A Publication for Infection Control, GI Endoscopy, Instrument Reprocessing, Risk Management, et al.

The X-Net Healthcare Review

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What's News

Welcome to the second issue of *The X-Net Healthcare Review*, which is the sequel to *The Q-Net Monthly*. The focus and format of these two newsletters are the same. These newsletters are associated with two websites. The first is an interactive infection-control blog (EndoscopeReprocessing.com), whereas the second (MyEndoSite.com) features all of these newsletters' back issues.

Founder of 'X-Net'

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

What is 'X-Net'?

X-Net is a technology assessment, infection control-based network of reviews, evaluations, and perspectives. Its newsletter, or journal, is *The* **X-Net** *Healthcare Review*.

The main goal of **X-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.

X-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.

Guidance for the Safe Use of "Disposable" Irrigation Tubing

Recommendations for its safe use during GI endoscopy

The third and final article in a series that discusses disposable irrigation tubing used during gastrointestinal (GI) endoscopy.

- The first article in this series—featured in the January-February-March, 2013, issue of *The Q-Net Monthly*—discussed the potential for infection as a result of, among other infection control lapses, the improper reprocessing of reusable tubing commonly used with an auxiliary water system to irrigate gastric and colonic mucosa during gastrointestinal (GI) endoscopy.
- The second article in this series—featured in the April-August, 2013, issue of *The X-Net Healthcare Review*—discusses the features, designs, labeling, and common uses of "disposable" irrigation tubing, which may be used as an alternative to a reusable auxiliary water system.
- This article herein—the final in this series—provides guidance for the safe and effective use of this disposable tubing used for irrigation during GI endoscopy.

BACKGROUND: This article is the third in a series that discusses the safe and effective use of both reusable and disposable tubing used for irrigation during gastrointestinal (GI) endoscopy.

The first article in this series—"Faulty Use of a Gastrointestinal (GI) Endoscope's Auxiliary Water System"[1]—focused on a well-publicized mishap associated with reusable tubing that is a component of a commonly used auxiliary water system intended for irrigation during colonoscopy. That article—download a copy of it at: *http://www.MyEndoSite.com*—introduced the use of disposable irrigation tubing as an alternative to reduce the risk of this mishap's recurrence during GI endoscopy.

Entitled "Disposable Irrigation Tubing used during GI Endoscopy,"[2] the second article in this series provides a 10-page discussion of this alternative technology, focusing on the features, designs, labeling, and common uses of disposable

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irrigation tubing used during GI endoscopy. Download a copy of this article at: *http://www.MyEndoSite.com.*

GUIDANCE, RECOMMENDATIONS: While its discussion was comprehensive, this series' second article, however, did not provide detailed guidance for the safe and effective use of either disposable irrigation tubing or the irrigation tubing used with reusable auxiliary water systems (e.g., the *Olympus* MAJ-855 water tube). This article—the third in this series—provides this guidance. A review of each of the two previously published articles in this series is recommended.

Whether reusable or disposable, irrigation tubing is routinely used to cleanse the GI tract as may be required to enhance visualization of the mucosa.

Note: Three companies that market disposable irrigation tubing—Byrne Medical (now MediVators), ERBE USA, and US Endoscopy (now a subsidiary of the STERIS Corporation)—participated in the researching and writing of this series of articles, providing this article's author (LFM) with samples and/or photographs of their disposable irrigation tubing and endoscope connectors.

SECTION 1—REUSABLE AUXILIARY WATER SYSTEMS: GI departments that are currently using a reusable auxiliary water system and its associated tubing, flushing pump, water bottle and other accessories—without difficulty, undue inconvenience, or attributable instances of infection—may be inclined to continue doing so, applying the adage that "if it isn't broken, then don't try to fix it." Use of a reusable irrigation system is acceptable, of course, provided, however, that a number of criteria, which are featured in **Table 1**, are met.

Whether disposable irrigation tubing may provide a safe alternative to reusable auxiliary water systems warrants consideration and discussion.

SECTION 2—DISPOSABLE IRRIGATION TUBING: GI endoscopy units that prefer instead to use disposable tubing along with an accompanying flushing pump and water bottle to provide for irrigation during GI endoscopy, however, may appreciate some of this alternative tubing's features. Arguably most convenient, the manufacturers of disposable tubing contraindicate its cleaning and high-level disinfection (or sterilization). Additional guidance for the safe and effective use of disposable irrigation tubing is featured in **Table 1**. ■

***Article At a Glance*: Disposable Irrigation Tubing**

♦ **BACKGROUND**: The first article in this series discusses the faulty use and improper reprocessing of a reusable auxiliary water system used by two Veterans Affairs medical centers to irrigate the gastrointestinal (GI) tract during GI endoscopy. As a result of these breaches, the Veterans Health Administration (VHA) notified almost 10,000 affected patients, in 2009, of the risk of infection.

