For: *Infection Control*, *Operating Room*, *Endoscopy and Reprocessing Staff*, *Risk Managers*, *et al*.

The Q-Net™ Monthly

Volume 15, Numbers 3, 4 March-April 2009

What's News

Thousands of patients were recently notified of the potential for the transmission of blood-borne pathogens including HIV at three Veterans Administration facilities in TN, FL, and GA. An improper valve was used to irrigate patients at one of these facilities, resulting in the potential for infection during colonoscopy. The contributing factors to this incident will be discussed in a future issue of this newsletter. For more information, please visit: www.MyEndoSite.com

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

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.

Endoscope Damage, Part 2

*This is the **second** and **final** article in a series that focuses on **endoscope damage** during reprocessing. Whether peracetic acid, 2% glutaraldehyde, or* ortho*-phthalaldehyde might damage endoscopes is discussed.*

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BACKGROUND: Entitled "Endoscope Damage, Part 1," last month's double issue of this newsletter (January-February, 2009) focuses on the potential for endoscope damage associated with the use of peracetic acid and other types of liquid chemical disinfectants.[1-7] Peracetic acid and aldehyde-based disinfectants, such as 2% glutaraldehyde (e.g., Cidex) and *ortho*-phthalaldehyde (e.g., Metricide OPA Plus), are commonly used to reprocess flexible endoscopes after each use, in accordance with *Standard Precautions*, to prevent the transmission of infectious agents.

The second in a series of two, this month's article completes this discussion about endoscope damage. (A review of both the November-December, 2008, and January-February, 2009, issues of this newsletter is recommended, to ensure that this discussion about endoscope damage is read in the proper context.[1,7])

INTRODUCTION: A liquid oxidizing agent that is chemically distinct from aldehyde-based disinfectants, peracetic acid is the active ingredient used by both the Steris System 1 and the Steris Reliance Endoscope Processing System (EPS), at the same concentration (0.2%) and elevated immersion temperature (50—56° C) (but at slightly different immersion times).[2,6] Whether endoscope damage acknowledged to be associated with the System 1 may, therefore, also be associated with the Reliance EPS is unclear, although the possibility is discussed in an evaluation of the Reliance EPS authored by the ECRI Institute ("ECRI").[2] A review of this evaluation is featured in this newsletter's November-December, 2008, issue.[7]

Whereas the Reliance EPS is labeled to supplement manual cleaning and both to wash and high-level disinfect gastrointestinal (GI) endoscopes, the System 1 is labeled to "sterilize" several different types of instruments, including GI endoscopes.[2] Having been declared last May (2008) to be "adulterated and misbranded" since 1988, the sale of the Steris System 1 in January (2009) became restricted.[8,9]

The misbranding of the Steris System 1, its countenanced use in the U.S. despite its discontinuation, and the lack of published position statements by infection-control organizations contraindicating the use of adulterated and misbranded

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KEYWORDS: Endoscope damage, 2% glutaraldehyde, *ortho*-phthalaldehyde, peracetic acid, materials' compatibility

devices in the healthcare setting will be discussed in a future issue of this newsletter. (The author of this article about endoscope damage is employed by the manufacturer of an automated endoscope reprocessor that, like the Reliance EPS, is labeled to wash and disinfect GI endoscopes.)

REVISITING A MANUFACTURER'S CLAIM: As if in a tone of exoneration, ECRI's evaluation of the Steris Reliance EPS recites and advances a manufacturer's account of the cause of endoscope damage acknowledged to be associated with the Steris System 1.[1-3,7] According to this account, the System 1 is not responsible for endoscope damage—rather, its peracetic acid uncovers pre-existing endoscope "defects" caused by "wear and tear and/or improper care and handling" of endoscopes by staff members.[2] This manufacturer suggests that aldehyde-based disinfectants (e.g., 2% glutaraldehyde and *ortho*-phthalaldehyde) used previously to reprocess the endoscope "mask" these pre-existing defects, which include small pin holes. The manufacturer adds that subsequent use of the Steris System 1 "unplugs" these pin holes, clogged over time with retained protein residue, appearing to (but not) cause endoscope damage.[2,3,6] (Please review both **Box A** in this newsletter and **Box B** on p. 3 of the January-February, 2009, issue of this newsletter.)

