

# The Q-Net™ Monthly

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## What's News -

✓ An article entitled, "Déjà vu ... all over again?," written by this newsletter's editor, appears in an upcoming issue of *Infection Control and Hospital Epidemiology*.

✓ Soon Q-Net's web page will be: [www.MyEndoSite.com](http://www.MyEndoSite.com). Current news and all of this newsletter's back issues will be available free of charge. Stay tuned ...

✓ Also, due to inherent problems with bulk mail delivery, you may receive this newsletter several days late. While all efforts are made to have this newsletter delivered on time, some delay is unavoidable.

## Editor-in-Chief

Unless stated otherwise, all articles in this newsletter are written by: **Lawrence F. Muscarella, Ph.D., Chief, Infection Control** at Custom Ultrasonics, Inc., Ivyland, PA 18974.

## 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.

## High-level disinfection, sterilization of flexible endoscopes

### A review of infection control concepts

**Introduction and background:** During the past few years, controversy has surrounded the cleaning and disinfection of medical instruments.<sup>1-3</sup> Recent reports cite the importance of adhering to recommended reprocessing guidelines to prevent patient infection.<sup>4,5</sup>

In one report, patient infection following colonoscopy was linked to biopsy forceps that had been soaked in a liquid chemical sterilant,<sup>4</sup> rather than sterilized using pressurized steam as guidelines recommended.<sup>5,6</sup> Other similar reports have linked patient infection to endoscopes that were reprocessed inadequately.<sup>7</sup> One news report suggested that health care facilities that were not 'sterilizing' their endoscopes using a specific automated process were placing their patients at risk,<sup>1</sup> (the established adequacy of high-level disinfection notwithstanding).<sup>5,8,9</sup> (Refer to this newsletter's March 1999 issue.)

In general, sterilization of many types of medical instruments is preferred, although it may not always be necessary (or feasible) to prevent infection. Steam sterilization is the favored method, because of its wide margin of safety, cost-effectiveness, availability, and unsurpassed effectiveness. Steam sterilization of biopsy forceps, for example,

has not been associated with patient infection.<sup>6</sup>

Some instruments, however, are made of delicate materials damaged by heat, precluding thermal sterilization. For these instruments, novel low-temperature sterilization processes ("LTSPs") have been developed. But while they have the advantage of satisfying the temperature parameters of most heat-sensitive instruments, LTSPs are less reliable and have a narrower margin of safety than thermal sterilization.<sup>10</sup> As instruments, such as those used in endoscopy, become more and more physically complex and harder to clean, the obstacles that these LTSPs must overcome to be effective become more and more formidable.

To better appreciate the limitations that flexible endoscopes, biopsy forceps and other complex instruments impose on reprocessing, a review of the similarities and differences between sterilization and high-level disinfection is presented.

**What is disinfection?** Disinfection can be divided into three levels: high-, intermediate-, and low-level disinfection. High-level disinfection ("HLD") is a rigorous process that destroys virtually all pathogenic microorganisms, including *Mycobacterium tuberculosis*, but not necessarily high numbers of bacterial spores.

In the clinical setting, HLD is typically achieved using a liquid chemical sterilant ("LCS") that has been shown to

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destroy bacterial spores, albeit usually during long immersion times. (Refer to this newsletter's July 1998 issue.) An example is 2% glutaraldehyde, which is used often to achieve HLD in 20 minutes but may require as long as 10 hours to destroy high numbers of bacterial spores. Similarly, ortho-phthalaldehyde (OPA) achieves HLD in 12 minutes but is reported to be sporicidal in 32 hours.

According to the Food and Drug Administration's (FDA) published guidelines, the immersion time necessary for a LCS to achieve HLD is dictated by the time required to destroy 100% of a population of one million mycobacteria — that is, achieve a 6 log reduction of mycobacteria<sup>9,11,12</sup> (see Box A). Because in the clinical setting the number of mycobacteria on a pre-cleaned instrument has not been reported to exceed  $10^6$ , HLD is expected to render an instrument free of all pathogenic microorganisms<sup>13</sup> (see Box B).

