

# The Q-Net™ Monthly

Volume 16, Numbers 8, 9

August-September 2010

## What's News

This month's double issue provides Q-Net's annual self-study quiz. After completing it, readers will have a better understanding of all of the topics discussed in this newsletter during 2009. Available only on-line, this quiz's answers can be easily downloaded at the website of "The Q-Net Monthly." Visit: <http://www.MyEndoSite.com>

## Editor-in-Chief

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

## What is 'Q-Net'?

**Q-Net** is a technology assessment, 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.

## Q-Net's Annual Quiz

■ This quiz focuses on all of the topics discussed in this newsletter during 2009. These topics include: endoscope damage; the discontinued marketing of the STERIS System 1; the use of adulterated and misbranded devices; and endoscope storage. Prior to taking this self-study quiz, a review of all of the articles published in this newsletter in 2009 is recommended.

■ This quiz may be used to provide continuing educational units (CEUs). Or, it may be used as part of the management of a medical facility's quality assurance and safety program. (Note: For each question, be sure to read every one of the provided answers before selecting the correct one.)

➔ **QUIZ INSTRUCTIONS:** Write your answers on the form provided on p. 18S. The correct answers to this self-study quiz are provided on this same form—which is available only on-line at this newsletter's website: <http://www.MyEndoSite.com>

**PART 1A: Endoscope damage, Part 1.** (Refer to this newsletter's January-February, 2009, issue.)

1. A manufacturer provides EACH of the following claims to explain the association between endoscope damage and the use of its peracetic acid-based automated processing system labeled to "sterilize" instruments, except: (A) The manufacturer openly acknowledges that peracetic acid may cause endoscope damage. (B) The manufacturer asserts that endoscope damage may instead be due to improper care and handling. (C) The manufacturer claims that peracetic acid uncovers—but does not cause—endoscope damage, which had been "masked" by aldehyde-based disinfectants. (D) The manufacturer claims that peracetic acid "unplugs" small "pin holes" (inside the endoscope) that became clogged with debris not removed by aldehyde-based disinfectants.

2. Which ONE of the following statements is TRUE: (A) Several independent studies clearly demonstrate that the peracetic acid used by an automated processing system labeled to "sterilize"

(Continued on page 16)

➔ An important study about disease transmission during ERCP, accompanied by an editorial authored by L.F. Muscarella, will appear in the November, 2010, issue of *ESGE's* peer-review journal *Endoscopy*.

### The newsletters, their topics published in 2009

- ◆ Endoscope Damage, Part 1: ... Jan-Feb 2009
- ◆ Endoscope Damage, Part 2: ... Mar-Apr 2009
- ◆ Q-Net's Annual Quiz: ..... May-June 2009
- ◆ STERIS System 1: ..... Jul-Aug-Sep 2009
- ◆ Adulterated Devices ..... Oct-Nov 2009
- ◆ Endoscope Storage ..... Dec 2009

(Continued from page 15)

instruments is not associated with endoscope damage. (B) Independent studies have linked this “sterilizing” processing system to endoscope damage. (C) An evaluation (performed by a non-profit healthcare institute) of the performance of another peracetic acid-based processing system (labeled instead to clean and high-level disinfect endoscopes) objectively distinguishes a manufacturer’s claims about the cause of endoscope damage from scientific data. (D) Independent studies demonstrate that flexible endoscopes reprocessed using aldehyde-based disinfectants are far more prone to damage than those reprocessed using peracetic acid. ●

