

The Q-Net™ Monthly

Volume 9, Number 8, 9

August, September 2003

What's News

This newsletter's double issue is the third in a series of articles that discuss drying the endoscope with a 70% alcohol rinse followed by forced air. The first article in this series appeared in the *March-April 2003* issue of this newsletter. The second article was published in the May 2003 issue of *Healthcare Purchasing News* (p. 67).

Remember to visit Q-Net's **updated** homepage at www.myendosite.com for important news and a list of topics published in this newsletter.

Editor-in-Chief

The articles published in this newsletter are written by: **Lawrence F Muscarella, PhD, Chief, Infection Control at Custom Ultrasonics, Inc.** Ivyland, PA 18974.

What is 'Q-Net'?

Q-Net is a technology-assessment network of questions and answers. Its newsletter is *The Q-Net™ Monthly*.

Q-Net's main goal is to encourage the infection control and endoscopy communities to not only ask good questions but to also demand succinct and well referenced responses.

Q-Net addresses the needs of both the health care provider whose goal is to provide the best care possible, and the patient who deserves affordable quality health care.

To dry or not to dry?

This article, the third in a series, discusses drying the endoscope after reprocessing. Although its contribution to reducing the risk of nosocomial infection is well documented, endoscope drying is not universally endorsed.

Background

In its March (2003) issue, *Healthcare Purchasing News (HPN)* published an article I wrote entitled, "Lessons from the bronchoscope case: What happened at Allegheny General?" I recommend in this article drying the endoscope after reprocessing—that is, after cleaning, chemical immersion, and terminal water rinsing.

Drying is recommended to prevent the colonization of waterborne bacteria, such as *Pseudomonas aeruginosa*, in the internal channels of gastrointestinal (GI) flexible endoscopes and bronchoscopes. It can be easily and inexpensively accomplished by manually flushing all of the endoscope's channels with 70% alcohol (which is used as a facilitator of drying) followed by forced or compressed air. I recommend performing these two steps *both* between patient procedures and before storage of the endoscope.

In addition, I recommend drying the endoscope not only after rinsing the endoscope (after chemical immersion) with tap water, but also after rinsing the endoscope with bacteria-free water,

bottled sterile water, and 0.2 micron filtered water labeled as "sterile." It is my opinion that the risk of nosocomial infection caused by waterborne bacteria during flexible endoscopy—more so during bronchoscopy than GI endoscopy—is under-appreciated (refer to the *May-June 2003 issue of this newsletter*), and the functional limitations of water filtration systems and their bacterial filters, such as those used by most automated endoscope reprocessors (AERs) to produce filtered rinse water, routinely overlooked.

Rebuttal

Despite its importance to patient safety, the recommendation to dry flexible endoscopes after reprocessing has surprisingly become controversial and a lightning rod for criticism. Mr. Richard "Ric" Rumble, vice president of a marketing division for a company that sells the only liquid-based, point-of-use process cleared by the FDA for "sterilizing" flexible

(Continued on page 16)

Table of Contents

Background	15
Rebuttal	15
Confusing stance	16
Discussion	17
Conclusion	18

(Continued from page 15)

endoscopes, wrote a letter that was published in *HPN's* May (2003) issue (p. 67). In his letter, Mr. Rumble declares my recommendation to dry the endoscope after reprocessing in his company's *sterilizing system*—which he refers to as an “AER”—irresponsible and unsafe.

While defending in his letter the unique claims of his company's *sterilizing system*, Mr. Rumble acknowledges that the label claim of this point-of-use AER requires that its rinse water, which is produced by passing tap water through a water filtration system that includes a 0.2 micron bacterial filter, be sterile (as opposed to being unfiltered tap water or bacteria-free water).

► *In short, the label of this sterilizing system (somehow) “guarantees” instrument sterilization (indeed, an enviable feat) as well as the production of sterile filtered rinse water.*

(Nota Bene: The label claims of this *sterilizing system* are unique. Although almost 15 years ago the FDA granted to Mr. Rumble's company a 510(k) clearance for its liquid-based, low-temperature system labeled to “sterilize” flexible endoscopes, neither prior to nor since its introduction on to the United States' market has another medical device with a similar label claim of “sterilization” of flexible endoscopes or “sterile” filtered rinse water been granted a 510(k) clearance.)