Unlike HLD, intermediate-level disinfection is not usually sporicidal, although it does destroy mycobacteria, vegetative bacteria, and most viruses. Examples include ethyl and isopropyl alcohol. Low-level disinfection does not destroy either bacterial spores or mycobacteria. Some phenolic and quaternary ammonium detergents are classified as low-level disinfectants.

**What is sterilization?** Sterilization is a process that destroys or inactivates all types of microorganisms, including high numbers of spores<sup>9-12</sup> (see Box B). A device labeled for sterilization of surgical instruments typically achieves at least a 6 log reduction of bacterial spores during a *half-cycle* — that is, during a time equal to one half of the process's indicated sterilization cycle. For example, a sterilizer labeled for a 10 minute (full) cycle would have to destroy 100% of a population of one million spores within 5 minutes.

A sterilizer that destroys this number of bacterial spores during a half-cycle conveys a *sterility assurance level* ("SAL") of  $10^{-6}$ . From a probability standpoint, this low a SAL value confers a negligible risk of instrument contamination and therefore patient infection, permitting only one spore on one instrument to survive from an initial population of one million spores inoculated onto one million instruments. (Note: In a few instances, the FDA may classify a 'sterilizer' as a device that is associated with a SAL of  $10^{-3}$ , achieving a 6 log reduction of bacterial spores during its full cycle.)<sup>11</sup>

**Medical device classification:** Determining which reprocessing method is most appropriate for a specific medical instrument may not always be obvious or straightforward. Some instruments require sterilization, while for others one of disinfection's three levels may be recommended. To simplify selection of a suitable reprocessing method, medical devices are typically classified as *critical*, *semicritical*, and *noncritical*, depending on the potential risk of nosocomial infection associated with their uses.<sup>8</sup>

Critical devices, such as cardiac catheters, routinely enter

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### Box A: "What is a log reduction?"

In the science of decontamination, a log reduction describes the number of microorganisms destroyed or removed from a contaminated instrument and can be determined from the equation:

$$\log_{10} \frac{\text{FINAL microbial population}}{\text{INITIAL microbial population}}$$

As an example, a decontamination process that reduces an initial population of microorganisms from 1,000,000 to 100 achieves a 4 log reduction. (Inserting the respective values into this equation yields  $\log_{10} [100/1,000,000]$ , or: - 4.) This log reduction is the same as reducing the initial number of microorganisms by 99.99%. (Note: The negative sign indicates that the number of microorganisms was reduced. If the number of microorganisms increases, which can occur during overnight storage of a wet endoscope, this equation would yield a positive value.)

### Box B: "What is a bacterial spore, mycobacterium?"

**Bacterial spores:** A bacterial spore is a resistant and dehydrated structure that forms inside the cell membranes of certain types of bacteria. This structure protects the cell from adverse environmental conditions, such as extreme heat. Only one endospore forms per cell. Two examples of non-pathogenic bacterial spores are *Bacillus stearothermophilus* and *B. subtilis*, both of which are used to validate the effectiveness of sterilization processes. Some spores, however, may cause disease: *Clostridium difficile* is a major cause of pseudomembranous colitis (and can be found in the intestinal flora of a small percentage of adults) and *B. anthracis* causes anthrax.

**Mycobacteria:** Mycobacteria are slender curved rods, whose cell walls contain complex waxes. These microorganisms are generally classified as members of either the: (a) *Mycobacterium tuberculosis* complex, which includes *M. tuberculosis* and *M. bovis*, or (b) nontuberculous species, also known as atypical mycobacteria. *M. gordonae*, *M. chelonae*, *M. terrae* and *M. bovis* are examples of atypical mycobacteria, the latter two of which are often used to validate the effectiveness of high-level disinfection processes.

Whereas *M. tuberculosis* is an airborne contagion responsible for tuberculosis, atypical mycobacteria are typically acquired from environmental sources such as soil and water. Many types of atypical mycobacteria are opportunistic pathogens.

sterile tissue. These devices require sterilization because they pose a high risk of infection if contaminated with microorganisms. Semicritical devices, on the other hand, contact mucous membranes (but do not ordinarily enter sterile tissue). High-level disinfection is recommended for semicritical devices, which include bronchoscopes and gastrointestinal (GI) endoscopes<sup>8</sup> (see Box C). Noncritical devices, such as blood-pressure cuffs, either do not touch the patient or only come in contact with the patient's intact skin. Although washing with a detergent may be sufficient, intermediate or low-level disinfection of these items is often recommended.

