Guideline for Use of High-Level Disinfectants & Sterilants in the Gastroenterology Setting

Acknowledgements

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SGNA Practice Committee 2016 – 17
Midolie Loyola, MSN RN CGRN, Chair
Susan Bocian, MSN BSN RN Co-Chair
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Lea Anne Myers, MSN RN CGRN
Candice M. Quillin, BSN RN CGRN
Susan Selking, BSN RN CGRN
Contributor: Ann Herrin, BSN RN CGRN

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Department of Membership Services
Society of Gastroenterology Nurses and Associates, Inc.
330 North Wabash
Chicago, IL 60611-4267
Tel: (800) 245-SGNA or (312) 321-5165
Fax: (312) 673-6694
Online: www.SGNA.org
Email: SGNA@smithbucklin.com

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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). This guideline provides general information about the principles, product safety, and characteristics of high level disinfectants/sterilants. It is beyond the scope of this document to review each individual product. The United States Food and Drug Administration (FDA) has cleared many products as sterilants and high-level disinfectants with general claims for reprocessing reusable medical and dental devices (FDA, 2015). All personnel using chemicals should be educated about biologic and chemical hazards present while performing procedures that use disinfectants (Petersen et al., 2011).

A detailed protocol of the essential steps for reprocessing endoscopes is found in SGNA's *Standards of Infection Prevention and Reprocessing of Flexible Gastrointestinal Endoscopes* (2016).

Refer to the 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). AERs 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 (Roberts, 2013).

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.

Ethylene oxide (EtO) gas sterilization refers to a method of sterilization for moisture-sensitive medical equipment. It consists of five stages: pre-condition and humidification, gas introduction, exposure, evacuation, and air washes (Rutala et al., 2008).

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 at al., 2013).

High-level disinfection (HLD) refers to the destruction of all microorganisms with the exception of high levels of bacterial spores (Rutala et al., 2013).

Liquid chemical sterilization refers to a method of sterilization that uses a liquid chemical germicide and then rinsed in water to remove the chemical residue (FDA, 2014).

Low-level disinfection refers to a process that can kill most vegetative bacteria, some viruses, and some fungi. Note that it cannot be relied on to kill resistant organisms such as tubercle bacilli or bacterial spores (Rutala et al., 2013).

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, 2015; FDA, 2015; 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).

Safety Data Sheet (SDS) refers to a descriptive sheet that accompanies a chemical or chemical mixture, which 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.

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; FDA, 2014).

Sterile refers to the state of being free from viable microorganisms (AAMI, 2015; Rutala et al., 2008).

Sterilization refers to a process resulting in the complete elimination or destruction of all forms of microbial life including bacterial spores. 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., 2013).

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).

I. General Principles

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; Rutala et al., 2013).

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. Examples include endoscopic cutting and biopsy devices.
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. Examples include gastrointestinal endoscopes.
3. **Noncritical**: Devices that do not ordinarily touch the patient or touch only intact skin. These devices may be cleaned by low-level disinfection. Examples include blood pressure cuffs, EKG cables, and stethoscopes.

B. Levels of Disinfection

Sterilization cannot be achieved without meticulous cleaning and HLD prior to EtO or liquid sterilization.

Three levels of disinfection include:

1. **Sterilization**: Gastrointestinal endoscopes are heat-sensitive and can be sterilized using the following methods:
   a. EtO gas is a complex process with an average turn-around time of greater than 12 hours, a potential hazard to staff and patients, and a costly alternative to HLD (SGNA, 2015b).
   b. Liquid chemical sterilization produces sterility only if proper cleaning, which eliminates organic and inorganic material, precedes sterilization. Other factors that need to be met are the proper concentration, contact time, temperature, and pH (FDA, 2014; Humphrey & McDonnell, 2015).

   There are limitations with liquid chemical sterilization and gastrointestinal endoscopes. Endoscopes cannot be wrapped during processing so it is impossible to maintain sterility after processing, during the water and alcohol rinse, and during storage (Rutala & Weber, 2016b).

   The FDA (2014) recommends that only critical devices that are heat-sensitive and incompatible with steam, gas, vapor, or plasma low-temperature processes use a liquid chemical sterilization.

2. **High-Level Disinfection**: Minimally required for semi-critical devices. Cleaning followed by HLD should eliminate enough pathogens to prevent transmission of infection (Rutala & Weber, 2016b).
3. **Low-level disinfection**: Uses an EPA-registered hospital disinfectant with no tuberculocidal claims (Rutala & Weber, 2016a). The device and disinfectant must be compatible; refer to manufacturer IFU for specific contact time.

Staff must be familiar with and have readily accessible the product/brand-specific SDS for all chemicals used and stay current with developments in products, protective equipment, and practice.

C. General Characteristics

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 the following qualities: a broad antimicrobial spectrum; prolonged reuse and shelf life; rapid-acting, noncorrosive, and not harmful to the scope and its parts; non-toxic to humans and the environment; odorless and non-staining; cost effective; and capable of being monitored for concentration and effectiveness (Rutala & Weber, 2016a).

High-level disinfection prevents transmission of infection when used on endoscopes and other semi-critical instruments which do not penetrate mucosal membranes (Rutala & Weber, 2016a). 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 & Weber, 2016a).

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). Therefore, 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).

Meticulous manual cleaning of all instruments must precede exposure to any high-level disinfectant or sterilant (Petersen et al., 2011; SGNA, 2015a). 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).

Simethicone, often used during endoscopy procedures, may foster microbial growth and biofilm development despite proper reprocessing because it contains sugars and thickeners. Minimize use of simethicone pending further studies (Ofstead et al., 2016).

