

## To dry or not to dry the endoscope?

by Lawrence F Muscarella, PhD



Last spring, *Healthcare Purchasing News* published an article I wrote entitled, "Lessons from the bronchoscope case: What happened at Allegheny General?" (March 2003, p. 26).

Among other commentary discussed in my article, I recommend drying the endoscope after reprocessing - that is, after cleaning, chemical immersion, and terminal water rinsing. Drying is necessary to prevent the colonization of waterborne bacteria, such as *Pseudomonas aeruginosa*, in the internal channels of gastrointestinal (GI) flexible endoscopes and bronchoscopes between reuses. 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.

Moreover, I recommend drying the endoscope not only after terminally rinsing the endoscope (after chemical immersion) with tap water, bacteria-free water, or bottled sterile water, but also after reprocessing endoscopes using the STERIS System 1, which uses a water filtration system that is uniquely labeled to produce "sterile" rinse water. I stress the importance of drying the endoscope after reprocessing based on having reviewed over 1,500 papers in the fields of infection control, instrument reprocessing and water filtration technology; having written over 100 articles in these fields, many of which appear in peer-reviewed medical journals; and having searched over the past ten years the causes of several bacterial outbreaks and pseudo-outbreaks linked to contaminated bronchoscopes and GI endoscopes. It is my opinion that the risk of patient infection caused by waterborne bacteria during flexible endoscopy, more so during bronchoscopy than GI endoscopy, is under-appreciated, and the functional limitations of water filtration systems and their 0.1 or 0.2 micron bacterial filter membranes, such as those used by most automated endoscope reprocessors (AERs) to produce filtered rinse water, routinely overlooked.

Despite its contribution to the improvement of patient safety, the recommendation

to dry bronchoscopes and other flexible endoscopes after reprocessing has apparently become controversial and a lightning rod for acrimonious criticism. Mr. Richard "Ric" Rumble, vice president of STERIS Corporation's global marketing healthcare division, wrote a letter (*HPN*, May 2003, p. 67) which declares my recommendation to dry the endoscope after reprocessing in the System 1 - which Mr. Rumble refers to as an "AER" - irresponsible and unsafe. In addition, Mr. Rumble's letter defends the unique sterilization claims of the System 1, the only point-of-use process cleared by the FDA for "sterilizing" flexible endoscopes. As acknowledged by Mr. Rumble, the label claim of the System 1 as a sterile processing system requires that its water filtration system, which includes a 0.2 micron bacterial filter, produce sterile rinse water. In short, the label of the System 1 (somehow) "guarantees" instrument sterilization and the production of sterile rinse water by filtering a hospital's (unprocessed) tap water across a bacterial filter membrane. (The label claims of the System 1 are unique and unprecedented. Although the FDA granted STERIS a 510(k) clearance for the System 1 almost 15 years ago, neither prior to nor since its introduction to the U.S. market has a medical device with a similar claim of "sterilization" of flexible endoscopes and "sterile" filtered rinse water been granted 510(k) clearance by the FDA).

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 the System 1, I must humbly confess that it would be disingenuous of me to take sole credit for this recommendation. To be sure, several agencies and organizations have previously published the importance of endoscope drying. And while in his letter Mr. Rumble's classification and entitlement of the System 1 as an "AER" may seem irrelevant and moot, it has significant clinical and regulatory implications. As a result of several *Pseudomonas aeruginosa* and mycobacterial outbreaks (and pseudo-outbreaks) linked to bronchoscopes inadequately reprocessed by the STERIS System 1, the FDA and the CDC jointly published in 1999 a Public Health Advisory ([www.fda.gov/cdrh/safety/endoreprocess.html](http://www.fda.gov/cdrh/safety/endoreprocess.html)). Among its rec-

ommendations, the FDA and CDC instruct healthcare practitioners using the System 1 (or another AER, or after manual reprocessing) to "consider incorporating a final drying step in (the) reprocessing protocol. There are studies which 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 waterborne microorganisms. The American Society for Testing and Materials (ASTM) has incorporated this recommendation in its ASTM Standard F1518-94."

As expressed in this advisory, it is therefore clear that I am not the only one who has emphasized the importance of drying the endoscope after reprocessing in the System 1. Mr. Rumble's castigation of me and the recommendation I published in *HPN* to dry the endoscope's channels after reprocessing in the System 1 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 also therefore inextricably directed at and critical of, among others, the FDA, CDC and ASTM.