♦ **DISPOSABLE IRRIGATION TUBING**: The second article in this series focused on "disposable" irrigation tubing, which, along with an accompanying flushing pump and water bottle, functions similarly to, and may be used in lieu of, a reusable auxiliary water system for irrigation of the colonic and gastric mucosa during GI endoscopy.

♦ **GUIDANCE**: Guidance for the safe and effective use of both reusable and disposable irrigation tubing during GI endoscopy is provided in this article, which is the third and final in this series. Use of disposable irrigation tubing with a single-use endoscope connector (equipped with its own, secondary one-way valve to improve quality and safety and to prevent the backflow of blood, fluids and other potentially infectious materials) is a recommended "best practice."

Periodic audits of a GI endoscopy department's practices, policies and procedures are important to optimize and control its quality and safety. Lawrence F Muscarella, PhD, this newsletter's founder, has developed a customizable program specifically designed to prevent healthcare-associated infections (HAIs). Download a copy of this program's brochure at:

► http://www.MyEndoSite.com/literature/Brochure.pdf

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

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Table 1: *Guidance for the safe use of both disposable and reusable irrigation tubing that connects to the GI endoscope's auxiliary water channel.*

❍

I. DISPOSABLE TUBING AND THE REUSABLE TUBING OF AUXILIARY WATER SYSTEMS USED FOR IRRIGATION:

The following guidance is provided no matter whether using disposable tubing or an auxiliary water system's reusable tubing, such as the MAJ-855 auxiliary water tube (or "AWT"; manufacturer: Olympus America), *for irrigation of the GI tract's mucosa during GI endoscopy:*

1. *Confirm* prior to beginning GI endoscopy that the disposable or reusable irrigation tubing:

a. is securely connected to the GI endoscope's auxiliary water channel (via the correct port) and that none of the other connections or fittings of either type of tubing are loose, disconnected, or leaking water;

b. is primed with water (or another type of irrigant);

c. along with the water bottle, is not contaminated with blood or another potentially infectious fluid or material;

Only use disposable or reusable irrigation tubing that is fitted with or otherwise uses a one-way "backflow" valve to prevent the tubing's contamination and patient-to-patient disease transmission due to the backflow of potentially infectious fluids and materials.

d. uses a one-way "backflow" valve (*see: Figure 1 and Figure 2* of the first article in this series[1] and *Figure 1* and *Figure 3* of this series' second article[2]).

- *Do not use* either type of tubing if it is not fitted (or used) with a one-way valve designed to prevent the backflow of potentially infectious fluids and materials that could result in patient-to-patient disease transmission due to the contamination of the tubing (and the water bottle) during GI endoscopy.
  - *Further, do not use* the AWT if it is fitted with a green, *single-winged* connector (that is designed for use with the MH-974 washing tube; *manufacturer*: Olympus America). The AWT's correct one-way valve, although also green, is *double-winged* (refer to *Figure 1* of the first article in this series[1]).
  - If contamination of the tubing or the water bottle is confirmed or suspected, do not use either. Instead, *replace* both with new ones.
  - *Confirm* with the tubing's manufacturer that, under worst-case clinical conditions, the tubing's one-way valve (and, if featured, the one-way valve used with the endoscope connector; *see below*) has been validated to prevent fluid backflow. (Remember that the GI endoscope's auxiliary water channel does not itself feature a one-way valve to prevent the backflow of patient debris.)

2. *Verify* (through documentation and a visual inspection) that the entire GI endoscope, including its auxiliary water channel, is being thoroughly reprocessed (e.g., cleaned and high-level disinfected) after each endoscopic exam.

a. Refer to this link: *http://goo.gl/BTcwK* for instructions by this article's author about how to reprocess the GI endoscope's auxiliary water channel.

3. Re-read the first and second articles in this series.[1,2]

II. REUSABLE TUBING OF AUXILIARY WATER SYSTEMS:

If a GI endoscopy department is safely using a reusable auxiliary water system and tubing (such as Olympus America's reusable *AWT) for irrigation without difficulty, confusion, or having identified any significant errors or instances of disease transmission attributed to this tubing's use, then its continued reuse is suggested. The following additional guidance is provided for a GI endoscopy department using an auxiliary water system with reusable tubing:*

Verify the proper setup of the reusable auxiliary water system prior to each endoscopic procedure.

