For: ***Infection Control, Operating Room, Endoscopy and Reprocessing Staff, Risk Managers, et al.***

The Q-Net™ Monthly

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What's News

● An **FDA Public Health Notification** was issued on June 19, 2006. Entitled "*Reprocessing of Reusable Ultrasound Transducer Assemblies Used for Biopsy Procedures,*" this alert (and others) can be read by visiting this newsletter's website at **http://www.myendosite.com** and navigating to its "Alerts" page. ● An article I (*LFM*) wrote that discusses **inconsistencies in infection-control guidelines** appears this September (2006) in a leading medical journal.

Editor-in-Chief

All of the articles published in this newsletter are written by: **Lawrence F Muscarella, PhD**, *Chief, Infection Control* at **Custom Ultrasonics, Inc**. Ivyland, PA

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.

Cidex OPA

A tale of three labels

QUESTION: *"I recently learned that under some circumstances* ***Cidex OPA*** *is* ***contraindicated*** *for processing* ***urological instrumentation****. But I am confused, because the label insert my endoscopy unit has on file for Cidex OPA does not include this* ***contraindication****. Please explain the details of this contraindication and why my unit's label insert does not include it."*

This article provides rare insight into the evolution of the labeling of a liquid chemical sterilant.

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Cidex OPA is a liquid chemical sterilant/disinfectant (LCS) that is used to high level disinfect gastrointestinal (GI) endoscopes and other types of reusable *semi-critical* instruments. This product, which is often referred to simply as "OPA" because of its active ingredient—0.55% ***o****rtho*-**p**hthal**a**ldehyde, is a clear, light blue solution that provides healthcare facilities with an alternative to 2% glutaraldehyde. Although its chemical structure classifies it as an aldehyde, Cidex OPA is different from, and is not to be confused with, "Cidex" or another glutaraldehyde solution. Cidex OPA has a slightly alkaline pH of 7.5; does not require chemical activation; is rapidly tuberculocidal; can be reused for as many as 14 days; has a shelf-life of up to 75 days; and, like most LCSs, requires that its concentration be monitored for effectiveness. Like Cidex, Cidex OPA is marketed and distributed by *Advanced Sterilization Products* (ASP).

This newsletter first discussed Cidex OPA in 1999 soon after its clearance by the *Food and Drug Administration* (FDA) for reprocessing flexible endoscopes. This product and its application to instrument reprocessing have not been formally addressed or reviewed in this newsletter since 2001.

Primarily because of its short immersion time, Cidex OPA may be favored by busy endoscopy units. Whereas 2% glutaraldehyde solutions usually require 20 or 45 minutes to achieve high-level disinfection, Cidex OPA is labeled to achieve high-level disinfection in 12 minutes (at a minimum temperature of 20° C, or 68° F, which is room temperature), making it one of the first LCSs marketed in the U.S. to achieve high-level disinfection in less than 20 minutes. Medical depart-

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☛ **HIGHLIGHTS:** *This article—the first in a series—provides a discussion of* ***Cidex OPA*** *and* ***reviews*** *its "Instructions for Use" as detailed in three different versions of its label.* ***Tables 1, 2*** *and* ***3*** *facilitate the easy comparison and understanding of each of these three versions of Cidex OPA's label.*

