

The Q-Net™ Monthly

Volume 15, Numbers 1, 2

January-February 2009

What's News

Welcome to this newsletter's 15th year of publication. The first of two articles about endoscope damage, this issue focuses on the results of a review of the literature. The second article in this series will continue a discussion of these results. • More than 100 of this newsletter's articles have been archived and are available on-line. • This newsletter's website—MyEndoSite.com (or [Endoscope Reprocessing.com](http://EndoscopeReprocessing.com))—is being revised and updated for your convenience.

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 1

Do glutaraldehyde and peracetic acid damage endoscopes?

This article—the first in a series of two—investigates the potential for 2% glutaraldehyde and peracetic acid to cause endoscope damage. Peracetic acid is the active ingredient used by both the Steris System 1 and the Steris Reliance EPS.

questions about the scientific merit of this claim. No independent studies or data were identified that substantiate this manufacturer's claim. On the contrary, this review identified published studies that report the System 1's peracetic acid to be the cause of damage to endoscopes.

SUMMARY: An evaluation of the Steris Reliance EPS was published in 2007. Authored by the ECRI Institute, this evaluation includes Steris's claim that peracetic acid—used by the Reliance EPS at the same concentration and immersion temperature as the Steris System 1—is not responsible for the endoscope damage associated with the System 1.

Rather, Steris contends in ECRI's evaluation that peracetic acid uncovers "prior defects that had resulted from wear and tear and/or improper care and handling" of endoscopes by staff members, adding that these defects had been "masked by aldehyde-based" disinfectants, such as 2% glutaraldehyde and *ortho*-phthalaldehyde, previously used to reprocess these endoscopes.

The medical literature was reviewed to evaluate the validity of this manufacturer's claim and explanation of the cause of endoscope damage associated with the System 1. The results of this review raise

BACKGROUND: The November-December, 2008, issue of this newsletter features a review of an evaluation of the Steris Reliance™ Endoscope Processing System ("EPS")—a recently introduced automated endoscope reprocessor ("AER") labeled to wash and high-level disinfect gastrointestinal (GI) endoscopes.¹ Authored by the ECRI Institute ("ECRI"), this evaluation rates the Reliance EPS "preferred over traditional AERs for facilities that use compatible endoscopes."² Further, this evaluation "strongly encourage(s) healthcare facilities ... that do not have Pentax endoscopes ... to purchase the Reliance EPS rather than a traditional AER."²

To be sure, this commendatory rating and firm instruction would be salient and warrant attention if it were

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

evidence-based. Yet, while this evaluation provides some important details about the Reliance EPS, such as this AER's use of a novel pressurized "boot,"² this rating and instruction are difficult to rationalize and justify. Discussed in this newsletter's November-December, 2008, issue, two oversights are identified that raise legitimate questions about the quality and scientific merit of this evaluation's rating and instruction.^{1,2}

First, this evaluation did not conduct any performance or microbiologic tests as would be required to rate the effectiveness and safety of the Reliance EPS.^{1,2} Second, this evaluation did not include or test any of these disfavored "traditional" AERs to which the Reliance EPS was compared.^{1,2} (A review of both the September-October, 2008, and November-December, 2008, issues of this newsletter is necessary to place this article about endoscope damage in context.)

ECRI rates a product *preferred* if it "meets all major performance and safety criteria ... and offers significant advantages over other alternatives."² Which raises a fair question: *What was the scientific rationale for rating the Reliance EPS "preferred," realizing that this evaluation did not conduct any performance or safety tests and did not include for comparison any of these "alternative" AERs?* Whether interactions with manufacturers might have played a role in rating this AER, compromised this evaluation's quality, or contributed to its incompleteness is also a fair question to ask.¹ Please read **Box A**. (Note: Several models of "traditional" AERs are marketed in the U.S. The author of this article on endoscope damage is employed by the manufacturer of one that, like the Reliance EPS, is labeled to wash and disinfect GI endoscopes.)

