OR Best Practices: The Time is Right for Terminal Sterilization

According to experts, there is a definite move toward terminal sterilization in the OR. Terminal sterilization means that a device has been processed in a system that delivers a sterility assurance level of 10^{-6} and is packaged in a manner that will preserve its sterility and allow it to be transferred to a sterile operating field without contamination.

Cynthia Spry, RN, MSN, MA, CNOR, co-chair of the Association for the Advancement of Medical Instrumentation (AAMI) Committee that writes the standard on steam sterilization and sterility assurance, recently stated that the “AAMI doesn’t recommend flash sterilization or just in time sterilization any more than the CDC does… It really focuses on terminal sterilization.”

This trend toward terminal sterilization, combined with the FDA’s recent requirement that users transition from the STERIS System I* (SS1), a just-in-time processor, may provide an ideal time for facilities to upgrade their technologies to enhance their standard of care in the OR. According to Spry, with terminal sterilization, “…you decrease the risk of contaminated instruments, which decreases the risk of a patient incurring a surgical site infection, which is all part of patient safety goals, that is, preventing patient injury. …Terminal sterilization is the gold standard. I can think of no reason why one shouldn’t transition to it, and now is the perfect time.”

IS IT STERILE? Clearing the Confusion About Liquid Chemical Sterilization

The controversy continues for hospitals using the STERIS System 1* (SS1) for “just-in-time” sterilization following the FDA mandate that hospitals transition to a legally marketed alternative. STERIS will be offering a new liquid chemical sterilizer—the STERIS System 1E* (SS1E). At first glance, this unit might seem a viable alternative, but several key limitations prevent the assurance of device sterility, including the use of non-sterile rinse water and the exposure of wet, unwrapped devices to the ambient room environment upon removal from the processor.

Non-Sterile Rinse Water
The SS1E utilizes filtration and ultraviolet (UV) irradiation to treat water used to rinse devices at the end of the sterilization phase to remove residual chemical sterilant. The inability of the SSIE to assure the sterility of devices after rinsing recently was highlighted by the FDA:

“It is treated to minimize any bioburden that may be naturally occurring in the water. Because the rinse water is not sterile, devices processed using liquid chemical sterilization cannot be assured to be sterile.”
reprocessor Q&A

With just-in-time sterilization, the FDA says that devices should be used “immediately.” What exactly does this mean?

As indicated by its name, with just-in-time sterilization, instruments must be used as soon as processing has been completed—similar to flash sterilization. For example, according to an FDA overview about the STERIS System 1E, “The processed loads should be used immediately.”

As a result, if instruments remain in the processor upon completion of the cycle, they may need to be processed again before they can be used for procedures, increasing reprocessing costs as well the potential for instrument damage. Unfortunately, there is no specific definition of “immediately,” and there are many of different interpretations and policies.

For example, some facilities state that the device must stay in the processor with the lid closed, some state that the tray can be removed and set on a counter for a specific period of time, and some state that it must be used immediately. As a result, facilities need to carefully determine their specific policies—and be able to document them in case Joint Commission regulators ask about them during a survey. For more information, refer to the instructions for use for both the processor and the instruments to be processed. In addition, facilities should ask their processor representative what is the specific definition of “immediately” and request an exact time frame.

References

Can full instrument sets such as arthroscopy sets be processed in the STERIS System 1E?

The FDA states that the “SS1E should be used only for processing heat-sensitive semi-critical and critical devices that are compatible with the S40 sterilant and processing system and cannot be sterilized by other legally marketed traditional sterilization methods validated for that type of device.” This statement indicates that heat-stable instruments such as stainless steel items or autoclavable endoscopes should be processed using other appropriate methods, such as steam or hydrogen peroxide gas plasma—especially if those instruments must be sterile. In fact, the FDA states that, “The SS1E should NOT be used on devices that must be sterile, unless they cannot be sterilized by other legally marketed, traditional, validated sterilization methods.” (See the Expert Insights article in this issue of Frontiers for important information about the lack of sterility assurance with the SS1E.)

As a result, if the SS1E is utilized, sets that contain a variety of instruments—such as endoscopes, stainless steel ancillary instruments, and other instrumentation—may need to be separated, processed in different modalities, and reassembled by central processing or OR staff members. In particular, autoclavable endoscopes may need to be processed using alternative methods, such as hydrogen peroxide gas plasma or steam. Keep in mind that breaking up instrument sets may increase the likelihood that pieces may be lost, interfere with efficient workflow, and increase the risk of instrument damage in the case of steam sterilization. As an alternative, many instrument sets can be safely processed together using hydrogen peroxide gas plasma sterilization, eliminating the need to split up instrument sets and the difficulties this brings.
Go Green with ASP

ASP is pleased to announce two recent developments aimed at protecting the environment:

New packaging for CIDEX® Activated Dialdehyde Solution, available now, uses less plastic—and that means less waste, which is better for the environment. In addition, with 20% more solution in each bottle, fewer bottles are required to do the same amount of high-level disinfection, so there is less packaging to throw out. Trusted by hospitals around the world, CIDEX Activated Dialdehyde Solution provides rapid, cost-effective high-level disinfection for a wide range of endoscopes and other medical instruments.

IFUs for CIDEX® Activated Dialdehyde Solution (2266) and CIDEX® OPA Solution (20390) now are available online at www.e-ifu.com or via fax the company’s FAX-On Demand System (888-783-7723), which means less printed paper and fewer trees destroyed. Over time, IFUs for more ASP products will be available on the site. The e-IFU Website provides Johnson & Johnson customers with convenient access to IFUs and other related information anytime, anywhere. The site is easy to use—customers can browse products by company, product name, or catalog number. Visit www.e-ifu.com to learn more.

The Spaulding Classification System

By Barbara Trattler, RN, MPA, CNOR, CAN

The Spaulding Classification System divides medical devices into categories based on the risk of infection involved with their use. The system is used to...
determine the degree of disinfection or sterilization required for various medical devices. It defines three categories of medical devices and their required level of disinfection or sterilization:1

- **Critical**—A device that enters normally sterile tissue or the vascular system. These devices should be sterilized.
- **Semicritical**—A device that comes into contact with intact mucous membranes and does not ordinarily penetrate sterile tissue. These devices should receive at least high-level disinfection.
- **Noncritical**—Devices that do not ordinarily touch the patient or touch only intact skin. These devices may be cleaned by low-level disinfection.

It is important for anyone involved in instrument processing to understand the Spaulding Classification System as a guide to determining the appropriate reprocessing methods for medical devices and surgical instruments, especially in light of rapid changes in the industry. For more information, visit [www.sgna.org](http://www.sgna.org).

References