☛ This label recommends complete immersion of the device for a minimum of **12 minutes** at **20° C** (68° F) or higher to achieve high-level disinfection of heat-sensitive, *semi-critical* medical devices. This claim applies whether manually reprocessing the device using a bucket and tray or using an automated endoscope reprocessor (AER).
☛ Although it does not include a "sterilization" claim, this label indicates that Cidex OPA passes the "AOAC Sporicidal Activity Test," and therefore is sporicidal, in 32 hours at 20° C. *(Refer to the November, 1999, issue of this newsletter.)*
☛ This label includes one contraindication that instructs the user not to use Cidex OPA to sterilize (heat-sensitive) devices.
☛ This label warns that direct contact with Cidex OPA may stain exposed skin or clothing, and that repeated contact with the skin may cause skin sensitization. The use of personal protective equipment (PPE) is recommended.
☛ This label cautions users to avoid exposure to Cidex OPA's vapors. Use of Cidex OPA in closed containers with tightly fitting lids and in areas that are well-ventilated with fresh air is recommended. (These same precautions apply to other LCSs.)
☛ This label recommends that the medical facility obtain from the reusable device's manufacturer a validated procedure for re-processing the device using Cidex OPA. This device's labeling may provided additional water rinsing instructions.
☛ The use of Cidex OPA in an automated endoscope reprocessor (AER) requires validation of the reprocessing procedure.
☛ After chemical exposure to Cidex OPA, this label requires: (**a**) complete immersion of the device in a large volume of fresh rinse water (*e.g.,* **2 gallons**) for a minimum of **1 minute** (unless otherwise indicated by the device's manufacturer); (**b**) flushing the channels or lumens of the device with at least **500 ml** of fresh rinse water (again, unless otherwise indicated by the device's manufacturer); and, (**c**) repeating these two steps twice, for a total of **3 separate fresh water rinses**.
☛ This label notes that Cidex OPA is indicated for reprocessing Pentax and Olympus—but not Fujinon—flexible endoscopes.
☛ This label requires discarding the solution of Cidex OPA if precipitates of insoluble salts due to hard water are identified.
☛ This label states that the shelf-life of the unused portion of an opened bottle of Cidex OPA is **30** days, provided this date does not extend past the solution's expiration date, which is provided on the bottle.

Table 1. ***Original Cidex OPA label (1999)***. Important information about the safe use of **Cidex OPA** that is included in its first and original label. Some of these instructions, such as the requirement to use Cidex OPA in a well-ventilated area to minimize exposure to its vapors, apply to **all** types of liquid chemical disinfectant/ sterilants (LCSs) used to reprocess endoscopes.

ments that might use Cidex OPA to reprocess flexible endoscopes and other types of reusable *semi-critical* instruments include gastrointestinal endoscopy, bronchoscopy, urology, cardiology, gynecology, and the operating room.

Demonstrating a shift in a long-standing regulatory paradigm, the FDA cleared Cidex OPA without a specific "sterilization" claim. All previously cleared LCSs labeled for reprocessing flexible endoscopes include a label claim not only for high-level disinfection (typically during a short immersion time of, for example, 45 minutes), but also for "sterilization" (typically during a long immersion time of, for example, 10 hours). Though the label of Cidex OPA does not include a "sterilization" claim, an FDA website confirms that during sporicidal testing Cidex OPA satisfied the current regulatory requirements to claim "sterilization" during an exposure time and temperature of 32 hours and 20° C, respectively (*refer to the November, 1999, issue of this newsletter*).

Methods: As a result of this nurse's question (p. 13) and expressed confusion about contraindications associated with Cidex OPA, this product's label was reviewed. The goal of this review was to determine whether Cidex OPA is contraindicated under some circumstances for processing urological instrumentation and, if so, why this contraindication is not included in the label that this inquiring nurse's endoscopy unit has on file.

Results: This review revealed that the labeling of Cidex OPA has been changed twice since 1999, resulting in the publication of (at least) *three* different versions of labeling, each version containing additional information regarding the safe use of Cidex OPA. Salient information and instructions that are provided in the first and original label of Cidex OPA are highlighted in Table 1. The two subsequent versions of Cidex OPA's labeling, which are different from one another, are discussed in Tables 2 and 3 and contain significant changes and additions to Cidex OPA's original labeling. (Due to space constraints, not all of the contents of each respective version of Cidex OPA's label are listed in Tables 1-3.) A side-by-side comparison of these three tables simplifies an understanding of both the differences between each of these three versions of Cidex OPA's label and the significant additions to each subsequent version.

A. The original label (1999): The first and original label of Cidex OPA, published and cleared by the FDA in 1999, provides a singular contraindication that instructs the user not

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to use Cidex OPA to sterilize (heat-sensitive) medical instruments (Table 1). This specific contraindication provides additional information, stating that high-level disinfection of rigid endoscopes is recommended by the *Centers for Disease Control and Prevention* (CDC), among other organizations, whenever the use of a biologically-monitored sterilization process is not feasible.

