Study conducted by Dr. Dunkelberg. Please ask your representative for a reprint. This study was not funded by KC/Halyard Health.
Dunkelberg Study Method

- Prof. Dunkelberg tested containers from various hospitals in Germany
- Containers tested ranged in age from new to 15+ years of usage
- All containers were still in use at hospitals
- Hospitals were under the impression that their containers provided a sufficient microbial barrier
Test Methodology

• Petri plates were placed into the container, then closed and steam sterilized
• After sterilization, the container was placed in a chamber where the air pressure was changed to simulate tray cool down and transport
• The air surrounding the tray contained bacteria to check if there were open pathways in filters, retention plates, gaskets, etc.
• The closed containers were stored in an incubator
• Finally, the container was opened to check how many colony forming units of bacteria developed
Rigid Containers Used in Hospitals Inspected for Integrity, Then Challenged

<table>
<thead>
<tr>
<th>Filter type</th>
<th># Tested (4 hospitals)</th>
<th># Containers Let Bacteria Through</th>
<th>Percent Nonsterile</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paper</td>
<td>69</td>
<td>57</td>
<td>82.6%</td>
</tr>
<tr>
<td>Reusable Textile Filters</td>
<td>132</td>
<td>115</td>
<td>87.1%</td>
</tr>
<tr>
<td>Permanent Plastic Filters*</td>
<td>15</td>
<td>1</td>
<td>6.7%</td>
</tr>
<tr>
<td>All filters (216 containers)</td>
<td>216</td>
<td>173</td>
<td>80.1%</td>
</tr>
</tbody>
</table>

* Of the 15 plastic filter containers, 5 (33%) were brand new, rest less than
Study Data Per Paper & Textile Filter Containers

- Dunkelberg analyzed data by container size & by filter type as designators.
- However, failures occur not only at the filters, but also anywhere on the containers, as this test challenged the “whole container“.

<table>
<thead>
<tr>
<th>gaskets</th>
<th>bolts</th>
<th>handle attachment</th>
</tr>
</thead>
<tbody>
<tr>
<td>chips</td>
<td>dents/cracks</td>
<td>gaps in filter-housing</td>
</tr>
<tr>
<td>latches</td>
<td>valves</td>
<td>poor filter securement</td>
</tr>
<tr>
<td>nuts</td>
<td>filter</td>
<td>more often used, more likely breaches</td>
</tr>
</tbody>
</table>
All 105 Standard Sized Containers From Study

* Of the 15 plastic filter containers, 5 (33%) were brand new, rest less than 2 years

- Shows how many bacteria (CFU) enter sealed container per surface area of Petri plates lining the container floor

- Example: 79 containers with textile filters (yellow triangles):
  - 9 containers had no bacteria so there are 9 yellow triangles on the zero CFU base line
  - 45 containers (yellow) had \( \leq 100 \) bacteria/600 cm\(^2\) (Petri plates lining bottom)
  - 4 containers had the highest contamination rate at approx. 800 bacteria per 600cm\(^2\)
Sterile? How Confident Are We?

- A rigid container is washed, processed through sterilization, and used on thousands of patients throughout its life cycle.
  - Junghannss estimated that containers were reprocessed and re-used 1,400 to 2,300 times (this is probably a low estimate)

- Study raises the question: How may surgeries are performed on patients with non-sterile instruments or implants from failed containers?

## Surgical Infection Perspective

- 27 million surgical procedures performed annually in the United States
- 780,000 surgical site infections (SSI)
- $27,000 is the average cost per SSI: (varies significantly)
- Example: Initial hip replacement infection averages $26,812; if a second re-admission due to a recurrence of the infection: an additional $31,046 = $57,858! (no CMS reimbursement – hospital eats cost of both)
- Approximately 12.5% of hip replacement SSI recur.
Dunkelberg on Opportunities for Barrier Integrity Damage

• Dunkelberg emphasized that there are many ways to compromise the barrier integrity of a rigid container
  — Latch securement to container can deteriorate
  — Seals can be damaged by repeated high heat, steam, mechanical stress
  — Rivets, bolts, nuts can be loosened with reprocessing, transport and jostling
  — Transport and handling can dent, crack, chip and stress
  — Filters can be poorly secured, housings fasteners fail, seals deteriorate and filters can be punctured, abraded overused
Is It Performing The Purpose Intended?

