Successfully Navigating Adverse Events and IFU Complexity

BY WILLIAM LEIVA, MPD, MBA, STERILIZATION SUBJECT MATTER EXPERT—TUNNELL GOVERNMENT—AND PRINCIPAL RESEARCHER, EUIS

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LEARNING OBJECTIVES

1. Discuss common challenges identified by facilities and supported by current evidence
2. Describe current information in instructions for use (IFU) and its interpretation
3. Describe potential opportunities to improve understanding of and compliance with new device IFU

Adverse events in surgical patients are defined as situations where care delivery resulted in undesirable clinical outcomes not caused by the underlying disease. The situations may prolong patient hospitalization, cause permanent patient harm, require lifesaving interventions, or contribute to death.[1] Arguably, one of the factors that may lead to adverse events pertains to the complexity of surgical instruments, and yet another can be traced to the instructions for the use (IFU) for some surgical devices. This lesson provides information about common challenges associated with adverse events and ways to improve understanding of and compliance with device and equipment IFU.

Objective 1: Discuss common challenges identified by facilities and supported by current evidence

Internationally published Sterile Processing-related studies link up to 6% of adverse events to sterilization failure and up to 32% to decontamination.[2] While literature points to a low risk of infection from surgical instruments, such adverse events can and do occur. Among the clearest link between adverse events and infections is related to duodenoscopes[4,5], where significant infection rates have been linked to inadequate processing.

With an increasing number of complex procedures and the never-ending development of new instruments and technologies, the challenges continue to grow. These issues are often related to materials, geometry and packaging. Let's explore those three aspects. The materials used to manufacture reusable medical devices play a significant role in the ease of decontamination and sterilization by affecting the heat transfer and condensation of steam. For example, during the exposure phase, metallic materials condensate steam quickly, while plastic materials require longer times. During the drying phase, metallic materials enable water to vaporize and

evacuate the chamber, while plastic materials lead to lower vaporization rates and, therefore, may lead to wet packs.

The geometry of the reusable device may lead to accumulation of residues. That, in turn, makes decontamination more difficult and may eventually lead to biofilm formation (this has been observed in duodenoscopes and suction cannulas used in plastic surgery). Geometry also plays a role during inspection. Smaller, complex devices are more difficult to visually inspect than simpler and larger ones.

Lastly, the packaging or sterile barrier used plays another important role. Although each instrument and device had been thoroughly validated before being approved for sale under U.S. Food and Drug Administration (FDA) approval or clearance requirements[7], even small changes in the sterile barrier can affect the sterilization system's ability to ensure device sterility. Moving from one wrapping material density to another or changing the rigid container system may alter the sterilant's ability to effectively diffuse through the sterile barrier. This applies to all common sterilants used in hospital settings (i.e., saturated steam or chemical sterilants such as ethylene oxide or hydrogen peroxide).

Given these facts, learning to address the challenges and prevent or substantially reduce the occurrence of adverse events becomes paramount for Sterile Processing (SP) professionals.

Objective 2: Describe current information in instructions for use (IFU) and its interpretation

Thanks to stringent FDA regulations, all manufacturers seeking to bring new products to market must provide specific and highly detailed information to obtain the approval or clearance. Although the extent of the information manufacturers must provide varies widely, for the SP segment, the most important information is usually contained in the IFU.

User instructions are developed based on evidence gathered by the manufacturer to comply with the current regulation[8] that requires both general and specific information. In more general terms, device design must consider the challenges of decontamination and sterilization and ensure that the devices are safe.

There are six criteria[8] the FDA requires when medical device labeling is developed and submitted for approval or clearance. The criteria covers multiple aspects and takes a holistic approach to help SP professionals effectively manage device processing. Any information provided on an IFU should reflect the intended use of the device, including possible contamination during clinical use and the appropriate processing instructions. Instructions should advise users to thoroughly clean the device. Although this seems obvious, including this statement guides users to understand that even when devices are not used during a surgical procedure, thorough decontamination and processing must take place.

Processing information should indicate an adequate microbicidal process; this ties to the Spaulding Classification for critical, semi-critical, and noncritical devices. Although some reusable medical devices cannot undergo sterilization, most processed items in the SPD do. Therefore, the microbicidal process must be clearly identified within specific parameters. For devices processed in other hospital or healthcare settings, an adequate microbicidal process must be documented, including for the disinfecting agents used.

