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

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What's News

In response to a question from one of its readers, this newsletter's issue discusses a manufacturer's revised instruction eliminating the use of detergent to pre-clean soiled GI endoscopes at bedside. (This manufacturer requires the use of detergent to clean the GI endoscope in the reprocessing room, however, before high-level disinfection.) Visit **Q-Net** at: *www.MyEndoSite.com*

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.

Revised Instructions for Pre-Cleaning Gastrointestinal Endoscopes at Bedside

Question: *"Is it acceptable to use only water, without detergent, to 'pre-clean' gastrointestinal endoscopes at the patient's bedside?"*

In addition to the delayed reprocessing of gastrointestinal (GI) endoscopes, this article—which is the second in a series of two—discusses one manufacturer's revised reprocessing instruction sanctioning the use of water, without detergent, to pre-clean GI endoscopes.

BACKGROUND AND REVIEW: Summarized in **Box A** (*next page*), this newsletter's *January-February-March, 2012*, issue examines the topic of delayed reprocessing.[1] Defined as the cleaning and high-level disinfection of a soiled gastrointestinal (GI) endoscope more than one hour after its clinical use,[1] delayed reprocessing also may be applicable to other comparable types of flexible endoscopes and reusable medical instruments.

Although published guidelines urge staff to reprocess the GI endoscope promptly after its use,[1] circumstances may arise that hinder adherence to this directive, abetting a backlog of soiled GI endoscopes and their delayed reprocessing as many as several hours after their clinical use. These circumstances include an occasionally encountered "reprocessing bottleneck" and the unavailability of trained reprocessing staff, the latter of which may happen, for example, when GI endoscopy is performed "off hours."[1]

While limited, some guidance about delayed reprocessing has been published.[1] In fact, one manufacturer of GI endoscopes condones it, provided, however, that a number of criteria are satisfied and caveats are understood.[1]

Criteria, caveats: These criteria and caveats are discussed in this newsletter's *January-February-March, 2012*, issue,[1] and they include the manufacturer's requirement that several steps be performed to "prep," or pre-treat, the GI endoscope in advance of its delayed reprocessing.[1] These preparatory steps include "leak testing" and the prolonged

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Box A. *Summary of the discussion of delayed reprocessing in this newsletter's Jan-Feb-Mar, 2012, issue.*[1]

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■ Delayed reprocessing is defined as the cleaning and high-level disinfection of a GI endoscope (and, possibly, of other comparable types of reusable medical instruments) more than one hour after its clinical use. (Refer to this newsletter's *January-February-March, 2012,* issue.)

■ Any delay in the GI endoscope's terminal cleaning and high-level disinfection is controversial, because published guidelines recommend reprocessing the GI endoscope "immediately" or "promptly" after the procedure.[1]

– Failure to comply with this recommendation may result in patient materials, fluids and secretions drying and hardening on the GI endoscope's surfaces, posing an increased risk of, in addition to the GI endoscope's malfunction, ineffective reprocessing and the transmission during GI endoscopy of infectious microorganisms shielded by and embedded in the encrusted debris.[4]

■ Delayed reprocessing is seemingly inevitable. Not only might trained reprocessing staff not be available to reprocess promptly a GI endoscope that, for example, had just been used during an emergency procedure performed "off hours," but even a well-managed out-patient GI endoscopy center that operates during normal working hours is likely to encounter an occasional reprocessing bottleneck.

– An alternative to delayed reprocessing would be to have *un*trained staff reprocess the GI endoscope promptly after the procedure; however, guidelines contraindicate this option, which, too, can pose an increased risk of ineffective reprocessing.

■ One manufacturer of GI endoscopes condones delayed reprocessing (the recommendation of guidelines to reprocess the GI endoscope promptly after its use notwithstanding[1]) provided, however, that a number of caveats are understood and criteria are satisfied, including that the GI endoscope be "prepped," or pre-treated, in advance of its delayed reprocessing.

– This prepping procedure includes: (*i*) leak testing the GI endoscope; (*ii*) flushing its channels with a detergent solution; and (*iii*) its prolonged immersion in this detergent solution (for not longer than 10 hours[1]).

