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

The Q-Net™ Monthly

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What's News

Q-Net's website, whose domain name is *www.MyEndoSite.com*, has been redesigned for your ease of use. Visit it today to download any of this newsletter's previous issues, which are organized by their publication date. Future topics that will be discussed in this newsletter include a discussion of disposable irrigation tubing used during GI endoscopy and the study of arthroscopic infections.

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.

A Legal Case about Improperly Reprocessed Flexible Endoscopes

Verdict: A jury finds a hospital "negligent" for improperly cleaning and disinfecting gastrointestinal endoscopes

- Discussed is a legal case that began in 2005 and focuses on a hospital's improper reprocessing of gastrointestinal endoscopes.
- This legal case was presented to a jury, which this past July found the hospital to be negligent.
- Recommendations to improve quality and prevent infections due to an improperly reprocessed GI endoscope are provided.

BACKGROUND: SPOTLIGHTING THE IMPORTANCE of proper instrument reprocessing as much to the prevention of disease transmission as to a medical facility's quality and management of risk, this past July (2012) a jury in a western Pennsylvania county found a hospital to be "negligent" for having improperly cleaned and high-level disinfected gastrointestinal (GI) endoscopes.[1]

Six years earlier, in February, 2005, this hospital—located near Pittsburgh (PA) and referred to herein as *Hospital A*—learned that for almost 4 months it had not been reprocessing an internal channel featured in one of its models of GI endoscopes. Two of this hospital's colonoscopes were of this model type, and, posing an increased risk of disease transmission, both were used on a total of more than 200 patients between October, 2004, and February, 2005.[1-4]

Within weeks, in March, 2005, *Hospital A* mailed certified letters to these affected patients notifying them of this colonoscope-reprocessing breach and its potential to have exposed each patient to infectious agents, including bacteria, the hepatitis B and C viruses and HIV.[1-4]

A study of this infection-control lapse not only reveals some interesting legal facts, but also provides a timely opportunity to review, if not to learn for the first time, a number of reprocessing

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***Article at a Glance*: A Jury's Verdict**

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♦ **BACKGROUND**: This past July a jury found a hospital negligent for having improperly cleaned and high-level disinfected colonoscopes used in 2004 and 2005.

♦ **IMPLICATIONS**: This legal case's outcome demonstrates that a medical facility can be found legally responsible for an instrument-reprocessing breach even if the breach was not linked to patient infection.

♦ **RECOMMENDATIONS**: To prevent patient harm, as well as to improve a medical facility's quality and reduce its legal exposure, endoscope reprocessing requires a robust quality assurance program that ensures staff members understand the GI endoscope's design. ●

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principles and instrument-design features that are crucial to the prevention of healthcare-associated infections.

DETAILS OF THE LAWSUIT: DUE TO THE potential for this reprocessing breach to have resulted in patient-to-patient disease transmission, two of these more than 200 affected patients sued *Hospital A* on April 14, 2005, just days after both had received *Hospital A*'s certified letter acknowledging this medical error.[2-4] In their lawsuit these plaintiffs requested (by way of legal counsel) that the court not only grant class action status to their complaint, but also award the claimants compensatory and punitive damages.

Available on-line, this class-action lawsuit provides important details about Hospital A's breach.[3]

This jury's verdict permits individual trials to proceed and determine whether these plaintiffs might be entitled to damages for, but not limited to, "mental anguish," "embarrassment and humiliation," and "pain and suffering."[3]

DETAILS OF THE BREACH: THE TIMELINE AND details of *Hospital A*'s colonoscope-reprocessing breach are provided in **Table 1** ("*A Timeline of Events*," p. 22). Briefly, according to the plaintiffs' filed lawsuit and other published reports,[1-4] *Hospital A* began using two new colonoscopes, both of the model: CF-Q160AL (manufacturer: Olympus America*), on

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* Although GI endoscopes manufactured by *Olympus America* are the subject of this article, the details and recommendations provided herein are not necessarily unique to this one manufacturer and may also apply to similar types of GI endoscopes (and other flexible endoscopes) marketed and sold by other manufacturers.

Box A. ***The functions of the GI endoscope's: (a) auxiliary water channel and (b) air/water channel system.***

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Auxiliary water channel: The auxiliary water channel of GI endoscopes (including of the two new colonoscopes used by *Hospital A* at the time of its breach; *see*: main article) is the conduit through which flows a pressurized stream of water designed to rinse the GI tract and enhance visibility of the examined mucosa. This channel's opening is displayed in **Figure 1**.

