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 first issue of *The X-Net Healthcare Review*. Because it is the sequel to *The Q-Net Monthly*, which had been in publication for almost 20 years, this new medical newsletter begins its first issue on page 7, picking up right where *The Q-Net Monthly's* last issue (Jan-Feb-Mar, 2013) left off. The format and focus of these two newsletters are the same.

Founder of 'X-Net'

This medical newsletter'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 interactive reviews, evaluations, and perspectives. Its newsletter 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 the quality of care by not only asking good questions but also by expecting well referenced, evidence-based responses.

X-Net focuses on the interests of the *healthcare practitioner*, whose goal is to provide quality care; the *patient*, who deserves safe and affordable care; and the *manufacturer*.

"Disposable" Irrigation Tubing Used During GI Endoscopy

A Discussion of its Features, Designs, and Labeling

Second in a series of articles that discusses the features, designs and labeling of 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 disease transmission due to the improper reprocessing of reusable irrigation tubing, among other infection control breaches. This tubing is part of a reusable auxiliary water system commonly used for irrigation during GI endoscopy.

► This article—the second in this series—focuses on "disposable" irrigation tubing and the connectors that attach this tubing to the GI endoscope (via a port). Along with a flushing pump and water bottle, this tubing may be used for irrigation as an alternative to a reusable auxiliary water system.

► The third article in this series, which will be published soon, will provide detailed guidance for the safe use of disposable tubing.

INTRODUCTION: Entitled "Faulty Use of a Gastrointestinal (GI) Endoscope's Auxiliary Water System,"[1] the first article in this series—download a copy at: *http://www.MyEndoSite.com*— discusses the potential for disease transmission associated with several infection-control breaches confirmed at the two Veterans Affairs Medical Centers (VAMCs) in Murfreesboro (Tennessee) and Miami (Florida), in 2008 and 2009, respectively.

Table 1 (*below*) summarizes that article's focal points.[1]

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As a result of these infection-control breaches, along with those contemporaneously identified at the VAMC in Augusta (GA), the Veterans Health Administration (VHA), in 2009, informed almost 10,000 affected patients of their potential exposure to bloodborne viral diseases during flexible endoscopy.[2] These breaches received national attention in 2009 and, as the reader may recall, were not only the primary focus of an investigative report published by the *Veterans Affairs Office of Inspector General* (VA-OIG),[2] but also were the subject of a congressional hearing in Washington, DC.[3]

REUSABLE AUXILIARY WATER SYSTEM: The several infection-control breaches identified by the VHA at these two VAMCs are listed in *Box C* of the first article in this series.[1] One of these breaches—the improper reprocessing of a reusable component of an auxiliary water system (*manufacturer*: Olympus America),[2] namely, the *MAJ-855 auxiliary water tube*, (or, "AWT")—was identified at both of these VAMCs.

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

Like comparable systems sold by other manufacturers for the same intended use, this reusable auxiliary water system provides for the irrigation of the gastric and colonic mucosa exclusively via the gastrointestinal (GI) endoscope's auxiliary water channel. On occasion, such irrigation may be necessary to remove patient materials and debris, enhance visualization, and provide for the proper diagnosis and treatment of disease.

In addition to the GI endoscope's auxiliary water channel itself, this reusable auxiliary water system features the reusable AWT and other tubing; connectors; a water pump; and a water bottle (it may also feature a particulate water filter).[1] Another of this system's tubing is the *short OFP irrigation tube* (or, "SIT"[1]), which, along with the water bottle, this article defines as "reposable" (i.e. a *single-day* item).[†] The proper setup and use of this reusable system are discussed in the first article in this series (refer to its *Box A* and *Figure 1*).[1]

Despite the AWT (which is approximately 4-foot in length) being designed for use with a one-way valve whose primary function is to prevent this tubing's contamination due to the "backflow" of potentially infectious patient materials and fluids during GI endoscopy, its manufacturer nonetheless labels the AWT to be reprocessed—that is, cleaned and either high-level disinfected or sterilized—after *each* GI endoscopic exam, apparently to further mitigate the potential risk of this tubing's becoming a source of cross-infection.[1,2]

[†] Whereas this series of articles defines "disposable" items as those that are used on *one* patient and are then discarded (e.g., disposable biopsy forceps), it defines "reposable" items as those that are reused throughout the day on *several* patients and are then discarded (i.e., a *single-day* item), without reprocessing. The definitions of these two terms, along with that of a "reusable" item, are provided in *Box B* of the first article in this series, on its p. 4.[1]

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

- **BACKGROUND**: The first article in this series discussed the faulty use and improper reprocessing of a reusable auxiliary water system by two Veterans Affairs medical centers (VAMCs) in Murfreesboro (TN) and Miami (FL). As a result of these breaches, the Veterans Health Administration (VHA) notified almost 10,000 affected patients, in 2009, of the risk of cross-infection.
- **IRRIGATION:** The second in this series, this article herein focuses 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. Like the reusable water system, disposable irrigation tubing may be used during GI endoscopy to irrigate gastric and colonic mucosa, as may be required to enhance visualization.
- **DISPOSABLE IRRIGATION TUBING**: The aforementioned breaches identified at these two VAMCs in Murfreesboro (TN) and Miami (FL), possibly more than any other recent infection-control misstep in the GI endoscopic setting, draw attention to the use and marketing of disposable irrigation tubing. Whether this tubing may be easier to use and less prone to contamination than its reusable counterpart warrants consideration.
- **DISCUSSION:** This article discusses not only the features, designs, and labeling, but also the common uses of disposable irrigation tubing. This series' next article will provide detailed guidance for this tubing's safe use.

