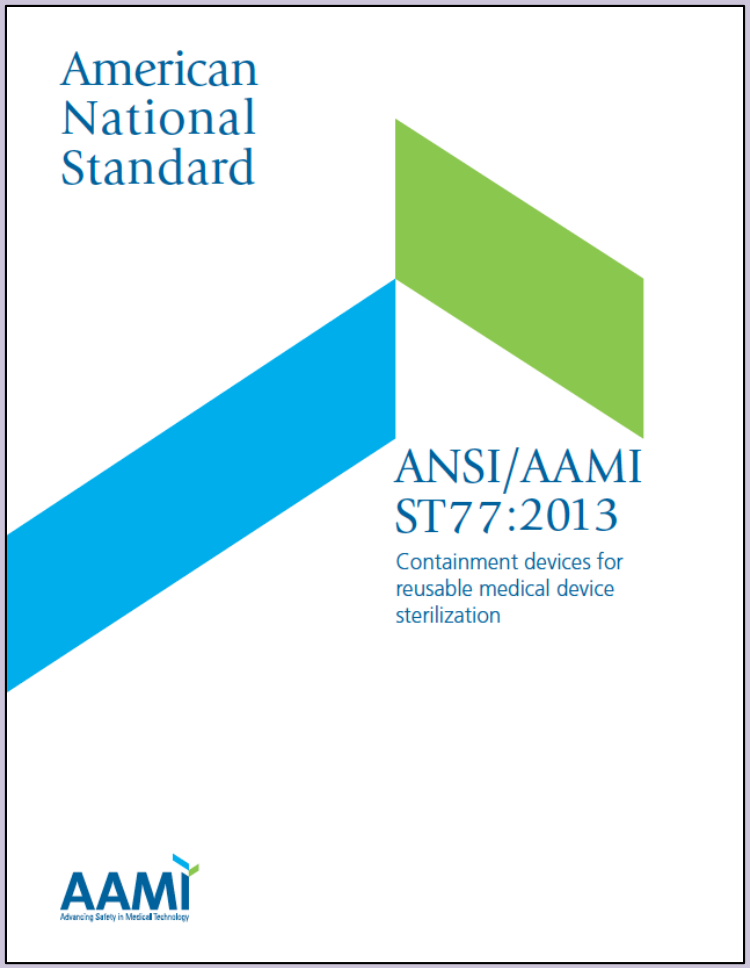
ANSI/AAMI ST77



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 healthcare 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.

ANSI/AAMI ST77



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.

Dynamic Air Movement

ANSI/AAMI ST77

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- Static test
- SPSs are exposed to a defined aerosol of microorganisms
- Contamination of packages' interior is assessed

