

**Standards of Infection Prevention
in
Reprocessing Flexible Gastrointestinal
Endoscopes**



Society of Gastroenterology Nurses and Associates, Inc.

Acknowledgements

Copyright © 2018 Society of Gastroenterology Nurses and Associates, Inc. (SGNA).
First published in 1996, revised 2000, 2005, 2007, 2008, 2011, 2012, 2015 & 2016.

This document was prepared and written by the members of SGNA Practice Committee and adopted by the SGNA Board of Directors in 2018. It is published as a service to SGNA members.

SGNA Practice Committee 2017-18

Midolie Loyola, MSN RN CGRN, Chair
Eileen Babb, BSN RN CGRN CFER
Susan Bocian, MSN BSN RN
Angela Diskey, MSN RN CGRN
Cynthia M. Friis, MEd BSN RN-BC
Amy Granato, MSN RN CGRN
Annett Schmit, BSN RN CGRN
Susan Selking, BSN RN CGRN

Society of Gastroenterology Nurses and Associates, Inc.
330 North Wabash, Suite 2000
Chicago, Illinois 60611
Tel: (800) 245-SGNA or (312) 321-5165
Fax: (312) 673-6694
Online: www.SGNA.org
Email: SGNA@smithbucklin.com

Disclaimer

The Society of Gastroenterology Nurses and Associates, Inc. presents this guideline for use in developing institutional policies, procedures, and/or protocols. Information contained in this guideline is based on current published data and current practice at the time of publication. The Society of Gastroenterology Nurses and Associates, Inc. assumes no responsibility for the practices or recommendations of any member or other practitioner, or for the policies and practices of any practice setting. Nurses and associates function within the limits of state licensure, state nurse practice act, and/or institutional policy. The Society of Gastroenterology Nurses and Associates does not endorse or recommend any commercial products, processes, or services. A commercial product, process, or service is recognized as being consumed by or used on patients.

Table of Contents

Preface.....	4
Definitions.....	6
Introduction.....	8
Personnel.....	10
Leadership.....	11
Quality Assurance.....	12
Reprocessing Environment.....	13
Spill Containment Plan.....	14
Reprocessing Accessories.....	15
Endoscope Reprocessing Protocol.....	15
Summary.....	28
References.....	29

Preface

These standards are presented by the Society of Gastroenterology Nurses and Associates, Inc. (SGNA) to be used for all settings where gastrointestinal endoscopy is practiced. The current version complements SGNA's *Guideline for the Use of High-level Disinfectants and Sterilants for Reprocessing of Flexible Gastrointestinal Endoscopes* and the *SGNA Standard of Infection Prevention in the Gastroenterology Setting*.

Proper reprocessing of endoscopes and accessories is critical to the safe and successful treatment of patients. Any deviation from the reprocessing protocol can lead to the survival of microorganisms and increased risk of infection (ASGE, 2014; Rutala & Weber, 2015).

Endoscope reprocessing is under scrutiny as improper reprocessing has been identified as one of health care's most dangerous health technology hazards (ECRI Institute, 2015). The carbapenem-resistant enterobacteriaceae (CRE) outbreaks occurring between 2008 and 2015 were highly publicized, with a large number of people affected, resulting in infections or deaths. In response to this situation, the complex design of the duodenoscope was examined. The Centers for Disease Control and Prevention (CDC) and the United States Food and Drug Administration (FDA) established standards and enhanced measures on duodenoscope reprocessing, with careful attention to the elevator mechanism. The FDA outlined strict adherence to duodenoscope reprocessing, emphasizing the importance of exactly following manufacturers' instructions, and taking enhanced measures where feasible on microbiologic culturing; ethylene oxide (EO) sterilization; FDA-cleared low-temperature sterilization; liquid chemical sterilization or repeated high-level disinfection (HLD) (CDC, 2017). Manufacturers of automated endoscope reprocessors (AERs) labeled for duodenoscope reprocessing must now provide validation testing to the FDA, demonstrating that reprocessing provides an effective margin of safety (FDA, 2018). The FDA updates the list of approved AERs periodically. Facilities are responsible for accessing this information. In addition, standardized protocols for duodenoscope surveillance sampling and culturing have been outlined for those facilities with the resources to implement this testing (CDC, 2018).

HLD is the method generally used in endoscope reprocessing. In the absence of defective equipment, reported cases of hospital-acquired infection associated with a contaminated gastrointestinal (GI) endoscope were linked to a breach or violation of at least one of several requisite reprocessing steps (Kovaleva, Peters, van der Mei, & Degener, 2013; Ofstead, Wetzler, Snyder, & Horton, 2010; Petersen et al., 2017). However, in the CRE outbreaks, infections persisted even though no breaches in the reprocessing protocol were reported (Rutala and Weber, 2016; Ofstead, Wetzler, et al., 2017). Literature states that HLD processes are not as effective as once thought. Contamination of gastroscopes and colonoscopes still persist even when reprocessing guidelines are followed (Ofstead et al., 2015; Ofstead, Wetzler et al., 2017). Several studies have suggested that current practices in HLD are not sufficient to ensure successful decontamination. There is lack of standardization on cleaning verification methods, visual inspection, drying, storage, and quality surveillance (Kovaleva, 2017; Petersen et al., 2017; Ofstead et al., 2015).

The directive to follow the manufacturer's validated instructions for use and reprocessing of endoscopes remains unchanged. It is necessary to stay vigilant with proper decontamination, cleaning and disinfection/sterilization, drying, and storage. The added focus must be on improving the HLD process. This centers on:

1. The effectiveness of manual cleaning.
 - a. Visual inspection and verification testing, which play an important part in evaluating the effectiveness of manual cleaning.
 - b. Strengthen training and educating reprocessing staff. In addition to observing for staff competency and compliance, consider reprocessing certification.
 - c. Monitoring and tracking of the endoscope, which include timing of events and who performs the key steps (Petersen et al., 2017).
 - d. Manufacturers' efforts to improve endoscope design to increase reliability of HLD and help improve manual cleaning.
2. Limiting microbial growth and cross-contamination.
 - a. Age and use of endoscopes. Damage to internal channels from use, repeated HLD, and drying can promote an environment for microbial growth (Ofstead et al., 2015; Ofstead, Wetzler et al., 2017). It is suggested that identifying early internal damage of all endoscopes - including new ones - through frequent assessments and repairs may be helpful in curbing residual contamination.
 - b. Biofilm development. Biofilm is difficult to remove and can render disinfectants ineffective against microbes.
 - c. Microbial growth and AERs.
 - d. Water quality.
3. The choice of disinfectants.
 - a. Role of glutaraldehyde fostering biofilm development (Ofstead, Wetzler, 2017; Rutala, 2010).
 - b. Considerations for sterilants, including EO.
4. Assurance that a quality program be in place.
 - a. Adherence to strict reprocessing standards as outlined by the manufacturer.
 - b. Consistent oversight, compliance, documentation, and process improvements in place to support a quality program.

Current literature is replete with thoughts on a shift from HLD to sterilization for duodenoscopes, reclassifying them as critical devices (Petersen et al., 2017; Rutala, 2017). It has been suggested that since duodenoscopes are used in sterile body cavities, the scope and its components should be reclassified as critical devices and be sterilized (Rutala & Weber, 2016). Rutala (2015) states there is a low margin of safety with endoscope reprocessing because of the complexity of the endoscope and the microbial load. Where HLD offers a 6 log₁₀ reduction, sterilization provides a greater margin of safety with a 12 log₁₀ reduction. The modification of Spaulding would identify medical devices such as the duodenoscope that directly or secondarily pass through a mucous membrane into a sterile cavity or vascular system be sterilized. In order for this change to occur, there must be collaboration between the FDA, professional organizations, and the industry (Rutala, 2015). SGNA supports further research on

this topic.

The cost, process, and time of sterilization will have an effect on throughput, facility budget, and operations. Increasing endoscope inventory may need to be considered. However, since HLD is effective when stringently adhered to, SGNA supports further research on developing standardized, effective processes to improve HLD.

SGNA recognizes that some facilities may choose ethylene oxide sterilization and provides a general FAQ sheet on Gas Sterilization of Endoscopes (SGNA, April, 2015). While this document does not address gas sterilization, sterilization cannot be effective unless the device has first been meticulously cleaned and high-level disinfected (Rutala & Weber, 2013; CDC, 2015).

The focus of this standard is to highlight the expectations of reprocessing staff, management responsibilities, the reprocessing environment, the steps in reprocessing and rationale for their use, and quality assurance.

Definitions

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

Anionic detergent refers to a type of surfactant (see surfactant definition below).

Automated endoscope reprocessor (AER) refers to machines designed for the purpose of cleaning and disinfecting endoscopes and accessories.

Bioburden refers to the microbiological load (i.e., number of viable organisms in or on an object or a surface) or organic material on a surface or object prior to decontamination or sterilization; also known as "bioload" or "microbial load" (Rutala et al., 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).

Cleaning refers to the physical removal of soil and contaminants from an item to the extent necessary for further processing or for the intended use (Food and Drug Administration (FDA), 2015). Cleaning must precede disinfection or sterilization.

Competency refers to an expected level of performance that integrates knowledge, skills, abilities, and judgment (American Nurses Association [ANA], 2015).

