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What's News

This newsletter discusses the quality of water used to rinse reusable medical instruments. This same topic is the focus of AAMI's forthcoming technical information report (TIR-34). Several important considerations are provided in this newsletter for inclusion in, and both for the scientific validity and completeness of, this TIR report. For example, this newsletter discusses the importance of periodically monitoring the rinse water *inside* of any liquid-based processor that claims to produce "sterile" rinse water and to "sterilize" surgical instruments.

Editor-in-Chief

All of the articles published in this newsletter are written by **Lawrence F. Muscarella, Ph.D.**, Chief, Infection Control at **Custom Ultrasonics, Inc.** Ivyland, PA 18974.

What is 'Q-Net'?

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

The main goal of **Q-Net** is to encourage the infection control, endoscopy, and OR communities not only to ask good questions but also to demand 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.

"Sterile" filtered rinse water?

This article has significant implications to aseptic technique and the content of infection-control guidelines, including APIC's, AORN's, and the soon-to-be-published HICPAC guideline entitled "Disinfection and Sterilization in Healthcare Facilities."



BACKGROUND: A lecture entitled "Sterilization and Disinfection—Meeting the Requirements" was presented on February 29, 2008, in Los Angeles (CA) during a day-long seminar sponsored by *The Greater Los Angeles Chapter of APIC* (The Association for Professionals in Infection Control and Epidemiology; see: <http://www.apicla.org>). One of the topics discussed during this lecture warrants clarification, to prevent health-care-acquired infections (HAIs).

GUIDELINES: As part of the complete reprocessing procedure, SGNA (*The Society of Gastroenterology Nurses and Associates*) recommends drying flexible endoscopes: (a) before storage and between patient procedures; (b) whether reprocessing the endoscope manually or using an automated system; and (c) no matter whether the instrument is rinsed after chemical immersion with "clean water, tap water, fresh water, rinse water labeled as bacteria-free, or rinse water labeled as sterile."¹⁻³ Drying is routinely achieved by flushing the instrument's lumens with a bolus of 70% isopropyl alcohol followed by forced air drying.¹⁻⁹

THE PROBLEM: Some of the slides presented during this lecture discuss the Steris System 1—a peracetic acid-based processor marketed for the "liquid sterilization" of immersible surgical instruments, including endoscopes.^{10,11} SGNA's guidelines notwithstanding, these presented slides do not discuss the importance of drying the endoscope, which is wet with rinse water, after being processed by the Steris System 1. Indeed, these presented slides presume that the effectiveness and claims of both this processor and its water filtration system—which are labeled to "guarantee"¹¹ the "sterilization"^{10,11} of surgical instruments and to produce "sterile"¹⁰⁻¹² filtered rinse water, respectively—have been verified and validated.

But, for a presentation or publication to discuss the Steris System 1 without underscoring the importance of instrument drying is to overlook the evidence-based recommendations of SGNA (and others) and to endorse tacitly the clinical use of surgical instruments wet with rinse water—a practice reported to significantly increase the risk of HAIs.^{1-9,12}

Moreover, no design verification and validation data have been published to substantiate the claim (and "guarantee"^{10,11}) that the Steris System

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Keywords: *The Greater Los Angeles Chapter of APIC, "sterile" filtered rinse water, instrument drying, 0.2 (or 0.1) micron bacterial filters*

1's water filtration system, which includes a 0.2 micron bacterial filter, reliably and consistently produces "sterile" filtered rinse water from a medical facility's tap during *worst-case* testing conditions as the FDA requires^{13,14}—namely, during high water pressures, large water volumes, and over the 0.2 micron bacterial filter's entire use-life.