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

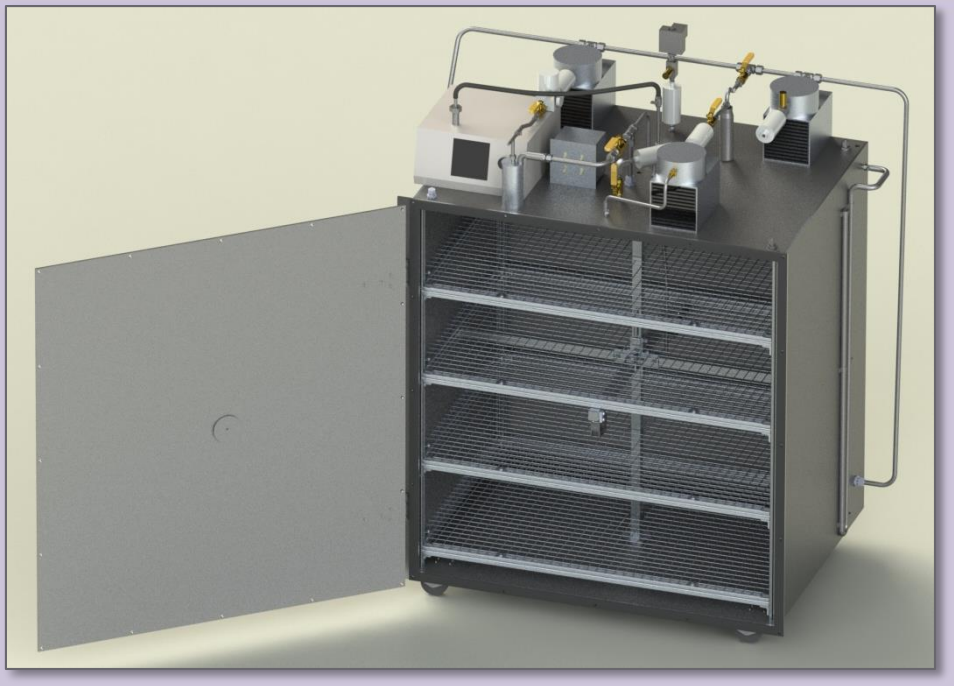
Dynamic Air Movement

Processing Stage	Environmental Event
Post-sterilization Cool Down	Temperature change causes influx of air into SPS
Storage	Temperature difference from sterilization to storage
	Air exchange during storage
	Human traffic
	Opening and closing of doors
Transport	Elevator transport
	Movement of SPSs
	Temperature differences between locations

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



Sterility Maintenance Study

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

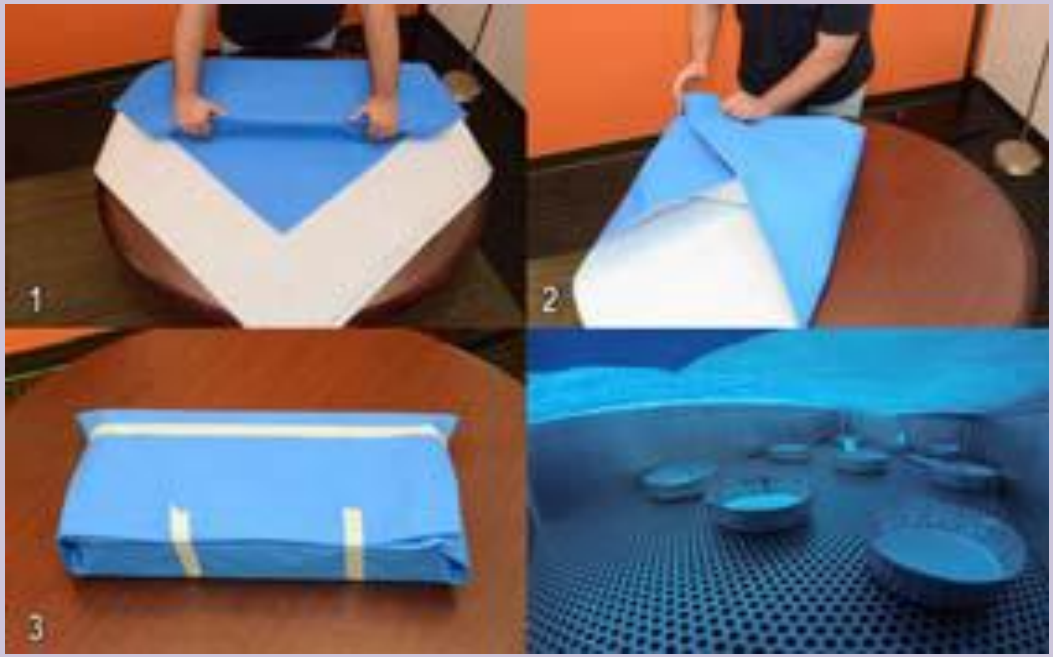
Rigid Containers

- Multiple designs and ages were evaluated
- New containers were purchased from multiple vendors
- In-use containers were obtained from: nine acute care hospitals, two teaching hospitals, one children's hospital, one ambulatory surgery center and one government hospital throughout the U.S. and Canada

Sterilization Wrap

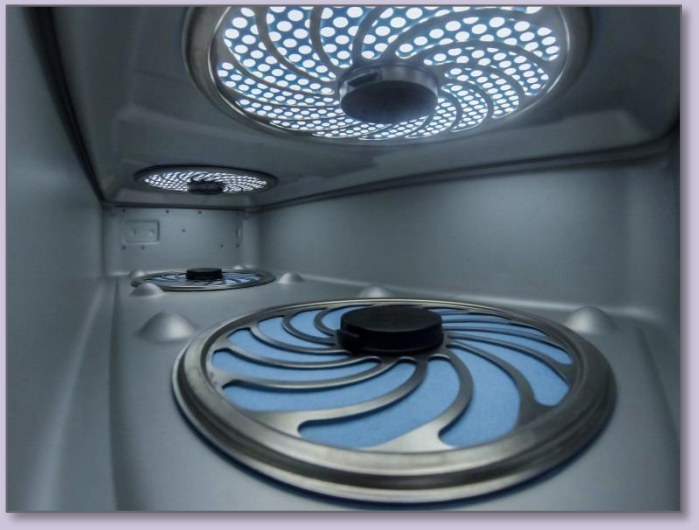
- Three grades of single-use polypropylene wrap from a single manufacturer were evaluated

