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

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What's News

This issue marks this newsletter's 18th year of publication. Future topics that will be discussed in this newsletter include the details of an outbreak of *Pseudomonas aeruginosa* in Houston, Texas. This outbreak has been linked to reusable medical equipment that, despite apparently being cleaned and sterilized according to the manufacturer's instructions, reportedly transmitted disease.

Editor-in-Chief

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.

The Delayed Reprocessing of Gastrointestinal Endoscopes

A discussion of whether a soiled flexible endoscope's terminal reprocessing can be delayed for several hours

This article provides insight into the delayed reprocessing of gastrointestinal endoscopes. Guidelines are reviewed and recommendations are provided. A protocol for "prepping" the endoscope prior to its delayed reprocessing is also provided.

INTRODUCTION: The word is used ubiquitously in the lexicon of instrument reprocessing. Namely, guidelines that provide advice for the prevention of disease transmission during gastrointestinal (GI) endoscopy routinely urge staff to reprocess the GI endoscope "immediately" after the procedure (*see*: **Box A**).[1-4] Although this instruction is certain, adherence to it is not foregone.

Briefly, endoscope reprocessing may be divided into two sequential phases, based on the location within the medical facility where each phase is performed: (1) *pre-processing* of the endoscope—or *phase 1*—which is an initial set of reprocessing steps that is performed in the procedure room upon removal of the endoscope from the patient's GI tract; and (2) *terminal reprocessing* of the endoscope—or *phase 2*—which features a more comprehensive set of subsequent reprocessing steps, including leak testing, that is performed once the endoscope is transported to the reprocessing area.[5,6]

When the two are performed properly, in timely sequence, and as recommended by its manufacturer, these phases render the flexible endoscope safe for reuse, without risk of the endoscope transmitting diseases.[2] (Note: *Pre-processing* may also be referred to as *pre-cleaning* or *bedside cleaning*.[5])

TIMELY REPROCESSING: Box A provides the recommendation published by several professional organizations and manufacturers to reprocess the GI endoscope immediately after the procedure,

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the purpose of which is to minimize the likelihood of potentially infectious patient fluids, secretions, and debris drying and hardening on the GI endoscope's external surfaces and internal channels.[1-4] Once encrusted, these patient materials can become formidable to remove and may remain on the GI endoscope despite its cleaning, posing an increased risk of ineffective reprocessing, as well as of the GI endoscope's improper functioning.[6] While the guidelines of other organizations may use a different adverb such as "promptly" (*see:* **Box A**),[7] the importance of reprocessing's timeliness is no less evident or emphasized.

DELAYED REPROCESSING: No matter the adverb used to describe the imperative, reprocessing the flexible endoscope after the procedure, without delay, is integral to patient safety and the prevention of healthcare-associated infections (HAIs).[1-7] Nevertheless, on occasion, the GI endoscope's preprocessing (phase 1) or terminal reprocessing (phase 2) may be delayed for more than an hour* after the procedure. This scenario—which may be described as *delayed reprocessing*—is not without controversy, because, as displayed in **Box A**, any delay in the endoscope's cleaning and high-level disinfection is inconsistent with the instructions of published reprocessing guidelines.[1-7]

Even a well-managed out-patient endoscopy center may encounter a "reprocessing bottleneck" that results in the GI endoscope's delayed reprocessing.

"24 hours a day, 7 days a week": Endoscope reprocessing is as important to the prevention of HAIs as it can be challenging to manage and delegate. Although it is ideal for a medical facility to have available at all times, "24 hours a day, 7 days a week," trained (if not also certified) staff to ensure the timely (i.e., within one hour of its use*) reprocessing of every GI endoscope model in inventory—indeed, it would seem to be necessary of any hospital that performs emergency GI endoscopic procedures during "off hours" or late in the night—the expense of having such trained staff always available can be financially prohibitive for some medical facilities.

