

# The Q-Net™ Monthly

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## What's News

An article on SARS entitled "Recommendations for the prevention of transmission of SARS during gastrointestinal endoscopy" appears in the November 2004 issue of ASGE's *Gastrointestinal Endoscopy*. A second article entitled "Dear Los Angeles Times: The risk of disease transmission during gastrointestinal endoscopy" will appear in the November-December 2004 issue of SGNA's *Gastroenterology Nursing*. Both articles were written by this newsletter's editor (LFM).

## Editor-in-Chief

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## What is 'Q-Net'?

**Q-Net** is a technology-assessment network of questions and answers. *The Q-Net™ Monthly* is its newsletter.

The main goal of **Q-Net** is to encourage the infection control and endoscopy communities to not only ask good questions but also to demand well referenced responses.

**Q-Net** addresses the needs of both the health care provider whose goal is to provide the best care possible, and the patient who deserves affordable quality health care.

## Guidelines for reprocessing rigid laryngoscopes

**A step-by-step guideline for the cleaning and high-level disinfection, sterilization of rigid laryngoscopes**

~ Fourth in a series of articles ~

**Background:** Over the past several months, three articles that discuss the use, care, handling, and reprocessing of flexible and rigid laryngoscopes were sequentially published in this newsletter. Highlights of these three articles include the following:

• A formal set of standardized and universally-accepted instructions for reprocessing flexible laryngoscopes has not been published. A step-by-step set of instructions for reprocessing these instruments was therefore provided in the *May-June 2004 issue* of this newsletter.

• Flexible and rigid laryngoscopes—both their blades and handles—are classified as *semicritical* devices and, therefore, require cleaning and high-level disinfection ("HLD") or sterilization.<sup>1-6,9,25</sup>

• Quaternary ammonium products and other cleaner/disinfectants labeled to achieve intermediate-level (or low-level) disinfection are contraindicated for

reprocessing flexible and rigid laryngoscopes (and other *semicritical* devices).

• HLD destroys all types of pathogenic microorganisms identified in the endoscopic setting, including *Clostridium difficile*, a spore-forming bacterium. Very few spore-forming bacteria are pathogenic. Those that do produce disease—such as *Bacillus anthracis* and some *Clostridium* species—either are destroyed by HLD or have not been associated with infection following endoscopy.<sup>28</sup>

### Step-by-step reprocessing guidelines:

A formal set of standardized and universally-accepted instructions for reprocessing rigid laryngoscopes has not been published. It is not surprising, therefore, that surveys report that the majority of responding medical facilities do not have on file a written policy or procedure for reprocessing rigid laryngoscopes.<sup>12,20,23</sup>

Moreover, reports indicate that reprocessing practices for the laryngoscope's blade and handle are often inadequate and vary from one medical facility to another.<sup>7,9,12,13,17,20,22,23</sup> Variations in ➔

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**"Dear AORN, Part II"**  
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reprocessing practices (and guidelines; refer to the article entitled “Dear AORN, Part II” on page 19) can result in inconsistencies in the standard of care, ineffective reprocessing, and an increase the risk of nosocomial infection.<sup>5,7,11-13,20,23,24</sup>

Both the laryngoscope’s blade and handle can become contaminated during use and transmit disease from one patient to another.<sup>3,5,8-12,20,23</sup> The following set of step-by-step instructions for reprocessing rigid laryngoscopes is provided, therefore, to minimize the risk of nosocomial infection. These instructions, which may be used by medical facilities to develop policies and procedures for reprocessing rigid laryngoscopes, may lack some details and are to be used in conjunction with—not as a replacement for—the reprocessing instructions provided by the rigid laryngoscope’s manufacturer. Some additional reprocessing steps may be required. Failure to adhere to these (or comparable) guidelines may result in not only nosocomial infection but also instrument damage.

#### **STEP 1. Transportation** (from the procedure room):

*Purpose:* To transfer the laryngoscope from the procedure room to the decontamination area for prompt reprocessing.

1. After use, promptly **transport** the blade and handle in an enclosed bag, package, or container to a dedicated decontamination area for reprocessing.

**Note:** Prolonged delay between use of the laryngoscope and reprocessing can result in the drying and hardening of patient debris on the laryngoscope’s surfaces. Dried patient debris can pose a formidable challenge to cleaning, can interfere with the effectiveness of the high-level disinfection or sterilization process, and can damage the laryngoscope.