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

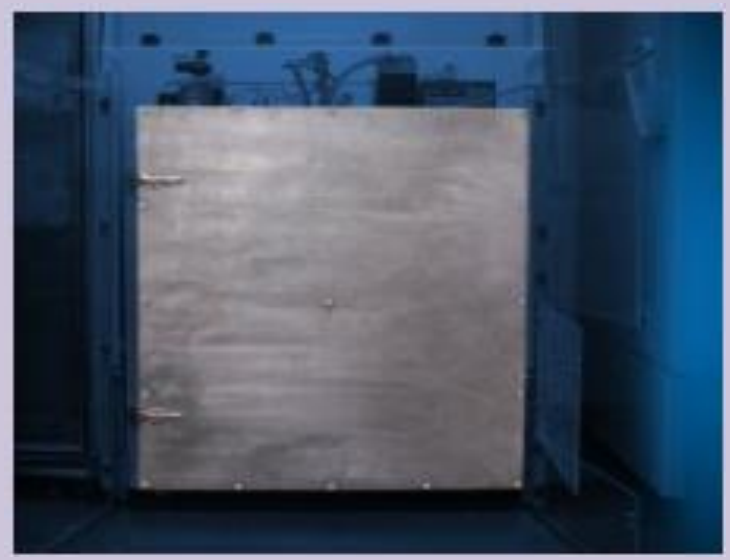
- Hydrophilic polycarbonate membranes (47-mm, 0.4-µm pore size) were used
- Membranes were placed in aluminum dishes fixed to the bottom of the containers/trays with heat-resistant tape

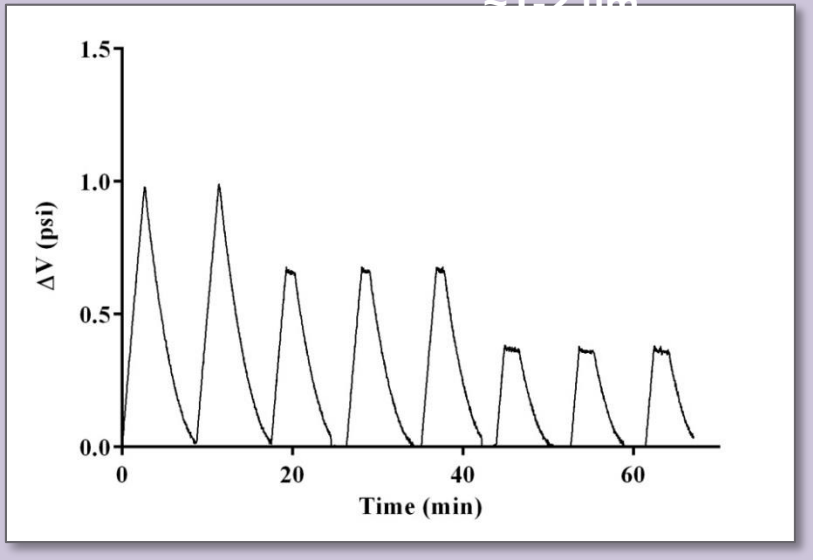
Sterility Maintenance Study - Sterilization

- SPSs were placed in sterility maintenance covers and transferred to a local hospital for sterilization
- Containers were sterilized using standard pre-vacuum cycle (four-minute exposure at 132 °C) followed by a 30-minute drying time
- Following a 1-1 ½ hour cool down, the SPSs were placed in new covers and transferred back to ARA's Bioaerosol and Microbiology Laboratory for evaluation