A CONVERSE QUESTION: In sync with this manufacturer's account, ECRI's evaluation of the Reliance EPS states that "ECRI has seen quite a few reports of endoscopes developing leaks or exhibiting damage after reprocessing in the System 1 sterilizer after *formerly* being reprocessed with other, aldehyde-based" disinfectants.[2] Interestingly, ECRI's evaluation does not complete this discussion by addressing or answering the obvious converse question:

Has ECRI also received (or is it aware of) reports of damage to endoscopes that had been reprocessed only *in the Steris System 1 and that had* not *been formerly reprocessed using an aldehyde-based disinfectant?*

(Presumably, it has.) That ECRI's evaluation does not provide an answer to this salient question is confusing. (Please review **Box A** on p. 2 of the January-February, 2009, issue of this newsletter.)

DISCUSSION: In addition to ECRI's evaluation of the Steris Reliance EPS, a number of published articles and studies discuss the acknowledged association between endoscope damage and the Steris System 1.[2-5] In general, each of these papers either implicates or, on the other hand, claims to rule out peracetic acid as the cause of endoscope damage. The repairing and servicing of endoscopes damaged during reprocessing can be considerable and expensive.[4,5] Therefore, in addition to investigating whether these published articles are evidence-based, researching and understanding the potential causes of endoscope damage is important.

Box A. ***A manufacturer's claims or evidenced-based-conclusions?***

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An evaluation of the Steris Reliance EPS authored by the ECRI Institute ("ECRI") does not consistently distinguish a manufacturer's unsubstantiated claims from evidenced-based conclusions.[1,2,7] For example, as detailed in the November-December, 2008, issue of this newsletter,[7] ECRI's evaluation inferentially suggests that the Reliance EPS activates an audible alarm at the moment bacteria begin leaking across its 0.2 micron water filter.[2]

But, despite the potential for an increased risk of healthcare-acquired infections associated with bacteria breaching this filter and contaminating the endoscope during water rinsing,[10,11] ECRI did not test this alarm to verify that it reliably monitors this filter's bacterial integrity and is not prone to *false-negative* "silence" – that is, bacteria leaking through this filter's 0.2 micron membrane, contaminating the filtered rinse water, and, in turn, the endoscope, too, but *without* activating this alarm.

In short, evaluations of medical devices that provide a manufacturer's account about, for example, the performance of a 0.2 micron water filter—or the cause of endoscope damage—are recommended to include the requisite statement "*According to the manufacturer* …" This measure is necessary to eliminate confusion and to prevent the improper amalgamation of a manufacturer's unsubstantiated claims with evidence-based findings. ❍

Damage to new endoscopes: Two published studies—authored by Fuselier and Mason (1997) (see **Box B**) and by Abraham et al. (2007) (see **Box C**)—provide findings that are inconsistent with this manufacturer's account that the Steris System 1's peracetic acid "unplugs" clogged pin holes and uncovers, but does not cause, endoscope damage—an account advanced in ECRI's evaluation of the Reliance EPS but that has not been independently substantiated.[1,2,4,5]

These studies (one of which pre-dates the publication of ECRI's evaluation) report that the System 1's peracetic acid caused measurable damage to endoscopes—including *new* endoscopes that not only had *not* been "formally" reprocessed using an aldehyde-based disinfectant, but reportedly were damaged by the System 1 after just *one* completed cycle.[4,5] The findings of these two studies suggest that ECRI's intimation that damage linked to the System 1 is only associated with endoscopes "formerly"[2] reprocessed using aldehyde-based disinfectants is in error.

In its evaluation of the Reliance EPS (and any of its subsequent publications), ECRI does not cite these two independent studies or reconcile their results with the manufacturer's claim that the System 1's peracetic acid does not cause endoscope damage. Further, ECRI's evaluation does not discuss the conspicuous possibility that peracetic acid *itself* might be

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Box B. *Fuselier and Mason (1997):* Fuselier and Mason (1997)[4] studied the relative compatibility and clinical effectiveness of both 2% glutaraldehyde and the Steris System 1, which are labeled to achieve high-level disinfection and "sterilization" of flexible endoscopes, respectively. Focusing on performance and both operating and maintenance costs, these researchers found that cystoscopes reprocessed using 2% glutaraldehyde were not associated with damage or repairs. In contrast, the use of the System 1 to reprocess seven cystoscopes (manufactured by Surgitek, Storz, and Olympus) over a period of one year resulted in endoscope damage (with an associated cost of $11,500). One of these seven endoscopes manufactured by Olympus was *new*, had not been previously reprocessed, and was damaged by the System 1 after just one completed cycle. Not discussed in ECRI's evaluation of the Reliance EPS, Fuselier and Mason (1997)'s[4] findings are inconsistent with the manufacturer's account of the cause of endoscope damage.

responsible for the endoscope damage reportedly associated with the System 1 (see **Box C**). The rationale for these omissions is unclear, if inexplicable. (Please review **Box A** on p. 2 of this newsletter's January-February, 2009, issue.)

