

The Q-Net™ Monthly

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What's News

Happy Holidays

This month's newsletter provides the final in a series of three articles that discusses Cidex OPA. **Specific recommendations for the safe and proper use of Cidex OPA are provided.** The first and second articles in this series, published in the [July-August, 2006](#), and [September-October, 2006](#), issues of this newsletter are essential reading.

Editor-in-Chief

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What is 'Q-Net'?

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

The mail goal of **Q-Net** is to encourage the infection control, endoscopy, and OR communities to not only ask good questions but to also demand 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.

Recommendations for the safe and proper use of Cidex OPA

~ FINAL IN A SERIES ~

Background: Cidex OPA is a high-level disinfectant routinely used to reprocess reusable (heat-sensitive) *semi-critical* instruments including gastrointestinal (GI) endoscopes. As for all types of liquid chemical sterilants/disinfectants (LCSs), a comprehensive review of Cidex OPA's label and reprocessing instructions is necessary to ensure its safe and proper use.

As discussed in the first article in this series published in the [July-August, 2006](#), issue of this newsletter, three different versions of Cidex OPA's label have been sequentially published between 1999 and 2006, each version of which provides additional and useful information about the safe and proper use of Cidex OPA, whose active ingredient is 0.55% (w/w) *ortho-phthalaldehyde*.

Whereas the details of each of the three versions of Cidex OPA's label are presented in Tables 1–3 of the first article in this series, the second article in this series, published in the [September-October, 2006](#), issue of this newsletter, discusses the significance and implications of some of the differences between each version of Cidex OPA's label.

When used in accordance with its label, Cidex OPA, which is not to be confused with *Cidex* (2% glutaraldehyde), is

reported to be safe, effective and a valued addition to an endoscopy department's armamentarium of instrument reprocessing products. Often referred to as "OPA," Cidex OPA has become a popular alternative to formulations of glutaraldehyde, hydrogen peroxide, and peracetic acid and may be favored by some endoscopy departments, because it is easy to use, does not require activation, and rapidly achieves high-level disinfection, both in 12 minutes at room temperature (20° C or 68° F) and in 5 minutes at 25° C (77° F).

Cidex OPA and other LCSs that are rapidly tuberculocidal facilitate the quick decontamination of instruments, which are usually limited in number, for prompt reuse throughout the day, reducing strain on reprocessing staff. Conversely, LCSs associated with a longer immersion time, such as 20 to 45 minutes, may require an endoscopy department to purchase additional instruments—some of which, like a colonoscope, may cost as much as \$30,000 (refer to the [November-December, 2005](#), issue of this newsletter)—to meet patient demand. GI endo-

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scopy, bronchoscopy, anesthesiology, cardiology, gynecology, and the operating room are some of the departments and settings within a medical facility that may use Cidex OPA.

Recommendations: *The following recommendations are provided for the safe and proper use of Cidex OPA. These recommendations are an adjunct to, not a replacement for, the most recent (third) version of Cidex OPA's label. Many of these recommendations are not unique to Cidex OPA and are also provided for the safe and proper use of other LCSs. Adherence to these recommendations will minimize the risk of injury to patients and to healthcare staff members.*

I. General Recommendations:

1. **Review** the most recent (third) version of **Cidex OPA's label** prior to its use. (Also, **review Table 1**, next page.)

