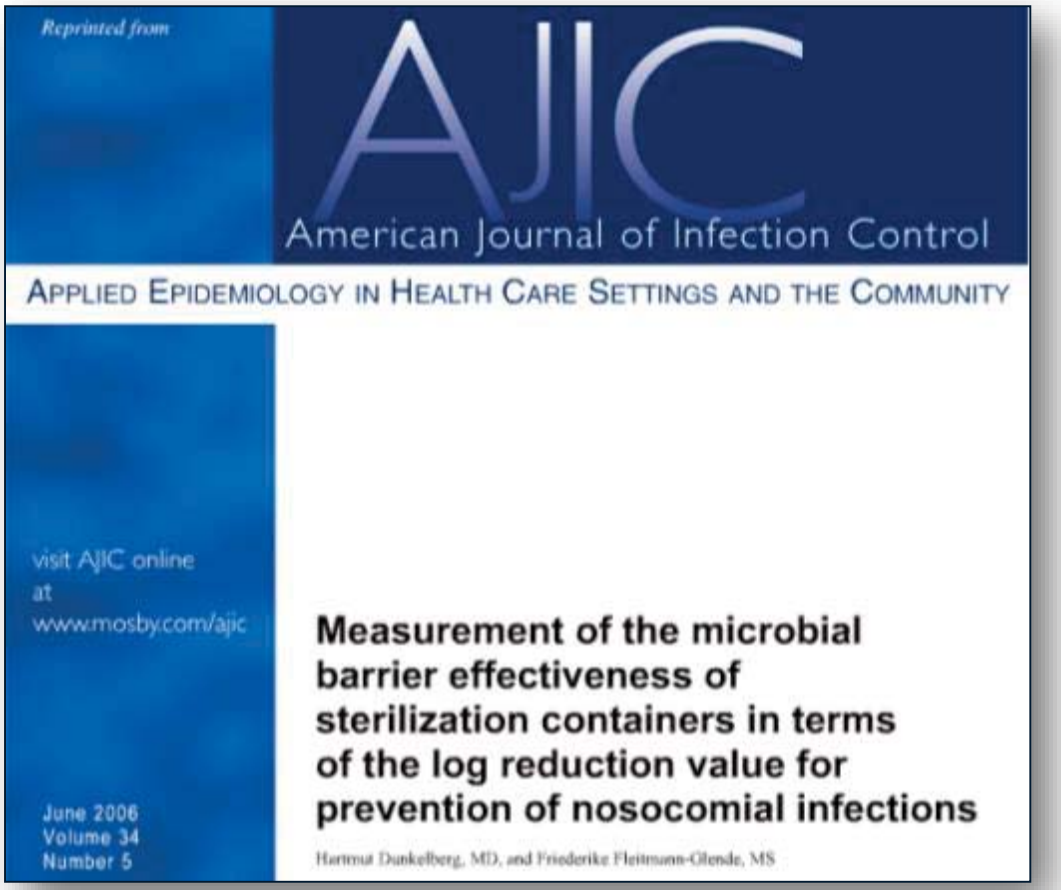
Dunkelberg Study:

Summary Presentation



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

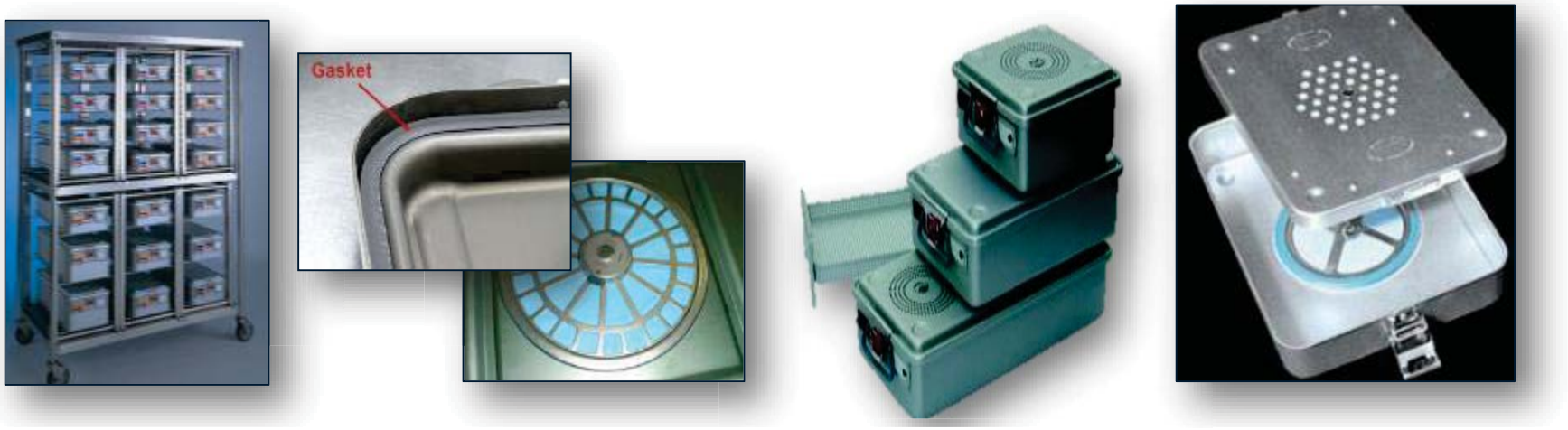
Test Methodology

- 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

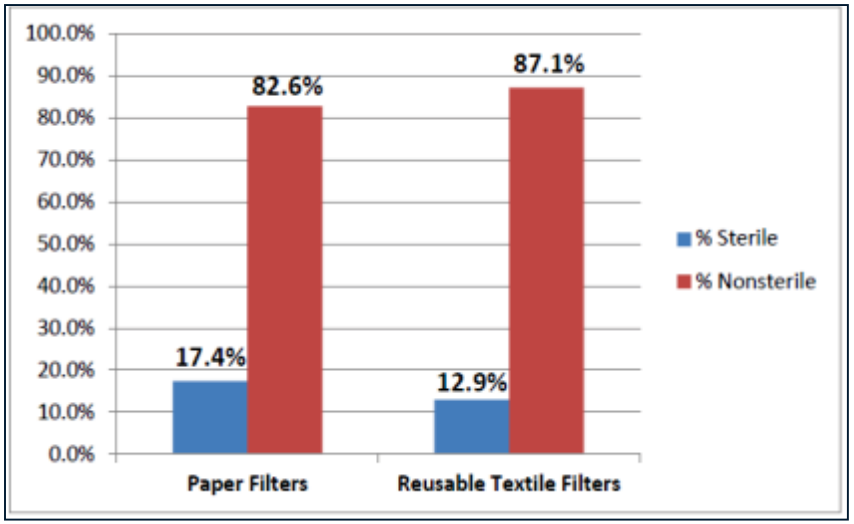
Rigid Containers Used in Hospitals Inspected for Integrity, Then Challenged

All Containers Tested (standard and half-size)			
Filter type	# Tested (4 hospitals)	# Containers Let Bacteria Through	Percent Nonsterile
Paper	69	57	82.6%
Reusable Textile Filters	132	115	87.1%
Permanent Plastic Filters*	15	1	6.7%
All filters (216 containers)	216	173	80.1%