1. *Review* the reusable auxiliary water system's setup and operating instructions, which is most likely provided along with (or in) the GI endoscope's operator's manual. (Contact the GI endoscope's manufacturer with questions.)

a. *Verify* this reusable auxiliary water system's proper setup and use, in accordance with these operating instructions, prior to each endoscopic procedure.

b. *Ensure and document* the competency and training of those staffers responsible for the daily setup of the auxiliary water system and its reusable tubing.

c. *Confirm* that this auxiliary water system's reusable tubing is being used with the appropriate endoscope connector (e.g., the one provided with the GI endoscope) for proper connection to the GI endoscope.

If using a reusable water bottle, ensure that it is cleaned and either high-level disinfected or sterilized daily (or, if disposable, that the water bottle is discarded at the end of the day, or sooner if emptied).

2. Similarly, *review* the reusable auxiliary water system's reprocessing instructions.

a. *Ensure* that this system's reusable tubing (e.g., the AWT) is being reprocessed (along with the endoscope connector) after *each* endoscopic procedure. (Refer to this link: *http://goo.gl/BTcwK* for instructions about how to reprocess the AWT.)

b. *Discard daily* (sans reprocessing) those components of this reusable water system that are labeled as *single-day* (or "reposable"[1]) items—for example, the short OFP irrigation tube and the disposable water bottle.

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c. If reusable, *reprocess* the water bottle daily.

d. *Ensure and document* the competency and training of those staffers responsible for reprocessing the auxiliary water system's reusable tubing (e.g., the AWT).

Ensure and document the competency and training of those staffers responsible for both the daily setup and the reprocessing of the auxiliary water system's reusable tubing and other components.

Note: *The proper setup, use, and reprocessing of a reusable auxiliary water system, including its tubing, are crucial to the prevention of disease transmission.*

III. Disposable Irrigation Tubing:

Alternatively, a GI endoscopy department may consider using disposable irrigation tubing (along with a flushing pump, a water bottle, and an endoscope connector). Compared to an auxiliary water system's reusable tubing (e.g., the AWT), some staffers may find disposable irrigation tubing to be easier to use, although its cost may be more expensive. Moreover, unlike its reusable counterpart, disposable tubing (as its name suggests) is not reprocessed and, therefore, may be preferred by a GI endoscopy department that does not have access to the resources required to clean and high-level disinfect (or sterilize) reusable irrigation tubing.

1. Even though its reuse on multiple patients may be a common practice,[1,2] this newsletter suggests that GI endoscopy departments consider the feasibility of using disposable irrigation tubing (along with a single-use endoscope connector; *see below*) as a *single-patient* item.

Whether the FDA originally intended "disposable" irrigation tubing to be used only on one patient is not entirely clear, but appears likely.

a. A review of their clearances suggests that the Food and Drug Administration (FDA) may have intended disposable irrigation tubing to be used on one patient only, not reused on multiple patients throughout the day.[1,2] Indeed, this review did not identify any disposable irrigation tubing used during GI endoscopy whose clearance or "indications for use" specify its reuse.[1,2]

b. This review's findings suggest that the labeling on the disposable irrigation tubing's packaging suggesting a multiple-patient-use indication (e.g., a "24-hour use" claim) may not be consistent with the tubing's FDA-cleared indications for use (i.e., single-patient use).[1,2]

2. For those GI endoscopy departments that have determined, however, that to use disposable irrigation tubing only on one patient would be financially prohibitive or is otherwise infeasible, this newsletter suggests that these departments reconsider either using the type of auxiliary water system and reusable tubing discussed in *section II*, above, or discuss with relevant stakeholders the quality and safety of reusing disposable irrigation tubing on multiple patients throughout the day (sans reprocessing).

a. These stakeholders would likely include, among possibly others, the medical facility's risk manager, quality assurance officer, infection control coordinator and the disposable irrigation tubing's manufacturer.

3. The following guidance is provided for those GI endoscopy departments that, after consultation with these stakeholders, decide to reuse disposable irrigation tubing on multiple patients throughout the day:

a. *Contact* the disposable irrigation tubing's manufacturer and confirm that its reuse is not "off-label."

