STERILITY MAINTENANCE STUDY

Frequently Asked Questions

PRODUCT QUESTIONS

Q: WHAT IS A RIGID CONTAINER AND HOW DO THEY WORK?

A: A rigid container is a type of Sterilization Packaging System (SPS). It is a device that serves as a packaging material for items prior to, during and after sterilization. They are reusable and come in a variety of materials and sizes (various metals, aluminum and polymers).

Most sterilization containers have a filter mechanism designed to permit the sterilant to enter and exit the container as well as to act as a microbial barrier. Most container systems are designed for terminal sterilization and extended storage, utilizing a disposable filter secured by a filter retention plate. Some containers have a filter-less system equipped with a pressure sensitive or thermostatic valve which opens and closes within the sterilizer.

Q: WHAT IS STERILIZATION WRAP AND HOW DOES IT WORK?

A: Sterilization wrap is a three-layer laminate composed of a layer of meltblown polypropylene bonded on both surfaces with a layer of spunbonded polypropylene. The sheets of sterilization wrap are square or rectangular fabric produced using a polypropylene three-layer SMS (spunbond-meltblown-spunbond) process.

The wrap is intended to allow sterilization of the enclosed medical device(s) and also to maintain sterility of the enclosed device(s) until opened. Sterilization wrap works by allowing the sterilizing agent (e.g., steam, ethylene oxide, hydrogen peroxide gas plasma, etc.) to penetrate and then providing a barrier to maintain sterility of the wrapped surgical instruments.

The Halyard Health sterilization wrap portfolio includes innovations such as the QUICK CHECK* Wrap, the first dual-color wrap in the U.S. market, and SMART-FOLD* Wrap, a new type of sterilization wrap designed to be three times more tear-resistant and twice as fast to use as conventional wrap.

Q: HOW DO THEY DIFFER?

A: Rigid sterilization containers are made of rigid, durable material with a permeable filter and sterilization wrap is made of pliable permeable fabric.

Q: WHO DECIDES WHETHER A HOSPITAL WILL USE RIGID CONTAINERS OR STERILIZATION WRAPS? HOW IS THIS DECISION MADE?

A: The decision around what Sterilization Packaging System to use is a multidisciplinary effort between hospital leadership, infection control and perioperative specialists and materials management, among others. While factors impacting this decision typically include cost, efficacy, and ease-of-use, they are unique to each organization and influenced by its patient population and central processing workflows.

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Q: IN WHAT SETTINGS ARE THESE PRODUCTS USED?

A: Sterilization Packaging Systems are used in the following settings: They are applied within the Sterile Processing department, provide a barrier during storage (either on or offsite) during transportation to the Operating Room, and are opened during the actual surgical procedure.

Q: ARE STERILIZATION WRAPS RECYCLABLE?

A: Yes, HALYARD* Sterilization Wrap is made from recyclable #5 polypropylene.

MARKET QUESTIONS

Q: ARE THERE OTHER STERILIZATION PRODUCTS IN THIS MARKET?

A: There are several Sterilization Packaging System options, including rigid containers, peel-open pouches (e.g., self-sealed or heat-sealed plastic and paper pouches), roll stock or reels (i.e., paper-plastic combinations of tubing designed to allow the user to cut and seal the ends to form a pouch) and sterilization wraps (woven and nonwoven). Healthcare facilities may use any of these options, including a combination of the systems.

STUDY METHODOLOGY QUESTIONS

Q: WHAT WAS THE PURPOSE OF THE STUDY?

A: The purpose of the study was to examine the ability of Sterilization Packaging Systems to effectively maintain sterility of surgical instruments and devices from the time of sterilization until use.

Q: WHAT WAS THE DESIGN OF THE STUDY? HOW WAS IT CONDUCTED?

A: The study was designed to evaluate the capability of sterilized rigid containers and sterilization wrap, sterilized using North American sterilization protocols, to maintain a sterile internal environment (post-sterilization) when challenged with aerosolized bacteria under dynamic environmental conditions.

The study was conducted using a custom aerosol chamber, 111 rigid containers of various durations of use (unused, <5 years, 5-9 years) and 161 wrapped trays using three grades of sterilization wrap. Each product was challenged with ~102 colony forming units per liter of a Micrococcusluteus aerosol with a median particle size of 1-µm, while simultaneously experiencing air volume exchanges due to vacuum cycles – two 1 psi cycles, three 0.7 psi cycles, and three 0.4 psi cycles – to simulate air exchange events which occur during the sterilization, transportation, and storage of sterilized instrument sets in healthcare facilities.

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Q: WHY WAS A 1 MICRON SIZED BACTERIUM USED?

A: The test bacterium, Micrococcus luteus, is comparable in size and shape to Staphylococcus aureus and coagulase-negative Staphylococci, which together represent over 43% of surgical site infections (SSIs) in the United States.

Q: WERE HEALTHCARE PRACTITIONERS/PERSONNEL INVOLVED IN THE STUDY?

A: The study design was developed in conjunction with central supply professionals and other industry consultants. The study was conducted by researchers from Sterilization Consulting Services, LLC, Highlands Ranch, CO; Applied Research Associates, Panama City, FL; and the United States Air Force Academy, Colorado Springs, CO.