Reprocessing should be technically feasible and include only legally marketed devices and accessories. This criterion spans two aspects: first, the feasibility during reprocessing, which is arguably difficult to achieve in all healthcare facilities where devices are commonly used. The second aspect refers to processing equipment available for the U.S. market. This was likely developed to prevent recommending the use of technologies not approved or cleared by the FDA (e.g., ozone for respiratory devices systems or low-temperature formaldehyde for heat-labile devices).

Device processing instructions should be clear and comprehensive. The IFU must clearly describe what is to be done and how, and the specific accessories or devices needed. A good example relates to the use of brushes to clean lumens or cannulated devices; overly simplified instructions to "use a brush to clean the internal lumen of the device," for example, is not acceptable. Specific information is needed, such as the appropriate brush type, size, diameter, bristle material, etc.

Additionally, information should be included about point-of-use treatment requirements. This can often include details about the use of enzymatic and moistening agents, disassembly and assembly of the device, proper cleaning agents and methods, and details for rinsing, lubrication, inspection, disinfection and sterilization. Other detailed instructions can pertain to chemical sterilant residual removal, drying time and more, depending on the nature of the device.

Medical device manufacturers must also provide the FDA with information to support validation of a product. Validation of cleaning or decontamination steps must be done using a worst-case scenario that uses

surrogate soils. The same applies to microbicidal processes; if the device should be low-level disinfected, suitable evidence must support this, and the same will apply for high-level disinfection and sterilization. When sterilization is required, specific information regarding agents, cycle configuration, and drying or sterilant removals must be validated and provided.

Objective 3: Describe potential opportunities to improve compliance with a new device IFU

Among the key challenges SP professionals routinely encounter is the balance between IFU implementation, interpretation and the real-world conditions processing technicians face. Although statements such as "follow the manufacturer's IFU" are common, the challenge is how to comply with IFU when there are many different processes and devices to be decontaminated, inspected and sterilized in the same cycles.

For sterilization, one of the biggest challenges is matching the sterilization requirements in the IFU to many devices in the same cycle. This becomes more challenging when sterilizing multiple devices with different materials (metals and plastics), different sterile barriers (containers, pouches and sterilization wraps), and different cycle parameters requirements (e.g., 20 versus 40 minutes of drying time). Because of these challenges, IFU implementation must be carefully assessed, particularly when sterilization is required.

An "approximation" is the implementation of sterile product families—groups of products with similar characteristics that can be sterilized in the same cycle. Although the families of these products have been described for years in international standards[9], their implementation remains elusive in some facilities, and one potential reason is the continuous need for external surgical sets or loaned devices. Although the empirical product family is useful, a systematic approach is a more robust way to address current and future challenges.

When developing a systematic approach to IFU compliance, a few critical factors should be considered, which are likely already familiar to SP professionals: device size, sterile barriers, and device weight. When a product/device family is created based on device size, the general idea is that loads will primarily contain devices of a predetermined size, either large, medium or small. Size is arbitrarily determined by the SP professional doing the assessment; however, gathering colleagues' feedback about the criteria to determine the size of the "similar" pack is valuable.

Similarly, when selecting families based on sterile barriers, a criterion must be decided about what the most common sterile barriers are and how the load can best be distributed on the sterilization cart. Lastly, when determinations are based on weight, there are two factors to consider: ergonomics and occupational safety and how weight can contribute to sterilization failure due to excess condensation and potential wet loads.

The creation of families of sterile products must be based on each of the sterilization modalities available in the SPD. For steam sterilization, in addition to the use of biological and chemical indicators and physical parameters, it is vital to evaluate whether cycle parameters need adjustment. This may be done in the conditioning phase to modify the pre-vacuum pulses, their profile, and the vacuum pressure during the drying phase. This is particularly important when the load includes a mixture of metal and plastic devices and may require the support of sterilization equipment partners and hospital Biomedical equipment technicians.

