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Perspectives on Sterilization Best Practices Help Clear Confusion about Recent STERIS System 1® and STERIS System 1E™ Announcements

On April 30, Advanced Sterilization Products (ASP) hosted the second in a series of informational Webinars, “Transitioning from the STERIS System 1® -- Real-World Perspectives,” to help the healthcare community sort through information about changing sterilization and high-level disinfection processes. The Webinar featured operating room nurses and representatives from leading healthcare companies sharing experiences and best practices to help hospital staff manage the transition smoothly and in a timely manner.

If you were unable to attend the live broadcast of the Webinar, **an archive is now available for on-demand viewing at www.aspii.com/alternatives.**

Speakers included:

- June Wyrwas, RN, Director for Perioperative Services at Capital Health
- Michelle Santello-Hunt, RN, Manager, Operating Room at Mercer Medical Center
- Howard Klymas, Director of Marketing, Gynecology and Urology, and Jason Singer, Supervisor, Technical Services, of KARL STORZ Endoscopy-America, Inc.
- Chris Nader, Senior Product Manager, and Edward Nuber, Product Manager - Sterile Containers, of Aesculap, Inc., a member of the BBRAUN group of companies
- Barbara Trattler, RN, MPA, CNOR, CNA, Director, Clinical Education for ASP
- Joseph Jay Houser, Worldwide Director, MDM Program Commercial for ASP

Real-World Perspective Take-Aways:

- Howard Klymas of medical device company KARL STORZ, noted, “Terminal sterilization provides the hospital with the ability to sterilize product and put it on the shelf for when it is needed. This provides a number of benefits, not only to the patient but to the staff of the hospital. I think customers should take a hard look at the options available to them and make a decision – sooner than later.”
- Speaking from her first-hand experience in the OR, Michelle Santello-Hunt noted, “Terminal sterilization provides us the best method or process to have a

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- sterile instrument set to be used today, tomorrow or whenever the staff needs to utilize it...Having terminally sterilized instrument sets is basically a win-win situation. It's a great option to have within an OR since you want to keep that balance of providing safe patient care as well as making sure your OR is running efficiently.”
- Edward Nuber of medical device company Aesculap, noted, “Once customers have made that decision to move to a terminal sterilization process, there are three main choices: steam, ETO, and low temperature, such as a STERRAD® System. The instructions for use need to be consulted to make sure that instruments are compatible with the various sterilization modes.”
 - June Wywras, an OR director at Capital Health, explained, “Continuing to use something that is not FDA approved is not something we wanted to do any longer than necessary, regardless of how long we had been using the item in the past... We did look at other alternatives, but we quickly came back to the STERRAD® NX™. The STERRAD® NX™ offers the technology of terminally sterilized flexible endoscopes, which is something that we did not have in the past. So this gives us an additional sense of comfort in knowing that we will have a terminally sterilized product...This is a good choice for us. It's almost a relief to know that we are going to meet a high standard of patient safety and quality care by going with a terminally sterilized product.”
 - Chris Nader of medical device company Aesculap highlighted that the FDA mandated transition from SS1® to a legally-marketed alternative “has brought to light the need for additional education regarding sterilization and various sterilization methods to enhance patient care.” He noted, the situation presents an opportunity for healthcare facilities to improve patient safety and infection prevention by transitioning to terminal sterilization.

Q&A Session:

Following are the most popular and pressing questions answered regarding the FDA-mandated transition:

Q: Did the FDA letter to medical device manufacturers change the transition time period?

A: The FDA has given health care institutions 18 months, or July 2011, to transition from the SS1® to another legally-marketed alternative. However, the FDA also gave medical

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device manufacturers only 12 months to make the transition, to remove the SS1® from their instructions for use, or February 2011.

Medical device manufacturers are actively working right now in order to begin this process. This means that you may start seeing some changes in instructions for use as early as this summer. It is important for you to maintain contact with the medical device manufacturer, to assure that you receive the latest changes in their instructions for use.

ASP has spoken with the Joint Commission, and the Joint Commission has stated simply that healthcare institutions should follow the most updated instructions for use for their medical devices.

Q: What is the Steris System 1E™ (SS1E), and does it offer terminal sterilization?

A: The SS1E™ does not offer terminal sterilization. It is a liquid chemical sterilant processing system. The SS1E™ can be used to process reusable heat-sensitive devices such as endoscopes and their accessories. However, the SS1E™ is not a general sterilizer. The sterilant used in the SS1E™ is a peracetic acid germicide. Because the rinse water is not sterile, devices processed using liquid chemical sterilization cannot be assured to be sterile.

Q: What are ASP's reprocessing alternatives to the SS1®?

A: For current SS1® users, there are two popular options, the [STERRAD® NX™ System](#), and the [EVOTECH® Endoscope Cleaner and Reprocessor \(ECR\) System](#). The STERRAD® NX™ provides the ideal environment for low-temperature sterilization for delicate devices and for other surgical implements where low-temperature sterilization may be an advantage.

The EVOTECH® provides high-level disinfection, and automated endoscope cleaning and reprocessing. This is a good alternative for those devices which don't require terminal sterilization.

Q: What do I do if no legally marketed reprocessing option exists for my device?

A: It's important to check with the manufacturer of each device for changes that they're making in the instructions for use. ASP is working with a number of medical device manufacturers to determine if their devices can be processed in a STERRAD® System or

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in an EVOTECH® system. But it is up to the healthcare facility to check with the manufacturer for updates as to their sterilization instructions.

Q: What flexible endoscopes can be sterilized in the STERRAD® NX™ System?

A: ASP has been working with a number of medical device manufacturers. KARL STORZ, Olympus, Gyrus and Richard Wolf have all released flexible endoscopes that can be processed in the STERRAD® NX™ System. You may also consult the [STERRAD® Sterility Guide](#), as medical device manufacturers update their instructions for use, we will add these to the *STERRAD® Sterility Guide*.

More questions will be answered and continually updated on www.aspji.com/alternatives.

View the Webinar

If you were unable to attend the live broadcast of the Webinar today, **an archive is now available for on-demand viewing at www.aspji.com/alternatives.**

The Webinar is just one of the new resources and educational initiatives ASP has recently launched to help smooth the transition to SS1® alternatives. For more information about these additional resources, please visit www.aspji.com/alternatives.

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