For: *Infection Control, GI Endoscopy, Operating Room, Instrument Reprocessing, Risk Management, et al.*

The Q-Net™ Monthly

Volume 19, Numbers 1-3 January-February-March 2013

What's News

Visit this newsletter's new interactive infection-control blog at: ►*DiscussionsInInfectionControl.com* This issue marks this newsletter's 19th year of publication. Its main article presents the first in a series of two articles about reusable and disposable tubing systems used to irrigate the GI tract's mucosa during GI endoscopy. This discussion is continued in this newsletter's next issue.

Founder

This newsletter/journal's articles are written by its founder, **Lawrence F. Muscarella, Ph.D.** *Email:* **editor@myendosite.com**

What is 'Q-Net'?

Q-Net is a technology assessment, infection control-based **net**work of **q**uestions, answers, and perspectives. Its newsletter, or journal, 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.

Faulty Use and Reprocessing of a GI Endoscope's Auxiliary Water System

First in a Series of Two Articles about Irrigation during GI Endoscopy

- This article discusses the potential for disease transmission associated with the misuse, faulty setup, and improper reprocessing of an auxiliary water system.
- Featuring a number of reusable components, this auxiliary water system is used to irrigate the gastrointestinal (GI) tract's mucosa during GI endoscopy.
- The second article in this series will discuss "disposable" irrigation tubing sets, which may be used as an alternative to reusable auxiliary water systems. This sequel will discuss the features of these tubing sets, as well as provide recommendations for their safe use.

BACKGROUND: Almost four years ago, in December, 2008, clinicians identified an adverse event at the Veterans Administration medical center (VAMC) in Murfreesboro (TN) that sparked a national discussion about the quality and oversight of health care, infection control, and the safe and effective use of reusable medical equipment.[1-5]

This adverse event prompted the Veterans Health Administration (VHA) —which oversees this VAMC and other VA medical facilities—to publish a patient safety alert on December 22, 2008.[2] Placing emphasis on the importance of training and quality assurance, this alert, among other instructions, enjoined directors to perform audits of their respective VA medical facility and to notify the VHA if they identified any breaches similar to the Murfreesboro VAMC's.

After performing a risk assessment, the VHA on February 9, 2009, notified 6,387 patients who underwent colonoscopy at the Murfreesboro VAMC of this adverse event.[1] On this same day, the VHA also issued a directive that provided VA medical facilities with procedures to design and implement "a systematic approach" for the proper setup, use, and reprocessing of reusable medical equipment.[3]

(Continued on page 2)

TABLE OF CONTENTS

(Continued from page 1)

Four months later, on June 16, 2009, the VA's Office of Inspector General (VA-OIG) published a comprehensive, if also fault-finding, report that—based on a number of recently confirmed infection-control breaches including those of the Murfreesboro VAMC[†]—concluded that a number of VA medical facilities have been lax and have not complying with directives about the reprocessing of flexible endoscopes, resulting in "a risk of infectious disease to veterans."[1]

Figure 1 displays the proper setup of the Olympus auxiliary water system,[1] which is used to irrigate the GI tract during GI endoscopy.

THE MURFREESBORO VAMC'S ERRORS: An adverse event whose cause apparently had not been previously reported, clinicians noticed blood in the GI endoscope's accompanying auxiliary water system (Olympus America[††]) while performing colonoscopy at the Murfreesboro VAMC.[1] The primary function of this auxiliary water system is to irrigate the GI tract's mucosa during GI endoscopy. An investigation determined that for as many as 5 years, from 2004 until December, 1, 2008, when this breach was detected, this VAMC had been misusing and improperly reprocessing some of this auxiliary water system's reusable components.[1]

More specifically, one of this auxiliary water system's components—the Olympus MAJ-855 Auxiliary Water Tube, referred to herein as the "AWT"[1]—is intended to be fitted and used exclusively with a green, double-winged, *one-way* valve, whose purpose is to ensure the *uni*-directional flow of water (or, for example, saline, either of which is usually sterile) during irrigation, from the water bottle into the GI tract (via the GI endoscope's auxiliary water channel). **Figure 1** displays the Olympus auxiliary water system,[††] with the AWT properly fitted with this valve. This figure's green arrows indicate the *correct* direction of the irrigant's flow.