Moreover, in addition to providing the time and temperature required for Cidex OPA to achieve high-level disinfection (*i.e.,* 12 minutes at 20° C), Cidex OPA's original label instructs users, as with all types of LCSs, to wear personal protective equipment (PPE) (*e.g.,* gloves, gowns, and eyewear) and to use Cidex OPA only in well-ventilated areas, to minimize exposure of personnel to its vapors (Table 1). This label emphasizes that direct contact with Cidex OPA may stain exposed skin or clothing, and that rinsing the instrument three times with fresh water after immersion in Cidex OPA is essential to remove chemical residue and prevent patient injury. Cidex OPA's original label does not include a contraindication regarding its use to process urological instrumentation, such as cystoscopes. For quality control and reference purposes, the original label of Cidex OPA may contain the designation "**LC 20390-003 Rev. A**" and the code "**ASP 1999**" at the end of its text.

B. The second label (2003): The use of a product in the clinical setting can result in observations, applications, and important information not addressed in the product's original label or 510(k) submission. This review of Cidex OPA's labeling and product literature revealed that ASP received clearance from the FDA in 2003 to modify Cidex OPA's original label, the reason for which was primarily to provide users with updated information and a second claim to achieve high-level disinfection. Whereas Cidex OPA's original label provided only one claim of 12 minutes at 20° C (68° F) to achieve high-level disinfection (Table 1), this product's revised (second) label provided an additional claim of 5 minutes at 25° C (77° F) to achieve high-level disinfection (Table 2). According to this second label, this elevated temperature claim requires use of a legally marketed automated endoscope reprocessor (AER) that can heat Cidex OPA to a minimum of 25° C. (Immersion of an instrument in Cidex OPA for 5 minutes at a temperature below 25° C can pose an infection risk.) This revised, or second, label of Cidex OPA may contain the designation "**LC-20390-006 Rev. B**" and the code "**ASP, 2003**" at the end of its text, distinguishing it from the first and original version of Cidex OPA's label.

These and other salient changes to Cidex OPA's original

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Table 2. ***Second Cidex OPA label (2003).*** Additional information about the safe use of Cidex OPA that is not included in the first and original version of its label (see Table 1).

☛ This label features a **dual** label claim for high-level disinfection that requires immersion of the device for: (**1**) a minimum of **12 minutes** at **20° C** or higher during manual reprocessing; and (**2**) a minimum of **5 minutes** at **25° C** (77° F) or higher during automated reprocessing. To achieve this latter claim's elevated temperature, this label requires use of a legally marketed automated endoscope reprocessor (AER) that can be set to a minimum temperature of 25° C and that can monitor this temperature. Otherwise, this label requires that the device be manually reprocessed (*i.e.,* 12 minutes at 20° C).
☛ Although it does not include a "sterilization" claim, this label indicates that Cidex OPA passed the "AOAC Sporicidal Activity Test," and therefore is sporicidal, in 32 hours at both 20° C and 25° C.
☛ This label notes in bold that direct contact with Cidex OPA solution may stain exposed skin or clothing.
☛ During manual reprocessing, this label requires after chemical exposure to Cidex OPA: (**a**) complete immersion of the device in a large volume of fresh rinse water (*e.g.,* 2 gallons) for a minimum of 1 minute (unless otherwise indicated by the device's manufacturer); and (**b**) flushing the channels or lumens of the device with at least **100 ml** of fresh rinse water (again, unless otherwise indicated by the device's manufacturer). This label refers the user to the labeling of the device's manufacturer for additional water rinsing instructions. This label clarifies and emphasizes the importance of manually performing these two steps **3 separate times** using fresh rinse water.
☛ For automated reprocessing, this label sets minimum water rinsing requirements—namely, that each water rinse must be fresh and at least 1 minute in duration; and that the device must be rinsed with water using an AER that has been validated for use with Cidex OPA. This label refers the user to the labeling of the device for additional water rinsing instructions.
☛ This label provides special instructions for manually reprocessing transesophageal echocardiography (TEE) probes, noting that immersion of TEE probes in Cidex OPA for longer than 1 hour and/or not rinsing the TEE probe 3 times using a fresh volume of water for each rinse after immersion in Cidex OPA may result in Cidex OPA remaining on the probe, the use of which may cause irritation, staining, and burning of the patient's mouth (i.e., "black mouth syndrome"), throat, esophagus, and stomach.
☛ This label states that Pentax, Olympus and Fujinon endoscopes are compatible with Cidex OPA.
☛ This label states that the shelf-life of the unused portion of an opened bottle of Cidex OPA is **75** days, provided this date does not extend past the solution's expiration date, which is provided on the bottle.