As a consequence, the reprocessing of GI endoscopes may not be prompt, but delayed. Even a well-managed outpatient GI endoscopy center that performs procedures only during normal working hours is likely to encounter an occasional "reprocessing bottleneck" that, too, may delay the timely reprocessing of GI endoscopes. No matter whether due to the unavailability of trained reprocessing staff or to a reprocessing bottleneck, delaying a GI endoscope's reprocessing seems counterintuitive and inapt, and it can pose an increased risk of disease transmission.

An alternative: An alternative to delaying the reprocessing of a GI endoscope until trained staff are available, or a bottleneck is resolved (possibly as many as several hours later), may be to assign untrained members of the staff, whose knowledge and understanding of the GI's endoscope's design and demanding reprocessing requirements may be admittedly

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Box A. ***Recommendations to reprocess GI endoscopes immediately after their clinical use.***

1. The Society of Gastroenterology Nurses and Associates (SGNA)—whose guidelines provide advice that is the "gold standard" for both the pre-processing and terminal reprocessing of GI endoscopes—states that:[1]

   – *"the initial steps in the reprocessing protocol begin in the patient room immediately after removal of the insertion tube from the patient (and prior to disconnecting the endoscope from the power source);* and

   – *"manual cleaning of endoscopes is necessary immediately after removing the endoscope from the patient and prior to automated or manual disinfection."*

2. The American Society for Gastrointestinal Endoscopy (ASGE) advises staff to:[2]

   – *"meticulously clean the entire endoscope, including valves, channels, connectors, and all detachable parts with an enzymatic detergent † compatible with the endoscope immediately after use, according to the manufacturer's instructions."*

3. The Association of Perioperative Registered Nurses (AORN) writes that:[3]

   – *"immediate cleaning (of the flexible endoscope) reduces the amount of microbial contamination and the formation of biofilms."* ††

4. Manufacturers recommend that GI endoscopes (and their accessories):[4,16-18]

   – *be cleaned "immediately" after the procedure.*

5. Similarly, the Association for Association for Professionals in Infection Control and Epidemiology (APIC) writes:[7]

   – *that "cleaning of endoscopes ... should be performed (in the procedure room) ... promptly after use."*

† Data demonstrating that an enzymatic detergent performs more effectively than a non-enzymatic detergent are limited.

†† Readers are referred to this newsletter's November, 2007, issue, which discusses biofilms in the context of GI endoscopes.

* *One hour* is usually the time specified to define *delayed reprocessing*, because the endoscope manufacturer's reprocessing instructions have typically been validated for effectiveness up to, but not longer than, one hour after the endoscopic procedure.[5]

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limited or poor, the responsibility of reprocessing the GI endoscope promptly after its use.[6] But, like delayed reprocessing, this alternative, too, can have potentially adverse infection-control consequences, having been reportedly associated with deviations in reprocessing practices.[6] Indeed, the ineffective reprocessing of flexible endoscopes, including (but not limited to) their improper "leak testing," has been linked to patient morbidity and mortality.[3,8,9]

Delayed reprocessing is as anomalous a practice as it is inevitable an occurrence.

"To reprocess or not reprocess?" The delayed reprocessing of a GI endoscope is as anomalous for its contravention of **Box A**'s instruction to reprocess the GI endoscope immediately after its use as it is inevitable. At some time, virtually every medical facility performing GI endoscopy will be faced with the dilemma "*to reprocess or not to reprocess*"—namely, to have untrained staff members reprocess the GI endoscope promptly after its use or instead to delay the GI endoscope's reprocessing until trained reprocessing staff are available.

AIM AND METHODOLOGY: Often, the outcome of this quandary is the latter, and the endoscope's reprocessing is delayed. Therefore, a number of infection-control guidelines, published papers, and the reprocessing instructions of different manufacturers of GI endoscopes were reviewed for guidance about delayed reprocessing. This article also aimed to identify whether a set of instructions has been published for pretreating the GI endoscope prior to a delay in its reprocessing, to reduce the likelihood of patient materials drying and hardening on the GI endoscope's surfaces.

