

Guideline for Use of High Level Disinfectants & Sterilants for Reprocessing Flexible Gastrointestinal Endoscopes



Society of Gastroenterology Nurses and Associates, Inc.

Acknowledgements

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Preface

Professional associations and regulatory agencies recognize high-level disinfection as the standard of care in reprocessing flexible endoscopes (American Society for Gastrointestinal Endoscopy [ASGE], 2001). As of May 13, 2005, the U.S. Food and Drug Administration has cleared twenty-five products as sterilants and high-level disinfectants with general claims for reprocessing reusable medical and dental devices (United States Food & Drug Administration [FDA], 2005).

Many high-level disinfectants/sterilants are distributed under different brand names, but contain the same chemical composition. This guideline provides information about the properties of the main ingredients of these solutions, their safe and effective use, and their compatibility with flexible endoscopes. The current FDA document has listed these products by brand name. It is beyond the scope of this document to review each individual product.

Definition of Terms

For the purpose of this document, SGNA has adopted the following definitions:

Biofilm refers to a complex community of microorganisms that form a matrix of extracellular material composed of exopolysaccharides (EPS). This extracellular material facilitates the retention and adherence of the microbial community to surfaces and can protect it from disinfectants.

Endoscope refers a tubular instrument used to examine the interior of the hollow viscera (ASTM, 2000). In this document, endoscope refers only to flexible gastrointestinal endoscopes.

Low-level disinfection refers to a process that can kill most bacteria, some viruses and some fungi. Note that it cannot be relied on to kill resistant organisms such as tubercle bacilli or bacterial spores (FDA, 2005; Rutala, 1996)

High-level disinfectant (HLD) refers to a chemical germicide that has been cleared by the FDA as capable of destroying all viruses, vegetative bacteria, fungi, mycobacterium and some, but not all, bacterial spores (Rutala, 1996).

High-level disinfection (HLD) refers to the destruction of all microorganisms with the exception of high levels of bacterial spores (FDA, 2005; Rutala, 1996).

Material Safety Data Sheet (MSDS) refers to a descriptive sheet that accompanies a chemical or chemical mixture, providing the identity of the material; physical hazards, such as flammability; acute and chronic health hazards associated with contact with or exposure to the compound.

Minimum effective concentration (MEC) refers to the lowest concentration of active ingredient necessary to meet the label claim of a reusable high-level

disinfectant/sterilant (Association for the Advancement of Medical Instrumentation [AAMI], 2005).

Mutagen refers to a substance capable of inducing or accelerating changes in a gene or chromosome.

Reuse-life refers to a statement by the manufacturer indicating the maximum number of days a reusable high-level disinfectant/sterilant might be effective (AAMI, 2005).

Sterilant refers to a chemical germicide that has been cleared by the FDA as capable of destroying all microorganisms, including all bacterial spores (Rutala, 1996).

Sterile refers to the state of being free from all living organisms.

Sterilization refers to a process which results in the complete elimination or destruction of all forms of microbial life. The Spaulding Classification identifies sterilization as the standard for medical devices that enter the vascular system or sterile tissue, such as biopsy forceps (World Health Organization [WHO], 1999; Rutala, 1996).

Threshold limit value ceiling (TLV-C) refers to the airborne concentration of a substance that should not be exceeded during any part of the work experience (American Conference of Governmental Industrial Hygienists [ACGIH], 1998).

Threshold limit value time-weighted average (TLV-TWA) refers to the airborne concentration of a substance to which all workers may be exposed day after day without experiencing any adverse health effects (ACGIH, 1998).

I. General Principles Common to the Use of All High Level Disinfectants and/or Sterilants

A. Medical Device Classification system

Dr. E. H. Spaulding devised a classification system that divided medical devices into categories based on the risk of infection involved with their use (Reichert & Schultz, 2001). This classification system is used by the FDA, the Centers for Disease Control and Prevention (CDC), epidemiologists, microbiologists, and professional medical organizations to aid in determining the degree of disinfection or sterilization required for various medical devices. Spaulding defines three categories of medical devices and their associated level of disinfection or sterilization.

Critical: A device that enters normally sterile tissue or the vascular system. These devices should be sterilized.

Semicritical: A device that comes into contact with intact mucous membranes and does not ordinarily penetrate sterile tissue. These devices should receive at least high-level disinfection.

Noncritical: Devices that do not ordinarily touch the patient or touch only intact skin. These devices may be cleaned by low-level disinfection.

