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MEDICAL DEVICE AND DIAGNOSTIC INDUSTRY

In Reprocessing Devices, Human Factors Matters

The growing complexity of medical devices has presented challenges for medical device reprocessors.

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Today's demand for more complex medical devices has led to the introduction of devices that are difficult to reprocess. These design advances are challenging the sterile processing units in hospitals. Often medical device manufacturers do not give enough consideration to the human factors involved in reprocessing a device, including working conditions and individual characteristics of sterile processing personnel that affect work behavior. Complex medical device designs and other enhancements that do not take these human factors considerations into account may make it difficult or even impossible for hospitals to clean, disinfect, and resterilize these devices in an effective manner.

A study director performs a disinfection study.

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FDA Expectations

Infections resulting from improper cleaning and sterilization practices have captured the attention of FDA and manufacturers of reusable medical devices. These improper cleaning and sterilization practices are often a result of incomplete, unclear, or impractical instructions for use (IFU) provided by the medical device manufacturers. Poorly written IFUs, insufficient training, and limited understanding of the function of the device add to the already difficult challenges service department personnel face. This lack of clear instructions and inadequate training often encourages misinterpretation and may result in insufficient cleaning and sterilization of a medical device.

FDA published a draft guidance document in May 2011 that provides manufacturers with guidelines for writing an IFU.[1] The document emphasizes the need to perform parameters commonly used in the clinical setting. By designing medical devices and processing instructions with cleaning and sterilization in mind, manufacturers can supply IFUs that the end user can easily follow to produce safe instruments in an efficient manner while keeping up with current trends and guidance from FDA.

Need for Consistency

Many healthcare facilities are unable to follow every IFU due to time constraints and the frequent need of devices and trays for surgery. Hospitals reprocess thousands of instruments per day, and asking sterile processing departments to read each instruction for every device is not feasible. Many times, similar devices from different manufacturers have different reprocessing instructions, which can cause confusion and error in reprocessing.

The current struggle between healthcare facilities and manufacturers has brought increased awareness in the medical device industry. Hospitals are asking manufacturers to standardize cleaning parameters in a manner similar to standard sterilization cycles in order to correlate IFUs to contain all necessary instructions for reprocessing similar medical devices. Most cleaning processes are performed manually, therefore the

negative effects of human factors are most prevalent. The use of mechanical and automated cleaning processes has increased with the intent to reduce the problems encountered by human factors. Healthcare facilities and medical device manufacturers are focusing on reducing manual cleaning methods for safety and operating convenience.

FDA has encouraged collaboration between healthcare facilities and manufacturers to address the problems associated with complex device designs and human factor reprocessing considerations. Additionally, AAMI has started new working groups—WG85: Human Factors for Device Reprocessing and WG12: Instructions for Reusable Device Reprocessing—to address some of these issues from all industry perspectives. However, technology and the need for complex devices are hindering industry harmonization.

Although standardizing sounds possible and may reduce risks associated with reprocessing, it may be a long time before the industry achieves that goal. Because human factors considerations are still a concern in the reprocessing of reusable medical devices, manufacturers, healthcare facilities, and contract laboratories should consider human factors during device design, validation, and when writing IFUs.

Simulating hospital prerinsing practices for validation.

Design Considerations

In many cases, reusable medical device manufacturers do not consider reprocessing until after the design is complete. Provisions for cleaning and sterilization should be considered during the first stages of device design. The following are examples of design considerations that can help manufacturers achieve functional yet cleanable and sterilizable product designs.

Material Type. The type of materials chosen for the medical device or device container can have a significant effect on thermal conductance, which, in turn, can affect optimal sterilization conditions. Materials such as braided cables, aluminum-based metals, and pliable materials (silicone and rubber) may decrease the ability to clean a device. Material compatibility with sterilization methods, alkaline detergents, or chemical disinfectants must also be considered, as outlined in AAMI TIR 30:2011.[2]

Design Features. Inaccessible areas of a medical device pose a potential challenge for effective reprocessing. When designing medical devices, consider finding alternatives to the following:

- Textured surfaces.
- Hinges.
- Springs.
- Narrow or dead-end lumens.
- Cracks and crevices.
- Mated surfaces.