Confirm that the auxiliary water system is being used correctly, fitted with a one-way valve.

Entitled "Proper Setup of the Auxiliary Water System," **Box A** discusses this auxiliary water system, its proper use and setup, and the reprocessing requirements of its individual components, as applicable. The AWT's one-way valve is critical because (the Olympus) GI endoscope's auxiliary water channel does not itself feature an internal valve to prevent the backflow of potentially infectious materials and fluids.

Instead of using the AWT as intended by its manufacturer, with the requisite one-way valve fitted firmly in place, however, the Murfreesboro VAMC unwittingly modified this water tube, accidentally fitting it with a similar looking—but an incorrect—green, single-winged *two-way* connector (that is designed to be used with the Olympus MH-974 washing tube— *not* the AWT).[1] The improper fitting of the AWT with this wrong connector—this error is displayed in **Figure 2**—unintentionally facilitated that which the AWT's one-way valve is specifically intended to prevent: the backflow of potentially infectious materials and fluids (*see:* the black arrows in **Figure 2**), from the patient's GI tract (which was, at times, at a higher pressure) into the auxiliary water system (due to it being, at times, at a lower relative pressure) via the GI endoscope's auxiliary water channel.[1,2] As a result of this mix-up, blood flowed retrogradely into the auxiliary water system,

(Continued on page 4)

At a Glance: Part 1: The Auxiliary Water System

- **BACKGROUND:** In 2008 and 2009 a number of infection-control breaches were identified at two Veterans Affairs medical centers (VAMCs).
- **BREACHES:** The misuse and improper reprocessing of the Olympus auxiliary water system were among the identified breaches at these two VAMCs. Used for irrigation of the gastrointestinal (GI) tract during GI endoscopy, this water system includes, among other components, the auxiliary water tube ("AWT"), the GI endoscope's auxiliary water channel, and a water bottle.
- **INFECTION RISK:** As a result of the breaches identified at these two VAMCs, 9,647 affected patients were notified of the potential for disease transmission.
- **PROPER SETUP:** Crucial to prevent disease transmission, the proper setup, use and maintenance of this auxiliary water system are discussed and displayed.
- **REUSABLE vs. "DISPOSABLE":** Instead of using this auxiliary water system, some medical facilities may use instead a "disposable" tubing set for irrigation of the GI tract via the GI endoscope's auxiliary water channel.
- **NEXT ISSUE—PART 2:** These "disposable" irrigation tubing sets are the focus of the second article in this series, which will provide some guidance for their safe use, along with a discussion of their designs and features. ■

[†] Some additional aspects of the Murfreesboro VAMC's infection-control breach are also discussed in this newsletter's: (*i*) April-May-June, 2010, and (*ii*) January-February-March-April, 2011, issues, both of which the reader is requested to study.

[††] Although it focuses on the auxiliary water system used with those models of GI endoscopes by Olympus America that feature an auxiliary water channel, this article's discussions may also be applicable to similar water systems used with the GI endoscopes of other manufacturers, including Pentax and Fujinon. Nevertheless, this article's discussion is limited to those water systems that connect to the GI endoscope's auxiliary water channel.

Box A. *Proper Setup of the Auxiliary Water System*

❍

The proper setup and maintenance of the GI endoscope's accompanying auxiliary water system are crucial to performing GI endoscopy safely. Featuring a conduit of tubes, accessories, and connectors, as well as a water bottle and flushing pump, this system—which is displayed in **Figure 1**—is used to irrigate the patient's gastric and colonic mucosa for the purpose of enhancing visibility.