B. Product Safety

All high level disinfectants and sterilants may have adverse health effects (Rutala, 1996). It is imperative that healthcare workers who use any high-level disinfectant and/or sterilant follow Occupational Safety and Health Administration (OSHA) guidelines. They should be familiar with and have readily accessible the product/brand-specific MSDS for all chemicals used and stay current with developments in products, protective equipment, and practice.

C. General Characteristics

“The characteristics of an ideal chemical sterilant used as a high-level disinfectant should include broad antimicrobial spectrum, rapid activity, material compatibility, lack of toxicity to humans and the environment, odorless, nonstaining, unrestricted disposal, prolonged reuse life and shelf life, easy to use, resistant to organic material, ability to be monitored for concentration and cost effective” (Rutala & Weber, 1999).

D. Manual Cleaning

Meticulous manual cleaning of all instruments must precede exposure to any high-level disinfectant or sterilant (SGNA, 2005). Inadequate cleaning of instruments has been one factor cited in transmission of infection by flexible endoscopes (Alvarado & Reicheldelfer, 2000; Rutala & Weber, 2004a & b; Moses & Lee, 2004). Studies demonstrate that appropriate manual cleaning of endoscopes reduces the number of microorganisms and organic load by 4-6 logs or 99.9% (Chu, McAlister & Antonoplos, 1998; Vesley, Melson & Stanley, 1998). This process significantly reduces the organic and microbial challenge to the high-level disinfectant or sterilant. A detailed cleaning protocol for endoscopes is found in SGNA’s *Standards for Infection Control and Reprocessing of Flexible Gastrointestinal Endoscopes* (2005). Refer to endoscope manufacturers’ guidelines for design features unique to a particular instrument.

E. Determining Minimum Effective Concentration (MEC)

Glutaraldehyde, 7.5% hydrogen peroxide, 0.08% peracetic acid/1% hydrogen peroxide and 0.55% ortho-phthalaldehyde are reusable products (FDA, 2005). The following factors may result in a gradual reduction of the effectiveness of

reusable high-level disinfectants/sterilants (Rutala, 1996; ASGE, 2001; AAMI, 2005):

1. Challenges of microbes and organic matter;
2. Dilution by rinse water; and
3. Age of the chemical solution.

Reusable high-level disinfectant/sterilants must be changed whenever the MEC fails or the reuse life expires, whichever comes first. If additional chemical solution is added to an automated endoscope reprocessor (AER) or basin (if manually disinfected) the reuse life should be determined by the first use/activation of the original solution. The practice of “topping off” of the chemical does not extend the reuse life (Nelson, Jarvis, Rutala, Foxx-Orenstein, Isenberg, Dash et al., 2003).

The appropriate number of reuses of each of these products must be determined by testing that the solution is at or above its MEC. Use product-specific test strips. MEC should be monitored according to the manufacturer’s instructions (AAMI, 2005) and a log of test results should be maintained (SGNA, 2005).

F. Final Rinse/Alcohol Purge/Storage

All high-level disinfectants or sterilants used to reprocess flexible endoscopes have the potential to injure mucous membranes if not thoroughly rinsed from the endoscope (Rutala, 1996; Weber & Rutala, 2001). In addition, rinse water may contaminate the endoscope following chemical exposure (Alvarado & Reicheldelfer, 2000). After high-level disinfection, the endoscope must be rinsed and the channels flushed with sterile, filtered, or tap water to remove the disinfectant/sterilant (Nelson et al. 2003).

Irrespective of the quality of the water used to rinse flexible endoscopes during manual or automated reprocessing (e.g., “clean” water, tap water, “fresh” water, rinse water labeled as “bacteria-free”, or rinse water labeled as “sterile”), the entire endoscope must be dried, with each of its internal channels being flushed with 70% alcohol, followed by forced-air drying, both between patient and prior to storage (Muscarella, 2001). This step greatly reduces the possibility of recontamination of the endoscope by waterborne microorganisms (Nelson & Muscarella, 2006; Nelson et al. 2003; Muscarella, 2001) and it also facilitates drying the instrument (Alvarado & Reicheldelfer, 2000; ASTM, 2000). All water types, including sterile water, have been linked to bacterial contamination and must therefore be subject to the above final drying step (Alvarado & Reicheldelfer, 2000; Nelson & Muscarella, 2006).

Storage of the endoscope in a dry and well-ventilated environment in accordance with the endoscope manufacturer’s instructions is important to prevent the

colonization of bacteria and patient infection. The endoscopes must hang vertically with its control valves and biopsy inlet cap removed to facilitate air movement (Muscarella, 2001; SGNA, 2005).

