

# The Q-Net™ Monthly

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## What's News

SGNA's revised guideline (2003) for the use of high-level disinfectants and sterilants for reprocessing flexible endoscopes was recently posted on the Internet. In agreement with the published stance of this newsletter, SGNA's guideline provides an all-inclusive recommendation for drying endoscopes. See: <http://www.sgna.org/resources/HLD.html> Also, visit Q-Net's website ([www.myendosite.com](http://www.myendosite.com)) to read this newsletter's back issues and to take Q-Net's quiz on infection control.

## Editor-in-Chief

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## What is 'Q-Net'?

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

**Q-Net's** main goal is to encourage the infection control and endoscopy communities to not only ask good questions but to also demand succinct and 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.

## Cleaning Laryngoscopes

### Question

*"Our facility uses a quaternary ammonium product to clean and disinfect flexible rhinolaryngoscopes, flexible nasopharyngo-laryngoscopes, and the blades and handles of rigid laryngoscopes. Is this a safe and acceptable practice?"*

**Background and answer:** Similar to the concern expressed last month in this newsletter's article entitled "**Dear AORN,**" the response to this question about reprocessing laryngoscopes — one of several different types of rigid and flexible endoscopes sometimes referred to as ENT (or, "ear-nose-throat") endoscopes — impacts clinical practice, patient safety, and the standard of care.

To provide a complete response to this question, a review of published endoscope reprocessing and infection control guidelines is necessary. Also necessary are a review and discussion of the following topics: (1) the three categories into which medical instruments are classified, based on the risk of nosocomial infection associated with their use; (2) sterilization; (3) the three "levels" of disinfection; (4) the relative resistance of different microorganisms to sterilization and disinfection; and (5) the label claims and effectiveness of quaternary ammonium

products for cleaning and disinfection.

**Laryngoscopes:** Flexible rhinolaryngoscopes use fiber-optic or video technology to examine, diagnose, and evaluate the normal physiologic and pathologic conditions of, among other organs, the larynx. Most models are used for diagnostic procedures and do not have any internal channels. Some models, however, feature a single working channel, a suction control valve, and a biopsy inlet port that can be used for aspiration, removal of foreign objects, and performing biopsies. Flexible nasopharyngo-laryngoscopes are similar in design and function to flexible rhinolaryngoscopes.

Rigid laryngoscopes, on the other hand, are used to expose and view the larynx to facilitate endotracheal intubation. These endoscopes feature a fiber-optic disposable or reusable blade that is available in different sizes, may be curved or straight, and connects to the laryngoscope's handle.

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**Critical instruments:**

- Penetrate sterile tissue, enter the vasculature, or contact the patient's blood.
- Examples: cardiac catheters, biopsy forceps, and implants.

**Semicritical instruments:**

- Contact mucous membranes or non-intact skin.
- Examples: rhino-laryngoscopes, naso-pharyngo-laryngoscopes, and the blades and handles of rigid laryngoscopes.<sup>1-4</sup>

**Noncritical instruments:**

- Do not directly contact the patient, or only contact the patient's intact skin.
- Examples: blood pressure cuffs, stethoscopes, and bedpans; and environmental surfaces, such as walls, floors, and sink tops.

**TABLE 1: Classification scheme for medical instruments.**

**Classification of medical instruments:** Before it can be determined whether selection of a quaternary ammonium product is appropriate for cleaning and disinfecting rigid and flexible laryngoscopes, it is first necessary to evaluate the risk of nosocomial infection associated with the use of these instruments. Application of a widely accepted three-tiered classification scheme for medical instruments aids in the evaluation of this risk. According to this scheme, medical instruments that penetrate sterile tissue, enter the vasculature, or contact the patient's blood are classified as *critical* instruments, because the risk of nosocomial infection associated with their use is high (Table 1).<sup>1-4</sup>

*Semicritical* instruments, on the other hand, contact mucous membranes or non-intact skin, but do not typically penetrate sterile tissue (Table 1). The risk of nosocomial infection associated with instruments in this second category, while still potentially significant, is markedly less than the risk associated with *critical* instruments. Flexible rhino-laryngoscopes, flexible naso-pharyngo-laryngoscopes, and the blades and handles of rigid laryngoscopes are classified in this second category.<sup>1-4</sup> Medical instruments that either do not directly contact the patient or only contact a patient's intact skin pose a low risk of nosocomial infection and therefore are classified as *noncritical* instruments (Table 1).<sup>1,2</sup> Most environmental surfaces, including walls, floors, and sink tops, are included in this third and low-risk category.

