

# CONSENSUS STATEMENT ON STERILITY MAINTENANCE OF STERILE PACKAGING SYSTEMS IN THE HOSPITAL SETTING

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## INTRODUCTION

### A. OVERVIEW

Sterile Packaging Systems (SPS) are designed to protect surgical instruments during and post-sterilization until use in the operating room (OR). The two primary types of SPS include rigid sterilization containers and sterilization wrap. Rigid sterilization containers are reusable and come in a variety of materials (e.g., various metals, aluminums and polymers) and sizes, while single-use sterilization wrap is typically composed of polypropylene. Until now, little consideration has been given to SPS as a potential cause of surgical site infections (SSIs), 300,000 of which occur annually in the United States, resulting in 9,000 attributable deaths.<sup>1-3</sup>

When addressing factors that contribute to SSIs, healthcare professionals often overlook SPS as a potential cause. However, a recent study- (Sterility Maintenance Study) funded by Halyard Health, Inc., a manufacturer of sterilization wrap, published in the American Journal of Infection Control<sup>4</sup> (AJIC) underscores the fact that additional attention should be given to SPS as a potential source of SSIs. In light of this new information, the healthcare community should reassess the usage of rigid containers as a way to reduce the potential for SSIs, thereby improving patient outcomes and increasing hospital safety

### B. STERILITY MAINTENANCE STUDY

Applied Research Associates, an independent laboratory, conducted the second study<sup>5</sup> of its kind within a decade, examining the ability of rigid sterilization containers and sterilization wrap to maintain sterility of their contents from the time of terminal sterilization, through transport and handling, until use in the OR. The testing protocols of the study, published in the December 2015 issue of AJIC and titled "Sterility Maintenance Study: Dynamic Evaluation of Sterilized Rigid Containers and Wrapped Instrument Trays to Prevent Bacterial Ingress" were intended to represent conditions within a hospital setting. SPS were placed in an aerosol chamber and challenged with aerosolized bacteria under dynamic environmental conditions that simulated the air movements an SPS may encounter in a hospital.

#### According to the study:

- Rigid sterilization containers, both used and unused, failed to maintain barrier performance under the test conditions: 87 percent (97 out of 111) of the interiors of rigid sterilization containers tested positive for bacteria.
  - Specifically, of the 111 rigid containers tested, 14 (12.6 percent) had no bacterial ingress, 25 (22.5 percent) had ingress of 1-9 colony forming unit (CFU), 52 (46.8 percent) had ingress of 10-99 CFU, and 20 (18.0 percent) had ingress >100 CFU.
  - Even unused rigid sterilization containers had high levels of bacterial contamination: 72 percent of the interiors of the unused rigid containers tested positive for bacteria.
- Rigid sterilization containers are less effective the longer they are in use: Contamination rates of rigid sterilization containers increased as duration of use increased.

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- Rigid sterilization containers with 5-9 years of use were significantly more likely to have bacterial ingress than unused rigid sterilization containers.
- Sterilization wraps provided no detectable ingress of bacteria: 100 percent (161 out of 161) of the wrapped trays using sterilization wrap maintained sterility, preventing the entrance of bacteria.

## C. OBJECTIVE OF SUMMARY REPORT

The findings of this study have far-reaching implications across multiple stakeholders within a hospital setting. To address these findings and develop an action plan for healthcare professionals working with SPS, a group of six experts across the fields of infection prevention, sterile processing/central services, protocol regulation, nursing and research convened in a roundtable discussion at the 2016 International Association of Healthcare Central Service Material Management (IAHCSMM) Annual Conference. The panel discussed their insights and reactions to the study findings and made recommendations based on their extensive experience working in each of their respective fields of expertise.

This report aims to:

- Offer necessary guidance on the use of sterilization wrap versus rigid sterilization containers in the hospital setting,
- Encourage healthcare professionals to reassess container usage in their facilities, and
- Drive consensus among healthcare practitioners and patient safety-focused associations and professional groups regarding a recommendation for SPS usage.

With these priorities as the call-to-action, the expert panel is committed to driving awareness of the study results, and ultimately, changing healthcare professionals' approach to SPS.

