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

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] Standards of Practice Committee et al., 2008). As of March 2009, the U.S. Food and Drug Administration has cleared thirty products as sterilants and high-level disinfectants with general claims for reprocessing reusable medical and dental devices (United States Food & Drug Administration [FDA], 2009). Although several chemicals are cleared by the FDA as both sterilants and high level disinfectants, this document will focus on the high level disinfectant chemicals. All personnel using chemicals should be educated about biologic and chemical hazards present while performing procedures that use disinfectants (Petersen et al., 2011).

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.

A detailed cleaning protocol for endoscopes is found in the Society of Gastroenterology Nurses and Associates, Inc. (SGNA) *Standards of Infection Control and Reprocessing of Flexible Gastrointestinal Endoscopes* (2012). Refer to endoscope manufacturers' guidelines for design features unique to a particular instrument and chemical compatibility. Refer to the FDA for approved high level disinfectants/sterilants for use.

Definition of Terms

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

Automated endoscope reprocessor (AER) refers to machines designed for the purpose of cleaning and disinfecting endoscopes and accessories. Meticulous manual cleaning must precede the use of AERs (Petersen et al., 2011). Automated endoscope reprocessors limit exposure of personnel to the chemical disinfectants (American Society for Gastrointestinal Endoscopy Technology Committee et al., 2010; Rutala, Weber, & Healthcare Infection Control Practices Advisory Committee [HICPAC], 2008).

Biofilm refers to a matrix of different types of bacteria and extracellular material that can tightly adhere to the interior surfaces of endoscopes (Association for the Advancement of Medical Instrumentation [AAMI], 2010; Miner, Harris, Ebron, & Cao, 2007; Rutala et al., 2008).

Endoscope refers to a tubular instrument used to examine the interior of the hollow viscera. 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 (United States Food and Drug Administration, 2009; Rutala et al., 2008; Rutala & Weber, 2011).

High-level disinfectant 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 et al., 2008).

High-level disinfection (HLD) refers to the destruction of all microorganisms with the exception of high levels of bacterial spores (Rutala et al., 2008).

Material Safety Data Sheet (MSDS) refers to a descriptive sheet that accompanies a chemical or chemical mixture, and provides the identity of the material; physical hazards, such as flammability; and both 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 (AAMI, 2010; Rutala et al, 2008).

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, 2010).

Sterilant refers to a chemical germicide that has been cleared by the FDA as capable of destroying all microorganisms, including all bacterial spores (Rutala et al., 2008; Occupational Safety and Health Administration [OSHA], 2012).

Sterile refers to the state of being free from viable microorganisms (AAMI, 2010; Rutala et al., 2008).

Sterilization refers to a process resulting 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 (Rutala et al., 2008).

Threshold Limit Value (TLV) refers to airborne concentrations of substances and represents conditions under which it is believed that nearly all workers may be repeatedly exposed day after day without adverse effects, according to the American Conference of Governmental Industrial Hygienists (ACGIH) (AAMI, 2010).

Threshold limit value ceiling (TLV-C) refers to the airborne concentration of a substance that should not be exceeded during any part of the working exposure (AAMI, 2010).

Threshold limit value time-weighted average (TLV-TWA) refers to the airborne concentration for a normal 8-hour work day and a 40-hour workweek, to which nearly all workers may be exposed day after day without experiencing any adverse health effects (AAMI, 2010).

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 (Petersen et al., 2011).

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.

1. **Critical**: A device that enters normally sterile tissue or the vascular system. These devices must be sterilized.
2. **Semi-critical**: A device that comes into contact with intact mucous membranes and does not ordinarily penetrate sterile tissue. These devices must receive at least high-level disinfection.

3. **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 & Weber, 2013). 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. Considerations when using high-level disinfectants and/or sterilants include adequate ventilation, exposure limits, proper personal protective equipment (PPE), a spill containment plan or spill kit, and proper disposal after use. Endoscopes and other devices that have been exposed to high level disinfectants/sterilants must be thoroughly rinsed to ensure that patients are not exposed to the chemicals (Rutala & Weber, 2013).