This water stream, which exits the GI endoscope's distal tip, is pressurized by either manually depressing a filled syringe or using an automated flushing pump. This syringe or pump delivers the water to this *channel* via an auxiliary water *tube* (e.g., MAJ-855 water tube†) that connects to the GI endoscope's auxiliary water *inlet*. As displayed in **Figures 2** and **3**, for some models of GI endoscopes, including the CF-Q160AL, the auxiliary water inlet is located on the GI endoscope's light guide connector.

Notably, not all models of colonoscopes feature an auxiliary water channel. A contributing factor to *Hospital A's* reprocessing error (*see*: main article), staff members reportedly were unaware that the two recently purchased colonoscopes *were* equipped with an auxiliary water channel. As a consequence, both of these colonoscopes were reprocessed as if neither featured this specialized channel. (This confusion can be mitigated through training.) Failure to reprocess the auxiliary water channel, or any of the GI endoscope's other internal channels, after every clinical procedure can result in disease transmission.

Air/water channel system: The auxiliary water channel is not to be confused with the GI endoscope's water channel, which is *not* a stand-alone channel and, along with the air channel, comprises the GI endoscope's air/water channel system.†† The conduit through which pressurized air or water flows from the GI endoscope's air/water nozzle (*see:* **Figures 1** and **3**), this system is used for insufflation or to clean the objective lens for better visibility, respectively.

If this air/water channel system's pressurized water is insufficient and the GI endoscope does not feature a dedicated auxiliary water channel (e.g., the CF-130 series of videoscopes[5]), supplemental water under pressure can be provided to enhance the washing of the objective lens (at the GI endoscope's distal tip) by connecting a filled syringe to the auxiliary water inlet (via an auxiliary water tube).[5] ●

† This newsletter's featured article in its *April-May-June, 2010,* issue discusses a well-publicized reprocessing breach at a Veterans Affairs medical center (in Murfreesboro, TN) that resulted in the contamination of the MAJ-855 auxiliary water tube.

†† The air/water valve is another component of the air/water channel system. Depression of this valve causes pressurized water to flow from the GI endoscope's air/water nozzle. Covering the hole in the center of this (deactivated) valve with a fingertip, however, causes pressurized air instead to flow from this same nozzle.

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October 28, 2004. Almost four months later, in early February, 2005, staff observed fecal matter dripping from one of these two colonoscopes after the instrument had been ostensibly "reprocessed."[1] Staff suspected that damage to the GI endoscope might be the cause of this dripping debris.

Hospital A, therefore, had the colonoscope serviced; determined, however, that it was not damaged; and subsequently reused the colonoscope on patients.[1] A few weeks later, fecal matter was similarly observed to be dripping from the other of these two recently-purchased colonoscopes (same model: CF-Q160AL).[1] The hospital had this colonoscope serviced, too, only to learn that, as with the other colonoscope, it was not damaged and was functioning as intended.

On two separate occasions, fecal matter was seen dripping from a "reprocessed" colonoscope.

Shortly thereafter, by the end of February, 2005, *Hospital A* had stopped using both of these two suspect colonoscopes and contacted their manufacturer (Olympus America) to discuss the possible causes of this apparent reprocessing breach.[1] During this discussion *Hospital A* learned that both of these colonoscopes (which the hospital had been using on patients since October, 2004) were of a model type that featured an auxiliary water channel. Although the hospital had not been doing so, this channel requires cleaning and high-level disinfection after each procedure to prevent disease transmission,[1] whether or not the channel was used during the examination.

Due to this finding, *Hospital A* soon notified the more than 200 affected patients (on whom either of these two colonoscopes was used) of this infection-control breach (*see*: **Table 1**).[1-4] (*Note*: A distinction without a difference, whereas one manufacturer may refer to this dedicated channel as the "auxiliary water channel," another manufacturer may refer to it as a "forward water jet channel.")