Detergent refers to a surfactant or mixture of surfactants used for cleaning.

Disinfection refers to a process that destroys pathogens and other microorganisms by physical or chemical means (FDA, 2015). Disinfection processes do not ensure the same margin of safety associated with sterilization processes

Duodenoscope refers to a side-viewing endoscope used during an endoscopic retrograde cholangiopancreatography (ERCP).

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.

Enzymatic detergent refers to low-foaming detergents which add enzymes such as proteases, amylases, and lipases that are capable of digesting organic material such as blood and mucous.

Echoendoscope refers to an endoscope with an ultrasound transducer used for endoscopic ultrasound (EUS) procedures. In this document, it may also be referred to as EUS scope or endoscopic ultrasound gastrovideoscope.

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 within the labeled exposure time and temperature (Rutala et al., 2008; Miner, 2013). HLD chemicals and processes must be able to demonstrate the ability to kill 6 logs (1×10^6 or 1,000,000 organisms) (FDA, 2015).

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

Personal Protective Equipment (PPE) refers to specialized clothing or equipment worn by an employee for protection against a hazard (ASGE, 2008; OSHA, 2012).

Reprocessing refers to validated processes used to render a medical device, which has been previously used or contaminated, suitable for a subsequent single use. These processes are designed to remove soil and contaminants by cleaning and to inactivate microorganisms by disinfection or sterilization (FDA, 2015). In relation to endoscopy, it includes all the steps from pre-cleaning to drying.

Residual organic soil refers to substances such as blood, carbohydrates, or proteins that are left on the endoscope after manual cleaning (Alfa, 2013).

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, 2015).

Safety Data Sheet (SDS) refers to the descriptive information that accompanies a chemical or chemical mixture and provides data regarding the identity of the material; physical hazards, such as flammability; and 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; OSHA, 2012).

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

Sterilization refers to a validated process resulting in the complete elimination or destruction of all forms of microbial life.

Surfactant refers to a substance that has both a hydrophilic group and a hydrophobic group. Surfactants are a broad class of molecules that function to bind and lift soil. They may be natural such as soap (anionic) or synthetic, derived from petroleum products. Some types of surfactants serve as wetting agents to lower the surface tension of the cleaning solution (Kern, 2001).

Training refers to the action of teaching a person a particular skill or type of behavior.

Introduction

The field of gastroenterology and the number of procedures performed continues to expand each year. With growth brings new challenges in technology and infection prevention. It is imperative to understand each requisite step in reprocessing and fully comprehend the transmission of infection to ensure safety in the GI setting.

The Spaulding classification system is universally used to determine what type of disinfection or sterilization is appropriate for medical devices (Peterson et al., 2017; Rutala & Weber, 2013). These three classes, critical, semi-critical, and non-critical, stratify the risk of infection associated with each device. Critical devices break the mucosal barrier and should be sterilized (e.g., reusable biopsy forceps). Semi-critical devices (e.g., endoscopes) come in contact with mucous membranes or non-intact skin and should be sterilized or receive high-level disinfection (HLD). Non-critical devices are those that come into contact with intact skin such as blood pressure cuffs and stethoscopes. These items can be cleaned with soap and water or disinfected with a germicide.

Endoscopes are considered semi-critical and should receive HLD with an FDA-approved high-level disinfectant (Petersen et al., 2017; Rutala & Weber, 2013). Since endoscopes are used repeatedly, they must undergo reprocessing to ensure that all pathogenic microorganisms are removed before the endoscope is used on

the next patient. Every patient must be considered a potential source of infection, and all endoscopes must be decontaminated with the same degree of rigor following every endoscopic procedure.

Reprocessing is highly effective when stringently adhered to but several factors may impact its effectiveness (Edmiston & Spencer, 2014; Petersen et al., 2017; Rutala & Weber, 2015). These factors can be considered in relation to the endoscope itself, the reprocessing personnel, the reprocessing steps, and the equipment.

Endoscope-related factors include:

- Complex endoscope design features that make it difficult to clean the endoscopes thoroughly enough to remove all organic debris and microorganisms (e.g., elevator channel of duodenoscope) (Edmiston & Spencer, 2014; Rutala & Weber, 2015; Rutala, 2017);
- A variety of endoscope models that require different cleaning procedures, brushes, etc.;
- Age, history of use, and repair. As endoscopes age through frequent use and reprocessing, internal surfaces become damaged. This results in the increased retention of residue from accumulation of organic substances and microorganisms, potentially increasing infection risk (Ofstead et al., 2015; Ofstead, Wetzler et al., 2017).

Personnel factors include:

- Lack of access to, and/or understanding of, manufacturer's validated instructions for reprocessing;
- Lack of knowledge or unfamiliarity with endoscope channels, accessories, and reprocessing devices (Peterson et al., 2017);
- Inadequate number of staff to support volume, workflow, and throughput;
- Frequent disruptions or interruptions during reprocessing (AAMI, 2015);
- Inadequate training;
- Limited accountability;
- Lack of mindfulness and underestimation of risk; and
- Time pressures or demands for rapid endoscope turn-around.

Reprocessing has certain characteristics that impede its effectiveness, which include:

- Numerous reprocessing steps that must be followed meticulously;
- Steps that are prone to human error (e.g., pre-cleaning, manual cleaning);
- Lag time or delay in reprocessing;
- Inadequate cleaning prior to HLD;
- Inadequate enzymatic concentration, temperature, or time;
- Inappropriate use of disinfectant (e.g., wrong concentration or temperature, expired reuse life, inadequate exposure time) (Kovaleva, 2016);

- The use of certain sterilants and disinfectants that may fixate (Rutala, 2016);
- Inadequate concentration because the endoscope was not dried adequately and excess water diluted the disinfectant;
- Inadequate drying before storage; and
- Lack of quality control measures to detect problems or lapses in reprocessing.

Problems can occur with reprocessing equipment such as:

- Equipment malfunction or contamination (e.g., with flushing pumps or AERs);
- Use of incorrect connectors for flushing aids or AERs; and
- Unrecognized problems with water supply effecting water quality.

Infection prevention principles must be followed to maintain a safe environment and prevent the spread of disease to patients and endoscopy personnel. Refer to SGNA's *Standard of Infection Prevention in the Gastroenterology Setting* for specifics on personnel, education and training, and quality measures and assurance.

The factors outlined in this document must be followed to ensure safe and effective GI endoscope reprocessing.

Personnel

Ensuring consistently effective endoscope reprocessing and safety is a multidisciplinary effort involving clinical and reprocessing staff, infection prevention personnel, and management.

Reprocessing personnel must accomplish the following:

- Understand the rationale and importance of each step in reprocessing;
- Readily access the manufacturer's instructions for use (IFU);
- Be able to read, understand, and implement the manufacturers' instructions on the proper cleaning and high-level disinfection of gastrointestinal endoscopes and accessories (CDC, 2017);
- Demonstrate model-specific competency for all steps of endoscope reprocessing as outlined by the manufacturer, including proper use of validated automatic endoscope reprocessing systems and other equipment, at least annually (AAMI, 2015; AORN, 2015; Rutala & Weber, 2014; Petersen et al., 2017);
- Undergo more frequent validation of competency for specialty endoscopes that are used infrequently;
- Complete reprocessing training with documented competency for new models of endoscopes, accessories, valves, and automatic endoscope reprocessors as soon as they are introduced in the facility (AAMI, 2015; CDC, 2017);
- Complete all endoscope reprocessing steps meticulously and efficiently, maintaining strict adherence to reprocessing protocol (Edmiston & Spencer, 2014);
- Comply with methods of tracking and documentation required for each

phase of reprocessing (e.g., tagging of equipment) as outlined by the facility (Alfa, 2016);

- Immediately report any breaches in reprocessing according to facility policies and protocols;
- Support identification, reduction, and reporting of errors to promote a culture of safety for patients and personnel;
- Understand the safety hazards of endoscope reprocessing and take appropriate action to protect oneself and others;
- Follow manufacturers' guidelines for maintenance, repair, and replacement of endoscopes and equipment used for reprocessing (e.g. AER) (CDC, 2015; Lee et al., 2015) including loaner equipment.

Temporary personnel should *not* be allowed to clean or disinfect instruments in either a manual or an automated reprocessing system until competency has been established (Peterson et al., 2017).