Confusing stance

Although I would not mind being the sole recipient of Mr. Rumble's expressed angst with the recommendation to dry the endoscope after reprocessing in his company's *sterilizing system*, I must humbly confess that I cannot take sole credit for this recommendation. To be sure, several agencies and organizations have previously published the importance of drying the endoscope. And while in his letter Mr. Rumble's classification and entitlement of his company's *sterilizing system* as an “AER” may seem insignificant, such a label has important clinical and regulatory implications.

As a result of *P aeruginosa* and mycobacterial outbreaks (and pseudo-outbreaks) linked to bronchoscopes inadequately reprocessed by the *sterilizing system* marketed by Mr. Rumble's employer, the FDA and the CDC jointly published in 1999 a Public Health Advisory (see: www.fda.gov/cdrh/safety/endoreprocess.html). Among others recommendations provided in this health advisory, the FDA and CDC instruct health care practitioners using this *sterilizing system* (or any other AER, as well as after manual reprocessing) to “consider incorporating a final drying step in (the) reprocessing protocol. There are studies that have demonstrated that a final drying step that includes flushing all channels with alcohol followed by purging the channels with air (to remove the alcohol) greatly reduces the possibility of recontamination of

the endoscope by water-borne microorganisms. The American Society for Testing and Materials (ASTM) has incorporated this recommendation in its ASTM Standard F1518-94.”

As expressed in this federal health advisory, it is therefore clear that I am not alone in emphasizing the importance of drying the endoscope's channels after reprocessing in this *sterilizing system*. Mr. Rumble's castigation of me and my drying recommendation published in *HPN's* March (2003) issue as being “without (the backing) of science” and serving “only to create a potentially unsafe and damaging environment—one which practitioners may interpret as encouraging experimentation in the field” is therefore also inextricably directed at and critical of, among others, the FDA and CDC.

Mr. Rumble's firm and determined instruction *not* to dry the endoscope after reprocessing in his company's *sterilizing system*—which could result in wet bronchoscopes, potentially contaminated with waterborne bacteria, being introduced into the lungs of critically ill patients (*refer to the February-March 2000, January-February 2003, and March-April 2003, issues of this newsletter*)—is perplexing, without scientific foundation, and inimical to patient safety.

► *There are no data in the medical literature that support the contention that drying the endoscope after reprocessing in this sterilizing system (or any other AER) is unsafe, experimental, or superfluous. To the contrary, the medical literature is replete with studies and reports that showed that drying the endoscope both after manual and automated reprocessing terminated outbreaks.*

Wet endoscopes have been reported to transmit waterborne bacteria, while dry endoscopes have not. Despite the millions of procedures performed each year using a flexible endoscope, there are *no* reports of infection linked to waterborne bacteria, such as *P aeruginosa*, when the endoscope was reprocessed in accordance with published guidelines and thoroughly dried before reuse (with the exception of a few reports of infection linked to several recalled endoscope models; *refer to the April-May 2002 issue of this newsletter*).

The FDA and CDC are not the only authorities whose acknowledgement of the importance of drying the endoscope after reprocessing in this *sterilizing system* is at odds with Mr. Rumble's confusing instruction and stance. The *Society for Gastroenterology Nurses and Associates* (SGNA), in its “Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes” (<http://www.sgna.org/resources/guideline3.cfm>), recommends drying the endoscope by flushing each of its channels with 70% alcohol followed by forced air, a practice that I endorse and has become the standard of care. SGNA states that “bacteria such as *P aeruginosa* have been identified in both tap and filtered water, and may multiply in a moist environment.” SGNA also states in these standards that “alcohol flushes should be used even when *sterile* water is used for rinsing,” a reference to this *sterilizing*

(Continued on page 17)

(Continued from page 16)

system's sterile filtered rinse water label claim, as well as to bottled, sterile water.

In a reference to all AERs including this *sterilizing system*, SGNA in these same standards stresses, under the heading of 'automated reprocessing:' "If a final alcohol rinse cycle is not included in the (AER), this step should be done manually followed by purging all the channels with air." In its guideline for the use of high-level disinfectants and sterilants (*Gastroenterol Nurs* 2000 Jul-Aug;23(4):180-7), SGNA notes that "most automated reprocessors incorporate an optional water filtration system. Such systems may reduce the number of tap water contaminants but do not eliminate the need for the air/alcohol/air purge as the final step prior to storage." And, at least one endoscope manufacturer recommends that its endoscopes be thoroughly dried using 70% alcohol specifically after reprocessing in this *sterilizing system*. Why Mr. Rumble would so staunchly attempt to dissuade users of his company's AER from drying the endoscope after reprocessing—one of the most basic and inexpensive endoscope reprocessing steps shown to prevent bacterial colonization and nosocomial infection—is confusing and inexplicable.

