



# The Q-Net™ Monthly

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## What's New

In last month's issue, as well as in the January, May, and December 1996 issues of this newsletter, low-temperature sterilization processes (LTSPs) were briefly discussed. *This month's issue further expounds on this topic and discusses whether the clinical definition of "sterilization" is more contextual than absolute.*

## GI: 'General Interest'

We have received many requests for our book, "Q-Net 96: Questions and Answers in Infection Control and Endoscopy, Part 1," which is a collection of all of Q-Net's 1996 newsletters. To obtain a copy, please call or fax us your order. The cost is \$9.95. This monthly newsletter is free!



## 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.

## Three levels of 'sterilization'?

This article discusses the probability for success of different low-temperature sterilization processes (LTSPs):

*gases, plasmas, vapors and liquid chemical sterilants*

## Background

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Over the past few years, several manufacturers have sought FDA clearance to market low-temperature processes that use chemical agents to process flexible endoscopes and other complex medical instruments. The primary goal of these manufacturers is to use a gas, plasma,

vapor, or liquid chemical sterilant to effect the same outcome achieved by pressurized steam, but without damaging delicate and expensive instruments sensitive to heat.

Because of sterility's uncompromising definition, common sense suggests that the reliability and effectiveness of these low-temperature sterilization processes (LTSPs) are the same as thermal sterilization processes that use moist or dry heat.

In general, however, the probability of instrument contamination after exposure to a LTSP is expected to be higher than with a heat-based sterilization process. Unlike low-temperature chemical agents, heat can contact otherwise inaccessible surfaces by conducting through many different types of fabrics and materials, such as metals and organic debris.

When functioning properly, heat-based processes provide the greatest probability  
*(Continued on page 14)*

## Bacterial spores and endoscopy

Because of their high resistance to sterilizing agents, various species of bacterial spores are used to challenge and monitor the effectiveness of sterilization processes.

If the sterilization process destroys one million of these hard-to-kill "bugs" in a half-cycle, as indicated by the biological indicator's negative result, then, by inference, the processed instrument is presumed to pose a negligible infection risk.

✓ *But what is the clinical significance of bacterial endospores in endoscopy?*

There are *no* reports of properly cleaned and high-level disinfected endoscopes contaminating patients with bacterial spores. Each documented case of patient infection resulted from a breach in the endoscope's recommended processing procedure.<sup>33</sup>

Almost all bacterial spores are nonpathogenic, and those that do produce disease (i.e., anthrax and some clostridia species), are either destroyed by high-level disinfection or have not been reported to pose an infection risk following endoscopy.

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that the processed instrument, regardless of the complexity of its physical design or the inadequacy of the cleaning process, poses a negligible infection risk to the patient.<sup>1</sup> Even if embedded deep within patient material not removed during cleaning, microorganisms are more likely to be destroyed by a thermal process than by a chemical process.

A formidable obstacle to the success of LTSPs is the complex internal design of many heat-sensitive instruments. In contrast to dry and moist heat, the physical properties of low-temperature chemical agents may limit their penetration and flow through small orifices and long and narrow lumens, such as the ERCP side-viewing duodenoscope's elevator wire channel,<sup>2</sup> that are difficult to access and clean.<sup>3-7</sup>

Also, because chemical agents cannot easily (if at all) contact underlying microorganisms shielded and protected by layers of organic soil and other patient material, the importance of thorough cleaning to the successful outcome of a LTSP cannot be overemphasized. (Different types of materials used in the design and construction of some complex medical devices may also affect the success of LTSPs.<sup>8</sup>)

### Variations in the reliability of LTSPs

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In general, LTSPs are not expected to be as reliable as heat-based sterilization processes.<sup>1</sup> For example, the probability of instrument contamination after exposure to a thermal sterilization process (moist or dry heat) is  $10^{-6}$  (i.e., a one in a million probability that one bacterial endospore, from an initial population of one million, will survive the process).<sup>1</sup> From a clinical perspective, this very low probability indicates that the risk of patient infection from a thermally-processed instrument is virtually nil.