– The prolonged immersion of the GI endoscope: (*i*) should be performed "only when necessary,"[1] not routinely; (*ii*) may damage the GI endoscope (voiding its warranty) if performed consecutively; and (*iii*) is an additional measure—it is not a replacement for the GI endoscope's manual cleaning and high-level disinfection, which are to be performed in the reprocessing room once the reprocessing bottleneck is resolved or trained reprocessing staff become available.

– In addition to when the GI endoscope's reprocessing is delayed, this manufacturer recommends performing this prepping procedure when the GI endoscope: (*i*) was used during a procedure with excessive bleeding; or (*ii*) is suspected of being contaminated with dried and hardened patient materials.[1]

■ A step-by-step protocol that includes prolonged immersion in a detergent solution and may be suitable for prepping the GI endoscope (or another type of flexible endoscope or comparable reusable instrument) in advance of its delayed reprocessing was developed and is provided in this newsletter's *January-February-March, 2012,* issue.

– Before performing this protocol, however, it is recommended that staff contact the instrument's manufacturer to confirm this protocol's suitability. ●

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immersion of the GI endoscope in a detergent solution (for up to 10 hours during the reprocessing hiatus). Once the reprocessing bottleneck is resolved or trained reprocessing staff become available, the GI endoscope is then cleaned and high-level disinfected as if its reprocessing had not been delayed.[1]

Step-by-step protocol: A protocol featuring each of these several preparatory steps is discussed in the *January-February-March, 2012,* issue of this newsletter.[1] This protocol may be suitable for prepping a soiled GI endoscope (or a comparable type of flexible endoscope or reusable medical instrument) in advance of its delayed reprocessing, and the reader's review of this protocol is recommended. (Two other applications for which this protocol also may be appropriate are discussed herein in **Box A**, p. 8.[1])

Delayed reprocessing may be permissible, provided the GI endoscope has been "prepped," which includes its prolonged immersion in detergent.

No matter this protocol's relative convenience or this manufacturer's conditional condonation of delayed reprocessing, however, guidelines recommend the prompt reprocessing of GI endoscopes.[1] Otherwise, potentially infectious patient materials may dry and harden on the instrument's surfaces, posing an increased risk of ineffective reprocessing and disease transmission, as well as of endoscope damage.

Bedside cleaning: Endoscope reprocessing may be divided into two sequential phases, based on the different locations within the medical facility where either is ordinarily performed. *Bedside cleaning,* or *pre-cleaning,* of the GI endoscope (referred to as *phase 1*) is an initial set of practices that are performed in the procedure room immediately after the exam. These practices, which include flushing the GI endoscope's water channel with water, are detailed in **Box B** (on p. 10). *Terminal reprocessing* of the GI endoscope

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(referred to as *phase 2*), on the other hand, is a more comprehensive set of practices that are subsequently performed in the reprocessing room. These steps include the GI endoscope's leak-testing, manual cleaning, high-level disinfection (at a minimum), and drying.[1]

The prompt reprocessing of GI endoscopes is urged, to prevent the drying and hardening of patient materials that could pose an increased risk of patient-to-patient disease transmission.

When performed properly, in timely sequence, and as recommended by published guidelines, these two phases render a (well-maintained) GI endoscope safe for reuse, with virtually no risk of it transmitting disease.[1] Whereas the importance of using a detergent to clean GI endoscopes during terminal reprocessing (*phase 2*) is not debated, a manufacturer no longer requires that a detergent solution be used to pre-clean models of its GI endoscopes immediately following the exam, at bedside (*phase 1*).[2,3]

A REVISED REPROCESSING INSTRUCTION: On February 19, 2010,[2] and December 13, 2011,[3] this manufacturer (Olympus America) announced via two written notices, respectively, that it had validated several practices to improve the efficiency of endoscope reprocessing. As a result of these improvements, this manufacturer accordingly revised the reprocessing manual of more than two dozen models of its *140-*, *160-*, and *180-series* of upper and lower GI endoscopes. One of these improvements was to no longer require that a detergent be used to pre-clean the GI endoscope in the procedure room (*phase 1*). For example, according to this manufacturer's revised manual, the GI endoscope may be wiped during its pre-cleaning using a gauze, sponge or clean, lint-free cloth soaked with (fresh, clean) water, *without* detergent.*

A manufacturer sanctions using water, without detergent, to pre-clean the GI endoscope at bedside.