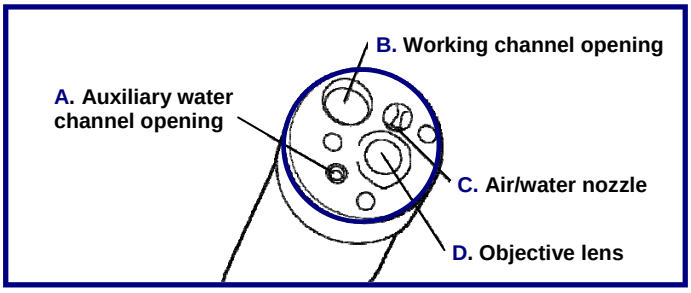

Figure 1. *The openings of a gastrointestinal (GI) endoscope.* Displayed are the openings, objective lens, and air/water nozzle, each of which is located at the GI endoscope's distal tip (*see*: **Box A**). (Diagram by LFM, adapted from Olympus America with permission.[8])

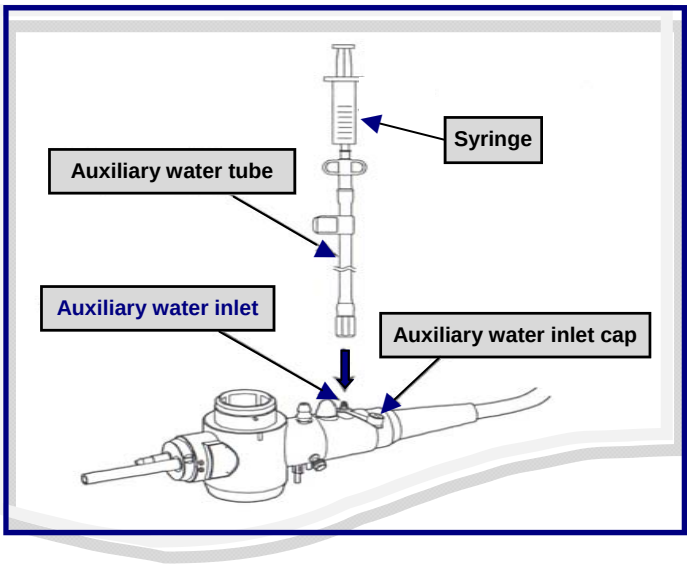

Figure 2. *Location of the auxiliary water inlet.* As displayed, the auxiliary water inlet of some models of Olympus America's GI endoscopes, including the CF-Q160AL model that *Hospital A* used, is located on the GI endoscope's light guide connector. For other models, however, this inlet may be located on the GI endoscope's control section either above the suction valve (e.g., CF-1T140L) or just below the grip (e.g., GIF-2T100). (Diagram by LFM, adapted from Olympus America with permission.[9])

ROOT CAUSE OF THE BREACH: THE ROOT CAUSE of these two recently purchased colonoscopes remaining soiled with fecal matter, despite having been "reprocessed," was the unwitting failure to have reprocessed the dedicated auxiliary water channel—whose function and intended use are described in **Box A** (*also see:* **Figure 1**).

CONTRIBUTING FACTORS: A NUMBER OF factors contributed to *Hospital A's* colonoscope-reprocessing breach. For example, the hospital reportedly lacked training and knowledge about the internal designs of these two recently-purchased colonoscopes (model: CF-Q160AL), and it was unaware that both featured a dedicated auxiliary water channel requiring reprocessing.[1-4] A related contributing factor, *Hospital A*'s other, older colonoscope models in inventory did not feature this specialized channel,[1,3] an incongruity that understandably might have caused diligent staff members confusion.

Moreover, colonoscopes equipped with an auxiliary water channel are not necessarily easily distinguishable from those that are not. It is true that GI endoscopes with an auxiliary water channel feature a distinct auxiliary water inlet (that provides access to this channel for both its clinical use and reprocessing). But, the location of this inlet may not be

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Table 1. ***Timeline of Events (in chronological order) of Hospital A's colonoscope-reprocessing breach.***

February 10, 2003: Olympus America publishes an "important safety notice"[9] in response to concerns that medical facilities may not be aware of and properly reprocessing a specific internal channel featured in some of its *160-series* of gastrointestinal (GI) endoscopes. This notice lists the 6 models of this series that feature this channel. One of these—the CF-Q160AL—is the model of colonoscope that is the subject of the main article.