**Sterilization and the three levels of disinfection:** Once the risk of nosocomial infection associated with the use of rigid and flexible laryngoscopes has been evaluated and their classification as *semicritical* instruments understood, a review of: published endoscope reprocessing and infection control guidelines; the definitions of *sterilization* and *disinfection*; and the labels of quaternary ammonium products is necessary to determine whether they are sufficiently effective to satisfy the minimum reprocessing standards required to prevent rigid and flexible laryngoscopes (and other *semicritical*

instruments) from transmitting disease.

Whereas *sterilization* is an absolute term and refers to a process that destroys all types of microorganisms including high numbers of resistant bacterial endospores, *disinfection* is a relative term and refers to different types of processes that vary in effectiveness. As displayed in Table 2 in decreasing order of biocidal effectiveness, disinfection processes can be classified into one of three categories, or "levels": *high-level disinfection* (HLD), *intermediate-level disinfection* (ILD), and *low-level disinfection* (LLD).<sup>1-4</sup> Each of these three levels of disinfection is, in effect, defined and differentiated from one

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**Sterilization**

- Destroys all microorganisms, including bacterial endospores.
- Sporocidal, tuberculocidal, virucidal, fungicidal, and bactericidal.
- Uses bacterial endospores as biological indicators.
- Examples: pressurized steam, ethylene oxide gas, hydrogen peroxide plasma.
- Primarily used for **critical** instruments.

**High-level disinfection (HLD)**

- Destroys all pathogenic microorganisms, including some bacterial endospores during short exposure times.
- Typically destroys high numbers of bacterial endospores during long exposures times.
- Sporocidal (limited), tuberculocidal, virucidal, fungicidal, and bactericidal.
- Uses mycobacteria as indicators of effectiveness.
- Examples: 2% glutaraldehyde, 7.5% hydrogen peroxide, 0.2% peracetic acid.
- Primarily used for **semicritical** instruments.

**Intermediate-level disinfection (ILD)**

- Destroys many types of microorganisms including mycobacteria.
- Not sporocidal.
- Tuberculocidal, virucidal, fungicidal, and bactericidal.
- May use mycobacteria, viruses as indicators of effectiveness.
- Examples: 70% isopropyl alcohol, iodophor and phenolic compounds, concentrated quaternary ammonium compounds (e.g., hospital cleaner/disinfectants *with* a tuberculocidal claim).
- Primarily used for **noncritical** instruments.

**Low-level disinfection (LLD)**

- Destroys some types of microorganisms.
- Neither sporocidal nor tuberculocidal.
- Virucidal (limited), fungicidal, and bactericidal.
- May use the hepatitis B virus, HIV as indicators of effectiveness.
- Examples: diluted quaternary ammonium compounds (e.g., hospital cleaner/disinfectants *without* a tuberculocidal claim).
- Primarily used for **noncritical** instruments.

**TABLE 2: The definitions, characteristics, and relative effectiveness of sterilization, disinfection.** Sterilization or the level of disinfection appropriate for **critical**, **semicritical**, and **noncritical** medical instruments is listed.

another by specific “indicator” microorganisms that each respective level can — and cannot — reliably destroy. The relative resistance of microorganisms to sterilization and the three levels of disinfection is displayed in Table 3.<sup>1</sup> The more resistant the microorganism, the higher the level of disinfection (or sterilization) required to destroy it.

Defined as the highest and most effective level of disinfection, HLD destroys mycobacteria (i.e., is tuberculocidal), viruses, fungal spores, and vegetative bacteria.<sup>1</sup> HLD also destroys some, but not all, bacterial endospores. It is the limited sporicidal activity of HLD that distinguishes it from sterilization (which destroys all microorganisms, including high numbers of bacterial endospores) and the other two levels of disinfection (neither of which is sporicidal) (Tables 2, 3). Most important, HLD destroys all pathogenic microorganisms encountered in the endoscopic setting, including *Clostridium difficile*, a spore-forming bacterium. (Almost all spore-forming bacteria are non-pathogenic. Those few that do produce disease—such as *Bacillus anthracis* and some species of the *Clostridium* genus—either are destroyed by HLD or have not been associated with infection following endoscopy.<sup>5</sup>) It is for this reason that differences in the infection rates of rigid and flexible endoscopes subjected to sterilization or HLD have not been documented.<sup>5</sup> Liquid chemical sterilants (LCSs) are frequently used to achieve HLD of endoscopes (Table 2). LCSs that achieve HLD during short immersion times typically are sporicidal and destroy high numbers of bacterial endospores during long exposure times.