Leadership

Frontline leadership in the GI setting must contribute to the effectiveness and safety of endoscope reprocessing. Their responsibilities include:

- Be competent to reprocess scopes and able to adequately train and verify the competency of staff (CDC, 2017);
- Support reprocessing procedures as outlined by the manufacturer;
- Ensure staff compliance with the manufacturer's validated IFU for reprocessing (Alfa, 2016);
- Follow manufacturers' guidelines for maintenance, repair, and replacement of endoscopes and equipment used for reprocessing (e.g. AER) (CDC, 2015; Lee et al., 2015) including loaner equipment;
- Have a plan in place for replacing endoscopes.
- Verify there is documentation of compatibility with each endoscope, AER, and method of HLD (Armellino, 2016);
- Ensure that the reprocessing protocol and related competencies are reviewed and updated to ensure compliance with current standards and manufacturers' guidelines;
- Consult with individuals responsible for infection prevention and reprocessing when considering modifications to the reprocessing protocol and when purchasing new reprocessing equipment (CDC, 2015);
- Collaborate with other disciplines such as infection prevention and quality to assess for risk of disease transmission in the reprocessing environment (CDC, 2017);
- Have policies and procedures detailing the facility's response to a reprocessing breach or failure (CDC, 2015; CDC 2017);
- Provide timely corrective action for patient safety issues related to reprocessing (Rutala & Weber, 2016);
- Consider the number and category of personnel who will be responsible

for instrument reprocessing. All staff involved in endoscope reprocessing are identified, trained, and demonstrate initial and continued competency based on the manufacturer's IFU (Armellino, 2016);

- Ensure availability of adequate staff to support meticulous and timely reprocessing;
- Allow adequate time for endoscope reprocessing to ensure adherence to all reprocessing steps recommended by the manufacturer (CDC, 2015);
- Have facility protocols to ensure that health care personnel can readily identify endoscopes that have been properly reprocessed and are ready for use (CDC, 2015);
- Maintain documentation of reprocessing activities (e.g. AER maintenance records, test results verifying HLD concentration, reuse life, etc.) (CDC 2015). Detailed records are essential for recognizing a reprocessing error, identifying all endoscopes affected by that error, and naming individual patients who could be at risk (CDC, 2017);
- Observe staff for adherence to policies and protocols, possibly using a checklist for endoscope reprocessing areas (Joint Commission, 2014);
- Monitor adequate documentation at all stages of reprocessing (CDC, 2017; Alfa, 2016);
- Promote a culture of safety so that staff can be free to communicate concerns.

Quality Assurance

Quality assurance is essential to the continued safety and effectiveness of endoscope reprocessing. Process monitoring with documentation at all stages is required (Alfa, 2016). Documentation may include, but is not limited to, the following:

- procedure date and time;
- patient's name and medical record number;
- endoscopist's name;
- endoscope model and serial number or other identifier;
- AER (if used) model and serial number or other identifier; and
- names of individuals who reprocessed the endoscope (Peterson et al., 2017).

Other documentation essential for infection control includes information and audits on the following:

- timing of reprocessing activities;
- evidence of equipment performance and maintenance records; and
- records verifying that high-level disinfectants were tested and replaced appropriately.

Audits should monitor all reprocessing steps, with feedback provided to personnel regarding their adherence to cleaning and disinfection procedures (CDC, 2015).

Rutala (2016) suggests that infection preventionists be involved in audits to verify reprocessing competencies. There should also be ongoing risk assessments and a plan to address risk. Infection preventionists should ensure that institutional policies are consistent with national guidelines and manufacturers' instructions for use. Infection prevention rounds should be conducted periodically (e.g., at least annually) in areas where endoscopes and other semicritical items are reprocessed to make certain there is compliance with policy.

Health care facilities must have policies and procedures detailing the response to any suspected or identified breaches in reprocessing. The procedure should indicate how the potentially affected patients should be identified, notified, and followed. A multidisciplinary approach is warranted for breach evaluation (CDC, 2017).

Microbiologic testing after reprocessing, during storage, or before use is not required. However, the FDA, CDC, and American Society for Microbiology (ASM), along with other endoscope culturing experts, recently released protocols on voluntary, standardized duodenoscopy surveillance sampling and culturing (2018).

Surveillance cultures can aid in identifying particular endoscope defects that hamper effective reprocessing (Buss et al., 2007; Rutala & Weber, 2015). The use of a borescope to inspect internal endoscope channels has been suggested. Any channel abnormalities detected may require that the endoscope be returned to the manufacturer for repair (Alfa, 2016). Audits could also include rapid cleaning monitors to assess competency of reprocessing staff.

Reprocessing Environment

The reprocessing environment includes procedure rooms and reprocessing rooms. Procedure rooms contain clean areas and contaminated areas. To prevent cross-contamination, most areas of the room should be designated as clean areas. Contaminated areas, where accessories and specimens are handled, should be separated from clean counter areas. All contaminated areas must be cleaned and decontaminated between patients with an Environmental Protection Agency (EPA)-registered, hospital-grade disinfectant appropriate for the specific microorganism (ASGE, 2014). With the exception of pre-cleaning, reprocessing of endoscopes should not be conducted in patient care areas because of the risk of patient exposure to contaminated surfaces and devices (Petersen et al., 2017). Refer to the *SGNA Standards of Infection Prevention in the Gastroenterology Setting* for more details on environmental cleaning.

Gloves should be worn during all phases of endoscope handling, including moving clean scopes from storage to a procedure room, removing scopes from AERs, and taking the scope into storage (Ofstead, Quick, Eiland, & Adams, 2017).

The reprocessing room must be a designated, dedicated area separate from where endoscopic procedures are performed (AAMI, 2015). Current local regulations, state codes, and federal guidelines should be incorporated into the design of any reprocessing area. Considerations include;

- adequate space for reprocessing activities;
- proper airflow and ventilation requirements;
- work flow patterns (dirty to clean with no cross-contamination);
- work surfaces, lighting, and magnification;
- adequate utilities such as electrical support and water, hand washing, and eye washing facilities;
- air drying capability; and
- storage.

Filtered or sterile water must be available in the reprocessing room (Petersen et al., 2017). The role of water quality in both automated and manual cleaning is an important consideration and should be compatible with detergents selected (Alfa, 2016). Water used for reprocessing of endoscopes must meet the specifications outlined by the manufacturers' instructions for the device and reprocessing equipment (CDC, 2017).

Staff should have access to a handwashing sink separate from the reprocessing sink. Eye wash stations, either plumbed or self contained, should not be installed in the sink where reprocessing occurs (CDC, 2017).

The careful use of oil-based and silicone lubricants is warranted and should follow manufacturers' IFU on the recommended agent and proper use. If simethicone must be used, the lowest possible concentration must be used (FDA, 2015; Ofstead, Wetzler et al., 2017). Residue from these products promote an environment that protects microorganisms and promotes biofilm formation. This has an effect on HLD and sterilization, including EO.

Spill Containment Plan

Each endoscopy setting should have a spill containment plan for the chemicals used in their area. The plan must include:

- Information from the specific SDS;
- Written procedures for actions to contain the spill and deactivate the chemical;
- An intra- and inter-departmental communication plan; and
- An evacuation plan.

Persons working in the setting must be trained and have documented competencies in the safe handling of high-level disinfectants/sterilants and spill containment procedures. Refer to the manufacturer's instructions for information on the specific solution.

Reprocessing Accessories

Refer to manufacturers' guidelines for specifics on reprocessing of endoscopic accessories. The FDA requires the manufacturers of reusable devices to provide validated instructions for cleaning and HLD or sterilization (Petersen et al., 2017). The validation provides evidence that reprocessing instructions as outlined are effective.

Sterile water must be used in water bottles and irrigation systems for endoscopic procedures. Accessories classified as critical devices (i.e., those that break the mucus membrane and/or come into contact with sterile tissue or the vascular system) require sterilization. Refer to current SGNA Position Statement *Management of Endoscopic Accessories, Valves, Water and Irrigation Bottles in the Gastroenterology Setting*.

Endoscope Reprocessing Protocol

The reprocessing protocol presented here outlines basic steps for cleaning, high-level disinfecting, drying, and storing of gastrointestinal endoscopes, as well as the rationale for each step. According to the literature, compliance with accepted guidelines for the reprocessing of endoscopes between patients is critical to the safety and success of their use. Pathogen transmission can be effectively minimized when these guidelines are followed (Peterson et al., 2017).

It is imperative that reprocessing personnel have access to and be thoroughly familiar with the validated manufacturer's instructions for each endoscope that they are responsible for reprocessing. Personnel must always refer to and follow FDA labeling and manufacturer's instructions for device-specific reprocessing steps for each endoscope's unique design (Petersen et al., 2017).

Reprocessing personnel must also know which AERs, high-level disinfectants, and mechanical devices used to assist in the manual cleaning process are compatible with a particular endoscope and use the equipment and products according to the manufacturer's instructions (SGNA, 2017).

Reprocessing personnel must be up-to-date on current issues related to endoscopy and reprocessing, as well as information provided by regulatory agencies, manufacturer's instructions, and institutional policies. A readily available source of current information is the SGNA Resources for Quality and Safety found on the SGNA website.

Endoscope reprocessing includes the following steps (Alfa, 2013; AAMI, 2015; Petersen et al., 2017; Gastroenterological Society of Australia [GESA] & Gastroenterological Nurses College of Australia [GENCA], 2010):

1. Pre-cleaning;
2. Leaktesting;

3. Manual cleaning;
4. Rinse after cleaning;
5. Visual inspection;
6. High-level disinfection (manual or automated);
7. Rinse after high level disinfection;
8. Drying (alcohol and forced air); and
9. Storage.

The nine steps are discussed in the following sections.