This notice[†] stresses that this internal channel—known as the auxiliary water channel—requires cleaning and high-level disinfection "each time the endoscope is used" even if this channel is not utilized during the endoscopic procedure.[9] Olympus America reportedly mailed this notice to *Hospital A's* staff (*see*: main article).[1]

March 3, 2003: Olympus America writes a letter to its customers discussing this auxiliary water channel.[5] Similar to the aforementioned notice, dated almost one month earlier,[9] this letter not only states, again, that the GI endoscope's auxiliary water channel (and its associated inlet) requires cleaning and high-level disinfection after each use (whether or not the channel was used), but it also clarifies: (*i*) which GI endoscope models feature the auxiliary water inlet on the light guide connector; the control section above the suction valve; or the control section below the grip;[††] (*ii*) the difference between the function of the auxiliary water channel and of the air/water channel system (*see*: **Box A**); and (*iii*) that the inlet used to reprocess the (exposed) elevator-wire channel of some models (e.g., all of the PJF, JF, and TJF models) is located on the GI endoscope's control section above the suction valve.

October 28, 2004: *Hospital A* begins using two new colonoscopes, both of which are of the model: CF-Q160AL. Unknown to the hospital and unlike any of the other, older models of GI endoscopes in its inventory, these two new colonoscopes feature a dedicated auxiliary water channel that requires cleaning and high-level disinfection after every procedure using an auxiliary water tube.[1,3]

February 2, 2005: *Hospital A* observes one of these two new colonoscopes (that it had begun using four months earlier, in October, 2004) to be dripping fecal matter, despite the endoscope having ostensibly been "reprocessed."[1] In response, the hospital has the colonoscope inspected and serviced by a repair company, only to learn that the colonoscope is not damaged and is functioning as intended. *Hospital A* continues to reuse this colonoscope, although without being aware of (and without reprocessing) its auxiliary water channel—an oversight that poses an increased risk of disease transmission.[1]

Circa mid-February 2005: A few weeks later, *Hospital A* similarly observes the other of these two new colonoscopes (model: CF-Q160AL) to be dripping fecal matter, despite it, too, having ostensibly been "reprocessed" and ready for reuse on patients.[1] This colonoscope is similarly inspected by a service company and is also found to be functioning as intended and not requiring repair.

This past July a jury in Pennsylvania found that Hospital A was "negligent" for having improperly reprocessed colonoscopes.

February 26, 2005: Demonstrating concern for patient safety, *Hospital A* removes these two suspect colonoscopes from service and contacts their manufacturer, only to be notified that both feature a dedicated auxiliary water channel (that the hospital had been unaware of and had not been reprocessing as required to prevent disease transmission).[1] Both colonoscopes are removed from service and are no longer used on patients. None of the hospital's other models of colonoscopes feature this specialized channel (whose function is discussed in **Box A**).

March 26, 2005**:** *Hospital A* mails certified letters to the more than 200 affected patients on whom these two suspect colonoscopes had been used between October 28, 2004, and February 26, 2005, notifying them of the potential for infection due to this hospital's failure to have reprocessed the auxiliary water channel.[1,2,4]

March 30, 2005**:** *Hospital A* publicly acknowledges its failure to have reprocessed the auxiliary water channel featured in the two colonoscopes (*model*: CF-Q160AL) it purchased and had begun using in 2004.[2,3]

April 14, 2005**:** Due to concerns that *Hospital A's* failure to have properly reprocessed two of its colonoscopes might have resulted in disease transmission, two plaintiffs sue the hospital for negligence and for more thorough and frequent medical testing and monitoring for infections related to this infection-control breach.[3]

July 19, 2012: A jury finds *Hospital A* to be negligent for having improperly reprocessed these two colonoscopes that were used on more than 200 patients.[1]

[†] This notice[9] also stated that users can quickly identify whether a *160-series* model of a GI endoscope is designed with this auxiliary water channel by identifying the auxiliary water *inlet* located on its light guide connector (although for other models of GI endoscopes by this same manufacturer—for example, the CF-1T140L, this inlet may be located on another section of the endoscope, such as on the control section above the suction valve).[5]

[††] Depending on the GI endoscope's model, the auxiliary water tube that connects to the auxiliary water inlet to provide access to the auxiliary water channel may vary in design and type—for example, the MH-974 tube may be used for the model: GIF-1T140, whereas the MAJ-855 tube may be used for model: CF-Q160AL.[5]