**Reliability of different sterilization processes:** Depending on several factors, including the instrument's design (*Is it simple or complex?*), the adequacy of the cleaning procedure (*Was all of the patient debris removed?*), and the physical properties of the sterilizing agent (*Can it conduct through patient debris?*), the anticipated reliability of different sterilization processes may vary. (Refer to this newsletter's July-August 1997 issue.)<sup>10</sup>

For example, because it is more reliable and likely than ethylene oxide (EtO) gas to penetrate coiled and spring-like surfaces, pressurized steam is universally recommended to sterilize biopsy forceps (and other instruments not damaged by heat).<sup>10</sup> Whereas heat can conduct through most patient materials and destroy otherwise inaccessible and shielded microorganisms, low-temperature chemical agents, such as EtO gas, plasmas, vapors and LCSs, typically require direct contact with each contaminated surface to be effective.<sup>8,9</sup>

Processes that use these low-temperature chemical agents have been reported to be less reliable and have a higher SAL than thermal sterilization, conferring a theoretically higher risk of patient infection.<sup>10</sup> Realizing that the reliability of different sterilization processes may vary is essential to the selection of the most appropriate process for a specific instrument. Selecting an inappropriate process or chemical agent, such as a LCS for reprocessing biopsy forceps, can result in patient infection.<sup>4</sup>

**Liquid chemical sterilants (LCSs) and sterilization:** LCSs are commonly used to reprocess flexible endoscopes and other semicritical instruments damaged by heat. These low-temperature chemical agents are rapid-acting, relatively inexpensive, and can be used to reprocess instruments in or near the procedure room. In general, LCSs are used to achieve high-level disinfection (not sterilization). The viscous properties of LCSs can hinder their flow through the narrow orifices and long channels of flexible endoscopes and other complex instruments, limiting their effectiveness and reliability.<sup>10,11</sup>

Further, according to the FDA, the unique kinetics of LCSs (that is, the relationship between the flow of a LCS and the forces that affect its motion) may preclude determination of a SAL<sup>11,12</sup> (see Box D). Processes for which a SAL has not been determined would not be expected to yield sterile instruments. Moreover, LCSs prevent instrument wrapping

(which protects the instrument from environmental recontamination), reliably monitoring them biologically is problematic,<sup>10,12</sup> and instruments immersed in a LCS generally require rinsing with water to remove potentially toxic chemical residue. The water used by health care facilities to rinse endoscopes is rarely sterile (although may be filtered) and may be responsible for more nosocomial infections caused by opportunistic pathogens than reported<sup>3</sup> (see Box C). Both thorough drying and proper storage of endoscopes become paramount, as inadequately dried instruments colonized with bacteria have been linked to serious patient infection.

**Discussion:** Health care staff evaluating the benefits and shortcomings of a specific reprocessing method often ask whether high-level disinfection of bronchoscopes, GI endoscopes and other semicritical items poses an infection risk. Also often asked by health care staff is whether two standards of patient care are exercised by facilities that sterilize rigid endoscopes in their central supply department, but high-level

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### Box C: "Sterilize bronchoscopes?"

Review of discussions posted recently on the Internet appear to suggest a trend in favor of 'sterilizing' bronchoscopes. This trend is somewhat puzzling, as bronchoscopes, like laryngoscopes and gastrointestinal endoscopes are *semicritical* devices for which the Centers for Disease Control and Prevention (CDC) recommend high-level disinfection.<sup>8</sup>

One plausible explanation for this trend may be found (ironically) in the CDC's "Guidelines for the Prevention of Nosocomial Pneumonia."<sup>16</sup> According to this guideline, the CDC prefers that "sterile" rinse water be used to remove residue that may remain on the bronchoscope after chemical immersion. Unfortunately, this recommendation can be misinterpreted to suggest that endoscopes require sterilization. *In truth, high-level disinfection of endoscopes has not been reported to pose a higher infection risk than sterilization. Nor have independent studies documented that flexible endoscopes can be reliably sterilized using any method.*<sup>14</sup>