The firm and determined instruction by Mr. Rumble not to dry the endoscope after reprocessing it in the System 1 - which could result in wet bronchoscopes potentially contaminated with waterborne bacteria during rinsing being introduced into the lungs of critically ill patients - is perplexing, without scientific foundation, and inimical to patient safety. There are no data in the medical literature that support Mr. Rumble's contention that drying the endoscope after reprocessing in the System 1 (or another AER) is unsafe, experimental, or superfluous or redundant. To the contrary, the medical literature is replete with clinical studies and reports that emphasize the importance of drying the endoscope to patient safety. 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 caused by the transmission of waterborne bacteria, such as *P. aeruginosa*, when the endoscope was reprocessed in accordance with published guidelines and dried before reuse (with the exception of a few re-

ports of infection caused by defective and recalled endoscope models).

The FDA and CDC are not the only authorities whose acknowledgement of the importance to dry the endoscope after reprocessing in the System 1 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>), states that "bacteria such as *Pseudomonas aeruginosa* have been identified in both tap and filtered water, and may multiply in a moist environment." As a result, SGNA 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 stresses in these standards for reprocessing endoscopes that "alcohol flushes should be used even when sterile water is used for rinsing," a reference to the System 1's sterile rinse water claim as well as bottled sterile water. In its guideline for the use of high-level disinfectants and sterilants, SGNA states 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" (<http://www.sgna.org/resources/HLD.html>), an indication that applies to the System 1. And, at least one endoscope manufacturer recommends that the endoscope be thoroughly dried using 70% alcohol (isopropyl or ethyl) specifically after reprocessing in the System 1. Why Mr. Rumble would so staunchly attempt to dissuade users of an AER from drying the endoscope after reprocessing - one of the most basic and inexpensive endoscope reprocessing steps shown to prevent bacterial colonization and patient infection - is inexplicable.

In addition to his claim that those who recommend drying the endoscope after reprocessing in the System 1 are in violation of the System 1's labeling and creating an unsafe environment, Mr. Rumble in his letter provides several other confusing and misinformed statements and commentary that beg attention. First, I reaffirm my opinion that, had Allegheny General Medical Center in Pittsburgh been instructed to dry its bronchoscopes after reprocessing in the System 1 using a manual 70% alcohol flush followed by forced air, this medical facility's recent *P aeruginosa* outbreak might have been prevented. It is also my opinion that similar outbreaks at other medical facilities that were

linked to bronchoscopes contaminated with *P aeruginosa*, including an outbreak about which a report was published in 1999 by the CDC in *Morbidity and Mortality Weekly Report* (<http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/mm4826a1.htm>), might also have been prevented, had the bronchoscopes been thoroughly dried after reprocessing in the System 1.

Second, as noted in Mr. Rumble's letter, I am employed by Custom Ultrasonics Inc. But Mr. Rumble's depiction of Custom Ultrasonics as a "competitor" of STERIS is somewhat odd and inconsistent with STERIS' longstanding published marketing claims. Through the years, STERIS has always asserted that the System 1's only

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competitors were other sterilizers, such as those that use ethylene oxide gas. STERIS has also always claimed that the System 1's higher associated reprocessing costs were well-justified because, according to STERIS, the outcome of the System 1 for flexible endoscopes is distinct from and superior to high-level disinfection, a process that STERIS - despite the lack of data - has always maintained is unsafe and poses an infection risk. The rationale for Mr. Rumble's statement that the System 1 - the only process labeled to "sterilize" flexible endoscopes and therefore presumably has no competition - is an AER that competes with Custom Ultrasonics, a company not associated in any way with a sterilization claim, process, or technology, is inconsistent and unclear.

Third, Mr. Rumble suggests my published articles are part of a duplicitous scheme "to market (my) company's technology." Those who have read my articles through the years, every one of which has always fully disclosed my affiliations and employer, would be hard pressed to identify one that

discusses or promotes Custom Ultrasonics or 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 published articles, drying is a crucial reprocessing step, and its only beneficiary is the patient. Custom Ultrasonics does not financially benefit by recommending that endoscopes be manually dried after reprocessing using a 70% alcohol flush 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, the hospital about which I have written and that linked patient injury and death to contaminated bronchoscopes reprocessed by the System 1. While discretion limits my discussion of some 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 details of this outbreak. Fur-

ther, at no time has Mr. Rumble (or any of his company's colleagues) talked to or corresponded with me as required for a fair evaluation of either my direct or indirect knowledge of this outbreak.