## D. ROUNDTABLE/SUMMARY REPORT DEVELOPMENT PANEL

### **Mark Duro\***

Director of Sterile Processing Operations  
New England Baptist Hospital in Boston

### **Sharon Greene-Golden, CRCST, FCS\***

Manager of Sterile Processing  
Adventist Healthcare Shady Grove Medical Center

### **William Jarvis, MD\***

Former Acting Director, Hospital Infections Program (HIP)  
Centers for Disease Control and Prevention (CDC)  
President and Co-founder  
Jason and Jarvis Associates, LLC

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**Peg Luebbert, MS, CIC, CHSP, CBSPD\***

Infection Preventionist  
Nebraska Orthopaedic Hospital Select Specialty LEACH  
President and Founder  
Healthcare Interventions

**Rose Seavey MBA, BS, RN, CNOR, CRCST, CSPDT\***

President and CEO  
Seavey Healthcare Consulting, LLC

**Harry Shaffer, MS\***

Lead study author  
Member of Committee on Microbiology for Sterilization  
AAMI  
President  
Sterilization Consulting Service

\*These individuals have a financial relationship with Halyard Health, Inc.

## 2. RECOMMENDATIONS FOR HEALTHCARE PROFESSIONALS, INDUSTRY AND REGULATORY BODIES WORKING WITH SPS

The below represents the panel's collective analysis, evaluation, and recommendations for healthcare professionals working with SPS, based on both individual opinions and the group discussion.

### A. ENFORCE PROPER MAINTENANCE AND HANDLING OF SPS

The study demonstrated that even brand new rigid sterilization containers allowed the entrance of bacteria between the time of sterilization until use in the OR. This points to the fact that the inherent design of many rigid sterilization containers allows for the entrance of bacteria after sterilization, during transport and handling until use, with older containers at highest risk for bacterial contamination. Although a longer-term solution is needed to address that issue, Sterile Processing Department (SPD) and Central Supply (CS) professionals can take immediate steps in the meantime to reduce patient risk of SSIs by enforcing proper maintenance and handling of sterile packaging systems, as defined by the instructions for use (IFUs), and receiving additional training on how to pinpoint signs of defective rigid sterilization containers.

While CS staff can follow the IFUs of the rigid sterilization containers in service at their facilities – and put into practice proper handling, maintenance and tracking programs to ensure they're protecting the supplies contained within them, they cannot control the overall quality and design of SPS. The onus is on rigid container manufacturers to develop SPS that don't allow for bacterial contamination after sterilization.

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The results of the study demonstrate the importance of Infection preventionists working closer with their SPD and OR counterparts. In addition, they should conduct form and function testing of rigid sterilization containers to the same rigorous standards as surgical instruments. This testing should include:

- Assurance that lids fit neatly on the base of the sterilization container.
- Implementing an inspection system to confirm integrity of gaskets and filters: Ensuring through regular checks that bases and lids fit tightly, there are no cracks in the gaskets, and no holes in the filters.
- Inspecting the containers for damage, including dents.

The study also showed that the longer rigid sterilization containers are in use, the higher the risk of bacterial ingress/contamination. Even more surprising is the fact that 72 percent of brand-new sterilization containers tested revealed bacterial contamination. The potential danger to patients caused by keeping old rigid sterilization containers in circulation is too great to ignore. A comprehensive life cycle assessment should be performed to understand the true clinical, cost and efficiency performance levels of all SPS in use within the facility. We urge facilities to replace older rigid sterilization containers and consider replacing them with sterilization wrap. The science clearly demonstrates that sterilization wrapped trays are significantly more effective at maintaining sterility of their contents.

Finally, infection preventionists should examine infection rates for different departments handling patients with high risk for infection. Serious consideration should be made to replace rigid sterilization containers with wraps, particularly if other measures have not succeeded in reducing infection rates.

## **B. FOSTER COLLABORATION AMONG STERILE PROCESSING DEPARTMENT (SPD) OR CENTRAL SUPPLY (CS) PROFESSIONALS, INFECTION PREVENTIONISTS, AND OTHER DIVISIONS WITHIN THE HOSPITAL REGARDING BEST PRACTICES FOR MAINTAINING AND HANDLING SPS**

In many hospital settings, SPD/CS departments operate with very little contact with infection preventionists and other divisions of the hospital. Once an SPS leaves these departments, the end-user in the OR potentially gives little thought to where the items came from, their condition, and how they were handled. Moreover, the activities/protocols that take place in the SPD or CS department are seldom linked to potential causes of SSIs. This is due in large part to the fact that communication is often limited between SPDs and infection preventionists, and that the vast majority of infection preventionists do not incorporate SPS into their risk assessments. This study demonstrates the importance of collaboration between SPDs and infection preventionists in improving patient safety and reducing risk for SSIs. In order to implement this type of communication the panel recommends that SPD/CS professionals:

- Share the study findings directly with their infection preventionists
- Encourage their colleagues to familiarize themselves with the study findings

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Additionally, it is incumbent that infection preventionists:

- Schedule frequent and regular meetings with SPD/CP professionals to uncover new, potential causes of SSIs
- Share the study findings with surgeons, whose patients are most at risk for contracting SSIs
- Include SPS in their risk assessments

Surgeons—particularly orthopedic, neuro and cardiac surgeons—play a critical role in helping to shed light on these new study findings as their patients are at critical risk for contracting SSIs. We urge surgeons to:

- Require their OR staff to receive training on proper SPS handling and how to identify faulty SPS, to prevent the use of instruments stored in ineffective SPS from being used on patients

## **C. INCREASE RIGOR OF SPS PROTOCOLS AND GUIDELINES**

Professional groups, standards and accreditation bodies, and Federal regulators need to work together to refine SPS testing protocols and guidelines. Dynamic aerosol challenges are critical to determining rigid sterilization containers' ability to keep contents sterile from the time of sterilization, through transport and handling, until use in the OR. Historically, microbial ingress studies couldn't be standardized, thereby excluding them from all regulatory body approval processes and becoming the responsibility of the individual manufacturers/users at the hospital level. Without standardization, microbial testing is performed inconsistently, if at all, and at various levels of rigor.

However, today's technology, as demonstrated by the study published in AJIC, enables this type of testing to be standardized. As a result, prior to approval, classification, and accreditation, the US Food and Drug Administration (FDA), the Association for the Advancement of Medical Instrumentation (AAMI) and The Joint Commission should strongly consider requiring a dynamic aerosol test to be performed on all SPS on two separate occasions between the time of sterilization until use in the OR, as the Sterility Maintenance Study clearly demonstrates that achieving sterility at the time of sterilization is not a predictor of continued sterility after transport and handling, until use in the OR.

## **D. ACHIEVE CONSENSUS ACROSS HEALTHCARE PROVIDER AND PATIENT SAFETY ASSOCIATIONS**

In the current landscape, healthcare provider and patient safety associations and professional groups do not recognize proper use of SPS as a solution for improving patient outcomes and reducing risk for SSIs. The roundtable panelists call for this community to review the Sterility Maintenance Study, as well as the recommended calls-to-action outlined in this summary report, and agree on integrating SPS use into the national discussion on patient safety and SSI prevention. This will involve identifying relevant organizations and stakeholder

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groups, developing a consensus statement, and crafting messaging to drive awareness and implementation of the recommended practices outlined in section B. The groups who sign the consensus statement will be responsible for activating stakeholders to consider the link between SPS and SSIs and drive reform.

## 3. CONCLUSION

The primary duty of all hospital staff—including surgeons, nurses, infection preventionists, and SPD/CS professionals—is to keep patients safe. A patient’s trust is rooted in the knowledge that they will consistently receive the highest quality care. Integrity plays a large role in this, and it is critical that healthcare professionals do everything in their power to prevent infection. This starts in the SPD/CS department, with the use of effective surgical instruments and SPS, as well as the consistent and proper handling of these items. Healthcare professionals cannot afford to ignore the recommendations outlined above. Our patients’ lives depend on it.

## 4. PANELIST BIOGRAPHIES

### **Rose Seavey MBA, BS, RN, CNOR, CRCST, CSPDT**

Rose Seavey is the President and CEO of Seavey Healthcare Consulting, LLC, and the former Director of the Sterile Processing Department at The Children’s Hospital of Denver.

Ms. Seavey is a member of several Association for the Advancement of Medical Instrumentation (AAMI) working group committees and is on the ST79 Advisory Council (2013-2015). She sat on the AAMI National Nominating Committee for 2011-2014 and co-chaired the AAMI Working Group for Hospital Steam Sterilizers from 2006-2013.

Ms. Seavey has been recognized by numerous industry organizations as a leader in her field. In 2003, Rose served as President of the American Society of Healthcare Central Service Professionals (ASHCSP) and was awarded the National Educator of the Year award in 2002.

Ms. Seavey also served on the Association of periOperative Registered Nurses (AORN) Board of Directors from 2008-2010. She received AORN’s award for Outstanding Achievement in Mentorship in 2012 and the Outstanding Achievement in Clinical Nurse Education in 2001. Ms. Seavey also received the 2013 national IAHCSSM Award of Honor, the Industry Leadership Award from the Massachusetts chapter and the Educator of the Year Award from the Golden West chapter.

