

# The Q-Net™ Monthly

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## What's News

This newsletter presents a *special triple issue*, providing a convenient, if necessary, format to discuss a difficult, though requisite, topic that applies to infection control, risk management, operating-room technique, and the reprocessing of surgical instruments, including rigid and flexible endoscopes: the discontinued marketing of the **STERIS System 1**. Note that two of this article's pages, p. 18S<sub>1</sub> and p. 18S<sub>2</sub>, are only available in this *on-line* version.

## Editor-in-Chief

This article was written by this newsletter's editor-in-chief, **Lawrence F. Muscarella, Ph.D.**

## What is 'Q-Net'?

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

The main goal of **Q-Net** is to encourage the infection control, endoscopy, and operating room communities to improve patient care by not only asking good questions but also by demanding well referenced, evidence-based answers.

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

## The STERIS System 1

### Lessons taught by its discontinued marketing

*This article discusses the discontinued marketing of the **STERIS System 1**. Although the FDA declared it to be "adulterated" and "misbranded," this automated processor and its peracetic acid sterilant, according to its manufacturer, will continue to be sold in the U.S. for at least two more years (albeit with some qualifications).*

○

**INTRODUCTION:** Few violations of infection-control standards have received more scrutiny than recent reports of reprocessing breaches at three medical centers within the Veterans Health Administration (VHA).<sup>1-5</sup> Located in Murfreesboro (TN), Miami (FL) and Augusta (GA), these three VA medical centers this past winter did not properly clean, disinfect, or use reusable endoscopic instrumentation, potentially exposing more than 10,000 U.S. veterans to HIV, the hepatitis C virus and other infectious agents.<sup>1-5</sup> (Refer to this newsletter's Apr-May-Jun 2010, issue for a discussion of these breaches.).

As the incidents at these three medical centers and others demonstrate, the improper reprocessing of reusable instrumentation can be associated with adverse outcomes. The **STERIS System 1** Sterile Processing System ("System 1")—an automated reprocessing device that was

introduced to the U.S. market in 1988—is labeled both to achieve "liquid chemical sterilization" using peracetic acid and to produce "sterile" rinse water using a 0.2 micron bacterial filter.<sup>6-11</sup> Save the System 1, no other device has been labeled with either of these two claims.<sup>12</sup> Please review **Table 1**, "**A Timeline of Events**," on p. 18S<sub>1</sub> of this newsletter.

The System 1 is labeled to "sterilize" not only flexible endoscopes and other reusable endoscopic instrumentation, but also laparoscopes and arthroscopes;

(Continued on page 14)

## TABLE OF CONTENTS

1. Introduction .....	13
2. FDA warning letter .....	14
3. FD&C Act .....	14
4. A mislabeled device? .....	14
5. Steris's letter .....	14
6. Discussion .....	15
7. Mission statements.....	16
8. My perspectives .....	17
9. Conclusions .....	18
10. References .....	18
11. Box: Summary .....	14
12. Box: "Updated" SS1? ...	15
13. Box: What is a 510(k)?...	18S <sub>1</sub>
14. Box: Investigational?.....	18S <sub>2</sub>
15. Table 1 .....	18S <sub>1</sub>
16. Table 2 .....	16
17. Table 3 .....	18S <sub>2</sub>

microsurgical, ophthalmic, and dental instruments; and biopsy forceps, among other types of surgical instruments.<sup>6-11</sup>

**FDA WARNING LETTER:** The Food and Drug Administration (FDA) published a warning letter, dated May, 15, 2008, asserting that the System 1 is “adulterated” and “misbranded.”<sup>13</sup> With potentially significant infection-control implications, this warning letter’s conclusions were the apparent culmination of a federal investigation that began circa 2004 to evaluate the safety, effectiveness, and labeling of the System 1.<sup>14</sup> (Please review Table 1 on p. 18S<sub>1</sub>.) The FDA asserts in this letter that during the past 20 years both the System 1 and its accompanying sterilant – a single-use, peracetic acid-based concentrate known as the “Steris 20” – have undergone several “significant changes or modifications” that could “significantly affect (their) safety or effectiveness.”<sup>13</sup>

In short, the FDA’s warning letter asserts that the System 1 and Steris 20 sterilant are without a clearance or approval as required to be legally marketed,<sup>13</sup> adding that the agency was not notified of the System 1’s significant changes as required by the Federal Food Drug and Cosmetic Act (“FD&C Act”)<sup>15-17</sup>—changes that include, for example, altering the Steris 20’s formulation.<sup>13</sup> These changes—each of which the FDA’s warning letter itemizes and states was unapproved and “itself would necessitate submission” of a new application for clearance or approval—raise doubts, according to the FDA, about, not only the Steris 20’s chemical “stability,” but also the System 1’s safety and “ability to sterilize” surgical instruments and flexible endoscopes.<sup>13</sup>

**THE FOOD DRUG AND COSMETIC ACT (“FD&C ACT”):** The Medical Device Amendments to the FD&C Act (in 1976) prohibit the introduction into *interstate commerce*<sup>†</sup> of a significantly modified device whose changes did not receive from the FDA a “510(k) clearance” or a “premarket approval” (PMA).<sup>15-17</sup> For more details about 510(k) clearances, PMAs, and the introduction into interstate commerce of a new or significantly modified *class II* or *class III* device, please refer to the two box articles: “What is a 510(k) clearance, PMA?” on p. 18S<sub>1</sub>; and “What is an investigational device?” on p. 18S<sub>2</sub> (both pages of which are available only in this *on-line* version of this article).

**A MISLABELED DEVICE?** The implications of the FDA’s warning letter are salient and complement conclusions the FDA previously published in another letter it wrote seven years earlier (2001) suggesting that the System 1 may be

mislabeled.<sup>18</sup> Specifically, this letter states that the “association of the Steris System 1 processor with patient infections usually caused by waterborne organisms leads (the FDA) to question the ability of the processor to provide a sterile water rinse,” adding that the FDA “believe(s) that the processor may not be functioning as it is labeled” (i.e., is mislabeled).<sup>14,18-20</sup> (Refer to: this newsletter’s April, 2008, issue.)

**STERIS’S LETTER TO ITS CUSTOMERS:** Steris responded to the FDA’s warning letter in a letter it wrote to its customers, dated January 20, 2009 (see: Table 1, p. 18S<sub>1</sub>).<sup>21</sup> Aiming to market another “sterilizing” device, Steris states in this letter that two weeks earlier (in early January) it applied for a new 510(k) clearance to market this modified model of the System 1—known as the System “1E.”<sup>21,22</sup> According to Steris, it seeks to market this updated device to achieve “liquid chemical sterilization” and to produce “sterile” filtered rinse water

(Continued on page 15)