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). 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). Reports of carbapenem resistant (CRE) transmission have led to challenges in achieving effective HLD, requiring added reprocessing steps in all phases. The complex design of duodenoscopes has prompted manufacturers to implement changes in reprocessing (FDA, 2015).

Prions and other transmissible spongiform encephalopathies (TSE), including Creutzfeldt-Jakob disease (CJD) and variant Creutzfeldt-Jakob disease (v-CJD) 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).

TSEs 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).

v-CJD may be present in lymph, gut, and tonsils. Although the likelihood of patient having v-CJD and transmission by endoscopy is negligible, endoscopy should be avoided in known or suspected cases (Nelson & Muscarella, 2006; Rey et al., 2011).

F. Compatibility

Refer to the FDA for a complete list of cleared sterilants and high-level disinfectants.

Disinfectants are not interchangeable between AERs. Therefore, manufacturers' instructions must be followed for use (e.g., AER vs. manual), temperature, and disinfection time. Incompatibility may result in changes in appearance, integrity, and performance of endoscopes, accessories, and AERs.

Before using a high-level disinfectant and sterilant, refer to the manufacturer instructions for use (IFU) to determine compatibility with the endoscope and reusable accessories (e.g., wire guided dilators, buttons, and guidewires). Compatibility among high-level disinfectants and sterilants must be reviewed and established in order to ensure effective HLD. Resolve any inconsistencies between endoscope and AER manufacturer's instructions (Rutala & Weber, 2004; FDA, 2009).

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.

II. Safety Considerations

All high-level disinfectants and sterilants may have adverse health effects (Rutala & Weber, 2013). It is imperative that health care workers who use any high-level disinfectant and/or sterilant follow Occupational Safety and Health Administration (OSHA) guidelines. There should be evidence of education, training, and documented competency.

A. 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 or sterilant (National Institute of Occupational Safety and Health [NIOSH], 2001; Petersen et al., 2011). Refer to HLD/sterilant SDS and manufacturer's instructions for specific details of PPE.

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. Gloves should be long enough to extend up the arm to protect the forearm or clothing from splashes

or seepage. To avoid cross-contamination, follow hand hygiene principles. 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 that allows for ventilation is recommended. Do not use high filtration masks because they may actually trap vapors. Emergency eyewash stations must be accessible within a 10-second travel time (OSHA, 2006). Refer to SDS for recommendations on duration of eye flush, and seek immediate medical attention. The eyewash station must be activated weekly to ensure proper use during a potential chemical exposure. Refer to the eye wash manufacturer for proper maintenance of the device.

B. Ventilation guidelines

High-level disinfectants/sterilants require special ventilation to limit employee exposure. 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 includes but is not limited to the following conditions:

1. There should be negative air pressure in the reprocessing room and a minimum of 10 exchanges per hour, with at least two being fresh, outside air (American Institute of Architects Academy of Architecture for Health [AIA], 2001; FGI, 2014; Joint Commission, 2014).
2. Exhaust should be vented directly outside. Air must not be recirculated.
3. Routine maintenance and surveillance of the system are necessary to ensure continued proper functioning.

C. Recommended exposure limits

The American Conference of Governmental Industrial Hygienists (ACGIH) has recommended exposure limits for high level disinfectants and sterilants (OSHA, 2006). 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. Manufacturers' directions must be followed to ensure that the monitoring 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 handled (AAMI, 2010; Rutala et al., 2008).

D. Determining Minimum Effective Concentration (MEC)

The high-level disinfectants/sterilants 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):

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. Monitor minimum effective concentration according to the disinfectant/sterilant manufacturer's instructions, and maintain a log of test results. Reusable high-level disinfectant/sterilants must be disposed and replaced whenever the MEC fails or the reuse life expires, whichever comes first. Chemical HLD/sterilants that are single use and prepared onsite also need to be tested. It is important to use the product-specific test strip or chemical monitoring device (AAMI, 2015).

Because chemical test strips deteriorate with time, the bottle should be labeled with the manufacturer's expiration date and date when opened, and the strips should be used (or discarded) within the period of time specified by manufacturer. Follow the manufacturer's recommendations regarding the use of quality control procedures to ensure the strips perform properly (Rutala et al., 2008). Document quality control results.

If additional chemical solution is added to an 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).

E. Rinsing

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). The amount of rinsing required is dependent on the specific chemical used.

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). Thoroughly rinse and flush the channels with sterile, filtered, or tap water to remove the disinfectant/sterilant (Petersen et al., 2011).

F. Disposal

Disposal of HLD/sterilant must be in accordance with local, state, and Federal regulations (OSHA, 2006; Rutala et al., 2008). Some regulations 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 SDS for specific product disposal guidelines.

G. Spill Plan

All spills must be managed immediately to control the amount of vapor and prevent contact with skin and eyes. The 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 may 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 may change the ceiling threshold limit, thus increasing exposure (OSHA, 2006). Refer to manufacturer's specific recommendations and supporting technical data to determine the chemicals needed to clean up the specific HLD/sterilant and if neutralization is required. The necessary chemicals must be readily available to manage the spill. A plan for handling spills, which has been developed in collaboration with the institution's Safety Officer, should be in place .

Personnel must be familiar with the SDS recommendations for spill or leak procedures.

III. Summary

This guideline has reviewed the general principles and safety considerations common to the use of all high level disinfectants/sterilants. It is beyond the scope of this document to outline the specific chemicals and their use. It is essential to review the most up to date IFUs on an ongoing basis to ensure safe and effective high level disinfection or sterilization.

SGNA supports further research and evidence-based practice in the area of high level disinfection and sterilization in the gastroenterology setting.

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