- **Retain** on file a copy of this version of Cidex OPA's label. **Display** this version for staff members to routinely review. **Discard** all earlier label versions.
 - ◆ This most recent version of Cidex OPA's label contains the text 'ASP, 2004,' 'ASP, 2006,' or 'mailer, 4/04' at the end of the label, below its manufacturer's address and contact information. This code distinguishes this version of its label from older, outdated versions. If unsure about the specific label version on file, contact its manufacturer to obtain the most up-to-date label version.
 - **Focus attention** on the label's *directions for use* – specifically, the requisite *immersion time* and *temperature* – as well as its *instructions for use* (IFU), *warnings*, *precautions*, and *contraindications*.
 - ◆ Cidex OPA is associated with two immersion times and temperatures to achieve high-level disinfection. Caution is advised whenever using a LCS associated with more than one immersion time and temperature. *Use of the incorrect temperature and/or time during manual or automated reprocessing can result in inadequate high-level disinfection and patient injury.* (Review Tables 1-3 in the *July-August, 2006*, issue of this newsletter.)
 - ◆ Cidex OPA can be used to achieve high-level disinfection during manual reprocessing using a bucket and tray, or with an automated endoscope reprocessor (AER).
2. **Review the label** and reprocessing instructions of the **reusable instrument** prior to using Cidex OPA. Verify that the instrument's manufacturer has provided a validated procedure for reprocessing the instrument using Cidex OPA.
- Review the instrument's *instructions for use* to determine whether: leak testing is indicated (as for an endoscope), disassembly of the instrument is necessary, and addi-

tional water rinsing after chemical immersion is required.

- Verify that the instrument is reusable and *semi-critical* (i.e., does not require sterilization) and that it is constructed of materials compatible with Cidex OPA.
 - ◆ Review the [March-April, 2004](#), issue of this newsletter for the definitions of a *semi-critical* instrument, *sterilization* and *high-level disinfection*.
- As with all decontamination processes, ensure the reusable instrument is thoroughly pre-cleaned prior to manual or automated reprocessing using Cidex OPA.
- Verify that Cidex OPA is part of a validated water rinsing procedure as provided by the instrument's manufacturer.
- Determine the microbiological quality of the water (e.g., tap water, bacteria-free water, sterile water) required to rinse the instrument after chemical immersion.
 - ◆ While sterile water is preferred for rinsing reusable instruments, bacteria-free water, and even potable tap water, may be acceptable. If followed by complete drying of a *semi-critical* instrument, potable tap water used for rinsing may not pose a higher risk of nosocomial infection than sterile rinse water. The importance of instrument drying to the prevention of nosocomial infection cannot be overstated. (Review the CDC's "*Guideline for prevention of nosocomial pneumonia*," 1997.)

II. Manual Reprocessing and Water Rinsing Recommendations:

1. **High-level disinfect** the reusable instrument by completely immersing it in Cidex OPA for a minimum of **12 minutes** at **20° C** (or 68° F) or higher. (This immersion time and temperature may also be used to achieve high-level disinfection using an AER. Refer to *Section III*, below.)
- Use a timer and a thermometer to monitor the immersion time and temperature of the Cidex OPA. *If the temperature of the Cidex OPA drops below 20° C (i.e., "room temperature") at any time during chemical immersion, repeat high-level disinfection.* Although difficult, manually heating Cidex OPA may be necessary if the reprocessing room or area is cooled by air conditioning or central air to a temperature below 20° C.
 - Avoid prolonged immersion of the instrument in Cidex OPA.
2. **Thoroughly rinse** the reusable instrument with fresh water after high-level disinfection. *Inadequate water-rinsing of the instrument can result in patient injury.*

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- **Completely immerse** the instrument in a large volume of fresh water (i.e., *at least 2 gallons*) for a *minimum of 1 minute* (unless the label of the instrument specifies a longer time); **manually flush** the channels or lumens of the instrument with *at least 100 ml* of fresh rinse water (unless otherwise indicated by the instrument's manufacturer); **remove** the instrument; and **discard** the rinse water. **Repeat** this water-rinsing procedure **two additional times** for a total of **3 separate water rinses**. Do not reuse the rinse water. **Review** the instrument's label for additional water-rinsing instructions.

◆ This newsletter defines these manual water-rinsing instructions as the "3-2-1 recommendation," because **3** separate water rinses are indicated, each rinse of which is required to be a large volume of at least **2** gallons of fresh water for a minimum of **1** minute in duration.

III. Automated Reprocessing and Water Rinsing Recommendations:

1. **Review the label** and reprocessing instructions of the AER prior to using Cidex OPA. Verify that the AER is legally marketed and cleared by the Food and Drug Administration (FDA) for reprocessing the reusable instrument.