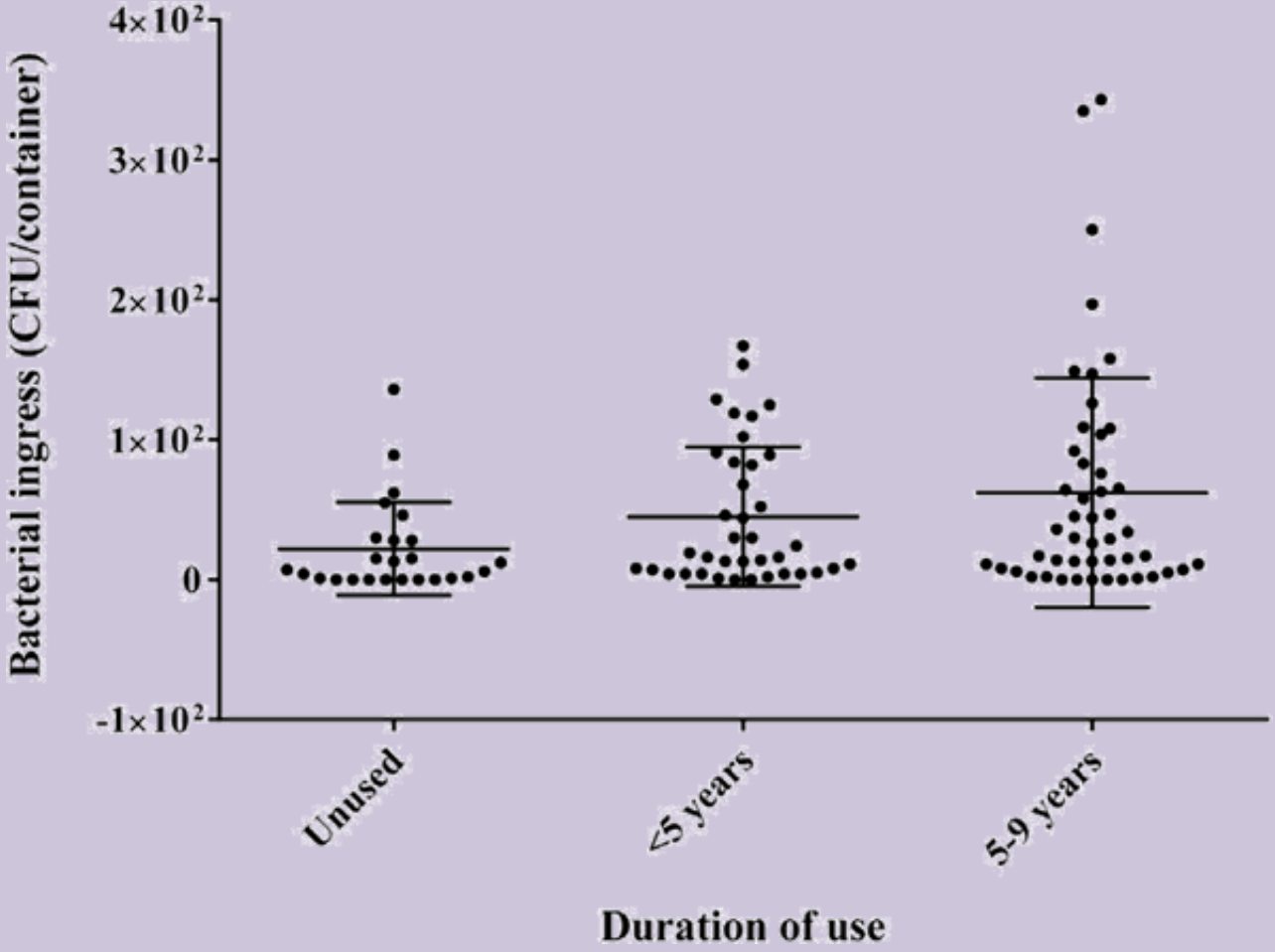
Sterility Maintenance Study – Dynamic Bioaerosol Test