#### **STEP 2. Disassembly** (in the decontamination area):

*Purpose:* To expose all of the surfaces of the laryngoscope’s blade and handle to both the cleaning and high-level disinfection (or sterilization) processes.

**2.a Disconnect** the blade from the handle. **Disassemble** the blade and handle as described in the laryngoscope’s reprocessing instructions. Depending on the laryngoscope’s design (i.e., conventional, fiber optic), removal of the light bulb or fiber optic light pipe (or light bundle) from the blade, and/or the lamp cartridge assembly from the handle, may be required prior to reprocessing. In some models, this light pipe (or light bundle) is encased in the blade and cannot be removed.

**2.b Remove** the batteries from the handle (unless otherwise instructed). Some models of handles may only require removal of the batteries prior to steam sterilization. Refer to the laryngoscope’s reprocessing instructions.

#### **STEP 3. Cleaning:**

*Purpose:* To remove patient debris and reduce the number of microorganisms on the laryngoscope’s blade and handle.

3. **(A) Clean** the blade and handle (and, if necessary, the fiber optic light pipe) using fresh, clean warm potable water, a mild (e.g., enzymatic) detergent, a soft brush, and a wipe or cloth. Mix the detergent ensuring its dilution and temperature are in accordance with its labeling. **(B) Soak** the entire blade and handle in the detergent solution (unless complete immersion of either is contraindicated) for the recommended time. Do not immerse a hot light pipe into cold water or a cold detergent solution. **(C) Rinse** the blade and handle with a large volume of fresh, clean warm potable water (or, clean, demineralized water). **(D) Dry** the blade and handle with a clean, dry, soft lint-free cloth or towel. **(E) Examine** the blade and the handle for cleanliness and for damage.

**Note:** Do not **ultrasonically clean** the blade and/or handle unless it is recommended in their reprocessing instructions.

#### **STEP 4. Sterilization, high-level disinfection:**

*Purpose:* To prevent disease transmission during laryngoscopy by destroying any remaining microorganisms.

##### **4.a Wrap and steam sterilize** the blade and handle.

**Note 1: Steam sterilize** the blade and handle unless it is contraindicated for either in the laryngoscope’s reprocessing instructions. Also, although some models may be labeled as “steam-autoclavable,” repeated exposure to steam sterilization may result in decreased performance and instrument damage.<sup>16,22</sup> Contact the manufacturer to ensure steam sterilization does not void the laryngoscope’s warranty.

**Note 2:** The recommended sterilization method for the blade may not be the same as for the handle. For instance, whereas steam sterilization may be recommended for the laryngoscope’s blade, it may be contraindicated for the handle.

**Note 3: Flash sterilization** of a rigid laryngoscope is generally contraindicated and may void its warranty, due to damage that may result from rapid cooling.

**4.b** If steam sterilization of the blade and/or handle is contraindicated, consider using a **low-temperature sterilization process** (eg, ethylene oxide gas).<sup>29</sup> Refer to the laryngoscope’s reprocessing instructions for a list of recommended low-temperature sterilization processes.

**4.c** Alternatively, **high-level disinfect** the blade and/or handle.<sup>1,28,29</sup> **(A) Immerse** the blade and/or handle in a liquid chemical sterilant (LCS) listed in the laryngoscope’s reprocessing instructions as compatible. **(B) Soak** the blade and/or handle in the LCS for the recommended time and temperature to achieve high-level disinfection. Completely immerse the blade and/or handle, unless otherwise noted in the reprocessing instructions. **(C) Rinse** the blade and/or handle with a large volume of sterile,

demineralized water (or, fresh, clean warm potable water). Do not reuse the rinse water. Three or more separate water rinses may be necessary; refer to the LCS's label. **(D) Dry** the blade and/or handle with a clean, dry, soft lint-free cloth or towel. A wipe lightly dampened with 70% alcohol may be used to facilitate drying.

**Note 1:** If high-level disinfection (or sterilization) of the handle is not feasible or cannot be "tolerated,"<sup>35</sup> then it may be acceptable to use a single-use, FDA-cleared (sterile) sheath to cover the handle during the procedure, followed by intermediate-level disinfection of the handle after the sheath's removal. (Refer to the accompanying "Dear AORN, Part II" box article on p. 19 for more information.)