C. General Characteristics

High level disinfection prevents transmission of infection when used on endoscopes and other semi-critical instruments which do not penetrate mucosal membranes (Rutala et al., 2008). When used correctly, high level disinfectants completely remove all microorganisms from endoscopes except for a small numbers of bacterial spores. Although spores are more resistant to high level disinfection than bacteria, mycobacteria, and viruses, they are more likely to be killed when endoscopes undergo thorough manual cleaning to reduce their numbers. Also, survival of small numbers of bacterial spores is acceptable because the intact membranes of the lungs and gastrointestinal tract are resistant to bacterial spores, but not to bacteria, mycobacteria and viruses (Rutala et al., 2008).

The efficacy of chemical sterilants and disinfectants depends on their concentration, their temperature, the physical nature of the endoscope (e.g., crevices, hinges, lumens, channels), the nature of the microorganisms on the endoscope, the size of the organic and microbial load on the endoscope, and the length of exposure of the scope to the chemical solution. Since the chemicals are harmful to human tissue and the environment, careful handling, thorough rinsing, and appropriate disposal are essential for human safety. The ideal chemical high-level disinfectant/sterilant should have a broad antimicrobial spectrum and a prolonged reuse and shelf life, act rapidly, be noncorrosive and not harm the scope and its parts, be non-toxic to humans and the environment, be odorless and non-staining, be cost effective, and be capable of being monitored for concentration and effectiveness (Rutala et al., 2008). Currently, none of the high-level disinfectants meet all of these criteria.

D. Biofilm

Biofilm can form on endoscopes, within water supply lines, and in automated endoscope reprocessors (AERs). Biofilm forms when bacteria group together on a wet surface and secrete large amounts of polysaccharide which create a protective mass that cannot be removed with high level disinfection (Muscarella, 2010). Prompt, meticulous manual cleaning to remove biologic material and strict adherence to reprocessing guidelines is the best approach to preventing biofilms (Alfa & Howie, 2009; Fang et al., 2010; Ren et al., 2013).

E. 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* (VRE), and Methicillin-

resistant *Staphylococcus aureus* (MRSA) are susceptible to high level disinfectants and sterilants (Rutala et al., 2008; ASGE Standards of Practice Committee et al., 2008). Strict adherence to the established high level disinfection process for endoscopes effectively prevents transmission of infection (Muscarella, 2010) and is critical for protecting patients from healthcare associated infections. Outbreaks of infection have been traced to lack of adherence to reprocessing guidelines, endoscopes which are damaged or difficult to clean, and AER design problems or failures such as breakdowns in AER water filtration systems (Rutala et al., 2008).

Concern has been raised over possible endoscopic transmission of prions and other transmissible spongiform encephalopathies (TSE), including Creutzfeldt-Jakob disease (CJD), and variant Creutzfeldt-Jakob (v-CJD). These agents are resistant to conventional disinfectants and sterilants. In order for an endoscope or medical/surgical device to act as a vehicle of prion transmission, it must come in contact with infective tissue (Rutala & Weber, 2013). Transmissible spongiform encephalopathies and CJD are confined to the central nervous system and are transmitted by exposure to infectious brain, pituitary, or eye tissue. Since endoscopes do not come in contact with brain, pituitary, or eye tissue, transmission is highly unlikely (ASGE Standards of Practice Committee et al., 2008; Nelson & Muscarella, 2006; Rutala & Weber, 2013). Dedicated instruments are not necessary and standard reprocessing using HLD is acceptable (ASGE Standards of Practice Committee et al., 2008; Gastroenterological Nurses College of Australia & Gastroenterological Society of Australia, 2010; Nelson & Muscarella, 2006).

However variant CJD is a rare, but fatal condition caused by the consumption of beef contaminated with a bovine spongiform. It differs from CJD in that the mutated protein can be found in lymphoid tissue throughout the body including the gut and tonsils (Nelson & Muscarella, 2006; Rey et al., 2011). Only three cases of v-CJD have been reported in the United States, and all three contracted the disease elsewhere, two in Great Britain and one in Saudi Arabia (Centers for Disease Control and Prevention [CDC], 2013). Since v-CJD is resistant to conventional disinfectants and sterilants, endoscopy should be avoided in known or suspected cases (Rey et al., 2011). The likelihood of patient having v-CJD and transmission by endoscopy is negligible (Nelson & Muscarella, 2006).