Discussion

In addition to his claim that those who recommend drying the endoscope after reprocessing in his company's *sterilizing system* are in violation of its labeling and are creating an unsafe environment, Mr. Rumble in his letter published in *HPN's* May (2003) issue provides several other confusing statements that beg attention and discussion.

► *First, I reaffirm my opinion that, had Allegheny General Medical Center in Pittsburgh, PA, been instructed to dry its bronchoscopes after reprocessing in this sterilizing system using a 70% alcohol (isopropyl or ethyl) flush followed by forced air, this medical facility's recent P aeruginosa outbreak might have been prevented (refer to the March-April 2003 issue of this newsletter).*

It is also my opinion that similar outbreaks at other medical facilities that were linked to bronchoscopes contaminated with *P aeruginosa* (refer to the September 2001 issue of this newsletter)—including an outbreak about which a report was published in 1999 by the CDC in *Morbidity and Mortality Weekly Report* (MMWR) (<http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/mm4826a1.htm>)—might have been prevented, had the bronchoscopes been thoroughly dried after reprocessing in this *sterilizing system*.

Second, as noted in Mr. Rumble's letter, I am employed by *Custom Ultrasonics*. But his depiction of my employer as a "competitor" of his company is somewhat odd and inconsistent with his company's longstanding published marketing strategies and claims. Through the years, Mr.

Rumble's employer has always aggressively asserted that the only competitors of its *sterilizing system* were other sterilizers, such as those that use ethylene oxide gas. Mr. Rumble's company has also always claimed that its *sterilizing system's* significantly higher associated reprocessing costs were well-justified because, according to his company, the outcome of its *sterilizing system* for flexible endoscopes is distinct from and superior to high-level disinfection, a process that his company—despite the lack of data—has always maintained is unsafe and poses an infection risk. The rationale for Mr. Rumble's statement that his company—which, again, markets the *only* "AER" labeled to "sterilize" flexible endoscopes and which therefore presumably has no competition—competes with *Custom Ultrasonics*, a company that is not associated in any way with a sterilization claim, process, or technology, is confusing and inconsistent.

Third, Mr. Rumble suggests my published articles are part of a duplicitous effort to surreptitiously "market (my) company's technology." Those who have read this newsletter and my articles through the years, every one of which has always fully disclosed my affiliations and my employer, would be hard pressed to identify one that discusses or promotes *Custom Ultrasonics* or any of its line of products. In point of fact, there is one published document I wrote that discusses *Custom Ultrasonics'* products, and it was part of a 510(k) application to the FDA that required inclusion of my name. As I express in several of my articles, drying is a crucial reprocessing step, and its only beneficiary is the patient. *Custom Ultrasonics* does not financially benefit by me recommending that endoscopes be manually dried after reprocessing using 70% alcohol followed by forced air.

Fourth, Mr. Rumble states in his letter that I have "no direct knowledge of the situation or events" at Allegheny General Medical Center, in Pittsburgh, PA, the hospital about which I have written and which linked a *P aeruginosa* outbreak to bronchoscopes reprocessed by his company's *sterilizing system*. While discretion limits a discussion of all of the aspects of this hospital's *P aeruginosa* outbreak, I am rather familiar with it, having read more than two dozen newspaper articles and other documents that are readily available in the public domain and that provide in significant detail many of the scientific facts of this outbreak. Further, at no time has Mr. Rumble (or any of his company's colleagues) talked to or corresponded with me as would be required for a fair evaluation of either my direct or indirect knowledge of this medical facility's *P aeruginosa* outbreak.

Fifth, Mr. Rumble notes that his company's *sterilizing system* is labeled and advertised to produce "sterile" rinse water by filtering a hospital's tap water through a 0.2 micron bacterial filter. As with all AERs, the water used to rinse the endoscope after chemical immersion is arguably its Achilles' heel: the outcome of any AER's process is limited by and can only be as good as the quality of its rinse water. Therefore, the requirement that this *sterilizing system's* rinse water be

(Continued on page 18)

(Continued from page 17)

sterile represents the linchpin of its endoscope sterilization label claim. If its rinse water were not sterile, then this *sterilizing system's* processed and rinsed endoscopes, although not necessarily unsafe, would also not be sterile, a conclusion that would have obvious implications in an operating room setting, where aseptic technique is required.