When the auxiliary water system is used properly, with the auxiliary water tube (AWT) correctly fitted with its *one-way valve*, water (pressurized by the flushing pump) flows in one direction (*see:* the green arrows in **Figure 1**), from a water bottle into the patient's GI tract. Discussed in this newsletter's main article, contamination of the auxiliary water system can pose an increased risk of infection.[1,2,5]

In contrast, **Figure 2** displays the Murfreesboro VAMC's *faulty* setup of this auxiliary water system, with the AWT having been inadvertently fitted with a *two-way connector*, which facilitated the backflow of blood from the patient's GI tract into the AWT resulting in its contamination.

Some of this auxiliary water system's components are reusable requiring reprocessing after each use, while others are reposable and may require being discarded and replaced daily sans reprocessing.[1] None of this system's components are disposable, however, as defined in **Box B**, which also provides the definitions of *reusable* and *reposable*. Displayed in **Figure 1**, the individual components of the auxiliary water system, along with their reprocessing instructions, are, in sequence:

1. *the Olympus MAJ-855 auxiliary water tube (AWT)*: One end of this tube connects via a port to the GI endoscope's auxiliary water channel, which is also a component of this system.

– The AWT and the auxiliary water channel are both reusable, supplied non-sterile and require reprocessing before their initial use and after *each* procedure, no matter whether the auxiliary water system was used;[1,2]

2. *the Olympus OFP Filter*: This is a particulate water filter, one side of which connects to the AWT's other end (which is fitted with the one-way valve);

3. *the short Olympus OFP Irrigation Tube* (named herein and in the main article as the "SIT"): One end of this tube connects to the other side of the OFP Filter.

– Both the SIT and the Olympus OFP Filter are reposable and labeled for *single-day* use (i.e., may be used on multiple patient during the day) without being reprocessed (*see*: **Box B)**. Both components are discarded at the end of the day, supplied non-sterile, and require steam sterilization prior to their initial use;[1,2] and

4. *a water bottle (and cap)*: Into this water bottle is fitted the SIT's other end (the SIT also passes through a flushing pump), and this bottle is filled typically with sterile water.)

– The reusable water bottle requires sterilization prior to its initial use. It is not reprocessed throughout the day (*see:* **Box B**), but is steam sterilized prior to its use the next day (or, if disposable, it is discarded daily).[1,2] ■