The Center for Public Integrity: *Instruments in hospitals "sometimes sit around for hours, or days, before they are cleaned, which allows blood and tissue to dry and harden."* [10,11]

RESULTS: Some published advice about the delayed reprocessing of GI endoscopes was identified during this review, and it is summarized in **Box B**.[1,4-6,12-14] This review also identified a set of instructions published by one manufacturer of GI endoscopes (Olympus America) that seemingly condones delayed reprocessing, albeit conditionally and provided, for example, that it is not routinely practiced (delayed reprocessing's deviation from the recommendation to reprocess the GI endoscope promptly after its use notwithstanding).[4-6] (This review did not identify another manufacturer of GI endoscopes that discusses delayed reprocessing.[4-6]) This review also identified several competency checklists that may help readers better understand the necessary steps both to preprocess and terminally reprocess GI endoscopes.[15-17]

DISCUSSION: Detailed in **Box A**, the "standard" practice of endoscope reprocessing is defined by the GI endoscope's immediate pre-processing in the procedure room (phase 1) followed by the GI endoscope's transportation to—and its prompt leak testing, manual cleaning, and terminal high-level disinfection (or sterilization) in—the dedicated reprocessing room or area (phase 2).[5] After the completion of these two phases, the endoscope may be safely reused or stored in accordance with its manufacturer's instructions. *(Readers are referred to this newsletter's December, 2009, issue, which discusses a GI endoscope's safe storage.)*

This review identified a set of instructions published by a manufacturer of GI endoscopes that condones delayed reprocessing, albeit conditionally.

Some circumstances may occasionally arise, however, that interfere with the GI endoscope's prompt reprocessing (the instructions in **Box A** notwithstanding). From these circumstances arises the term *delayed reprocessing*, which is defined as terminally reprocessing the GI endoscope more than an hour after its clinical use. Warranting circumspection, delayed reprocessing may pose an increased risk of HAIs, due to the potential for infectious patient debris to dry on the GI endoscope's surfaces during this hiatus. Once hardened and encrusted, this debris can shield and protect underlying infectious agents, preventing their removal and destruction during the GI endoscope's terminal reprocessing.

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Article at a Glance: Delayed Reprocessing

- **BACKGROUND**: Despite the instructions of guidelines, flexible endoscopes may not always be promptly reprocessed. The practice of cleaning and high-level disinfecting (and drying) a GI endoscope more than an hour after its use may be referred to as *delayed reprocessing*.
- **IMPLICATIONS**: Delayed reprocessing is controversial. Indeed, the failure to reprocess the flexible endoscope promptly after its use can facilitate the drying and hardening of patient debris on its surfaces and in its internal channels, posing an increased risk of ineffective reprocessing and disease transmission.
- **AIM**: To provide guidance about the delayed reprocessing of GI endoscopes.
- **RECOMMENDATIONS**: Prompt reprocessing of GI endoscopes is urged. When their reprocessing is delayed, however, published advice suggests that a number of preparatory steps be taken to minimize the likelihood of ineffective reprocessing. In addition to its leak testing, these steps include the GI endoscope's prolonged immersion in a suitable detergent solution.

Box B. *Published guidance about the delayed reprocessing of GI endoscopes.* *

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1. Manitoba Public Health:[12]

   – *"If unable to initiate the manual cleaning process immediately, the endoscope may be flushed and left soaking in an enzymatic detergent solution."*

2. The Society of Gastroenterology Nurses and Associates (SGNA):[1]

   – *"Prolonged soaking of the channels in the enzymatic detergent solution may be beneficial if there has been a delay in beginning the cleaning process"*; and

   – *"If, due to time constraints, it is not possible to complete the reprocessing immediately, the endoscope should be leak-tested, flushed, brushed, and allowed to soak in a detergent solution until it can be thoroughly reprocessed. Follow manufacturer's recommendations for the maximum liquid exposure time."*

3. Olympus America:[4-6,13]

   – *"In the event that manual cleaning of the endoscope is delayed for more than one hour from the time precleaning is completed or patient fluid/material has dried onto the endoscope surfaces, the endoscope should be reprocessed according to the instructions in the endoscope manual for 'Presoak for Excessive Bleeding and/or Delayed Reprocessing' "*[5] *see:* Box C;