**Box: Summary of both the FDA’s warning letter and, in reply, Steris’s “Dear Customer” letter.**

1. The FDA’s warning letter concludes that the **STERIS System 1** (and Steris 20 sterilant) is:
  - “adulterated,” “misbranded,” and significantly different from the model originally submitted to and reviewed by the FDA in 1988;<sup>13</sup>
  - an “altered” device whose safety and effectiveness cannot be assured;<sup>13</sup>
  - a device that is not legally marketed;<sup>13</sup> and
  - an unapproved device without a 510(k) clearance (or premarket approval), having not been shown to be “substantially equivalent” to a legally marketed predicate device (see: box article on p. 18S<sub>1</sub>).<sup>13</sup>
  - The FDA’s letter **questions** the System 1’s **safety, effectiveness, and “ability to sterilize”** instruments.<sup>13</sup>
2. In its “Dear Customer” letter, written in reply to the FDA’s warning letter, Steris states that it:
  - **discontinued** the marketing of the System 1;<sup>21</sup> but
  - will nevertheless **continue to sell** for at least two more years in the U.S. the **System 1**, although only as replacements for existing units. Steris will also continue to sell the **Steris 20** sterilant;<sup>21,22</sup> and
  - applied for a 510(k) clearance to market this **modified** and unapproved **System 1** that was the subject of the FDA’s warning letter (see: box article on p. 15).<sup>21,22</sup>
  - According to Steris, medical centers can continue using the System 1 and Steris 20 “**without any change**” in clinical practice.<sup>21,22</sup> •

<sup>†</sup> *Interstate commerce* refers to the manufacture, packaging, shipment and commercial distribution (e.g., marketing, selling, and buying) of a product, including a medical device, within and across the States’ borders. This term originates from the Commerce Clause of the U.S. Constitution (see: the U.S. Constitution’s Article 1, Section 8, Clause 3).<sup>15-17</sup>

from a tap.<sup>21,22</sup> Refer to the adjacent box article: “*Might the FDA clear an ‘updated’ System 1?*”

Steris further states in this letter that it is “discontinuing” sales in the U.S. of the modified (and unapproved) System 1.<sup>21</sup> But the details of this action are qualified, if not unique. As it describes in this letter and a contemporaneously published press release, Steris will continue to sell in the U.S. the modified (and unapproved) System 1 for at least two more years (albeit only as a “product replacement”—that is, to replace a previously purchased System 1 processor).<sup>21,22</sup>

**DISCUSSION:** A study of the System 1’s history, regulatory oversight, and marketing teaches a litany of insightful, if not fascinating and far-reaching, lessons about medical devices and infection control. Indeed, articles focusing on risk management and current instrument-reprocessing practices would be arguably incomplete if they were not to discuss the System 1’s recent censure and continued use by, among others, VA medical centers—withstanding the FDA having concluded that the System 1 is adulterated, misbranded, and without regulatory approval<sup>13</sup> (considerations that would ordinarily result in termination of a device’s use).

Providing a rare glimpse into the marketing and use of infection-control devices, a study of the System 1 also yields insight into the mutual quest by manufacturers and healthcare practitioners for the ideal, rapid-acting processor to “sterilize” heat-sensitive surgical instruments; the complex financial and “working” relationships between manufacturers and healthcare organizations and institutes;<sup>23,24</sup> and the acquiescence through the years by healthcare organizations of the System 1’s seemingly implausible<sup>14,25-28</sup> “guarantee”<sup>†,14,26,29</sup> both to achieve “liquid chemical sterilization”<sup>6-11</sup> and to produce “sterile” filtered rinse water from a tap.<sup>6,8,9,14</sup>

Adding to the System 1’s mystique and alluring singularity, these two labeling claims have proved to be otherwise elusive. Listed in Table 2 (p. 16) are several of the articles published in this newsletter and authored by its editor (Muscarella) that call into question the validity of the System 1’s two “sterilization” labeling claims.

**A. The Food Drug and Cosmetic Act (“FD&C Act”):** Legitimate questions may arise within the healthcare community about the System 1 and the soundness of its continued use (and sale, whether or not as a replacement). These questions follow both from the FDA’s warning letter, which concludes that the System 1 (and Steris 20) has been adulterated and misbranded since 1988,<sup>13,21</sup> and from a basic understanding of the FD&C Act, which prohibits the manufacture; commercial distribution; receipt; and introduction into interstate commerce of an adulterated and misbranded device.<sup>16,17</sup> The

### Box: Might the FDA clear an “updated” System 1?

In January, 2009, Steris submitted to the FDA a modified, if updated, model of the System 1 labeled both to achieve “liquid sterilization” and to produce “sterile” filtered water from a tap.<sup>21,22</sup> (The manufacturer also likely submitted an application to the FDA to market an accompanying biological indicator, or BI, as required to monitor the peracetic acid’s effectiveness, as well as presumably having submitted an application to market a different type of BI for monitoring and verifying the “sterility” of the rinse water.)

A fair question to ask is whether the FDA might issue a 510(k) clearance to Steris for this updated System 1 model. Although conjecture, the answer to the question would appear to be in the *may*, not only because the inherent limitations of liquid sterilants and bacterial water filters invalidate such a claim of “liquid chemical sterilization,” but also because no legally-marketed predicate device—with a similar or comparable labeling claim of “liquid sterilization” and demonstrated to be substantially equivalent to the updated model—is available. Whether the censured System 1 (which is not legally marketed<sup>13</sup>) would be used, if problematically, as a *de facto* “predicate” device for the 510(k) clearance of this updated System 1 is unclear.

Steris might consider for this updated System 1 three claims that are scientifically sound and, therefore, likely to be more palatable to the FDA. **First**, this device would be labeled as “sporicidal,” as opposed to claiming to achieve “liquid sterilization”—an important difference with a regulatory distinction. **Second**, this device would claim to rinse the endoscope with “bacteria-free” (not “sterile”) water. And, **third**, this device would be labeled to require terminal drying of the endoscope’s internal channels (using 70% isopropyl alcohol) after the completion of *each* cycle.

Because it appears that no legally marketed predicate device labeled to achieve “liquid sterilization” is available, it is also possible that the FDA might require this updated System 1 to receive a premarket approval (PMA) instead of a 510(k) clearance, the former of which is a considerably more formidable, time-consuming, and expensive application. Yet, the System 1 was cleared in 1988 for “liquid sterilization” and the production of “sterile” water. So, that the updated System 1 might, too, be cleared with these two lock-and-key claims remains a possibility. ●

FD&C Act also requires a manufacturer to report to the FDA whenever it has significantly modified a device already being shipped and commercially distributed within the U.S.<sup>16</sup>

Indeed, some provisions of the FD&C Act also oversee a device’s clinical use. A significantly modified *class II* or *class III* device without a 510(k) clearance or PMA (but that would otherwise require either) may be referred to as “investigational,” requiring for its use the approval of an *investigational device exemption* or IDE.<sup>13,17</sup> According to the FDA, in addition to being *misbranded* for having been

(Continued on page 16)

† “Sterility” cannot be “guaranteed”<sup>26</sup> but is defined as a probability for contamination—namely as a “sterility assurance level,” or SAL, of, for example, 10<sup>-6</sup>.<sup>73</sup>



introduced into commercial distribution without a 510(k) clearance, the System 1 and Steris 20 are also *adulterated* for lacking a PMA or an approved IDE.<sup>13</sup> Among other provisions, investigational devices (i.e., “unapproved devices”<sup>17</sup>) notably require informed patient consent. *Refer to:* the box article: “What is an ‘investigational’ device?” on p. 18S<sub>2</sub>.