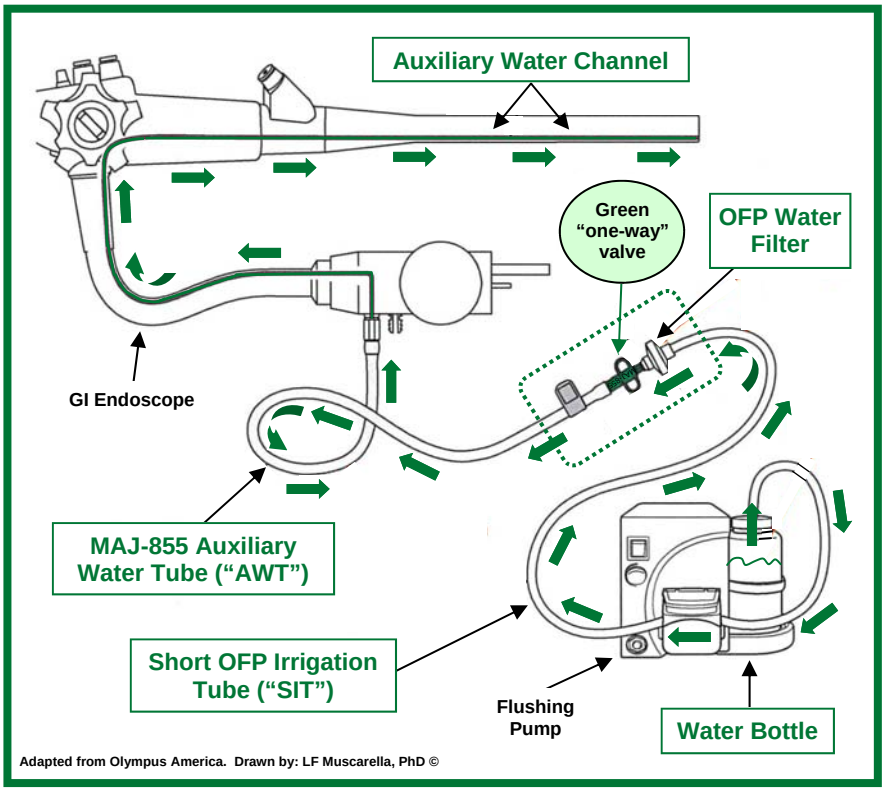

Figure 1: *The Olympus Auxiliary Water System.* Displayed are the proper setup and the components of the Olympus auxiliary water system, with the green arrows indicating the correct, forward direction of flow. The MAJ-855 auxiliary water tube (AWT), which is approximately 4-foot in length, is intended to be fitted and used only with the displayed green, double-winged *one-way* valve, which prevents blood and other materials in the GI tract from flowing backwards and contaminating this system. Box and labeled with green text, this system's components are reused during the day, but each is not necessarily reprocessed after every procedure (*see:* **Box A**).

(Continued from page 2)

posing an increased risk of exposing the 6,387 affected patients to bloodborne pathogens, including HIV and the hepatitis B (HBV) and C viruses (HCV).[1,2]

Displayed in Figure 2, using the auxiliary water tube (AWT) improperly fitted with a two-way connector can facilitate this tube's contamination.[1,2]

Other breaches in Murfreesboro: The investigation of this error also determined that the Murfreesboro VAMC had been reprocessing the AWT only *once* at the end of the day—*not* after each patient procedure as would be *especially* required of an AWT that had been improperly fitted with a two-way connector. Discussed in **Box A**, the AWT is reusable and required by its labeling to be reprocessed after each use.[1]

Reprocessing is not indicated for every one of the auxiliary water system's reusable components, however. Some, like the Olympus OFP (water) Filter, which is displayed in **Figure 1**, are labeled instead to be replaced and discarded daily.[1] This newsletter labels these types of components, which are reused without being reprocessed, as *reposable*, or *single-day*, devices. The definitions of a *reposable* device, along with a *reusable* and *disposable* device, are provided in **Box B**, for clarity. (None of the auxiliary water system's components are labeled as *single-use*.)

Confirm that the auxiliary water tube (AWT) is being reprocessed after each GI endoscopic procedure, to prevent the potential exposure of patients to blood and other infectious materials.

A third breach, investigators also determined that the Murfreesboro VAMC had been reusing from one day to the next both the Olympus OFP Filter and the Short Olympus OFP Irrigation Tube (referred to herein and in **Figure 1** as the "SIT"), instead of having discarded both at the end of the day as their labeling requires (*see:* **Box A**). Each of the Murfreesboro VAMC's confirmed infection-control breaches is listed in **Box C**, and its review by the reader is recommended.[3]

THE MIAMI VAMC'S ERRORS: In response to the VHA's aforementioned patient safety alert (dated December 22, 2008),[2] staff at the VAMC in Miami (FL) performed an audit and, two weeks later, reported on January 5, 2009, that the auxiliary water system's AWT *was* fitted with the correct one-way valve (as displayed in **Figure 1**), without, however, necessarily investigating the possibility of another related reprocessing breach or deviation being performed.[1]

One month later, on February 4, 2009, the VHA issued a memorandum to all VA medical facilities requesting, among other tasks, that each evaluate the competency of its endoscope-reprocessing personnel.[1] (The requirements specified in this memorandum were formalized into the VHA's directive

(Continued on page 5)

