

The Q-Net™ Monthly

Volume 9, Number 7

July 2003

What's News

Last October the *Federal Food, Drug, and Cosmetic Act* was amended to include a new section, denoted '510(o),' that provides new regulatory requirements for reprocessed single-use devices (SUDs). Submitted 510(k) applications for certain reprocessed SUDs will be required to include validation data that demonstrate the SUD will remain substantially equivalent to its predicate device after reprocessing. Performance as well as cleaning and sterilization data will be required.

Editor-in-Chief

The articles published in this newsletter are written by: **Lawrence F Muscarella, PhD, Chief, Infection Control at Custom Ultrasonics, Inc.** Ivyland, PA 18974.

What is 'Q-Net'?

Q-Net is a technology-assessment network of questions and answers. Its newsletter is *The Q-Net™ Monthly*.

Q-Net's main goal is to encourage the infection control and endoscopy communities to not only ask good questions but to also demand succinct and well referenced responses.

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

Dear LA Times, ~ Part 2 ~

This is the second of two articles that discuss the risk of infection following gastrointestinal (GI) endoscopy and bronchoscopy.



Background: The editorial published last month in this newsletter expressed concern with the reporting and focus of an article recently published in the *Los Angeles Times*.¹ This newspaper article misleadingly portrayed colonoscopes and other types of flexible endoscopes as "probes" that cannot be adequately reprocessed. Using anecdotal and unsubstantiated reports and claims as presumed proof, this newspaper article suggested the risk of infection caused by contaminated colonoscopes is significantly higher than acknowledged by clinicians, government agencies, and endoscope manufacturers.

This *Los Angeles Times* article's questionable reporting notwithstanding, over the last ten years only thirty-five cases of likely or possible infection caused by a contaminated gastrointestinal (GI) endoscope have been reported.^{8,11,15} And only five of these reports were linked to a contaminated colonoscope. With 4.4 million colonoscopies being performed each year in the U.S.,⁹ the reported risk of disease transmission during colonoscopy is approximately one in 9 million (refer to the May-June 2003 double issue of this newsletter).

Recommendations: Although it did not accurately characterize the very low reported risk of infection associated with colonoscopy, this *Los Angeles Times* article brings to the public's attention the importance of colonoscopy as a crucial screening tool for colon cancer. This newspaper article also provides the public with critical insight into the potential adverse consequences associated with improper endoscope reprocessing, a topic with which the public needs to become more familiar and knowledgeable.

Finally, this newspaper article's discussion provides the opportunity to review several important infection control recommendations applicable to both GI endoscopy and bronchoscopy. Review of the health care facility's policies and procedures for inclusion of these recommendations is suggested:

1. Develop and implement a written procedure that includes step-by-step instructions for properly reprocessing the endoscope after each use. Ensure all reprocessing steps are in accordance with the endoscope manufacturer's reprocessing instructions and as required with published endoscope reprocessing guidelines.^{4,3} Different endoscope models can feature unique channels—such as the colonoscope's water jet channel, or the duodenoscope's elevator-cable channel—that may require specialized or additional reprocessing steps. It is therefore important to review the reprocessing instructions, diagrams and schematics of every endoscope model in inventory to ensure each channel is reprocessed even if it is not used during the procedure.⁵

2. Ensure endoscope reprocessing staff

(Continued on page 14)

are well-trained and knowledgeable in endoscope design, the principles of infection control, and standard precautions. Periodically conduct competency tests to evaluate the staff's knowledge of the specific reprocessing instructions and channel adapters required for every endoscope model in inventory. Additional reprocessing training and testing may be required whenever a new endoscope model is introduced into use.