2. **Set the AER** for a minimum of **5 minutes** at **25° C** (or 77° F) or higher. This immersion time and temperature are exclusive to automated reprocessing and are contraindicated during manual reprocessing, which requires a 12-minute immersion time at 20° C (refer to *Section II*, above).

3. Verify that the following **additional reprocessing criteria** are satisfied. Specifically, confirm that the AER:

- ✓ completely immerses the instrument in Cidex OPA;
- ✓ has a temperature setting of 25° C and monitors the temperature of the Cidex OPA; and
- ✓ terminates the reprocessing cycle with documentation (e.g., a print-out) if the temperature of the Cidex OPA is not maintained at 25° C or higher.
- ✓ Also ensure that the use of Cidex OPA in the AER is part of a validated reprocessing procedure; and that the AER is properly connected to all of the instrument's channels.

- If any of these reprocessing criteria is not satisfied, manually high-level disinfect the instrument in accordance with the instructions provided in *Section II*, above.

4. Verify that the AER satisfies the following **water-rinsing criteria**:

- ✓ the AER features a terminal water-rinse cycle that has been validated by its manufacturer (and is cleared by the FDA) for use with Cidex OPA;

1. Review the most recent version (third) of Cidex OPA's label prior to its use. Discard earlier label versions.
2. Review the reusable instrument's label and, if one is used, the label of the automated endoscope reprocessor (AER) prior to using Cidex OPA.
3. Thoroughly clean the instrument prior to immersion in Cidex OPA.
4. Completely immerse the instrument in Cidex OPA for 12 minutes at 20° C during manual reprocessing. If using an AER, the instrument may be immersed in Cidex OPA for 5 minutes at 25° C.
5. Avoid prolonged immersion of the instrument in Cidex OPA.
6. Caution is advised when using Cidex OPA to reprocess TEE probes.
7. Thoroughly rinse the instrument with a large volume of fresh water after immersion in Cidex OPA.
8. Do not use Cidex OPA to reprocess urological instrumentation, such as cystoscopes, used to treat patients with a history of bladder cancer.
9. Wear PEE when using Cidex OPA.
10. Do not use Cidex OPA to sterilize heat-sensitive items.
11. Monitor the reused solution of Cidex OPA per its label.

Table 1. Important recommendations for the safe and proper use of Cidex OPA (and other types of LCSs).

- ✓ the AER rinses the instrument, including its channels, with large volumes of fresh water in accordance with the instructions provided by the instrument's manufacturer;
- ✓ each of the AER's rinses uses fresh (not reused) water and is a minimum of 1 minute in duration (unless the label of the instrument specifies a longer time).
- Manually rinse the instrument with fresh water in accordance with *Section II*'s "3-2-1 recommendation," above, if any of these water-rinsing criteria is not satisfied, or if the effectiveness of the AER's terminal water-rinse cycle is in question. (*Note:* Cidex OPA's label does not provide the recommended number of terminal water-rinses, such as three water-rinses, or the volume of each terminal water-rinse during automated reprocessing.)
- Refer to the discussion of the required microbiological quality of the rinse water discussed in *Section I.2*, above, to prevent re-contamination of the instrument.
- Review the reusable instrument's label for additional water-rinsing instructions.
 - ◆ Caution is advised whenever the AER's terminal water-rinsing parameters (i.e., number of rinses, volume

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of each rinse, time of each rinse) are different from the “3-2-1 recommendation” provided in Section II.2, above. *Inadequate water rinsing can result in patient injury.*

- ◆ If switching from another LCS to Cidex OPA (or *vice versa*), contact the manufacturer of the AER to ensure it is set to the appropriate immersion time and temperature.