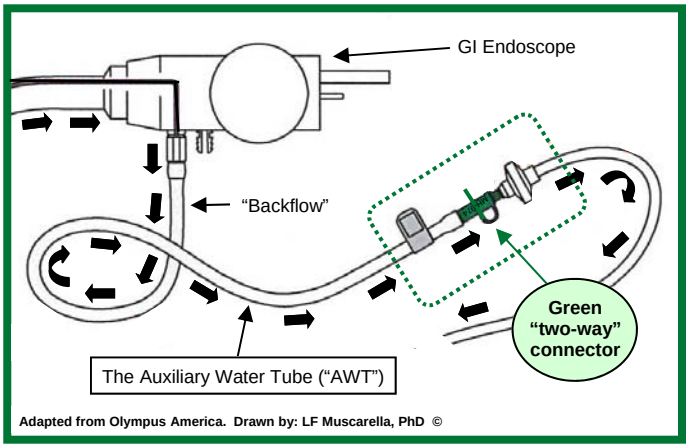

Figure 2. ***Misuse of an Auxiliary Water System.*** Displayed is the Murfreesboro VAMC's faulty use of the Olympus auxiliary water system in 2008, with the approximately 4-foot long MAJ-855 auxiliary water tube (AWT) having been unwittingly fitted, not with the correct *one-way* valve (*see:* **Figure 1**), but with the similar-looking *two-way* connector that is ordinarily fitted into the 10-inch long MH-974 washing tube. The improper use of the AWT with the incorrect connector facilitated the "backflow" of blood from the GI tract (*see:* black arrows) into this water system.

Box B: ***Definitions of and differences between a 'reusable', 'reposable,' and 'disposable' device.***

❍

These definitions, which are provided to avoid confusion, are applicable to this newsletter's main and box articles (but not necessarily to other publications):

- a *reusable device* is designed for reuse on multiple patients, requiring its reprocessing after *each* use (i.e., the GI endoscope's auxiliary water channel and the auxiliary water tube, or AWT; *see*: **Box A**). An exception to this definition, a reusable water bottle is typically reprocessed only once at the end of the day;
- a *reposable, or single-day, device* is labeled for multiple patient uses without being reprocessed, although it is required to be discarded and replaced within a specified timeframe (e.g., within 24-hours). A reposable device is intended for a *single-day's* use, which is distinguished from a *single-use* device. The auxiliary water system's SIT and the OFP water filter are both reposable devices (*see:* **Box A**); and
- a *disposable,* or *single-use, device* is neither reused nor reprocessed, but is discarded after its use on *one* patient. (Per this definition, none of the auxiliary water system's components in **Figure 1** are disposable.) ■

(Continued from page 4)

dated February 9, 2009.[3]) In response to this memorandum (and directive), the Miami VAMC performed a second audit in early March, 2009, and this time it identified two breaches similar to the Murfreesboro VAMC's documented errors.[1]

The second and third articles in this series will provide guidance for the safe use of "disposable" irrigation tubing sets, which may be used as an alternative to a reusable auxiliary water system.

Namely, according to the VA-OIG's report of June, 2009,† staff of the Miami VAMC found during this second audit that, although it was fitted with the correct valve, the auxiliary water system's AWT, for as many as 5 years, had not been reprocessed after each use as required by its labeling, having instead been only flushed or rinsed with (sterile) water.[1] Further, staff determined that clinicians had often not been priming the GI endoscope's auxiliary water system *prior* to colonoscopy, instead connecting the AWT to the colonoscope *after* the procedure was already in progress "in approximately half" of the procedures.[1] The VHA concluded that, coupled together, these breaches posed a "significant" risk of transmitting diseases and, as a result, it notified 3,260 patients of the potential for their exposure to viruses.[1]

Also during this second audit, staff found that, since May, 2004, the Miami VAMC, like the Murfreesboro VAMC, had not been discarding and replacing daily the auxiliary water system's SIT (i.e., the short Olympus OFP Irrigation Tube) or the OFP Filter (*see:* **Figure 1**).[1] And, in late March, 2009, the Miami VAMC identified "debris" in the auxiliary water channel of "reprocessed" colonoscopes.[1] *(Please review this newsletter's October-November-December, 2012, issue).* **Box C** lists each of the Miami VAMC's confirmed infection-control breaches.