F. <u>Determining Minimum Effective Concentration (MEC)</u>

The high level disinfectants / sterilants containing glutaraldehyde, hydrogen peroxide, peracetic acid/hydrogen peroxide and ortho-phthalaldehyde are reusable products (United States Food and Drug Administration, 2009), and must be monitored to ensure they maintain their effectiveness.

The following factors result in a gradual reduction of the effectiveness of reusable high-level disinfectants/sterilants (Rutala et al., 2008; ASGE Standards of Practice Committee et al., 2008; AAMI, 2010):

1. Decreased concentration because of challenging loads of microbes and organic matter
2. Dilution by rinse water from endoscopes or items not sufficiently dried
3. Aging of the chemical solution

Each solution's minimum effective concentration (MEC) and reuse life are established by the manufacturer. The appropriate number of reuses of each of these products must be determined by testing the solution to ensure that it is at or above its MEC, using product-specific test strips. Minimum effective concentration should be monitored according to the disinfectant/sterilant manufacturer's instructions *(*AAMI, 2010*)* and a log of test results should be maintained (Rutala et al., 2008).

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 (Petersen et al., 2011).

Since chemical test strips deteriorate with time, the bottle should have the manufacturer expiration date, be dated when opened, and be used within period of time specified by manufacturer. The user should follow manufacturer's recommendations regarding the use of quality control procedures to ensure the strips perform properly (Rutala et al., 2008).

G. Personal Protective Equipment (PPE)

Personal protective equipment should be used when reprocessing endoscopes, as exposure to high-level disinfectants, sterilants and/or body fluids may occur. Gowns, gloves, protective eyewear and/or face protection are recommended when handling any high-level disinfectant/sterilant (National Institute of Occupational Safety and Health [NIOSH], 2001; Petersen et al., 2011).

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 impervious to the chemical, inspected for tears or holes before use, and appropriate for the task (i.e., chemical handling vs. general use). Do not use an imperfect glove or reuse disposable gloves (OSHA, 2006). The permeability of gloves varies considerably, depending on manufacturer; therefore the recommendations of the glove manufacturer and the high level disinfectant manufacturer should be consulted (AAMI, 2010). 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.

3. Eye and/or face protection is necessary. Eye glasses or 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. Emergency eyewash stations must be accessible within a 10 second travel time (OSHA, 2006). 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 (AAMI, 2010; Rutala et al., 2008). Consult manufacturers of endoscopes and reprocessors for results of compatibility studies when choosing the appropriate disinfectant/sterilant product. Incompatibility may result in changes in appearance and function of an endoscope/AER.

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. Manual Cleaning

Meticulous manual cleaning of all instruments must precede exposure to any high-level disinfectant or sterilant (Petersen et al., 2011; SGNA, 2012). Inadequate cleaning of instruments has been reported as one factor responsible for transmission of infection by flexible endoscopes (ASGE Standards of Practice Committee et al., 2008; Rutala et al., 2008). This process significantly reduces the organic and microbial challenge to the high-level disinfectant or sterilant and is a vital step in preventing biofilm (Alfa & Howie, 2009). A detailed cleaning protocol for endoscopes is found in SGNA's *Standards of Infection Control and Reprocessing of Flexible Gastrointestinal Endoscopes* (2012).

J. Final Rinse/Alcohol Purge/Drying/Storage

All high-level disinfectants or sterilants used to reprocess flexible endoscopes can injure mucous membranes if not thoroughly rinsed from the endoscope (Rutala et al., 2008). After high-level disinfection, the endoscope must be thoroughly rinsed and the channels flushed with sterile, filtered, or tap water to remove the disinfectant/sterilant (Petersen et al., 2011).

Irrespective of the quality of the water used to rinse flexible endoscopes during manual or automated reprocessing (e.g., tap, filtered or sterile water) each internal channel must be flushed with 70% alcohol, and dried with forced air before it can be used on another patient or stored (Rutala et al., 2008; Muscarella, 2001). The alcohol flush facilitates the drying process (ASGE Standards of Practice Committee et al., 2008; Petersen et al., 2011) which greatly reduces the possibility of recontamination of the endoscope by waterborne microorganisms (Nelson & Muscarella, 2006; Petersen et al., 2011). All water types, including sterile water, have been linked to bacterial contamination and therefore all endoscopes must undergo the final drying step (Alvarado & Reicheldelfer, 2000; Nelson & Muscarella, 2006).