☛ This label provides two additional contraindications—namely, not to use Cidex OPA to process: (**1**) urological instrumentation (*e.g.,* cystoscopes) used to treat patients with a history of bladder cancer; and, (**2**) instrumentation to be used to treat patients with known sensitivity to Cidex OPA (or any of its components). The label adds that in rare instances, Cidex OPA has been associated with anaphylaxis-like reactions experienced by patients with bladder cancer undergoing repeated cystoscopies.
☛ This label states that in rare instances healthcare workers experienced an irritation or possible allergic reaction that may be associated with exposure to Cidex OPA. According to this label, "in the majority of these instances, healthcare workers were not using (Cidex OPA) in a well-ventilated room or not wearing proper personal protective equipment."
☛ This label includes the following additional symptoms that may occur as a result of exposure to Cidex OPA's vapors: wheezing, tightening of throat, urticaria (hives), rash, loss of smell, tingling of mouth or lips, and dry mouth.
☛ This label states that Cidex OPA is not to be used to reprocess "*critical* medical devices that are intended for use in a sterile area of the body (*e.g.,* cataract surgical instruments)."

Table 3. ***Third (current) Cidex OPA label (2004, 2006).*** Additional information about the safe use of Cidex OPA that is not included in either the first and original version of its label (see Table 1) or the second version of its label (see Table 2).

label are listed in Table 2. Among other additions and changes, this revised (second) label uses capitalized letters to clarify and emphasize that during manual reprocessing the instrument must be rinsed with water after chemical immersion *three* separate times, using a fresh and large volume of water (*e.g.,* 2 gallons) for each rinse. As significant, this revised label provides special instructions for reprocessing transesophageal echocardiography (TEE) probes that were not provided in Cidex OPA's original label, including not to immerse TEE probes in Cidex OPA for more than an hour (or for less than 12 minutes), and to ensure that TEE probes are rinsed with water in accordance with Cidex OPA's instructions (*i.e.,* three separate fresh water rinses). Like its original label, Cidex OPA's revised (second) label does not include a contraindication regarding its use to process urological instrumentation, such as cystoscopes. (This revised label provides only one contraindication–the same one provided in Cidex OPA's original label–that instructs the user not to use Cidex OPA to sterilize heat-sensitive medical devices.)

C. Product notification—The third label (2004, 2006): ASP wrote a "product notification" letter, dated April, 23, 2004, that notified customers of another significant modification to Cidex OPA's label. This letter stated that in rare instances Cidex OPA has been associated with anaphylaxis-like reactions experienced by patients with bladder cancer undergoing repeated cystoscopies (Table 3). Additionally, this letter reported that in rare instances healthcare workers experienced an irritation or a possible allergic reaction that may have been associated with exposure to Cidex OPA; for its part, ASP noted in this letter that in most of these cases healthcare workers were not using Cidex OPA in accordance with its "Instructions for Use" (IFU). (ASP notified its customers and healthcare professionals a second time of these reports by way of another letter dated January 3, 2005.)

These findings and clinical reports discussed in ASP's "production notification" letter were the basis for ASP to update and modify Cidex OPA's label for a second time. This modified (third) label was published in 2004 and, as displayed in Table 3, for the first time includes the contraindication that Cidex OPA is not to be used to process any urological instrumentation used to treat patients with a history of bladder cancer. This third label for Cidex OPA may contain the designation "**LC-20390-008 Rev. B (Rev. C or Rev. D)**" and the code "**ASP, 2004**," "**ASP, 2006**," or "**mailer, 4/04**" at the end of its text, distinguishing it from both the original (Table 1) and the second versions (Table 2) of Cidex OPA's label.

● **LFM** … ***To be continued in the next newsletter.***

☛ *Next month's article is the second in this series and provides a* ***discussion*** *of the significance of this current article's findings (pp. 13-16) including Tables 1-3. It also provides a number of important* ***recommendations*** *for the safe use of Cidex OPA.*

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, Ph.D.* Please direct all correspondence to:

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The Q-Net™ Monthly

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What's News

● **ESSENTIAL READING:** An article I wrote on the importance of writing and publishing infection-control, instrument-reprocessing, and healthcare guidelines that are committed to patient safety, and are not influenced by manufacturers or biased in favor of their products, appears in the September, 2006, issue of **THE AMERICAN JOURNAL OF GASTROENTEROLOGY.** ● Each article published in this newsletter can be read at: **http://www.myendosite.com**

Editor-in-Chief

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Cidex OPA, Part 2

This article discusses the labeling and safe use of Cidex OPA.

