Are My Rigid Containers Maintaining Sterility?
Objectives

1. List the observations to be taken each time a rigid container is prepared for use

2. Describe do-it-yourself tests your SPD can perform to do a “quick check” on the container’s integrity

3. Explain how a minute hole in a container is different from the same size hole in cotton, paper and polypropylene wrap
And the Inspection Begins!

- Inspect container for defects; should be free from
  - cracks
  - corrosion
  - pitting
- Rivets and screws should be secure
- Inspect edges of container lid and bottom to confirm no sharp burrs or dents that could affect the gasket seal or proper closure
Even with Diligent Visual Inspection, No Guarantees

<table>
<thead>
<tr>
<th>Object</th>
<th>Millimeters (mm)</th>
<th>Micrometers (µm) aka: microns</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smallest size human can see</td>
<td>0.100</td>
<td>100</td>
</tr>
<tr>
<td>Magnified hole above, too small to see</td>
<td>0.080</td>
<td>80</td>
</tr>
<tr>
<td><em>Staphylococcus aureus</em> bacterium</td>
<td>0.001</td>
<td>1</td>
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80 *Staphylococcus* bacteria standing in a row to reach across the hole that no one can see without magnification!!
All “holes” Are Not Created Equal

Bacteria go right through holes/cracks in containers because it is an open space = nothing to stop them

But not through polypropylene non-woven wrap. Why?

Two reasons:

1. Thousands of microscopic fibers make up multiple layers of particle traps: let air through, but trap bacteria: tortuous pathway like a complex maze

2. And in some, each fiber is electret treated, making it charged in order to attract & trap any bacteria trying to penetrate the fabric.
Contain hole or Crack

Woven cotton reusable

Polypropylene SMS (Spunbond-Meltblown-Spunbond)

Screen type; hole size capture

Tortuous pathway & electret, charged fibers

To bacteria “You can enter, but never leave”
Filters and Retention Plates

- Inspect retention plates for
  - distorted shape
  - bent levers that do not secure plates properly
  - Inadequate spring or compression

- Verify filter retention posts are secure (don’t wobble; not bent)

- Inspect filter holder to ensure there are no dents, cracks, chips or sharp places

- Inspect filters to make certain:
  - no holes
  - good fit in holder: fills the space without creases, folds, or crimped edges
Assembled Filter Unit

- Upon securing filter in holder, inspect retention plates to ensure proper locking of the mechanism; does not loosen or “pop-out”

- Reusable Valves: Valve itself must not have
  - dents
  - breaks
  - cuts
  - chips
  - foreign debris
Gasket

- Gasket seal must be completely inserted and undamaged with no:
  - cracks
  - cuts
  - tears
  - separation (from seated track position)
  - visible degradation or color change (indicates aging oxidation or chemical damage)
  - is not hardened
Gasket Seal

- Check container lid for “bounce” upon opening. Absence of “noticeable bounce” may indicate gasket
  - is degraded
  - no longer pliable
  - ruptured
  - requires gasket replacement

- Inspect gasket for visible compression indentation formed by the upper lip of the container bottom; should be:
  - uniform and continuous around entire gasket length
Latches and Handle

- Observe latches are
  - not separating from base
  - not loose
  - not bent
  - open up and down easily
  - latch spring is not protruding
  - latch bracket is not separated from lid

- A solid click must occur when closing latches to confirm securely clasped with enough pressure on gasket to create seal
Demonstration Video

Dollar Bill Seal Check
Demonstration Video

Water Leak Check
Demonstration Video

Water Leak Check
Rigid container locks:

- Confirm handle is not loose
- Handle sleeve is not cracked or torn

- Must have tamper-evident locks or seals

Never use a container with a lock that is not adequately sealed
Per Manufacturer

- Only components of the rigid container system specified by the manufacturer should be used

- Manufacturer’s written instructions for inspection, repair, cleaning and preventive maintenance should be followed
  - observe manufacturers identified indicators for maintenance
  - prescribed frequency per DFU

- Record date required for scheduled maintenance and document compliance and date
Washing

- When loading washer, all parts must be separated so detergent and water contact all surfaces of all containers

- Place:
  - container base such that water doesn’t collect
    - typically upside down
  - lids at an angle
  - retention plates in instrument basket and/or away from direct, high pressure spray

- Process per manufacturer’s Instruction for Use (IFUs)
- Use pH neutral detergent to avoid damage
- Ensure the container bottoms, lids and all components (filters, plates, etc.) are dry prior to assembly
Washed

- After washing and inspection
- All components completely dry
- Assemble
- Load following manufacturer’s instructions
- Follow manufacturer's instructions for sterilization of container and its specific contents
Sterilization

- Verify that the container system and the items to be sterilized have been tested and validated for sterilization cycles used within your facility
Sterilization

- When instructions conflict or are not sufficient, contact the instrument manufacturer for guidance.