Nevertheless, Steris claims that, in addition to selling in the U.S. both the System 1 and Steris 20 for at least two more years (albeit conditionally), medical centers including those within the VHA can continue using the System 1 and Steris 20, “without any change” in clinical practice (and without notifying the patient).<sup>21,22</sup> In the context of the FD&C Act’s provisions regarding investigational devices—which, like the System 1, are without a 510(k) clearance or PMA (and are not otherwise exempted)<sup>13,15,17</sup>—this instruction is understandably confusing, if not also controversial.

**B. Mission statements:** The mission statements of healthcare organizations in the fields of infection control, aseptic technique, and instrument reprocessing typically pledge a commitment to advancing public health, prioritizing patient safety, and preventing healthcare-associated infections. As a public display of their avowed responsibilities, these organizations, in addition to publishing guidelines, may periodically issue position statements, sentinel event alerts, or advisories, providing an important and worthy system of “checks and balances” that serves to monitor the safety and effectiveness of medical devices used by their respective membership.<sup>30-34</sup>

A review of the literature finds that these organizations have not published a general position statement, alert or advisory discussing the clinical use of adulterated and misbranded

devices. Further, despite its use having been common in the U.S.,<sup>14</sup> none of these organizations have provided written guidance for their respective membership discussing the System 1’s recent censure by the FDA or the potentially significant medical implications associated with this (or any unapproved) device’s use.<sup>†</sup> Their laudable missions notwithstanding, nor have any of these organizations discussed whether the continued use of the System 1 (or, again, of any adulterated or misbranded device) requires informed patient consent.

Learning that the VHA, for example, has not provided important guidance to VA medical centers about the FDA’s censure of the System 1 or Steris 20 is surprising, considering that the VHA has been under federal scrutiny, not only for the significant infection-control breaches identified this past winter at three of its medical centers,<sup>1-4</sup> but also because of the disclosure this past June that a significant number of recently inspected VA medical centers lack adequate quality assurance programs, which the VA’s Office of Inspector General acknowledged poses an increased risk of infection.<sup>5</sup>

That the VHA—and the Centers for Disease Control and Prevention (CDC) and Joint Commission (JCAHO) (among others), too—have not published any guidance, alerts or recommendations assessing whether the continued use of the System 1, or of any unapproved device whose safety and effectiveness cannot be assured,<sup>13,17</sup> is sound and permissible or, conversely, may pose medical risks and compromise a medical facility’s accreditation is similarly surprising.

*Patient injuries linked to the use of an adulterated and misbranded medical device may prove to be problematic for a healthcare facility.*

To be sure, position statements have been issued by healthcare organizations discussing the safety and effectiveness of medical devices and practices. Fulfilling a crucial role, several have published guidance, for example, evaluating the safety of reprocessing and reusing single-use devices.<sup>35-39</sup> Some organizations have also published evidence-based alerts addressing concerns about the safety, effectiveness, or labeling of infusion pumps and of another automated reprocessor.<sup>40-43</sup> These organizations having, to date, not similarly published guidance about the continued use of adulterated and misbranded devices—including the System 1, which in 1999 and 2003 was linked to patient morbidity and mortality<sup>14,20,44-46</sup>—not only adds to the confusion surrounding the System 1, but also misses a pivotal opportunity to promote patient safety and highlight the potential risks associated with the improper reprocessing of surgical instruments.

(Continued on page 17)

**Table 2. Several articles that question the safety, effectiveness and labeling of the Steris System 1, in ranking order of interest:<sup>†</sup>**

1. *‘Sterile’ filtered rinse water?* April 2008;14:4.
2. *“Let sleeping dogs lie?”* Sept-Oct 2008;14:9-10.
3. *FDA labeling of liquid sterilants.* November-December 2001;7:11,12.
4. *Limitations of flash sterilization, liquid chemical sterilants.* June 1997;3:6.
5. *To dry or not to dry?* August-September 2003;9:8,9.
6. *Double Standards.* May-June 2006;12:5,6.
7. *Going back to school.* March-April 2003;9:3,4.
8. *Antibiotic-resistant Pseudomonas aeruginosa.* October-November 2002;8:10,11.
9. *Review of a Pseudomonas aeruginosa outbreak.* September 2001;7:9.
10. *Déjà Vu ... all over again?* June 1999;5:6.

<sup>†</sup> Each of these articles was written by L.F. Muscarella, Ph.D.

<sup>†</sup> An exception, the ECRI Institute recommends continued use of the STERIS System 1, without also recommending informed patient consent—despite both the conclusions of the FDA<sup>13</sup> and the FD&C Act’s provisions regarding informed patient consent and the use of such unapproved devices.<sup>17,72,74-76</sup>

Rather, while not addressing the System 1's censure,<sup>13</sup> the guidelines of some healthcare organizations (published as recently as 2009) support this device's "sterilization" claim, deeming the System 1's clinical use safe and appropriate.<sup>14,43,47-52</sup> That the FDA's censure of the System 1 would warrant an erratum or the revision of these guidelines (including the CDC's guideline in 2008 about disinfection and sterilization<sup>48,49</sup>) is debatable, though would seem unavoidable, lest healthcare practitioners misconstrue these guidelines to be condoning, perhaps promoting, the use of an unapproved device whose safety and effectiveness cannot be assured.<sup>13,17</sup>

**C. The Abtox Plazlyte System:** Providing insight and perspective, the FDA in 1998 censured the Abtox Plazlyte Sterilization System ("Plazlyte System"), which, like the System 1, was marketed to "sterilize" heat-sensitive surgical instruments using peracetic acid (as a low-temperature vapor mixed with other chemicals).<sup>53</sup> Cleared by the FDA in 1994 and first discussed in this newsletter more than a decade ago, the Plazlyte System was investigated in 1998 for its association with six patient injuries (no deaths) following ophthalmic surgery.<sup>53</sup> As a consequence, the FDA issued an alert that year expressing concerns about the Plazlyte System's safety.<sup>54</sup>

*A comparison of the Abtox Plazlyte's marketing and labeling claims to those of the Steris System 1's (and Steris 20's) yields salient similarities.*

In addition to both "sterilizing" devices having been linked to patient injury,<sup>14,20,44-46,53,54</sup> the Plazlyte System and System 1 share other features, too, some of which are listed in Table 3 on p. 18S<sub>2</sub>. Like the System 1, the marketed model of the Plazlyte System reportedly was significantly different from the model that the FDA had originally cleared—for example, like the reformulation of the Steris 20,<sup>13</sup> the gas ratio of the sterilant used by the Plazlyte System had been modified without clearance or approval by the FDA.<sup>53-56</sup> Nevertheless, despite their similarities, there are differences, too. Whereas the Plazlyte System was promptly removed from the market on March 31, 1998,<sup>53-56</sup> the System 1, according to its manufacturer, will continue to be sold, along with the Steris 20, for at least two more years (albeit conditionally).<sup>21,22</sup> Notably, the FDA has not, to date, discussed whether the continued use of the System 1 is safe, appropriate, and, as its manufacturer asserts, neither warrants changes in clinical practice nor the notification of doctors or patients.<sup>22</sup>

**D. Surgical instrument manufacturers:** Some manufacturers of reusable surgical instruments discuss the System 1 in their labeling. For example, the operator's manuals and reprocessing instructions provided by some rigid-endoscope manufacturers claim that the STERIS System 1 is compatible with, and has been validated for the "sterilization" of, their endoscopes.<sup>57-61</sup> But, apparently presenting another breakdown in an important system of checks and balances, a review of the

literature finds that the requisite validation and verification data to support these claims about the System 1 are lacking.

