

Editorial

Medical-Device Reprocessing

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Medical devices that are used for surgical procedures that enter sterile body sites or penetrate the vasculature are considered "critical" according to the Spaulding classification system.¹ This designation reflects the invasiveness of the procedure and the potential risk for infection transmission.

Reprocessed critical medical devices, including reused single-use devices as well as reusable devices, need to be cleaned and decontaminated in such a fashion that the risk of infection transmission for all patients for whom the device is used is essentially nonexistent. To achieve such a goal requires that there are factors embedded in the reprocessing protocol that ensure an adequate margin of safety. Such safety factors include thorough precleaning prior to attempting sterilization, using only chemicals or methods that are approved and have proven efficacy for this purpose, and ensuring adequate exposure time to the active ingredient.

Often the robustness of the sterilization method for particular medical devices will be documented by inoculating the device with spore suspensions and testing the killing efficacy using shortened sterilizer cycles (overkill sterilization method, as described in Association for the Advancement of Medical Instrumentation Technical Information Report), as well as testing the killing efficacy of the sterilization method in the presence of an organic or inorganic challenge.² This provides some assurance that, even if conditions were not entirely optimal during the device reprocessing, the process still would have a high likelihood of providing a sterile device due to the good margin of safety.

Because of the critical nature of ensuring reproducible sterilization, the approval of methods and chemicals is closely controlled by the Food and Drug Administration (FDA) in the United States and by similar regulatory departments in other countries. In developing countries, where financial constraints are very different compared to developed countries, less stringent controls

are placed on reprocessing of medical devices. This is understandable when one considers that, in countries where financial constraints are severe, life-saving medical procedures could not be performed if, for example, reuse of single-use critical medical devices were prohibited. Despite this caveat, the ultimate goal for reprocessing of medical devices, no matter what the geographic location, is to ensure that the reprocessed critical device is sterile and suitable for use on another patient.

The most robust and cost-effective method for sterilization of medical devices is steam sterilization. Whenever possible, this is the preferred method to use. However, some medical devices are heat-sensitive and require low-temperature sterilization. Alternative low-temperature sterilization methods that currently are used in many hospital settings for reprocessing of medical devices include ethylene oxide, plasma, and liquid chemical sterilization. Each of these low-temperature methods has limitations: ethylene oxide requires lengthy aeration times, so turnaround time for devices is long; plasma has poor penetration ability in long or narrow lumens; and liquid chemical sterilization is designed for "point-of-use" sterilization, as there is not a way to provide long-term sterile storage of processed devices. All of the low-temperature sterilization methods have poorer penetration of organic and inorganic material (debris) compared to steam sterilization.

The manuscript by Penna and Ferraz³ describes reprocessing of angiographic catheters and spinal needles using hydrogen peroxide as part of the cleaning protocol, combined with plasma sterilization. The article focuses on optimization of a cleaning protocol that, when combined with plasma sterilization, provides an adequate level of microbial reduction. It is important to recognize that the stainless steel spinal anesthesia needles studied in this report would be optimally sterilized using steam sterilization, as they are not temperature-sensitive. Furthermore, the cardiac catheters studied in this report require a low-temperature sterilization method that is appropriate for the

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lumen dimensions. The Sterrad (Johnson & Johnson, Irvine, CA) system has not been given approval by the FDA in the United States for any lumened device that is >40 cm in length or <3 mm in diameter. As such, neither the needles (100 mm×0.6 mm) nor the catheters (100 cm×1.0 mm) evaluated in this study would be appropriately sterilized in the Sterrad 100 if FDA guidelines were followed. Lumen boosters that facilitate diffusion of hydrogen peroxide into the lumens are available for use with the Sterrad 100; however, these were not used in the current study (these lumen boosters do not have FDA approval in the United States).

Given these constraints, one might ask the question: "How did the authors obtain results suggesting that medical devices with length and lumen-diameter dimensions well outside the FDA cutoffs were found to have no detectable organisms postprocessing?" When interpreting the data in this manuscript, it is critical to consider two key factors: (1) the maximum microbial load that the Sterrad 100 was challenged with was 2×10^2 colony-forming units per device, and (2) the poststerilization test used by the authors does not assess the sterility of the device (ie, the devices were not immersed in broth poststerilization and incubated to determine if they were sterile).

Normally, validation of sterilization requires demonstration of at least 6-log_{10} killing in the presence of an organic or inorganic challenge. Since the microbial challenge was 4-log_{10} less than this, it is important to recognize that any deviations from the cleaning protocol that would leave a higher bioburden or more of an organic load might produce different results.

The problems with infectious disease transmission linked to inadequacy of cleaning of flexible endoscopes or breaks in accepted reprocessing procedures have recently been brought to the attention of reprocessing centers by the joint FDA–Centers for Disease Control Public Health Advisory.⁴ The importance of precleaning of medical devices before attempting either sterilization or disinfection is emphasized in all guidelines related to medical-device reprocessing.^{2,5-9} Despite this emphasis, it is the area where the highest in-use variability is observed. Because the cleaning stage in reprocessing frequently is performed manually, there is opportunity for the protocol to be altered. Ensuring consistent compliance with reprocessing protocols is a substantial challenge to the quality assurance program of most centers where reprocessing is performed.