Read a shorter version of this article in Dr. Muscarella's blog: www.EndoscopeReprocessing.com

INFECTION-CONTROL BREACHES: The improper reprocessing of the reusable (MAJ-855) AWT by both the Murfreesboro VAMC and Miami VAMC was a salient lapse (*see:* **Table 1**).[1] But the associated infection-control breach that received the most attention and discussion was the former VAMC's inadvertent use of the AWT fitted with—not the correct one-way valve (with which its manufacturer designed the AWT to be used)—but a similarly colored and shaped, although improper, two-way connector (also manufactured by *Olympus America*) that is intended to be used with another reprocessing accessory: the *MH-974 washing tube* (which is approximately 1-foot in length).[1]

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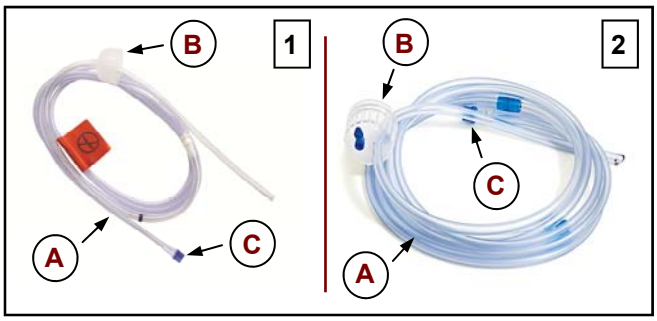

Figure 1. ***Disposable irrigation tubing.*** Disposable irrigation tubing marketed by two manufacturers for use during GI endoscopy are displayed. The tubing ("**A**") features a threaded cap ("**B**") (with a vent for air displacement) for a secure connection to a water bottle. Embedded into the tubing's other end is a permanent (primary) one-way valve ("**C**"; *also see:* **Figure 3**). An endoscope connector, which is not displayed in this figure—but three brands of which are displayed in **Figure 4**—is used to attach this tubing's end to the GI endoscope's auxiliary water channel via a port. (According to some manufacturers, this tubing ["**A**"] may also be used with an single-use adapter that may connect to the GI endoscope's biopsy port to achieve enhanced irrigation via the wider working channel.) The endoscope connector may be single-use or reusable, and if the former, is typically designed with its own (secondary) one-way valve. Activation of a flushing pump (*see:* **Figure 2**) causes water from the water bottle to flow through this tubing ("**A**") for irrigation of the GI tract's mucosa. (These two images are printed with the permission of their respective manufacturer.)

Figure 2. ***Flushing pump and water bottle.*** Whereas **Figure 1** displays only the disposable tubing, this figure displays two accessories used with this tubing, which is also displayed: an original equipment manufacturer's (OEM's) flushing pump and a water bottle, which are both purchased separately. (This photograph is printed with the permission of *Olympus America*.)

Figure 3. ***Disposable irrigation tubing's one-way valve.*** Displayed is an example of a one-way (primary) "backflow" valve that is embedded into one of this disposable irrigation tubing's two ends. An endoscope connector attaches to this end, connecting the tubing to the GI endoscope. This valve is intended to prevent both the tubing's contamination and water siphoning.

Table 1: *A summary of the first article in this series, which is entitled "Faulty Use of a GI Endoscope's Auxiliary Water System."*[1]

- Each of the several infection-control breaches that were identified in 2008 and 2009 at the two VAMCs in Murfreesboro (TN) and Miami (FL) is discussed.[1-6]
  - The Veterans Health Administration (VHA) notified approximately 10,000 affected patients of the potential for these breaches to have exposed each to potentially infectious viruses during colonoscopy.[1,2]
  - One of these breaches was the Murfreesboro VAMC's improper setup of the reusable auxiliary water system (manufacturer: *Olympus America*).[1,2]
    - More specifically, this VAMC inadvertently fitted this water system's auxiliary water tube, or "AWT," with a two-way connector that facilitated this tubing's contamination with blood. This misstep is displayed in a figure in the first article in this series.[1,2]
    - A figure of the reusable auxiliary water system's (*Olympus America*) proper setup is displayed.[1,2]
    - Further, this VAMC also failed to reprocess this AWT after each procedure, as required.[1,2]
  - Another of these confirmed breaches was the Miami VAMC's similar failure to clean and high-level disinfect (or sterilize) the reusable AWT after each GI procedure (again, as required by its manufacturer).[1,2]
- Discussed is which of this reusable water system's components (*Olympus America*) do, and do not, require reprocessing after each use.
  - While each of this auxiliary water system's components is reusable, several are not labeled to be reprocessed after each use, which can be confusing.[2]
- The use of disposable irrigation tubing in lieu of a reusable auxiliary water system is discussed.[1]
- The definitions of a *reusable* device, a *reposable* device, and a *disposable* device are provided.[1] ■

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Displayed in the first article in this series,[1] this mix-up by the Murfreesboro VAMC facilitated the contamination of the AWT, due to the confirmed backflow of blood during colonoscopy. (This backflow would have reasonably been prevented if the AWT had been fitted with the correct one-way valve.[2]) As a consequence of the AWT's contamination—coupled with this VAMC's reprocessing of this tube only once at the end of the day, not after each GI procedure as its manufacturer requires (*see:* **Table 1**)—the VHA notified 6,387 affected patients of the potential for an increased risk of infection with bloodborne pathogens during colonoscopy.[1-3]

The different reprocessing instructions that are associated with different components of a reusable auxiliary water system may cause confusion.[2]

DISPOSABLE IRRIGATION TUBING: The improper reprocessing of the auxiliary water system's reusable AWT by the two VAMCs in Murfreesboro and Miami necessarily introduces for discussion whether disposable tubing might be a safe alternative for irrigation during GI endoscopy (*see:* **Table 1**).[2] According to the VA-OIG, "different reprocessing instructions for components of the auxiliary water subsystem creates confusion."[1,2] Two brands of "disposable"† irrigation tubing with the potential to reduce some of this confusion are displayed in **Figure 1**. Two accessories that are used with this tubing, but that the healthcare provider would purchase separately, are a flushing pump and a water bottle (*see:* **Figure 2**).

Like the reusable auxiliary water system marketed by *Olympus America* (and comparable ones marketed by other manufacturers), disposable tubing is intended for the irrigation of colonic and gastric mucosa via the GI endoscope's auxiliary water channel,[2] although some manufacturers of this tubing may advertise its use, with a single-use adapter, for irrigation via the wider working channel if, for example, the GI endoscope is without an auxiliary water channel.††

But, unlike the reprocessing requirements of the reusable auxiliary water system's reusable AWT, disposable irrigation tubing is not reprocessed. Suggesting that this disposable tubing may be easier and safer to use (than the reusable AWT, which indeed requires reprocessing after each use[2]), at least two of its manufacturers issued statements that singled-out the Murfreesboro VAMC's and Miami VAMC's breaches as validation that reusable irrigation tubing can become contaminated with blood and not be properly reprocessed.[5,6]

Note: Three companies that market disposable irrigation tubing—*Byrne Medical*, now *Medivators; ERBE USA;* and *U.S. Endoscopy* (now a subsidiary of the STERIS Corporation)—participated in this review, providing this article's author (LFM) with samples and/or photographs of their disposable irrigation tubing and endoscope connectors. Each also reviewed a draft of this article for accuracy.