Further, as a consequence of the conclusions of the FDA's warning letter<sup>13</sup> (and Steris's reply to it<sup>21,22</sup>), these operator's manuals and other labeling referencing the System 1 would presumably warrant revision. Reprocessing instructions published by a manufacturer (like an infection-control guideline) that condone (if not, at times, recommend) the use of an adulterated and misbranded device to "sterilize" a reusable instrument would seem to be legally problematic and to have arguably misbranded this manufacturer's reusable instrument (under section 502[f][1] of the FD&C Act).

**E. My perspectives:** The 510(k) clearance of which was first queried by Bond in 1993,<sup>28</sup> few researchers have questioned the safety, effectiveness, and labeling claims of the System 1.<sup>14,20,25-27</sup> Published reports,<sup>6-10</sup> guidelines<sup>47-50</sup> and evaluations<sup>14,24,51</sup> (and surgical-instrument operator's manuals<sup>57-61</sup>) discussing the System 1 often overlook its shortcomings—for example, not acknowledging that the validation and verification data in support of the System 1's claim to achieve "sterilization," under worst-case clinical conditions, are lacking. Nor do these publications note that the Steris 20's peracetic acid has not been challenged by the Association of Official Analytical Chemists' (AOAC) *Sporicidal Test*<sup>28</sup>—a standardized test otherwise required by the Environmental Protection Agency (EPA) to evaluate the effectiveness of a sterilizing agent.<sup>62</sup> Instead of questioning the System 1's singular claims, these publications focus on this device's apparent strengths, of which there are some, including its ease-of-use; relatively rapid-acting cycle; containment and use of a single-use disinfectant; portability; and its relatively small footprint.<sup>6-10</sup>

During the past fifteen years, Muscarella has authored several articles published in medical journals that discuss the inherent limitations of liquid sterilants.<sup>20,25,63-65</sup> In several articles published in this newsletter, too—refer to Table 2, p. 16, for a listing of some of these articles, one of which was published as recently as April, 2008—Muscarella discusses that, while some liquid chemical sterilants, such as peracetic acid, may under certain conditions be *sporicidal* (see: box article, p. 15), their limitations—including that their potentially toxic residues be removed from the instrument's surfaces following chemical immersion using large volumes of rinse water, the microbial quality of which is not routinely monitored microbiologically and, therefore, rarely known—preclude claiming that any processor can reliably and consistently achieve *liquid sterilization*, particularly of instruments, such as flexible endoscopes, that may feature inaccessible surfaces.<sup>25-27,65-69</sup>

Further, in agreement with Daschner,<sup>26</sup> Muscarella has also written not only that the "guarantee" that a process achieves "sterilization" is dubious, but also that the limitations of 0.2 (and 0.1) micron bacterial water filters, used by virtually every automated endoscope processor to improve the quality of its rinse water, prevent these filters from reliably

(Continued on page 18)

producing, from a facility's tap, "sterile" water (or any quality of water that exceeds that which is produced by reverse osmosis)—a shortcoming of bacterial filters that is an Achilles' heel and belies any liquid-based processor's claim to achieve "sterilization" of surgical instruments.<sup>19,20,25,52,63,65,68,70</sup>

In short, Muscarella has questioned on the front page of *The Wall Street Journal*<sup>14</sup> and another national daily newspaper<sup>67</sup> the soundness and appropriateness of labeling any automated liquid-based processor: to achieve *liquid sterilization*; to produce *sterile* filtered rinse water; and not to require terminal drying of the endoscopes, an otherwise requisite reprocessing step crucial to patient safety.<sup>14,20,52</sup> Daschner, too, has challenged the System 1's "sterilization" claim, referring to the System 1 instead as a device that "disinfects."<sup>26,27</sup> Like Bond, Muscarella has also questioned the scientific basis for labeling a biological indicator to monitor the effectiveness of this or any other liquid-based "sterilization" process.<sup>14,28,66</sup>

Though some have maintained the validity of the System 1's claims,<sup>6-11,14,29,47-51,57,71,72</sup> the conclusions of the FDA's warning letter, along with the manufacturer's discontinuation of the System 1 and Steris 20 (albeit with some qualifications), is consistent with and reaffirms the merit of several of the concerns about the System 1's safety and labeling that Muscarella, Bond and Daschner have published for years.

*That the System 1 was recently declared by the FDA to be adulterated and misbranded since 1988 is consistent with and reaffirms the concerns that Muscarella, Bond and Daschner have published about the safety and labeling of the System 1.*

**CONCLUSIONS:** An infection-control device whose use has been common in the U.S.,<sup>14,48</sup> this is the first article to discuss the censure and discontinuation of the System 1 as they may apply to the FD&C Act. Indeed, a review of this Act's relevant provisions—along with the FDA's warning letter; both the medical and legal literature; and articles discussing the marketing, design changes, and recall of the Abtox Plazlyte System—provides important insight and perspective, suggesting that the approbation or endorsement of the use of any adulterated and misbranded device would appear to be injudicious and incongruous with patient safety.

Several questions remain unanswered, such as whether the use of an adulterated or misbranded device would adversely affect a medical facility's accreditation, or whether in past years the use of another adulterated or misbranded device had been sanctioned or approved. While patient injuries linked to the use of an unapproved device (without an IDE) would seemingly be prejudicial, less clear is whether it is necessary to notify patients whose injuries were linked to a device subsequently determined by the FDA to have been adulterated and misbranded at the time of the injuries.<sup>44-46</sup>

To be sure, several lessons about infection control and instrument reprocessing are taught by this study of the System 1 and Steris 20, underscoring the importance to patient safety:

- of **healthcare staff members** having a basic understanding of, *first*, the inherent limitations of liquid sterilants and 0.2 micron bacterial water filters; and, *second*, the regulation of medical devices; along with, *third*, consideration of all of the potential implications, if not risks, associated with using an adulterated, misbranded, or otherwise unapproved device;
- of **manufacturers** being circumspect and not incautiously claiming in their operator's manuals that a specific device "sterilizes" their surgical instruments, unless these manufacturers have in their quality-assurance records validation and verification data substantiating the claim; and
- of **healthcare organizations** enhancing their commitment: to patient safety; to their respective mission statement's pledges; to the issuance of timely safety alerts; and to writing guidelines that are evidence-based and revised as warranted.

Also taught by this study's lessons is the importance of the both FDA and the FD&C Act to public health. Indeed, this study of the STERIS System 1 teaches many lessons about infection control, instrument reprocessing, and patient safety. No time is better than now to learn them. ● **The End.** (Recommendations will be provided in the next issue of this newsletter. This article was written by: *Lawrence F. Muscarella Ph.D.*)

- The **REFERENCES** to this article are available at:  
[www.myendosite.com/htmlsite/2009/refs78909.pdf](http://www.myendosite.com/htmlsite/2009/refs78909.pdf)

- **NOTE:** Pages **18S<sub>1</sub>** and **18S<sub>2</sub>**—which include two important **BOX ARTICLES** and **TABLES 1 AND 3**—were not included in the mailed version of this newsletter, but are attached and available only in this **on-line** version.