   – *"If pre-cleaning is not initiated within an hour, the endoscope should be soaked in an appropriate enzymatic detergent according to the manufacturer's recommendations, before continuing with mechanical cleaning and then terminal cleaning. This process will allow for any dried debris to be loosened and ensure its removal during cleaning";*[6,13] ** *and*

   – *"If there was excessive bleeding during the patient procedure or if precleaning could not be performed immediately after the patient procedure, presoaking the endoscope in detergent solution before manually cleaning the endoscope may be required to wet and loosen debris" that has hardened on the endoscope;*[4] *but, also*

   – *"Unnecessary long-term immersions should be avoided. Consecutive reprocessing sessions using extended immersion may damage the endoscope."*[4]

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* Whether other manufacturers of GI endoscopes similarly condone delayed reprocessing is unclear.

** Although applied to rigid laryngoscopes (not GI endoscopes), the California Department of Health writes that: a *"prolonged delay between use of the laryngoscope and reprocessing can result in the drying and hardening of debris on the laryngoscope's surfaces. Dried debris can be difficult to clean, can interfere with the effectiveness of disinfection or sterilization, and can damage the laryngoscope."* [14]

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"Prepping" the GI endoscope: Even though GI endoscopes are labeled to be reprocessed promptly after their use (*see*: **Box A**),[4,16-18] some published guidance discusses their delayed reprocessing (*see*: **Box B**), and one manufacturer condones it (*see*: **Box B)**—albeit conditionally, provisionally, and provided the GI endoscope is pre-treated, or "prepped" prior to its terminal reprocessing more than an hour later.[4-6,13]

Briefly, this manufacturer's procedure for "prepping" the GI endoscope features its leak testing; the flushing of its channels with a detergent solution; and its prolonged immersion† in the detergent solution (for up to, but not longer than, 10 hours).[6] Once trained reprocessing staff become available (or a reprocessing bottleneck is resolved), the GI endoscope is then cleaned and terminally high-level disinfected, either manually or using an automated endoscope reprocessor, followed by its reuse or storage.

"Prepping" the GI endoscope before its delayed reprocessing includes, in sequence, its leak testing, the flushing of its channels with a detergent solution, followed by its prolonged immersion in this detergent solution (for not longer than 10 hours).

Moreover, as this manufacturer has published, a number of important caveats are associated with "prepping" the GI endoscope for its delayed reprocessing (as many as 10 hours later). Namely, prolonged immersion: (*i*) should be performed "only when necessary" (according to this manufacturer, unnecessary immersions should be "avoided");[4,5] (*ii*) may damage the GI endoscope if performed routinely or consecutively;[4-6,13] and (*iii*) is an additional reprocessing step that is not a replacement for the GI endoscope's manual cleaning or terminal reprocessing.[5]

Limiting this "prepping" procedure's uses, this manufacturer counsels that it only be performed, in addition to when the GI endoscope was not promptly reprocessed after its use, when the GI endoscope's surfaces are suspected of being contaminated with hardened patient debris and/or when the GI endoscope was used during a procedure with excessive bleeding.[4-6,13] Based, in part, on this manufacturer's published procedure, a more detailed protocol that may be suitable for the delayed reprocessing of a GI endoscope (or of another type of flexible endoscope or comparable reusable medical instrument) was developed and, for the reader's convenience, is provided in **Box C** (p. 5).[Ψ] Several caveats and restrictions that apply to this protocol are also provided in **Box C**.

For clarification, this newsletter's article discusses, but

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† Some manufacturers may similarly recommend that the GI endoscope be immersed in a detergent solution during its transportation from the procedure room to the reprocessing area for "standard" terminal reprocessing. Refer to the GI endoscope's instructions.