One level below HLD is a less effective process known as ILD (Table 2).<sup>1</sup> Whereas processes that achieve sterilization and HLD are regulated by the Food and Drug Administration (FDA), ILDs (and LLDs) are regulated instead by the Environmental Protection Agency (EPA). In general, ILD destroys lipid or medium-sized viruses, most non-lipid or small viruses, fungal spores, and vegetative bacteria. Like HLD, ILD is tuberculocidal. But what differentiates ILD from HLD (and sterilization) is its inability to destroy bacterial endospores, even during long exposure times. Examples of ILDs include iodophor and phenolic compounds. Concentrated quaternary ammonium cleaner/disinfectants may also be classified as ILDs.

The third and lowest level of disinfection, LLD destroys fungal spores, vegetative bacteria, and lipid or medium-sized viruses.<sup>1</sup> But unlike ILD, LLD is not tuberculocidal (Tables 2, 3). Examples include diluted quaternary ammonium cleaner/disinfectants.

**Selection of a sterilization, disinfection process:** For many reasons, selection of an appropriate sterilization or disinfection process or technology for reprocessing a specific reusable medical instrument (or environmental surface in the health-care setting) is not always straightforward. If every reusable medical instrument were constructed of stainless steel and other durable materials not damaged by heat, pressure, and moisture, few reprocessing dilemmas would arise, and the

Decreasing resistance of microorganisms to sterilization, disinfection	<b>Prions</b>
	<ul style="list-style-type: none"> <li>• May require extended, multiple sterilization cycles.</li> <li>• May be responsible for transmissible spongiform encephalopathies.</li> </ul>
	<b>Bacterial endospores</b>
	<ul style="list-style-type: none"> <li>• Destroyed by sterilization.</li> <li>• Some bacterial endospores can also be destroyed by HLD.*</li> <li>• Example: <i>Bacillus sterothermophilus</i></li> </ul>
	<b>Mycobacteria</b>
	<ul style="list-style-type: none"> <li>• Destroyed by sterilization, HLD, and ILD.<sup>†</sup></li> <li>• Example: <i>Mycobacterium tuberculosis</i></li> </ul>
	<b>Non-lipid or small viruses</b>
	<ul style="list-style-type: none"> <li>• Destroyed by sterilization, HLD, and ILD.</li> <li>• Example: the polio virus</li> </ul>
	<b>Fungi (molds and yeasts)</b>
	<ul style="list-style-type: none"> <li>• Destroyed by sterilization, HLD, and ILD.</li> <li>• Some fungi are also destroyed by LLD.<sup>‡</sup></li> <li>• Example: <i>Candida albicans</i></li> </ul>
<b>Vegetative bacteria</b>	
<ul style="list-style-type: none"> <li>• Destroyed by sterilization, HLD, ILD, and LLD.</li> <li>• Example: <i>Pseudomonas aeruginosa</i></li> </ul>	
<b>Lipid or medium-sized viruses</b>	
<ul style="list-style-type: none"> <li>• Destroyed by sterilization, HLD, ILD, and LLD.</li> <li>• Example: the hepatitis B virus, HIV</li> </ul>	
<p>* HLD = High-level disinfection; † ILD = Intermediate-level disinfection; ‡ LLD = Low-level disinfection</p>	
<p><b>TABLE 3: The relative resistance of different types of microorganisms to sterilization, disinfection.</b> In general, bacterial endospores (and prions) are the hardest to destroy and lipid (or medium-sized) viruses the easiest to destroy.</p>	

simple and obvious, if only, choice for reprocessing instruments would be steam sterilization. Indeed, steam sterilization is the method of choice, because it is effective, fast acting, and inexpensive.<sup>6</sup>

But the demand to improve patient morbidity, minimize the invasiveness of surgery, and reduce healthcare costs, coupled with significant advances in fiber-optic technology and materials engineering, spurred the development of delicate instruments, many of which are heat-sensitive and arguably designed more to simplify complicated medical procedures than to facilitate reprocessing. For these heat-sensitive instruments, several different types of low-temperature sterilization and disinfection processes were developed.