A MANUFACTURER'S CLAIM? Also discussed in this newsletter's November-December, 2008, issue, ECRI's evaluation of the Reliance EPS does not, at times, clearly distinguish a manufacturer's promotional (and unsubstantiated) claims from evidence-based conclusions—another of this evaluation's more significant oversights.^{1,2} For example, ECRI's evaluation concludes that the Reliance EPS "eliminates" personnel exposure to peracetic acid and its fumes, and that this AER "disinfects (the GI endoscope's) suction valves."^{1,2}

But, ECRI's evaluation did not perform the necessary air-sampling and microbiologic tests, respectively, to render these two conclusions—suggesting that each is a manufacturer's claim, not an evidence-based conclusion. Nevertheless, no example might be more evident of the failure to distinguish clearly a manufacturer's claim from an evidence-based conclusion than this evaluation's discussion of materials' incompatibility and the cause of endoscope damage associated with the Steris System 1. (The forthcoming March-April, 2009, issue of this newsletter provides a box article that discusses in more detail the importance of distinguishing between a manufacturer's claim and an evidence-based finding.)

ENDOSCOPE DAMAGE: Although ECRI's evaluation of the Reliance EPS does not rate the performance of the Steris System 1 (both models are marketed by Steris and flush the

Box A: Potential conflicts of interest in the field of infection control.

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Focusing on potential conflicts of interest in the fields of infection control and endoscope reprocessing, the September-October (2008) and November-December (2008) issues of this newsletter recommend that organizations that publish infection-control guidelines (or, the contracted authors) disclose in the text of their guidelines the details of any working relationships and associations they may have with manufacturers of infection-control products. Adoption of this policy by non-profit institutes that publish evaluations of the performance and safety of infection-control products is also recommended.

Because such interactions with manufacturers can pose potential conflicts of interest, the rigorous and transparent management of these interactions—including their full disclosure (the importance of which is often under-appreciated)—is recommended to mitigate the potential adverse impact these interactions may have on objectivity and public health. Studies suggest that associations (and working relationships) with manufacturers that include, for example, accepting from manufacturers gifts or free samples of products to evaluate their performance can introduce bias and result in the overstatement of the products' benefits.¹

This newsletter's November-December, 2008, issue discusses working relationships with manufacturers and the potential effect of these interactions on the quality of an evaluation of an automated endoscope reprocessor (AER).¹ Similarly, the January-February, 2004, and May-June, 2006, issues of this newsletter discuss whether working relationships with manufacturers of infection-control products may have contributed to the authorship of infection-control guidelines whose recommendations are inconsistent and countenance medical practices that pose an *increased* risk of healthcare-acquired infections—for example, guidelines that recommend that bronchoscopes be used immediately after reprocessing while still wet with rinse water, without first being dried. Few "recommended" clinical practices would be as dubious.^{17,18} A greater commitment to the advancement of evidence-based recommendations is encouraged. ●

flexible endoscope's internal channels under pressure with peracetic acid at an elevated temperature, although the System 1 claims to achieve "sterilization"), this evaluation nevertheless acknowledges the System 1's association with endoscope damage.² Because the Reliance EPS uses peracetic acid at the same concentration and elevated immersion temperature as the System 1 (the immersion times of the two processes are slightly different),³ ECRI's evaluation concedes that the Reliance EPS, too, may be associated with endoscope damage.²

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As if to clarify an ongoing misunderstanding about peracetic acid, ECRI's evaluation recites—without a rebuttal or a debate of its scientific merit—a manufacturer's controversial three-part claim to explain the Steris System 1's association with endoscope damage.² Provided in **Box B**, this manufacturer claims that peracetic acid uncovers "prior (endoscope) defects that had resulted from wear and tear and/or improper care and handling" by staff.² This manufacturer adds in ECRI's evaluation that these defects and endoscope leaks had been "masked" by aldehyde-based disinfectants, such as 2% glutaraldehyde and 0.55% *ortho*-phthalaldehyde (e.g., Metri-cide and Cidex OPA, respectively), and that the damage associated with the System 1 "may be the result of the peracetic acid removing protein residue" that was not removed by these aldehyde-based disinfectants (**Box B**) used previously to reprocess these endoscopes.²⁻⁴

Does peracetic acid cause endoscope damage?