Note that drying the endoscope after every reprocessing cycle, both between patient procedures and before storage is a requisite practice crucial to the prevention of bacterial transmission, bacterial growth, and nosocomial infection. Drying is as important to the prevention of disease transmission and nosocomial infection as cleaning and high level disinfection (Muscarella, 2006).

Endoscopes should be stored in a manner that will protect them from contamination. Hang the endoscope in a vertical position to facilitate drying (with caps, valves, and other detachable components removed per manufacturer's instructions). A storage area should be clean, well ventilated and dust free thus discouraging any microbial contamination (SGNA, 2012). The interval of storage after which endoscopes should be reprocessed before use has had limited investigations and warrants further data and research (Petersen et al., 2011).

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

Please refer to the FDA for a complete list of cleared sterilants and high level disinfectants. Some HLD products may have multiple label claims and/or may be FDA cleared for use in a legally marketed AER machines which can maintain higher temperature usage parameters and some are not cleared for manual processing. Disinfectants are not interchangeable. Therefore, manufacturers' instructions must be followed for use (e.g., AER vs. manual), temperature and disinfection time.

Before using a high level disinfectant, check with the endoscope manufacturer to determine whether the high level disinfectant is compatible with their product. See section I. H. above.

A. Glutaraldehyde

1. Characteristics

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 sulfydryl, hydroxyl, carboxyl and amino groups, which alters RNA, DNA and protein synthesis within microorganisms (Rutala et al., 2008).

Glutaraldehyde products are marketed under a variety of brand names and are available in a variety of concentrations, with and without surfactants. Glutaraldehyde requires MEC testing. Refer to manufacturer's instructions for maximum reuse life and appropriate MEC test strip.

2. Soak time exception

The Society of Gastroenterology Nurses and Associates, Inc., 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 on Reprocessing Flexible Gastrointestinal Endoscopes* (American Society for Gastrointestinal Endoscopy Quality Assurance in Endoscopy Committee et al., 2011). 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 greater than 2% glutaraldehyde solution which tests above its minimum effective concentration (Petersen et al., 2011; AAMI, 2010; United States Food and Drug Administration 2009). These conditions may not be extended to other glutaraldehyde solutions. This recommendation differs from the label claims on a greater than 2% glutaraldehyde stating a 20-90 minute exposure at 25°C for HLD because the current federal labeling regulation assumes no cleaning of the medical device prior to chemical exposure.

3. Advantages and disadvantages

Glutaraldehyde has numerous advantages and disadvantages which are summarized in the table below. Except where indicated, all of the information in the table was obtained from Rutala et al. (2008), Rutala & Weber (2011), and Rutala & Weber (2013).

Advantages	Disadvantages
• Over 30 years of use in healthcare settings • Excellent biocidal activity • Effectiveness is supported by numerous studies • Relatively inexpensive • Does not degrade endoscopes • Non corrosive to metals, rubbers and plastics • Not classified as a human carcinogen (AAMI, 2010) • Can be used for manual or AER systems • Some products achieve high-level disinfection with a shorter exposure time but require a higher temperature (e.g. Rapicide ™) (United States Food and Drug Administration, 2009)	• Healthcare personnel exposure (short or long-term) may cause skin irritation or dermatitis, mucous membrane irritation (eye, nose, mouth), or pulmonary symptoms (epistaxis, asthma, rhinitis) • Patient exposure may cause nausea, vomiting abdominal cramps, diarrhea, and colitis if the endoscope is not thoroughly rinsed • Pungent & irritating odor • Relatively slow mycobacterial activity • Fixes proteins which allows for biofilm formation • May not be compatible with all AERs • May require neutralization prior to disposal (OSHA, 2006)

4. Managing glutaraldehyde disadvantages

Glutaraldehyde is an irritant and therefore poses a risk to both patients (if scopes have not been thoroughly rinsed) and to the staff who are responsible for endoscope reprocessing (NIOSH, 2001; OSHA, 2006). Symptoms of irritation include itching of the skin with slight redness, (which may progress to greater redness and swelling or yellowing of the skin with prolonged exposure), irritation of the 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 (AAMI, 2010; OSHA, 2006). 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. Whenever the glutaraldehyde solution is not being accessed, it should be covered with a tight-fitting lid (AAMI, 2010; Alvarado & Reicheldelfer, 2000; OSHA, 2006). PPE and appropriate ventilation, monitoring for exposure and product knowledge related to spills and disposal are essential for protecting healthcare personnel, and are described below.