This practice of cleaning, high level disinfection (or “sterilization”), rinsing, flushing with 70% alcohol, forced-air drying, and proper storage eliminates the need to reprocess each endoscope before the first patient of the day. There is no independent data that suggests reprocessing endoscopes in the morning before the first patient of the day, an expensive and time-consuming process, reduces the risk of patient infection (Muscarella, 2001). “Adhering to published guidelines that emphasize the importance of rinsing endoscopes’ channels with 70% alcohol followed by forced-air drying before storage, as well as hanging endoscopes vertically in a clean, well ventilated storage area with its control valves and biopsy inlet cap removed to facilitate air movement, is essential to prevent bacterial colonization and patient infection “(Muscarella, 2001).

G. Personal Protective Equipment

Personal protective equipment should be used when reprocessing endoscopes, as exposure to high-level disinfectants, sterilants and/or body fluids may occur. Gowns, gloves and protective eyewear are recommended when handling any high-level disinfectant/sterilant (Jordan, 1995; Alvarado & Reicheldelfer, 2000; National Institute for Occupational Safety and Health [NIOSH], 2001; Nelson et al. 2003).

1. Gowns should be impervious to fluid, have long sleeves that fit snugly around the wrist, and wrap to cover as much of the body as possible. Dispose of or launder gowns if they become wet or are exposed to contaminated material.
2. Gloves should be inspected for tears or holes before use. Do not use an imperfect glove or reuse disposable gloves. Gloves should be long enough to extend up the arm to protect the forearm or clothing from splashes or seepage. To avoid cross-contamination, change gloves and wash hands whenever moving from a dirty to clean task or environment (Jordan, 1996).
3. Eye and/or face protection is necessary. Contact lenses are not sufficient eye protection. A face shield (or safety glasses in combination with a face-mask allowing for ventilation) is recommended. Do not use high filtration masks since they may actually trap vapors. Each reprocessing area must contain an eyewash station (American National Standard Institute [ANSI], 2004). The

MSDS for all high-level disinfectant/sterilants recommends evaluation by a physician in the event of eye exposure.

H. Material Compatibility

Endoscopes and automated reprocessors are composed of a variety of materials such as rubbers, plastics and metals that may be affected by ingredients in high-level disinfectants or sterilants (Reichert & Schultz, 2001). Consult manufacturers of endoscopes and reprocessors for results of compatibility studies as part of the process of choosing a product. Incompatibility may result in changes in appearance and function of an endoscope. See Appendix A for a chart summarizing HLD compatibility listing of endoscope manufacturers.

Use of a high-level disinfectant or sterilant for which a manufacturer has not issued a compatibility statement may void the instrument's warranty. Third-party repair companies may use different materials in replacement components than those of the original equipment manufacturer. If using the services of a third party for repairs, consult them for compatibility and warranty information.

I. Susceptibility of Resistant Organisms

Organisms of concern in gastroenterology settings, such as *Clostridium difficile*, *Helicobacter pylori*, *Escherichia coli*, Human immunodeficiency virus (HIV), Hepatitis C virus, Hepatitis B virus, multidrug-resistant *M tuberculosis*, Vancomycin-resistant enterococcus, Methicillin-resistant *Staphylococcus aureus* (MRSA) are susceptible to high level disinfectants and sterilants" (Rutala, 1996; Rutala & Weber, 2004a & b). It is not necessary to deviate from routine reprocessing protocols when exposure to pathogenic organisms is suspected, since to do so would constitute a "double standard" of care (Rutala & Weber, 1999). "Endoscopes reprocessed appropriately in accordance with reprocessing and infection-control guidelines, pose virtually no risk of transmission of patient - borne or environmental organisms" (Nelson & Muscarella, 2006).

Concern has been raised over possible endoscopic transmission of prions and other transmissible spongiform encephalopathies (TSE), including Creutzfeldt-Jakob disease, kuru, and bovine spongiform encephalopathy. There have been no reported cases of transmission of these agents by endoscopy (Nelson & Muscarella, 2006). The World Health Organization recommends that the infectivity level of the tissue contaminating the instrument should guide the decontamination of medical instruments (WHO, 1999; Nelson & Muscarella, 2006). Saliva, gingival tissue, intestinal tissue, feces, and blood are classified as having no detectable infectivity and, for the purposes of infection control for these agents, are regarded as noninfectious (Rutala, 2001; Nelson & Muscarella, 2006). A draft statement on TSE and endoscopes from the CDC concluded that

current guidelines for cleaning and disinfection of the instruments need not be changed (Nelson et al. 2003).