1. PRE-CLEANING

Pre-cleaning removes organic material (e.g., blood, body fluids, body soil) and decreases the bioburden, making it much more likely that subsequent reprocessing steps will be successful. Pre-cleaning occurs in the procedure room immediately after removal of the insertion tube from the patient and prior to disconnecting the endoscope from the power source. Pre-cleaning should be performed at point of use, before bioburden has an opportunity to dry and before complete decontamination (Miner, 2013; Petersen et al., 2017). Necessary supplies include:

- 1) PPE; at a minimum gloves, eye protection, impervious gown, and face shield or simple surgical mask that will not trap vapors;
 - 2) Container with detergent solution;
 - 3) Sponge or soft, lint-free cloth;
 - 4) Air and water channel cleaning adapters per the manufacturer's instruction;
 - 5) Protective video caps if using video endoscopes, where applicable; and
 - 6) Transport bin, container, etc.
-
- a. Immediately after removing the endoscope from the patient, wipe the insertion tube with the wet cloth or sponge soaked in the freshly prepared detergent solution (Peterson et al., 2017). Dispose of cloth/sponge according to the manufacturer's instructions.
 - b. Place the distal end of the endoscope into the appropriate detergent solution, and suction a large volume of detergent solution through the endoscope until clear (Petersen et al., 2017). Finish by suctioning air.
 - c. Flush and manipulate the forcep elevator of duodenoscope or echoendoscope per the manufacturer's instructions.
 - d. Flush air and water channels in accordance with the endoscope manufacturer's instructions.
 - e. Flush the auxiliary water channel per the manufacturer's instructions.
 - f. Detach the endoscope from the light source and suction pump.
 - g. Attach protective video caps where applicable.
 - h. Transport the soiled endoscope to the reprocessing area in a closed, puncture-resistant container that prevents exposing staff, patients, or

the environment to potentially infectious organisms (Petersen et al., 2017). The transport container must be labeled to indicate biohazardous contents (ASGE, 2011; AAMI, 2015). Containers must be large enough to prevent damage to the endoscope by being coiled too tightly.

THE REMAINING STEPS OCCUR IN THE REPROCESSING AREA

Have the following available:

- a. PPE; at minimum gloves, eye protection, impervious gown, and face shield or simple surgical mask that will not trap vapors;
- b. Leak testing equipment;
- c. Channel cleaning adapters (model-specific);
- d. Large basin or sink;
- e. Detergent solution prepared according to the manufacturer's instructions;
- f. Appropriate size channel cleaning brushes. Consider disposable, single use when available;
- g. Sponge and/or lint-free cloth;
- h. Automated flush pump device where applicable; and
- i. Lighted magnification.

2. LEAK TESTING

Leak testing detects damage to the interior channels and exterior surfaces of the endoscope that can lead to inadequate disinfection and further damage (CDC, 2017). The leak test is done before immersion of the endoscope in reprocessing solutions to minimize damage to parts of the endoscope not designed for fluid exposure. Leak testing can be performed by manual (dry), mechanical (wet), mechanical (dry), and mechanical-in-AER means (AAMI, 2015). Follow the manufacturers' instructions to ensure endoscope and leak tester compatibility.

For purposes of this document, one of the more commonly used methods of leak testing will be highlighted. Users should carefully consider the most appropriate leak testing method for their reprocessing needs.

- a. Mechanical (wet) leak testing:
 - 1) Remove suction valves, air water valves, and biopsy valves.
 - 2) Discard those parts that are designated as disposable. The endoscope must be completely disassembled so that all surfaces may be reached for thorough cleaning.
 - 3) Attach the leak tester and pressurize the endoscope before submerging it in clear water.
 - 4) Never add detergent to water before or during leak testing. Detergent will obscure bubbles leaking from the endoscope, and a leak may be missed. Refer to the specific manufacturer's instructions

to determine if it is necessary to remove other detachable parts before leak testing.

- 5) With the pressurized endoscope completely submerged, flex the distal portion of the endoscope in all directions, observing for bubbles. Depress the freeze and release buttons while observing the control head of the endoscope for bubbles. Check the insertion tube, distal bending section, and universal cord for bubbles coming from the interior of the endoscope.
- 6) Remove the endoscope from the sink or basin. Turn off the leak tester. Disconnect the leak tester from the video cap. Allow the endoscope to depressurize. Ensure that the video cap is secure and has not loosened with the removal of the leak tester. Continue with the reprocessing steps when the test is complete unless a leak is detected.

Remove the endoscope from service if a leak has been identified or detected, and follow the endoscope manufacturer's instructions on how to proceed.

3. MANUAL CLEANING

Manual cleaning of endoscopes is necessary prior to automated/manual HLD or sterilization. It is important to follow the manufacturer's time frame for completing manual cleaning of the scope. If a delay occurs, follow the delayed cleaning protocol in the manufacturer's IFU (Peterson et al., 2017). **This is the most critical step in removing the microbial burden from an endoscope.** It requires focused and deliberate attention.

Manual cleaning of complex endoscope components such as elevators requires optimal lighting and may benefit from magnification (Petersen et al., 2017). Retained debris contributes to biofilm development (Fang et al., 2010) and interferes with the HLD capability to effectively kill and/or inactivate microorganisms (Roberts, 2013; CDC, 2017). Manual cleaning and thorough brushing of channels is required and must follow manufacturers' instructions (FDA, 2009; Petersen et al., 2017).

The composition of soil found on endoscopes includes proteins, fats, carbohydrates, and the various chemical salts that exist in blood and other body fluids. A cleaning solution should have a broad spectrum of effectiveness against these various contaminants and not harm the device being cleaned. Low-foaming detergents are recommended so that the device can be clearly visualized during the cleaning process, preventing personnel injury and allowing for complete cleaning of lumen surfaces.

Enzymatic cleaning solutions use surfactants to break down and digest

bioburden. Endoscopes exposed to synthetic lipids may require additional cleaning with a detergent formulated to remove synthetic lipids.

Manual cleaning follows these steps:

- a. Fill a sink or basin with freshly-made solution of water and a medical grade, low-foaming, pH-neutral detergent formulated for endoscopes that may or may not contain enzymes (Marion et al., 2006).
- b. Dilute and use the detergent according to the manufacturer's instructions. Freshly prepared detergent solution should be used for each endoscope to prevent cross-contamination.
- c. Ensure that the video cap is secure, if applicable. Immerse the endoscope.
- d. Wash all debris from the exterior of the endoscope by brushing and wiping the instrument while submerged in the detergent solution. The endoscope should be submerged in the detergent solution when performing all subsequent cleaning steps to prevent splashing of contaminated fluid and aerosolization of bioburden.
- e. Use a small, soft brush to clean all reusable, removable parts, including inside and under the suction valve, air/water valve, and biopsy port cover and openings. Use non-abrasive and lint-free cleaning tools to prevent damage to the endoscope. It is recommended that single-use, disposable cleaning tools be used when possible.
- f. Brush all accessible endoscope channels, as well as the body, insertion tube, and the umbilicus of the endoscope. Use a brush size compatible with each channel. All internal and external surfaces of the endoscope and its removable parts must be thoroughly cleaned, and all auxiliary channels (even if not used) must be brushed and flushed according to the manufacturer's specific instructions for each endoscope model (Peterson et al., 2017; SGNA, 2013).
- g. Because the elevator channel of a duodenoscope is difficult to effectively clean, additional steps are required in all phases of reprocessing (CDC, 2015). Other specialty endoscopes such as an endoscopic ultrasound gastrovideoscope and double channel endoscope may require additional steps and brushes to adequately clean manually; refer to the specific manufacturer's instructions.
- h. After each passage, rinse the brush in the detergent solution, removing any visible debris before retracting and reinserting it.
- i. Continue brushing until there is no debris visible on the brush.
- j. Clean and high-level disinfect reusable brushes between cases. Reusable brushes must be inspected between uses and replaced when worn, frayed, bent, or otherwise damaged. Worn bristles are ineffective in cleaning, and damaged brushes may damage

- endoscope channels. Discard single-use brushes.
- k. Attach the endoscope manufacturer's cleaning adapters for suction, biopsy, air, and water channels. Automated pumps are available for this step that eliminate the manual flush. Refer to the manufacturer's guidelines for the use of these devices and to determine whether they are compatible with the endoscope. Pay particular attention to the specific manufacturer's instructions on those endoscopes with elevator channels and other specialty endoscopes.
 - l. Attach the manufacturer's cleaning adapters for special endoscope channels (e.g., elevator channel, auxiliary channel, and double-channel scopes).
 - 1) To achieve adequate flow through all lumens, various adapters or channel restrictors may be required. Refer to the manufacturer's instructions.
 - 2) The elevator channel of a duodenoscope may require manual flushing and manipulation; refer to the most current, validated manufacturer's instructions for specific steps.
 - m. Flush all channels with the detergent solution to remove debris, and soak the endoscope and its internal channels for the period of time specified by the detergent manufacturer's label.

All steps should be completed sequentially and within the manufacturer's recommended time frame (Petersen et. al., 2017). A process must be in place to record the procedure end time and the manual cleaning start time. This process will allow personnel to determine whether routine reprocessing within the manufacturer's recommended time frame is achievable and, if not, to implement the manufacturer's procedures for delayed reprocessing (CDC, 2017). **Reprocessing personnel must refer to the manufacturer's recommendations for delayed re-cleaning and reprocessing.**

4. RINSE AFTER MANUAL CLEANING

- a. Thoroughly rinse the endoscope and all removable parts with clean water to remove residual debris and detergent.
- b. Purge water from all channels using forced air. Dry the exterior of the endoscope with a soft, lint-free cloth to prevent dilution of the HLD used in subsequent steps.
- c. Rinsing may be performed in AERs that provide this feature.