- Discussed in the last issue of this newsletter,[2] the off-label use of a device, while not necessarily unsafe, may shift the legal responsibility associated with the device's use, which is otherwise generally reserved for the device's manufacturer, onto the healthcare provider or facility. (A device's off-label reuse could come under particular scrutiny if the device were associated with an adverse event.)

Reports linking the reuse of disposable irrigation tubing to instances of patient-to-patient disease transmission have not been published.

b. If its manufacturer asserts the safety and regulatory validity of reusing disposable irrigation tubing, then request from it the maximum number of patients on whom its marketed tubing may be reused daily.

c. Download directly from the FDA's website (and keep on file) a copy of the disposable tubing's 510(k) clearance letter (*visit*: www.http://goo.gl/vAJcVF).

- It is acknowledged that, while arguably not a "best practice," the reuse of disposable irrigation tubing on multiple patients throughout the day (e.g., during a 24-hour time frame) has not been publicly linked to any reported instances of disease transmission.
- But it is also acknowledged that while the *potential* for disease transmission due to the faulty use, setup, or reprocessing of an auxiliary water system's reusable tubing (e.g., AWT) has been recently reported (refer to the first and second articles in this series[1,2]), instances of infection attributed to such reusable tubing has not been documented either.
- Moreover, while seemingly inconsistent with the FDA's cleared use of disposable irrigation tubing, its reuse on multiple patients (sans reprocessing) appears ironically to be sanctioned by the FDA.[1,2]

d. *Never reuse* disposable irrigation tubing (or a disposable water bottle) from one day to the next.

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e. *Clarify* with the disposable tubing's manufacturer whether it has filed any medical device reports (or, "MDRs") with the FDA as a result of the potential for patient injury or infection associated with disposable irrigation tubing's reuse on multiple patients. Also, search the FDA's MAUDE database for reported errors.

4. For those GI endoscopy departments that decide to reuse disposable irrigation tubing (fitted with its own primary one-way valve) on multiple patients, this newsletter recommends using this tubing with a *single-use* endoscope connector (sold by the tubing's manufacturer) that itself is designed with, or can be connected to and used with, a (secondary) one-way (backflow) valve.

a. This newsletter recommends using a single-use connector with a one-way valve (that are discarded after a *single* patient's use) as a "best practice" and to improve both quality and safety. (Whereas reusable endoscope connectors sold by the manufacturers of disposable tubing often are not designed with one, these manufacturers' single-use connectors are generally designed with their own one-way valve.[1,2])

Use of a single-use connector equipped with its own one-way valve (to prevent backflow and the tubing's contamination) is a recommended "best practice."

b. Use of disposable tubing with a reusable endoscope connector (which is currently an available option offered by most tubing manufacturers), especially if this reusable endoscope connector is not equipped with a (single-use) one-way valve, is not recommended (unless the endoscope connector is intended and labeled to be reprocessed after each use; *see below*), because of concern that the connector and possibly the disposable irrigation tubing (and the tubing's one-way valve) may become contaminated with blood or another potentially infectious material, posing an increased risk of infection during the tubing's reuse throughout the day.

- If the endoscope connector sold by the disposable tubing's manufacturer is not equipped with one, separately purchase from this manufacturer a single-use, one-way valve (offered as a stand-alone option) that can be manually fitted onto the endoscope connector prior to performing GI endoscopy.

- As with the disposable tubing, it is acknowledged, however, that instances of disease transmission attributed to the use of a reusable endoscope connector (sans reprocessing) sold by the tubing's manufacturer, even if the connector were used without a (secondary) one-way (backflow) valve, have not been documented.

c. Alternatively, it might be permissible to use disposable irrigation tubing with the reusable endoscope connector provided by the GI endoscope's manufacturer.

- It is not advised to "mix and match" such components, however—namely, to use disposable irrigation tubing with the reusable endoscope connector sold by the GI endoscope's manufacturer, unless the endoscope connector's compatibility, safety and effectiveness when used with the disposable tubing has been validated either by the GI endoscope's or the disposable tubing's manufacturer.

The reuse of such disposable items as hypodermic needles and syringes is prohibited and has resulted in patient-to-patient disease transmission.

– Remember that the GI endoscope's manufacturer requires that its reusable endoscope connector (and one-way valve) be reprocessed after each use, whereas the disposable tubing's manufacturer contraindicates the reprocessing of its reusable connector (and tubing).

d. Do not reuse an endoscope connector (or other item) whose packaging states it is a "single-use item."

