

# The Q-Net™ Monthly

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## Clarification

Last month's newsletter discusses Creutzfeldt-Jakob Disease (CJD) and methods for assessing the risk of prion transmission. To be clear, sterilization is recommended for each of the four presented scenarios, which describe the use of *critical* instruments during surgery.

Flexible endoscopes were not addressed directly in last month's discussion, although they could have been included in *scenario 3*. For these and other *semi-critical* instruments, high-level disinfection is universally recommended to prevent patient infection.

## 'Q-Net 00'



'Q-Net 00,' a bound collection of all of 2000's newsletters, will be published in January 2001. Order your copy on-line today.

## 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.

## FDA clears another liquid sterilant

*During the past few years, several oxidizing liquid chemical sterilants (LCSs) have been developed. Marking a noteworthy departure from this trend is Rapicide™.*

Glutaraldehyde is routinely used by health care facilities to reprocess *semi-critical* instruments. A survey published in this newsletter (*April-May 1999*) indicated that as many as 80% of the respondents use glutaraldehyde to reprocess flexible endoscopes.

Last year Cidex® OPA (*Advanced Sterilization Products, Irvine CA; www.sterrad.com*) received 510(k)-clearance from the Food and Drug Administration (FDA).† Unlike Cidex®, which contains glutaraldehyde, Cidex® OPA contains 0.55% *ortho*-phthalaldehyde and achieves high-level disinfection in 12 minutes at room temperature. (*Refer to this newsletter's October 1999 and November 1999 issues for a discussion of Cidex® OPA.*)

**Noteworthy FDA-clearance:** This past August, MediVators, Inc. (*Eagan, MN; www.cantelmedical.com/medivators.html*) received 510(k)-clearance from the FDA to market **Rapicide™**.† The introduction of this liquid chemical sterilant (LCS), which contains 2.5% glutaraldehyde,

bucks the market's recent trend away from glutaraldehyde-based products and towards oxidizing LCSs.

During the past decade, the reprocessing community seemed to indicate that glutaraldehyde had become undesirable and would soon be all but dead. Complaints by health care staff that the vapors and odor emitted by most glutaraldehyde-based LCSs were irritating provided manufacturers with an incentive to develop alternatives to glutaraldehyde for reprocessing flexible endoscopes. As a result, Cidex® OPA and several oxidizing agents including Sporox® were developed (*see Box A, next page*).

**Rapicide's™ characteristics:** Rapicide™ marks a noteworthy return to the use of glutaraldehyde for reprocessing flexible endoscopes. Unlike most glutaraldehyde formulations (which are alkaline), Rapicide™ is acidic, with a pH between 6.0 and 7.0. According to its manufacturer, Rapicide™ is substantially equivalent to Wavicide®-01 (*Medical Chemical Corporation; Torrance, CA; www.med-chem.com*), an acidic 2.5% glutaraldehyde LCS.

The label of Rapicide™ demonstrates that elevating the temperature of this glutaraldehyde-based LCS reduces the exposure time required for it to be both sporicidal and mycobactericidal. Whereas Wavicide®-01 (Rapicide's™ 510[k] predicate device) achieves high-level disinfection in 45 minutes at 22° C (eg, room temperature), Rapicide™ requires only 5 minutes at 35° C to achieve high-level disinfection.

† For a discussion of the FDA's 510(k) process, refer to this newsletter's July 2000 issue and the December 2000 issue of "Gastroenterology and Endoscopy News" at: [www.gastroendonews.com](http://www.gastroendonews.com).

The label of Rapicide™ requires an immersion time of 7 hours 40 minutes at 35° C to destroy 100% of a population of 10<sup>6</sup> resistant bacterial spores. (Refer to this newsletter's August-September 2000 issue for a discussion of the differences between the definitions of 'sterilization' and 'sporicidal'.) Chemical test strips that monitor Rapicide™ to ensure its glutaraldehyde content remains above its minimum effective concentration (MEC) during reuse are available.

Further, Rapicide's™ elevated temperature requirement may explain why it is contraindicated for manual reprocessing and labeled only for use in automatic flexible endoscope reprocessors (AFERs). Heating LCSs manually is problematic and may require an immersion heater. But heating LCSs using an AFER is ordinarily simple and straightforward, provided the AFER is equipped with a LCS heater and is designed to monitor and control the LCS's temperature.

**Advantages and disadvantages:** The ideal LCS: (1) rapidly destroys mycobacteria and bacterial spores; (2) neither damages flexible endoscopes nor emits irritating vapors; and is (3) inexpensive, (4) environmentally safe, and (5) easy to use. Such an ideal LCS has yet to be marketed. Nevertheless, many LCSs are acceptable for reprocessing flexible endoscopes and other *semi-critical* instruments (refer to Box B).

Like any biocidal agent, Rapicide™ has its own unique set of advantages and disadvantages, each of which should be reviewed and understood before its use. One of Rapicide™'s most salient advantages is its short immersion time of 5 minutes, which decreases instrument "down-time." Moreover, like Wavicide®-01, Rapicide™ does not require activation before use and can be reused for a maximum of 28 days - twice as long as Cidex® - or until its glutaraldehyde concentration drops below 1.5%, whichever occurs first.

Rapicide™ will, however, require adequate air ventilation. It will likely cost more than Wavicide®-01 and Cidex®, and because of its elevated temperature and acidic pH, Rapicide™ may be less compatible with instruments than alkaline glutaraldehyde-based LCSs. And unlike most other LCSs, Rapicide™ cannot be used during manual reprocessing. Rather, its use is limited to AFER models equipped with a heater, which may not always be available. ■ LFM

### Box A: 'LCSs ... on the horizon?'

Last April the Minntech Corporation ([www.minntech.com](http://www.minntech.com)) announced that it is seeking 510(k) clearance to market an automated endoscope reprocessor and companion sterilant. According to Minntech, these two products are designed to "thoroughly clean and sterilize flexible endoscopes."

And Sterilox Technologies, Inc. ([www.sterilox.com](http://www.sterilox.com)) is currently in the process of completing several tests and preparing a 510(k) filing for Sterilox®, a proprietary LCS that uses electrochemically activated water to destroy bacteria and other microorganisms.

### Box B: 'Choosing the best LCS'

No liquid chemical sterilant (LCS) is ideal. What's best for one health care facility may be unsuitable to another. The following 3 options are provided as a guide for selecting an appropriate LCS for reprocessing flexible endoscopes:

- For a GI lab that has very limited funding; has a reprocessing room that is well-ventilated (ie, at least 10 room exchanges per hour); and for which compatibility of the endoscope with the LCS is essential, then Cidex® (or its equivalent) may be suitable;
- For a GI lab that has a large number of patients such that even a 15 minute immersion time is prohibitively long; has a reprocessing room that is well-ventilated; and for which compatibility of the endoscope with the LCS is essential, then Cidex® OPA may be appropriate. If the GI lab has an automated reprocessor (AFER) equipped with a LCS heater, then Rapicide™ may also be suitable; and
- For a GI lab whose reprocessing room is poorly ventilated, then an oxidizing agent, such as Sporox®, may be the LCS of choice. (Check with the endoscope's manufacturer to ensure compatibility with these and any other oxidizing agents.)

### Editor-in-Chief

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

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, Editor-in-Chief.* Please direct all correspondence to:

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