DISCUSSION: This article discusses the features, design, and labeling, as well as the common uses, of disposable

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Table 2: *Some features that different brands of disposable irrigation tubing typically share in common:*

- The use of both a water bottle (e.g., a disposable bottle pre-packaged with sterile water) and a commercially available flushing pump (or electrosurgical unit) (*see:* **Figure 2**). A water filter may also be used.
- Several feet (e.g., 7-8 feet) of tubing (made of, for example, silicone or polyvinylchloride, or "PVC") through which water flows, from the water bottle, into the GI tract via the GI endoscope's auxiliary water channel. (This tubing—*see:* **Figure 1**—may be made of more than one strip of tubing to accommodate the design and operation of the flushing pump.)
- A threaded cap (*see:* **Figure 1**, **"B"**) that is designed to fit securely on the water bottle; features a small air vent; and through which one end of the irrigation tubing (which may be weighted) passes to be submerged in, and through which flows, the bottle's water.
- A one-way valve that is glued into the other end of the tubing to prevent the tubing's contamination with potentially infectious materials and fluids, including blood, due to the "backflow" of potentially infectious materials during GI endoscopy (*see:* **Figure 3**).
- The use of an endoscope connector that connects the irrigation tubing to the GI endoscope's auxiliary water channel via a port (*see:* **Figure 4**).
- Labeling or advertised claims asserting or intimating that this irrigation tubing (*see:* **Table 4**):[13-15]
  - is "disposable" and "sterile";
  - may be used on multiple patients during a 24-hour time frame before being discarded; and
  - is not reprocessed (even though it may be reused on multiple patients throughout the day). ■

† The "disposable" tag associated with its marketing and advertising notwithstanding, whether this type of irrigation tubing is intended for use on a single patient or for daily reuse on multiple patients before being discarded warrants clarification.

†† Although this article focuses on disposable irrigation tubing that connects to the auxiliary water channel of Olympus GI endoscopes, its discussions may also be applicable to: (*i*) other manufacturers of GI endoscopes (e.g., Pentax, Fujinon); *(ii)* other types of tubing and systems that may be similarly used for irrigation during GI endoscopy; and *(iii)* irrigation achieved using the GI endoscope's working channel (which may be performed, for example, if the GI endoscope is without an auxiliary water channel).

Periodic audits of a GI endoscopy department are necessary to optimize and control its quality and to ensure patient safety. Lawrence F Muscarella, PhD, this newsletter's founder and editor-in-chief, has developed a customizable program that is specifically designed to prevent infection control breaches. Download a copy of this program's brochure at:

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

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irrigation tubing used during GI endoscopy. For the readers convenience, this discussion, which is sectionalized, is summarized in **Table 3**. Guidance for the safe use of this type of tubing is featured in the next issue of this newsletter.

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

SECTION 1—COMMON FEATURES: Several companies market disposable irrigation tubing and its accessories to GI endoscopy departments. An alternative to reusable auxiliary water systems (such as *Olympus America's*) for irrigation via the GI endoscope's auxiliary water channel,[†] disposable irrigation tubing is relatively simple to setup and use, and those marketed by different manufacturers share a number of features in common. Several of these features are listed in **Table 2**. For instance, this tubing is used with a flushing pump and a water bottle (*see:* **Figure 2**).

Further, whereas near one of its two ends is a threaded cap that is designed to fit securely onto most types of disposable water bottles, embedded into the other end of virtually every manufacturer's disposable irrigation tubing is a one-way (primary) valve[††] intended, in part, to prevent the tubing's contamination due to the backflow of potentially infectious materials and fluids during GI endoscopy (*see:* **Figure 3**).[1] (Some earlier designs of this type of tubing may not have included this one-way backflow valve.) This valve is also designed to prevent water from leaking from the irrigation tubing whenever this tubing is disconnected from the GI endoscope (e.g., at the end of the endoscopic exam).

External audits of a GI endoscopy department are important to improve its quality and safety. Visit this link for more information: http://ow.ly/nIEmK

This type of tubing is universally marketed as "disposable." By virtue of this moniker, therefore, this tubing—most certainly, unlike the reusable auxiliary water system's AWT, which requires reprocessing after *each* GI endoscopic procedure—is not designed (or labeled) to be reprocessed. While its uses, labeling and designs are similar, however, there are a few features that may differentiate one manufacturer's disposable irrigation tubing (used during GI endoscopy) from another's (*see*: **SECTION 4**, *below*).

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Figure 4. ***Endoscope (port) connectors.*** The endoscope connectors marketed by three different manufacturers are displayed. Each of these connectors is intended for single-use and is manufactured with a one-way (secondary) valve, which is primarily designed to prevent contamination of the disposable tubing and its own embedded (primary) one-way valve during GI endoscopy. Manufacturers of disposable irrigation tubing may also market reusable (i.e., "24-hour use") endoscope connectors that are generally designed without a one-way valve, but to which can be attached a separately purchased, single-use one-way valve.[8,9] No matter whether single-use or reusable, the endoscope connector connects the disposable tubing (*see:* **Figure 1**), to a port that feeds directly into the GI endoscope's auxiliary water channel. In general, these endoscope connectors are accessories that are purchased separately from the tubing. (These images were printed with the permission of their respective manufacturer.)

— **Image #1** displays Byrne Medical's (now Medivators) single-use endoscope connector with a valve.

— **Image #2** displays ERBE USA's single-use endoscope connector with a valve.

— **Image #3** displays U.S. Endoscopy's (this company is not a subsidiary of the STERIS Corporation) single-use endoscope connector with a valve.

[†] This review does not, per se, evaluate and compare the performance of disposable irrigation tubing sold by different manufacturers, although differences in this tubing—for example, the internal diameter of one manufacturer's tubing may be narrower than another's—could impact performance by affecting the flow of the water delivered into the GI tract during irrigation.

