

Design Considerations For Medical Device Manufacturers

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As technology advances, so does the complexity of reusable medical devices. This creates greater challenges for cleaning, disinfecting, and sterilizing devices between patient uses. There is increasing concern from the U.S. Food and Drug Administration (FDA) and the reusable device industry that inadequately reprocessed devices are contributing to infections acquired in hospitals and other healthcare facilities.¹ This concern has led to a recently published draft guidance document for reusable device manufacturers, as well as meetings held by the FDA and AAMI in 2011, to address perspectives on these industry issues.

The FDA has encouraged reusable device manufacturers to consider design features that allow for simple and more effective reprocessing procedures. This is a challenge for engineers whose primary focus is to design devices that can meet demands for increased sophistication and functionality. However, intensified regulatory scrutiny of reprocessing validations requires design innovation.

Design Considerations for Cleaning

Cleaning is the critical first step in reprocessing a device. The cleaning process must remove sufficient debris from a device to make it safe for handling by sterile processing department (SPD) personnel, and to allow for effective disinfection

or sterilization. Many materials and design features such as braided cables, aluminum-based metals, and pliable materials such as silicone and rubber increase the difficulty of cleaning. Textured surfaces, hinges, springs, dead-end lumens, and inaccessible cracks and crevices are also problematic, and may harbor unwanted organisms and organic material.

Unfortunately, these features are often needed for device functionality. When this is the case, disassembly options or disposable components may be an effective alternative strategy. When disassembly is required, minimal manipulations and easy-to-understand disassembly and reassembly steps should be the focus, in order to avoid human error that could affect the safety and functionality of the device.

The incorporation of flush ports is a successful strategy for devices with areas that are difficult to clean. Typically, the sole function of flush ports is to allow access of detergents and rinse water to otherwise unreachable areas. Flush ports not only allow for ease of access, but also help standardize the method for cleaning, thereby creating a more reproducible process.

However, when incorporating flush ports, a design often requires the user to manipulate parts of the device that are not easy to see, such as internal channels of an endoscope. Therefore, effective instructions and/or visual aids

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may be necessary when incorporating flush ports into the design, to help the end user know when adequate flushing has been achieved.

Cleaning supplies should also be a consideration in device design. When cleaning validations are performed, manufacturers should incorporate supplies that are compatible with the device design and readily available to healthcare facilities. These include, for example, detergents, brushes, and sponges. If specialized equipment and supplies are necessary for cleaning, the manufacturer must ensure that they are either supplied with the device or that sufficient information is presented to facilitate correct acquisition.

Manufacturers should also consider providing SPD personnel with training on the proper cleaning of their products, including any disassembly, brushing, flushing, and rinsing. Training ensures that workers understand correct technique, instills confidence in their ability to perform the cleaning, and allows the manufacturer to observe any deficiencies in equipment and supplies in the SPD.

Most importantly, onsite training allows for two-way communication between the manu-

facturer and those entrusted to reprocess their devices. This can yield better processes, confirmed understanding, and ultimately, improved patient safety.

Design Considerations for Sterilization

Sterilization, like cleaning, can be greatly affected by the configuration design of the device, rigid sterilization container, and/or containment device (as defined in ANSI/AAMI ST77,² sections 3.4 and 3.5). In many ways, manufacturers are more limited in their sterilization process options than they are with cleaning processes, as they are expected to validate in 510(k)-cleared sterilizers, with 510(k)-cleared set points, using 510(k)-cleared packaging and accessories.

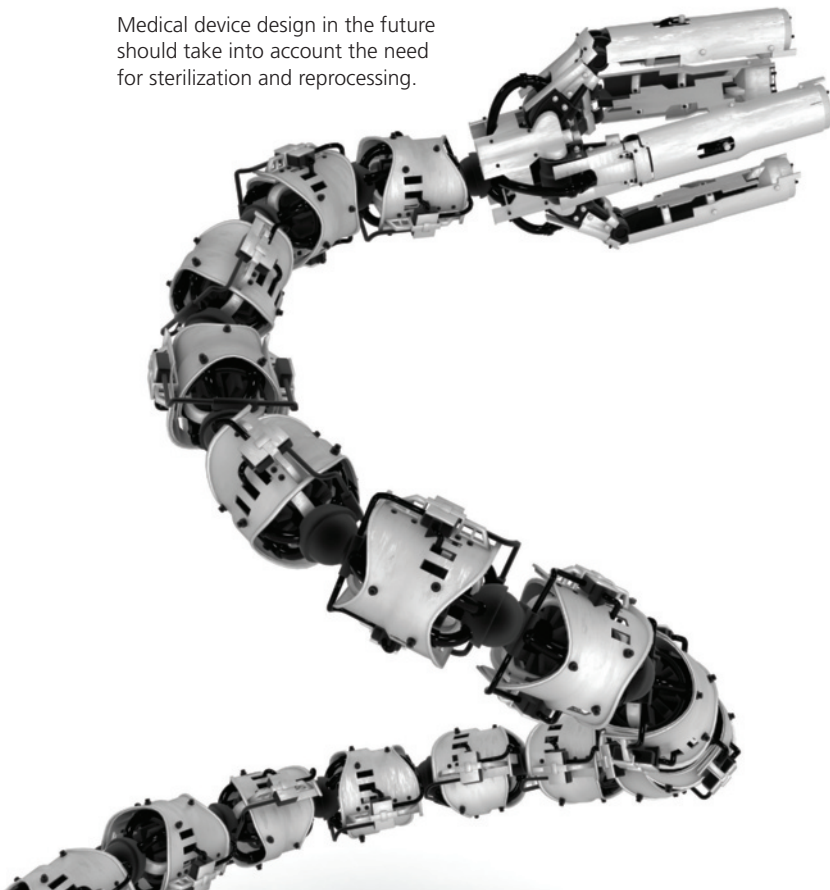
Common sterilization set points available to hospitals can be found in ANSI/AAMI ST79,³ tables 4 and 5. However, by designing devices with sterilization in mind, manufacturers can avoid unnecessary setbacks in their validation process, and ensure patient safety. In addition, users struggle with the number of parameters available and required by manufacturers, and developing features such as a standard sterilization cycle may be helpful.