#### PART 1B: Endoscope Damage, Part 2. (Refer to the March-April, 2009, issue of this newsletter.)

1. Which ONE of the following statements is FALSE: (A) The concentration of peracetic acid used by both the STERIS System 1 and the STERIS Reliance EPS is the same. (B) The immersion time of the peracetic acid used by both of these processing systems is the same and less than 5 minutes. (C) The temperature range of the peracetic acid used by both of these processing systems (to destroy microorganisms) is the same. (D) All of the above statements are false.
2. Concern is expressed (in the March-April, 2009, issue of this newsletter) about EACH of the following, except: (A) The misrepresentation of a manufacturer’s unsubstantiated claims as scientific fact. (B) The advancement of the claim that a liquid disinfectant (or sterilant) is not the cause of endoscope damage, without independent data to support this claim. (C) Evaluations performed by non-profit healthcare institutes that overlook and neither discuss nor reference peer-reviewed scientific studies that provide conclusions inconsistent with those advanced in these evaluations. (D) That the use of misbranded, adulterated, or otherwise unapproved medical devices, including rigid and flexible endoscopes, is generally a safe, effective, and routine practice.

3. Which ONE of the following statements is TRUE: (A) Peer-reviewed studies show that aldehyde-based disinfectants “fix” patient debris, resulting in the “build-up” of layers of organic materials transmitted to patients during flexible endoscopy. (B) Peracetic acid has been independently proven not only to “unplug” a flexible endoscope’s pre-existing pin holes filled with organic soils, but also to break down “protein encrustations” and reduce the risk of infection. (C) No independent, validated data demonstrate that liquid-based processing systems reliably produce “sterile” (filtered) rinse water. (D) Ortho-phthalaldehyde, like glutaraldehyde, is an oxidizing agent independently shown to cause endoscope damage.

4. Which of the following recommendations is neither true nor appeared in this newsletter’s article discussing endoscope damage: (A) Ensure flexible endoscopes are properly handled, reprocessed, stored and serviced in accordance with the manufacturer’s instructions. (B) Monitor several times a day the effectiveness of any reused formulation of peracetic acid, to ensure its concentration is above 35%. (C) Use high-level disinfectants and other reprocessing agents verified not to damage the endoscope. (D) The more rigorous management of (potential) conflicts of interest is recommended to improve infection-control standards. ●

#### PART 2A: The STERIS System 1. (Refer to the July-August-September, 2009, issue of this newsletter.)

1. Which ONE of the following correctly completes this sentence: “[BLANK] is an order issued by the FDA that grants manufacturers the legal right to market most types of (‘class II’) medical devices”? (A) An investigational device exemption (IDE). (B) A premarket approval (PMA). (C) A warning letter. (D) A 510(k) clearance. (E) A medical device citation. (F) A “Dear Customer” letter.
2. The FDA asserts in the warning letter it issued to STERIS on May 15, 2008, EACH of the following, except: (A) The Food, Drug and Cosmetic Act does not require a manufacturer to notify the FDA of any significant changes to a marketed device’s design. (B) Neither the STERIS System 1 nor its STERIS 20 sterilant has a regulatory clearance or approval from the FDA. (C) Changes to the STERIS System 1 by its manufacturer call into question this device’s safety and “ability to sterilize” instruments. (D) All of the above.
3. The FDA also asserts in this warning letter EACH of the following, except: (A) During the past 20 years the STERIS System 1 has undergone a number of significant changes that could affect its safety and effectiveness. (B) Some of these changes included altering the formulation of the STERIS 20

(Continued on page 17)

(Continued from page 16)

sterilant. (C) The STERIS System 1 has been independently shown to reliably achieve “sterilization” of instruments since 1988. (D) Among other changes, the manufacturer modified the STERIS System 1’s water filter housing.

**4. *Replying to the FDA’s warning letter, the STERIS System 1’s manufacturer included in its “Dear Customer” letter a discussion of EACH of the following, except:***

(A) That the STERIS System 1’s marketing had been discontinued. (B) That the Food, Drug and Cosmetic Act had been amended to permit this device’s continued sale through August 2011. (C) That the STERIS System 1 would continue to be sold for several months, albeit only as “product replacements.” (D) That the manufacturer had recently submitted to the FDA a new premarket notification, or 510(k) clearance application, to sell an “updated” STERIS System 1.

