# Sterile Processing intersects cost, quality and outcomes

*by Rick Dana Barlow*

Mince no words: Sterile Processing is essential to assuring and ensuring high-quality healthcare delivery. In fact, one may argue successfully that the sterile processing function – and the valuable team members who make it happen on a daily basis – represent the cornerstone of surgical repair and patient care.

Physicians and surgeons may balk at that notion (nurses know better because plenty support and work in sterile processing areas) until they notice their devices, instruments and tools are not accessible or available to them.

Critics and pessimists will label that inefficiency; cynics and optimists alike will call that power. Think about it.

The sterile processing profession attracted quite a bit of consumer and trade media attention this past year, stemming from devices (e.g., duodenoscopes) found to have been improperly cleaned, high-level disinfected and sterilized that may have or most likely contributed to infectious outbreaks in surgical patients, ranging from sepsis to superbug. Much depends on your preferred burden of proof – reasonable or shadow of a doubt or just plain logical and scientific theory.

Because sterile processing professionals – from technologists up to directors – are so important to healthcare progress, *Healthcare Purchasing News* debuted its annual Endoscope Care Guide a dozen years ago to serve as a valuable source of information for process improvement. Moreover, recognizing sterile processing's inherent value, *HPN* began covering the department and function since its inception 39 years ago. That will continue well into the next decade and beyond.

The Endoscope Care Guide strives to educate readers on costly, high-tech device maintenance in an easy-to-digest, entertaining and informative format. We created and developed this as a reader service to provide clinicians and administrators with useful information on cleaning, disinfecting, sterilizing, repairing, maintaining, storing and tracking all types of flexible and rigid endoscopes thoroughly, efficiently and cost-effectively. It's designed to serve a dual purpose as a healthy reminder for experienced industry veterans and an introductory refresher for those growing their experience.

Be sure to visit *HPN Online* where you'll find additional valuable content that could not make it into print.

Historically, *HPN's* exclusive guide highlights the obvious and overlooked dangers from improper cleaning, repair and storage, and identifies best practices for device longevity and reliability. *HPN* recruited experts and professionals from some of the leading companies that manufacture endoscopic products and offer endoscopic care services to share their expertise on making sure these costly surgical tools are ready for action all year long.

This year's Endoscope Care Guide concentrates on three primary topics governing its attention, intent and output: Manufacturer instructions for use (IFUs), duodenoscope design and outlook and the fundamental issue of cleaning strategies and tactics before high-level disinfection and sterilization.

**INSIDE...**



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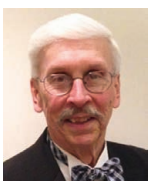
- Delineating IFU myths from truths
- Following guidelines necessary for pressure-cooker reprocessing
- Who will drive positive change?



## Manufacturer IFUs can stray from validation

### *SPD staff, patients suffer from lack of quality assurance*

*by James Schneiter*

The most misunderstood and overlooked aspect of any reusable device manufacturer's instructions for cleaning, disinfecting and sterilizing their product is whether those IFUs have been validated.

The single most dangerous mistake that healthcare personnel make is when they purchase difficult-to-clean reusable medical devices (e.g., endoscopes, laparoscopic instruments, Kerrison Rongeurs, etc.) whose IFUs have not been validated. If you purchase reusable medical devices without first checking to ensure that the cleaning IFUs have been validated using Food and Drug Administration (FDA) validation protocols, you are increasing the risk of patient harm caused by instruments that are difficult, if not impossible, to thoroughly decontaminate, clean and sterilize.

If a reusable device's IFUs have not been validated, you can meticulously follow all of the steps on the IFUs that come with the product, and you will still not have the assurance of clean, sterile, moisture-free devices after every reprocessing cycle.

#### Non-validated IFU consequences

First, numerous outbreaks of Carbapenem-resistant Enterobacteriaceae (CRE) causing patient harm and patient deaths during the past few years have been attributed to endoscopes whose cleaning IFUs had not been validated. As a result of these patient deaths, the FDA in August 2015 cited Pentax and Fujifilm[1] for failing to make sure their instructions for cleaning the scopes were valid.

Second, if you use devices that have not been validated, you are placing your patients at risk due to bioburden and biofilm remaining in the device after cleaning. A recent investigation by *The Detroit News* found that midtown hospitals of the Detroit Medical Center (DMC) have struggled for years to properly clean surgical instruments, stoking doctors' fears about patient safety. One

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newspaper quote: "Doctors are concerned because old blood and bone, even when sterilized, are biohazards that can trigger infection, septic shock and even death if they come into contact with patients." [2]

The fears over patient safety from devices that are difficult to reprocess led the FDA to issue new requirements in March 2015 that specifically require medical device manufacturers to "validate" their cleaning IFUs. On page 22 of the FDA publication, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff," the third paragraph states, "For class II and class III devices and select class I devices, manufacturers must establish and maintain procedures for validating the design of their device, which shall ensure that the device conforms to defined user needs and intended uses, 21 CFR 820.30(g). Manufacturers must also establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met, 21 CFR 820.75(b). Establishing procedures includes implementation, 21 CFR 820.3(k). FDA interprets these regulations to require manufacturers to validate the design, including reprocessing instructions, of reusable devices to ensure that the device can be effectively reprocessed and safely reused over its use life, as intended.