~ SECOND IN A SERIES ~

The **third** and **final article** in this series will be published **next month** in this newsletter and will provide specific **recommendations** for the safe and proper use of **Cidex OPA**.

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➤ ***A Tale of Three Labels:*** This article, which is the second in a series that investigates the safe and proper use of Cidex OPA, discusses the significance of some of the instructions provided in Cidex OPA's label, which has been modified twice since 1999—the year Cidex OPA was cleared by the *Food and Drug Administration* (FDA) for marketing. Published in last month's double issue of this newsletter, Tables 1-3 list important information about Cidex OPA. A side-by-side comparison of these three tables facilitates a clearer understanding of the contents of, additions to, and salient differences between, each of the three versions of Cidex OPA's label.

This series of articles on Cidex OPA provides rare insight into the evolution of the labeling of a popular liquid chemical sterilant/disinfectant (LCS) used to reprocess different types of reusable devices, including flexible endoscopes. The three different versions of Cidex OPA's label—published sequentially between 1999 and 2006—are a result, in part, of new clinical data that became available subsequent to Cidex OPA's introduction onto the market.

It is unclear whether most reprocessing staff members are aware that three different versions of Cidex OPA's label have been published, and that only in its most recent, or third, version does an important contraindication appear. Failure to review, understand, and comply with the instructions, precautions, and contraindications detailed in the third version of Cidex OPA's label–which can be distinguished from its previous two versions by the unique text "*ASP, 2004*," "*ASP, 2006*," or "*mailer, 4/04*" appearing at the end of the label–significantly increases the risk of ineffective reprocessing and injury to both patients and healthcare staff members.

➤ ***Cidex OPA is contraindicated for reprocessing urological instrumentation to be used to treat patients with a history of bladder cancer:*** Whereas 2% glutaraldehyde is indicated for reprocessing virtually all types of flexible endoscopes, Cidex OPA (and, presumably, other products that contain *ortho*-phthalaldehyde) is contraindicated for reprocessing urological instrumentation, such as cystoscopes, to be used to treat

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patients with a history of bladder cancer. (Cidex OPA is *not* contraindicated for reprocessing gastrointestinal [GI] endoscopes and bronchoscopes.) This specific contraindication is included in only the third version of Cidex OPA's label.

This review's identification of three different versions of Cidex OPA's label, only the third of which includes an important contraindication regarding urological instrumentation, would explain the nurse's question about Cidex OPA that was published in last month's double issue of this newsletter. As this nurse's question would suggest, the version of Cidex OPA's label that this nurse's endoscopy department was using and had on file was likely either its first or second, both of which were published prior to 2004–the year that its manufacturer mailed a "product notification" letter to customers, along with a copy of the third (and current) version of Cidex OPA's label, highlighting the addition of this contraindication for reprocessing urological instrumentation to be used to treat patients with a history of bladder cancer.

➤ ***The label of Cidex OPA does not include a "sterilization" claim:*** Prior to the FDA's clearance of Cidex OPA in 1999, virtually all LCSs marketed in the U.S. for reprocessing flexible endoscopes and other types of *semi-critical* reusable devices were labeled to achieve high-level disinfection *and* "sterilization" during relatively short and long exposure times, respectively. The labels of virtually all 2% glutaraldehyde solutions cleared by the FDA more than a decade ago, for example, claim to achieve high-level disinfection in 45 minutes and "sterilization" in 8 or 10 hours (at 25° C). Somewhat contrary to regulatory tradition, Cidex OPA was cleared by the FDA as a high-level disinfectant without a "sterilization" claim.

