

The Q-Net™ Monthly

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What's News

Wishing 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

Editor-in-Chief

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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?"



INTRODUCTION: 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,

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known as the Steris 20, have been “adulterated” and “misbranded” for more than 20 years.^{13,21,22}

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](#)).¹³ Moreover, the FDA wrote that these changes, which were neither cleared nor approved by

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.^{21,22}

- › 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.¹³

(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.”¹³

- › 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).¹³

(3) Despite the FDA’s published conclusions questioning the safety of both,¹³ 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).^{21,22}

- › 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.^{21,22}

(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).^{13,74,75}

(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”¹³ System 1, claims both to achieve “liquid chemical sterilization” and to produce “sterile” filtered water from a medical facility’s tap.^{21,22} ●

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).^{13,14,18-20}

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.¹³ 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”⁸⁴)—are discussed in more detail in the first article in this series.⁸³

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. 22S₁—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. 18S₁ in the *on-line* version of this newsletter’s July-August-September, 2009, issue.⁸³

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.¹³

◆ **RESPONSE:** In January, 2009, the manufacturer discontinued the marketing of the System 1 and Steris 20.^{21,22}

◆ **CONTROVERSY:** Despite the FDA’s acknowledgment that the safety and effectiveness of the System 1 cannot be assured,¹³ 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.^{21,22}

◆ **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).^{21,22}

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 1¹³) cannot be assured.^{13,15,17} Such "unapproved devices"¹⁷ are described as "investigational,"^{13,15} 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.^{74,75}

(Please refer to: [a] the box article on p. 22S₁, which is available only in this article's *on-line* version; and [b] the box article, "What is an investigational device?" on p. 18S₂ 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.⁸³ 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,⁵³⁻⁵⁶ the System 1, according to its manufacturer, will paradoxically continue to be sold for at least two more years (albeit conditionally).^{21,22} (More details about the comparison of these two devices are provided in Table 3 on p. 18S₂ 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.⁶⁻¹¹ 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).[†]

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.⁸³

(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.¹³
- 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^{14,25-28} claim and "guarantee"^{14,26,29} to achieve *liquid chemical sterilization* is discussed.^{6-11,14}
- 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,⁸³ 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^{74,75}—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

Note: Page 22S₁—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

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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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—notwithstanding the FDA's finding that the safety and effectiveness of this unapproved device cannot be assured^{13,17}—is self-evident.⁸³ 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.^{14,48}

The FDA's conclusion that the System 1 has been adulterated and misbranded for more than 20 years¹³ 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*^{21,22,83} (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.^{74-76,79,81} 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.^{74,75} (For more details about using unapproved devices, which may be referred to as "investigational,"^{13,17,74} 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.⁸³ Nevertheless, although the FDA has concluded that the System 1 and Steris 20 are similarly unapproved and without a clearance, premarket approval, or exemption,¹³ 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. 18S₂. ●

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**.^{13,17}

- The **FIRST ARTICLE** in this series is available at:
 - ➔ www.myendosite.com/htmlsite/2009/ss1.pdf

- The **REFERENCES** to this article are available at:
 - ➔ www.myendosite.com/htmlsite/2009/refs71009.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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