Some of the other improvements that this manufacturer of GI endoscopes included in its revised reprocessing manual were the addition of instructions for using this manufacturer's "OFP" pump to flush the GI endoscope's auxiliary water channel (with water) during pre-cleaning (in lieu of manually flushing this channel using a syringe as otherwise required).[2,3]

* Notwithstanding its claim to have validated the use of water, the manufacturer states that staff may continue using a detergent solution during the GI endoscope's bedside cleaning in accordance with the recommendations of published guidelines (*phase 1*; *see:* **Box B**).[4,5] Moreover, this manufacturer stresses the importance of always using detergent to clean the GI endoscope in the reprocessing room prior to high-level disinfection (*phase 2*).[2,3]

***Article at a Glance*: The use of water to pre-clean**

◆ **BACKGROUND**: Last month's issue of this newsletter discussed the delayed reprocessing of GI endoscopes.[1] A sequel to that discussion, this article herein discusses a manufacturer's revised reprocessing instruction sanctioning the use of water, without detergent, to pre-clean the GI endoscope in the procedure room.

◆ **QUESTION AND DILEMMA**: Published guidelines, however, recommend using a detergent solution to perform bedside cleaning of the GI endoscope. So, what are staff to do: *Should they comply with the manufacturer's revised reprocessing instruction or adhere to the recommendations of published guidelines?*

◆ **ADVICE**: Data demonstrating that the use of water, without detergent, during bedside cleaning poses an increased risk of an adverse outcome are lacking. Nevertheless, this newsletter suggests that staff consider continuing to use detergent to pre-clean the GI endoscope. This suggestion may be modified as more data about the quality of using only water become available. ●

(Users may obtain this revised reprocessing manual by contacting the manufacturer's [Olympus's] customer service or via the Internet at: https://www.olympusconnect.com/).[2,3]

QUESTION: In response to this manufacturer's notices and revised reprocessing manual,[2,3] readers of this newsletter asked whether using water, without detergent, to pre-clean the GI endoscope is suitable, or whether it remains advisable for staff to continue to adhere to any one of several published guidelines[4,5] that recommend using water *and* detergent during bedside cleaning as described in **Box B** (*next page*).[4,5]

Should staff continue to use detergent to pre-clean the GI endoscope or use only water as a manufacturer's notices and revised manual instructs?

RESPONSE: This newsletter's reply to this question (provided herein) dovetails with, and is a sequel to, the discussion about the delayed reprocessing of GI endoscopes that was featured last month in this newsletter.[1] From a quality perspective, trained staff's compliance with one—whether the manufacturer's revised instruction (to use water without detergent) or the guidelines' recommendation (to use a detergent solution)—would be a deviation that lacks consistency and conformity vis-à-vis the other.

Briefly, a "deviation" in this context is defined as an instrument-reprocessing practice that departs from an infection-control standard or a validated procedure. Although a non-conformance with the potential to adversely impact quality, a

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deviation in reprocessing may, but does not necessarily, pose an increased risk of patient harm. In general, the identification of a deviation in reprocessing (during, for example, an accreditation survey) would typically result in management's assessment of the deviation's risk of disease transmission, determination of the deviation's potential contributing factors and root causes, and implementation of one or more actions designed to correct the deviation (for example, the re-training of reprocessing staff). But, in this discussion, which is the deviation: *staff's adherence to the manufacturer's revised reprocessing manual or staff's compliance with the recommendations of published guidelines?*

A deviation in instrument reprocessing may be defined as a departure from an infection-control standard or a validated procedure.