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.*  
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1988	System 1 (and Steris 20) is granted a 510(k) clearance by the FDA (reference: K875280). <sup>9</sup>
1988	The FDA retrospectively determined the System 1 to have been adulterated and misbranded. <sup>13,21</sup>
1992-1994	Muscarella calls into question the safety, efficacy of the System 1. <sup>14</sup>
1993	Bond questions the validity of the System 1's claims, effectiveness. <sup>28</sup>
1994	Daschner authors an article questioning the labeling of the System 1. <sup>27</sup>
April 1998	Muscarella publishes an article questioning the capability of liquid sterilants to "sterilize." <sup>65</sup>
October 1998	Daschner authors a second article questioning the labeling of the System 1. <sup>26</sup>
1999	A hospital in New York City links patient morbidity and mortality to the System 1. <sup>44</sup>
1999	A FDA-CDC Public Health Advisory is issued linking the System 1 to patient morbidity, mortality. <sup>45</sup>
February 2000	Muscarella questions the effectiveness of the System 1 in the <i>Investors Business Daily</i> . <sup>67</sup>
October 2000	Muscarella authors an article questioning safety of System 1. <sup>63</sup>
April 2001	The FDA calls into doubt the "sterility" of the System 1's filtered rinse water. <sup>18</sup>
January 2002	Olympus calls into doubt the compatibility of its endoscopes with the System 1. <sup>77</sup>
July 2002	Muscarella authors another article questioning the safety of System 1. <sup>20</sup>
2003, 2004	A hospital in Pittsburgh (PA) links patient injuries, death to the System 1's "defective" water filters. <sup>46,78</sup>
2003	An ex-employee of Steris asserts that the System 1 "poses a public health risk." <sup>14,78</sup>
Circa 2004	The potential for the System 1 to have been "adulterated" <sup>78</sup> is investigated by the federal government. <sup>14</sup>
December 2004	Muscarella's research questioning the safety of the System 1 is discussed in the <i>Wall Street Journal</i> . <sup>14</sup>
May 2008	The FDA issues a warning letter concluding that the System 1 is adulterated and misbranded. <sup>13</sup>
January 2009	Steris "discontinues" marketing of the System 1, Steris 20 sterilant. <sup>21,22</sup>
January 2009	Steris submits an "updated" System 1 "liquid sterilizing" device to the FDA seeking clearance. <sup>21,22</sup>

**Table 1. Timeline of Events.** A timeline of significant events associated with the *STERIS System 1*.

### Box. What is a 510(k) clearance, PMA?

A *510(k) clearance* – named for the provisions detailed in *section 510, item k* of the Medical Device Amendments (1976) to the *Federal Food, Drug, and Cosmetic Act*<sup>45,79</sup> – is an order issued by the FDA, in the form of a letter, granting a manufacturer the clearance, or legal right, to market (and introduce into interstate commerce for commercial distribution) many types of medical devices.<sup>80</sup> Among other satisfied criteria, devices that receive a 510(k) clearance have been determined by the FDA to be *substantially equivalent* to a legally marketed device known as the *predicate*.

In contrast, a *premarket approval*, or PMA, is a more rigorous regulatory clearance granted by the FDA to a manufacturer whose medical device has been demonstrated, using clinical data, to be safe and effective (as opposed to being merely substantially equivalent to a predicate device).<sup>80,81</sup> Whereas most *class II* devices enter the market by way of a 510(K) clearance, *class III* devices generally require a PMA.<sup>79-81</sup>

Briefly, medical devices are classified by the FDA into one of three *classes*, based on risk and the level of regulatory controls necessary to ensure their safety and effectiveness.<sup>80</sup> *Class I* medical devices, for example, pose the lowest risk of patient injury, and therefore typically receive minimal regulatory control and oversight. These devices generally require neither a 510(k) clearance nor a PMA prior to their marketing.<sup>80</sup> A tongue depressor is an example of a *class I* device.

A *class II* device generally requires more regulatory control, and an application for its 510(k) clearance typically includes, not usually data from clinical studies, but rather performance comparisons and bench-testing data. A steam sterilizer and an automated endoscope reprocessor are examples of *class II* devices. That a 510(k) clearance may not always be sufficiently rigorous to ensure patient safety is a topic of current debate.

Generally requiring a PMA and accompanying clinical data, *class III* devices pose the most potential for patient injury and, therefore, receive the FDA's most rigorous control and premarket scrutiny.<sup>80,81</sup> A permanent implant is an example of a *class III* device. ●

### Box. What is an “investigational” device?

On occasion, a legally marketed medical device—such as the Abtox Plazlyte System—may be determined by the FDA to have been modified and to be significantly different from the model the FDA originally cleared by way of the 510(k) process. Examples of such modifications include significant design and engineering changes, a change in the device's intended use, and, for instance, the re-formulation of a liquid sterilant.<sup>13</sup>

Such significant modifications render the device's original 510(k) clearance no longer applicable, causing the device to be *misbranded*.<sup>13,82</sup> Indeed, as the FDA acknowledges,<sup>13</sup> the safety and effectiveness of misbranded devices cannot be assured, ordinarily resulting in their removal from the U.S. market. Notably, the Food Drug and Cosmetic Act (the “FD&C Act”) prohibits such modified devices from being marketed and introduced into interstate commerce—that is, to be sold, shipped, and commercially distributed within the U.S.—until the modified device receives from the FDA a new 510(k) clearance (or a premarket approval, or PMA).<sup>13</sup>

The FD&C Act acknowledges that the discontinued use of a faulty device can at times interfere with patient care. To temper this circumstance, the FD&C Act insightfully provides an “investigational device exemption,” or IDE,<sup>74</sup> that legally permits the clinical use of an otherwise unapproved device.

In short, an IDE allows the manufacturer of an unapproved device—considered “investigational”

because it lacks a requisite 510(k) clearance or PMA<sup>17</sup> (and is not otherwise exempted from either)—to circumvent legally the FD&C Act's prohibition on the introduction of an unapproved device into interstate commerce (refer to this newsletter's main article, p. 14). Indeed, an IDE may be used by manufacturers of unapproved (and not yet legally marketed) devices to acquire, in support of a PMA application (and, infrequently, a 510[k] application), the clinical data necessary to demonstrate that the device is both safe and effective when used in accordance with its labeling.