Personal protective equipment (PPE). Staff members must wear personal protective equipment to protect themselves from glutaraldehyde. Latex gloves are not recommended for use with glutaraldehyde (OSHA, 2006; Rutala et al., 2008). Either 100% nitrile rubber or 100% butyl rubber gloves provide the best protection from glutaraldehyde. Neoprene and polyvinyl chloride (PVC) gloves are not recommended as these materials absorb and retain glutaraldehyde (OSHA, 2006). Skin that comes in contact with glutaraldehyde should be washed for at least 15-20 minutes. Refer to section G for specific PPE recommendations.

Ventilation guidelines. 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. Adequate ventilation, as described by AAMI (2010) and OSHA (2006), includes the following conditions:

a. Room large enough to ensure adequate dilution of vapors.
b. Ten air exchanges per hour to allow the 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, 2001; OSHA, 2006).
c. 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 on a countertop and venting the vapors to the outside.
d. Fresh air return entering at ceiling level across the room from the exhaust vents.
e. Routine maintenance and surveillance of the system to ensure continued proper functioning.
f. Elimination of cross-draft effects.
g. 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.
h. In areas where local exhaust ventilation systems are not in place or inadequate, use self-contained, freestanding systems (e.g. a ductless fume ventilation devices that contain filters to absorb glutaraldehyde vapors from the air). These systems should achieve a face

velocity of at least 80-120 feet per minute with the airflow directed away from the user's breathing zone (OSHA, 2006).

Recommended exposure limits. The American Conference of Governmental Industrial Hygienists (ACGIH) lowered its recommended TLV-C to 0.05 ppm (AAMI, 2010; OSHA, 2006). Glutaraldehyde vapors must be monitored 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. Several devices are available for monitoring the work area and the employee's breathing zone. Manufacturer's directions must be followed to ensure that the device is used in a manner that will achieve the most accurate analysis. For example, the best time to measure peak exposure time is when fresh solutions are being mixed and transferred to containers (AAMI, 2010; Rutala et al., 2008).

Product safety- spill plan and disposal. All spills must be cleaned up immediately to control the amount of vapor and prevent contact with skin and eyes. The glutaraldehyde concentration, the volume of spill, the temperature of the room, the temperature of the solution, and the type of ventilation in the area of the spill will affect whether it can be cleaned up safely without the use of inactivating chemicals and respiratory equipment (e.g., breathing apparatus or respirator). Even a small spill can change the ceiling threshold limit thus increasing exposure above the limit(AAMI, 2010; OSHA, 2008) Refer to manufacturer's specific recommendations and supporting technical data to determine the chemicals needed to clean up the specific glutaraldehyde preparation at your institution and if neutralization is required. The necessary chemicals used for cleanup must be readily available wherever glutaraldehyde is used. Personnel should 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 (AAMI, 2010).

Disposal of Glutaraldehyde must be in accordance with local, state and Federal regulations (OSHA, 2006; Rutala et al., 2008). Some areas prohibit disposal into sewer systems and others require neutralization (OSHA, 2006). Empty containers from freshly activated solutions should be thoroughly rinsed with water prior to disposal. Refer to the MSDS for specific product disposal guidelines.

B. Ortho-phthalaldehyde (OPA)

1. Characteristics

Ortho-phthalaldehyde 0.55% (OPA) is a high-level disinfectant with an immersion time of 12 minutes at 20°C and 5 minutes at 25°C. OPA is a reusable product with a maximum reuse life of 14 days. It is a clear blue color and requires MEC testing (AAMI, 2010; Rutala et al., 2008). Instructions on the container provide information about the specific test strips to be used for that specific product.

Cidex OPA concentrate contains 5.75% ortho-phthaldehyde (OPA) and is a concentrated form of its predecessor, Cidex OPA (0.55% ortho-phthaldehyde). 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 devices in 5 min at an elevated temperature of 50°. This solution is currently for use in the Evo Tech Integrated Endoscopic Disinfection System only (United States Food and Drug Administration, 2009).