DISCUSSION: The answer to this question and whether it is advisable for staff to use a detergent solution, or only water, to pre-clean GI endoscopes is not straightforward or self-evident. On the one hand, it could be reasonably argued that, although sanctioned in this manufacturer's revised manual, not using detergent during the bedside cleaning of GI endoscopes is the deviation, because, as previously noted, this practice contravenes published reprocessing guidelines, which specifically advise using a detergent solution to pre-clean GI endoscopes.[4,5] To be sure, published reports have identified the improper reprocessing of GI endoscopes as the cause of the transmission of infectious agents, with associated morbidity and mortality.[4-7]

(Other considerations that might suggest that the use of water, without detergent, is a deviation include the description of these initial cleaning steps performed in the procedure room [*see*: **Box B**], not as bedside-*watering*, but as bedside *cleaning*, which manifestly implies the use of a detergent. Also, this manufacturer's revised instruction *eliminates* a reprocessing practice; it does not *add* a safety measure.)

A manufacturer's prerogative: On the other hand, the revision of a device's label or reprocessing instructions is generally the manufacturer's prerogative. Such a change is usually meritorious, and, if adequately validated, the change may establish a new, safe standard. Staff's compliance with a manufacturer's instruction that conflicts with a guideline's recommendation is not necessarily a *de facto* deviation. It is possible that the manufacturer's elimination in its revised manual of the requirement that a detergent be used to pre-clean the GI endoscope, which the manufacturer describes as a "validated" improvement,[2,3] does not compromise safety.

Regulatory oversight of labeling changes: Seemingly in support of the soundness of this manufacturer's revised reprocessing manual, reports (to date) have not associated the

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Box B. *The bedside cleaning of GI endoscopes.* Published reprocessing guidelines[4,5] recommend using a detergent solution, as described below, to pre-clean GI endoscopes in the procedure room immediately following the exam. (Nevertheless, one manufacturer reports that it has validated the bedside cleaning of GI endoscopes using water, *without* detergent; *see*: *main article*.[2,3])

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1. The GI endoscope's insertion tube:
   – Wipe the GI endoscope's insertion tube using a clean, lint-free cloth, sponge, or gauze soaked in a freshly prepared solution of detergent.[4]

2. The GI endoscope's suction channel:
   – With the GI endoscope still connected to its light source and suction pump, depress the GI endoscope's suction valve to aspirate the biopsy/suction channel with a detergent solution (e.g., for 30 seconds), followed with air (e.g., for 10 seconds). Repeat this step until the suctioned detergent solution appears clean and is visibly devoid of patient debris.[4] (Ensure that the biopsy port is capped during this procedure.[†])

3. The GI endoscope's air/water channels:
   – In accordance with manufacturer's instructions, flush the water channel with water (e.g., for 30 seconds), followed by purging the air channel with air (e.g., for 10 seconds). (The use of one or more cleaning adapters may be necessary during this step.[†])

4. The GI endoscope's auxiliary water channel (or forward water jet channel), if featured:
   – Flush this channel with a detergent solution either manually (e.g., using a filled 30 ml syringe) or using an automated flushing pump (e.g., the Olympus OFP pump), followed by purging this channel with air.[†,Ψ]

5. The GI endoscope's transportation:
   – Disconnect the GI endoscope from its light source and suction pump.[4,†] Transport the GI endoscope, along with its suction valve, air/water valve, and all of its other removable, reusable parts (e.g., a reusable biopsy-port cap), in an enclosed container to the reprocessing room for thorough cleaning and high-level disinfection (at a minimum).[μ,†] ●

[†] Refer to published guidelines or the GI endoscope's reprocessing instructions for more specific details.

[Ψ] Perform a similar procedure for the GI endoscope's other specialized channels, such as the elevator-wire channel, if featured.

[μ] Refer to Box C in this newsletter's *January-February-March, 2012,* issue if the GI endoscope's reprocessing will be delayed.[1]

Box C: ***The FDA's Quality System (QS) Regulation***.