- A review of the medical literature reveals that there are no published data that demonstrate sterile water can be produced by filtering a hospital's tap water through a 0.2 micron bacterial filter.

Also problematic, this *sterilizing system's* remiss labeling does not instruct the user to periodically monitor its rinse water microbiologically, as required to evaluate the in-use performance of its water filtration system and to document that the rinse water is sterile and associated with a sterility assurance level, or SAL, of, for example, 10^{-6} . As a result, the effectiveness of this *sterilizing system* may be in doubt. Efforts to obtain data from Mr. Rumble's company in support of its AER's sterilization and sterile rinse water label claims have proved fruitless and will probably remain so in light of his company's recent statement that the testing data that presumably support its *sterilizing system's* efficacy claims are "proprietary" and not for public review.

Sixth, in his letter Mr. Rumble professes that his company's *sterilizing system* "assures sterility." He adds that this *sterilizing system* "provides guaranteed performance and documented microbial reduction performance – something no other AER supplier has as yet been willing to provide." These statements are at best confusing and incomplete. How

could any AER "guarantee" endoscope sterilization when, in addition to other shortcomings, there is no documentation to support its sterile rinse water claim? And, how can sterilization of a flexible endoscope be guaranteed when several of the endoscope's narrow channels and complex internal surfaces cannot be directly sampled microbiologically to assess or document sterility?

- Data in support of the claim that flexible endoscopes can be reliably sterilized using any liquid-based or low-temperature sterilization process are lacking (as are the data demonstrating that a hospital's tap water supply can be sterilized using an AER's 0.2 micron bacterial filter).

Moreover, although belied by Mr. Rumble's published comments, *Custom Ultrasonics* has provided to the FDA data that document the effectiveness of its AERs. These data are not considered proprietary and have been posted on the Internet for public review and scrutiny (<http://www.myendosite.com/510kbooklet2002.pdf>). Maybe as a result of this educational discussion Mr. Rumble would be willing to post on the Internet the data supporting the claims of his company's *sterilizing system* for the public's review and comfort.

Conclusion

The FDA, CDC, ASTM, SGNA, myself, and, among others, at least one endoscope manufacturer recommend drying the endoscope's channels using 70% alcohol followed by forced air specifically after reprocessing endoscopes using the *sterilizing system* marketed by Mr. Rumble's company. Drying is crucial to prevent the transmission of *P aeruginosa* and other waterborne bacteria via a flexible endoscope. I therefore recommend that published endoscope reprocessing guidelines clearly elucidate the importance of drying the endoscope after reprocessing in any liquid-based AER, including any that claim to produce "sterile" rinse water.

This recommendation notwithstanding, instead of drying the endoscope, Mr. Rumble instructs users of his company's *sterilizing system*, in accordance with its "just-in-time" labeling, to reprocess each endoscope "immediately before use." Such labeling, however, is confusing and problematic. Even for a relatively small facility that uses only a few different endoscopes per day, reprocessing *each* of them in the morning before the first procedure may be impractical. And for a large facility, this practice is sure to be prohibitively expensive and time-consuming. Most important, there are no published data that suggest that this early morning practice reduces the risk of patient infection compared to simply drying the endoscope before storage the previous day, an inexpensive and common practice. Indeed, drying the endoscope is safe, simple, and inexpensive. Again, there are lessons out there to be learned, but there are also forests to be seen through the trees. LFM ○

Thank you for your interest in this newsletter. *I have addressed each issue to the best of my ability. Respectfully, the Publisher: Lawrence F. Muscarella, PhD.* Please direct all correspondence to:

Lawrence F Muscarella, PhD
Editor-in-Chief, *The Q-Net™ Monthly*
Director, Research and Development
Chief, Infection Control



Custom Ultrasonics, Inc.
144 Railroad Drive, Ivyland, PA 18974
Tele: 215.364.8577; Fax: 215.364.7674
E-mail: editor@myendosite.com
Internet: <http://www.myendosite.com>

Copyright © 1995-2003. All rights reserved. *It is a violation of federal copyright laws (17 U.S.C. Sec. 101 et seq.) to copy, fax, or reproduce any portion of this newsletter without its editor's consent. Q-Net is a registered trademark of Custom Ultrasonics, Inc.* augsept_v5_steris_ss1