[††] The purpose of the tubing's one-way valve is the same as that of the reusable auxiliary water tube's ("AWT"), although the former's valve is located in the end of the tubing that connects to the GI endoscope, whereas the AWT's valve is located in the end of the tubing that connects to the short OFP irrigation tube ("SIT"), which is often several feet from the GI endoscope.[1]

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The endoscope connector: Manufacturers of disposable irrigation tubing generally also sell an array of endoscope connectors—which, as their name suggests, connect this tubing to the auxiliary water channel of different models and brands of GI endoscopes (via a port). These connectors are purchased separately from, and are sold as accessories to, the tubing. Depending on the manufacturer, the packaging of these connectors may be labeled† for single-patient use or for 24-hour use (i.e., reuse on patients) sans reprocessing.

Virtually all disposable irrigation tubing features an embedded (primary) one-way "backflow" valve.

Moreover, whereas virtually all single-use endoscope connectors feature a one-way (secondary) valve to reduce the risk of contamination of the tubing, the tubing's embedded (primary) one-way valve, and the water bottle with potentially infectious patient materials and fluids (*see:* **Figure 4**),[7] endoscope connectors promoted†† for reuse on multiple patients throughout the day (sans reprocessing), however, may be designed without a one-way valve (again, depending on the tubing's manufacturer).[8,9] But, on to these reusable connectors manufactured without one, users may manually attach a separately purchased single-use, one-way valve that is removed and discarded after each GI endoscopic procedure.[8,9]

No doubt, the endoscope connector's design and labeling are important considerations. Not only whether it is single-use or reusable, but also whether the endoscope connector is manufactured (or manually fitted) with a one-way (secondary) valve can impact the irrigation tubing's safety, quality and effectiveness. Similarly, whether this tubing is used instead with a single-use adapter that provides for irrigation via the GI endoscope's working channel can, too, have important safety and infection control implications.†††

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† By "labeling," this article refers to any of a manufacturer's published materials that are associated with a device's use (e.g., the device's indications for use, the instructions on its packaging, or information about its use on the manufacturer's website).

†† By "promotion," this article refers to any of a manufacturer's written or stated claims, including those in the device's labeling and on the manufacturer's website, that support or encourage the device's sale, marketing and/or use in a specific manner.

††† This type of disposable tubing was originally cleared by the FDA for irrigation via the GI endoscope's auxiliary water channel (refer to the FDA's clearance: K031773). Nevertheless, this tubing may also be marketed for use with a single-use adapter for irrigation through the GI endoscope's working channel, via the GI endoscope's biopsy port, to provide for a greater volume of water during irrigation (the diameter of the working channel is wider than that of the auxiliary water channel), as may be required of a poorly prepped colon.

Table 3: ***Summary of this article's "Discussion," which is sectionalized for the reader's convenience:***

1. **SECTION 1—COMMON FEATURES OF THE TUBING:**

- No matter its manufacturer, irrigation tubing is used with a water bottle (e.g., a disposable bottle prepackaged with sterile water) and a commercially available flushing pump (or electrosurgical unit), both of which are purchased separately, to provide water during GI endoscopy (*see:* **Figure 2** and **Table 2**).
- One end of the tubing is embedded with a one-way valve primarily to prevent the tubing's contamination due to backflow of blood and other potentially infectious materials during GI endoscopy. Near the tubing's other end is a threaded cap for the water bottle.
- Sold by the tubing's manufacturer, an endoscope connector is used to attach the disposable tubing to the GI endoscope's auxiliary water channel via a port. This connector may be a single-use or reusable item, and, if the former, typically features a one-way valve.
- The tubing and its components (i.e., a one-way valve, the threaded water bottle cap) are not reprocessed after use (although the reusable endoscope connector provided by the GI endoscope's manufacturer, if used with this tubing, requires reprocessing).

2. **SECTION 2—THE TUBING'S ADVERTISED USES:**

- By eliminating reprocessing, disposable irrigation tubing may reduce confusion and the risk of user error.
- The tubing is typically marketed and advertised for multiple-patient uses during a "24-hour" time frame (sans reprocessing; see: **Table 4**).
- In contrast to the tubing, the endoscope connector may be advertised for use on only a single patient.[7]

3. **SECTIONS 3A AND 3B—THE TUBING'S LABELING:**

- Discussed in **Table 5,** disposable irrigation tubing either has been cleared by the FDA as a single-use item or it uses as its predicate device, directly or indirectly, irrigation tubing whose FDA clearance is associated with a single-use claim (*see:* the main article).
- As displayed by a review of each of their FDA clearances, none of the disposable tubing listed in **Table 5** was cleared by the FDA with a "reuse" claim.
- No matter their legal clearances, however, no reported cases of infection during GI endoscopy have been linked to the reuse of disposable irrigation tubing.

4. **SECTION 4—DIFFERENCES BETWEEN THE TUBING:**

- Some differences between different brands of disposable irrigation tubing are discussed (*see:* **Box C**). ■

Box A: *Questions that arise from a comparison of the advertised claims of disposable irrigation tubing to their FDA-cleared claims.*

Three questions, in particular, arise from the advertised claims and uses of disposable irrigation tubing (*see:* **Table 4**). *First, "What is the definition of "disposable"?"* In the context of such devices as hypodermic needles, syringes, medicine vials, and medical gloves, the FDA defines "disposable," of course, as a "single-use" device. The FDA states that "a single-use device, also referred to as a disposable device, (is) intended for use on one patient during a single procedure.[16] The CDC agrees.[12] Certainly, the reuse of such "disposable" devices poses a substantial risk of infection. Irrigation tubing used during GI endoscopy, however, appears to controvert this definition, and, while using the term "disposable" (*see:* **Table 4**), its instructions and brochures do not define it.

Which begets a *second* question: *"On how many patients throughout the day may this type of irrigation tubing be used?"* This is a good question, but one that only the tubing's manufacturer can provide. Primarily because of the cost effectiveness of a single-day item, healthcare providers might reasonably interpret irrigation tubing's advertised claim of "24-hour use," which is commonly promoted (*see:* **Table 4**), to suggest that this tubing (but not necessarily the endoscope connector) is intended for reuse on as many patients as can be treated in a single day, possibly like the water bottle—that is, a *single-day* device, as opposed to a single-*patient* device.