5. VISUAL INSPECTION

Visual inspection is an essential step to make sure the endoscope is visibly clean (AAMI, 2015; Rutala et al., 2008). According to Peterson (2017), all endoscopes and reusable accessories should be visually inspected during all stages of handling and reprocessing - before, during, and after use, in

addition to during and after cleaning and before HLD. Visual inspection is not a guarantee that decontamination from manual cleaning is complete, but it can be considered a safety stop or “time out” to ensure the endoscope is visually clean before proceeding to the next step of HLD.

- a. Visually inspect for conditions that could affect the disinfection process (e.g., cracks, corrosion, discoloration, retained debris) (FDA, 2009; AAMI, 2015).
- b. Use magnification and adequate lighting to help assist in visual inspection (AAMI, 2015; CDC, 2017; CDC, 2017).
- c. Use a camera or borescope for inspecting internal channels, if available.
- d. Repeat manual cleaning step(s) if determined not to be visually clean.
- e. Remove damaged endoscopes and accessories from service for repair or disposal (Petersen et al., 2017).

It is a challenge to visualize internal channels. Facilities should determine a method of manual cleaning verification. Literature suggests that, to confirm the adequacy of manual cleaning, a rapid cleaning monitor (or rapid audit tool) for residual organic soil can be used prior to HLD (Visrodia et al., 2014; Petersen et al., 2017). If the tool results are positive, this allows for the re-cleaning of the endoscope prior to disinfection. This test may also be useful for training, competency testing, and spot surveillance of the cleaning steps (Petersen et al., 2017). The frequency of the testing should be determined by the individual institutions (Alfa, Fatima, & Olson, 2013; Alfa, Olson, & Murray, 2014; AAMI, 2015; ASGE, 2014).

The cleaning process outlined above includes pre-cleaning, leak testing, manual cleaning, and visual inspection must precede HLD or sterilization. According to the literature, cleaning reduces the number of microorganisms and organic debris by four logs, or 99.99% (Kovaleva, 2016).

6. HIGH-LEVEL DISINFECTION

High-level disinfection (HLD) is recognized as the standard for reprocessing of gastrointestinal endoscopes by SGNA, the American Society for Gastrointestinal Endoscopy (ASGE), the American College of Gastroenterology (ACG), the American Gastroenterological Association (AGA), the Association for Professionals in Infection Control and Epidemiology (APIC), ASTM International, federal agencies such as the CDC and the FDA, and accrediting agencies such as the Joint Commission (JC). Sterilization of endoscopes is indicated when used as a critical medical device, where there is potential for contamination of an open surgical field (Petersen et al., 2017), or per individual institutional policy.

The effectiveness of the high-level disinfectant depends on:

- Effective pre-cleaning, manual cleaning, and rinsing to decrease the organic load and microbial content of the endoscope;
- Drying after rinsing to avoid dilution; and
- Proper preparation and use of the disinfectant in accordance with the manufacturer's directions.

It is essential that the level of active ingredient in the high-level disinfectant be at or above that required to kill and/or inactivate the desired microorganisms and that appropriate contact time to achieve germicidal kill should be followed (AAMI, 2015; ASGE, 2014). High-level disinfectants/sterilants are typically reused and must be tested to assure that they remain above their minimum effective concentration (MEC) (AAMI, 2015; Rutala et al., 2008; CDC, 2017).

Test and monitor the disinfectant according to the manufacturer's instructions for testing, and keep a log of the test results (Rutala et al., 2008). The MEC may never be used to extend the reuse life claim of the product or beyond the date specified on activation (AAMI, 2015; Rutala et al., 2008). High-level disinfectants/sterilants must be changed when the solutions fail to meet MEC or exceed the high-level disinfectants' manufacturer's recommended reuse life, whichever comes first (AAMI, 2015; AORN, 2015; ASGE, 2008; Petersen et al., 2017). Follow the manufacturer's instructions when the MEC of the product has failed by test strip.

Use the product-specific test strip to test the MEC, and follow the directions on the test strip container. Follow manufacturer's instructions for quality-control procedures.

In addition, there should be an established program for monitoring occupational exposure to regulated chemicals (e.g., formaldehyde, EO), which adheres to state and federal regulations (Rutala et al., 2008). For additional information, refer to SGNA's *Guidelines for Use of High-Level Disinfectants and Sterilants in the Gastroenterology Setting*. Maintain a SDS for all chemicals used for cleaning and disinfection. It is recommended that a SDS be used for training staff on each chemical's safe use (ASGE, 2014). Have a spill plan in place.

HLD can be achieved either manually or by using an automated endoscope reprocessor (AER).

6A. MANUAL HIGH-LEVEL DISINFECTION

Endoscopes must be purged with air and externally dried prior to immersion to minimize diluting the high-level disinfectant.

- a. Completely immerse the endoscope and all removable parts in a basin of high-level disinfectant/sterilant.
 - 1) The basin must be of a size to accommodate the endoscope without undue coiling (AAMI, 2015). Ventilation must be sufficient to remove chemical vapors.
 - 2) To prevent damage, the endoscope should not be soaked with other sharp instruments that could potentially damage the endoscope.
- b. Flush disinfectant into all channels of the endoscope until it can be seen exiting the opposite end of each channel. All channels must be filled with the chemical so that no air pockets remain within the channels. Complete microbial destruction cannot occur unless all surfaces are in complete contact with the chemical (FDA, 2009).
- c. Cover the soaking basin with a tight-fitting lid to minimize chemical vapor exposure. Exposure to chemical vapors may present a health hazard. The reprocessing area must have engineering controls to ensure good air quality.
- d. Soak the endoscope in the high-level disinfectant/sterilant for the time/temperature required to achieve HLD. Use a timer to verify soaking time. Do not exceed the manufacturer's recommended time for soaking, such as leaving a scope to soak overnight.
- e. Purge all channels completely with air before removing the endoscope from the high-level disinfectant/sterilant. Purging the channels preserves the concentration and volume of the chemical, and prevents exposure from dripping and spilling.

Go to reprocessing step #7 **RINSE AFTER HIGH-LEVEL DISINFECTION** to complete this process.

6B. AUTOMATED REPROCESSING

Endoscope reprocessors standardize the disinfection process and decrease personnel exposure to high-level disinfectants (Kovaleva et al., 2013).

The FDA has approved labeling some AERs as washer-disinfectors, which do not require prior manual cleaning and channel brushing. Manual cleaning and brushing are still necessary in order to assure the overall efficacy of HLD even when automated, brushless washing of endoscope channels is used. The redundancy achieved by adding an automated washing step following manual cleaning can provide an extra level of safety. Further studies in clinical settings are warranted for these technologies (Petersen et al., 2017).

If an automated endoscope reprocessor (AER) is used, ensure that the endoscope and endoscope components can be effectively reprocessed with the AER. The elevator wire channel of duodenoscopes is not effectively disinfected by most AERs and should be performed manually. Users

should obtain and review model-specific reprocessing protocols from both the endoscope and the AER manufacturers, and check for compatibility.

If the machine has a cycle that uses enzymatic detergent, it should be a product that is compatible with the reprocessor and the endoscope. Improper amounts and/or dilution of the enzymatic detergent may allow detergent residue to remain on the internal and external surfaces of the endoscope, and/or on the sink surfaces of the reprocessor. Enzymatic detergent residue may interfere with the action of the high-level disinfectant/sterilant.

If the AER cycle is interrupted, HLD or sterilization cannot be ensured; therefore, the cycle should be repeated (Peterson et al., 2017). A preventive maintenance plan should be in place for all automated reproprocessors, equipment, and accessories used to reprocess endoscopes. Quality controls recommended by AER manufacturers should be adhered to and documented.

An AER should have the following features (SGNA, 2013):

- a. The machine should circulate fluids through all endoscope channels at an equal pressure without trapping air. Channel flow sensors provide an added measure of compliance.
- b. The detergent and disinfectant cycles should be followed by thorough rinse cycles and forced air to remove all used solutions.
- c. The disinfectant should not be diluted with any fluids other than what is supplied through the AER.
- d. The machine should be self-disinfecting.
- e. No residual water should remain in hoses and reservoirs.
- f. Cycles for alcohol flushing and forced air drying are desirable.
- g. The machine should also feature a self-contained or external water filtration system.
- h. A method to automatically store or print verification of cycle completion.

To use an automated reprocessor:

- a. Follow steps for manual cleaning of the endoscope.
- b. Prepare the endoscope reprocessor according to the manufacturer's guidelines.
- c. Place the endoscope in the reprocessor, and attach all channel adapters according to the manufacturer's instructions.
Due to the complex design of duodenoscopes and linear echoendoscopes, follow the manufacturer's instructions for disinfecting the elevator channel and for positioning of the elevator during HLD.
- d. Strict compliance with duodenoscope reprocessing guidelines is

- necessary. Institutions may determine to enhance the HLD process by including one of the following supplemental measures: microbiological culturing, repeat HLD, EO, or liquid chemical sterilization (Kim & Muthusamy, 2016; Peterson et al., 2017).
- e. Place valves and other removable parts into the soaking basin of the reprocessor. Unless the reprocessor has a dedicated space for accessories, reprocess these items separately.
 - f. Set the machine for the appropriate time and temperature, depending on the chemical used.
 - g. Start the machine, and allow it to complete all cycles/phases. If cycles/phases are interrupted, HLD cannot be ensured and the full cycle must be repeated.
 - h. If a final alcohol rinse cycle is not included in the automated reprocessor cycle, this step should be done manually, followed by purging all the channels with air until dry (FDA, 2009).