Q: HOW WERE PRODUCT SAMPLES SELECTED FOR USE IN THE STUDY?

A: Rigid containers obtained from normal active hospital inventory, together with new containers purchased from the open market, were tested during the study. The rigid containers consisted of the four container brands which make up the top market share in the U.S

For sterilization wrap, multiple lots from several grades of single-use polypropylene wrap were obtained from a single manufacturer. Grades of sterilization wrap indicate fabric weight, with lower fabric weights used for lighter instrument trays and higher fabric weights for heavier instrument trays. Heavier wraps were chosen for the study because the contents normally placed in rigid containers are of a weight that, if wrapped, would require a heavier wrap.

Q: WHY WAS THE PRESSURE CHANGED IN THE CHAMBER? HOW DOES THIS RELATE TO MY HOSPITAL?

A: Air movement is caused by temperature and pressure differences. In the hospital environment, a variety of events cause air to move (e.g., opening doors, transportation, etc.) through Sterilization Packaging Systems. Dynamic air movement drives air particles into Sterilization Packaging Systems, providing a greater challenge than simply static air with no movement. The pressure was changed inside the chamber to simulate the air movement an Sterilization Packaging Systems may experience in the hospital environment.

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Q: WERE THE CONTAINERS WASHED BETWEEN TEST RUNS?

A. Yes

Q: WAS THE APPROPRIATE MONITORING (I.E., CHEMICAL INDICATORS) DONE THROUGHOUT THE STUDY?

A. Yes

Q: WHAT WERE THE STEPS USED TO CLEAN THE CONTAINERS AT EACH INTERVAL OF THE TEST?

A: All containers/trays were wiped down with bleach wipes at the end of each test, allowed to decontaminate (> 15 min), and then wiped down with water.

Q: AT MY HOSPITAL WE CLOSELY MONITOR THE CLEANING AND STERILIZATION PROCESS. WHO SUPERVISED THE CLEANING AND STERILIZING OF THE CONTAINERS DURING THE TESTING?

A: Post-test decontamination of containers was performed by ARA personnel. Sterilization of the containers was performed by the central processing staff of Bay Medical Center/Sacred Heart Health System.

Q: DID YOU EXAMINE THE FILTERS PRIOR TO USE TO BE SURE THERE WERE NO HOLES/BREECHES?

A: Yes

Q: ARE VALVED CONTAINERS BETTER?

A. This was a blind study where container brand was not specifically analyzed for clinical performance

Frequently Asked Questions

Q: WERE THE IFU's OF THE CONTAINER MANUFACTURER FOLLOWED FOR EVERY STEP?

A. Yes

Q: DID YOU TEST WRAPPED TRAYS WITH ANY HOLES IN THE WRAP BECAUSE THIS HAPPENS OFTEN?

A. No the wrap did not include any breaches.

Q: WERE THE CONTAINERS AND WRAPPED TRAYS STERILIZED IN THE SAME STERILIZER LOAD? WERE THEY RUN TOGETHER IN THE AEROSOL CHAMBER?

A. Yes and Yes

STUDY RESULT QUESTIONS

Q: WHAT WERE THE PRIMARY FINDINGS?

A: In this study utilizing a dynamic bacterial aerosol challenge, sterilized wrapped trays demonstrated significantly greater protection than sterilized rigid containers against ingress of airborne bacteria. Additionally, the average level of contamination found in rigid containers increased with level of use, with containers having 5-9 years of use being significantly higher than unused containers.

Q: WHY ARE THESE FINDINGS SIGNIFICANT?

A: This study puts into question the assumption that rigid containers, regardless of duration of use, maintain the sterility of their contents post-sterilization.

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HALYARD'S ROLE IN STUDY QUESTIONS

Q: WHAT WAS HALYARD'S ROLE IN THE STUDY?

A: Halyard Health, formerly Kimberly-Clark Health Care, funded the study, which was conducted by researchers from Sterilization Consulting Services, LLC, Highlands Ranch, CO; Applied Research Associates, Panama City, FL and the United States Air Force Academy, Colorado Springs, CO. It is common practice for manufacturers to fund scientific research.

Q: DID HALYARD HAVE ANY DIRECT INVOLVEMENT IN THE EXECUTION OF THE STUDY?

A: No, Halyard Health did not have any direct involvement in execution of the study. The study took place in an independent laboratory in Panama City, Florida, and the study was conducted by independent researchers.

Q: IS HALYARD SAYING THAT WRAP IS BETTER THAN CONTAINERS?

A: This study calls into question the assumption that rigid containers, regardless of duration of use, maintain the sterility of their contents post-sterilization. Results also demonstrated that rigid containers, even unused, had high levels of bacterial ingress while sterilized wrapped trays had a significantly higher level of protection from microbial contamination. Failures in sterile packaging systems may lead to contamination of the contents.

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 Aug 31. pii: S0196-6553(15)00761-0. doi: 10.1016/j.ajic.2015.07.010. [Epub ahead of print]

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