Box C: ***A step-by-step set of instructions that may be suitable for "prepping" a GI endoscope prior to its delayed reprocessing.***[†]

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The following steps are applicable to GI endoscopes:[*] *(a) that have not yet been pre-processed one hour after the GI procedure; (b) that were pre-processed promptly after the GI procedure, but have not yet been terminally reprocessed one hour later; (c) whose surfaces are suspected of being contaminated with dried and hardened patient debris and materials; and/or (d) that were used during a procedure with excessive bleeding.*[4-6,13]

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1. *Leak-test* the GI endoscope in accordance with its manufacturer's instructions. If the endoscope fails this test, do not proceed to *Step 2A.* Instead, refer to the GI endoscope's instructions for information about its repair. *Leak testing is important to reduce the likelihood of endoscope damage, fluid invasion and disease transmission*.

2A. *Fill* a clean basin with fresh, potable tap water.

– Ensure the basin (or sink or tub) is sufficiently wide and deep: (*i*) to accommodate and not place undue stress on the coiled GI endoscope's insertion tube and umbilical cord; and (*ii*) to immerse the entire GI endoscope, including its control head, in water.

– Determine the approximate volume of water in the basin (in gallons), which is necessary for *Step 2B*.

2B. *Add* a measured concentrate of detergent that is appropriate for the filled basin's estimated volume of water. Read the detergent's labeling and instructions for use.

– Ensure that the enzymatic (or non-enzymatic) detergent is not only specifically labeled for cleaning GI endoscopes,[6] but also is compatible with and will not damage the GI endoscope's materials and components during prolonged immersion (for as many as 10 hours) in the detergent solution.

– If the detergent's labeling requires its mixing with warm or hot water, then a method or device, such as an immersion heater, would seemingly be necessary during the GI endoscope's prolonged immersion to maintain the detergent solution at this elevated temperature, lest the detergent solution's temperature drop to room temperature (which is 68° F) over time, possibly become ineffective, and not loosen patient debris that dried and hardened on the endoscope's surfaces. Alternatively, a detergent labeled for use in water at room temperature may be considered.

– As a confirmation, users may consider requesting of the detergent's manufacturer a statement certifying materials compatibility and the detergent's effectiveness during prolonged immersion for loosening hardening debris from a GI endoscope's surfaces at the detergent label's indicated water temperature.

3. *Completely immerse* the carefully coiled GI endoscope in the detergent solution.

– To avoid costly damage, it likely will be necessary to securely attach one or more water resistant caps to the GI endoscope's electrical connectors (or, if featured, a "UPD scope connector"[6]) *before* immersing the GI endoscope in the detergent solution. *Refer to the GI endoscope's operator's manual for more information*.

– Remove from the GI endoscope and immerse in the detergent solution the suction and air/water valves and other detachable, reusable parts.

4A. *Manually flush* and *fill* each of the immersed GI endoscope's accessible channels with this detergent solution using the required reprocessing adapters, plugs, tubes, and other accessories.

– These channels include the suction, air, water, and, if featured, auxiliary water channels (possibly in addition to other channels). Refer to the endoscope's operating instructions for a description of these reprocessing adapters and accessories, which were included with the GI endoscope's original purchase.

– Different models and types of GI endoscopes may require the use of different types of reprocessing adapters, plugs, tubes, and other accessories.

4B. *Detach* from the GI endoscope (and remove from the basin) each of these reprocessing adapters, plugs, tubes, and other accessories. Cover the basin.

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[†] *This "prepping" protocol was adapted from instructions published by a manufacturer, who recommends, along with a number of other caveats, that the prolonged immersion of its GI endoscopes in a detergent solution be performed "only when necessary," not routinely.*[4] *Extended immersions should be avoided and may damage the GI endoscope when performed consecutively.*[4-6,13] *This protocol's Steps 2-5 are additional measures and are not replacements for manual cleaning or terminal reprocessing of the GI endoscope (as detailed in Step 6). This box article is not an endorsement of delayed reprocessing. Refer to the main article for more details about delayed reprocessing.*

[*] *Unless the manufacturer advises otherwise, this "prepping" procedure is not to be performed for any other application. Some manufacturers of GI endoscopes may contraindicate delayed reprocessing. Therefore, before performing this procedure, contact the manufacturer of the GI endoscope (or of another type of flexible endoscope or comparable reusable instrument) to confirm its acceptability, safety and effectiveness. For some reusable instruments whose manufacturers might condone this procedure, additional or fewer steps may be necessary. (Also, this procedure is to be performed in accordance with* Standard Precautions [e.g., *wearing protective personnel equipment*].)