3. Develop and implement a quality assurance (QA) program that monitors all of the steps of endoscope reprocessing and ensures staff are provided with and properly using all of the required reprocessing equipment (e.g., channel adapters, luer fittings, detergents, liquid chemical sterilants, cleaning brushes). It is recommended that this QA program include not only a surveillance procedure designed to detect and report infections (and pseudo-infections) that could be a result of inadequate endoscope reprocessing, but also a tracking system that permits quick identification of patients on whom a potentially contaminated endoscope was used.⁴⁵

4. If a bacterial outbreak occurs that is linked to a contaminated endoscope, microbiologically sample as recommended the endoscope and all other potentially contaminated environmental surfaces, such as the rinse water used during endoscope reprocessing (refer to the March and April 2001 issues of this newsletter). Transmission of waterborne bacteria, whether a strain resistant or susceptible to antibiotics, typically suggests inadequate drying of the endoscope (refer to the March-April 2003 issue of this newsletter).

5. Ensure the reprocessing procedure includes terminal drying of the endoscope's channels using 70% alcohol followed by forced air (refer to the March-April 2003 issue of this newsletter). Endoscope drying is necessary, particularly for side-viewing duodenoscopes and bronchoscopes, whether the water used to rinse the endoscope is tap water, bacteria-free water, bottled sterile water, or "sterile" filtered water.^{42,43}

6. Consider using endoscopes manufactured by a single manufacturer, to avoid confusion, enhance familiarization with the endoscopes' reprocessing requirements, and minimize the risk of using improper channel adapters or "irrigators," connection kits, connectors, fittings, and caps during reprocessing. In general, endoscope manufacturers provide their own unique set of reprocessing instructions.

7. When using an automated endoscope reprocessor (AER), ensure reprocessing staff understand its operating instructions and have in supply the AER's specific set of channel adapters required for every endoscope model in inventory. Resolve any conflicts or discrepancies between the reprocessing instructions provided by the AER and endoscope manufacturers.⁴⁵ Consider periodically conducting competency tests to evaluate the staff's knowledge of the proper operation of the AER and of the specific reprocessing instructions and channel

adapters required to connect the AER properly to every endoscope model in inventory. Also, consider using AERs from a single company to minimize the risk of user error.

8. Leak-test the endoscope in accordance with its manufacturer's instructions. Also, repair the endoscope as needed, and have the endoscope periodically serviced as recommended.⁴⁵ Failure to properly service and maintain an endoscope can result in disease transmission.³¹

9. Ensure aseptic technique is always practiced during the handling and administration of intravenous (IV) medications (refer to the March 2002 issue of this newsletter). Consider using single-dose IV medication vials. And, use a new sterile syringe and needle (and IV tubing line) for each patient.^{10,25,47}

10. Consider using single-use disposable biopsy forceps and other endoscopic accessories. Clean and steam sterilize all critical reusable instruments not damaged by heat.^{25,48,50} Maintain the sterility of these critical instruments prior to use. Steam sterilization is recommended because it is reported to be more reliable and effective than low-temperature sterilization processes.^{49,50}

11. Appoint a staff member to remain in close contact with the manufacturer(s) of the endoscopes in inventory (and with the manufacturer of the AER, if used) to learn quickly of device recalls and to resolve any confusing or conflicting endoscope reprocessing instructions. ■ The End

The references to this article are available at:
<http://www.myendosite.com/refs05603.htm>

Thank you for your interest in this newsletter. *I have addressed each issue to the best of my ability. Respectfully, the Publisher: Lawrence F. Muscarella, PhD.* Please direct all correspondence to:

Lawrence F Muscarella, PhD
Editor-in-Chief, *The Q-Net™ Monthly*
Director, Research and Development



Custom Ultrasonics, Inc.
144 Railroad Drive, Ivyland, PA 18974
Tele: 215.364.8577; Fax: 215.364.7674

E-mail: editor@myendosite.com
Internet: <http://www.myendosite.com>

Copyright © 1995-2003. All rights reserved. *It is a violation of federal copyright laws (17 U.S.C. Sec. 101 et seq.) to copy, fax, or reproduce any portion of this newsletter without its editor's consent. Q-Net is a registered trademark of Custom Ultrasonics, Inc.* july03_y11