In fact, some of its brochures and websites state that this irrigation tubing may be reused (*see:* **Table 4**).[13-15] In favor of reuse, **Box B** discusses precedents that may argue for this tubing's use as a *single-day* device. As displayed on the FDA's website, none of this type of tubing (*see:* **Table 5**), however, was cleared by the FDA with a "reuse" claim. (For more information, readers may review these tubings' FDA 510[k] clearance letters, which can be accessed via the FDA's website.[17,18])

Third, "Are the advertised claims associated with irrigation tubing necessarily the same as those of the endoscope connector?" The answer is no, although both are associated with only one 510(k) clearance. This tubing and the endoscope connector are typically sold separately as a two-part system,[19] with the tubing being marketed for "24-hour use," but with some endoscope connectors being advertised for "single use only"[7,10] (which raises a *fourth* question: *"Could an endoscope connector's reuse, sans its reprocessing, pose a risk of disease transmission?"*).

There is some evidence to suggest that the FDA may have originally intended both the irrigation tubing and its endoscope connector to be single-use devices.[7,10,17,18] While endoscope connectors may be marketed by a tubing's manufacturer for "24-hour use" (*see:* **Table 4**), too, those sold by the GI endoscope's manufacturer are reusable and labeled to be reprocessed (e.g., cleaned and high-level disinfected or sterilized) after each use. ■

Table 4: *Advertised claims and promoted uses of disposable irrigation tubing; the tubing's endoscope (port) connectors; and of "hybrid" tubing.*[†]

- **The claims of disposable irrigation tubing:**[α]
  - "sterile," "disposable,"[π] 24-hour irrigation tubing";
  - "cost-effective" and can be used "for a day";
  - "multiple patient use";
  - "eliminates manual cleaning and reprocessing";
  - "eliminates time and costs" associated with reprocessing the water bottle and reusable tubing;
  - "fits any sterile water bottle";
  - is equipped with a "backflow valve" that reduces the risk of cross contamination;
  - "provides sterile water from a water source to an endoscope through an irrigation pump";
  - "complies with SGNA guidelines, saves time"; and
  - may be used with a "single-use channel adapter" (when irrigating via the working channel).

- **The claims of the endoscope connector:**[β]
  - "sterile" and "discard daily";
  - "offers a single-use connector";[Φ] and
  - featuring "single use or 24-hour use scope-specific connector accessories."[8,9]

- **The claims of the "hybrid" tubing:**[Ω]
  - "utilizes a single disposable water bottle source";
  - "more cost effective - no need for 2 bottles";
  - "back flow valve reduces risks of cross contamination/infection";
  - "facilitates delivery of fluid from hybrid system for endoscope lens cleaning"; and
  - "facilitates irrigation and lavage of debris within the gastrointestinal tract."

[†] These advertised claims were identified during a review of the internet, company websites, and marketing brochures.[13-15]

[α] The advertised claims of disposable tubing are not necessarily consistent with the content of the tubing's FDA clearances.

[π] The definition of "disposable" is not provided in the instructions for use ("IFUs") that are supplied with the irrigation tubing.

[β] The endoscope connector interfaces the disposable tubing with the GI endoscope's auxiliary water channel via a port.

[Φ] The single-use endoscope connector is typically manufactured with a one-way valve. If reusable, however, the endoscope connector may not be manufactured with a one-way valve.[8,9]

[Ω] This "hybrid" tubing provides water for both irrigation of the GI tract and for lens cleaning via the air/water channels. ■

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Moreover, reusable endoscope connectors do not have to be purchased exclusively from the irrigation tubing's manufacturer. The manufacturer of the GI endoscope (i.e., Olympus America, Pentax and Fujinon), for example, generally equips its models, featuring an auxiliary water channel, with an endoscope connector that, if compatible, may be used with this tubing. Because this endoscope connector is reusable, however, unlike disposable tubing, it requires reprocessing.

Note: While anecdotal, correspondence with stakeholders suggest that the Food and Drug Administration [FDA] might require, sometime in the future, that the endoscope connectors sold by the manufacturers of this type of irrigation tubing both be labeled (and marketed) as single-use items and feature a one-way "backflow" valve.[5,7,10]

This article was written by Lawrence F Muscarella, the founder of this newsletter and of the popular blog "Discussions in Infection Control."

SECTION 2—ADVERTISED USES: Table 4 lists a number of the claims and advertised uses associated with disposable irrigation tubing. This tubing's "disposable" tag notwithstanding, these advertised claims include using this tubing "for a day" and "then throw it away" and, commonly, for "24-hour use," which may be construed by the healthcare provider as these claims suggesting that this tubing was cleared by the FDA for reuse throughout the day. This promoted application is notable because, as previously stated, the manufacturers of this irrigation tubing contraindicate its reprocessing.

Whether or not the endoscope connector features a one-way valve can impact the tubing's quality.

Like reusable auxiliary water systems, however, the use of disposable irrigation tubing may be associated with its own type of confusion. **Box A** discusses some questions that may arise from the marketing of this tubing—for example: *How do the manufacturers of this tubing define "disposable"?* Also discussed in **Box A**, while one of this tubing's selling points is that, by eliminating reprocessing, it can reduce confusion and the risk of user error (*see:* **Table 4**),[2,5,6] precisely how the FDA originally intended this tubing to be marketed and used is unclear. The reuse of some disposable items, like hypodermic needles, syringes, and single-patient medicine vials, is most certainly contraindicated because of this practice's significant risk of infection (see: **Box A**).

SECTION 3A—LABELING: A DEVICE'S INDICATIONS FOR USE: A centerpiece of any 510(k) application, which the manufacturer submits to the FDA prior to marketing a device, is, as much as a description of the device, the device's "indications for use." Formatted as a statement that is featured in a section of the device's submitted labeling, the indications for use include, for example, the device's specific purpose and its target population.[11]

The FDA reviews this submitted application, and if it determines that the device is "substantially equivalent" to another legally marketed device, known as the "predicate" device,[α] the FDA then "clears" the device by way of a letter,[β] granting the manufacturer the legal right to market the device in the U.S. The device's indications-for-use statement, along with its other labeling—for example, the device's instructions for use, or "IFUs"—have important legal implications, defining for the healthcare provider the device's "on-label" (i.e., "correct") use, as opposed to the device's "off-label" use.[ε]

Despite their "disposable" tag, irrigation tubing is usually marketed for "24-hour use," which understandably may be interpreted by the user to be synonymous with a "multiple patient use" claim.

