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2015 Endoscope Care Guide

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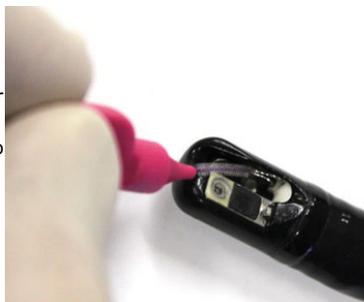
November 2014

2014 Endoscope Care Guide

Cracking the duodenoscope reprocessing case

Once media outlets broke the news earlier this year that scores of patients were exposed to infections that were linked to contaminated duodenoscopes used in certain minimally invasive surgery procedures, the daisy chain of blame emerged.

In a nutshell, patients and their families and friends pointed to the clinicians and administrators at hospitals for not reprocessing the devices properly and for not protecting their patients. Clinicians and administrators at hospitals pointed to the device manufacturers for making the devices too complex to clean, disinfect and sterilize properly, coupled with confusing and inadequate instructions for use (IFU) and reprocessing, and to the Food and Drug Administration (FDA) for not clarifying and enforcing its manufacturing regulations. Device manufacturers pointed to the FDA for not being more specific in its guidelines as well as the hospitals for not asking for better guidance prior to these incidents. The FDA pointed to the device manufacturers for not providing adequate reprocessing instructions to healthcare organizations and to healthcare organizations for not following the instructions they had.



Conversations ensued during the last few months that explored potential solutions to this controversial issue. From those conversations, four key strategies and tactics emerged as possible outcomes:

1. Redesign the duodenoscopes.
2. Dramatically improve IFUs with accompanying retraining of sterile processing professionals.
3. Limit or eliminate the duodenoscopes and the surgical procedures in which they are used.
4. Remake the reusable duodenoscope into a single-use-only device that is immediately disposed of after use.

Naturally, all four options can lead to positive and negative outcomes with considerable clinical, financial and operational ramifications. Not surprisingly, due to the controversial nature of the topic and the legal implications of disclosing or discussing anything related to it, few in the industry were willing to share any insights, even in general terms.

Ralph Basile, Vice President, Marketing, [Healthmark Industries Inc.](#), a provider

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of medical device sterilization, decontamination, storage, distribution and security needs, is one who did join the conversation, addressing each strategy with a thoughtful and logical approach.

Redesigning the device maybe shouldn't be so problematic.

"Manufacturers of these devices are the ones best able to answer this," Basile told *HPN*. "But if it were easy to produce a flexible endoscope, including duodenoscopes, that could be cleaned and sterilized by fully automated procedures, we probably would already have seen them. Having said that, flexible endoscope manufacturers should look to see what other medical device manufacturers, [who manufacture products] such as laparoscopic instruments, kerisons, etc., have done to make their devices easier to clean. Take-apart construction. More ports to make cleaning, flushing easier. Disposable accessories, components, etc. These are all steps that could be taken to improve the 'reprocessability' of these devices. Effective cleaning is the key to success. If organic contaminants are effectively removed, then high-level disinfection procedures will be effective."

More detailed and improved IFUs, coupled with more intense reprocessing training?

"This is obvious," he said, "but these devices are very expensive and any change to their design reflected in a new generation of devices will take significant time to work through the system, in terms of replacing an earlier generation of products. As far as SPD staff, as we have seen with other devices, if you make these easier to take apart, to clean, and to inspect for cleanliness, retraining SPD staff is not a barrier to success. It is the key to success."

Limiting or eliminating the device and the procedures in which it is used may not be the answer.

"I'm not a GI doctor by any means," he said. "But certainly I have heard and read enough from the experts to know that eliminating the use of these devices and employing other procedures would be far more dangerous to patients. Of all the options to try and make this better, this is the one that would make things far worse."

Manufacturing duodenoscopes as single-use-only devices may sound like an obvious solution but that raises serious implications.

"Single-use, or single patient use, as would be the more technically correct way of stating it, of course would offer all kinds of benefits from an infection control standpoint," he noted. "But what is the expense associated with this? It is not just the cost of the device itself, but also the cost to dispose, the risk to the environment, the contamination of land and water, potentially. We cannot always 'dispose' our way out of these challenges. These devices can be designed to be more easily and effectively cleaned. Just as important is to provide the guidance and tools to reprocessing staff to help them determine whether they were successful. Are they producing devices that are clean, disinfected and safe to use on the next patient?"



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