In addition to raising questions of materials compatibility, however, some low-temperature sterilization processes

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may be less effective and considerably more expensive per cycle than steam sterilization.<sup>6</sup> Moreover, complicating selection of an appropriate reprocessing process for a specific heat-sensitive reusable instrument, some low-temperature sterilization processes have limited applications and are contraindicated for reprocessing instruments with long and narrow internal channels, such as flexible gastrointestinal endoscopes. Also, not every reusable instrument requires sterilization. In many instances, disinfection is adequate to prevent patient-to-patient disease transmission.

Although at times challenging, selection of an appropriate reprocessing technology for a specific instrument can be simplified by dovetailing the three-tiered classification scheme for medical instruments displayed in Table 1 with the definitions and relative effectiveness of sterilization and disinfection (Tables 2, 3). In general, *critical* instruments, such as reusable biopsy forceps, require steam sterilization (Table 2).<sup>1,7,8</sup> For heat-sensitive *critical* instruments, such as some models of arthroscopes and laparoscopes, a low-temperature sterilization process may be indicated.<sup>1</sup> (Refer to the sterilizer's labeling and the instrument's reprocessing instructions regarding recommended processes, effectiveness, and compatibility.) Alternatively, if sterilization is not feasible, HLD is recommended.<sup>1</sup>

HLD is also recommended for *semicritical* instruments (although a low-temperature sterilization process may also be acceptable, as well as steam sterilization if the instrument is not damaged by heat).<sup>1,7,8</sup> Published guidelines emphasize that subjecting an arthroscope, laparoscope (*critical* instruments) or a flexible endoscope (a *semicritical* instrument) to HLD instead of sterilization is acceptable and does not pose an infection risk.<sup>1,5,7,8</sup> In accordance with published guidelines, their classification as *semicritical* instruments (Table 1), and their manufacturers' reprocessing instructions, HLD is recommended for flexible rhino-laryngoscopes, flexible nasopharyngo-laryngoscopes, and the blades and handles of rigid laryngoscopes (Table 1).<sup>1-12</sup>

Finally, products that achieve ILD and LLD – specifically, general purpose cleaner/disinfectants approved for use in medical facilities (Table 2) – are recommended for and limited to cleaning and disinfecting *noncritical* instruments and environmental surfaces.<sup>1</sup> (With very few exceptions, ILD may be acceptable for a limited number of *semicritical* devices, such as hydrotherapy tanks, but not endoscopes. Refer to the specific instrument's reprocessing instructions.)

**Quaternary ammonium products:** Quaternary ammonium products (or compounds) are broad spectrum, EPA-registered, cleaner/disinfectants. Depending on their concentrations, quaternary ammonium products intended for use in medical facilities are labeled for ILD or LLD and therefore may be used to clean, deodorize, and disinfect *noncritical* items and hard, non-porous environmental surfaces. In accordance with their labeling, quaternary ammonium products may also be used to pre-clean *critical* and *semicritical* medical instruments

prior to HLD or (sterilization). (Refer to the instrument's reprocessing instructions to ensure materials' compatibility with quaternary ammonium cleaner/disinfectants.)

**Conclusion:** Quaternary ammonium cleaner/disinfectants used in medical facilities are labeled for ILD or LLD — not HLD — and therefore, while indicated for cleaning and disinfecting *noncritical* items and environmental surfaces, are contraindicated for flexible endoscopes. *Use of a quaternary ammonium product to clean and disinfect flexible rhinolaryngoscopes, flexible naso-pharyngo-laryngoscopes, and the blades and handles of rigid laryngoscopes is not an accepted practice, potentially unsafe, and a violation of the standard of care.* Cleaning using an appropriate detergent (e. g., enzymatic detergent) followed by HLD at a minimum is required for these *semicritical* instruments as part of a complete and validated reprocessing protocol.<sup>1-4,10-12</sup> Use of quaternary ammonium products to clean and disinfect surgical instruments has been linked to disease transmission.<sup>9</sup>

Further, although the handles of rigid laryngoscopes may not always directly contact the patient, reports have demonstrated their contamination with opportunistic pathogens.<sup>10</sup> *Published guidelines recommend that these handles (and blades) be cleaned and subjected to HLD<sup>1-4,10,12</sup> (or sterilization).* Steam sterilization of the laryngoscope's handle and blade may also be acceptable, although flash sterilization may be contraindicated. Review the laryngoscope's reprocessing instructions for a list of compatible processes. ● LFM

The references for this article are available at:  
<http://www.myendosite.com/refs030404.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, PhD.* Please direct all correspondence to:

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