J. Biofilm

Biofilm, a complex community of microorganisms embedded in a matrix of extracellular material, may form on surfaces that come in contact with fluid (Pajkos, Vickery & Cossart, 2004) including all internal and external surfaces of endoscopes, reusable accessory equipment and automated reprocessors. Bacteria located in the biofilm has an altered phenotype and is much more resistant to chemical inactivation due to the bacteria's lowered metabolic state, slower growth rate, and exopolysaccharide production (Pajkos et al. 2004; Donlan & Costerton, 2002). Mechanical cleaning may be required to effectively remove established biofilms, according to J. Marx (personal communication, March 13, 2007). It is crucial to follow the cleaning protocol for endoscopes found in SGNA's *Standards for Infection Control and Reprocessing of Flexible Gastrointestinal Endoscopes* (2005).

II. High-Level Disinfectant and Sterilant Properties and Handling Recommendations

A. Glutaraldehyde

1. Characteristics:

Glutaraldehyde has been used for more than 30 years in many health care settings for high-level disinfection and cold sterilization. Glutaraldehyde, a saturated dialdehyde, has been the most widely used chemical for the high level disinfection of endoscopes. Most aqueous solutions of glutaraldehyde are acidic and must be activated (made alkaline to pH 7.5-8.5) to become sporicidal. The biocidal activity of glutaraldehyde is a consequence of its alkylation of sulfhydryl, hydroxyl, carboxyl and amino groups, which alters RNA, DNA and protein synthesis within microorganisms (Rutala & Weber, 1999).

Glutaraldehyde products are marketed under a variety of brand names and are available in a variety of concentrations, with and without surfactants. Glutaraldehyde solutions range in concentration from 2.4 - 3.4% and have varied maximum reuse lives. For example, the maximum reuse life of an alkaline (activated) 2% glutaraldehyde without surfactants is 14 days. The actual reuse life of any reusable HLD/sterilant must be determined by testing for MEC with product-specific test strips. Labeling regulations require the manufacturer to place the MEC on the container. For example, test strips for 2.4% glutaraldehyde

products are constructed to show failure when the concentration drops below 1.5% (Advanced Sterilization Products [ASP], 2005).

Soak time exception:

SGNA, in collaboration with the American Society for Gastrointestinal Endoscopy (ASGE), the American Gastroenterological Association (AGA), the American College of Gastroenterology (ACG), and the Association for Professionals in Infection Control and Epidemiology (APIC) adopted the Multi-society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes. This guideline, based on scientific data, supports the position that after meticulous manual cleaning, high-level disinfection is achievable with a 20-minute exposure at 20°C (room temperature) in a 2% glutaraldehyde solution which does not contain surfactant and which tests above its minimum effective concentration (Nelson et al. 2003). These conditions may not be extended to other glutaraldehyde solutions. This recommendation differs from the label claims on 2% glutaraldehyde stating a 45-minute exposure at 25°C for HLD because the current federal labeling regulation assumes no cleaning of the medical device prior to chemical exposure.

There are products that can achieve high-level disinfection with a shorter exposure time but require a higher temperature. An example of this is Rapicide™ (Olympus America Inc. [OAI], 2001). Manufacturers' instructions must be followed for temperature and disinfection time.

Advantages:

Glutaraldehyde has excellent biocidal activity, is active in the presence of organic matter and is non-corrosive to metals, rubbers and plastics (Rutala, 1996). Glutaraldehyde may be used in manual or automated reprocessing protocols. Olympus, Pentax and Fujinon list glutaraldehyde as compatible with their endoscopes. Glutaraldehyde is compatible with automated reprocessors except STERIS SYSTEM 1.

Glutaraldehyde is not reported to cause reproductive or mutagenic effects on humans (ASP, 2005).

In most states, glutaraldehyde solutions that have failed MEC tests can be discarded down the drain and flushed with large amounts of water. Empty containers from freshly activated solutions should be thoroughly rinsed with water prior to disposal. Refer to the MSDS for specific product disposal guidelines. Consult state and local regulations for possible differences in disposal requirements.

Disadvantages:

Glutaraldehyde's failure to eliminate all atypical Mycobacteria using standard contact times creates cross infection risk in immune compromised patients. This is further complicated by the emergence of glutaraldehyde-resistant mycobacteria (Stanley, 1999). Glutaraldehyde can fix proteins and allows for biofilm formation (Rutala & Weber, 2004a; ESGE/ESGENA, 2003).