Manufacturers should consider device and container design features that allow for maximum sterilant penetration. An isolated device can often be sterilized easily in a commonly available sterilization cycle. However, when placed into a loaded container, its ability to be sterilized is compromised. This can be overcome by designing an effective containment device layout.

Manufacturers should design a containment device configuration that enables the end user to place the devices in an optimal open position. With the use of prepositioned bracketing, the medical device manufacturer can take the guesswork out of the containment device loading for SPD personnel. Printing on the containment device surfaces showing proper device placement can also be helpful.

Some devices, due to their complexity, may not be able to be sterilized while fully assembled, especially in standard sterilization cycles. In these cases, even though disassembly may introduce issues for end users, it is sometimes unavoidable. It may be necessary to design devices that can be partially or fully disassembled. When disassembly is required, clear and precise instructions must be provided by the manufacturer.

Medical device design in the future should take into account the need for sterilization and reprocessing.



The mass of a device or container is an important design consideration. Greater masses require greater amounts of energy to achieve sterilization in processes where temperature is a critical parameter. This design consideration should be well understood since ST77 requires containers to weigh no more than 25 pounds when fully loaded.² Generally, devices and containers with less mass are easier to sterilize.

Temperature is a critical parameter for most sterilization methods. Even low temperature sterilization methods require the maintenance of specified temperature ranges. Device sterilization can be optimized by maximizing the use of highly conductive materials and reducing poorly conductive materials.

Device or container packaging is another factor that should be carefully considered prior to performing a sterilization validation. The selected packaging should be readily available to healthcare facilities. It should provide the strength and barrier properties necessary to maintain sterility. Most packaging manufacturers provide multiple grades and sizes to allow the packaging to be matched to the product and expected shelf life.

Packaging should be 510(k) cleared for the selected sterilization parameters. It should allow for adequate removal of moisture or residual sterilant, and be easy to use. Although wraps and pouches are common packaging options, the use of rigid sterilization containers that can maintain sterility can sometimes simplify the process.

When medical device manufacturers design their validations and prepare instructions for use (IFU), it is important that consideration is given to any accessories, such as tray liners, that may be required for proper sterilization. Accessories must be available, easy-to-use, and effective at their intended function.

Accessories selected for medical device sterilization should have 510(k) clearance for the medical device manufacturer's intended sterilization parameters. To assist with end user compliance to the IFU, manufacturers should include details such as the name of the accessory manufacturer, product number, and product name in the IFU, or provide the accessory with the product.⁴

Final Thoughts

As scientists working at an independent testing laboratory, we are in a unique position to see the challenges that affect both medical device manufacturers and SPD personnel. We have seen instances where cleaning and sterilization considerations have not been incorporated into the design of a device. When this happens, validation of reprocessing instructions can be difficult if not impossible. We recommend incorporating validation considerations early in the design process. This will help manufacturers to be more successful in the validation stage and avoid high cost and time setbacks.⁵ We also encourage the consideration of human factors and error-reducing strategies during the design process. Incorporating these recommendations will not only save time and money, and reduce frustration for manufactures, but will help achieve larger goals that we all care about: improved patient safety, fewer infections, and shorter hospital stays. ■

References

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Questions to Consider During Device Design

- Does the device design allow for effective cleaning and sterilization?
- Can design considerations be incorporated to allow for the validation of simplified reprocessing instructions?
- Does the design allow for minimal manipulation during reprocessing?
- Does the design allow for easy disassembly and reassembly?
- Are the materials compatible with the recommended cleaning solutions and sterilization method?
- Are accessories (reusable and disposable) necessary for reprocessing and, if so, are they readily available to SPD personnel?
- Will the device design allow for the validation of common SPD processing techniques? For example, could the use of disposable accessories help?