Glutaraldehyde, "pin holes": Advancing the manufacturer's account of the causes of endoscope damage, an article published in a trade magazine contends that 2% glutaraldehyde and *ortho*-phthalaldehyde are cross-linking agents that can "fix" patient debris, resulting in "layers" of "organic material and/or biofilm" to "build-up" over time inside endoscopes.[6] Without citing independent data to support its claims, this magazine article suggests that the subsequent use of oxidizing agents removes these layers of organic material and "unplugs" pre-existing pin holes, causing peracetic acid to appear to (but not) be the cause of endoscope damage associated with the Steris System 1.[6]

This magazine article, however, the claims of which are inconsistent with independent studies (please refer to **Box B** and **Box C**),[4,5] was not peer-reviewed and was sponsored and co-authored by Steris (the manufacturer of the Reliance EPS and the System 1).[6] Another article similarly suggests that peracetic acid "breaks down protein encrustations," claiming that by removing this "encrusted" patient debris, the Steris System 1's peracetic acid uncovers (but is not the cause of) "small channel perforations" and pin holes that were "masked" by aldehyde-based disinfectants used previously to reprocess the endoscope.[3] But this article, too, was not peer-reviewed and was authored by the System 1's manufacturer.

The conclusions of these two manufacturer-sponsored articles, which are in lock-step with the account advanced in ECRI's evaluation of the Reliance EPS,[2] are inconsistent with, in addition to both Fuselier and Mason's (1997)[4] and Abraham et al.'s (2007)[5] findings, the conclusions of Muscarella (1999), which question claims that glutaraldehyde's chemical properties are responsible for endoscopes being "visibly encrusted with debris."[12] Muscarella (1999) adds that "clinical data demonstrating a correlation between the build-up of patient material on an instrument and the type of liquid chemical sterilant used by the hospital are lacking."[12]

To be sure, independent data have not corroborated the manufacturer's claim (advanced in ECRI's evaluation of the Reliance EPS[2]) that endoscope damage attributed to the System 1 (and, possibly, the Reliance EPS[2]) is due, not to peracetic acid, but rather to this oxidizing agent's uncovering of pre-existing pin holes and small channel perforations, or endoscope "defects," that became clogged with "encrusted"[3] patient debris that built up over time during previous reproc-

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Box C. *Abraham et al. (2007):* Publishing data similar to those of Fuselier and Mason (1997)[4] (see **Box B**), Abraham et al. (2007)[5] prospectively studied and compared the effects of the Steris System 1 and Cidex OPA (0.55% *ortho*-phthalaldehyde) on the image quality, physical structure, and deflective properties of two *new* ("out-of-the-box") flexible fiber-optic (11278AU1) ureteroscopes (Karl Storz Endoscopy, Germany). One endoscope was exposed to the Steris System 1 for 100 cycles; the other was immersed in Cidex OPA for 15 minutes (at room temperature) also for 100 cycles. Abraham et al. (2007)[5] found that the endoscope reprocessed by the System 1 was unusable after 100 cycles, had a 12-mm tear on its shaft after the 17th cycle, and damage to 297 optical fibers after the 100th cycle.

The endoscope reprocessed using Cidex OPA, however, experienced only 10 damaged fibers after the 100th cycle, with no visible damage to the endoscope's exterior. The endoscopes were "crossed-over," and the test repeated, with each endoscope being exposed to the other process for 100 cycles. The endoscope initially reprocessed in Cidex OPA became damaged during reprocessing in the System 1, whereas the other endoscope (originally reprocessed in the System 1) experienced no further significant damage during exposure to the Cidex OPA.