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does not endorse, the delayed reprocessing of GI endoscopes and other types of reusable medical instruments.[Ψ] Readers are encouraged to discuss with the manufacturer(s) of their GI endoscopes the appropriateness of delayed reprocessing and of the protocol detailed in **Box C**, which includes the GI endoscope's prolonged immersion in a detergent solution. Indeed, failure to clean and high-level disinfect (and dry) the GI endoscope promptly after its clinical use may result in the drying of patient materials, ineffective reprocessing and damage to the GI endoscope voiding its warranty.[1-7,10-14]

The prolonged immersion of a GI endoscope is an additional reprocessing step—it is not a replacement for manual cleaning or terminal reprocessing.

SUMMARY AND RECOMMENDATIONS: Reprocessing the GI endoscope promptly after its use is urged (*see*: **Box A**). Otherwise, the risk of its ineffective reprocessing (and of damage to its materials) may increase. Nevertheless, if the GI endoscope's reprocessing is delayed, whether due to the limited availability of trained staff or to a reprocessing bottleneck, or if the GI endoscope either was used during a procedure with excessive bleeding or is suspected of being contaminated with hardened patient debris, users of GI endoscopes manufactured by one company[Ψ] (Olympus America) may "prep" the GI endoscope prior to its terminal reprocessing more than an hour later—provided, however, that several caveats are understood and criteria are satisfied (*see*: **Box B**).[4-6,13] This manufacturer's procedure for delayed reprocessing is included in the reprocessing manuals of most of its GI endoscopes, and its review by the reader is recommended.[5]

Box C provides a detailed step-by-step protocol that may be (but is not necessarily) suitable when a GI endoscope's reprocessing is delayed. Prior to performing this protocol, the manufacturer's procedure,[4] or another comparable one,[Ψ] however, it is recommended that the medical facility be circumspect and first contact the instrument's manufacturer(s) to discuss delayed reprocessing and whether the procedure provided in **Box C**, or a comparable one that includes the GI endoscope's prolonged immersion in a detergent solution, is suitable or might instead damage the instrument and void its warranty. Review of any of several published competency checklists for reprocessing GI endoscopes is also recommended to enhance the quality of infection control.[15-17]

Last, the use of water, without detergent, to "pre-clean" the GI endoscope in the procedure room will be discussed in a future issue of this newsletter. ❍ **The End** [Article by: *Lawrence F. Muscarella, Ph.D.*]

[Ψ] Whether the delayed reprocessing of another manufacturer's GI endoscopes or reusable medical instruments may be suitable and safe is unclear. Contact the reusable instrument's manufacturer for clarification before performing the procedure detailed in **Box C**.

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Box C: ***Delayed reprocessing*** ***(continued)***

5A. *Soak* the immersed GI endoscope (and its valves and other reusable parts) in the detergent solution for as long as required—for example, until hardened debris is loosened or trained staff become available to terminally reprocess the endoscope, but not for longer than 10 hours.[6]

– Again, use the detergent solution at the temperature (and concentration) indicated on its labeling.

– The use of a timer to ensure that the GI endoscope is not immersed for longer than 10 hours is recommended, as is the use of a log book to record the frequency of the GI endoscope's prolonged immersions.

5B. After its prolonged immersion, *remove* the GI endoscope (and its valves and other reusable parts) from the detergent solution.

6. *Thoroughly clean* and *terminally high-level disinfect* (or sterilize) and *dry* the GI endoscope (including its valves and other reusable parts) in accordance with the instructions provided by the GI endoscope's manufacturer.

– If using an automated endoscope reprocessor, refer to its labeling and operating instructions to minimize redundancy while ensuring that every necessary manual reprocessing step is performed. ●

➡ The **REFERENCES** to this article are available at:
www.myendosite.com/htmlsite/2012/refs01020312.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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