Third, there are now several lawsuits, most notably at Lutheran General Hospital in Park Ridge, IL, where the hospital is being sued by a deceased patient's family for using a reusable medical device whose cleaning IFUs had not been validated.[3] More than 38 patients became infected with CRE at Lutheran General from contaminated scopes. Hospital personnel were meticulously following all of the decontamination and cleaning steps on the IFUs that came with the product, but the scopes were still contaminated after reprocessing.[4] As this case tragically demonstrates, following a manufacturer's IFUs that have not been validated does not ensure against patient harm.

Fourth, while following a manufacturer's cleaning IFUs is always a good idea, if the manufacturer's IFUs have not been validated using FDA validation protocols, there is no way to ensure clean, sterile, moisture-free instruments, regardless of how thorough the reprocessing effort. The documented patient harm caused by devices whose IFUs had not been validated at facilities like Lutheran General and Virginia Mason[5] in Seattle, WA, is just the tip of the iceberg. Many of these deadly infections are caused by contaminated instruments whose cleaning IFUs have never been validated. Without independent validation of a device's cleaning IFUs, reprocessing personnel do not have the ability to ensure clean, sterile, moisture-free instruments for every patient.

As *Healthcare Purchasing News* noted in a May 2016 editorial column:

- To ensure device cleaning, disinfection and sterilization effectiveness, SPD staff should use validated IFUs provided by manufacturers.
- Device manufacturers should provide validated IFUs to their healthcare organization customers so they know how to clean, disinfect and sterilize products effectively to prevent patient infections from improperly reprocessed devices.
- The FDA stipulates in its guidelines that device manufacturers validate the design, functionality and end-user operation of the devices they make, including reprocessing instructions.

The *HPN* editorial went on to state that "Supply Chain and SPD pros (and GPOs) must demand that any and all devices and products include authentically validated IFUs as a requirement for contract consideration or they won't be acquired."[6]

## Written, not verbal, validation

Another commonly misunderstood aspect of a device manufacturer's IFUs is accepting a sales representative's verbal assurance that his company's IFUs "have been validated." Unless you request the sales representative to provide you with a copy of their validation report using FDA validation protocols, you have no assurance of clean, sterile, moisture-free instruments. Why would you continue to risk harming your patients by not requesting a copy of the manufacturer's validation report for their IFUs?

A frequently made mistake is to believe that a manufacturer's IFUs have been validated just because their IFUs on the company website uses the word "validated." Unless the manufacturer has validated its IFUs by following the FDA's validation protocol, those IFUs have not been validated.

The new FDA validation requirements for device manufacturers are very specific regarding the validation of processes designed to clean reusable medical devices. As stated on page 23 of the FDA publication "You (the device manufacturer) should validate the cleaning process you provide in your labeling. Your validation activities should be based on comprehensive validation protocols that use soils that are relevant to the clinical use conditions of the device. These should include the worst-case (least rigorous) implementation of the cleaning process, medical devices that represent the worst-case (most challenging to reprocess and most contaminated). These protocols should be designed to establish that the most inaccessible locations on your devices can be adequately cleaned during routine processing."

When a manufacturer of reusable devices tells the hospital that "our instruments have been validated," and yet they have not followed the FDA's validation protocol, all they are really saying is that the sterilization indicator worked when their instruments were run through a sterilizer. Prior to sterilization, their "test" instruments were not immersed in bioburden and then allowed to dry in the air to simulate the normal wait time between contamination and the start of reprocessing. Their non-contaminated instruments were simply placed into a sterilizer and then run through a normal sterilization cycle. After emerging from the sterilizer, the instruments were not cultured for the presence of biofilm, nor were they inspected for the presence of bioburden or residual moisture. The only thing 'validated' was that conditions were right (time, pressure, temperature and steam) to turn the sterilization indicator.

The last, and perhaps biggest, mistake people make is using "take-apart" or "modular" instruments who's IFUs rely on "visual verification" to ensure the removal of bioburden and biofilm. Visual verification is not an acceptable substitute for using instruments who's IFUs have been validated. That is because the human eye cannot see microscopic bioburden, nor can it see biofilm, making "visual verification"' physically impossible! Being able to "visualize" the inside of the instrument does not ensure a clean instrument (assuming that reprocessing personnel even remember to take the time to disassemble, manually clean and then properly reassemble the instrument). The only way to ensure clean, sterile, moisture-free instruments on every reprocessing cycle is to only use instruments who's IFUs have been validated using FDA validation protocols.

Failure to demand validated cleaning IFUs from device manufacturers is a tremendous patient safety issue. Healthcare facilities have a legal, ethical, financial and moral obligation to use only instruments whose IFUs have been validated using FDA validation protocols. HPN

*Visit www.hpnonline.com/sterile-processing-intersects for references.*

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