Not explained in the CDC guideline, although important, is the definition and parameters of "sterile water." Unclear from this guideline is whether bacterial-free (ie, 0.2 micron filtered) water or tap water is acceptable to the CDC for rinsing bronchoscopes. According to the Society of Gastroenterology Nurses and Associates (SGNA), "clean water" may be used to rinse endoscopes, provided the endoscope's internal channels are dried thoroughly before storage. Drying can eliminate significant microbiological differences between clean tap water and filtered water labeled as bacterial-free or sterile.<sup>16</sup> (Note: Disinfecting the endoscope in the morning before the first patient of the day may be necessary if the endoscope is stored wet. See Q-Net's June 2000 issue.)

disinfect flexible endoscopes in their GI endoscopy suite. Obtaining the answers to both of these questions is important, as each has significant clinical and financial implications.

In short, high-level disinfection of thoroughly cleaned bronchoscopes and GI endoscopes is not associated with a higher infection rate, nor has it been shown to be less safe, than sterilization (*see Box C*).<sup>14</sup> Consequently, facilities performing both high-level disinfection and sterilization would not be practicing two standards of care, provided the endoscopes are thoroughly cleaned as standard practice demands.

In marketing, theoretical differences between sterilization and disinfection are often argued. Speculative scenarios describing the potential for instrument contamination and patient injury due to bacterial spores are often presented verbally (although without supporting documentation). It is important to realize that most bacterial spores are non-pathogenic, such as those used to challenge the effectiveness of sterilization processes (*see Box B*). And those types of bacterial spores that do produce disease are either inactivated by high-level disinfection, such as *Clostridium difficile*, or have not been linked to patient infection following an endoscopic procedure.<sup>14</sup>

⇒ *Sterilization of a flexible endoscope may on occasion be possible, but no independently published study has demonstrated that clinically used flexible endoscopes can be sterilized consistently and reliably using any method.*<sup>14</sup>

In the universal mission to provide safe and cost-effective health care, basing clinical decisions and practices on sound scientific data, not speculative claims, is essential.

In conclusion, although the labels of most LCSs indicate a sterilization claim during prolonged immersion times (*see Box D*), questions about the inappropriateness of labeling them for the sterilization of instruments have been raised.<sup>10-12,14,15</sup>

⇒ *Labeling LCSs used to reprocess endoscopes as sporicidal, while limiting their application to high-level disinfection, may be more appropriate (than labeling them for sterilization), if for no other reason than to prevent a false level of sterility assurance that could jeopardize patient safety.*<sup>3,10,15</sup>

Expecting a LCS (or any low-temperature chemical agent) to destroy every adhering microorganism inside a flexible endoscope, such as a colonoscope — whose long, narrow and complex internal channels and pathways not only prevent direct microbiologic sampling with a swab to verify sterilization but also cannot always be accessed and cleaned with a brush — is probably unrealistic. ■ LFM

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## Box D: "Does a sporicide sterilize?"

Liquid chemical sterilants used to achieve high-level disinfection are required by the FDA to be sporicidal, which warrants clarification. A sporicide is a biocidal agent that destroys bacterial spores. A process that achieves sterilization uses a sporicide, but a process that is sporicidal does not necessarily achieve instrument sterilization.

For example, 2% glutaraldehyde is sporicidal within 10 hours. *Does the single step of immersing an endoscope in this sporicide for 10 hours achieve sterilization? No. Why?* Because sterilization is a multi-step process that, in addition to exposing the instrument to a sporicide, requires performing several other steps, including: (a) instrument cleaning and preparation, (b) packaging and aseptic technique, to prevent environmental recontamination, and (c) sterility validation using biological indicators. Moreover, a sterilization process is associated with a sterility assurance level (eg, 10<sup>-6</sup>), while immersing an instrument in a liquid chemical sterilant is not.

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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:

**Lawrence F Muscarella, PhD**  
Director, Research and Development  
Chief, Infection Control

**Custom Ultrasonics, Inc.**

144 Railroad Drive  
Ivyland, PA 18974

Tele: 215.364.8577; Fax: 561.258.8051

E-mail: [q-net@email.msn.com](mailto:q-net@email.msn.com)

