

# The Q-Net™ Monthly

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## Survey's Results...

The results of the survey presented in this newsletter's May-June 1998 issue will be published later this year.

Along with the presentation of the survey's data, several questions will be addressed: (1) How common is the reuse of disposables? What about 'outsourcing'? (2) How do the infection control practices of a small, not-for-profit hospital in the Northeast (US) differ from a large for-profit hospital in the Southwest (US)? (3) How do reprocessing practices in the United States compare with other countries? (4) Are disposable biopsy forceps more popular than reusables? (5) Is "flashing" becoming less popular?

If you have not yet participated in this survey - but still would like to - please contact this newsletter's publisher as soon as possible.

## 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 not only to ask good questions but also to 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.

## Endoscopes and teeth, gums

### What do they have in common?

**TERMS:** *low-temperature chemical agents, sampling techniques, complex instrument designs, simulated-use tests, dental rinses*

### Viewpoint

*During the past decade, the Food and Drug Administration (FDA) has cleared several devices that use low-temperature chemicals (e.g., vapors, gases, plasma, liquid sterilants) to process instruments that are damaged by heat. These devices offer many advantages. But like heat-based sterilization processes, their applications are restricted.*

**Introduction:** Steam autoclaves use moist heat to destroy microorganisms. Because heat can diffuse through many different types of materials, pressurized steam (and dry heat) can destroy otherwise inaccessible microorganisms embedded under layers of organic debris.

Unlike heat, low-temperature chemicals require direct contact with the microorganisms to be effective, making their outcomes more susceptible (than heat) to the ill-effects of complex instrument designs and inadequate cleaning. As a result, low-temperature sterilization processes (LTSPs) are not typically indicated for processing flexible endoscopes and other complex instruments that are difficult to clean. (Channel irrigators may be

necessary to enhance - but not ensure - delivery of the LTSP's chemical agent to all of the instrument's surfaces.)

☞ *Indeed, the anticipated reliability of different sterilization processes are not all alike (Muscarella, LF. AORN J 1998 May;67(5):966-970).*

One type of LTSP that uses hydrogen peroxide plasma recently expanded its label claims to include the processing of more complex instruments. Gastrointestinal endoscopes, bronchoscopes, and other instruments with channels narrower than 3 mm (in diameter) or longer than 400 mm, however, remain verboten (Zafar A. *Am J Infect Control* 1996 Aug;24(4):312).

In addition to the physical properties of the LTSP's chemical agent(s) (*Does it use a gas, plasma, or vapor?*), and the contaminated instrument's physical design (*Does it contain narrow and long lumens that are difficult to clean?*), the materials used in the construction of reusable instruments can preclude the use of some LTSPs (Fuselier HA, Mason C. *Urology* 1997;50:337-340). (*Refer to this newsletter's April 1998 issue.*)

**Simulated-use tests:** Satisfying several criteria is required before a LTSP can be labeled for processing instruments. For example, the FDA requires manufacturers to perform simulated-use tests that demonstrate the LTSP's effectiveness under *worst-case* conditions. Most studies satisfy this requirement by contaminating either complex instruments (e.g., side-viewing duodenoscopes) or surrogate devices with a mixture of microorganisms, organic and inorganic debris (Alfa MJ, et al. *Infect Control Hosp Epidemiol* 1996;17:92-100).

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**Quality control:** The effectiveness of a sterilization process is routinely monitored using biological indicators (BIs). For its result to be meaningful, however, the BI must be placed at a site inside the vessel's chamber that is *at least as* challenging for the sterilizing agent to contact as the load's most inaccessible contaminated surface. Otherwise, the BI's result is of little, if any, value.

To be sure, a BI's "negative" result is a necessary condition to claim sterilization, but it alone is not usually sufficient: Determining whether a specific instrument was successfully sterilized by a LTSP requires sampling all of the instrument's surfaces using a well-established microbiological technique. But the internal designs of some complex instruments, such as flexible endoscopes and biopsy forceps, can hinder - if not preclude - direct sampling of their internal channels using the *swab* (or *wipe*) technique (refer to this newsletter's February 1997 issue).

In lieu of destroying the instrument to swab its internal surfaces, the *rinse* technique is sometimes performed in the clinical setting to sample endoscopes during an epidemiologic investigation. As this technique's name suggests, a sterile fluid is rinsed through the instrument's channels, aseptically collected in a container and then assayed for the presence (or lack) of microorganisms.

But like BIs, the *rinse* technique can yield misleading data. Consider this: If the *rinse* technique's result is positive ("growth"), indeed the instrument is likely to be contaminated. *But what if the BI's result is negative, i.e., "no growth"? Does such a result augur a sterile instrument?*

Unfortunately not. Reports have shown that the *rinse* technique can yield a negative result, even though the instrument's sampled channel may be contaminated with viable microorganisms (Pappas SA, et al. *Am Rev Respir Dis* 1983;127:391-2). In short, the *rinse* technique has shortcomings that limit its reliability, as this technique can only account for those surviving microorganisms that rinsing can remove and capture from the instrument's surfaces.

To circumvent the limitations that some complex instrument designs impose on direct microbiological sampling techniques, the use of long and narrow surrogate devices that can be disassembled is recommended (Rutala W, et al. 1998; Alfa MJ, et al. *Infect Control Hosp Epidemiol* 1996;17:92-100). These dispensable mockups are usually inexpensive, easy to design and permit direct and reliable sampling of their otherwise inaccessible internal surfaces.

**Dental rinses:** The *rinse* technique's shortcomings also apply

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to dental rinses. Like flexible endoscopes, teeth contain difficult-to-clean surfaces that may become contaminated with bacteria and other debris. Not surprising, guidelines for cleaning both endoscopes and teeth recommend brushing.

And like fluid rinses sometimes used to sample microbiologically the endoscope's internal channels, dental rinses aid in the removal of bacteria. But dental rinses cannot always provide the necessary pressures to dislodge adhering bacteria and therefore are not suitable replacements for brushing and flossing. Similarly, the indirect *rinse* technique is not as reliable as the direct *swab* technique, and therefore using the latter to evaluate a lumen's "sterility" is contraindicated.

**Conclusion:** Due in part to differences in their label claims, deciding which of several LTSPs is best suited for processing a specific instrument has become a challenging task (*refer to this newsletter's September 1998 issue*). If all instruments could withstand the rigors of heat, pressure and moisture, this task would be greatly simplified.

Because of the inexorable constraints that minimally invasive surgery imposes on the design of many endoscopic instruments, not only is the development of complex, heat-sensitive instruments likely to continue, but so are restrictions on the label claims of current and future LTSPs.

☞ *Published data that demonstrate that the lumens of flexible endoscopes and biopsy forceps can be reliably and reproducibly sterilized using any LTSP are lacking.*

Attempts to mollify tensions between the designs of complex instruments and the limitations of LTSPs have spurred a *leap of faith* that, based on unreliable sampling methods like the *rinse* technique, may conclude an instrument is sterile (when it isn't). Before claiming sterilization, manufacturers should ensure their data are reproducible and based on reliable microbiological sampling methods.

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 mail all correspondence to:*

**LAWRENCE F MUSCARELLA, PHD**  
Director, Research and Development  
Chief, Infection Control

**CUSTOM ULTRASONICS, INC.**  
144 Railroad Drive  
Ivyland, PA 18974  
Tele: 215.364.1477; Fax: 215.364.7674

E-mail: [q-net@msn.com](mailto:q-net@msn.com)  
<http://www.myendosite.com>