- For safety & efficiency we service cars at specified intervals
- Brakes, tire wear, belts, gaskets, seals, air filters, oil filters
- Why? They: become worn, oxidized, damaged, stretched, dented; lose seal integrity, shake lose, get dirty, occlude, tear, abrade, puncture
- Failure to do so, puts lives at risk:
Sterile

- Hospital-associated infections (HAI) kill more people in the US than motor vehicle, breast cancer and HIV combined
- SSI represent 17% of all HAIs
- With over 27 million operative procedures performed annually, isn’t it essential that the instruments, devices and implants that we certify as sterile, are indeed sterile?
- Our initials represent our personal professional assurance

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

<table>
<thead>
<tr>
<th>Item</th>
<th>Each Use</th>
<th>Yearly</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dents, cuts, cracks</td>
<td>☑</td>
<td></td>
</tr>
<tr>
<td>Handle</td>
<td>☑</td>
<td></td>
</tr>
<tr>
<td>Filter Housing</td>
<td>☑</td>
<td></td>
</tr>
<tr>
<td>Latch</td>
<td>☑</td>
<td></td>
</tr>
<tr>
<td>Bolts, rivets, nuts for movement</td>
<td>☑</td>
<td></td>
</tr>
<tr>
<td>Test bacterial barrier effectiveness</td>
<td>☑</td>
<td></td>
</tr>
</tbody>
</table>
### Even 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>
</tr>
</tbody>
</table>

80 *Staphylococcus* bacteria standing in a row to reach across the hole that no one can see without magnification!!
Compare Performance to Non-woven Sterilization Wrap

• 5 double layered polypropylene\(^1\) non-woven wrapped packs also tested with rigid containers

• Contents (agar plates within the packs) of all found to be sterile after the bacterial challenge and pressure changes

• Statistically, too few to be significant, but all 5 remaining sterile after the rigorous full package test is important

• Question: If a “pin-hole” occurs in non-woven wrap, will it let bacteria through like a hole in a rigid container?

1. Author communication: Confirmed non-woven was polypropylene
Holes in Wrap Compared to Rigid Containers

Bacteria go right through holes/cracks in containers; nothing to stop them
But not through polypropylene non-woven wrap. Why?

Three 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. Each fiber is electret treated making it charged in order to attract & trap any bacteria trying to penetrate the fabric
3. In some, tortuous pathway & electret property maintained during transport/storage: with PowerGuard* technology

“Surround” Full Tray Protection
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“Surround” Full Tray Protection

- **Bacteria**
  - **Spunbond Fibers (Strength)**
  - **Melt-blown polypropylene**
  - Charged-Capture-Retain Cross-section

- **Bacteria Captured on charged fiber & retained:** Power-Guard* technology
Summary & Conclusions

• In this study, 216 rigid sterilization containers obtained from in-use inventory of 4 hospitals were visually inspected and deemed appropriate for maintaining sterility.

• However, the majority of containers failed to prevent recontamination after sterilization when subjected to bacterial aerosols under changes in atmospheric pressure.

• 5 wrapped non-woven packages tested did preserve sterility.

• We cannot assume passing visual inspection is a guarantee against sterility failure.

• Dunkelberg concludes: Rigid containers must be inspected before each use for visual damage, but should also be tested by whole container barrier integrity using varying pressure bacterial aerosol challenge annually.
Appendix

Methicillin-resistant
*Staphylococcus aureus* (MRSA)
Why Pressure Variation Levels for Sterile Containers or Wrapped Packs?

- After sterilization cycle completed, containers cool, **air from environment sucked into container** thru filter or breaches

- Most SPD in basements: As elevator goes up external pressure decreases; air pulled **out of containers/packs**

- OR ventilation is cool, positive pressure pushing air **into containers/packs through filters** (or holes or cracks if any)

- If not used, containers transported back down elevator air pressure increases outside– pushing air **into containers/packs**

**Recommended practice**

- Containers may remain in sterilizer to cool with sterilizer door ajar, reducing condensation formation

- Once removed, should remain on cart in low traffic area
  — ANSI/AAMI ST79 states may take 30 minutes to 2 hours

- Do not place on cold racks until containers cooled as condensation within container may occur
Dunkelberg Study

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