**5. *Which ONE of the following is TRUE:*** (A) The FDA determined that the STERIS System 1 had been adulterated and misbranded for more than 20 years. (B) In 1999 a federal public-health advisory linked the STERIS System 1 to patient morbidity and mortality. (C) Muscarella first began expressing his concerns about the STERIS System 1’s safety, effectiveness, and labeling claims as early as 1992. (D) In April, 2001, the FDA wrote a letter to the manufacturer calling into doubt the “sterility” of the STERIS System 1’s filtered rinse water. (E) All of the above statements are true.

**6. *The AbTox Plazlyte Sterilization System and the STERIS System 1 share EACH of the following in common, except:***

(A) The FDA determined that the marketed model was adulterated, misbranded, and/or otherwise unapproved. (B) The marketed model was unconditionally (and understandably) removed from the market (i.e., federally recalled) once the FDA determined that it was without a regulatory clearance or approval. (C) The marketed model has been linked to patient injuries. (D) The marketed model was significantly modified, rendering its 510(k) clearance invalid. ●

**PART 2B: STERIS System 1 (continued).** (Refer to the *Jul-Aug-Sep, 2009*, issue of this newsletter.)

**1. *Which ONE of the following statements is FALSE?*** (A) A medical device that receives a 510(k) clearance has been determined by the FDA to be substantially equivalent to another, legally marketed device known as the predicate. (B) In contrast, a premarket approval, or PMA, is a less rigorous regulatory clearance that focuses on the effectiveness of the predicate device. (C) Whereas most *class II* devices enter the market by way of a 510(k) clearance, *class III* devices generally require a PMA. (D) All of the above are false.

**ANSWER FORM, CORRECT ANSWERS:** Remember to write your answers on the form provided on p. 18S. This form—along with this quiz’s correct answers—is available *only* on-line and by visiting the home of “The Q-Net Monthly” at: <http://www.myendosite.com>

**2. *Which ONE of the following statements is TRUE?*** (A) An automated endoscope reprocessor is a *class II* device. (B) A tongue depressor is a *class III* device, requiring a premarket approval. (C) A steam sterilizer is a *class I* device that generally requires a premarket approval before it can be marketed and sold in the U.S. (D) A permanent orthopedic implant is a *class I* device, requiring a 510(k) clearance.

**3. *A “misbranded” medical device:*** (A) is without a premarket approval (PMA) or an approved investigational device exemption (IDE); (B) lacks a valid 510(k) clearance; (C) is an investigational device with a premarket approval (PMA); (D) is an investigational device with a 510(k) clearance; (E) can be legally marketed in most, but not all, of the U.S.

**4. *Muscarella (this newsletter’s founder) concludes that as much as for having been significantly modified, the discontinued marketing of the STERIS System 1 may have been due to:*** (A) the mislabeling of this device to produce “sterile” filtered rinse water. (B) The inherent limitations of liquid chemical sterilants and bacterial water filters. (C) The filtration of a hospital’s tap water through a 0.2 micron bacterial membrane not being sterile. (D) No valid predicate device, as required by the 510(k)-clearance process, was legally marketed to achieve “liquid chemical sterilization” at the time that the STERIS System 1 was reviewed by the FDA in 1988. (E) Biological indicators (BIs) used to monitor liquid sterilants may yield invalid results. (F) All of the above.

**5. *Which ONE of the following is FALSE:*** (A) The STERIS System 1 can apparently continue to be used through August, 2011—despite not having a legal regulatory clearance or approval. (B) Muscarella suggests that the STERIS System 1 would appear to be an “investigational” device whose continued use would require, among other considerations, patient notification and an IDE (investigational device exemption). (C) The Food, Drug and Cosmetic Act makes exceptions for devices labeled to achieve “liquid sterilization.” (D) A study of the STERIS System 1 provides a rare glimpse into the marketing and use of an infection-control product.