Given the limited number of cycles that use chemical sterilant, the families must be sterilized using a predetermined cycle available in the sterilizer. Once this has been completed, it is necessary to document the criteria used to create the sterile product families as well as the general characteristics, including description and photos. This is reflected in the SPD's standard operating procedures (SOPs). As with any quality management system, documenting on SOPs allows training of current and future SP professionals and evaluates over time the need to update the SOP and the characteristics of sterile product families.

This is certainly not a 15-minute improvement plan. Instead, it requires thorough planning and execution, as most SPDs will carry out implementation while continuing to deliver sterile materials to the facility's customers. The benefits of developing and implementing the improvement plan include load optimization, prevention of wet loads, adequate sterilant diffusion, sustainable quality improvements, and effectively adapting to and addressing changes and challenges associated with new and complex reusable medical devices.

Conclusion

Processing requirements for reusable medical devices have a limited set of variables that include point-of-use treatment, cleaning, inspection and sterilization. Still, in each of these subsets of processing steps, there is significant variation based on device type, material, construction, sterile

barriers, and information available in the device IFU.

Implementing a process to determine the similarities of medical devices based on specific criteria can help SP professionals proactively address the challenges of their daily activities. This allows them to deliver consistent quality and prevent adverse events, such as wet loads or delayed delivery of instruments, and other factors that can contribute to adverse patient outcomes. P

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CRCST Self-Study Lesson Plan Quiz:
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1. Adverse events in surgical patients can cause:
   a. Death
   b. The need for additional intervention
   c. Permanent physical damage
   d. All the above

2. The material of medical devices does not contribute to wet loads.
   a True
   b. False

3. The complex geometry of medical devices may cause:
   a. Cleaning challenges
   b. The inability to successfully disinfect or sterilize the items
   c. An increase in drying time
   d. Device geometry has no affect on medical device processing

4. Changes in sterile barriers:
   a. Rarely affect the sterilization process
   b. Play a role in sterilization
   c. Only affect immediate use steam sterilization processes
   d. Affect device storage time

5. Instructions for use (IFU) are a requirement from which regulatory agency?
   a. The U.S. Food and Drug Administration
   b. The Occupational Health and Safety Administration
   c. The Environmental Protection Agency
   d. The National Institute of Occupational Health and Safety

6. The Spaulding Classification is used to determine an adequate microbicidal process.
   a. True
   b. False

7. Processing instructions should be:
   a. Feasible, lengthy, detailed and validated
   b. Clear and comprehensive
   c. Validated and approved by the facility and the FDA
   d. Created by the FDA based on manufacturing criteria

8. Validation of cleaning or decontamination steps must be:
   a. Accomplished by the FDA
   b. Performed by the manufacturer and an FDA market approval expert
   c. Done using a worst-case scenario
   d. Performed by Sterile Processing (SP) professionals semi-annually or as needed

9. Given the limited number of cycles that use a chemical sterilant:
   a. All items should undergo steam sterilization
   b. Product families must be sterilized using a predetermined sterilizer cycle
   c. It is necessary to hire a consultant to guide the process
   d. The infection preventionist should work with the SP team to determine the best process

10. Sterilizing multiple products and materials:
   a. Enables adequate sterilant diffusion
   b. Must be validated onsite by the Sterile Processing manager and lead technician
   c. Requires careful assessment to ensure safety and effectiveness
   d. Always requires extended drying times

11. A sterile product family is a group of products:
   a. From the same manufacturer
   b. With the same sterile barrier
   c. Organized in the same container
   d. With similar characteristics

12. When developing a systematic approach to IFU compliance, which factors should be considered?
   a. Device size and weight and age of the sterilizer
   b. Device weight, sterilizer capacity, and composition of device accessories
   c. Device size and weight and sterile barriers
   d. Device geometry, composition, weight and years of use

13. Documenting standard operating procedures is important because it:
   a. Facilitates training
   b. Prevents processing errors
   c. Ensures that proper sterile barriers are used
   d. Clearly demonstrates compliance with FDA requirements

14. IFU are developed based on:
   a. Device design
   b. Decontamination and sterilization challenges
   c. Regulations
   d. All the above

15. SP technicians should:
   a. Thoroughly process instruments in a set, even those not used during a procedure
   b. Follow the six criteria outlined by the FDA and OSHA
   c. Clean and inspect items based on requirements for Spaulding Classification
   d. Always sterilize metals and plastics together in the same load

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