Moreover, the FDA ordinarily requires that the contents of the device's cleared application (e.g., the indications-for-use statement) necessarily be consistent with all of the device's published labeling, advertised claims, and IFUs, because this documentation specifies important details—for example, whether the device is reusable or a single-use item. In general, if a device's labeling does not provide reprocessing instructions, then, by default, the device is a single-use device that is not to be reused or shared among patients.[12]

The off-label use of a medical device, in contrast, is ordinarily one for which the FDA did not specifically clear the device (e.g., the use is not included in the device's indications-for-use statement),[11] and, therefore, while permissible and at times an acceptable medical standard,[11] a device's off-label use may (but does not necessarily) increase legal exposure and the risk of patient harm, shifting liability (in part or totality) from the device's manufacturer to the user, which could be a concern if an instance of patient injury (e.g., disease transmission) were linked to the device.[7]

As one manufacturer aptly writes in the IFU of its irrigation tubing's single-use endoscope connector: "This disposable medical device is not intended for reuse. Any institution, practitioner, or third party who reprocesses, refurbishes, re-

(Continued on page 16)

[α] Or, it could be cleared via a "de novo classification," which provides a regulatory route for low- to moderate-risk devices that are not substantially equivalent to a legally marketed device.

[β] Available on-line, a device's 510(k) clearance letter clarifies the specific indications for which the FDA cleared the device. An example of the clearance letter of a related device, inclusive of the device's indications for use, is available at: http://goo.gl/Gp5xxj

[ε] When solicited, a manufacturer may discuss off-label uses of a device (e.g., for the purpose of education), but it is legally precluded from promoting the device for its use in a manner for which the FDA did not expressly clear it.

Table 5: *Clearances of disposable irrigation tubing.*

Three sections are provided for clearances by the FDA of: (1) tubing that supplies sterile water to the GI endoscope's air/water channels; (2) tubing that provides sterile water for irrigation via the GI endoscope's auxiliary water channel; and (3) "hybrid" tubing that supplies sterile water both to the GI endoscope's air/water channels and to its auxiliary water channel. This list may not be complete.

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I. Two clearances by the FDA of tubing that supplies sterile water from a water bottle to the GI endoscope's air/water channels.[α]

1. ***1997:*** "The Endo SmartCap" is cleared as a "*sterile, single patient use"* device. Its clearance number is K971125, and its predicate (or, substantially equivalent) device is a refillable, reusable water bottle that is designed to be reprocessed at the end of the day.

   – This clearance states that "by replacing a reusable device with a single use, disposable device, the risks associated with cross-contamination—which are inherent with reusable devices—are eliminated."[17]

2. ***2009***: "The Endo SmartCap" is cleared (again). Its clearance number is K093665, and its predicate device is the EndoSmart Cap: K971125 (*see above*).

   – Unlike its predicate device, however, this device's clearance does not describe whether this device is intended for *single-patient* use or for reuse on *multiple patients*, which reasonably suggests that its predicate device's (K971125) *single-patient* claim is in effect.[β]

❍

II. Clearances by the FDA of disposable tubing for irrigation via the GI endoscope's auxiliary water channel.[Δ]

1. ***2003***: "The EndoGator System" is cleared as a *sterile, "single patient use only"* device for connection to the auxiliary water channel of Olympus 160 series GI endoscopes. Its clearance number is K031773, and one of its predicate devices is: K971125 (*see above*).

2. ***2009***: "The EndoGator System" is cleared (again). Its clearance number is K092429, and its predicate device is: K031773.

   – Unlike its predicate device's, however, this device's clearance does not describe whether this device is intended for *single-patient* use or for reuse on *multiple patients* (or whether this device is cleared only for irrigation via the auxiliary water channel, or also via the working channel).[Δ] Reasonably in effect, therefore, is the predicate device's *single-patient* claim.[β]

3. ***2010***: "The ERBEFLOW 2" is cleared. Its clearance number is K103235, and its predicate device is: K092429.

   – Like its predicate device's, this device's clearance does not describe whether this device is intended for *single-patient* use or for reuse on *multiple patients.*[Δ] Reasonably in effect, therefore, is the *single-patient* claim of the predicate device's (K092429) own predicate device (K031771; *see:* II, 2, above).[β]

4. ***2010***: "The Torrent" is cleared. Its clearance number is K103239, and its predicate device is: K092429.

   – Similarly, this device's clearance does not describe whether this device is intended for *single-patient* use or for reuse on *multiple patients*.[Δ] Reasonably in effect, therefore, is the *single-patient* claim of the predicate device's (K092429) own predicate device (K031771; *see:* II, 2, above).[β]

5. ***2012***: "The ClearPath Tubing" is cleared. Its clearance number is K112318, and one of its predicate devices is: K092429. This device is "*single use, disposable*" tubing.[†]

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III. Two additional clearances by the FDA of "hybrid" tubing intended both for irrigation of the GI tract via the GI endoscope's auxiliary water channel and for supplying water via the endoscope's air/water channels.

1. ***2010***: The "The EndoGator Hybrid" is cleared. Its clearance number is K102855, and one of its predicate device is the previously cleared device: K092429.

   – Notably, this clearance's comparative table answers "*Yes (24-hr.)*" to whether this device, along with the EndoGator System (K092429) and the Endo SmartCap (K093665), is a *"single-use*" device.

2. ***2011***: "The ERBEFLOW Clever Cap Hybrid" is cleared. Its clearance number is K103696, and one of its predicate devices is: K092429.

   – The device is described as: "*sterile*" and "*disposable*" with a duration of use of "(*24 hour use*)". Whether the device is intended to be used on only one patient or can be safely reused on multiple patients during this time frame is not clarified. ■

[α] This tubing is not the same as the cleared tubing that, as the focus of this newsletter's main article, is indicated for the irrigation of the GI tract via the GI endoscope's auxiliary water channel (and, possibly, via its working channel).

[β] This clearance does not provide a time frame during which this device may be safely and effectively used (e.g., 24-hours).

[Δ] As displayed on the FDA's website, none of the clearances associated with the listed disposable tubings include a claim for their reuse on more than one patient during any time frame.

[†] The device associated with this clearance may not be like the other tubing listed in this table. This device is cleared for use with the components and accessories of a proprietary system.

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manufactures, resterilizes, and/or reuses this disposable medical device must bear full responsibility for their safety and effectiveness."[7] The healthcare provider's clear understanding of a device's on-label use, therefore, has legal implications and is important to the device's safe and effective use.†

Like reusable water systems, the use of disposable tubing is not entirely without confusion.

