NEW SCIENTIFIC STUDY[1] REVEALS 87% OF RIGID CONTAINERS TESTED POSITIVE FOR BACTERIAL CONTAMINATION

Research was funded by Halyard Health, Inc. (formerly Kimberly-Clark Heath Care) and conducted by Applied Research Associates, an international research laboratory.

HOW ARE CONTAINERS AND STERILIZATION WRAP USED?

Containers and sterilization wrap (also known as sterile packaging systems) protect surgical instruments from contamination from the time of sterilization until the surgical procedure, decreasing risk for SSIs.

THE BIG PICTURE

With approximately **300,000 SSIs occurring annually** in U.S. hospitals[1] and the implementation of Affordable Care Act mandates, hospitals are experiencing unprecedented pressure to reduce SSIs.

25% of facilities will see a 1% reduction in Medicaid/Medicare reimbursement.[3] For a mid-size facility with over $100 million in Medicare payments, this penalty could exceed $1 million just for HACs.

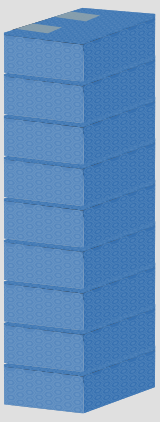
THE STUDY

To help hospitals identify ways to reduce SSI occurrence, ARA conducted a new study to validate research from 2006, which found that sterilization wrap was more effective than rigid containers at maintaining sterility of surgical instruments.[2]

THE METHODOLOGY[1]

After being sterilized ...

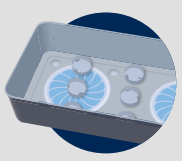
111 rigid containers



161 wrapped trays

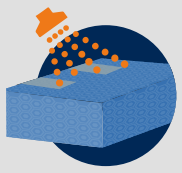
... were tested for bacteria

THE TESTING PROTOCOL[1]



Membranes in sterilization packaging

Sterilization occurs (Pre-Vac)



Aerosol chamber to emulate real-life environmental changes

Containers & wrapped trays wiped down

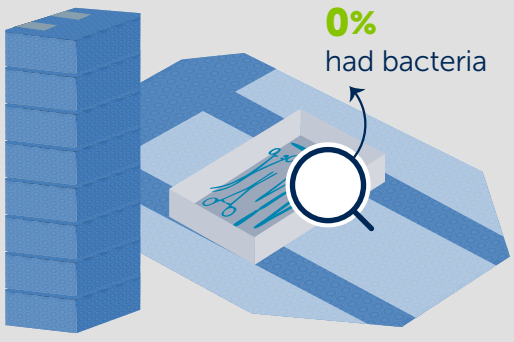
Membranes put into petri dishes & bacteria counted

These findings validate the 2006 research.[2]

THE RESULTS[1]

Even unused rigid containers had high levels of contamination**

*Out of 111 rigid containers tested, 14 (12.6%) had no bacterial ingress, 25 (22.5%) had ingress of 1-9 CFU, 52 (46.8%) had ingress of 10-99 CFU, and 20 (18.0%) had ingress >100 CFU.
**72% of unused containers showed bacterial ingress



100% of the wrapped trays maintained sterility until use

[1] Harry L. Shaffer MS*, Delbert A. Harnish MS*, Michael McDonald MS, Reid A. Vernon BS, Brian K. Heimbuch MS*. Sterility maintenance study: Dynamic evaluation of sterilized rigid containers and wrapped instrument trays to prevent bacterial ingress. Am J Infect Control. 2015 Dec;43(12)1336–1341
* Harry L. Shaffer MS, Delbert A. Harnish MS, and Brian K. Heimbuch MS contributed to/authored the above article at the time they had a financial consulting relationship with Halyard Health, Inc.; however, they were not compensated by Halyard Health, Inc. for their respective contributions/authorship of the article.

[2] The 2006 study, "Measurement of the microbial barrier effectiveness of sterilization containers in terms of the log reduction value for prevention of nosocomial infections," was published in the American Journal of Infection Control and conducted by Hartmut Dunkelburg, MD, and Friederike Fleitmann-Glende, MS, from the Medical Institute of General Hygiene and Environmental Health, University of Goettingen in Germany. The study was conducted with a microbial challenge of 216 sterilization containers of four central sterile supply departments of different hospitals in Germany. It found that nine out of 11 containers with paper filters and 70 out of 79 containers with textile filters failed to maintain barrier performance.

[3] US Department of Health and Human Services/Centers for Medicare and Medicaid Services, Data Compendium, 2009 Edition.