Nevertheless, because the safety and effectiveness of investigational devices cannot be assured,<sup>17</sup> the FD&C Act requires that several criteria be met and measures be in place to reduce the risk of an adverse patient outcome. Among other stipulations, an approved IDE requires that an “institutional review board” (IRB) be established to oversee and monitor the investigational device's clinical use.<sup>74</sup> In addition, the FD&C Act requires that the device display the labeling: “Caution – investigational device” and that informed patient consent be obtained before its use.<sup>74,75</sup>

In summary, the FDA's warning letter (refer to: this newsletter's main article)<sup>13,21,22</sup>—which concludes that the model of the System 1 that has been sold since 1988 is: significantly modified; an adulterated and misbranded device whose safety and effectiveness cannot be assured; and without regulatory approval or an approved IDE (refer to Table 3, below)—would seemingly suggest that the FDA might consider the System 1 to be an investigational device.<sup>13,17,74,75</sup>

Questions for Comparisons	Plazlyte System	Steris System 1
<i>Is the device labeled to achieve low-temperature “sterilization”?</i>	YES	YES
<i>Does the device use an oxidizing chemical agent (e.g., peracetic acid)?</i>	YES	YES
<i>Was the device intended to replace ethylene oxide (EtO) gas sterilization?</i>	YES	YES
<i>Did the device originally receive a 510(k) clearance (as opposed to a PMA)?</i>	YES	YES
<i>Was the marketed model unapproved and different from the cleared device?</i>	YES	YES
<i>Was the marketed model determined by the FDA to be adulterated or misbranded?</i>	YES <sup>53-56</sup>	YES <sup>13</sup>
<i>Was the device's intended use changed after it received 510(k) clearance?</i>	YES <sup>53-56</sup>	NO
<i>Was the device sold and used after the FDA deemed it to be adulterated?</i>	NO <sup>53-56</sup>	YES <sup>21,22</sup>
<i>Was the device recalled and removed from the market, voluntarily or not?</i>	YES <sup>54</sup>	NO <sup>21,22</sup>
<i>Has the device been linked to multiple patient injuries?</i>	YES <sup>53-56</sup>	YES <sup>14,45,46</sup>

**Table 3.** Similarities between the Abtox Plazlyte System and the Steris System 1. A shaded answer indicates that it is different for the two devices.



# The Q-Net™ Monthly

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## What's News

**W**ishing readers a happy holiday season. • This newsletter's main article is the second in a series of two that discusses the discontinued marketing of the **STERIS System 1**. • The FDA, CDC, and VA issued a safety communication, dated 11-19-09—download a copy by visiting this newsletter's website at: [www.MyEndoSite.com](http://www.MyEndoSite.com)

## Editor-in-Chief

**A**ll 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, infection control-based network of questions, answers, and perspectives. Its newsletter is *The Q-Net™ Monthly*.

The main goal of **Q-Net** is to encourage the infection control, endoscopy, and operating room communities to improve patient care by not only asking good questions but also by demanding well referenced, evidence-based answers.

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

## Adulterated and Misbranded Devices: A Position Statement

**QUESTION:** "I read the article featured in the last issue of this newsletter, which focuses on the discontinued marketing of the **STERIS System 1**. Could you please review this article's most significant considerations and provide guidance to help healthcare staff make informed, evidence-based decisions about using this or any unapproved device?"



**I**NTRODUCTION: THIS IS THE second article in a series of two that discusses the discontinued marketing of the **STERIS System 1** ("System 1"). A review of the first article in this series—published in this newsletter's July-August-September, 2009, issue—is recommended for completeness, context and clarity. To date, no other article other than these two has provided guidance regarding the System 1's regulatory status, use, and discontinued marketing.

**PURPOSE:** SUPPLEMENTING THE FIRST article in this series, this article herein provides guidance to help medical facilities not only make informed and evidence-based decisions, but also to understand more clearly the federal regulation and oversight of medical devices and to prevent disease transmission.

Specifically, this article summarizes both the most salient aspects of the discontinued marketing of the System 1 (see: **Table 1**) and, too, the most significant considerations noted in the first article of this series (see: **Table 2**). This article also features a position statement that provides guidance for healthcare practitioners debating the medical soundness of using an unapproved device.

**REVIEW:** DISCUSSED IN THE first article in this series, the marketing of the System 1 was discontinued by its manufacturer in response to the Food and Drug Administration's (FDA) published conclusion (in May, 2008) that this device, along with its accompanying peracetic-acid sterilant,

(Continued on page 20)

## TABLE OF CONTENTS

1.	Introduction .....	19
2.	Purpose .....	19
3.	Review .....	19
4.	Table 1 .....	20
5.	Discussion .....	20
6.	Table 2 .....	21
7.	Position Statement .....	22
8.	Recommendations .....	22
9.	References .....	22
10.	Box Article .....	22S <sub>1</sub>

known as the Steris 20, have been “adulterated” and “misbranded” for more than 20 years.<sup>13,21,22</sup>

According to the FDA, the System 1 and Steris 20 have undergone several “significant changes” since 1988—for example, modification of the Steris 20’s original chemical formulation—that could “significantly affect (their) safety or effectiveness” (see: Table 1).<sup>13</sup> Moreover, the FDA wrote that these changes, which were neither cleared nor approved by

the FDA—in addition to rendering the System 1 (and Steris 20) adulterated, misbranded, and without regulatory approval—call into question this device’s “ability to sterilize” (i.e., that the System 1 may be mislabeled).<sup>13,14,18-20</sup>

As provided by Section 520(e) of the Food, Drug and Cosmetic (FD&C) Act, the FDA is authorized to restrict the sale of adulterated and misbranded devices, which lack a 510(k) clearance, premarket approval, or approved exemption.<sup>13</sup> This and other sections of this Act—which apply to the use of such unapproved devices (though do not appear to be entirely congruous with some of the instructions of a recently published safety communication entitled “Preventing Cross-Contamination in Endoscope Processing”<sup>84</sup>)—are discussed in more detail in the first article in this series.<sup>83</sup>

**Table 1: A summary of the discontinued marketing of the STERIS System 1 and Steris 20 sterilant.**

(1) This past January (2009) Steris discontinued the marketing of the System 1 and its accompanying peracetic-acid sterilant, the Steris 20 concentrate.<sup>21,22</sup>

- › This decision was in response to the FDA’s published conclusion in May, 2008, that both the System 1 and Steris 20 have been “adulterated” and “misbranded” for more than 20 years.<sup>13</sup>

(2) According to the FDA, the System 1 and Steris 20 have undergone several “significant changes” since 1988—for example, modification of the Steris 20’s original chemical formulation—that could “significantly affect (their) safety or effectiveness.”<sup>13</sup>

- › The FDA published that each of these changes was unapproved and “itself would necessitate submission” of a new application for 510(k) clearance (or premarket approval, or PMA).<sup>13</sup>

(3) Despite the FDA’s published conclusions questioning the safety of both,<sup>13</sup> the manufacturer states that the System 1 and Steris 20 will continue to be sold for at least two more years in the U.S. (albeit conditionally).<sup>21,22</sup>

- › As of November, 2009, the FDA notably has not published either (a) that the continued sale of the System 1 and Steris 20 is sound, with precedent, and in accordance with the Food Drug and Cosmetic Act; or (b) that the continued use of the System 1 is safe, appropriate, and, as its manufacturer asserts, does not warrant “any change” in clinical practice—for example, does not require notification of doctors or informed patient consent.<sup>21,22</sup>

(4) Ordinarily, a device without a 510(k) clearance or premarket approval may be described as “investigational,” requiring for its clinical use, among other considerations, an approved *investigational device exemption* (IDE).<sup>13,74,75</sup>

(5) Seeking a 510(k) clearance, Steris submitted to the FDA this past January (2009) an “updated” model of the System 1 that, like the “altered”<sup>13</sup> System 1, claims both to achieve “liquid chemical sterilization” and to produce “sterile” filtered water from a medical facility’s tap.<sup>21,22</sup> ●

**DISCUSSION: SEVERAL RECOMMENDATIONS, CONSIDERATIONS** and notations arising from the discontinued marketing of the System 1 were addressed in this newsletter’s July-August-September, 2009, issue and are listed in Table 2 (below). A box article on p. 22S<sub>1</sub>—which is available *only* in this article’s *on-line* version—provides additional insight into the significance of this device’s discontinued marketing.