IV. Recommendations for Reprocessing TEE Probes:

1. Caution is advised when using Cidex OPA to reprocess transesophageal echocardiography (TEE) probes.

- High-level disinfect the TEE probe in accordance with its label and Section II, above.
- After immersion in Cidex OPA, thoroughly rinse the TEE probe with fresh water in accordance with the “3-2-1 recommendation” provided in Section II.2, above.
 - ◆ Review the label of the TEE probe for additional water-rinsing instructions. Confirm that Cidex OPA has been validated for reprocessing the probe by the probe’s manufacturer, and that after immersion in Cidex OPA the probe is rinsed with water using a procedure that also has been validated by the probe’s manufacturer.

2. Do not immerse TEE probes in Cidex OPA for a prolonged period of time. *Immersion of TEE probes in Cidex OPA for longer than 1 hour (or less than 12 minutes during manual reprocessing) may result in patient injury.*

3. Although Cidex OPA can be used to reprocess TEE probes, use of 2% glutaraldehyde or another LCS that does not contain *ortho*-phthalaldehyde may be advisable.

4. The labels of some TEE probes (and other reusable *semi-critical* instruments) may recommend covering the instrument with a disposable sheath, to prevent its contamination with bioburden during clinical use. The use of a protective sheath does not, however, obviate instrument reprocessing.

V. Contraindications, Precautions:

1. **Do not use Cidex OPA** to reprocess **urological instrumentation**, such as cystoscopes, used to treat patients with a history of bladder cancer.

- In rare instances, Cidex OPA has been associated with anaphylaxis-like reactions in patients with bladder cancer undergoing repeated cystoscopies. Use another LCS, such as 2% glutaraldehyde, to reprocess urological instrumentation used to treat this population of patients.
 - ◆ Caution is advised whenever using Cidex OPA to reprocess urological instrumentation that will be used

on patients not known to be adversely affected by Cidex OPA. (Cidex OPA is not contraindicated for reprocessing bronchoscopes or GI endoscopes.)

2. Wear **personal protective equipment** (PEE), including gloves, eye protection, and fluid-resistant gowns, when using Cidex OPA (or another LCS) to reprocess instruments.

- Direct contact with Cidex OPA may stain exposed skin or clothing, and with repeated contact with the skin may cause skin sensitization. (Always practice *Standard Precautions* when handling soiled instruments.)

3. Use Cidex OPA only in well-ventilated areas – namely, rooms that achieve at least 10 room exchanges per hour of fresh (not filtered, re-circulated) air. Ensure all containers of Cidex OPA are closed and feature tightly fitting lids.

4. Use Cidex OPA in compliance with its label to prevent rare instances of healthcare staff members or patients experiencing irritation or an allergic reaction. Do not use Cidex OPA to reprocess instrumentation used to treat patients with a known sensitivity to Cidex OPA (or any of its components).

VI. Additional Recommendations:

1. Although sporicidal (in 32 hours at 20° and 25° C), do not use Cidex OPA to sterilize reusable, heat-sensitive *semi-critical* or *critical* instruments, or to high-level disinfect *critical* instruments, such as cataract surgical instruments. Cidex OPA is indicated for the high-level disinfection of reusable, heat-sensitive *semi-critical* instruments. (Review the November, 1999, issue of this newsletter.)

- Steam sterilize reusable *critical* (and *semi-critical*) instruments not damaged by heat, pressure, and moisture. (Also, do not use Cidex OPA to reprocess single-use, disposable instruments.)

2. **Monitor** the reused solution of Cidex OPA in accordance with its label’s instructions using appropriately labeled chemical indicators (e.g., *Cidex OPA Solution Test Strips*).

- Monitor Cidex OPA during both manual and automated reprocessing, to ensure its concentration is not below its *minimum effective concentration*, or MEC, of 0.3%.

- ◆ Discard the solution of Cidex OPA after 14 days of reuse, or whenever the solution drops below its MEC and is no longer effective, *whichever occurs first*.

3. Visually inspect the Cidex OPA solution before each use.

- Discard the solution if any precipitates of insoluble salts

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are observed. These precipitates may be due to the mixing of Cidex OPA with small amount of hard water during rinsing. Use of a water softener may minimize or eliminate the formation of precipitates of insoluble salts.