**6. *ALL of the following are TRUE, except:*** (A) Few, if any, manufacturers have listed in the labeling of their rigid endoscopes the STERIS System 1 as an acceptable reprocessing method. (B) Some manufacturers claim (but have not proven)

(Continued on page 18)

(Continued from page 17)

that the STERIS System 1 has been validated for the “sterilization” of their rigid endoscopes. (C) Published validation data supporting claims that the STERIS System 1 “sterilizes” rigid endoscopes are lacking. (D) Muscarella published for the first time (in 2009) that, as a consequence of their operator’s manuals listing the STERIS System 1 as an acceptable processing system, these rigid endoscopes themselves became misbranded and adulterated devices.

**7. An approved investigational device exemption (IDE) would appear to apply to the continued use of the STERIS System 1, because:** (A) A Certificate of Medical Necessity (CN) is different from an IDE. (B) The STERIS System 1 is without a 510(k) clearance or premarket approval. (C) An approved IDE would be necessary, because it legally permits the clinical use of such an unapproved device. (D) The FDA has concluded that the modified STERIS System 1’s safety and effectiveness cannot be assured. (E) All of the above. ●

**PART 3: Position Statement on adulterated devices.**  
(Refer to the **Oct-Nov, 2009**, issue of this newsletter.)

**1. Which ONE of the following is FALSE:** (A) The continued use of the adulterated and misbranded STERIS System 1 without an approved investigational device exemption (IDE) could adversely affect a facility’s accreditation. (B) Several healthcare organizations have often published objection to the STERIS System 1’s implausible labeling claim “guaranteeing” sterilization. (C) No alert, advisory, or position statement, other than expressed in this newsletter, has been published (by any professional or federal healthcare organization or agency) providing guidance on the infection-control (and accreditation) implications of the continued use of the STERIS System 1 (through August 2011). (D) The modified STERIS System 1’s safety cannot be assured. ●

**PART 4: Endoscope storage.** (Refer to the **December, 2009**, issue of this newsletter.)

**1. Guidelines about endoscope storage recommend which ONE of the following:** (A) removal of the gastrointestinal endoscope’s suction valve, but not its air/water valve; (B) that the endoscope be hung vertically over the weekend, but be stored in a carrying case during the week; (C) that the endoscope’s internal channels be dried before storage; (D) that the storage area be a square room with an ajar door.

**2. Which ONE of the following is FALSE?** (A) A solution of 70% alcohol facilitates endoscope drying by increasing the

surface tension of water, precluding the evaporation of any residual water. (B) Endoscope drying is typically achieved by flushing its internal channels with 70% alcohol followed by forced air. (C) Endoscope-reprocessing guidelines recommend drying the endoscope before storage. (D) Proper storage of the flexible endoscope is important to the prevention of bacterial growth within its internal channels.

**3. Which ONE of the following is FALSE:** (A) At least one published study suggests that colonoscopes may be stored for as long as a week (7 days) without requiring reprocessing before reuse. (B) Virtually every guideline suggests that side-viewing duodenoscopes can be safely stored for 21 days. (C) ASGE does not provide a specific number of days after which a stored gastrointestinal endoscope requires reprocessing before reuse. (D) AORN recently revised its guideline, suggesting that flexible endoscopes may be safely stored (without requiring reprocessing before reuse) for up to 5 days.

**4. Which ONE of the following is TRUE:** (A) At least one guideline recommends that bronchoscopes be reprocessed before reuse. (B) Muscarella suggests consideration of reprocessing side-viewing duodenoscopes before reuse. (C) At least one guideline suggests that flexible endoscopes may be safely stored (without requiring reprocessing before reuse) for 12 hours. (D) All of the above are true. ● (Written by: LF Muscarella, PhD) SEE P. 18S FOR THIS QUIZ’S ANSWERS.