2. Advantages and disadvantages

A summary of OPA's advantages and disadvantages are summarized in the table below. Except where indicated, all of the information in the table was obtained from Rutala et al. (2008), Rutala & Weber (2011), and Rutala & Weber (2013).

Advantages	Disadvantages
• Fast acting • Excellent microbiocidal activity and superior myobactericidal activity compared to glutaraldehyde • No activation required • Odor not significant • Excellent materials compatibility • Does not coagulate blood or fix tissues to surfaces • Does not require exposure monitoring • No carcinogen classification (AAMI, 2010) • Stable in wide range of pH (3 to 9) • In an AER, it lasts longer before reaching its MEC limit (about 82 cycles) than glutaraldehyde (about 40 cycles) • May be used in manual or automated reprocessors	• Stains skin, mucous membranes, clothing and environmental surfaces • Repeated exposure may result in hypersensitivity in some patients with bladder cancer • More expensive than glutaraldehyde • Irritates eyes and damages them when it comes in contact • Can aggravate pre-existing bronchitis or asthma conditions • Slow sporicidal activity • May not be compatible with all AERs • Potential irritant of eyes, skin, nose and other tissues • May require neutralization prior to disposal • Concentrate limited use to one specific AER, and contraindicated for manual reprocessing

3. Managing OPA disadvantages

OPA has disadvantages that require additional considerations which must be understood and controlled for the safety of the healthcare providers and patients.

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.

Personal Protective Equipment (PPE). PPE must be worn to protect the eyes skin, and nose. Polyvinylchloride and nitrile or butyl rubber gloves are suitable for routine use. Any skin contact with OPA should be washed immediately with soap and water, then rinsed for at least 15 minutes. Any eye contact should be immediately rinsed with plenty of water for at least 15 minutes and medical advice sought. Refer to Section G for specific PPE recommendations.

Ventilation guidelines. OPA requires the same ventilation guidelines as glutaraldehyde. However there are no occupational exposure limits for OPA (AAMI, 2010; Rutala et al., 2008)

OPA exposure causes staining on linen, skin, instruments and automated reprocessors due to reactions with amino radicals and thiol radicals. Refer to manufacturer's recommendations for repeated rinse cycles (e.g., 3 water rinses).

Product safety- spill plan and disposal. Small spills may be cleaned up with a damp sponge or absorbent pad. Larger spills should be deactivated with glycine (free base) powder per HDL

chemical manufacturer (AAMI, 2010; Rutala et al., 2008). Personnel should 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.

Disposal of OPA must be in accordance with local, state and Federal regulations (OSHA, 2006; Rutala et al., 2008). Some areas prohibit disposal into sewer systems and others require neutralization (OSHA, 2006). Empty containers from freshly activated solutions should be thoroughly rinsed with water prior to disposal. Refer to the MSDS for specific product disposal guidelines.

C. Peracetic Acid (PAA)

1. Characteristics

Peracetic acid is part of the family of peryoxygen compounds. The mechanism of action is not well understood. It is thought to function similarly to other oxidating agents in that it denatures proteins, disrupts the cell wall permeability, and oxidizes sulfhydryl and sulfur bonds in proteins, enzymes, and other metabolites (Rutala et al., 2008).

2. Advantages and disadvantages

A summary of its advantages and disadvantages is shown in the following table which are summarized in the table below. Except where indicated, all of the information in the table was obtained from Rutala et al. (2008), Rutala & Weber (2011), and Rutala & Weber (2013).

Advantages	Disadvantages
• Rapid sterilization cycle time (30-45 minutes) • Low-temperature (50-55^{0}C) liquid immersion sterilization • Has a significantly greater efficacy at higher temperatures(e.g. a 6 log reduction of spores at 50° centigrade in less than two minutes) • Rapidly sporicidal • Environmentally friendly byproducts (acetic acid, O_2, H_2O) and leaves no residue • No adverse health effects when used under normal operating conditions • Compatible with many materials and instruments • Does not coagulate blood or fix tissues to protein • Does not allow biofilm creation and has the ability to remove glutaraldehyde hardened bioburden from biopsy channels (Beilenhoff et al., 2008) • Has not caused resistant organisms (Beilenhoff et al., 2008)	• Potential material incompatibility (e.g. aluminum anodized coating becomes dull) • Can corrode copper, brass, bronze, plain steel and galvanized iron • Oxidizing ability may expose the leaks in internal channels of scopes previously disinfected with glutaraldehyde (Beilehoff et al., 2008) • Considered unstable, particularly when diluted • More expensive (endoscope repairs, operating costs, purchase costs) • Serious eye and skin damage (concentrated solution) with contact • Concentrates are used only in specific AER

3. Managing peracetic acid disadvantages

Peracetic acid 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. Therefore, PPE must be worn

to protect the eyes skin, and nose. Refer to section G for specific PPE recommendations. General or local exhaust ventilation systems provide adequate ventilation (Beilenhoff et al., 2008).