Also discussed in the first article in this series were my perspectives and my finding, too, that the requisite validation and verification data to support the claim that any instrument-reprocessing device can achieve *liquid chemical sterilization* and produce *sterile* (filtered) rinse water from a tap are lacking. And, a timeline detailing some of the history of the System 1 is available on p. 18S<sub>1</sub> in the *on-line* version of this newsletter’s July-August-September, 2009, issue.<sup>83</sup>

*No change in clinical practice?* Discussed in the first article  
(Continued on page 21)

### THE DISCONTINUED MARKETING OF THE SYSTEM 1

◆ **PROBLEM:** In May, 2008, the FDA published that the STERIS System 1 and Steris 20 sterilant have been adulterated and misbranded for more than 20 years.<sup>13</sup>

◆ **RESPONSE:** In January, 2009, the manufacturer discontinued the marketing of the System 1 and Steris 20.<sup>21,22</sup>

◆ **CONTROVERSY:** Despite the FDA’s acknowledgment that the safety and effectiveness of the System 1 cannot be assured,<sup>13</sup> the manufacturer claims that: *first*, it will continue to sell this device (albeit conditionally), along with the Steris 20 sterilant, for at least two more years; and, *second*, healthcare facilities can continue using both “without any change” in clinical practice.<sup>21,22</sup>

◆ **POSITION STATEMENT:** A position statement is provided herein to help guide healthcare practitioners evaluating the soundness of using an unapproved device.

in this series (*see*: Table 1), the manufacturer claims that, despite the device's federal censure, the System 1 (and Steris 20): first, will continue to be sold for at least two more years (albeit only to replace previously installed devices); and, second, can continue to be used "without any change" in clinical practice (e.g., without notification of doctors or patients).<sup>21,22</sup>

The rationale and justification for these two claims are obscure and not manifest. In accordance with specific provisions of the FD&C Act, and, too, statements published by the FDA, the safety and effectiveness of devices that have been significantly modified and lack regulatory approval (such as the System 1<sup>13</sup>) cannot be assured.<sup>13,15,17</sup> Such "unapproved devices"<sup>17</sup> are described as "investigational,"<sup>13,15</sup> and their use would require *changes* in clinical practice—for example: (a) the establishment of an institutional review board (or, IRB); (b) the approval of an IDE (investigational device exemption); and, to be sure, (c) informed patient consent.<sup>74,75</sup>

(Please refer to: [a] the box article on p. 22S<sub>1</sub>, which is available only in this article's *on-line* version; and [b] the box article, "What is an investigational device?" on p. 18S<sub>2</sub> in the *on-line* version of this newsletter's July-August-September, 2009, issue.)

**A tale of two "sterilizing" devices:** An interesting juxtaposition that adds further to the interest and confusion surrounding this "sterilizing" device, the first article in this series compared the federal censure of the System 1 (and the Steris 20 sterilant) to the regulatory rebuke of the Abtox Plazlyte System.<sup>83</sup> Labeled for reprocessing some types of surgical instruments, the Plazlyte System, like the System 1, was a low-temperature "sterilizing" device whose design had been similarly adulterated and misbranded by its manufacturer.

But, whereas the Plazlyte System was promptly removed from the market for these regulatory breaches,<sup>53-56</sup> the System 1, according to its manufacturer, will paradoxically continue to be sold for at least two more years (albeit conditionally).<sup>21,22</sup> (More details about the comparison of these two devices are provided in Table 3 on p. 18S<sub>2</sub> of the *on-line* version of this newsletter's July-August-September, 2009, issue.)

**Some of the System 1's advantages:** Attracting the attention of the infection-control community for years, the System 1 is uniquely labeled to achieve *liquid chemical sterilization* of flexible endoscopes and many types of surgical instruments.<sup>6-11</sup> As alluring and advantageous a claim, the System 1 is also singularly labeled to produce *sterile* (filtered) rinse water, irrespective of the microbial quality of the facility's (unfiltered) tap water (refer to the footnote on p. 22).<sup>†</sup>

In addition to acknowledging some of the System 1's other apparent advantages—including its convenience and ease-of-use; relatively rapid-acting cycle; portability; and small footprint—the first article in this series discusses the System 1's incomparable (if not fascinating) history, committed focus, and remarkable marketing.<sup>83</sup>

(Continued on page 22)

**Table 2: Some of the issues and considerations that are discussed in this newsletter's July-August-September, 2009, issue, and arise due to the discontinued marketing of the STERIS System 1.**

- As of November, 2009, no position statement, alert or notice has been published discussing the infection-control soundness of using an adulterated, misbranded or otherwise unapproved device.

- The lack of specific guidance focusing on the clinical implications associated with the continued use of the System 1 and Steris 20 is noted.

- According to the FDA, the safety and effectiveness of the System 1 (and Steris 20) cannot be assured.<sup>13</sup>

- That the approbation or endorsement of the use of an adulterated and misbranded device would appear to be injudicious and incongruous with patient safety is noted.

- That patient injuries linked to the use of an adulterated, misbranded or otherwise unapproved device would seemingly be problematic and prejudicial is discussed.

- Whether the use of an adulterated or misbranded (or otherwise unapproved) device would adversely affect a medical facility's accreditation is considered.

- Several similarities between the FDA's censure of both the System 1 and Abtox's Plazlyte System are listed.

- That the censure of the System 1 might require that some infection-control guidelines and surgical-instrument operator manuals be revised is discussed and would seem unavoidable, lest they be misconstrued to be condoning, if not promoting, the use of an unapproved device.

- An enhanced commitment by healthcare organizations to their respective mission statements and pledges to advance patient safety and reduce healthcare-associated infections is noted.

- Featuring in a surgical-instrument manufacturer's reprocessing instructions only those claims and instructions for which sound validation and verification data have been published is also noted.

- The infection-control community's acquiescence and acceptance without demur of the System 1's seemingly implausible<sup>14,25-28</sup> claim and "guarantee"<sup>14,26,29</sup> to achieve *liquid chemical sterilization* is discussed.<sup>6-11,14</sup>

- That the FDA's censure of the System 1 appears to be consistent with the concerns that Bond, Daschner, and Muscarella have published questioning the safety and labeling claims of the System 1 is presented.

