

Standards of Infection Prevention in Reprocessing Flexible Gastrointestinal Endoscopes



Society of Gastroenterology Nurses and Associates, Inc.

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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. They were developed to complement documents developed by the American Society for Gastrointestinal Endoscopy (ASGE), Association for Professionals in Infection Control and Epidemiology (APIC), and SGNA. The current version complements SGNA's *Guideline for the Use of High Level Disinfectants and Sterilants for Reprocessing of Flexible Gastrointestinal Endoscopes* (2013) and the new SGNA *Standard of Infection Prevention in the Gastroenterology Setting* (2015).

Proper reprocessing of endoscopes and accessories is critical to the safe and successful treatment of patients. Although endoscopes reprocessed in accordance with manufacturer's reprocessing instructions and infection prevention guidelines pose low risk of transmission of patient-borne or environmental microorganisms, any deviation from the reprocessing protocol can lead to the survival of microorganisms and increased risk of infection (ASGE, 2014; Rutala & Weber, 2015). In the absence of defective equipment, every reported case of hospital acquired infection associated with a contaminated gastrointestinal (GI) endoscope has been linked to a breach or violation of at least one of several requisite reprocessing steps (Koveleva, Peters, van der Mei, & Degener, 2013; Ofstead, Wetzler, Snyder, & Horton, 2010; Petersen et al., 2011).

Drug-resistant infection outbreaks have recently occurred and have been traced to endoscopes that were reprocessed following strict adherence to reprocessing procedures (FDA, August 4, 2015). The outbreaks were specifically related to duodenoscopes used for endoscopic retrograde cholangiopancreatography (ERCP). The elevator channel was found to be particularly difficult to clean and required additional cleaning steps.

In response to the problems with duodenoscope reprocessing, the U.S. Food and Drug Administration (FDA) provided a list of supplemental duodenoscope reprocessing measures (2015), and the CDC released an official health advisory alerting health care facilities to review their reprocessing procedures (September 11, 2015).

The FDA listed supplemental measures to consider when reprocessing duodenoscopes, including microbiological culturing, ethylene oxide sterilization, use of a liquid chemical sterilant, and repeated high-level disinfection (August 4, 2015). They recommended that health care facilities performing ERCP evaluate whether they have the resources necessary to perform these options but did not mandate any changes at the time this document was published.

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 (*Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes*) does not address gas sterilization, it is important to note that 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 and 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 removal of all soil and organic material. 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], 2013).

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

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.

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).

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

Material Safety Data Sheet (MSDS) refers to a descriptive sheet that accompanies a chemical or chemical mixture and provides information 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.

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; Food and Drug Administration (FDA), 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; FDA, 2015; OSHA, 2012).

Reprocessing refers to the validated process of cleaning then disinfecting, or sterilizing endoscopes and accessories. 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 scope 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, 2010).

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

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.

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 understand 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., 2011; 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. 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 high-level disinfection with an FDA-approved high-level disinfectant (Petersen et al., 2011; 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.

Increased awareness of the challenges in reprocessing has occurred because of high-profile reprocessing breaches that may have exposed patients to bloodborne pathogens and confirmed outbreaks of bacterial infections that are resistant to even the most powerful antibiotics. The true rate of transmission during endoscopy may go unrecognized because of inadequate or nonexistent surveillance, difficulty connecting an infection to endoscopy because of the passage of time, and absence of clinical symptoms (Rutala & Weber, 2015).

Reprocessing is highly effective when used appropriately, but several factors impact its effectiveness (Edmiston & Spencer 2014; Dirlam Langlay, Ofstead, Mueller et al., 2014; Petersen et al., 2011; Rutala & Weber, 2015). These factors can be considered in relation to the endoscope itself, the reprocessing personnel, the reprocessing steps, and the equipment.

Factors related to the endoscope itself 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);
- A variety of endoscope models that require different cleaning procedures, brushes, etc.; and

- Occult damage (e.g. scratches, crevices) that sequester microorganisms and promote biofilm.

Personnel factors that influence the quality of reprocessing include:

- Lack of knowledge or unfamiliarity with endoscope channels, accessories, and specific steps (Peterson et al., 2011);
- Inadequate number of staff to support volume, workflow, and throughput;
- Frequent disruptions or interruptions during reprocessing (AAMI, 2015);
- Inadequate training;
- Limited accountability; 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., precleaning, manual cleaning);
- Lag time or delay in reprocessing;
- Inadequate enzymatic concentration, temperature, or time;
- Inappropriate use of HLD (e.g. wrong concentration or temperature, expired reuse life, inadequate exposure time) (Dirlam Langlay, Ofstead, Mueller et al., 2014);
- Inadequate concentration because the endoscope was not dried adequately and excess water diluted HLD;
- Inadequate cleaning prior to HLD;
- 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 (e.g., with flushing pumps or AERs);
- Use of incorrect connectors for flushing aids or AERs; and
- Unrecognized problems with water supply.

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 following pages address factors that 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 should accomplish the following:

- Understand the rationale and importance of each step in reprocessing;
- Be able to read, understand, and implement the manufacturer's instructions on the proper cleaning and high-level disinfection of gastrointestinal endoscopes and accessories (ASTM International [ASTM], 2007; AAMI, 2010);
- Demonstrate competency for all steps of endoscope reprocessing, including proper use of automatic endoscope reprocessing systems and other equipment at least annually (AAMI, 2015; AORN, 2015; Petersen et al., 2011; Rutala & Weber, 2014);
- 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; AORN, 2015);
- Complete all endoscope reprocessing meticulously and efficiently, maintaining strict adherence to reprocessing protocol (Edmiston & Spencer, 2014).
- Immediately report any breaches in reprocessing according to facility policies and protocols.
- Understand the safety hazards of endoscope reprocessing and take appropriate action to protect oneself and others.