The medical literature indicates, however, that use of a high-level disinfectant whose label does not include a sterilization" claim, such as Cidex OPA (and the Sterilox Solution), is not clinically problematic and does not increase the risk of nosocomial infection. Its label's lack of a "sterilization" claim notwithstanding, Cidex OPA is reported to destroy high numbers of bacterial endospores during the *AOAC Sporicidal Test*, albeit in 32 hours at 20° C and 25° C. This standardized sporicidal test is an important benchmark that must be satisfied to label a LCS to achieve "sterilization." *(Refer to the November, 1999, issue of this newsletter.)*

Whether the FDA's clearance of Cidex OPA as a high-level disinfectant without a "sterilization" claim reflects a shift in a long-standing regulatory paradigm that is in response to several articles, including some published in this newsletter, that question the appropriateness and scientific validity of labeling a LCS to achieve "sterilization" is unclear. *(Refer to the November-December, 2001, issue of this newsletter.)* Based on a thorough review of the medical literature, labeling as "100% sporicidal" (at a specified immersion time and temperature) a LCS that has passed, among other tests, the *AOAC Sporicidal Test* is more appropriate and scientifically valid than labeling the LCS to achieve "sterilization." It is recommended, therefore, that the "sterilization" claim on the labels of LCSs, including 2% glutaraldehyde solutions, be removed and replaced with the evidence-based "100% sporicidal" claim (in, for example, 8 or 10 hours at 25° C).

High-level disinfection destroys all types of pathogens encountered in the clinical setting, including the hepatitis C virus, HIV, *Mycobacterium tuberculosis*, which is the causative agent of pulmonary tuberculosis, and *Clostridium difficile*–a spore-forming bacterium that may be encountered during lower GI endoscopy. Because high-level disinfection prevents disease transmission, it is not surprising that endoscopes that have been properly cleaned, high-level disinfected, rinsed with clean water, and dried with forced air have *not* been associated with disease transmission. While there is an academic distinction between high-level disinfection and sterilization, clinical differences between the two have not been demonstrated in the endoscopic setting.

➤ ***No LCS is ideal and without shortcomings:*** Some of the warnings and precautions included on its label are not necessarily unique to Cidex OPA and may also be included on the labels of other LCSs used to reprocess reusable devices. *No LCS is ideal and without potentially significant shortcomings*. For example, reports of medical staff members experiencing respiratory sensitization following repeated exposure to 2% glutaraldehyde have been documented. Moreover, the MSDS ("material-safety-data-sheet") of 0.2% peracetic acid and 7.5% hydrogen peroxide—two other LCSs used to reprocess flexible endoscopes—state that, among other safety concerns, both can cause irreversible eye damage and be corrosive to skin and mucous membranes (and delicate instruments).

Indeed, it would be myopic and erroneous to conclude that only Cidex OPA requires, for example, that reprocessing staff members wear personal protective equipment (PPE) and that the reprocessing room be ventilated with at least 10 room exchanges of fresh air per hour. In truth, Cidex OPA has some advantages compared to several other LCSs, such as its claim to achieve high-level disinfection in 5 minutes at a minimum of 25° C. But, despite this and other advantages, Cidex OPA is the only FDA-cleared LCS used to reprocess flexible endoscopes that is contraindicated for reprocessing urological instrumentation to be used to treat patients with a history of bladder cancer (refer to a previous section, above).

➤ ***Cidex OPA's high-level disinfection claim at an elevated temperature contraindicates manual reprocessing:*** In 2003, the manufacturer of Cidex OPA received clearance by the FDA to modify Cidex OPA's original label, cleared in 1999 with the claim to achieve high-level disinfection in 12 minutes at 20° C, and to market Cidex OPA with the additional claim to achieve high-level disinfection in 5 minutes at 25° C. Prior to the clearance of this second version of Cidex OPA's label (in 2003), virtually all LCSs cleared by the FDA to achieve high-level disinfection at an elevated temperature

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are indicated for both manual and automated reprocessing. For example, solutions of 2% (alkaline) glutaraldehyde, cleared by the FDA more than a decade ago and labeled to achieve high-level disinfection at 25° C, are indicated for both manual and automated reprocessing.

The labels of some recently cleared LCSs that claim to achieve high-level disinfection at an elevated temperature, even if only 5° C above room temperature (*i.e.,* 25° C), however, contraindicate manual reprocessing and require their exclusive use in an automated endoscope reprocessor (AER). Cidex OPA, for example, must be used in a legally-marketed AER whenever Cidex OPA is used to achieve high-level disinfection in 5 minutes at an elevated temperature of 25° C. (Cidex OPA's label does not contraindicate manual reprocessing, however, when used at room temperature during an immersion time of 12 minutes.) Moreover, the label of Rapicide—a 2.5% (acidic) glutaraldehyde formulation that achieves high-level disinfection in 5 minutes at 35° C (*i.e.,* 95° F)—also contraindicates manual reprocessing and requires the use of an AER. Whether these clearances reflect a potential shift in another long-standing regulatory paradigm that would appear to suggest that the FDA no longer considers manual heating of LCSs safe or effective is unclear.