In contrast, the probability of instrument contamination after exposure to a low-temperature chemical (e.g., gas, plasma or vapor, but not a liquid chemical sterilant) has been estimated to be on the order of  $10^{-3}$ , (i.e., a probability of one in a thousand that one bacterial endospore, from an initial population of one million, will survive the process), providing a probability for success that may be as many as three orders of magnitude less than expected with pressurized steam.<sup>1</sup>

The probability of contamination after processing an instrument using a liquid chemical sterilant (LCS), however, is expected to be even higher, and has been reported to be on the order of  $10^{-2}$  (i.e., a probability of one in a hundred that one bacterial endospore, from an initial population of one million, will survive the process).<sup>19</sup>

Like other low-temperature chemical agents, the reliability

(and effectiveness) of LCSs is limited by the instrument's physical design and the presence of patient material.<sup>2-6,10,11</sup> As a result, LCS-based processes may not always achieve the desired outcome if the instrument's internal design is complex and cleaning inadequate.<sup>2-7,10-13</sup> Also, LCSs are intrinsically viscous, which can limit their flow through narrow lumens, as may be required to contact the internal surfaces of some complex instruments.<sup>2,14</sup>

Moreover, LCSs preclude wrapping, as required to maintain instrument sterility during storage, and reliably monitoring them using biological indicators may not be possible,<sup>1,15-17</sup> which effectively reduces their anticipated probability for success.<sup>1,18-21</sup> Also significant, the outcome of instruments processed in a LCS may be adversely compromised by poor rinse water quality.<sup>22-24</sup>

If the rinse water is poor, the instrument may become recontaminated with potentially pathogenic waterborne (opportunistic) microorganisms, indigenous to the facility's water supply, during the final water rinse step that follows chemical immersion. Indeed, bacterial filters can improve the quality of the rinse water, but they are neither fail-safe nor foolproof. And bacterial filters are designed, under ideal conditions, to produce 'bacteria-free' water, not sterile water, from a health-care facility's water supply.<sup>22-24</sup>

Often overlooked, rinse water filtered through a bacterial filter can contain viruses,<sup>23</sup> endotoxins, pyrogens and microbial debris smaller than the bacterial filter's pore rating size, which is usually 0.2 (or 0.1) microns. Filtered water has been reported to contain (even) bacteria suspected of colonizing on, and penetrating through, the bacterial filter's 0.2 micron membrane.<sup>24</sup> (Proper maintenance of the filters and their housings is essential to prevent instrument recontamination.)

### Discussion

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The design of some complex instruments damaged by heat has created a challenging reprocessing dilemma. Thermal sterilization, while unparalleled in its anticipated probability for success, damages many delicate and expensive instruments sensitive to heat, limiting its application. But current LTSPs, which overcome this obstacle by using low-temperature chemicals, are associated with a lower probability for success than heat-based sterilization processes.

In order for a LTSP to be successful, several criteria must be satisfied, including the removal of all patient material during cleaning, and contact of the chemical agent with *all* of the instrument's internal (and external) surfaces, no matter how complex the instrument's internal configuration may be. (A

LTSP's potential for failure in the internal channels of a 'dirty' instrument<sup>3</sup> warrants particular attention now that the FDA (appropriately so) requires demonstration of the LTSP's effectiveness under *worst case* conditions, which includes the omission of each initial cleaning step.)

Several published reports suggest that most LTSPs may fail if the instrument's internal design is complex and cleaning inadequate,<sup>2,3,6,11,13,15,25</sup> which may explain why the FDA has not cleared either the Sterrad™ system (Advanced Sterilization Products, Irvine, CA) or the Plazlyte™ system (AbTox, Mundelein, IL) for processing flexible endoscopes with long and narrow lumens.

Cleaning is a prerequisite for all sterilization (and disinfection) processes. And unless all of the instrument's surfaces can be accessed and thoroughly cleaned using a validated and standardized process, the LTSP is unlikely to produce a sterile instrument,<sup>13</sup> although it may produce a 'patient-safe' instrument, which, while not necessarily 'sterile,' will not (by definition) transmit disease from one patient to another.

### Published guidelines

Published recommendations and guidelines acknowledge that the anticipated probability for success of different 'sterilization' processes varies. The Society of Gastroenterology Nursing and Associates (SGNA), for example, recommends that flexible biopsy forceps be sterilized only with pressurized steam because low-temperature chemical agents may be precluded from effectively and reliably penetrating the forceps' spring-like metal coils, as often required to destroy microorganisms embedded in patient debris not removed during cleaning.<sup>27</sup>

The Association for Professionals in Infection Control and Epidemiology (APIC), also understanding the limitations imposed by complex instrument design, recommends that instruments be steam sterilized whenever possible.<sup>28</sup> Both APIC's and SGNA's guidelines indicate that heat is the most effective sterilizing agent available and that the probability of instrument contamination associated with a thermal sterilization process is virtually nil.