**Note 2:** Monitor the concentration of the LCS to ensure it is equal to or above its *minimum effective concentration*. (Refer to section "4.b" of the May-June 2004 issue of this newsletter.)

**Note 3: Pasteurization** may also be a recommended method for reprocessing the laryngoscope's blade and/or handle. Refer to the laryngoscope's reprocessing instructions.

**Note 4:** Although steam sterilization is always preferred due to its wider margin of safety, high-level disinfection of the laryngoscope's blade and handle has not been reported to pose an infection risk. *Clinical differences in the infection rate between sterilized and high-level disinfected, or pasteurized, laryngoscopes, as well as other rigid and flexible endoscopes, have not been reported.*<sup>28,29</sup> Several factors such as cost may contribute to a medical facility's selection of a specific sterilization or high-level disinfection process.

**4.d** If they are to be immediately reused, **transport** the blade and handle from the decontamination area to the point of use. **Reassemble** the blade and handle if required and as described in the laryngoscope's reprocessing instructions. Some laryngoscope manufacturers may recommend reassembly prior to, instead of after, sterilization or high-level disinfection.

**Note:** Adhere to proper handling techniques (e.g., clean or sterile gloves) to prevent re-contamination and damage of the blade and handle during transportation and reassembly.

#### STEP 5. Storage, handling, and care:

*Purpose:* To prevent re-contamination and damage of the blade and handle during storage, handling, and care.

**5.a Transport** the blade and handle from the decontamination area to the storage area.

**5.b Store** the blade and handle in a clean, dry area. Refer to the laryngoscope's manual for proper storage instructions. Do not store the blade or the handle wet or in a closed carrying case, container, or kit.

**5.c** When needed for rigid laryngoscopy, **transport** the blade and the handle from storage to the point of use. **Examine** the blade and the handle for damage. Confirm that the batteries have been placed back into the handle and are charged. **Test** the blade and handle for proper functioning and to ensure the light is bright and is not flickering or otherwise operating improperly. Have available spare batteries, bulbs, light pipes, lamp assemblies, and other replacement parts as required.

**Note:** Adhere to proper handling techniques (e.g., clean or sterile gloves) to prevent re-contamination and damage of the blade and handle during transportation, storage, reassembly, and examination prior to reuse. *The End* ● LFM

**References:** <http://www.myendosite.com/refs071004.htm>

## "Dear AORN, Part II"

**"Do the handles of laryngoscopes require high-level disinfection or sterilization?"**

~ Inconsistencies in published guidelines ~

**Background:** This newsletter's *January-February 2004 issue* discussed a significant inconsistency in several reprocessing guidelines with regard to endoscope drying. For unclear reasons, several of the *Association of periOperative Registered Nurses'* (AORN) published "*Recommended Practices*" support the clinical use of *just-reprocessed-and-wet-with-rinse-water* rigid and flexible endoscopes. Specifically, rather than recommending that the endoscope be dried after completion of every reprocessing cycle, AORN recommends use of the wet endoscope "immediately" after reprocessing.<sup>30</sup>

This recommendation is problematic, however, because it encourages, for example, the introduction of wet bronchoscopes into the lungs of critically-ill patients suffering from pneumonia and AIDS in a ICU (or, the introduction of wet arthroscopes, laparoscopes, and cystoscopes into patients' knees, peritoneal cavities, and bladders, respectively).<sup>31</sup> It would be difficult to identify another "recommended" medical practice that poses as significant a risk of nosocomial infection (and pseudo-infection) from, for example, water-borne bacteria (including *Pseudomonas aeruginosa*) as the introduction of wet endoscopes into patients' organs and cavities.<sup>31</sup> (*Nota bene:* No data or studies have been published that support the claim that "sterile" rinse water can be produced by filtering a hospital's tap water through a water filtration assembly that includes a 0.2 micron bacterial filter.)

The risk of transmission of bacteria during flexible (and rigid) endoscopy can be virtually eliminated, however, by drying the endoscope after completion of every reprocessing cycle—a practice that, while not supported by AORN (and a few other organizations), is recommended by the *Society of Gastroenterology Nurses and Associates* (SGNA) and ➔

the American College of Chest Physicians.<sup>31,32</sup>

**Handles of rigid laryngoscopes:** Published reprocessing guidelines are not only inconsistent with regard to endoscope drying. The *July-August 2004 issue* of this newsletter published a review of several reprocessing and infection control guidelines, to evaluate the minimum infection control standards required for reprocessing rigid laryngoscopes. In addition, an unpublished review of AORN's pending "Proposed Recommended Practices for cleaning, handling, and processing anesthesia equipment"<sup>33</sup> was performed. Both reviews reveal an inconsistency in published guidelines with regard to reprocessing the laryngoscope's handle. Indeed, the resolution of this inconsistency has significant infection control and economic implications.