The duodenoscope and linear echoendoscope elevator and elevator channel must be manually flushed and dried per the manufacturer's instructions.

All endoscopes that have completed reprocessing should not be allowed to sit in the AER for long periods, such as overnight.

7. RINSE AFTER HIGH-LEVEL DISINFECTION

Thoroughly rinse all surfaces and removable parts, and flush all channels of the endoscope and its removable parts with clean water according to the disinfectant and endoscope manufacturers' recommendations. Rinsing prevents exposure and potential injury of skin and mucous membranes from chemical residue. Fresh clean water should be used for each rinse of the endoscope. Rinsing is required for manual HLD.

8. DRYING

Drying is a critical element in reprocessing. Moisture allows microorganisms to survive and multiply; therefore, all channels and the surface of the endoscope must be thoroughly dried before storage. Outbreaks of *Pseudomonas aeruginosa*, *Acinetobacter spp.*, carbapenemase-producing *K pneumoniae*, and other pathogens have been traced to inadequately dried endoscopes (Alfa, 2013; Carbonne et al., 2010; Kovaleva et al., 2013). Even when reprocessing steps are performed meticulously, a few microorganisms may survive HLD. Those few microorganisms can multiply to over a million colony-forming units in just a few hours if any moisture remains in the endoscope channels or on its surface (Miner, 2013).

Moisture also promotes biofilm development (Alfa, 2013; Kovaleva et al., 2013,

2017). Biofilm accumulation results in decreased efficiency of cleaning solutions and high-level disinfectants. Because the bacterial load is not reduced, possible transmission can occur.

In order to ensure that endoscopes are thoroughly dried, they must be flushed with 70% to 90% ethyl or isopropyl alcohol prior to being dried with pressurized, filtered air either by AER or manually (Kovaleva et al., 2013; Peterson et al., 2017; Rutala et al., 2008). Alcohol displaces water and evaporates more easily than water. Alcohol mixes with the remaining water on the channel surfaces and encourages evaporation of the residual water as air flows through the channel. Store the alcohol in a closed container between uses. Alcohol evaporates rapidly when exposed to air, and the remaining solution may be too diluted to effectively promote drying of endoscope channels.

Drying the endoscope after every reprocessing cycle, both between patient procedures and before storage, is crucial. Dry all channels with forced instrument air (Rutala & Weber, 2016; Petersen et al., 2017). Follow the manufacturer's reprocessing manual to determine the air pressure limits for the particular model of endoscope. Drying and storage is as important to the prevention of disease transmission and nosocomial infection as cleaning and HLD (Kovaleva et al., 2013; Muscarella, 2006).

Follow the manufacturer's instructions for specific AER, endoscope model, and channel.

- a. Flush all channels with alcohol until the alcohol can be seen exiting the opposite end of each channel. Alcohol flushes should be used even when sterile water is used for rinsing.
- b. Purge all channels with air.
 1. Use compressed air that has been filtered to remove microorganisms.
 2. Avoid the use of excessively high air pressure that can damage the internal channels of flexible endoscopes.
- c. Remove all channel adapters.
- d. Dry the exterior of the endoscope with a soft, clean, lint-free towel.
- e. Thoroughly rinse and dry all removable parts. Do not attach removable parts (e.g., valves, etc.) to the endoscope during storage. Storage of endoscopes with the removable parts detached lowers the risk of trapping liquid inside the instrument and facilitates continued drying of the channels and channel openings.
- f. Ensure that a system exists for identifying endoscopes that have been reprocessed and are ready to use, such as a tagging system (CDC, 2015; Petersen et al., 2017).

9. STORAGE

Cabinets and endoscopes must be visually inspected to ensure cleanliness before storing. Endoscopes must be stored in an area that is clean, well-ventilated, and dust-free in order to keep the endoscopes dry and free of microbial contamination.

An endoscope that is not dry must be reprocessed before use. Endoscopes should also hang freely so that they are not damaged or contaminated by physical impact. Endoscopes should be stored in accordance with the endoscope and storage cabinet manufacturers' IFU. Store reprocessed endoscopes in a cabinet that is of sufficient height, width, and depth to allow flexible endoscopes to hang vertically without coiling and without touching the bottom of the cabinet, or designed and intended by the manufacturer for horizontal storage of flexible endoscopes (CDC, 2017).

Two major types of storage cabinets exist: drying cabinets and conventional cabinets. There is not a general consensus by professional organizations as to which type is best.

Drying cabinets are designed to control air quality and humidity (Courné & Geysens, 2011; Foxcroft, Monaghan, & Faoagali, 2008; Grandval, Hautefeuille, Marchetti, Pineau, & Laugier, 2013; Pineau, Villard, Luu, & Marchetti, 2008). They have bacteria-free air under pressure to keep surfaces dry. High efficiency particulate air (HEPA) filters provide microbial-free air that is blown through the endoscope channels to ensure that they remain dry. Conventional cabinets may or may not have a drying function that utilizes HEPA-filtered air.

A drying cabinet dries the entire endoscope, the channels, and the outside (Kovela, 2017). The exact drying time depends upon the endoscope and the type of cabinet used and could take anywhere from 30 minutes to four hours depending upon manufacturer's guidelines.

Length of storage "hang time" is a controversial issue, and there is no consensus between professional organizations. A number of researchers have investigated the safety of various lengths of storage (Brock et al., 2015; Foxcroft et al., 2008; Grandval et al., 2013; Ingram et al., 2013; Rejchrt, Cermak, Pavlatova, Mickova, & Bures, 2004; Riley, Beanland, & Bos, 2002; Vergis, Thomson, Pieroni, & Dhalla, 2007; Wardle, 2007).

The authors of a systematic review concluded that endoscopes can be stored for 7 days if they have been effectively reprocessed and are stored in a way that keeps them completely dry and free from environmental and human contamination (Schmelzer, Daniels, & Hough, 2015).

Key considerations in storage include:

- a. Use storage cabinets that are made of a material that can be cleaned and disinfected with an EPA-registered hospital-grade disinfectant. The institution should determine the frequency of cleaning.
- b. In conventional storage, hang endoscopes in a vertical position with caps, valves, and other detachable components removed to prevent moisture accumulation and subsequent microbial growth. Make sure that they hang freely so they are not damaged by contact with one another.
- c. When using drying cabinets, follow the cabinet manufacturer's instructions. Since drying does not rely on gravity, the endoscopes can be stored horizontally or vertically, depending on the design of the cabinet.
- d. Each facility should determine a method of documentation and traceability to the endoscope and reusable accessories. Traceability to the endoscope involves documentation which includes patient, date, type of procedure, person performing reprocessing or sterilization, and medical record, if applicable (BSG, 2017).
- e. SGNA supports a 7-day storage interval for reprocessed endoscopes but only if they were reprocessed and stored according to professional guidelines and manufacturer instructions.
- f. Staff should wear clean gloves when handling processed endoscopes (Seavey, 2016).
- g. Endoscope tip protectors can be considered as a way to assist with reduction of distal tip damage from improper handling. Choose a protector that does not trap moisture, allows the endoscope to aerate, provides protection from impact, is single use, has varying diameters to fit different types of endoscopes, and is easy to place and remove.

Summary

Reprocessing of flexible gastrointestinal endoscopes according to the manufacturer's instructions and professional guidelines is critical to patient and staff safety. Understanding the reprocessing continuum from procedure room to storage is imperative. Diligence in the application of all reprocessing steps remains paramount in the safe delivery of endoscopic services.

SGNA supports further research in the areas of infection prevention that promote optimal and effective endoscope reprocessing. These areas include, but are not limited, to:

- Detergent efficacy against biofilm;
- Improved endoscope design;
- Clear and concise reprocessing steps;
- Efficient drying methods and storage;

- Water quality; and
- Standardized quality monitoring to validate effective cleaning and reprocessing.