Product safety- spill plan and disposal. In the event of a spill, peracetic acid that has been mixed in water to make a 0.2% solution has been shown to be non-toxic and environmentally safe and should be disposed of in accordance with local, state and federal regulations (Rutala et al., 2008). Refer to the MSDS for specific product disposal guidelines.

D. Hydrogen Peroxide

1. Characteristics

Hydrogen peroxide at a concentration intended for high level disinfection works by producing destructive hydroxyl free radicals that can attack membrane lipids, DNA, and other essential cell components. The reuse life and MEC testing is product specific.

2. Advantages and disadvantages

A summary of hydrogen peroxide's advantages and disadvantages is shown in the table below. Except where indicated, all of the information in the table was obtained from Rutala et al. (2008), Rutala & Weber (2011), and Rutala & Weber (2013).

Advantages	Disadvantages
• No activation required • May enhance removal of organic matter and organisms • Active against a wide range of microorganisms • No disposal issues • No odor or irritation issues • Does not coagulate blood or fix tissues to surfaces • Inactivates *Crytosporidium*	• Material compatibility concerns (brass, zinc, copper and nickel/silver plating) both cosmetic and functional • Severely irritating and corrosive to eyes, skin and gastrointestinal tract (AAMI, 2010) if inadequately rinsed • Excessive exposure could cause irreversible tissue damage to the eyes, including blindness, inhalation of hydrogen peroxide vapors can be severely irritating to the nose, throat, and lungs (AAMI, 2010)

3. Managing hydrogen peroxide disadvantages

Hydrogen Peroxide is severely irritating and corrosive to eyes, skin, and GI tract. Therefore the following are ways to manage such issues:

PPE. Must be worn to protect the eyes skin, and nose. Refer to Section G for specific PPE recommendations. Cup-type chemical goggles, a full face shield, or both should be worn. Eyes should be flushed with large amounts of water for at least 15 minutes. Liquid-proof rubber or neoprene gloves should be worn (AAMI, 2010).

Ventilation guidelines. Hydrogen peroxide solutions should be used in a well-ventilated area (AAMI, 2010). Follow ventilations guidelines as described in glutaraldehyde section.

Exposure limits. The ACGIH recommended TLV for hydrogen peroxide is 1 ppm as an 8-hour TWA (AAMI, 2010).

Product safety- spill plan and disposal. In the event of a spill hydrogen peroxide has been shown to be non-toxic and environmentally safe. It should be contained immediately. Prior to

disposal, it should be diluted with large amounts of water. It should be disposed of in accordance with manufacturer's instructions and with local, state and federal regulations (Rutala et al., 2008; AAMI 2010). Refer to the MSDS for specific product disposal guidelines.

E. Peracetic Acid/Hydrogen Peroxide

Although the FDA has approved products containing a combination of peracetic acid and hydrogen peroxide as high-level disinfectants/sterilants, they have not been found to be compatible with the flexible gastrointestinal endoscopes manufactured by Olympus, Pentax, Fujinon or EndoChoice.

III. Summary

There are many high level disinfectants/sterilants cleared and approved by the FDA. This guideline has reviewed the most common products used and their compatibility with flexible gastrointestinal endoscopes.

The Society of Gastroenterology Nurses and Associates, Inc. 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 care. Personnel should receive education on the chemicals they use (Petersen et al., 2011). 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. As newer disinfectants become available, selection should be guided by FDA clearance of these products and by information in the scientific literature (Rutala, et al., 2008). Always cross reference manufacturer's instructions of endoscopes, AER's and high level disfectants/sterilants for compatibility, safety issues, and uses. The high level disinfectant/sterilant selected must be appropriate for the endoscopes being reprocessed and the reprocessing method used (e.g., manual or AER).

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