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The current good manufacturing practice (CGMP) requirements of the FDA's *Quality System* (QS) regulation mandate that manufacturers of medical devices sold in the U.S. develop and employ a quality system (unless the device is exempt from this regulation). Among other activities, the employed quality system is required to establish and maintain procedures to manage and control[†] the designs of medical devices, including any *changes* to their designs. This "design control" requirement applies to most medical devices[*] and, in part, is intended to ensure the proper execution of a design change—namely, that a modified device is consistent with the device's changed design specifications (i.e., that the "total finished design *output*"[14] conforms to the device's "design *input* requirements"[8]).

The QS regulation requires that changes to a reusable instrument's design or labeling—including its reprocessing instructions—be controlled.

Further, the FDA's QS regulation requires that a manufacturer's quality system establish and maintain procedures to manage and control the device's documentation, which includes its labeling, instructions for use (or, IFUs), and, if the device is reusable, its reprocessing instructions. An example of a manufactured device that lacks design control, displays faulty translation of its design specifications, and does *not* comply with the QS regulation—and, therefore, according to the FDA, is adulterated[11,13]—would be a reusable instrument whose design specifications require that the device withstand steam sterilization, but that was discordantly manufactured using plastic materials that are melted by heat.

Germane to this newsletter's main article, the FDA's QS regulation similarly requires that *changes* to a reusable device's labeling and reprocessing instructions (like changes to the device's design) also be managed and controlled to ensure the device's quality, safety, and effectiveness. A labeling change may be minor requiring limited control, including the manufacturer's review, approval, and verification (and, as required, validation) of the change; or, the change may be significant, or "major,"[9] with the potential to adversely affect the device's safety and effectiveness.[9] Unlike minor ones, significant labeling changes—an example would be a change to the device's intended uses—require additional control, including that the device receive a new 510(k) clearance (or a new premarket approval) to be legally marketed in the U.S.[9,11,13]

Whether a specific change to a device's labeling is minor or sufficiently significant to require a new 510(k) clearance may not always be obvious. One manufacturer may interpret to be minor and insignificant a device's revised reprocessing instruction that another may conclude invalidates its current 510(k) clearance. The elimination of the use of detergent during bedside cleaning may be such an example of a change to the device's labeling that the FDA may, or may not, deem significant (*see:* main article).

To avoid a device becoming adulterated and misbranded, its manufacturer may judiciously consider applying for a new 510(k) clearance whenever there is the reasonable possibility that the FDA would conclude that a specific change to the device's labeling is significant. ●

[†] "Control" in the QS regulation refers to, among other activities, the manufacturer's review, approval, documentation, verification and, as required, validation of a device's design and any changes to its design. *Verification* confirms that a change conforms to the device's design specifications, whereas *validation* confirms that the change is consistent with the device's intended uses.[8]

[*] The CGMP requirements of the FDA's QS regulation apply to all medical devices, no matter whether a class 1, class 2, or class 3 device.[8] While applying to all class 2 and class 3 devices, however, this regulation's provisions requiring that manufacturers control the device's design (and changes to its design) apply only to a few class 1 devices. Class 1 devices (e.g., examination gloves) pose a low risk of patient harm and are generally exempt from premarket review; class 2 devices (e.g., GI endoscopes) pose a moderate risk and usually receive a 510(k) clearance; and class 3 devices (e.g., implantable pacemakers) pose a high risk and require a premarket approval.[8,9]

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exclusive use of water (without detergent) to pre-clean the GI endoscope with an adverse outcome. Nevertheless, while it is generally at the manufacturer's behest (e.g., unless mandated by a regulatory agency), the revision of a device's labeling or reprocessing manual, like a modification to the device's design, requires control as prescribed by the Food and Drug Administration's (FDA) *Quality System* (QS) regulation,[8,9] a discussion of which is provided in **Box C** and to which the reader is referred.

Changes to a label that lack the necessary control could render the device adulterated, misbranded.