References

- Alfa, M.J. (2013). Monitoring and improving the effectiveness of cleaning medical and surgical devices. *American Journal of Infection Control*, 41(5 suppl), S56-S59.
- Alfa, M.J. (2016). Current issues result in a paradigm shift in reprocessing medical and surgical instruments. *American Journal of Infection Control*, 44, e41-45.
- Alfa, M.J., Fatima, I., & Olson, N. (2013). The adenosine triphosphate test is a rapid and reliable audit tool to assess cleaning adequacy of flexible endoscope channels. *American Journal of Infection Control*, 41, 249-253.
- Alfa, M.J., Olson, N., & DeGagne, P. (2006). Automated washing with the Reliance endoscope processing system and its equivalence to optimal manual cleaning. *American Journal of Infection Control*, 34(9), 561-570.
- Alfa, M.J., Olson, N., & Murray, B.L. (2014). Comparison of clinically relevant benchmarks and channel sampling methods used to assess manual cleaning compliance for flexible GI endoscopes. *American Journal of Infection Control*, 42, e1-e5.
- American Nurses Association (ANA). (2015). *Nursing: Scope and Standards of Practice* (3rd ed.). Silver Spring, MD: Author.
- American Society for Gastrointestinal Endoscopy (ASGE). (2015). Echoendoscopes [Technology Status Evaluation Report]. *Gastrointestinal Endoscopy*, 82(2), 189-202.
- American Society for Gastrointestinal Endoscopy (ASGE). (2014). Guidelines for safety in the gastrointestinal endoscopy unit. *Gastrointestinal Endoscopy*, 79(3), 363-372.
- American Society for Gastrointestinal Endoscopy (ASGE). (2008). Infection control during GI endoscopy. *Gastrointestinal Endoscopy*, 67(6), 781-790.
- Armellino, D. (2016). Infection prevention and control: Ongoing discovery of high-level disinfection of endoscope practices and the use of performance improvement methodologies in to improve processes. *The Joint Commission Journal on Quality and Patient Safety*, 42(6), 262-264.
- Association for the Advancement of Medical Instrumentation (AAMI). (2015). *Flexible and Semi-Rigid Endoscope Processing in Health Care Facilities* (ANSI/AAMI ST91: 2015). Arlington, VA: Author.
- Association of periOperative Registered Nurses (AORN). (2015). *Guidelines for Perioperative Practice: AORN Guidelines and Tools for the Sterile Processing Team*. Denver, CO: Author.
- British Society of Gastroenterology (BSG). (2017). *2017 Guidance on Decontamination of Equipment for Gastrointestinal Endoscopy: 2017 Edition*. Retrieved from <https://www.bsg.org.uk/resource/guidance-on-decontamination-of-equipment-for-gastrointestinal-endoscopy-2017-edition.html>

- Brock, A.S., Steed, L.L., Freeman, J., Garry, B., Malpas, P., & Cotton, P. (2015). Endoscope storage time: Assessment of microbial colonization up to 21 days after reprocessing. *Gastrointestinal Endoscopy*, 81(5):1150-4. doi: 10.1016/j.gie.2014.09.053. Epub 2014 Dec 5. 2014
- Buss, A.J., Been, M.H., Borgers, R.P., Stokroos, I., Melchers, W.J.G., Peters, F.T.M., ... Degener, J.E. (2007). Endoscope disinfection and its pitfalls: Requirement for retrograde surveillance cultures. *Endoscopy*, 40, 327-332.
- Carbonne, A., Thiolet, J.M., Fournier, S., Fortineau, N., Kassis-Chikhani, N., Boytchev, I., ... Jarlier, V. (2010). Control of a multi-hospital outbreak of KPC-producing *Klebsiella pneumoniae* type 2 in France, September to October 2009: Surveillance and outbreak reports. *European Communicable Disease Bulletin*. Retrieved from http://www.researchgate.net/profile/Nicolas_Fortineau/publication/49670420_Control_of_a_multi-hospital_outbreak_of_KPC-producing_Klebsiella_pneumoniae_type_2_in_France_September_to_October_2009/links/0912f50eaac88b7c75000000.pdf
- Centers for Disease Control and Prevention (CDC). (2018). Duodenoscope Surveillance Sampling & Culturing: Reducing the Risks of Infection. Retrieved from <https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/UCM597949.pdf>
- Centers for Disease Control and Prevention (CDC). (2017). Essential Elements of a Reprocessing Program for Flexible Endoscopes: Recommendations of the Healthcare Infection Control Practices Advisory Committee. Retrieved from <https://www.cdc.gov/hicpac/recommendations/flexible-endoscope-reprocessing.html>
- Centers for Disease Control and Prevention (CDC). (2015). Official Health Advisory: Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting and Sterilizing Reusable Medical Devices. CDC Health Alert Network. Retrieved from <https://www.emergency.cdc.gov/han/han00382.asp>
- Courné, E. & Geysens, S. (2011). Recommendations de bonnes pratiques d'utilisation des enceintes de stockage d'endoscopes thermosensibles (ESET). [Recommendations for good practice in use of storage cabinets for heat sensitive endoscopes]. *Acta Endoscopica*. 41(3), 153-159.
- ECRI Institute. (2015). Top 10 Health Technology Hazards for 2016: Executive Brief. *Health Devices*.
- Edmiston, C. & Spencer, M. (2014). Endoscope reprocessing in 2014: Why is the margin of safety so small? *AORN Journal*, 100(6), 609-615.
- Foxcroft L., Monaghan, W., & Faoagali, J. (2008). Controlled study of the Lancer FD8 drying/storage cabinet for endoscopes. *Journal Gastroenterological Nurses College of Australia*, 18, 5-11.
- Gastroenterological Society of Australia & Gastroenterological Nurses College of Australia. (2010). *Clinical Update: Infection Control in Endoscopy*. Retrieved from <http://www.gesa.org.au/professional.asp?cid=9&id=123>
- Grandval, P., Hautefeuille, G., Marchetti, B., Pineau, L., & Laugier, R. (2013). Evaluation of a storage cabinet for heat-sensitive endoscopes in a clinical setting. *Journal of Hospital Infection*, 84(1), 71-6.
- Ingram, J., Gaines, P., Kite, R., Morgan, M., Spurling, S., & Winsett, R. (2013). Evaluation of medically significant bacteria in colonoscopies after 8 weeks of shelf life in open air storage. *Gastroenterology Nursing*, 36(2), 106-111.
- Joint Commission. (2014). Tips for improving endoscope reprocessing and preventing the risk of

- infection. *Joint Commission Perspectives*. Retrieved from http://www.jointcommission.org/assets/1/23/jconline_April_9_14.pdf
- Kern, B. (2001). Enzymatic cleaning solution for a clean bill of health: Is it safe? *Infection Control Today*. Retrieved from <http://www.infectioncontrolday.com/articles/2001/04/enzymatic-cleaning-solution-for-a-clean-bill-of-h.aspx>
- Kim, S. & Muthusamy, V.R. (2016). *Curr Gastroenterol Rep*, 18:54. <https://doi.org/10.1007/s11894-016-0528-7>
- Kovaleva, J., Peters, F.T., van der Mei, H.C., & Degener, J.E. (2013). Transmission of infection by flexible gastrointestinal endoscopy and bronchoscopy. *Clinical Microbiology Review*, 26(2), 231-254.
- Kovaleva, J. (2016). Infectious complications in gastrointestinal endoscopy and their prevention. *Best Practice & Research Clinical Gastroenterology*, 30, 689-704. doi:10.1016/j.bpg.2016.09.008
- Kovaleva, J. (2017). Endoscope drying and its pitfalls. *Journal of Hospital Infection*, 97(4), 319-328. <https://doi.org/10.1016/j.jhin.2017.07.012>
- Marion, K., Freney, J., James, G., Bergeron, E., Renaud, F.N.R., & Costerton, J.W. (2006). Using an efficient biofilm detaching agent: An essential step in the improvement of endoscope reprocessing protocols. *Journal of Hospital Infection*, 64, 136-142.
- Miner, N. (2013). Cleaning, disinfection and sterilization of heat-sensitive endoscopes. In *Endoscopy*, S. Amornyotin, Ed. London, England: InterTechOpen. doi:10.5772/50355
- Muscarella, L.F. (2006). Inconsistencies in endoscope reprocessing and infection-control guidelines: The importance of endoscope drying. *American Journal of Gastroenterology*, 101(9), 2147-2154. doi:10.1111/j.1572-0241.2006.00712.x
- Ofstead, C., Quick, M., Eiland, J., & Adams, S. (2017). A Glimpse at the True Cost of Reprocessing Endoscopes: Results of a Pilot Project. *Communique' Hot Topics*. May 2017. The International Association of Healthcare Central Service Materiel Management.
- Ofstead, C., Wetzler, H., Doyle, E., Rocco, C., Visrodia, K., Baron, T., ... Tosh, P. (2015). Persistent contamination on colonoscopes and gastroscopes detected by biologic cultures and rapid indicators despite reprocessing performed in accordance with guidelines. *American Journal of Infection Control*, 43(8):794-801. doi: 10.1016/j.ajic.2015.03.003.
- Ofstead, C., Wetzler, H., Heymann, O. Johnson, E., Eiland, J., & Shaw, M. (2017). Longitudinal assessment of reprocessing effectiveness for colonoscopes and gastroscopes: Results of visual inspections, biochemical markers, and microbial cultures. *American Journal of Infection Control* 45(2):e26-e33. doi: 10.1016/j.ajic.2016.10.017.
- Ofstead, C., Wetzler, H., Snyder, A., & Horton, R. (2010). Endoscope reprocessing methods: A prospective study on the impact of human factors and automation. *Gastroenterology Nursing*, 33(4), 304-11.
- Petersen, B.T., Cohen, J., Hambrick III, R.D., Buttar, N., Greenwald, D., Buscaglia, J., ... Eisen, G. (2017). Multisociety guideline on reprocessing flexible GI endoscopes: 2016 update. *Gastrointestinal endoscopy*, 85(2), 282-294.
- Pineau, L., Villard, E., Luu Duc, D., & Marchetti, B. (2008). Endoscope drying/storage cabinet: Interest and efficacy. *Journal of Hospital Infection*, 68(1), 59-65.
- Rejchrt, S., Cermak, P., Pavlatova, L., Mickova, E., & Bures, J. (2004). Bacteriologic testing of endoscopes after high-level disinfection. *Gastrointestinal Endoscopy*. 60(1), 76-8.
- Riley, R.G., Beanland, C.J., & Bos, H. (2002). Establishing the shelf life of flexible colonoscopes. *Gastroenterology Nursing*, 25(3), 114-9.