Glutaraldehyde is an irritant and some individuals develop acute sensitivities (NIOSH, 2001). These sensitivities may be displayed as itching of the skin with slight redness, to redness and swelling or yellowing of the skin with prolonged exposure, or irritation to eyes and nasal membranes, headache, coughing, sneezing, and asthma-like symptoms. Glutaraldehyde can be absorbed by inhalation, ingestion and through the skin. It has a detectable odor at 0.04 parts per million volume (ppmv) and is irritating to skin and mucous membranes at 0.3 ppmv (Jordan, 1995). Vapors are released whenever solutions are disturbed and the surface tension is broken. Mixing, adding and removing equipment, or disposing of a glutaraldehyde solution can cause a break in the surface tension (Notarianni, 1992). Whenever the glutaraldehyde solution is not being accessed, it should be covered with a tight-fitting lid (AAMI, 2005. Alvarado & Reicheldelfer, 2000).

Changing latex gloves every 15 minutes during periods of glutaraldehyde exposure or using double gloves provides up to a four-fold increase in permeation time compared with single latex gloves. One hundred percent nitrile rubber or 100% butyl rubber gloves are recommended for the best protection from glutaraldehyde. Neoprene and polyvinyl chloride (PVC) gloves are not recommended as these materials absorb and retain glutaraldehyde (Jordan, 1996).

Adverse reactions on patients from glutaraldehyde residuals after insufficient rinsing can cause colitis, abdominal cramps, and bloody diarrhea (Rutala & Weber, 1999; ESGE/ESGENA, 2003).

Glutaraldehyde spills small enough not to cause tearing of the eyes and/or respiratory discomfort can be cleaned up with a mop, sponge or towel. Discard the saturated item in a tightly sealed biohazard bag. Rinse surfaces thoroughly with water. Large spills require neutralization (Dow, 2003) with sodium bisulfite or 2% dibasic ammonium phosphate (Metrex Research Corporation [MRC], 2001a, b, c & d). Have one of these chemicals available wherever glutaraldehyde is used. Be familiar with the MSDS recommendations for spill or leak procedures and consult with the institution's Safety Officer to prepare a plan for handling spills.

Special precautions:

Provide adequate ventilation in areas where glutaraldehyde is in use. Ventilation systems should be installed by certified heating, ventilation and air conditioning (HVAC) professionals in order to ensure that the system designed for removal of glutaraldehyde does not interfere with other HVAC systems in the facility (Burkhart, 1991). Adequate ventilation, as described by AAMI (1996) and Burkhart (1991), includes the following conditions:

1. Room large enough to ensure adequate dilution of vapors.
2. Ten air exchanges per hour to allow volume flow rate of air moving through the room to be at least 1.0 to 2.0 cubic feet per minute per square foot of floor area (NIOSH, 2003; Burton, 1994).
3. Exhaust located at the source of the discharge of vapors (pulling vapors away from the user's breathing zone). This can be done by placing the exhaust fan at foot level or on a countertop and venting the vapors to the outside.
4. Fresh air return entering at ceiling level across the room from the exhaust vents.
5. Routine maintenance and surveillance of the system to ensure continued proper functioning.
6. Elimination of cross-draft effects.
7. Care should be taken to ensure that the discharge of the vapors is sufficiently removed from windows, outside air intakes or other such openings to prevent reentry of the discharged air. Air must not be recirculated.

In areas where local exhaust ventilation systems are not in place, use ductless fume ventilation devices that contain filters to absorb glutaraldehyde vapors from the air. These hoods should achieve a face velocity of at least 100 feet per minute with the airflow directed toward the back of the hood, away from the user's breathing zone (Burkhart, 1991).

In 1998, the American Conference of Governmental Industrial Hygienists (ACGIH) lowered its recommended TLV-C from 0.2ppm to 0.05ppm (Dow Chemical Company, 2004). Monitor glutaraldehyde vapors if there is reason to believe the TLV-C exceeds the recommendation, if an employee exhibits symptoms of overexposure, or following any corrective action taken to lower vapor levels. Devices are available for area monitoring and for monitoring of an employee's breathing zone. Follow manufacturer's directions to ensure that the device is used in a manner that will achieve the most accurate analysis. Monitor at the peak time of exposure, such as when fresh solutions are being mixed and transferred to containers (AAMI, 2005).