The laryngoscope's blade and handle can become contaminated during routine use.<sup>3,5,8-12,20,23</sup> Proper reprocessing of both, therefore, is required to prevent patient-to-patient disease transmission (*refer to this newsletter's main article*).<sup>2,3,9</sup> These AORN-pending "Proposed Recommended Practices" state that "laryngoscope handles are non-critical" devices that are required to be "cleaned and low-level disinfected between patients" to prevent nosocomial infection.<sup>33</sup> According to the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and other organizations, however, instruments that directly or indirectly contact mucous membranes (or oral tissues) without ordinarily penetrating sterile tissue—examples include the laryngoscope's handle (as well as its blade and dental handpieces)—are *semicritical*.<sup>1-6,8-12,20,23,25,34,35</sup>

As discussed in this newsletter's *July-August 2004 issue*, the American Association of Nurse Anesthetists (AANA), like the CDC and FDA, also classifies laryngoscope handles (and blades) as *semicritical* instruments,<sup>2</sup> which require cleaning followed by high-level disinfection (or sterilization) to prevent cross-infection.<sup>1-6,8-12,20,23,25</sup> (These AORN-pending "Proposed Recommended Practices"<sup>33</sup> recommend low-level disinfection of the laryngoscope's handle based in part on a report by Phillips and Monaghan [1997].<sup>5</sup> This report, however, does *not* recommend low-level disinfection; rather, it recommends that the handle [and blade] be high-level disinfected or sterilized after each patient use.<sup>5</sup>)

A chain is only as strong as its weakest link: Once a high-level disinfected (or sterilized) blade is connected to a low-level disinfected handle to perform rigid laryngoscopy, the blade's integrity becomes compromised. The blade can arguably no longer be considered high-level disinfected but only low-level disinfected. It is necessary, therefore, to high-level disinfect (or sterilize) the handle as required for the blade to which it attaches.<sup>1-6,9,25</sup> It is suggested that AORN "strengthen the chain," revisit its rationale for recommending low-level disinfection of the laryngoscope's handle, and consider—for the sake of consistency, to raise the standard of care, and to improve patient safety—recommending high-level disinfection (or sterilization) of the handle, in accordance with the CDC's, FDA's, and AANA's guidelines.<sup>1,2,4</sup>

If high-level disinfection (or sterilization) of the laryngoscope's handle is not feasible, then medical facilities may want to consider using a single-use, sterile sheath to cover the handle, to help prevent its contamination during laryngoscopy. But use of a sheath may not eliminate reprocessing. The FDA requires the laryngoscope be reprocessed after removal of the sheath—out of concern that the sheath may break during use, or that the laryngoscope may become recontaminated during application or removal of the sheath.<sup>4</sup> If a manufacturer has shown that the sheath provides a barrier that is sufficiently "protective," the FDA recommends that the laryngoscope receive "intermediate-level disinfection."<sup>4</sup>

This recommendation (which appears to be in agreement with the CDC's guidelines for reprocessing specific types of barrier-protected *semicritical* devices in dentistry<sup>35</sup>), however, may be lacking. Viewed from a different perspective, if reprocessing of an instrument is required after the sheath's removal, then it could be argued that the instrument's classification should dictate the minimum level of disinfection or sterilization required to prevent nosocomial infection (*refer to this newsletter's March-April 2004 issue*). Because the laryngoscope's blade and handle are classified as *semicritical* devices,<sup>1-6,8-12,20,23,25,34,35</sup> it is suggested that the FDA consider recommending that both be cleaned followed by high-level disinfection (or sterilization)—not intermediate-level disinfection—after the sheath's removal.<sup>1-6,9,25</sup> Intermediate-level disinfection would only be indicated if a barrier-protected *semicritical* device could not "tolerate"<sup>35</sup> high-level disinfection (or sterilization). *The End* • LFM

The references for this current newsletter and the *July-August 2004 issue* of this newsletter are at:  
<http://www.myendosite.com/refs071004.htm>

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

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