Nor did any of this lecture's presented slides mention that published data suggest that the Steris System 1's "sterile" filtered water used to rinse instruments may at times be contaminated with waterborne bacteria—a finding that further underscores the importance of instrument drying. For instance, investigating the cause of a bacterial outbreak, the Centers for Disease Control and Prevention (CDC) identified in the filtered rinse water of the Steris System 1 bacteria that were "too numerous to count" (TNTC).¹²

And, focusing on the claims of this processor, the FDA published that it has "concerns pertaining to continued reports of patient infections ... associated with the Steris System 1 Processor. Review of the various reports submitted to (the) FDA indicates that the infections are usually caused by waterborne organisms. The association of the Steris System 1 Processor with patient infections usually caused by waterborne organisms leads us to question the ability of the processor to provide a sterile water rinse. We believe that the processor may not be functioning as it is labeled."^{6,12}

THE SOLUTION: Patient morbidity and mortality following endoscopy have been directly linked to the clinical use of instruments wet with rinse water.^{1-7,15} And, demonstrating drying's effectiveness, both true- and pseudo-outbreaks of bacteria have been abruptly terminated once instrument drying was implemented.^{1-8,15-17} As a consequence, the FDA⁸ and others recommend that the instruments be thoroughly dried after processing in the Steris System 1 (and all other liquid-based automated instrument reprocessing systems), to prevent disease transmission.^{1-9,15-18} Drying the instrument after processing also resolves (or "cuts") the operating room's proverbial *Gordian knot*, which—while correctly asserting that water or moisture on the outside packaging of a wrapped surgical instrument set renders the set contaminated and unsafe for patient use—inexplicably claims that instruments wet with filtered tap water after reprocessing (as opposed to flash-autoclaved condensate) are "sterile."¹⁵

CONCLUSION: The implications of this discussion to public health, aseptic technique, and HAIs are far-reaching and self-evident. Thousands of patients die each year in the U.S. from HAIs of waterborne (gram-negative) bacteria including *Pseudomonas aeruginosa*.¹⁵ Although not discussed by any of the slides presented during this lecture in Los Angeles, no data have been published verifying and validating the claim that the 0.2 micron bacterial filter of the Steris System 1 (or of any other liquid-based instrument reprocessing system) reliably and consistently produces "sterile" filtered rinse water (under *worst-case* conditions) from a healthcare facility's tap

water.^{3-7,12,14,15,19} And, it is for this reason, among others, that some researchers, such as myself, have questioned the labeling of this processor and any other liquid-based processor, including the Endoclen,²⁰ that claims to achieve "liquid sterilization" of surgical instruments.^{3-7,12}

Further, the slides presented during this lecture did not discuss the importance of the requisite practice of microbiologically monitoring (as opposed to filter integrity or water pressure monitoring) the Steris System 1's water filtration system, to verify periodically that its filtered rinse water (or the rinse water of any liquid-based "sterilizing" system) does not contain any waterborne microorganisms or pyrogens as required by its labeling (please refer to the "What's News" box on p. 7).^{14,19,21-23} (The importance of both practices to the prevention of HAIs notwithstanding, the manufacturer notably contraindicates both instrument drying and microbiological monitoring of its processor's filtered rinse water.^{8,12,24})

But, failure to monitor microbiologically the Steris System 1's water filtration system would violate operating room policies that require microbiological monitoring of processes labeled to produce a sterile product—such as a steam autoclave and, presumably, a 0.2 micron bacterial filter labeled to "sterilize" tap water. Violation of these policies is problematic and requires abrogation of the processor's claim to achieve "sterilization."^{5,6,23} → All of which underscores the importance of SGNA's recommendation to dry the instrument after reprocessing, to compensate for a bacterial filter's inherent limitations, limited use-life, and proneness to failure; and, to minimize the risk of HAIs.^{1-9,12,14,15,19,21-23} **The End** ○

✓ The 22 references to this newsletter's article are available at: <http://www.myendosite.com/APICLA022908.pdf>

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

Lawrence F. Muscarella, Ph.D.
 Editor-in-Chief, *The Q-Net™ Monthly*
 Director, Research and Development
 Chief, Infection Control
 Founder: www.myendosite.com



Custom Ultrasonics, Inc.
 144 Railroad Drive, Ivyland, PA 18974
 Tele: 215.364.8577; Fax: 215.364.7674
 E-mail: education@myendosite.com

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