B. 0.55% Ortho-phthalaldehyde

Characteristics:

Ortho-phthalaldehyde 0.55% (OPA) was introduced to market as CIDEX® OPA SOLUTION in 1999. It is cleared by the FDA as a high-level disinfectant at an immersion time of 12 minutes at 20°C and 5 minutes at 25°C (Advanced Sterilization Products, 2005). Cidex OPA has demonstrated excellent microbicidal activity and has shown superior mycobactericidal activity compared with glutaraldehyde (Rutala & Weber, 2001). A hospital-based study of ortho-phthalaldehyde found it to be effective in eradicating vegetative bacteria, fungi and parasites from bronchoscopes, gastroscopes and colonoscopes (Alfa & Sitter, 1994). Two studies have assessed its tuberculocidal properties. One found it to be more rapidly tuberculocidal than glutaraldehyde in the laboratory setting (Gregory, Schalke, Smart & Robison, 1999). The other suggests that OPA is effective against glutaraldehyde resistant mycobacteria (Walsh, Maillard & Russel, 1999).

Advantages:

CIDEX® OPA is a reusable product with a maximum reuse life of 14 days. CIDEX® OPA is a clear blue solution with little odor. No mixing or activation is required and it is stable at a wider pH range of 3 to 9 (Rutala & Weber, 2001; ESGE/ESGENA, 2003). Like all other reusable products, its actual reuse life must be determined by testing that the solution remains at or above its minimum effective concentration of 0.3% (ASP, 2004). OPA will last longer before reaching its minimum effective concentration limit (about 82 cycles) compared with glutaraldehyde (after 40 cycles) in an automated reprocessor (Rutala & Weber, 2001). Because OPA does not polymerize, the studies show that the concentration of active ingredient does not decrease with age alone (Gregory et al. 1999). Like other high-level disinfectants, meticulous manual cleaning of medical devices must precede exposure to this product (SGNA, 2005).

Ortho-phthalaldehyde has a wide range of material compatibility. Pentax and Fujinon list it as a compatible product. Olympus lists it as compatible with all endoscopes except the OSF and OSF-2. CIDEX® OPA may be used in manual or automated reprocessing protocols. Check with manufacturers of automated reprocessors for specific compatibility statements.

Disadvantages:

OPA is a potential irritant of eyes, skin, nose and other tissues resulting in symptoms such as stinging, excessive tearing, coughing and sneezing. It is also a potential skin and respiratory sensitizer that may cause dermatitis with prolonged or repeated contact and may aggravate pre-existing bronchitis or

asthma. There is little data available on long-term exposure. Like glutaraldehyde, OPA fixes proteins and allows for biofilm formation. Exposure causes staining on linen, skin, instruments and automated reprocessors by reaction with amino radicals and thiol radicals. Three large volume rinse cycles are required following endoscope disinfection with Cidex OPA (Rutala & Weber, 2001; ESGE/ESGENA, 2003).

Cidex OPA has a significantly higher cost compared to glutaraldehyde (Hession, 2003).

Small spills may be cleaned up with a damp sponge or absorbent pad. Larger spills should be deactivated with 25 grams of glycine (free base) powder per gallon over 5 minutes. See the MSDS for specific control measures. Triple-rinse empty containers with water prior to disposal. Spent solutions of ortho-phthalaldehyde may be disposed of down the drain unless prohibited by state and local regulations.

Special precautions:

See glutaraldehyde information.

Special Note:

Cidex OPA Concentrate was cleared by the FDA in April 2005. It contains 5.75% ortho-phthalaldehyde (OPA) and is a concentrated form of its predecessor, Cidex OPA (0.55% ortho-phthalaldehyde), which was cleared by the FDA in October, 1999. This concentrate is mixed with tap water to achieve a diluted, single-use solution of 0.05% OPA, which is labeled to achieve high-level disinfection of flexible endoscopes and other types of reusable medical and dental devices in 5 min at an elevated temperature of 50°. Cidex OPA Concentrate is contraindicated for manual reprocessing and is labeled exclusively for use in the EvoTech Integrated Endoscope Disinfection System, an automated endoscope reprocessor also recently cleared by the FDA and marketed by Advanced Sterilization Products (Nelson & Muscarella, 2006; ASP, 2005).

C. 0.2% Peracetic Acid

Characteristics

0.2% Peracetic acid is part of the family of peroxygen compounds. The STERIS Corporation has marketed STERIS 20 Sterilant Concentrate™, a 35% peroxyacetic acid concentrate, for use in the STERIS SYSTEM 1 since 1987. STERIS SYSTEM 1 is FDA-cleared as a liquid chemical sterilization processor for medical devices. The processor dilutes and mixes the Steris 20 sterilant concentrate to its final concentration of 0.2% peracetic acid with a neutral pH, which is sporicidal at

50°C. The processing cycle time is approximately 30 minutes and reaches temperatures of 50° -56°C during exposure time (STERIS Corporation, 1997).

Instruments processed with 0.2% peracetic acid for “just in time” (Alfa, 2004; Rutala & Weber, 2004a) use in the operating room must be used immediately upon removal from the STERIS SYSTEM 1 in order to be considered sterile (Association of periOperative Registered Nurses [AORN], 2005).