- SPSs 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



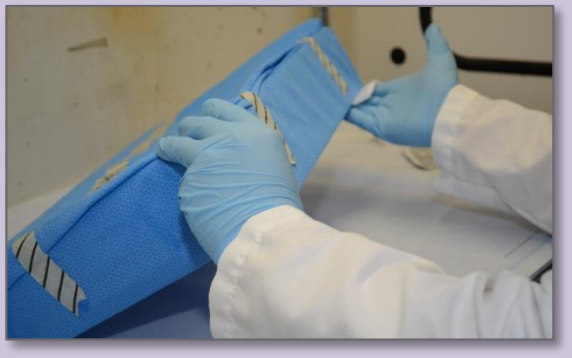


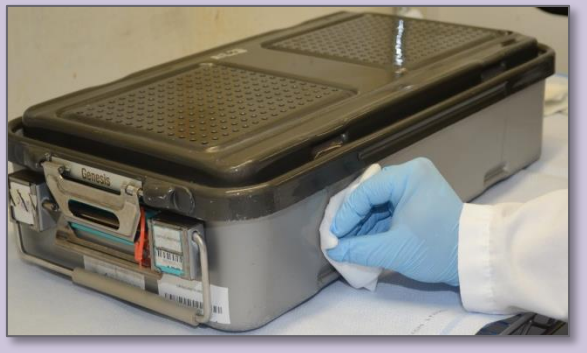
Results - Decay of Rigid Containers Based on Duration of Use



Sterility Maintenance Study – Enumeration of Microbial Ingress

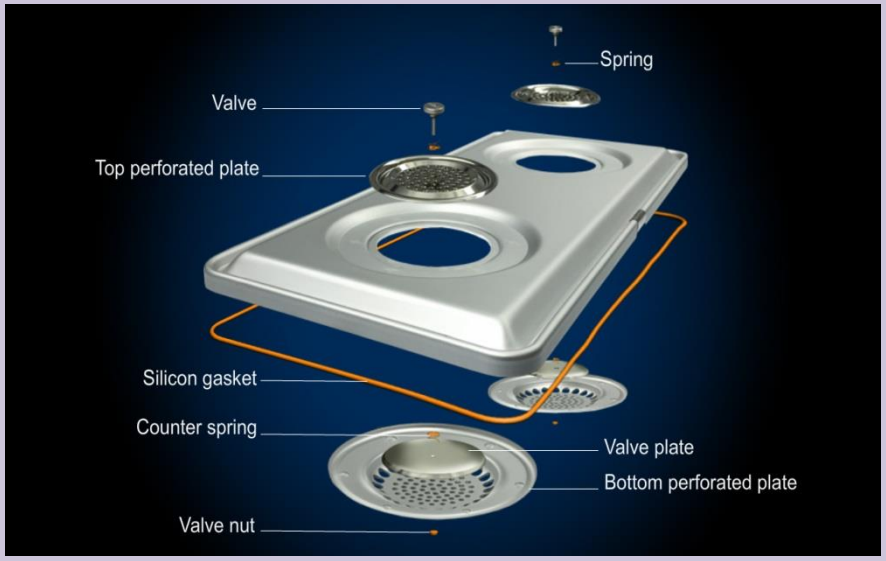
- SPSs were placed in a containment hood and decontaminated using disinfectant wipes
- SPSs were then placed in a Type II-A2 biological safety cabinet and membranes were aseptically placed on nutrient agar plates