Unfortunately, these design features are often unavoidable. However, manufacturers must recognize that these design features will require more stringent cleaning procedures, such as mechanical or automated cleaning methods. These types of features also have the potential to increase sterilization cycle times or drying times.

What to Think About During Validation

FDA has started to include human factors considerations in validations to simulate real-life scenarios in healthcare settings. By creating a worst-case clinically relevant environment, the validations have become more difficult, causing challenges that may make meeting acceptance criteria very difficult. By performing these kinds of validations, manufacturers can see and better understand the issues that human factors contribute to the reprocessing of their device.

Supplies. In healthcare facilities, cleaning is often performed using readily available detergents and by following the label claims on the container. Requiring specialized supplies hinders service department personnel from proceeding with their routine functions, causing more distress in the environment. Availability of cleaning agents, supplies, and equipment should be considered when determining the validation plan and thus the IFU.

Accessories. Manufacturers may be able to expedite the validation process by selecting the most appropriate accessories to be used in the reprocessing procedures. Specialized accessories, such as brushes and wrenches, can be made available to service center personnel by including them with the device.

Instructions. Unique instructions create situations where sterile processing personnel must alter everyday practice. Manufacturers are encouraged to use the predetermined sterilization cycles outlined in ANSI/AAMI ST79:2010, A1:2010, A2:2011, and TIR12:2010 for their validation of devices and containment trays.[3,4] Cycles outlined in these documents are commonly used in hospitals.

Standardizing the sterilization cycles for reprocessing allows sterile processing personnel to perform the cycles easily and efficiently. As a result, extended cycles or cycles not validated using the predetermined cycles in these documents have been scrutinized by FDA.

What to Include in IFU

Changes in the development and design of medical devices are occurring due to human factors considerations, with more on the horizon. IFU developers need to design instructions

A study director performs an automated cleaning cycle.

with end-users in mind. The FDA draft guidance contains a section specific to the content of IFUs. This section outlines what the reprocessing instructions should encompass and how they should be presented. It suggests that all instructions be grammatically correct, legible, and presented in logical order, from the initial reprocessing step through the terminal reprocessing step. Each step should be well written and in simple language when possible. Use of language such as, "a minimum of," "if appropriate," "if possible," or "if necessary" has been discouraged and is no longer acceptable. Such language allows for interpretation, and steps may be missed during reprocessing, resulting in inadequate cleaning.

Step-by-step instructions for adequate disassembly and supplies used for disassembly should be included in the IFU. Detailed illustrations, diagrams, and descriptions should also be used to assist end users, especially for disassembly steps that are vital to the cleaning process.

Details such as detergent dosage, temperature, and water quality, or type, time, brush type, and size used in the validation should be outlined in the IFU. If specialized supplies are needed for cleaning, the product manufacturer and part numbers should be documented in the IFU. Although it may seem unreasonable, the need for this information is necessary for effective reprocessing.

Human factors considerations play a main role in the reusable medical device industry because sterile processing personnel are the front-line people performing these tasks. In addition to a detailed IFU, manufacturers should provide on-site training and education for sterile processing personnel. This instruction opens communication and encourages collaboration on medical device designs that meet functional requirements and addresses human factor considerations.

Conclusion

The increasing complexity of medical device designs has presented challenges for reprocessors. To help eliminate these challenges, manufacturers should consider the human factors of reprocessing. Best practices include following FDA guidance for writing IFUs, collaborating with healthcare facilities to address problems, and considering potential human factors errors associated with reprocessing early on in the design phase as well as during validation.

References

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3. AAMI TIR12:2010, "Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Medical Device Manufacturers," (Arlington, VA: AAMI, 2010).
4. ANSI/AAMI ST79:2010 & A1:2010 & A2:2011, "Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities," (Arlington, VA: AAMI, 2011).

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