SECTION 3B—LABELING: THE TUBINGS' FDA CLEARANCES: A study of disposable irrigation tubing would be incomplete, therefore, if the content of its 510(k) clearances—which provides important information about the tubing's safe and effective use—was not reviewed. Bringing into clearer focus those practices that would define the on-label uses of disposable irrigation tubing, like those of any device, **Table 5** lists the FDA's 510(k) clearances of several of the irrigation tubing currently marketed in the U.S. A comparison of this table's listings with **Table 4** suggests some potential incongruities between this irrigation tubing's advertised claims and its FDA-cleared labeling (e.g., its cleared indications for use).

Displayed in **Table 5**, related tubing that delivers sterile water from a water bottle—not to its auxiliary water channel—but to the GI endoscope's air/water channels was cleared by the FDA in 1997 for "single patient use" (refer to FDA clearance number: K971125). Similar tubing with the same intended use was cleared again in 2009 (refer to FDA clearance number: K093665).

A study of disposable irrigation tubing would be incomplete if the details and content of its 510(k) clearances were not reviewed and discussed.

To be distinguished from these two clearances, **Table 5** shows that disposable tubing intended for irrigation specifically via the GI endoscope's auxiliary water channel—this type of tubing is the focus of this article—was first cleared by the FDA in 2003, also for "*single patient use*" (refer to FDA clearance number: K031773). Listed in **Table 5**, irrigation tubing for this same application was cleared by the FDA, for the second time, in 2009 (refer to FDA clearance number: K092429). Both of these clearances describe irrigation tubing that either has a single-use claim or uses as its predicate device tubing with a single-use claim. Like each of the tubing that the FDA subsequently cleared, however, the documentation of this latter tubing (cleared in 2009), including the indications-for-use statement, does not state whether the tubing is intended for single-patient use or reuse (the importance of such clarification notwithstanding).

Summarizing **Table 5**, this type of tubing (originally intended for irrigation via the GI endoscope's auxiliary water channel), to date, has been cleared by the FDA, either directly or indirectly via a predicate device, with a single-use claim—namely: — as tubing cleared for single-patient use only (i.e., K031773); — as tubing (i.e., K092429) that (lacking the number of patients in its clearance on whom the device is intended) uses, as its predicate device, this latter tubing cleared in 2003 (i.e., K031773), which has a single-patient-use claim; or — as tubing (e.g., K103239) that (also lacking the number of patients in its clearance on whom the device is intended) uses, as its predicate device, irrigation tubing (i.e., K092429) whose own respective predicate device is tubing cleared by the FDA for single-patient use (i.e., K031773).

Suggesting further the possibility that the FDA may have originally intended disposable irrigation tubing to be a single-use item, this review did not identify any such tubing, including those listed in **Table 5**, that was cleared by the FDA specifically for reuse on more than one patient (some of **Table 4**'s advertised clams notwithstanding).

Instances of disease transmission linked to the reuse of this disposable irrigation tubing have not been reported during GI endoscopy.

Three notable observations: Three notable observations arise from this review of the FDA's clearances of irrigation tubing (*see*: **Table 5**): *First*, while the reuse of "disposable" irrigation tubing on multiple patients during a 24-hour time frame (sans reprocessing) is not described in the tubings' FDA-cleared applications (and, therefore, appears to be an off-label use), cases linking this tubing's reuse (consistent with the tubing's advertised claims; *see:* **Table 4**) to specific instances of disease transmission (or another type of patient harm) during GI endoscopy have not been reported.

Second, it is only reasonable to conclude that the FDA is aware that this disposable irrigation tubing is marketed for reuse on multiple patients during a 24-hour time frame. Indeed, claims advertising (or implying) that this tubing can be reused have been available for some time both on manufacturers' websites and in product brochures.[5,8,9,13-15] And, having seemingly not demurred, the FDA appears to have tacitly approbated the reuse of this tubing (but not necessarily of the endoscope connector[7,10]), the tubing's "disposable" tag and clearances notwithstanding (*see:* **Table 5**).

And, *third*, considered in **Box B** is whether there may be precedents that rationalize the reuse of "disposable" irrigation tubing—like the "disposable" water bottle to which this tubing may be connected. Nevertheless, clarification of whether the FDA has indeed concluded that this tubing's reuse is safe, like the FDA's definition of "disposable" vis-à-vis this irrigation tubing, is respectfully requested.

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† The clarity of a device's labeling is paramount. Effective controls by the manufacturer that prevent the device's labeling from being misleading or confusing—examples would include unsubstantiated claims or ambiguous labeling—are crucial to patient safety, as well as to ensure the device is not misbranded.

Box B: *Valid Precedents for Reusing "Disposable" Irrigation Tubing?*

The manufacturer of the reusable auxiliary water system's *MAJ-855 auxiliary water tube* ("AWT") (*Olympus America*) requires that it be reprocessed after *each* use, despite this tube featuring a one-way valve.[1-3] This instruction is most likely a consequence of a concern about the possibility of the deviation identified at the Murfreesboro VAMC (*see:* main article)—namely, the contamination of the AWT due to the backflow of blood during colonoscopy.

Applying the same concern to the disposable irrigation tubing that is the focus of the main article, it would seem that, because manufacturers contraindicate its reprocessing, a fault mode analysis might result in limiting the use of this irrigation tubing to a *single patient*, despite this tubing's featuring, like the AWT, a backflow valve to prevent its contamination. Consistent with this concern, the labeling of the first "disposable" tubing cleared by the FDA for irrigation of the GI tract via the GI endoscope's auxiliary water channel, in 2003, describes the tubing as a "sterile, single patient use" device (*see:* **Table 5**).

Nevertheless, this specific type of irrigation tubing is typically marketed (but not necessarily cleared by the FDA), not for *single*-patient use, but as a *single-day* device (likely for reasons of cost-effectiveness) for the irrigation of *multiple* patients within 24 hours (*see:* **Table 4**). Although the marketing of such a "disposable" device for reuse on multiple patients (without being reprocessed after each use) might seem improper,[16] there are at least two precedents that may provide a rationale to justify the marketing and use of this irrigation tubing as a *single-day* device.