- If conflicting directions are not solvable and the device is needed urgently, the instrument manufacturers’ instructions must be followed.
Sterilization

- For steam sterilization cycles, pre-vacuum sterilizers are the preferred choice.
- Rigid containers:
  - SHOULD BE placed on shelves in a steam sterilizer below absorbent items
  - SHOULD NOT BE stacked in the sterilizer*

* EXCEPTION: the manufacturer has provided written recommendations and documentation that stacking of their containers in the sterilizer has been validated.
Cool, Then Store

- Allow rigid containers to cool before removing from sterilizer cart
- Do Not Place on shelves before cooled as will increase condensation (wet packs)
- Do Not Touch filters at all but especially while hot as can create contamination channel
- Protect from puncture and from contamination when transporting to storage area
- Maintain container in a position parallel with floor while shelving
Storage

- The integrity of a sterile packaged item is event-related.
- The chance of contamination increases over time and with increased handling.
- Sterile storage areas should be maintained with:
  - Temperature ranging from 68° – 75° F (20°-24° C)
  - Humidity level ranging from 30 – 70%
  - At least four positive pressure air exchanges per hour
How Many Times Are Your Containers Reused?

- Junghannss estimated that containers are:
  - disassembled
  - washed
  - reassembled
  - sterilized
  - transported within or outside the facility
  - handled with dirty sharps and disinfected
- re-used 1,400 to 2,300 times (a low estimate)
- That’s a lot of opportunity for damaging each container

Time to renew our insurance policies!
Renewed focus on inspection, maintenance, quality assurance
Quality Assurance
Quality Assurance

- Quality assurance testing of containers should be performed
  - before initial use and periodically thereafter
  - major change in packaging systems, materials, tray configuration, or content density
Quality Assurance

Biological testing
- Place the biological indicator inside the tray, set, or pack being tested, usually in each corner and in the center of the set.

Verification of the ability to dry the set under user conditions
- Observe the set for any:
  - condensate on the instruments or package contents
  - wet or moist towels or silicone mats
  - visible water inside the container

Evidence of retained moisture will require additional steps to determine the necessary cycle parameters and sterilizer load configuration.
Continued Sterility Confidence

- Fast periodic “checks” on several containers similar to video demonstrations shown are suggested:
  - leak check
  - dollar bill test gasket seal check
Quality Assurance

For instructions for periodic product quality assurance testing of rigid sterilization containers systems, refer to AAMI’s current ST 79

“Comprehensive guide to steam sterilization and sterility assurance in health care facilities”

http://www.aami.org/
Sterile

- Hospital-associated infections (HAI) kill more people in the US than motor vehicle, breast cancer and HIV combined
- Surgical Site Infections represent 17% of all HAIs
- Over 27 million surgical procedures performed annually
- Essential that every instrument, device and implant we certify as sterile, is indeed sterile
- Our initials represent our personal professional assurance

<table>
<thead>
<tr>
<th>Seals</th>
<th>Each Use</th>
</tr>
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<tbody>
<tr>
<td>• Worn</td>
<td>✔️</td>
</tr>
<tr>
<td>• Abraded</td>
<td>✔️</td>
</tr>
<tr>
<td>• Cuts. Creases</td>
<td>✔️</td>
</tr>
<tr>
<td>• Slipped from position</td>
<td>✔️</td>
</tr>
<tr>
<td>• Lose</td>
<td>✔️</td>
</tr>
<tr>
<td>• Hardened</td>
<td>✔️</td>
</tr>
<tr>
<td>• Degrading (oxidized)</td>
<td>✔️</td>
</tr>
<tr>
<td>• Stretched</td>
<td>✔️</td>
</tr>
</tbody>
</table>

| Dents, cuts, cracks                                                 | ✔️      |
| Handle                                                              | ✔️      |
| Filter Housing                                                      | ✔️      |
| Latches                                                             | ✔️      |
| Bolts, rivets, nuts for movement                                    | ✔️      |
| Test bacterial barrier effectiveness                                | ✔️      |
Dunkelberg Study

- 216 rigid sterilization containers obtained in-use inventory of 4 hospitals inspected per facilities policy
- All judged appropriate for maintaining content sterility
- However, 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
We Must Do A Better Job
Are My Rigid Containers Maintaining Sterility?

For Your Patient’s Safety
Take the Steps Necessary To Ensure You Are Confident They Are!

Thank You!!
Are My Rigid Containers Maintaining Sterility?


Selection and Use of Rigid Containers for Sterilization

Additional Resources

Association of periOperative Registered Nurses (AORN)
2170 South Parker Road, Suite 300
Denver, CO 80231-5711
Phone: 800-755-2676; Fax: 303-750-2927; www.aorn.org

Association for the Advancement of Medical Instrumentation (AAMI)
1110 North Glebe Road, Suite 220
Arlington, VA 22201-4795
Phone: 703-525-4890; Fax: 703-276-0793; www.aami.org

The Joint Commission
One Renaissance BLVD
Oakbrook Terrace, IL 60181
Phone: 630-792-5000; Fax: 630-792-5599; www.jointcommission.org

Centers for Medicare and Medicaid Services (CMS)
7500 Security Boulevard
Baltimore, MD 21244
Phone: 877-267-2323; www.cms.gov
Selection and Use of Rigid Containers for Sterilization

Additional Resources

American Hospital Association
Division of Quality Control and Management
One North Franklin
Chicago, Illinois 60606
Phone: 312-422-3000; Fax: 312-422-4796; http://www.hospitalconnect.com/ah; a/about/index.html

Association for Professionals in Infection Control and Epidemiology, Inc. (APIC)
1275 K Street, NW, Suite 1000
Washington, DC 20005-4006
Phone: 202-789-1890; Fax: 202-789-1899; www.apic.org

Centers for Disease Control and Prevention (CDC)
Hospital Infections Program
1600 Clifton Road
Atlanta, GA 30333
Phone: 800-311-3435; www.cdc.gov