Further, Cidex OPA's label requires that the AER be equipped with an immersion heater and be designed to automatically control and monitor Cidex OPA's elevated temperature during high-level disinfection. If the AER does not satisfy these requirements, then the reusable device must be manually reprocessed using Cidex OPA for 12 minutes at room temperature. (A drop in the temperature of Cidex OPA below 25° C during a 5-minute immersion time can result in disease transmission.) Indeed, using, for example, an aquarium heater to heat a LCS manually, as well as manually controlling and monitoring the LCS's elevated temperature during chemical immersion, can be problematic, cumbersome, and result in ineffective reprocessing.

Moreover, although elevating the temperature of a LCS typically increases its biocidal effectiveness, it may also increase the LCS's vapor pressure, which, particularly during manual reprocessing, increases the potential for irritation and sensitization to the skin, noses, throats, and respiratory tracts of medical staff members. Most AERs are designed with a tightly-fitting lid to minimize exposure of medical staff members and the surrounding environment to the LCS's potentially irritating vapors, which might further explain why the FDA requires at least some LCSs associated with an elevated temperature claim to be used exclusively in an AER.

➤ ***The importance of water rinsing:*** In addition to minimizing exposure of medical staff members and the surrounding environment to an LCS's potentially irritating vapors, there is another reason why the FDA might favor, if not encourage, the routine use of an AER, especially when using Cidex OPA. While manual reprocessing as a discipline has not been demonstrated to be associated with a higher incidence of nosocomial infection than automated reprocessing, the former is inherently prone to variability and an inconsistent outcome. AERs, however, standardize several reprocessing steps, including water rinsing, ordinarily allaying concerns that a crucial reprocessing step was skipped or overlooked. Patient injury due to failure of water rinsing to remove all of the chemical residue from the surfaces of a reusable device, such as a TEE (or, "transesophageal echocardiography") probe, has been reported (refer to the next section, below). LCSs that are not easily removed during rinsing due to their limited solubility in water would be of a particular concern. Whereas the MSDS of Cidex (2% glutaraldehyde) confirms that it is "completely soluble" in water, the MSDS of Cidex OPA lists it simply as "soluble" in water, which suggests that Cidex OPA is less soluble in water than Cidex and, therefore, harder to remove from a reusable device during water rinsing.

The importance of effective water rinsing is underscored by all three versions of Cidex OPA's label, which specify that during manual reprocessing the reusable device must be rinsed *three* separate times with fresh water following chemical immersion, to prevent potentially harmful residue of Cidex OPA from remaining on the device. Each version further specifies that, for each of these three rinses, the reusable device must be completely immersed in a large volume of fresh water *("2 gallons")* for a "minimum of *1 minute* in duration." (The second and third versions of Cidex OPA's label recommend that the lumens or channels of a reusable device be flushed with not "less than 100 mL [or milliliters] of rinse water" during each separate rinse.) While a potential concern to patient safety, any deviation from these specific water rinsing parameters and instructions–for example, rinsing the reusable device only once with water after high-level disinfection–might be permissible, but arguably *only* if, among other considerations, the manufacturer of the reusable device during manual reprocessing, or the manufacturer of the AER during automated reprocessing, provides the user with validated and "FDA-approved" data clearly demonstrating that the alternative water rinsing procedure completely removes potentially harmful residue of Cidex OPA (or another LCS) from all of the device's surfaces.

None of the three versions of Cidex OPA's label, however, specifies the *number* of water rinses, or the minimum water *volume* for each rinse, that are required during automated reprocessing, even though both parameters are important to rinsing a reusable device successfully after chemical immersion using an AER. Instead, Cidex OPA's label assigns the responsibility of determining these water rinsing parameters to the manufacturer of the AER (see below).