Fifth, Mr. Rumble notes that the System 1 is labeled and advertised to produce "sterile" rinse water by filtering a hospital's (unprocessed) tap water through its water filtration system that includes a 0.2 micron bacterial filter membrane. 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 the rinse water. Therefore, the requirement that the System 1's rinse water be sterile represents the linchpin of its instrument sterilization label claim. If the System 1's rinse water is not sterile, then its processed and rinsed instruments, although not necessarily unsafe for use, are also not sterile, a conclusion that may have implications in the operating room setting. A review of the medical literature reveals that there are no published data that demonstrate sterile rinse water can be produced by filtering a hospital's tap water through a

0.2 micron bacterial filter membrane. Moreover, its claim of instrument sterilization arguably may be further in doubt, because the labeling of the System 1 does not recommend routine and direct microbiologic monitoring of its rinse water as required for the healthcare facility to evaluate the in-use performance of the System 1's water filtration system and to validate that the rinse water is sterile and associated with a sterility assurance level, or SAL, of, for example,  $10^{-6}$ . Efforts to obtain data from STERIS in support of the label claim that the System 1 produces sterile rinse water have proved fruitless and will probably remain so in light of STERIS' recent statement in a newspaper article that the testing data that support its System 1's performance claims are "proprietary" and not for public review.

Sixth, in his letter Mr. Rumble professes: "The STERIS System 1 process assures sterility." He adds: "The STERIS process provides guaranteed performance and documented microbial reduction performance - something no other AER supplier has as yet been willing to provide." These statements are confusing and certainly misleading. First, how can the System 1 (or any "sterilizer" or AER) "guarantee" instrument sterilization when, in accordance with its label's failure to instruct users to monitor microbiologically the in-use performance of its water filtration system, little if anything is known about the microbial quality of its terminal water rinses? And, how can sterilization of a flexible endoscope be guaranteed when several of its narrow channels and complex internal surfaces, each of which can contain imperfections and tears that harbor adherent bacteria, cannot be directly sampled microbiologically to confirm sterility? Second, although belied by Mr. Rumble's comments, I have provided to the FDA data that document the microbial reduction performance (a measure that is generally used to describe the effectiveness of a high-level disinfectant - not a sterilizer) of Custom Ultrasonics' AER and, unlike STERIS, these data are not considered proprietary and have been posted on the Internet for public review and scrutiny ([www.myendosite.com/510kbooklet2002.pdf](http://www.myendosite.com/510kbooklet2002.pdf)). Third, data in support of the claim that flexible endoscopes can be reliably sterilized using the System 1, or any low-temperature sterilization technology, are lacking (as are the data demonstrating that a hospital's tap water can be sterilized using a 0.2 micron bacterial filter membrane). If any of these data exist, maybe as a result of this educational

discussion Mr. Rumble would be willing to post them on the Internet for the public's review and comfort.

In conclusion, drying the endoscope using a manual 70% alcohol flush followed by forced air after reprocessing, whether using tap water or bacteria-free or "sterile" filtered water as a final rinse, is recommended by SGNA, myself, at least one endoscope manufacturer, and, among others, the FDA and CDC. It is a practice that is crucial to the prevention of the transmission of *P. aeruginosa* or other waterborne bacteria via a flexible endoscope. Nevertheless, in lieu of drying the endoscope, Mr. Rumble's letter instructs users of the System 1, in accordance with its "just-in-time" labeling, to reprocess each endoscope "immediately before use, regardless of cleaning and storage processes." Such labeling, however, is puzzling and problematic. First, even for a relatively small facility that may perform dozens of flexible endoscopic procedures per week, reprocessing *each* endoscope in the morning before the first patient is impractical, time-consuming, and prohibitively expensive. Moreover, there are no published data that suggest this early morning practice reduces the risk of patient infection compared to simply drying the endoscope before storage, a significantly less expensive and practical practice. I therefore suggest that published endoscope reprocessing guidelines clearly recommend drying the endoscope after reprocessing in any AER including the System 1. Second,

it is unclear how STERIS defines "just-in-time," as its definition as it applies to the System 1 has not been published. Is Mr. Rumble referring to a process that is similar to "flashing" and intended only for emergency situations? Also unclear and unpublished by STERIS is the amount of time that can elapse after reprocessing an endoscope in the System 1 before its channels can become colonized with bacteria and require the entire endoscope be reprocessed again before reuse. Due in part to the physical separation between the endoscope reprocessing room and the patient's procedure room, which guidelines recommend be separate rooms, few if any endoscopes can be used "just-in-time" or immediately after reprocessing as instructed by Mr. Rumble and the System 1's labeling. Fortunately, there is a solution that is simple, safe, inexpensive and renders moot these problems, questions, and lacking data: drying the endoscope after reprocessing. There are lessons out there to be learned, but there are also forests to be seen through the trees. **HPN**

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