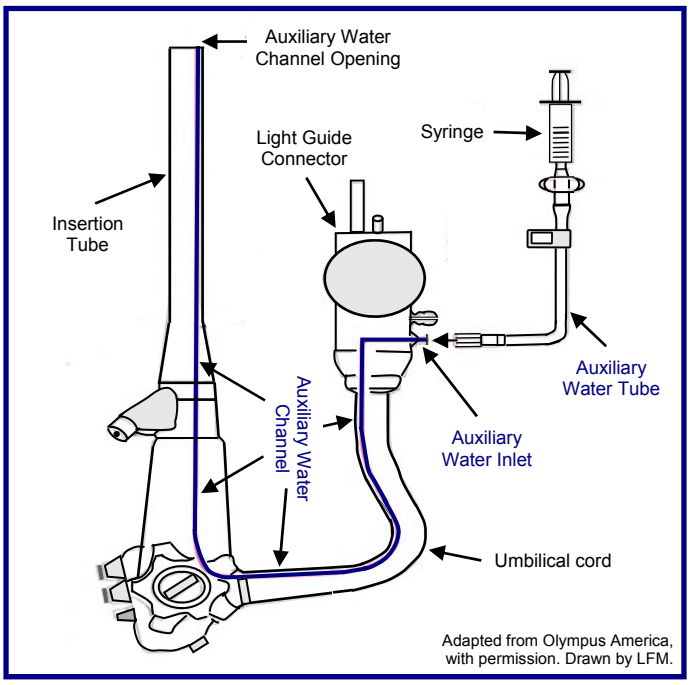

Figure 3. *Schematic of the GI endoscope's auxiliary water channel and inlet.* Although for some GI endoscope models this channel traverses the insertion tube and umbilical cord (see diagram), for other models it may only traverse the GI endoscope's insertion tube.

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obvious to untrained staff members. For some models of GI endoscopes, such as for *Hospital A's* two suspect colonoscopes, this inlet is located on the light guide connector (*see*: **Figures 2** and **3**), whereas for other models, this inlet may be located on another section of the GI endoscope—for example, on its control section (e.g., model: CF-1T140L; *see:* **Box A**).[5]

Yet another related factor that might have contributed to *Hospital A's* infection-control lapse, a GI endoscope with an auxiliary water inlet is not necessarily also equipped, *de facto*, with an auxiliary water channel. Some GI endoscopes without this specialized channel nevertheless feature an auxiliary water inlet that may be located just below the grip (e.g., the CF-130 series of videoscopes). For these models of GI endoscopes, the inlet is a "side-tap" that provides access to the standard water channel.[5]

DISCUSSION: THE DEGREE OF concern that a specific instrument-reprocessing breach may cause is a consequence of the breach's assessed risk of infection. One fact not disputed in *Hospital A's* legal case is that the failure to have reprocessed the GI endoscope's auxiliary water channel posed an increased risk of infection.[6] (Specific risk assessments associated with other infection-control breaches are provided in **Box B** of this newsletter's *January-February-March-April, 2011*, issue, whose review is recommended.[†])

A salient omission: Nevertheless, while the aforementioned lawsuit asserts that the plaintiffs have "suffered injury,"[3] notably missing in this lawsuit is the plaintiffs' claim that any were infected as a consequence of *Hospital A's* reprocessing breach. Indeed, a recent news report published this past summer stated that: "none of the patients (affected by *Hospital A's* breach) contracted a disease as a result of their exposure"[1]—the jury's verdict of negligence notwithstanding.[††]

This legal case demonstrates that a medical facility can be legally liable even if a reprocessing breach has not been linked to an infection.

This hospital's breach, plaintiffs' legal case, and jury's verdict present a surprising outcome with significant implications: *that a medical facility can be sued and found legally responsible (i.e., negligent), even if the instrument-reprocessing breach that is the focus of the lawsuit had not been documented to cause an infection.*

Inauspicious circumstances: The use of a GI endoscope that features an auxiliary water channel would not ordinarily have been a source of confusion, were it not for the combination of a number of inauspicious circumstances. First, *Hospital A's* older, familiar models of colonoscopes in its inventory were not equipped with an auxiliary water channel. Indeed, the apparent misconception that, therefore, the two new models of colonoscopes (sold by the same manufacturer) that *Hospital A* purchased would similarly not feature this specialized channel was reportedly an important factor that contributed to this hospital's error.[1-4]

A second complicating consideration, to an untrained staff member colonoscope models in inventory with, and without, an auxiliary water channel may not be easily identifiable, which can cause confusion. Moreover, mistaking one model of a colonoscope for another, or erroneously concluding that the reprocessing requirements of old and new colonoscope models sold by the same manufacturer do not markedly

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[†] The failure to notify potentially affected patients of an instrument-reprocessing breach that is associated with an "increased" risk of infection is arguably to advance the flawed conclusion that *proper* reprocessing is unnecessary and superfluous.