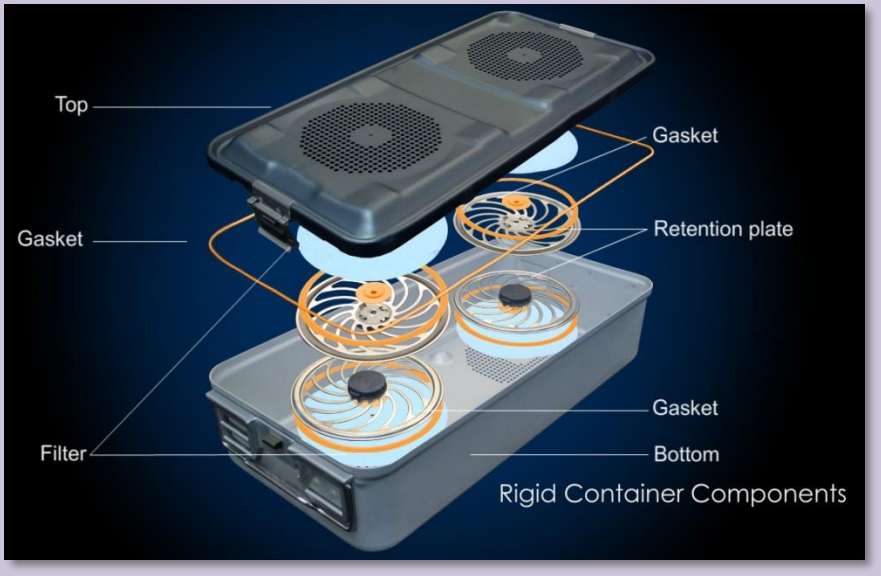




Complexity of Rigid Sterilization Containers

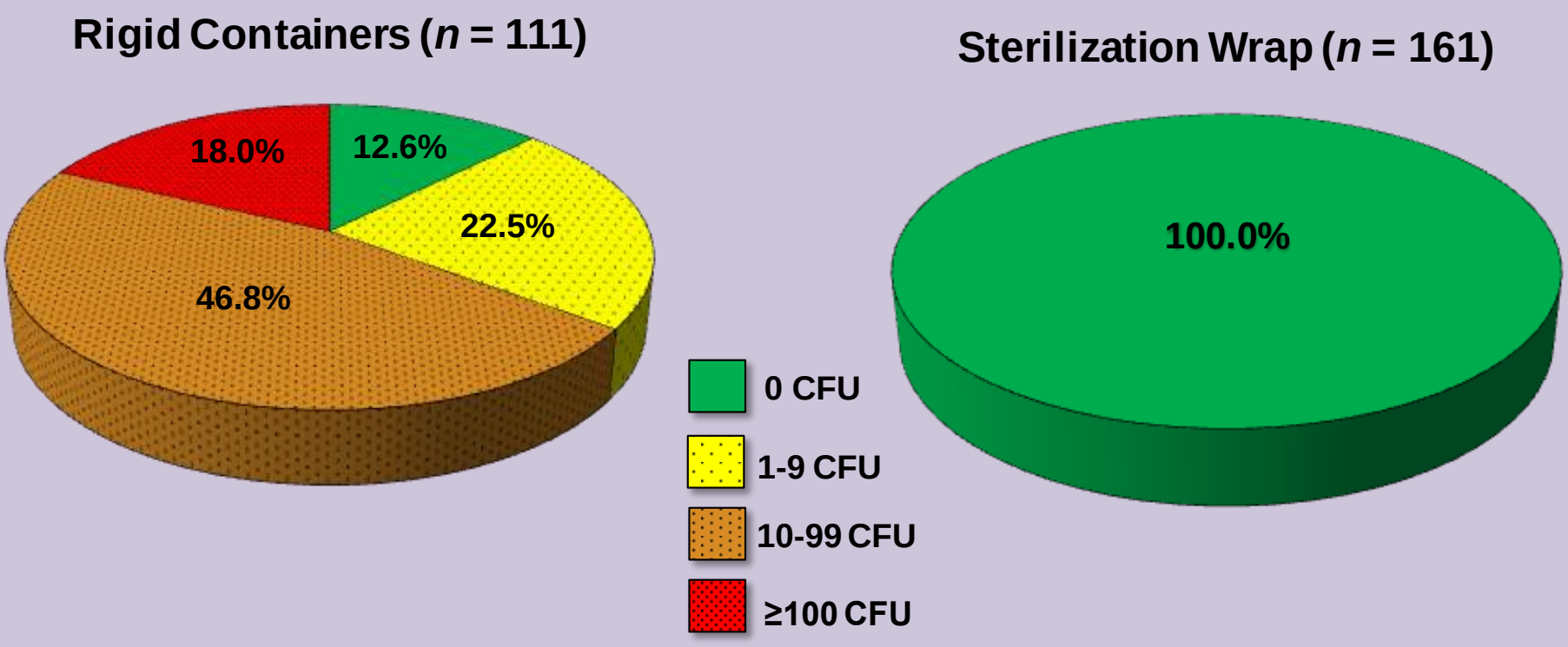
- New and used rigid containers allowed ingress
- Rigid containers contain many parts and, if they malfunction, it may lead to ingress of bacteria





Results – Level of Bacteria Ingress Based on SPS Type

Enumeration of Microbial Ingress



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

Improper Lid Function

Conclusion for Health Care Facilities

- Sterile environment critical to reducing SSIs
- Surgical instruments must be sterile at point of use
- Rigid containers are questionable because of duration of use
- Performance validation for SPSs is needed

Summary

- Infection prevention primary responsibility of perioperative RNs
- 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

Questions