Ms. Seavey is widely published in professional journals and is the author of the book titled *Sterile Processing in Healthcare Facilities: Preparing for Accreditations Surveys*, published by AAMI.

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## **HARRY SHAFFER, MS**

Harry Shaffer is the president of Sterilization Consulting Services, a company located in Denver, Colorado, that specializes in sterilization validation. With over 35 years of experience in the sterilization and manufacturing of medical devices, Mr. Shaffer is recognized as an industry leader. He has extensive experience managing microbiological laboratories and developing and validating sterilization cycles and procedures, including radiation, EO, and steam sterilization modalities.

Mr. Shaffer has been a member of AAMI for more than 30 years, serving on numerous committees, including the Committee on Microbiology for Sterilization, and has published extensively on AAMI's guidelines.

## **PEG LUEBBERT, MS, CIC, CHSP, CBSPD**

Peg Luebbert is the president and founder of Healthcare Interventions, assisting multiple facilities and organizations across the country improve their risk reduction strategies in infection prevention. In her more than 25 years in healthcare, Ms. Luebbert has served in a variety of capacities, including as an infection preventionist, safety officer and risk manager.

Ms. Luebbert has been awarded with more than 20 industry accolades, including the APIC Distinguish Service Award: National APIC Highest Member Award and the Nebraska Infection Control Network Distinguished Service Award. She is certified in infection control, healthcare safety, and as a clinical laboratory specialist.

## **MARK DURO**

Mark is the Director of Sterile Processing Operations at New England Baptist Hospital in Boston Massachusetts, a leader in orthopedics and the official hospital of the Boston Celtics. Duro has been in the sterile processing management space for over twenty years and currently serves as Vice President of the Massachusetts Chapter of Central Services professionals. As a long-time member of IAHCSSM, is on the Executive Board and chairs the association's orthopedic council.

In 2011 Duro was awarded fellowship status within IAHCSSM, joining 33 other fellows. He also is an IAHCSSM-approved instructor. Duro is also active in AAMI as a voting member and a part of the AAMI ST79 working group. Duro was recently appointed to the AAMI ST79 Advisory council, as well as the AORN news advisory for sterile processing.

Duro was awarded the 2012 Educator of the Year award by IAHCSSM. He also consults nationally and internationally in the area of sterile processing.

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## **SHARON GREENE-GOLDEN, CRCST, FCS**

Sharon Greene-Golden is the Manager of Sterile Processing for Bon Secours Health System DePaul Medical Center and the former president of IAHCSSM. For more than 30 years, Greene-Golden has worked in various CS departments across Virginia, including at Mary Immaculate Hospital and Sentara CarePlex Hospital.

Greene-Golden has presented on sterilization processes and cleaning techniques internationally, including in Bangladesh and at the 2013 and 2011 World Sterilization forums in Turkey and Portugal, respectively. She also has authored articles published in *Communiqué*, *Infection Control Today*, *OR Today* and for the *AORN Journal*.

Greene-Golden has received several awards, including Fellowship Status in the International Association of Central Sterile Materials Management in 2009, the 2008 Bertha Yanis Litsky, PHD Educator of the Year Award in, the 2007 and 2008 Madison Who's Who award, the 2006 and 2007 Strathmore Who's Who Award, and the 2004 IAHCSSM Golden Slipper Award in 2004.

## **WILLIAM R. JARVIS, MD**

Dr. William R. Jarvis currently serves as the president and co-founder of Jason and Jarvis Associates, LLC., where he is responsible for medical consulting in infectious diseases and infection control and prevention.

Previously, Dr. Jarvis worked at the Centers for Disease Control and Prevention (CDC) for 23 years where he held a number of leadership positions including Acting Director of the Hospital Infections Program (HIP). For 17 years, he was responsible for the supervision of outbreaks and epidemiologic studies in healthcare settings and for the development of guidelines designed to prevent healthcare-associated infections (HAIs).

Dr. Jarvis is board-certified in pediatrics and board-eligible in pediatric infectious diseases. He has published more than 400 peer-reviewed publications, edited six books--including the recently published book, *Hospital Infections*, and has received numerous awards, including the CDC Lifetime Scientific Achievement Award and the CDC Lifetime Achievement Award in Epidemiology.

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