- That the FDA might clear for marketing the "updated" System 1 for the *liquid chemical sterilization* of surgical instruments is discussed but considered unlikely. (Please refer to the box article on p. 15 of this newsletter's July-August-September, 2009, issue.) ●



**POSITION STATEMENT: TO DATE, NO** position statement, notice, guideline, alert, or patient-safety goal has been published that discusses, from an infection-control standpoint, the medical soundness of—or the clinical (and legal) criteria that must be satisfied when—using an adulterated, misbranded or otherwise unapproved device. More specifically, as of November, 2009, no such publication has focused on either the safety or accrediting implications associated with the continued use of the System 1 (and Steris 20). The following position statement is, therefore, provided for guidance:

► *Caution applies to the clinical use of an adulterated and misbranded device, a practice that – without the medical facility having received: (1) an approved investigational device exemption (IDE) in accordance with both the provisions of the FD&C Act and the FDA's regulations; or (2) a written\* statement from an official or supervisory healthcare or accrediting organization or agency, such as the FDA, the Centers for Disease Control and Prevention (CDC), the Veterans Health Administration (VHA), or the Joint Commission (JCAHO), approving or otherwise authorizing the use of an adulterated and misbranded device\*\* – is not recommended.*

**RECOMMENDATIONS AND CONCLUSIONS: THE USE (AND sale) of an adulterated and misbranded device (without an approved exemption) raises a number of legitimate questions, if not also concerns and dilemmas, for diligent healthcare practitioners. Several of these questions as they apply to the System 1 were raised in the first article in this series and remain unanswered—including whether the FDA would clear or approve an “updated” device, which the System 1’s manufacturer submitted to the FDA this past January, similarly labeled to achieve liquid chemical sterilization (see: the box**

#### THIS ARTICLE'S FOOTNOTES:

† Which is to suggest on p. 21 that a 0.2 micron bacterial water filter can guarantee the production of “sterile” water—a quality of rinse water that exceeds that which is produced by reverse osmosis water treatment systems. Further, whereas a biological indicator (BI) had been cleared by the FDA for monitoring the effectiveness of the Steris 20 sterilant, no BI has been cleared for monitoring the microbial quality of the System 1’s rinse water, as would otherwise be required to verify its “sterility.”

\* This position statement distinguishes between *implied* and *written* authorization, only the latter of which is legally accountable and minimizes the potential for confusion. That the use of an unapproved device may be prejudicial and could incur legal liability for the medical facility if the device were linked to patient injury is noted (see: Table 2).

\*\* In addition to obtaining written authorization from an organization or agency to use an adulterated, misbranded, or otherwise unapproved device, medical facilities continuing to use such a device may consider further reducing their legal exposure by requesting from the device’s manufacturer a “letter of indemnification” explicitly stating (in writing) that the manufacturer would bear all responsibility, legal and financial, if the adulterated and misbranded device were linked to patient injury.

article featured on p. 15 of this newsletter’s July-August-September, 2009, issue.)

In addition to those featured in the first article in this series,<sup>83</sup> two salient recommendations designed to reduce risk are provided for consideration: *first*, review the position statement, above, and consider its gist; and, *second*, seek clarification from healthcare and accrediting organizations (and federal agencies, too, including the, FDA, CDC and VHA) of the safety and medical soundness of using an adulterated and misbranded device—namely, determine (in writing) whether any changes in clinical practice (possibly overlooked by this device’s manufacturer)—such as obtaining an approved IDE or informed patient consent per the terms of the FD&C Act<sup>74,75</sup>—are indeed necessary if a medical facility were to continue using the System 1 (and Steris 20 sterilant).

In closing, emphasized is the importance of healthcare organizations and federal agencies both overseeing the safety of infection-control devices—especially those whose claims might otherwise be invalid (such as a “guarantee” to achieve “sterilization”)—and assuring that the patient’s safety and interests are considered. That few aspects of infection control are more important than the safe use of “sterilizing” devices is recognized. ● **The End** (By: L.F. Muscarella Ph.D.)

The **REFERENCES** to this article are available *on-line* at:

► [www.myendosite.com/htmlsite/2009/refs71009.pdf](http://www.myendosite.com/htmlsite/2009/refs71009.pdf)

**Note:** Page 22S<sub>1</sub>—which includes a **BOX ARTICLE**—is not included in the mailed version of this newsletter. It is available *only* in this article’s *on-line* version at:

► [www.myendosite.com/htmlsite/2009/ss2.pdf](http://www.myendosite.com/htmlsite/2009/ss2.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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**Box A: The discontinued marketing of the STERIS System 1:** Although complex, the discontinued marketing of the STERIS System 1 is a topic necessary to acknowledge and to highlight. In the fields of instrument reprocessing, risk management, and aseptic technique (among others), few other topics are as germane to healthcare management and the prevention of disease transmission. Indeed, the importance of healthcare organizations addressing the infection-control and legal implications of, and precedents established by, using the System 1—withstanding the FDA's finding that the safety and effectiveness of this unapproved device cannot be assured<sup>13,17</sup>—is self-evident.<sup>83</sup> This conclusion is especially true, considering that the use of the System 1 for reprocessing instruments including endoscopes has been common in the U.S.<sup>14,48</sup>

The FDA's conclusion that the System 1 has been adulterated and misbranded for more than 20 years<sup>13</sup> also provides a pivotal opportunity not only to underscore the significance of manufacturers employing comprehensive quality-assurance programs to control changes to the design or manufacturing of their medical devices, but also to encourage healthcare organizations, as part of a complex system of "checks and balances," to become more recognizable beacons for the advancement of infection control and patient safety.

That the implications to public health of the continued use of the System 1 (despite its discontinued marketing) are potentially far-reaching and warrant examination and debate is further supported by two recognized dichotomies. First, despite the censure of the System 1, its manufacturer claims that, in addition to continuing to sell it for at least two more years (albeit conditionally), the System 1, along with the Steris 20 sterilant, can continue to be used *without any change in clinical practice*<sup>21,22,83</sup> (see: main article).

These two claims, however, are juxtaposed against the Food, Drug and Cosmetic (FD&C) Act, whose provisions oversee both the sale and use of medical devices.<sup>74-76,79,81</sup> Among other proscriptions, this Act prohibits the introduction into interstate commerce (i.e., the commercial distribution) of any adulterated and misbranded device. Moreover, designed to protect the interests and safety of the patient, this Act also requires healthcare facilities using such an unapproved device to establish an institutional review board (IRB) and to obtain the patient's informed consent.<sup>74,75</sup> (For more details about using unapproved devices, which may be referred to as "investigational,"<sup>13,17,74</sup> please refer to this newsletter's main article and to its July-August-September, 2009, issue.)

In addition to providing both historical perspective and insight into the design, manufacturing, and regulation of medical devices, a comparison of the System 1's marketing and labeling claims to those of the Abtox

Plazlyte System yields a second recognized dichotomy. Rebuked by the FDA almost a decade ago, the Plazlyte System—which, like the System 1, was a low-temperature "sterilizing" device—was promptly removed from the market in 1998 once the FDA determined it to have been adulterated and misbranded by its manufacturer.<sup>83</sup> Nevertheless, although the FDA has concluded that the System 1 and Steris 20 are similarly unapproved and without a clearance, premarket approval, or exemption,<sup>13</sup> their manufacturer states that the System 1 and Steris 20 will continue to be sold for at least two more years (albeit only as replacement devices). For more details about the Abtox Plazlyte System, please review to this newsletter's July-August-September, 2009, issue, including its Table 3 on p. 18S<sub>2</sub>. ●

**Box. Definitions: Adulterated, misbranded devices.**

A medical device introduced into interstate commerce without a premarket approval (PMA) or an approved investigational device exemption (IDE) is **adulterated**, whereas a device commercially distributed without a 510(k) clearance is **misbranded**.<sup>13,17</sup>

- The **FIRST ARTICLE** in this series is available at:  
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- The **REFERENCES** to this article are available at:  
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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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