

## FDA Labeling of Liquid Chemical Sterilants

March 1, 2002

0 Comments

Posted in Articles, **Procedures**, Instrument Processing, Equipment, Endoscope  
Print

### FDA Labeling of Liquid Chemical Sterilants: Are Modifications Needed?

By Lawrence F. Muscarella, Ph

Developing and marketing a liquid chemical sterilant (LCS) for reprocessing endoscopes is a more formidable task than often appreciated. The ideal LCS, among other factors, is safe to healthcare staff and the environment, relatively inexpensive, rapidly sporicidal, compatible with delicate instruments, non-foaming, and remains active in the presence of protein and organic soil. No currently marketed LCS satisfies all of these criteria. With most drugs, for each of its benefits a LCS will typically have a salient shortcoming. For instance, LCSs that are rapidly sporicidal typically tend to be more corrosive, resulting in higher endoscope repair and maintenance costs.<sup>1,2</sup> Despite their limitations, LCSs are convenient, relatively fast-acting, and universally used to reprocess flexible endoscopes and other instruments. Among other advantages including convenience, LCSs are routinely used to reprocess gastrointestinal (GI) endoscopes in or near the patient's procedure room.<sup>3</sup> For healthcare facilities lacking a large inventory of endoscopes, the use of LCSs avoids having to transport these expensive instruments to a remote central processing department (CPD), which can be costly and can remove the endoscope from service for a prohibitively long period of time. However, the convenience and cost-savings afforded by LCSs are not without a down side. Tension can develop between patient safety and the healthcare facility's desire to reprocess endoscopes as quickly as possible. Two effective sterilization processes routinely used in CPDs are ethylene oxide (EtO) gas and steam autoclaves. The use of either for endoscope reprocessing is prohibitive: the former typically requires a 24-hour aeration time before the endoscope can be returned to service for reuse, and the latter destroys the heat-sensitive and delicate materials used in the construction of fiberoptic flexible endoscopes.

LCSs can, to some degree, mollify this tension, providing healthcare staff with an effective "point-of-use" reprocessing method that yields high-level disinfected endoscopes in less than 20 minutes. (Heating some LCSs, or altering their concentrations or pH, can enhance their biocidal properties and further reduce their immersion times.) To be sure, manufacturers relentlessly seek to develop and market LCSs labeled to 'sterilize' endoscopes (and other instruments) in less than an hour. Whether the US Food and Drug Administration (FDA) will only for the second time in almost 15 years approve an LCS labeled for the sterilization of endoscopes during an immersion time of less than an hour is unclear, although, in my opinion, not likely.

As with many biocidal agents, issues can arise with LCSs (e.g., glutaraldehyde, ortho-phthalaldehyde, hydrogen peroxide, and peracetic acid) that warrant consideration and caution. For instance, the labels of most FDA-cleared LCSs, which some infection control and healthcare staff may find confusing,<sup>3</sup> provide two instrument immersion times: one for *high-level disinfection*, and another, typically requiring a considerably longer immersion time (e.g., 3 to 10 hours), for *sterilization*.

Despite their dual label claims, it is my opinion that the FDA's original intent was to limit the use of LCSs intended for reprocessing flexible endoscopes only to high-level disinfection<sup>4,5</sup> having not fully anticipated that an LCS might be marketed exclusively for sterilizing endoscopes. Whereas sterilization is a multi-step process that includes, among other steps, cleaning, instrument wrapping, and specific quality controls such as the routine use of biological indicators (BIs), immersing an item in a LCS is virtually a single-step process.<sup>4,6</sup> Confusing a multi-step and complete *sterilization* process with an LCS's single-step and limited *sporicidal* process can, in my opinion, result in a false level of assurance and increase the risk of patient infection.<sup>7</sup>

LCSs are convenient and easy to use but have several salient shortcomings that limit their effectiveness and reliability, and call into question their current FDA-cleared labels that claim instrument *sterilization*. First, items reprocessed using an LCS lack a shelf-life, as they cannot be wrapped and therefore are susceptible to re-contamination during handling and storage. Second, in addition to conveying a higher sterility assurance level (SAL) than heat, EtO, and plasma sterilization processes,<sup>5,6</sup> LCS-based processes lack essential quality controls and cannot be reliably monitored using BIs: the bacterial endospores on the BI's strip may be rinsed-off during its handling and immersion in the LCS, rendering the BI's results meaningless.<sup>8</sup>

Third, unlike pressurized steam that can diffuse through instruments' materials and patient debris and kill otherwise inaccessible microorganisms, LCSs require direct contact with the microorganisms to be effective.<sup>6</sup> LCSs are also viscous, which can limit their flow through narrow lumens and orifices.<sup>5,6,9</sup> Fourth, unlike with heat and EtO gas (or plasma) sterilization, LCS-based processes uniquely require a final water rinse to remove potentially toxic residues. Indeed, the quality of the healthcare facility's water is often difficult to control and monitor. And if the final water rinse contains microorganisms, the instrument may become re-contaminated after chemical immersion.<sup>4,6,7</sup> As a result, this essential final water rinse is, in my opinion, the Achilles' heel of current LCS-based processes. Multiple cases of patient infection and deaths linked to contaminated rinse water have been recently reported.<sup>10-11</sup> When properly maintained and replaced, bacterial filters can improve the water's microbiological quality and minimize the likelihood of instrument re-contamination during the final water rinse. But bacterial filters are not fail-safe, and their effectiveness after only a few uses has been reported to fail and permit the passage of bacteria.<sup>9,12-14</sup>

In conclusion, due to the aforementioned limitations of LCSs and the challenges posed by complex instrument designs, claims that an LCS reliably 'sterilizes' flexible endoscopes are, in my opinion, suspect and warrant caution.

Lawrence F. Muscarella, PhD, is the director and research and development chief at Custom Ultrasonics, Inc, based in Ivyland, PA.

Share This

E-Mail

Facebook

Twitter

More Options...

0 Comments

### SIMILAR ARTICLES

- [The Dangers of Scope Leaks and How to Avoid Them](#)
- [Recommended Practices for Surgical Attire](#)
- [FDA Gives Clearance for Fully Covered Esophageal Stent](#)
- [Assessing Scope Processing: How Does Your Program Add Up?](#)
- [FDA Warns Against Acai Berry 'Colon Cleanser'](#)

### LATEST ARTICLES

- [University Hospital's Gastroenterology Unit Gets New Professor](#)
- [CCA Releases Results of Colon-Cancer Survey](#)
- [Johns Hopkins Offers 'Basics of Medication Errors' Class](#)
- [German Researchers: Remote-Controlled Capsules are Safe](#)
- [UCLA Study: Reform Can Align Medicare with Preventive Care](#)

### OTHER RESOURCES

Like

Dislike

ADD NEW COMMENT

Community

SHOWING 0 COMMENTS

Sort by

Popular now

[Subscribe by email](#) [Subscribe by RSS](#)

Post as ...