[††] The lack of infection does not ensure that a breach was not associated with disease transmission. Depending on the circumstances (e.g., the patient's health), an infectious disease can be transmitted to a patient without the patient eliciting symptoms of infection. (Some infections may also be asymptomatic or subclinical).

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differ, in addition to posing an increased risk of infection, brings into focus a third factor that, in part, reportedly contributed to *Hospital A's* error: the employment of a quality-assurance program that was not sufficiently robust to ensure that *every one* of the internal channels—namely, the auxiliary water channel—of *each* old and new models of GI endoscopes in *Hospital A's* inventory was being reprocessed.

RECOMMENDATIONS: THIS STUDY OF *Hospital A's* reprocessing error yields several recommendations that may be useful to a medical facility aiming to enhance patient safety, improve its quality-assurance program and endoscope-reprocessing practices, and minimize its potential legal exposure. While these recommendations focus on GI endoscopes, some may also be applied to other types of flexible endoscopes, such as those used in the fields of bronchoscopy.

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1. Employ a robust quality-assurance program that, among other responsibilities, ensures reprocessing staff members are trained and understand the internal design and reprocessing requirements of *every* GI endoscope model in inventory.

– Perform routine audits of staff members' reprocessing practices, correcting any noted deficiencies.

  › Such audits and training may be especially important if the medical facility uses different models and types of GI endoscopes; and/or has recently added a new model or series of GI endoscopes to its inventory. Remember that the internal designs and reprocessing requirements of new models of GI endoscopes may be unique, unlike older models, and require additional reprocessing steps.

2. In particular, ensure that *every one* of the (accessible) internal channels of *every* GI endoscope in inventory is being properly reprocessed after each procedure, whether or not the channel was used during the clinical examination.

– *Identify* those GI endoscopes in inventory featuring an auxiliary water channel (or another specialized channel) and *confirm* the location of the auxiliary water inlet. *Ensure* that the auxiliary water channel is being reprocessed using the proper adapter (e.g., MAJ-855 tube).

  › Caution is advised whenever models of GI endoscopes that do, and do not, feature an auxiliary water channel (or other specialty channel) are being used. These models are not necessarily easily distinguishable.

– Also, ensure that the GI endoscope's valves and other potentially contaminated internal and external surfaces are being properly reprocessed.

3. Review *Hospital A's* legal case, which, in addition to highlighting the importance of the proper reprocessing of GI endoscopes to the prevention of disease transmission, demonstrates that a medical facility can be found to be legally liable (i.e., negligent) even if an identified reprocessing breach has not been linked to an single instance of patient infection.[3]

4. Consider contacting the GI endoscope's manufacturer to: (*i*) confirm whether the reprocessing requirements of any recently purchased models or series of GI endoscopes are different and require additional steps, compared to those of an older model or series; and (*ii*) answer any questions that staff members might have about the reprocessing requirements of any GI endoscope in inventory.

5. Review this newsletter's *January-February-March-April, 2011,* issue (in particular, its **Table 1** and **Box A**): (*i*) for additional recommendations to prevent disease transmission during colonoscopy; and (*ii*) for instructions to reprocess the GI endoscope's auxiliary water channel and the MAJ-855 auxiliary water tube either manually or using an automated device.

6. Reprocess before its reuse any GI endoscope that is removed from storage and observed to be soiled with patient debris or otherwise is suspected of being contaminated.[7] Also, maintain and service GI endoscopes as required.

7. Manufacturers are encouraged to enhance their labeling and instructions to prevent a GI endoscope's improper reprocessing. **The End** ■ (*Article by*: L.F. Muscarella, Ph.D.)

➡ The REFERENCES to this newsletter are available at:
www.myendosite.com/htmlsite/2012/refs101112.pdf

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.*
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