➤ ***Reprocessing TEE probes using Cidex OPA:*** TEE probes are delicate instruments used non-invasively to provide clear ultrasound images of the functioning heart. Resembling a flexible GI endoscope without any internal channels, TEE probes are introduced during TEE into the

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upper gastrointestinal (GI) tract via the patient's oral cavity. The second and third versions of Cidex OPA's label provide special instructions for (manually) reprocessing these probes. Both versions caution that ineffective water rinsing due to immersion of the TEE probe in Cidex OPA for longer than an hour, and/or not rinsing the TEE probe three separate times with fresh water after chemical immersion, may result in chemical burns, irritation, and staining of the patient's mouth, throat, esophagus, and stomach. Because the first version of Cidex OPA's label does not include these specific instructions for reprocessing TEE probes, the inclusion of these instructions in the second and third versions of Cidex OPA's label would suggest that sometime between 1999 and 2003—the year the second version of Cidex OPA's label was published—Cidex OPA's manufacturer received reports associating the potential for patient injury to inadequately rinsed TEE probes reprocessed using Cidex OPA.

➤ ***Whose instructions are to be followed?*** In addition to providing important instructions, precautions, and contraindications, all three versions of its label assign some of the responsibility of using Cidex OPA to the manufacturer of the reusable device and, as discussed in a previous section, to the manufacturer of the AER, if one is used. In addition to none of the three versions of Cidex OPA's label providing the *number* of water rinses or the minimum water *volume* per rinse that is required to rinse any type of reusable device successfully with water during automated reprocessing, all three versions recommend:

(1) "*Refer to the reusable medical device manufacturer's labeling for additional (water) rinsing instructions";*

(2) *"The reusable device manufacturer should provide the user with a validated reprocessing procedure for that device using Cidex OPA Solution";*

(3) *"The use of Cidex OPA with* semi-*critical devices must be part of a validated (water) rinsing procedure as provided by the (reusable) device manufacturer";*

(4) *Immerse the reusable device during each rinse "for a minimum of 1 minute in duration" unless the device's manufacturer specifies a longer time;* and

(5) *The use of Cidex OPA Solution in automated endoscope reprocessors (AERs) must be part of a reprocessing (and water rinsing) procedure (provided and validated by the manufacturer of the AER).*"

Additionally, the second and third versions of Cidex OPA's label provide a sixth recommendation:

(6) *"Select a rinse cycle on an automatic endoscope reprocessor that has been validated for use with" Cidex OPA.*

While most of the reprocessing instructions detailed in all three versions of Cidex OPA's label are clear and sufficient for effective reprocessing and water rinsing, these six recommendations demonstrate that some of the instructions provided by the three versions of the label of Cidex OPA (and other LCSs) are limited and require cooperation by, and both information and input from, the manufacturer of the reusable device and the manufacturer of the AER, if one is used. Whereas the first four of these six recommendations instruct healthcare staff to obtain reprocessing instructions and validated data from the manufacturer of the reusable device, the fifth and sixth recommendations instruct the user to contact and obtain validated data from the manufacturer of the AER.

Which raises the following questions: ● *What if the label (and manufacturer) of the reusable device and/or the label of the AER provides a reprocessing recommendation, instruction, or contraindication that is inconsistent with the label and reprocessing instructions of the LCS? Which label and reprocessing instructions should the user follow?* Additional questions arise: ● *What is a medical facility to do if, in an attempt to comply with, for example, the second and fifth recommendations (above), it requests from the manufacturers of both the reusable device and the AER a copy of these validated procedures and data, but neither manufacturer complies, stating that these data are "proprietary" and not available for public review?* ● *And, what if a patient is injured as a result of residue of Cidex OPA remaining on a reusable device that was inadequately rinsed with water by an AER? Which of these three manufacturers would be accountable and to blame?* Medical facilities seek clear advice to these and other important reprocessing questions. ■ ***LFM***

☛ ***To be continued*** … The **final article** in this series will be published **next month** and will provides important **recommendations** for the safe use *of* ***Cidex OPA***.

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, Ph.D.* Please direct all correspondence to:

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For: Infection Control, Operating Room, Endoscopy and Reprocessing Staff, Risk Managers, et al.

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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

All of the articles published in this newsletter are written by: **Lawrence F Muscarella, PhD**, *Chief, Infection Control* at **Custom Ultrasonics, Inc**. Ivyland, PA

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) ***o****rtho*-**p**hthal**a**ldehyde.

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 additional 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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