- Roberts, C.G. (2013). The role of biofilms in reprocessing medical devices. *American Journal of Infection Control*, 41, S77-S80.
- Rutala, W.A. (2017). Duodenoscopes and endoscope reprocessing: A need to shift from disinfection to sterilization. Retrieved from <https://vtwqt464m234djrhibie88e10-wpengine.netdna-ssl.com/wp-content/uploads/2017/07/EndoReprCanada17no.pdf>
- Rutala, W.A. & Weber, D.J. (2013). New developments in reprocessing semicritical items. *American Journal of Infection Control*, 41, 560-566.
- Rutala, W.A. & Weber, D.J. (2014). Gastrointestinal endoscopes: A need to shift from disinfection to sterilization? *Journal of the American Medical Association*, 312(14), 1405-6. doi:10.1001/jama.2014.12559
- Rutala, W.A. & Weber, D.J. (2015). ERCP scopes: What can we do to prevent infections? [slide presentation, May 2015]. Retrieved from <https://disinfectionandsterilization.org/slide-presentations/>
- Rutala, W.A. & Weber, D.J. (2016). Disinfection and sterilization in health care facilities: An overview and current issues. *Infectious Diseases of North America*, 30, 609-637. <http://dx.doi.org/10.1016/j.idc.2016.04.002>
- Rutala, W.A., Weber, D.J., & the Healthcare Infection Control Practices Advisory Committee. (2008). Guideline for Disinfection and Sterilization in Healthcare Facilities. Retrieved from http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf
- Schmelzer, M., Daniels, G., & Hough, H. (2015). Safe storage time for reprocessed flexible endoscopes: A systematic review. *JBI Database of Systematic Reviews & Implementation Reports*. 13(9): 187-243. doi: 10.11124/jbisrir-2015-2307.
- Seavey, R. (2016). Processing flexible endoscopes. *Healthcare Purchasing News*, 36-38.
- Society of Gastroenterology Nurses and Associates, Inc. (SGNA). (2013). *Gastroenterology Nursing, A Core Curriculum*, (5th ed). Chicago, IL: Author.
- Society of Gastroenterology Nurses and Associates, Inc. (SGNA). (2015). *Standard of Infection Prevention in the Gastroenterology Setting*. [Practice standard]. Chicago, IL: Author.
- Society of Gastroenterology Nurses and Associates, Inc. (SGNA). (2017). *Guideline for the Use of High Level Disinfectants and Sterilants for Reprocessing of Flexible Gastrointestinal Endoscopes* [Practice standard]. Chicago, IL: Author.
- United States Food and Drug Administration (FDA). (2009). Preventing Cross-Contamination in Endoscope Processing. Retrieved from <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm190273.htm>
- United States Food and Drug Administration (FDA). (2015). Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling. Retrieved from <https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf>
- United States Food and Drug Administration (FDA). (2018). Information about Automated Endoscope Reprocessors (AERs) and FDA's Evaluation. Retrieved from <https://www.fda.gov/MedicalDevices/ucm483896.htm>
- United States Department of Labor, Occupational Safety & Health Administration (OSHA). (2012). Occupational Safety and Health Standards, Toxic and Hazardous, Blood-Borne Pathogens. Substances 29 CFR 1910.1030. Retrieved from https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS
- Visrodia, K.H., Ofstead, C.L., Yellin, H.L., Wetzler, H.P., Tosh, P.K., & Baron, T.H. (2014). The use of rapid indicators for the detection of organic residues on clinically used

gastrointestinal endoscopes with and without visually apparent debris. *Infection Control and Hospital Epidemiology*, 35(8), 987-994.

Wardle, B. (2007). Endoscope storage cabinets. *Journal Gastroenterological Nurses College of Australia*, 17(3): 5-11.

Recommended Reading

Alfa, M. & Howie, R. (2009). Modeling microbial survival in buildup biofilm for complex medical devices. *BMC Infectious Diseases* 2009, 9, 56.

Alfa, M., Olson, N., DeGagne, P., & Simner, P. (2012). Development and validation of rapid use scope test strips to determine the efficacy of manual cleaning for flexible endoscope channels. *American Journal of Infection Control*, 40, 860-865.

Alfa, M.J. & Sitter, D.L. (1991). In-hospital evaluation of contamination of duodenoscopes: A quantitative assessment of the effect of drying. *Journal of Hospital Infection*, 19(2), 89-98.

Alvarado, C.J. & Reichelderfer, M. (2000). APIC guideline for infection prevention and control in flexible endoscopy. *American Journal of Infection Control*, 28(2), 138-55.

American Society for Gastrointestinal Endoscopy. (2001). Transmission of infection by gastrointestinal endoscopy. *Gastrointestinal Endoscopy*, 54(6), 824-828.

Association for the Advancement of Medical Instrumentation. (2010). *Chemical Sterilization and High Level Disinfection in Health Care Facilities* (Revision of ANSI/AAMI ST58: 2005 ® 2010). Arlington, VA: Author.

Association for Professionals in Infection Control and Epidemiology, Inc. (APIC) (2017). Existing reprocessing techniques prove insufficient for flexible endoscopes. <https://apic.org/For-Media/News-Releases/Article?id=33d39d06-6a7a-4d54-9fac-02688ce21120>

Bisset, L., Cossart, Y.E., Selby, W., West, R., Catterson, D., O'Hara, K., & Vickery, K. (2006). A prospective study of the efficacy of routine decontamination for gastrointestinal endoscopes and the risk for failure. *American Journal of Infection Control*, 34(5), 274-280.

Fang, Y., Shen, Z., Li, L., Cao, Y., Gu, L-Y., Quing, G., ... Li, Y-M. (2010). A study of the efficacy of bacterial biofilm cleanout for gastrointestinal endoscopes. *World Journal of Gastroenterology*, 16(8), 1019-24.

Miner, N., Harris, V., Ebron, T., & Cao, T. (2007). Sporidical activity of disinfectants as one possible cause for bacteria in patient ready endoscopes. *Gastroenterology Nursing*, 30(4), 285-290.

Nelson, D.B. (2005). Recent advances in epidemiology and prevention of gastrointestinal related infections. *Current Opinions in Infectious Diseases*, 8, 326-30.

Nelson, D.B. & Muscarella, L.F. (2006). Current issues in endoscope reprocessing and infection control during gastrointestinal endoscopy. *World Journal Gastroenterology*, 12(25), 3953-3964.

Ren, W., Sheng, X., Huang, X., Zhi, F., & Cai, W. (2013). Evaluation of detergents and contact time on biofilm removal from flexible endoscopes. *American Journal of Infection Control*, 41, e89-e92.

Ren-Pei, W., Hui-Jun, X., Ke, Q., Dong, W., Xing, N., & Zhao-Shen, L. (2014). Correlation between the growth of bacterial biofilm in flexible endoscopes and endoscope reprocessing methods. *American Journal of Infection Control*, 42, 1203-1206.

Rey, J.F., Bjorkman, D., Duforest-Rey, D., Axon, A., Saenz, R., Fried, M., ... Krabshuis, J.H. (2005). WGO and OMED Practice Guideline: Endoscope Disinfection. Retrieved from <http://www.worldgastroenterology.org/assets/downloads/en/pdf/guidelines/>

09_endoscope_disinfection_en.pdf

- Rutala, W.A. (1996). APIC guideline for selection and use of disinfectants. *American Journal of Infection Control*, 24, 313-342.
- Rutala, W.A. & Weber, D.J. (2010). SHEA: Guideline for disinfection and sterilization of prion-contaminated medical instruments. *Infection Control and Hospital Epidemiology* (31)2.
- Saum, E. (2005). Evaluation of the efficacy of an endoscope drying/storage cabinet, Lancer Model FD8. *Institute of Decontamination Science (IDSc) Journal*. 10(1), 4.
- Soares, J.B., Goncalves, R., Banhudo, A., & Pedrosa, J. (2011). Reprocessing practice in digestive endoscopy units of district hospitals: Results of a Portuguese national survey. *European Journal of Gastroenterology and Hepatology*. 23(11), 1064-8.
- Society of Gastroenterology Nurses and Associates, Inc. (SGNA). (2013). *Reuse of Single-Use Critical Medical Devices*. [Practice standard]. Retrieved from https://www.sgna.org/Portals/0/Education/PDF/Position-Statements/SGNA_SUD_Position_Statement.pdf
- Society of Gastroenterology Nurses and Associates, Inc. (SGNA). (2016). *Reprocessing of Flexible Gastrointestinal Endoscopes* [DVD]. Chicago, IL: Author.
- Walter, V. (1996). Reprocessing of flexible gastrointestinal endoscopes: An American Society for Gastrointestinal Endoscopy white paper. *Gastroenterology Nursing*, 19(3), 109-112.
- World Health Organization. (2004). Practical guidelines for infection control in health care facilities. Retrieved from http://www.preventionweb.net/files/1965_VL206322.pdf