Download p. 18S at: <http://www.MyEndoSite.com>—  
the *home* of “The Q-Net Monthly” newsletter.

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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~ Answer Box and Key ~

**INSTRUCTIONS:** (1) First, review all of this newsletter's articles published in 2009. (2) Next, cover the inverted right-hand column, which provides the quiz's correct answers. (3) Then, write your answer to each question on the lines provided in the left-hand column, below.

**Part 1A.**

- Question 1: \_\_\_\_\_
- Question 2: \_\_\_\_\_

**Part 1B.**

- Question 1: \_\_\_\_\_
- Question 2: \_\_\_\_\_
- Question 3: \_\_\_\_\_
- Question 4: \_\_\_\_\_

**Part 2A.**

- Question 1: \_\_\_\_\_
- Question 2: \_\_\_\_\_
- Question 3: \_\_\_\_\_
- Question 4: \_\_\_\_\_
- Question 5: \_\_\_\_\_
- Question 6: \_\_\_\_\_

**Part 2B.**

- Question 1: \_\_\_\_\_
- Question 2: \_\_\_\_\_
- Question 3: \_\_\_\_\_
- Question 4: \_\_\_\_\_
- Question 5: \_\_\_\_\_
- Question 6: \_\_\_\_\_
- Question 7: \_\_\_\_\_

**Part 3.**

- Question 1: \_\_\_\_\_

**Part 4.**

- Question 1: \_\_\_\_\_
- Question 2: \_\_\_\_\_
- Question 3: \_\_\_\_\_
- Question 4: \_\_\_\_\_

**Bonus—Part 5.**

- Question 1: \_\_\_\_\_
- Question 2: \_\_\_\_\_

- Answer 2: B
- Answer 1: E
- **Bonus—Part 5:**
- Answer 4: D
- Answer 3: B
- Answer 2: A
- Answer 1: C
- **Part 4:**
- Answer 1: B
- **Part 3:**
- Answer 7: E
- Answer 6: A
- Answer 5: C
- Answer 4: F
- Answer 3: B
- Answer 2: A
- Answer 1: B
- **Part 2B:**
- Answer 6: B
- Answer 5: E
- Answer 4: B
- Answer 3: C
- Answer 2: A
- Answer 1: D
- **Part 2A:**
- Answer 4: B
- Answer 3: C
- Answer 2: D
- Answer 1: B
- **Part 1B:**
- Answer 2: B
- Answer 1: A
- **Part 1A:**

**Part 5. Bonus Questions.** (Refer to **Box A** in the **December, 2009**, issue of this newsletter.)

1. *The length of time that a gastrointestinal endoscope might be safely stored without requiring reprocessing before reuse depends on EACH of the following, except:* (A) the storage area's cleanliness and relative humidity; (B) the effectiveness of reprocessing (and drying) prior to storing the endoscope; (C) the medical facility's policies and procedures; (D) the flexible endoscope's type; (E) all of the above.

2. *Which ONE of the following is FALSE?* (A) The internal designs of different types and models of flexible endoscopes may vary significantly. (B) The risk of disease transmission is necessarily identical whether using a contaminated colonoscope or bronchoscope. (C) Not every medical facility has in place a quality assurance program that meticulously monitors and controls the specific humidity (of the air) in which flexible endoscopes are stored. (D) Nor does every medical facility have in place a quality assurance program that counts and documents the specific number of days every flexible endoscope in inventory has remained in storage. ● **The End**

This annual self-study quiz—like each of the other articles published in this newsletter—are written by its founder and editor-in-chief **Lawrence F. Muscarella, Ph.D.** To subscribe to this free educational newsletter, or to download a previously published issue, visit its website at: ➔ <http://www.MyEndoSite.com>

➔ If you have any questions about this self-study quiz or about any of its answers, send an email to its editor-in-chief at: [editor@myendosite.com](mailto:editor@myendosite.com)

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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