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



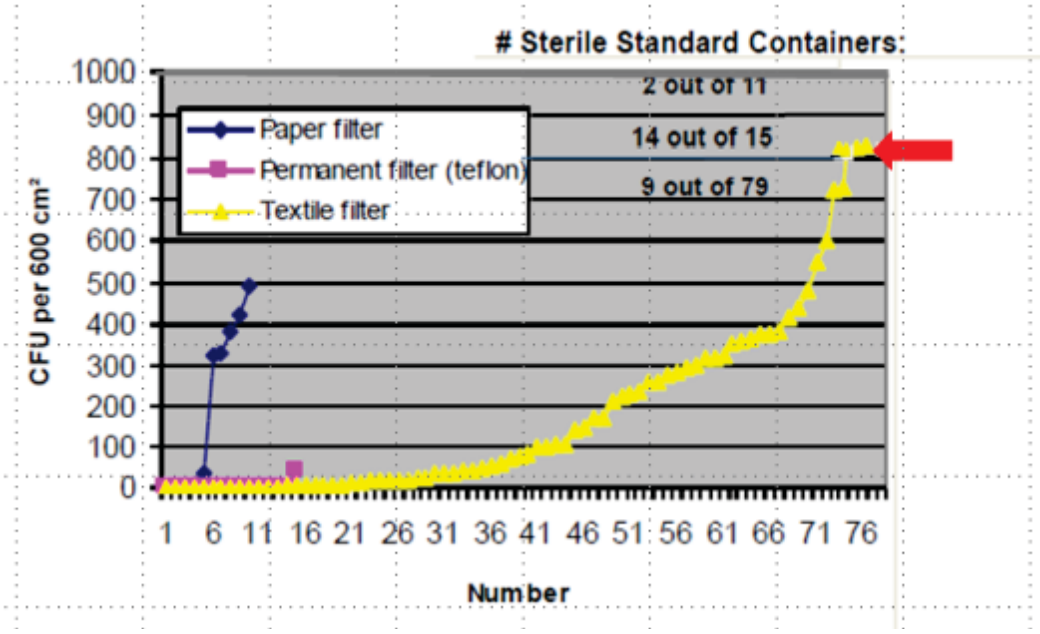
Study Data Per Paper & Textile Filter Containers



- 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 “.

gaskets	bolts	handle attachment
chips	dents/cracks	gaps in filter-housing
latches	valves	poor filter securement
nuts	filter	more often used, more likely breaches

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:

NUMBER OF MONTHS OR MILES	LUBE, OIL, FILTER	ENGINE FLUSH SERVICE	ROTATE TIRES	INSPECT WHEEL ALIGN	TUNE -UP	FUEL SYSTEM CLEANING SERVICE	POWER STEERING FLUSH	TRANS FLUSH SERVICE	COOLING SYSTEM SERVICE	INSPECT BRAKE SERVICE	BRAKE SYSTEM FLUSH	BATTERY SERVICE
3 month 3,000 miles	✔											
6 month 6,000 miles	✔		✔							✔		
9 month 9,000 miles	✔											
12 month 12,000 miles	✔		✔							✔		
15 month 15,000 miles	✔			✔				✔				
18 month 18,000 miles	✔		✔							✔		✔
21 month 21,000 miles	✔											
24 month 24,000 miles	✔	✔	✔			✔	✔			✔	✔	
27 month 27,000 miles	✔											
30 month 30,000 miles	✔		✔	✔	✔			✔	✔	✔		
33 month 33,000 miles	✔											
36 month 36,000 miles	✔		✔							✔		✔
39 month 39,000 miles	✔											
42 month 42,000 miles	✔		✔							✔		
45 month 45,000 miles	✔	✔		✔				✔				
48 month 48,000 miles	✔		✔			✔	✔			✔	✔	
51 month 51,000 miles	✔											
54 month 54,000 miles	✔		✔							✔		✔
57 month 57,000 miles	✔											
60 month 60,000 miles	✔		✔	✔	✔			✔	✔	✔		

Sterile

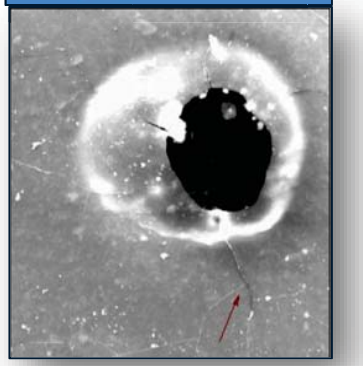
- Hospital-associated infections (HAI) kill more people in the US than motor vehicle, breast cancer and HIV combined
- SSI represent 17% of all HAIs
- With over 27 million operative procedures performed annually, isn't it essential that the instruments, devices and implants that we certify as sterile,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