Disposable irrigation tubing sets have received attention in part because of the Murfreesboro VAMC's and the Miami VAMC's breaches.[1]

DISPOSABLE IRRIGATION TUBING SETS: The breaches identified at both the Murfreesboro VAMC† and Miami VAMC†—listed in **Box C**, these breaches were assessed by the VHA to pose a clinically significant risk of infection that warranted patient notification—not only bring into focus the importance to patient safety of an otherwise obscure "one-

(Continued on page 6)

† The VA-OIG report of June, 2009,[1] focused on the reprocessing practices not only of the Murfreesboro VAMC and the Miami VAMC, but also of the VAMC in Augusta (GA). According to this report, the Augusta VAMC determined in November, 2008, that it had been improperly reprocessing flexible laryngoscopes for almost a year. This newsletter's April-May-June, 2010, issue provides more details about the Augusta VAMC's breach.[5]

Box C: ***The Murfreesboro VAMC's and Miami VAMC's infection-control breaches: Might disparate reprocessing instructions have been a cause?***

❍

A. The following breaches were identified in December, 2008, at the VAMC in Murfreesboro (TN):[1]

i) the AWT was improperly fitted with a *two-way* connector, instead of the requisite *one-way* valve;

ii) the AWT was not being reprocessed (cleaned and either high-level disinfected or sterilized) after each patient procedure; instead, it was being reprocessed only *once* at the end of the day, despite this tube's potential to have become contaminated; and

iii) the Short Olympus Irrigation Tube ("SIT") and the Olympus OFP (water) Filter were being reused from day to day without being discarded and replaced at the end of the day as required (*see:* **Box A**).[1,2]

B. The following breaches were identified in March, 2009, at the VAMC in Miami (FL):[1]

i) the AWT was not being reprocessed after each patient procedure; instead, it was being flushed or rinsed with water, despite this tube's potential to have become contaminated with blood;[1,2]

ii) the auxiliary water system (which includes the auxiliary water channel) was not always being primed with water prior to GI endoscopy; instead, the AWT was often being connected to the GI endoscope *after* the procedure was already in progress;

iii) the Short Olympus Irrigation Tube ("SIT") and the Olympus OFP (water) Filter were being reused from day to day without being discarded and replaced at the end of the day as their labeling requires; and[1,2]

iv) "debris" was identified in the auxiliary water channel of several "reprocessed" colonoscopes.[1]

Among other considerations, these two VAMCs' infection-control breaches bring into focus an important finding: that the reprocessing requirements of the Olympus auxiliary water system's individual components are neither necessarily self-evident nor the same. According to the VA-OIG (*see:* main article), "different reprocessing instructions for (different) components of the (reusable Olympus) auxiliary water subsystem 'creates confusion'."[1]

Whether this confusion was a primary cause of either the Murfreesboro VAMC's or Miami VAMC's breaches is unclear. No matter, however, such differences between which of the auxiliary water system's components are reprocessed after each use, or once daily; or, which are not reprocessed, but instead are replaced and discarded daily, can, without adequate training, cause user confusion and, as a consequence, an increased risk of error (*see*: **Figure 1**). Whether disposable irrigation tubing sets might be less prone to user error warrants investigation.[4] ■

(Continued from page 5)

way valve," but also raise for discussion whether an alternative system, namely, a "disposable" tubing set for irrigation of the GI tract via the GI endoscope's auxiliary water channel,[†] might be easier to use and reduce the risk of patient harm.

Consideration that use of a disposable irrigation tubing set might reduce the likelihood of a medical facility misusing or improperly reprocessing a component of a reusable auxiliary water system is all the more apt,[††] because if any one factor likely contributed (at least in part) to the breaches confirmed at the Murfreesboro VAMC and Miami VAMC, it might be confusion arising from the disparate reprocessing instructions associated with the individual components of the Olympus (or another manufacturer's comparable) auxiliary water system (*see:* **Box C**). The VA-OIG would seemingly agree, having stated in its aforementioned report of June, 2009, that the "different reprocessing instructions for components of the auxiliary water subsystem 'creates confusion'."[1]

Whether disposable tubing sets might be easier to use and less prone to contamination and disease transmission than reusable auxiliary water systems warrants consideration and discussion.