There are instances for which a change to its device's labeling (or design) is minor and requires that the manufacturer exercise only limited control (*see*: **Box C**), without regulations requiring that the FDA review and approbate the change. In other instances, however, federal regulations require additional control and that the manufacturer inform the FDA of the change, via a premarket notification, prior to marketing the device. At times a source of confusion for manufacturers, the regulatory significance and impact of a specific labeling change and whether it requires a new 510(k) clearance may not always be obvious. Reprocessing instructions are an important feature of a GI endoscope's labeling and performance, and, as a general rule, if a change to these instructions is significant with the potential to adversely affect

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the device's safety and effectiveness, then, as discussed in **Box C**, the FDA would most likely require additional control and that the device receive a new 510(k) clearance.

A "major" change? This manufacturer's announcement (via two notices) that it had "validated"[2,3] the use of water (without detergent) to pre-clean the GI endoscope reasonably suggests that this manufacturer concluded that this revised reprocessing instruction is a minor change, requiring only limited control in accordance with the FDA's QS regulation (*see:* **Box C**).[8] Warranting consideration, however, the FDA could plausibly conclude (as with any design or labeling change) that this is a "major" labeling change[9] with the potential to significantly impact the device's safety and effectiveness, therefore requiring additional control, namely, that the GI endoscope receive a new 510(k) clearance.*

The improper control of a device's label or reprocessing instructions may have potentially adverse consequences that are not limited to the manufacturer and may also include the medical facility.

The potentially adverse consequences of the improper control of a change to a device's design or labeling are not limited to the manufacturer—they may also impact the medical facility. The FDA may conclude that a device whose reprocessing instructions were changed significantly, but that did not receive a new 510(k) clearance (or premarket approval), is adulterated and misbranded, which could pose legal risk for a medical facility that uses the modified device.

(One recent regulatory action about which readers are likely familiar underscores the significance of a medical device's reprocessing instructions and changes to them. With as much national impact on instrument reprocessing as any other recent regulatory action, the FDA determined in 2009 that the STERIS System 1 [SS1] had been modified and without a 510[k] clearance or premarket approval since 1988.[10-12] As a consequence, the FDA concluded in 2010, that rigid endoscopes and any other reusable device whose labeling referenced the SS1 as a suitable, compatible, or recommended method for the device's reprocessing became themselves misbranded, like the SS1, for failing to provide adequate instructions for use as federal regulations require.[12] Refer to this newsletter's *July-August-September, 2009,* issue and to its *October-November, 2009,* issue for more details about the SS1 and the use of adulterated and misbranded devices.)

RECOMMENDATIONS: Consistent with published guidelines,[4,5] it is suggested that medical facilities consider continuing to use detergent to pre-clean the GI endoscope at bedside (at least) until more data are published independently confirming the suitability of using only water for this purpose. To be sure, effective bedside-cleaning is important to initiate the cleaning process, prevent the drying and hardening of potentially infectious patient materials on the GI endoscope's surfaces, and minimize the risk of infection (*see*: **Box B**).[1]

Alternatively, however, if a medical facility elects to comply with the manufacturer's revised instruction and uses water, without detergent, to pre-clean the GI endoscope, a practice that has not been reported to pose an increased risk of patient harm, then this newsletter suggests that the medical facility consider requesting from the manufacturer a written statement (independent of the manufacturer's aforementioned notices) certifying that this revision of its reprocessing manual is a minor change that neither adversely affects the GI endoscope's safety and/or effectiveness (*see*: **Box C**) nor adulterates and/or misbrands the GI endoscope (or, alternatively, acknowledging that this change was significant and that the FDA granted a new 510(k) clearance for each of the models of GI endoscopes that were the subject of the manufacturer's notices). ● **The End** [Article by: *L.F. Muscarella, Ph.D.*]

* If the manufacturer's rationale for revising the reprocessing instructions of a reusable instrument was based on an adverse event or customer complaints about the instrument; a failure mode analysis the manufacturer performed; or corrective actions the manufacturer issued, then the FDA may consider the label's revision a "major change" requiring not just validation that the change does not adversely impact the reusable instrument's safety and effectiveness, but, additionally, that the device receive a new 510(k) clearance.[9]

➡ The **REFERENCES** to this article are available at:
www.myendosite.com/htmlsite/2012/refs04050612.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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