	Each Use	Yearly
Seals • Worn • Abraded • Cuts. Creases • Slipped from position • Lose • Hardened • Degrading (oxidized) • Stretched	✓	
Dents, cuts, cracks	✓	
Handle	✓	
Filter Housing	✓	
Latch	✓	
Bolts, rivets, nuts for movement	✓	
Test bacterial barrier effectiveness		✓

Tiny crack in dent

Even Diligent Visual Inspection, No Guarantees

Tiny hole 80µm



Object	Millimeters (mm)	Micrometers (µm) aka: microns
Smallest size human can see	0.100	100
Magnified hole above, too small to see	0.080	80
Staphylococcus aureus bacterium	0.001	1

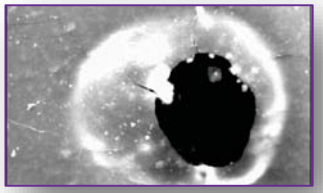
80 *Staphylococcus* bacteria standing in a row to reach across the hole that no one can see without magnification!!

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

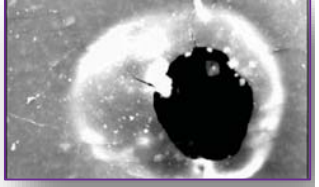
But not through polypropylene non-woven wrap. Why?

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

Holes in Wrap Compared to Rigid Containers



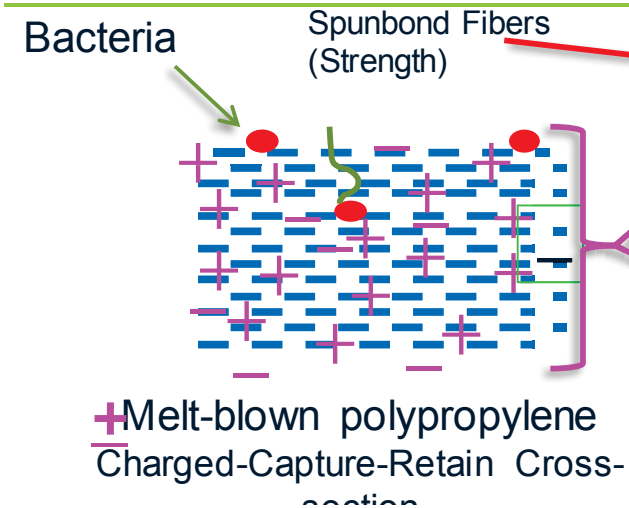
Bacteria go right through holes/cracks in containers; nothing to stop them

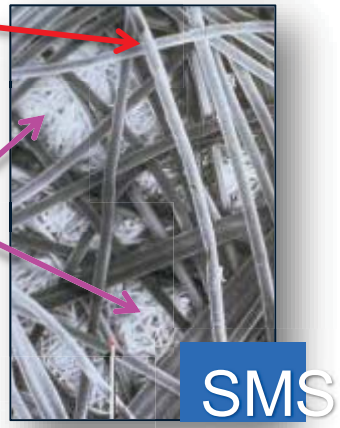
But not through polypropylene non-woven wrap. Why?

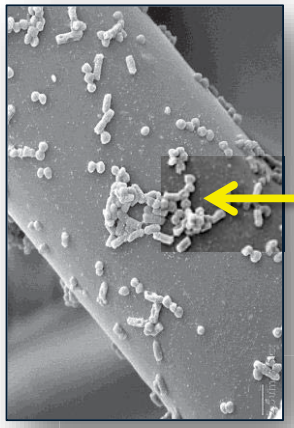
Three reasons:

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





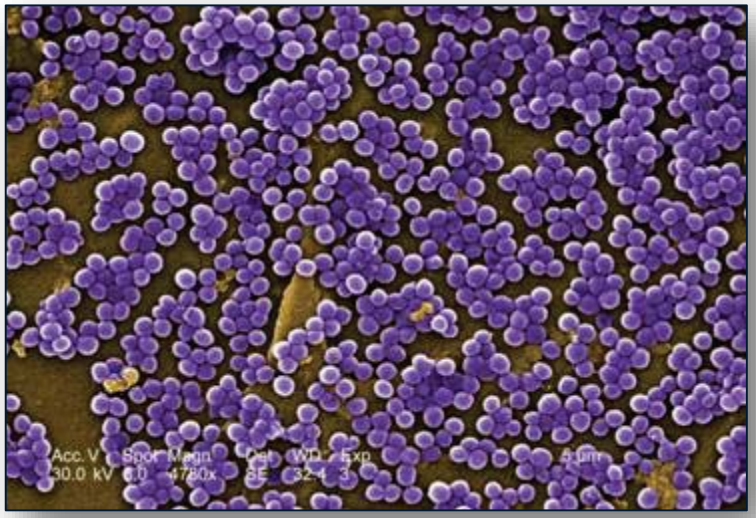


Bacteria Captured on charged fiber & retained: Power-Guard* technology

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)

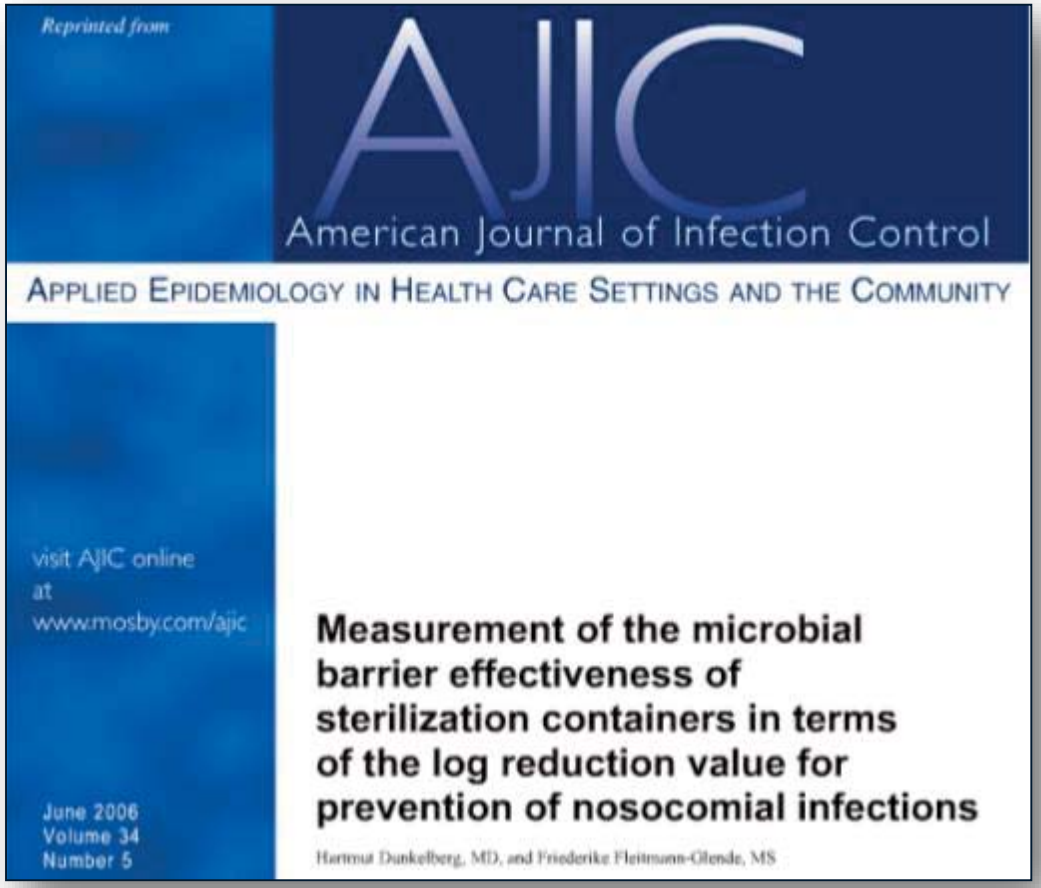
Why Pressure Variation Levels for Sterile Containers or Wrapped Packs?

- 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



Study conducted by Dr. Dunkelberg. Please ask your representative for a reprint.
This study was not funded by Kimberly-Clark.