- ◆ **BACKGROUND:** An evaluation of the Steris Reliance EPS features a manufacturer's claim that peracetic acid is not the cause of endoscope damage associated with the Steris System 1.
- ◆ **AIM:** The medical literature was reviewed to evaluate whether this claim is evidence-based.
- ◆ **RESULTS:** No independent data substantiating the scientific merit of this claim were identified. On the contrary, independent studies report the System 1's peracetic acid to be the cause of endoscope damage.
- ◆ **CONCLUSION:** The scientific merit of this manufacturer's claim detailed in **Box B** is questioned. Among other recommendations, evaluations of medical devices are encouraged to distinguish more clearly between a manufacturer's claim and an evidence-based conclusion.

Noteworthy, however, ECRI's evaluation of the Reliance EPS does not present any corroborating data or cite any independent studies to substantiate this three-part claim—which is advanced in this evaluation and also in some of this manufacturer's advertisements.²⁻⁴ Nor does this evaluation provide any other plausible or alternative account (save this manufacturer's) to explain the cause of endoscope damage associated with the System 1. That peracetic acid *itself* might be responsible is remissly ignored in this evaluation. Whether this manufacturer's claim is scientifically sound or lacks merit warrants examination. (*Note:* The sale of the Steris System 1, which the FDA declared in May 2008 has been "adulterated and misbranded" since 1988, was discontinued in January 2009.^{5,6} The discontinuation of this product will be discussed in a future issue of this newsletter.)

AIM AND METHODOLOGY: The medical literature, published infection-control guidelines, and the operator's manuals of a few flexible and rigid endoscopes were reviewed to investi-

gate the scientific merit of this manufacturer's claim that, not peracetic acid, but rather wear, tear, and/or improper care and mishandling of endoscopes by staff, "masked" by aldehyde-based disinfectants used previously during reprocessing, are the causes of the endoscope damage associated with the Steris System 1 (and, possibly, with the Reliance EPS).

RESULTS: No independent studies were identified during this review that scientifically substantiate this manufacturer's account and demonstrate that peracetic acid is not the cause of endoscope damage associated with the Steris System 1. Nor did this review identify any independent reports that suggest endoscopes reprocessed using an aldehyde-based disinfectant, whether or not subsequently reprocessed using peracetic acid, are more prone to damage and leaks than the same models of endoscopes (e.g., identically worn, aged, cared for and handled) reprocessed exclusively using the System 1.

On the contrary, this review identified two independent, peer-reviewed studies that identify the Steris System 1 as the cause of endoscope damage,^{7,8} this manufacturer's claim advanced in ECRI's evaluation notwithstanding. These two studies used methodologies that ruled out either aldehyde-based disinfectants or routine wear, tear, and/or improper care and mishandling of endoscopes as possible causes of endoscope damage. The first of these two studies published in 1997 was not discussed or cited in ECRI's evaluation,⁷ and no erratum published by ECRI discussing either of these studies was identified during this review. Two other articles suggest that peracetic acid may "unplug" small "pin holes" inside the endoscope that become filled with patient debris not removed

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Box B. A manufacturer's three-part claim to explain endoscope damage that ECRI's evaluation acknowledges is associated with the Steris System 1.

- ◆ Prior defects had resulted from wear and tear and/or improper care and handling" by staff members.²
- ◆ Aldehyde-based disinfectants (e.g., glutaraldehyde, *ortho*-phthalaldehyde) used to reprocess endoscopes had masked these prior defects and leaks.²
- ◆ Endoscope damage associated with the System 1 may be the result of the peracetic acid "unplugging" small "pin holes" filled with protein residue that may not have been removed during previous reprocessing using aldehyde-based disinfectants.*²⁻⁴

* This evaluation does not discuss the possibility that peracetic acid itself may be a cause of endoscope damage associated with the System 1. This possibility is supported by published studies that report peracetic acid to be the cause of endoscope damage. Further, guidelines discuss the Steris System 1's "potential material incompatibility."¹⁰⁻¹² ◆

during previous reprocessing using aldehyde-based disinfectants (see **Box B**).²⁻⁴ These articles suggest that, by removing this “protein residue,” the Steris System 1’s peracetic acid uncovers (but is not the cause of) endoscope damage.²⁻⁴ Neither of these articles was peer-reviewed, however, and, providing claims similar to those in ECRI’s evaluation, both were sponsored and authored by Steris.^{3,4,9}