In brief, the individual components of the Olympus auxiliary water system are associated with *three* different sets of reprocessing requirements (*see:* **Box A** and **Figure 1**):[1] (*i*) the OFP Filter and SIT (and *single-day* water bottles) are reposable (*see*: **Box B** for the definition of "reposable"), requiring daily replacement without reprocessing; (*ii*) the AWT and the GI endoscope's auxiliary water channel are reusable, requiring reprocessing after each procedure; and (*iii*) a reusable water bottle, which requires reprocessing, but only once at the end of the day (not after each procedure). Without adequate training of staff, such dissimilar reprocessing instructions could cause confusion and, possibly, the reusable device's misuse, posing the potential for an increased risk of infection.

What's Next: In summary, this article discusses the misuse and improper reprocessing of an auxiliary water system by the Murfreesboro VAMC and Miami VAMC (*see:* **Box C**), which resulted in the notification of thousands of affected patients of the potential for infection. The VHA and others have published recommendations and actions to prevent such reprocessing breaches, including the instruction to ensure staff are trained and to perform audits routinely.[2,4,5]

Another action—consideration of the appropriateness of using "disposable" tubing sets (for irrigation via the GI endoscope's auxiliary water channel) in lieu of a reusable auxiliary water system[4] (some of whose components, as discussed in **Box A**, require reprocessing)—will be discussed in both the forthcoming second and third articles in this series. In addition to a number of important recommendations that are based on this current issue's discussions and figures, these two sequels will discuss the features, designs, labeling, and common use of these disposable irrigation tubing sets.[†††] ■ **LFM**

(Series continued next month)

[†] This article's discussion applies to the use of disposable tubing sets for the indicated purpose of irrigation of the GI tract via the GI endoscope's auxiliary water channel, not necessarily of irrigation via a flexible endoscope's working, or biopsy, channel.

[††] As mentioned in the VA-OIG's report of June, 2009,[1] two days after the VHA issued its aforementioned directive,[3] dated February 9, 2009, a manufacturer's representative visited the Miami VAMC to recommend replacement of the Olympus auxiliary water system with a disposable irrigation tubing set advertised as comparable.

[†††] This article was written by *Lawrence F Muscarella, PhD*, who has no financial association whatsoever with any manufacturers or distributors of flexible endoscopes or disposable irrigation tubing sets.

References

1. VA Office of Inspector General. Healthcare Inspection: Use and Reprocessing of Flexible Fiberoptic Endoscopes at VA Medical Facilities. Report No. 09-01784-146. June 16, 2009. (pp. 1-45)
2. Veterans Health Administration (VHA). Improper Setup and Reprocessing of Flexible Endoscope Tubing and Accessories. *Patient Safety Alert* AL09-07. December 22, 2008. (pp. 1-7)
3. Department of Veterans Affairs. VHA Directive. 2009-004. February 9, 2009. Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities. (pp. 1-5)
4. Muscarella LF. Recommendations to Prevent HAIs. *The Q-Net Monthly* 2011 Jan-Apr;17(1-4):1-8.
5. Muscarella LF. Patient Safety Concerns in Puerto Rico. *The Q-Net Monthly* 2010 Apr-May-Jun;16(4-6):7-11.

Thank you for your interest in this newsletter, which I founded. *I have addressed each topic to the best of my ability. Respectfully, Lawrence F. Muscarella, Ph.D.*
Please direct all correspondence to:

Lawrence F. Muscarella, Ph.D.
Founder, Publisher of: "The Q-Net™ Monthly"

Website: www.MyEndoSite.com
Blog: *DiscussionsInInfectionControl.com*
Custom Ultrasonics, Inc.
Chief, Infection Control
144 Railroad Drive, Ivyland, PA 18974
Tele: 215.364.8577; **Fax:** 215.364.7674
E-mail: Larry@myendosite.com