As with all high level disinfectants, endoscopes must be meticulously pre-cleaned (SGNA, 2005). The HLD 0.2% Peracetic acid will fix dried blood to a variable but significant extent (Kampf, Bloß & Martiny, 2004).

A concentration of 0.2% peracetic acid is rapidly active against all microorganisms including bacterial spores, and is effective in the presence of organic matter. It is only available in the United States in conjunction with the automated STERIS SYSTEM 1. A chemical indicator for each cycle measures the ionic strength of buffering agents.

A biological indicator is available, but may not be suitable for routine monitoring of liquid sterilants (Rutala & Weber, 2004b). Two criticisms are that the indicator cannot be placed in the least accessible location of an endoscope, and that liquid sterilants are thought to cause spores to wash off the indicator strip (Rutala & Weber, 1999). Fuselier & Mason (1997) published a study comparing STERIS SYSTEM 1 and manual reprocessing with a 2% glutaraldehyde solution for flexible cystoscopes. They concluded that clinical outcomes were the same.

When handled properly, the 0.2% peracetic acid used in the STERIS SYSTEM 1 is self-contained, circulated around and through the endoscope via channel connectors, and discarded down the drain. The processor then rinses the instrument with large amounts of filtered water. STERIS SYSTEM 1 does not have the capability to circulate enzymatic detergent solutions.

Peracetic acid, once mixed in water to a 0.2% use solution, has been shown to be non-toxic and environmentally safe for disposal down the sewer (Rutala & Weber, 2004a; Alfa, 2004).

Advantages

Compared to glutaraldehyde, peracetic acid has similar or better biocidal efficacy. A solution of 0.2% Peracetic acid has a significantly greater efficacy at higher temperatures e.g. a 6 log reduction of spores at 50° centigrade in less than two minutes (Rutala, 1999).

With adequate ventilation, peracetic acid is claimed to be less irritating for staff and safer for the environment when the sealed container is not violated and when used according to manufacturer's instructions (Rutala & Weber, 2004; ESGE/ESGENA, 2003).

A solution of 0.2% Peracetic acid does not allow for biofilm creation and has the ability to remove glutaraldehyde hardened bioburden from biopsy channels. Furthermore, 0.2% Peracetic acid has not caused the development of resistant organisms (Alfa, 2004; ESGE/ESGENA, 2003).

Pentax and Fujinon list the STERIS SYSTEM 1 as compatible with its endoscopes.

Disadvantages

0.2% Peracetic acid can be corrosive dependent on temperature, pH, concentration and composition. It can cause cosmetic discoloration of endoscopes and damage the seals and fittings of some disinfectant processors. The oxidizing ability of 0.2% peracetic acid may expose the leaks in internal channels of scopes previously disinfected with glutaraldehyde. Peracetic acid has a significantly higher cost compared to other high level disinfectants (Fuselier & Mason, 1997; Rutala & Weber, 2004a).

Olympus does not list STERIS SYSTEM 1 as compatible with its endoscopes (OAI, 2002).

Cartons of the peracetic acid concentrate should be stored upright in a cool, dry area (< 86°F). They have a shelf life stability of six months. Care should be taken not to damage the STERIS 20 Concentrate™ sealed container. The concentrate may cause irritation of the nose, throat and lungs, and is corrosive to the eye and skin, potentially causing irreversible eye damage or severe burns. General or local exhaust ventilation systems are adequate. In the event of a spill or leak of the concentrate, increase ventilation and shut off ignition sources. Wearing protective equipment, flush spilled material with large quantities of water (at least 20 times the volume spilled). Consult the STERIS 20 Concentrate™ MSDS for information to assist in cleaning up a spill. Once diluted to 0.2%, peracetic acid is not considered a hazardous waste and can be safely discarded down the drain (STERIS Corporation, 2001).

D. 7.5% Hydrogen Peroxide

Although the FDA has approved products containing 7.5% Hydrogen Peroxide as a high-level disinfectant/sterilant, it has not been found to be compatible with flexible gastrointestinal endoscopes manufactured by Olympus, Pentax or Fujinon.

E. 0.08% Peracetic Acid/1% Hydrogen Peroxide

Although the FDA has approved products containing 0.08% Peracetic Acid/1% Hydrogen Peroxide as a high-level disinfectant/sterilant, it has not been found to be compatible with flexible gastrointestinal endoscopes manufactured by Olympus, Pentax or Fujinon.