Understanding the superiority of thermal sterilization processes underscores the importance of designing heat-safe instruments that facilitate thorough cleaning. In general, thermal sterilization is always recommended for reusable critical (and semi-critical) instruments that can withstand the rigors and stresses associated with repeated exposure to heat, pressure, and moisture. Thermal sterilization processes afford the highest probability that the instrument will be successfully sterilized.

When processing heat-sensitive instruments that can be thoroughly cleaned, LTSPs that use gases, vapors, or plasmas should be considered, although they may be more costly and time-consuming. (In a future issue of this newsletter, an algorithm for choosing the appropriate processing procedure for a specific type of medical instrument will be published.)

Even if it can be safely steam-autoclaved, a complex instrument that cannot be thoroughly cleaned should not be reused (i.e., a disposable).<sup>29</sup> While it is not considered 'sterile' ('sterile' dirt?), exposing a complex instrument that contains residual patient material, such as 'dirty' flexible biopsy forceps, to a complete steam autoclave cycle is unlikely to pose an infection risk to the patient.

### Recommendations

Indeed, liquid chemical sterilants (LCSs) are a popular choice for 'point-of-use' instrument processing.<sup>30</sup> Some LCSs are cost-effective (although others may not be), all are likely to reduce instrument down-time, and, when used according to recommended guidelines, typically yield a patient-safe instrument. Processing instruments in a LCS, however, precludes wrapping to maintain instrument sterility, may not be reliably monitored using BIs,<sup>1,15-17</sup> and can be adversely compromised by poor rinse water quality,<sup>22-24</sup> giving rise to the question:

➤ *Can LCSs be used to effectively sterilize instruments?*

To compensate for the shortcomings of LCSs, the instrument, after processing, should be:

- (1) used immediately to prevent recontamination during handling<sup>31,32</sup> (unwrapped instruments do not have a shelf-life);
- (2) rinsed with a large volume of water filtered through a bacterial filter to minimize the risk of instrument recontamination during the final water rinse (the use of sterile, bottled water is costly and impractical); and,
- (3) whether rinsing the instrument with tap water or filtered water, terminally flushing the instrument's internal channel(s) with 70% alcohol, followed by forced air drying, to facilitate drying and prevent bacterial colonization in the instrument's internal channel(s) during overnight storage is recommended.<sup>30</sup>

In conclusion, the probability for success associated with LTSPs is not expected to be as high as heat-based sterilization processes. Although in a laboratory setting they may destroy one million highly resistant bacterial spores during a half-cycle (just like a steam autoclave), LTSPs in the clinical setting can only be successful if, among other factors, all of the complex instrument's surfaces have been thoroughly pre-cleaned and are contacted by the sterilizing agent.<sup>1,2,13,15,18,33</sup>

From a probability standpoint, the appropriate label claim for LTSPs used to process complex instruments with long and narrow lumens and orifices, such as flexible endoscopes, may be limited to disinfection (even during long exposure times),<sup>1,13</sup> if for no other reason, to prevent a false level of "sterility" assurance. Because high-level disinfection has not been reported to pose a higher infection risk than sterilization in endoscopy,<sup>33</sup> this potential limitation of LTSPs is not clinically significant.

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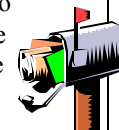
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## The Q-Net™ Monthly: An interactive newsletter

Q-Net's monthly newsletter, *The Q-Net™ Monthly*, was established to answer your questions about endoscopy and infection control. References are provided at the end of each response to provide you with a list of germane papers should you choose to further research the discussed topic.

If you have a question that you would like to have answered in a future issue of this newsletter, please submit it to the address provided below. Every attempt will be made to publish a response. Your comments are always welcomed.



Abstracts of past issue of this newsletter can be found by pointing your Internet browser to the World Wide Web's site:

<http://www.iserv.net/~mshcsp>



Thank you for reading this newsletter. *I have addressed the above issues to the best of my ability. Respectfully, the Publisher: Lawrence F. Muscarella, PhD.* Please direct all correspondence to:

Lawrence F Muscarella, PhD, Author, Editor, Publisher  
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Chief, Infection Control

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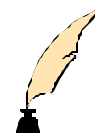
144 Railroad Drive, Ivyland, PA 18974

Tele: 215.364.1477

Fax: 215.364.7674

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

<http://www.iserv.net/~mshcsp>



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