4. Discard unused portions of opened bottles or containers of Cidex OPA after 75 days, or by the expiration date printed on the bottle, *whichever occurs first*.

Conclusion: These comprehensive and detailed recommendations are provided for the safe and proper use of Cidex OPA, and many of them may also be applicable to 2% glutaraldehyde and other types of LCSs. *Adherence to these recommendations will reduce the risk of both disease transmission to patients during flexible endoscopy and injury to healthcare staff members.* The use of an LCS to reprocess reusable (heat-sensitive, *semi-critical*) instruments manually or with an AER is ubiquitous in healthcare facilities and presents a challenging dynamic. In some instances, the labels of the LCS, the reusable instrument, and the AER may provide inconsistent reprocessing instructions, causing confusion and the potential for an increased risk of injury to both patients and healthcare staff members.

Healthcare facilities may resolve some potential reprocessing conflicts by a more thorough review of each label or by formal discussions with the manufacturers of the LCS, the instrument, and the AER, if one is used. But, these efforts may not always yield a timely or suitable resolution, as a manufacturer may be unwilling to deviate, if only slightly, from the reprocessing instructions provided in its product's label. *In these instances, adherence to whichever label of the three that provides the widest margin of safety for the patient is recommended.* Adoption of this paradigm may prove useful to the resolution of a reprocessing impasse or conflict.

Consider the following hypothetical example: The label of an LCS recommends rinsing an instrument *three* times with water following high-level disinfection, while the instrument's label recommends *two* terminal water-rinses. Further, an AER that may be used by the healthcare facility can be set to provide a single, double, or triple water-rinse after high-level disinfection. *What are reprocessing staff members to do? Would patient safety be compromised if staff were to manually rinse the instrument twice or to set the AER to rinse the instrument only once following high-level disinfection?*

Adoption of the paradigm to err on the side of patient safety would suggest that healthcare staff members follow the label of the LCS during manual reprocessing, because its recommendation for *three* terminal water-rinses would presumably provide a wider margin of patient safety than *two* (assuming the volumes and durations of the two water-rinses are comparable). Manually rinsing the instrument with water *twice* after chemical immersion as instructed by the instrument's label would seem permissible and safe, however, provided the instrument's manufacturer had demonstrated the safety and effectiveness of *two* water-rinses following high-

level disinfection using this specific LCS, and that these data had been reviewed by the FDA. (In general, while it might not pose a risk, caution is advised whenever rinsing an instrument with water fewer times than indicated on the LCS's label.)

If using an AER, however, that features a *single* water-rinse setting to follow chemical immersion—a different and potentially less thorough and rigorous water-rinse than recommended by the labels of either the LCS (*three* water-rinses) or the instrument (*two* water-rinses)—adoption of the aforementioned paradigm would suggest that staff set the AER to rinse the instrument *three* times with water as instructed for manual reprocessing by the LCS's label (e.g., the “3-2-1 recommendation” provided in Section II.2, above). In this example, however, setting the AER to rinse the instrument *once* with water after high-level disinfection would seem permissible and safe, provided the manufacturer of the AER had demonstrated the safety and effectiveness of rinsing this specific reusable instrument only *once* with water following high-level disinfection using this specific LCS in the AER, and that these data had been reviewed by the FDA.

If a manufacturer is unwilling to provide these data to a healthcare facility for its review, claiming, for instance, that these data are proprietary, then adoption of the paradigm to adhere to the label of the three that, again, provides the widest margin of patient safety would seem warranted. Manufacturers of LCSs, reusable instruments, and AERs might want to consider more collaboration with one another to prevent the labels of their respective products from including potentially conflicting reprocessing instructions. If a patient is injured by an instrument as a result of inadequate automated water-rinsing, it is likely that the manufacturers of all three of these devices would be considered at fault. *The End* **LFM** ■

Thank you for your interest in this newsletter. *I have addressed each issue and topic to the best of my ability.* Respectfully, *Lawrence F. Muscarella, Ph.D.* Please direct all correspondence to:

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