Abraham et al. (2007)[5] suggest that the damage associated with the Steris System 1 "probably is multifactorial" and may be due to the peracetic acid, the System 1's "luminal" flushing pressure, and/or its relative high immersion temperature (50 – 56^{o} C). At the end of this study, the two endoscopes were returned for analysis to Storz, which evaluated the integrity of both endoscopes and independently confirmed that the reported endoscope damage was caused by the Steris System 1.[5] These findings are inconsistent with the manufacturer's account advanced in ECRI's evaluation of the Reliance EPS (refer to the main article and to **Box B**.)

essing using 2% glutaraldehyde and other "cross-linking agents."[2,3,6] Nor have independent data been published demonstrating that an aldehyde-based disinfectant damages endoscopes. Indeed, both Fuselier and Mason (1997) (**Box B**) and Abraham et al. (2007) (**Box C**) implicate the Steris System 1 and/or its peracetic acid as the cause of endoscope damage.[4,5]

RECOMMENDATIONS: The following recommendations are provided to improve patient safety and minimize the likelihood of endoscope damage and costly repairs:

(1) Ensure endoscopes are properly handled, reprocessed, stored, and serviced per the endoscope manufacturer's instructions, to maintain the endoscope's integrity, to prevent damage, and to ensure its safe and long-lasting functioning.

(2) Only use high-level disinfectants, sterilants, or other reprocessing agents verified via documentation, certified and controlled by the instrument manufacturer's quality assurance department, to be compatible with each endoscope (and automated endoscope reprocessor) model in inventory.

(3) Work to improve infection control standards by requiring that: (a) conflicts of interest in infection control be more rigorously managed (refer to **Box A** in this newsletter's January-February, 2009, issue); (b) healthcare organizations publish timely infection-control position statements—for example, contraindicating the use of adulterated and misbranded medical devices;[8,9] and (c) endoscope manufacturers publish reprocessing instructions that display more of a commitment to evidence-based conclusions and patient safety (please refer to **Box D**), and that, unless supporting data are available, these manufacturers not claim that their endoscopes are "compatible" with certain reprocessing agents or that these agents are safe and effective (please review **Box A**).

(4) Last, the following additional recommendations are provided to improve the quality of infection-control guidelines and evaluations of the performance of medical devices, including infection-control products: (a) distinguish more conspicuously a manufacturer's claim from an evidence-based (scientific) finding (please review **Box A**); (b) use caution before advancing a manufacturer's unsubstantiated claims—for example, consider and publish in the guideline or evaluation all possible causes, not just one, of endoscope damage; and (c) also for balance and perspective, discuss and cite studies whose findings or conclusions are inconsistent with a position, scenario, or recommendation advanced in the guideline or evaluation. ● **(The End)** *Article by:* L.F. Muscarella Ph.D.

Box D. ***Endoscope manufacturers and endoscope damage:*** Karl Storz Endoscopy ("Storz")—which manufactured the two endoscopes used in Abraham et al. (2007)'s study[5] (**Box C**) and one used in Fuselier and Mason's (1997)[4] study (**Box B**)—commonly lists the Steris System 1's peracetic acid as a "compatible" chemical for reprocessing its endoscopes.[13] Storz has reported that no damage to its ureteroscopes was identified after 100 cycles of processing in the System 1—findings that appear to be inconsistent with Abraham et al.'s (2007).[5]

Whether Storz is aware of, for example, Abraham et al.'s (2007) findings or the published potential for materials' incompatibility associated with peracetic acid is unclear.[2-5] Independent data supporting Storz's conclusion that peracetic acid is both "compatible" with and "sterilizes" its endoscopes,[1,13] however, have not been published. (Please review **Box A**, which discusses the importance of distinguishing between marketing claims and evidence-based conclusions.)

Olympus—the manufacturer of the new cystoscope studied by Fuselier and Mason (1997)[4] that had not been previously reprocessed and was damaged after just one completed cycle using the System 1 (*see:* the main article and **Box B**)—issued a notice in 2002 stating that: Olympus "does not list the Steris System 1 as a compatible product" for reprocessing its bronchoscopes and GI endoscopes.[14] (In 2007, Olympus issued a second, more placatory letter.[15]) Like many similar oversights, the reasons for ECRI's evaluation of the Reliance EPS to have not cited this notice by Olympus are unclear. For the record, Pentax claims that the System 1 is compatible with—but contraindicates the use of Reliance EPS for reprocessing any of—its flexible endoscopes.[1,7] ❍

➡ **The REFERENCES for this article is available at:**
www.myendosite.com/htmlsite/2009/refs030409.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:

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