Summary

Products containing glutaraldehyde, 0.55% ortho-phthalaldehyde, 0.2% peracetic acid, 7.5% hydrogen peroxide, and 0.08% peracetic acid/1% hydrogen peroxide, are cleared by the FDA as high-level disinfectants/sterilants. Only glutaraldehyde, 0.55% ortho-phthalaldehyde and 0.2% peracetic acid, and are compatible with flexible gastrointestinal endoscopes. Each product has advantages, disadvantages and special precautions.

SGNA reminds practitioners that all high level disinfectants and sterilants require adherence to published reprocessing protocols in order to maintain the integrity of equipment while providing the public with endoscopic instruments that are safe and effective. All chemicals must be handled with respect. Selection of a product must be weighed against the needs of a particular setting, taking into consideration factors such as compatibility, toxicity, environmental controls and cost.

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Appendix A: HLD Compatibility with Endoscopes

(Data provided by Olympus, Pentax and Fujinon manufacturers)

	Olympus	Pentax	<i><u>Fujinon</u></i>
Glutaraldehyde	C	C	C
0.55% Ortho-pthalaldehyde	C	C	C
0.2% Peracetic Acid	NC	C	C
<u>7.5% Hydrogen peroxide</u>	NC	NC	NC
0.08% peracetic acid/1% hydrogen peroxide	NC	NC	NC

C = company lists as compatible

NC = company does not list as compatible

Appendix B: FDA-Cleared Sterilants and High Level Disinfectants

The United States Food and Drug Administration's (FDA) most recent list of Sterilants and High Level Disinfectants cleared in a 510(k) with General Claims for Processing Reusable Medical and Dental Devices can be accessed at <http://www.fda.gov/cdrh/ode/germlab.html> or by calling FDA's Division of Dental, Infection Control and General Hospital Devices, at (301) 443-8879.

Appendix C: List of several different liquid chemical sterilants/disinfectants for reprocessing flexible (GI) endoscopes in the United States

Trade Name	Formulation	Use concentration	High-level disinfection claim	Sporicidal claim	MEC	Maximum days of reuse	Activation required?	Manufacturer/distributor
Cidex, Metricide	Glutaraldehyde	2.4%, 2.6%	45 mins @ 25° C	10 hours @ 25° C	1.5%	14	Yes	ASP/J&J, Metrex Corp
Cidex 7, Metricide 28	Glutaraldehyde	2.5%	90 mins @ 25° C	10 hours @ 20-25° C	1.8%	28	Yes	ASP/J&J, Metrex Corp
Cidex Plus	Glutaraldehyde	3.4%	20 mins @ 25° C	10 hours @ 20-25° C	2.1%	28	Yes	ASP/J&J
Rapicide	Glutaraldehyde	2.5%	5 mins @ 35° C *	7 hrs 40mins @ 35° C	1.5%	28	No (acidic)	MediVators
Steris 20	peracetic acid	0.2%	12 mins @ 50-56° C *	12 mins @ 50-56° C	NA	single-use	No	Steris Corp
Sporox, Sporox II	hydrogen peroxide	7.5%	30 mins @ 20° C	6 hours @ 20° C	6.0%	21	No	Sultan Medical, Inc.
Cidex OPA (dual label claim)	<i>ortho</i> -phthalaldehyde	0.55%	(1) 12 mins @ 20° C	No claim; NA	0.3%	14	No	ASP/J&J
	<i>ortho</i> -phthalaldehyde	0.55%	(2) 5 mins @ 25° C *	No claim; NA	0.3%	14	No	ASP/J&J
Cidex OPA Concentrate	<i>ortho</i> -phthalaldehyde	0.05% (use)	5 mins @ 50° C	No claim; NA	NA	single-use	No	ASP/J&J
Acecide	peracetic acid (PA), hydrogen peroxide	7.0% 8.3%	5 mins @ 25° C	5 hours @ 25° C	1900 ppm of PA	5	No (mix 2 chemicals)	Minntech
Aldehol III	glutaraldehyde, isopropyl alcohol	3.4% 26%	10 mins @ 20° C	10 hours @ 20° C	2.1%	14	Yes	Healthpoint, LTD
Sterilox	hypochlorous acid	650 ppm AFC	10 mins @ 25° C	No claim; NA	NA	single-use	No	Sterilox Technologies

* Intended for use only in an automated endoscope reprocessor (AER)

PA: peracetic acid

NA: not applicable

MEC: minimum effective concentration

ASP: Advanced Sterilization Products (a division of Johnson and Johnson Medical)

AFC: available free chlorine

ppm: parts-per-million

20° C equals "room temperature"

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