IV. Miscellaneous Recommendations:

1. *Ensure* that other types of "disposable" items used during GI endoscopy—for example, hypodermic needles and syringes, intravenous (IV) tubing sets, single-dose medicine vials, and sterile medical gloves—are used only on one patient and are then promptly discarded.

a. The reuse of these items can result in disease transmission with associated patient morbidity.

2. *Confirm* that any types of "channel adapters" that might be used with this disposable tubing to provide for irrigation via the GI endoscope's working (or instrument) channel are used only on one patient and are then discarded, in accordance with the adapter's instructions.

The FDA is respectfully requested to clarify its definition of "disposable" at it applies to disposable irrigation tubing (e.g., does it define a single-day item?).

a. Although not a focus of this review, this type of a channel adapter might be used if the GI endoscope's model does not feature an auxiliary water channel. (The disposable tubing might also be instead connected to the GI endoscope's biopsy port inlet for irrigation.)

b. The auxiliary water system's reusable tubing is not intended or labeled for irrigation via the GI endoscope's working channel—only via its auxiliary water channel.

3. If using hybrid tubing, namely, disposable tubing designed to supply water from a single water source (i.e., bottle) both to the GI endoscope's air/water channels (for lens cleaning) and to its auxiliary water channel (for irrigation of the GI tract's colonic or gastric mucosa):

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a. *Confirm* that the tubing's segment that connects to the GI endoscope's air/water channels, like the segment that connects to its auxiliary water channel, features a one-way valve (unless, perhaps, if the air/water valve of the GI endoscope's air/water system has been validated to prevent the backflow of potentially infectious materials for all models of GI endoscopes with which the disposable hybrid tubing may be used).

4. *Review* the differences between this newsletter's definition of a *disposable*, *reusable*, and *reposable* device, which is provided in the first article in this series.[1,2]

5. *Review* each of the following related documents:[1,2]

a. the Veterans Health Administration's (VHA) patient safety alert, entitled "Improper Setup and Reprocessing of Flexible Endoscope Tubing and Accessories," dated December 22, 2008, which may be read at: http://goo.gl/o4Vxj;

b. the VHA's directive entitled "Use and Reprocessing of Reusable Medical Equipment in Veterans Health Administration Facilities," dated February 9, 2009, which may be read at: http://goo.gl/4pq7l; and

c. the first article in this series, which may be downloaded at: http://goo.gl/n8kXT

A review of this newsletter's definition of a disposable, reusable, and reposable device is emphasized.[1]

6. The FDA is requested to clarify for GI endoscopy departments and manufacturers:

a. the Agency's definition of "disposable" at it applies to disposable irrigation tubing (e.g., did the FDA intend this type of disposable irrigation tubing to be a single-patient or single-day item?).

- This newsletter defines "disposable" as a single-use device and "reposable" as a single-day device that does not require reprocessing after each use;[1]

b. precisely how the Agency intended disposable tubing used for irrigation during GI endoscopy to be marketed (i.e., as a single-use or multiple-use item); and

c. whether the Agency countenances the reuse of disposable irrigation tubing during GI endoscopy, the tubing's FDA-clearances notwithstanding.[2]

7. Additional research into the safety of disposable irrigation tubing and its reuse is recommended. ■ [The End]

All articles in this series written by Lawrence F Muscarella, PhD.

REFERENCES:

1. **Muscarella LF. Faulty use of a GI endoscope's auxiliary water system. *The Q-Net Monthly* 2013 Jan-Mar;19(1-3):1-6.**
2. **Muscarella LF. "Disposable" irrigation tubing used during GI endoscopy. *The X-Net Healthcare Review* 2013 Apr-Aug; 19(4-8):7-16S$_2$.**

A New Blog: Lawrence F Muscarella, PhD, recently founded the on-line blog "*Discussions in Infection Control*." In addition to infection control, this comprehensive and interactive blog—which may be read at: http://**EndoscopeReprocessing.com**—focuses on GI endoscopy, other flexible endoscopic disciplines, root cause analyses, and risk assessments. This blog is the most comprehensive of its type in the world.

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► http://www.MyEndoSite.com/literature/Brochure.pdf

Series of Three Articles: This is the third in a series of articles that discusses the use during GI endoscopy of both reusable and disposable irrigation tubing. It is recommended that readers review the first two articles in this series, to ensure that this article herein is read in the proper context. Each of the three articles in this series are available for downloading at:

http://myendosite.com/newsletter-archives/2013-newsletters/

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

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