Although Penna and Ferraz³ have studied reprocessing protocols that would not be acceptable in some countries due to regulatory guidelines, they have demonstrated the value of effective precleaning to reduce the microbial load prior to plasma sterilization. Indeed, this is a very thorough study that systematically documents that extensive cleaning, including hydrogen peroxide, enzymatic detergent, and large volumes of endotoxin-free rinse water effected a 5-log_{10} microbial reduction in such devices. Each spinal needle had a total fluid volume of 310 mL drawn through the lumen, and each cardiac catheter

had a total volume of 3,100 mL of fluid drawn through the lumen. These volumes are far greater than would routinely be used for reprocessing in most hospital settings where the cleaning is done manually. In addition to the large volume of fluid drawn through the lumens, the effective microbial-load reduction obtained with this cleaning method may be reflective of the ability of 1.5% H_2O_2 for 5 minutes at room temperature to reduce the bioburden by killing some of the spores, in addition to acting as a cleaning agent to help remove the spores.

Hydrogen peroxide at 7.5% with a contact time of 30 minutes at 20°C is an approved high-level disinfectant.^{8,9} As reviewed by Rutala,⁸ for reprocessing of flexible endoscopes, hydrogen peroxide has been shown to have varying degrees of sporicidal ability, depending upon concentration and contact time. It may be that the success of the Sterrad plasma sterilizer in the current study is an indication that a combined approach that encompasses microbial killing during the cleaning stage with plasma sterilization may be effective enough for reprocessing of critical medical devices. The concept of low-temperature sterilization technologies being effective for nonlumened medical devices that have a low bioburden has been suggested by Rutala et al.⁶ Although the report by Penna and Ferraz³ is suggestive, further studies would be needed to validate this concept for long narrow-lumened medical devices and to determine what the margin of safety was for such a reprocessing method.

In addition to the issues related to efficacy of reprocessing using plasma sterilization, it is important to consider that reuse of critical single-use medical devices is highly controversial. Cost containment has pressured many centers in North America into undertaking such procedures. Cardiac catheters, with and without balloons, are examples of critical single-use medical devices that have been reprocessed because of their cost. Reprocessing of balloon catheters is especially difficult, as the dead end created by the balloon makes cleaning exceedingly difficult. Even nonballoon cardiac catheters can be difficult to clean reliably because of the long narrow dimensions, which make it difficult to flush fluid through the lumen manually. Because of the critical nature of these catheters that are inserted into blood vessels, process validation is crucial prior to reprocessing them on a routine basis.

Although the method for cleaning and sterilization presented by Penna and Ferraz³ addresses one aspect of the reprocessing and presents data that are encouraging, it is critical to recognize that the test protocol used does not reliably confirm sterility, given that an indirect test method was used. Because of the critical nature of cardiac catheters, caution is recommended to ensure that the results of this study are not used as a basis for reprocessing of cardiac catheters without due consideration to the complexity of all the issues surrounding reprocessing of single-use critical medical devices.

Excellent reviews of the important issues are provided by the Canadian Healthcare Association,⁵ and the

FDA Center for Devices and Radiological Health's page at www.fda.gov/cdrh/reuse/1029.pdf provides updated information on the FDA's proposed regulatory requirements for third-party and hospital reprocessors of single-use devices.

In summary, reprocessing of critical medical devices that are reusable or intended for single use is an area requiring research data to provide guidance for the optimal combinations of device cleaning and sterilization methods. The cleaning stage is critical regardless of what sterilization method is subsequently used, and research into what cleaning methods will facilitate optimal killing by low-temperature sterilization methods is urgently needed. However, ensuring a reasonable margin of safety in reprocessing of critical medical devices is also crucial.

REFERENCES

1. Spaulding EH. Chemical disinfection and antisepsis in the hospital. *J Hosp Res* 1972;9:5-31.
2. Association for the Advancement of Medical Instrumentation. Technical Information Report No. 12. *Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers*. Arlington, VA: AAMI; 1995.
3. Penna TCW, Ferraz CAM. Cleaning of blood-contaminated reprocessed angiographic catheters and spinal needles. *Infect Control and Hosp Epidemiol* 2000;21:499-504.
4. Feigal DW Jr, Hughes JM. FDA and CDC Public Health Advisory: infections from endoscopes inadequately reprocessed by an automated endoscope reprocessing system. Washington, DC: Food and Drug Administration; Atlanta, GA: Centers for Disease Control and Prevention. September 10, 1999. <http://www.fda.gov/cdrh/safety/endoreprocess.html>.
5. Canadian Healthcare Association. *The Reuse of Single-Use Medical Devices. Guidelines for Healthcare Facilities*. Ottawa, Ontario, Canada: Canadian Healthcare Press; 1996.
6. Rutala WA, Gergen MF, Jones JF, Weber DJ. Levels of microbial contamination on surgical instruments. *Am J Infect Control* 1998;26:14-35.
7. Rutala WA, Weber DJ. Infection control: the role of disinfection and sterilization. *J Hosp Infect* 1999;43(suppl)S43-S55.
8. Rutala WA, Weber DJ. Disinfection of endoscopes: review of new chemical sterilants used for high-level disinfection. *Infect Control Hosp Epidemiol* 1999;20:69-76.
9. Society of Gastroenterology Nurses and Associates Inc. Guideline for the use of high-level disinfectants and sterilants for reprocessing of flexible gastrointestinal endoscopes. *Gastroenterology Nursing* 1999;22:127-134.