1. A labeling precedent: First, the water bottle used with this reusable auxiliary water system, like the *short OFP irrigation tube* (manufacturer: *Olympus America*), is intended as a *single-day* product that may be reused throughout the day, but with the requirement that this "disposable" bottle be discarded at the end of the day (or, if reusable, the bottle be reprocessed at the end of the day).[1,17] Application of this same *single-day* paradigm to "disposable" tubing used for irrigation via the GI endoscope's auxiliary water system (but not necessarily via its working channel) would argue for its safe reuse on multiple patients (their clearances discussed in **Table 5** notwithstanding).

2. Precedents of a risk-assessment origin: And, second, the report by the VA-OIG (dated June, 2009) that is discussed in the main article notes that sixteen VA medical facilities (other than the Murfreesboro VAMC and Miami VAMC) reported reprocessing breaches after performing audits in response to the VHA's patient safety alert of December, 2008.[2] The breaches of ten of these sixteen facilities involved the improper use and reprocessing of this reusable auxiliary water system's accessories that were "upstream" of the AWT fitted with its one-way valve.[1-3]

According to the VHA, *first*, these breaches could have been due to confusion arising from "the different reprocessing instructions for components of this auxiliary water system—*note:* whereas the reusable AWT requires reprocessing after each procedure, the reusable *short OFP irrigation tube* ("SIT") is to be discarded daily, sans reprocessing; and, *second*, provided that the AWT was properly fitted with this one-way valve, one of the breaches of these ten facilities, namely, their failure to have discarded these "upstream" accessories daily as prescribed by their labeling (e.g., the SIT)[1]—posed a risk of disease transmission that "was so small as to be clinically insignificant."[1-3]

This report by the VA-OIG also notes that the VHA was aware that thirteen of these sixteen VA medical facilities, like the Murfreesboro VAMC and the Miami VAMC, were not reprocessing the AWT after each patient procedure as required. Based on another of its risk assessments, the VHA concluded that *provided*: (a) the AWT is fitted with the proper *one-way* valve; (b) the auxiliary water system, including the AWT and the GI endoscope's auxiliary water channel, is primed (or flushed) with water; and (c) the AWT is connected to the GI endoscope's auxiliary water channel *prior* to beginning (and remains connected during) colonoscopy, then the risk of viral transmission associated with failure to reprocess the AWT after each patient procedure is "clinically insignificant" and, therefore, would not warrant patient notification.[1,2]

These two examples present precedents that might be used by a manufacturer or medical facility to argue reasonably that the use of "disposable" irrigation tubing (with a one-way valve), not necessarily as they were cleared by the FDA (e.g., *single-patient* use), but on multiple patients within, for example, a 24-hour[†] time frame (e.g., *single-day* use) may be safe and would appear not to be an unprecedented practice. Additional research into the safety of disposable irrigation tubing's reuse is recommended. ■

[†] This origin of disposable tubing being marketed for use within a "24-hour" time frame is not entirely clear. Possibly, it is related to the precedent established by those components of the auxiliary water system that are reused throughout the day and are then discarded (e.g., the disposable water bottle).[1]

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: **EndoscopeReprocessing.com**—focuses on GI endoscopy, other flexible endoscopic disciplines, root cause analyses, and risk assessments.

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SECTION 4—IRRIGATION TUBING DIFFERENCES: The features, design, and labeling of different brands of disposable irrigation tubing and its accessories are not all alike. For example, one tubing manufacturer's endoscope connector may be constructed primarily of plastic, whereas another's may contain more durable metal (which is intended to perform better and to be less prone to water leakage).[7,8] Some other differences between the tubing are provided in **Box C**.

CONCLUSIONS: This study of disposable irrigation tubing raises some interesting questions about the marketing, clearances, and uses of medical devices, as well as their regulation by the FDA. Few other examples might display the FDA's apparent countenancing of the reuse on multiple patients of a device whose clearances by the FDA are associated, either directly or via a predicate device, with a single-use claim (*see:* **Table 5**). Not so much between the tubing, but the differences between the design, labeling, and marketing of the endoscope connector, and, too, whether the tubing might be used instead with an adapter for irrigation via the GI endoscope's working channel, provide an opportunity both for circumspection and to enhance both quality and safety.

Guidance for using this disposable irrigation tubing is featured in the next article in this series.

Providing some guidance, GI departments that are using—without trouble, inconvenience, or identified missteps—reusable auxiliary water systems and their tubing may be inclined to continue doing so, applying the adage that "if it isn't broken, then don't try to fit it." The use of these reusable systems is acceptable, of course, provided a number of criteria are satisfied—for example, that the reusable auxiliary water system's AWT (and its accompanying endoscope connector) is reprocessed after *each* use.

GI endoscopy units that prefer to use disposable irrigation tubing, however, whose reprocessing its manufacturers contraindicate, may appreciate some of the conveniences it offers. In closing, more detailed guidance for the safe use of disposable irrigation tubing (as well as of reusable auxiliary water systems) is featured in the next issue of this newsletter. ■ **THE END** [Article by: *Lawrence F. Muscarella Ph.D.*]

REFERENCES: *The references to each of this newsletter's embedded articles, figures and tables are available at:*

http://www.myendosite.com/references/refs04-08-13.pdf

Box C: *Differences between irrigation tubing.*

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As with any technology, disposable irrigation tubing sold by different companies are not all alike. For instance:

- one company's tubing may be cleared by the FDA for *single-patient use*, whereas another tubing's clearance may not indicate the number of patients on whom the tubing may be used (*see:* **Table 5**);
- one company may market its tubing for use with a reusable (i.e., 24-hour use) endoscope connector that does not feature (but that can be retrofitted by the user with) a one-way (secondary) backflow valve,[8,9] whereas another may market its tubing for use with an endoscope connector that is both single-use and manufactured with a one-way (secondary) valve;[7]
- one tubing company's endoscope connector may be constructed primarily of plastic, whereas another's may contain more durable metal (that may perform better and be less prone to water leakage);[7,8]
- one company's tubing may be a more complicated "hybrid" type that delivers water, not just for irrigation (for which this segment of tubing is equipped with a one-way valve), but also to clean the GI endoscope's lens during colonoscopy (for which this segment of tubing may also feature a one-way valve);
- one company's website might state that the marketed tubing can be used on multiple patients,[8] while another's may state that the tubing is intended for "24-hour use,"[9] without, however, specifying precisely on how many patients (i.e., one patient or multiple patients) the tubing may be safely reused; and
- possibly affecting performance, the diameters of one company's tubing may be wider than another's. ■

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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