Further, this review identified published guidelines stating that 2% glutaraldehyde and *ortho*-phthalaldehyde display “excellent material compatibility” but that the System 1’s peracetic acid is associated with “potential material incompatibility.”¹⁰⁻¹² One manufacturer (Olympus) has raised concerns about the potential for the Steris System 1 to cause “chemically induced damage” to its GI endoscopes.¹³ Another manufacturer (Pentax) lists the System 1’s peracetic acid as an agent that is “compatible” with its GI endoscopes,¹⁴ but this same manufacturer contraindicates the use of the Reliance EPS for reprocessing any of its endoscopes.² A manufacturer of rigid and flexible endoscopes (Karl Storz) states that the System 1 can be used to reprocess its endoscopes.^{15,16}

No independent data were identified during this review that substantiate the validity of the claim that, not peracetic acid, but masked defects, improper care or mishandling by staff, plugged holes, or aldehyde-based disinfectants are the causes of endoscope damage associated with the System 1.²

DISCUSSION: The scientific soundness of this manufacturer’s three-part claim, which is provided in **Box B** and which ECRI advances in its evaluation of the Reliance EPS, to explain the cause of endoscope damage associated with the Steris System 1 is questioned. Similarly questioned is the balance, validity, and completeness of ECRI’s evaluation of the Reliance EPS, primarily for having failed to have: performed any safety, effectiveness, or materials’ compatibility tests; included and tested any of the disfavored “traditional” AER models; and distinguished more clearly between a manufacturer’s claim and an evidence-based result. (Please review this newsletter’s November-December, 2008, issue.)

In general, a study’s inclusion and discussion of a manufacturer’s controversial claim, without providing an accompanying rebuttal or questioning the claim’s merit for perspective and soundness, might be justifiable, provided that certain criteria are met—for example, that independent studies have verified the claim’s plausibility, if not merit; or, certainly, that no independent studies refuting this claim’s soundness have been published. Otherwise, the inclusion, if advancement, of this manufacturer’s claim might cause the study to appear partial, incomplete, or concessionary.¹

➔ The **REFERENCES** for this article is available at:

www.myendosite.com/htmlsite/2009/refs010209.pdf

But such criteria most certainly were not met, and ECRI’s evaluation of the Reliance EPS did not provide or cite any independent data to substantiate the scientific merit of this manufacturer’s three-part claim.² To the contrary, scientific studies report that the Steris System 1’s peracetic acid—not protein residue, masked defects, or aldehyde-based disinfectants—caused damage to endoscopes, some of which were brand new.^{7,8} (Refer to the discussion in this newsletter’s March-April, 2009, issue.)

That ECRI’s evaluation acquiesces, presumes its *a priori* legitimacy and soundness, and neither debates, rebuts, nor questions the validity of this manufacturer’s claim is difficult to understand. Perhaps even more perplexing is ECRI’s failure to provide, as required for balance, an alternative explanation—namely, to raise for discussion the possibility that peracetic acid *itself* might be (at least in part) responsible for the System 1’s noted association with endoscope damage.²

Indeed, ECRI’s evaluation of the Reliance EPS attributes this expressed three-part claim of the cause of endoscope damage to the manufacturer (*see: Box B*). But, its evaluation’s concurrent failure to investigate and probe this claim’s validity; to note that this manufacturer’s claim has not been independently substantiated; and—most important—to cite and discuss scientific studies that contrarily report peracetic acid to be the cause of the endoscope damage associated with the System 1^{7,8} causes, at best, unnecessary confusion. Blurring the line that distinguishes a manufacturer’s claim from an evidence-based finding, these oversights raise important questions about the objectivity of ECRI’s evaluation and of its discussion of the causes of endoscope damage. ● By: LFM

This discussion is continued in the next issue.

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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The Q-Net™ Monthly

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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

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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.*

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?

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)’s⁴ 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 Mus-

carella (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 EPS²) that endoscope damage attributed to the System 1 (and, possibly, the Reliance EPS²) 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 repro-

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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° 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.

Box D. Endoscope manufacturers and endoscope damage:

Karl Storz Endoscopy (“Storz”)—which manufactured the two endoscopes used in Abraham et al. (2007)’s study⁵ (**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} ○

(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.

► 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.*
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