NOTE: 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., 2011).

Management

Individuals involved in facility management contribute to the effectiveness and safety of endoscope reprocessing. Their responsibilities include:

- Allowing adequate time for endoscope reprocessing to ensure adherence to all reprocessing steps recommended by the manufacturer (CDC, 2015);
- Ensuring availability of adequate staff to support meticulous and timely reprocessing;
- Having facility protocols to ensure that health care personnel can readily

identify endoscopes that have been properly reprocessed and are ready for use (CDC, 2015);

- Ensuring that the reprocessing protocol is reviewed and updated according to institutional policy;
- Consulting with individuals responsible for infection prevention and reprocessing when considering modifications to the reprocessing protocol and when purchasing new reprocessing equipment (CDC, 2015);
- Conducting an annual review of policies and competencies to ensure compliance with current standards and manufacturers' guidelines;
- Maintaining 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, naming individual patients who could be at risk (Weber & Rutala, 2013);
- Following manufacturers' guidelines for maintenance and repair of endoscopes and equipment used for reprocessing (e.g. AER) (CDC, 2015);
- Ensuring that all staff involved in endoscope reprocessing are identified, well trained, and demonstrate initial and continued competency.
- Ensuring that decisions made in each endoscopy setting consider the number and category of personnel that will be responsible for instrument reprocessing;
- Having policies and procedures detailing the facility's response to a reprocessing error (CDC, 2015);
- Observing staff for adherence to policies and protocols, possibly using an environmental tour checklist for endoscope reprocessing areas (Joint Commission, 2014).

Quality Assurance

Quality assurance is essential to the continued safety and effectiveness of endoscope reprocessing. Health care facilities must have documentation that 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,
- names of individuals who reprocessed the endoscope (Peterson et al., 2011).

Other documentation essential for infection control includes information and audits about reprocessing activities, equipment performance and maintenance records, and records verifying that high-level disinfectants were tested and replaced appropriately. Audits should monitor all reprocessing steps and

provide feedback to personnel regarding their adherence to cleaning and disinfection procedures (CDC, 2015).

Health care facilities must have policies and procedures detailing the response to any suspected or identified breaches in reprocessing (CDC, 2015). The procedure should indicate how the potentially affected patients should be identified, notified, and followed.

Routine culturing of endoscopes following reprocessing is not currently recommended in the United States but may be considered in the event of an identified outbreak (Petersen et al., 2011). Surveillance cultures can be used as a method for assessing reprocessing quality (Frohlich, Leiss, & Muller, 2013; Kovaleva, Peters, van der Mei, & Degener, 2013; Rutala & Weber, 2015) and aid in identifying particular endoscope defects that hamper effective reprocessing (Buss et al., 2007; Rutala & Weber, 2015). Facilities should be aware of recent interim guidelines and consider culturing duodenoscopes to validate the cleaning process of these particular scopes (CDC, 2015).

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). Refer to the *SGNA Standards of Infection Prevention in the Gastroenterology Setting* for more details on environmental cleaning.

The reprocessing room is a designated area that is dedicated to reprocessing. It must be a room that is 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, work surfaces, lighting, adequate utilities such as electrical support and water, hand washing and eye washing facilities, air drying capability, and storage. Tap water and/or water that has been filtered by passage through a 0.2 micron filter or water of equivalent quality (i.e., suitable for drinking) should be available in the reprocessing area (Petersen et al., 2011). Bottled sterile water may be used.

A Food and Drug Administration (FDA) cleared high-level disinfectant or sterilant and 70% isopropyl alcohol are needed in the reprocessing room for high-level disinfection. An EPA-registered hospital-grade disinfectant should be used

for surface cleaning appropriate for the specific microorganism (ASGE, 2014).

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 MSDS;
- 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 in the safe handling of high-level disinfectants or sterilants and spill containment procedures. Refer to the manufacturer's instructions for information on the specific solution.

Reprocessing Accessories

Refer to the manufacturer's guidelines for specifics on reprocessing of endoscopic accessories. The FDA requires the manufacturers of reusable devices to provide instructions for cleaning and high-level disinfection or sterilization (Petersen et al., 2011). 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: *Reuse of Single-Use Critical Medical Devices*.

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. More specific information is found in the individual endoscope manufacturer's instructions that include specific reprocessing details for the unique endoscope design.

It is imperative that reprocessing personnel be intimately familiar with the manufacturer's instructions for each endoscope that they are responsible for reprocessing and follow the instructions exactly. They must also know which AERs, high-level disinfectants, etc. are compatible with a particular endoscope and use the equipment and products according to the manufacturer's instructions (SGNA, 2013).

Everyone involved in reprocessing must be up-to-date on current issues related to endoscopy and reprocessing, as well as information provided by regulatory agencies, manufacturers' instructions, and institutional policies. A readily

available source of current information is the SGNA Resource on Quality and Safety found on the SGNA website.

Endoscope reprocessing includes the following steps (Alfa, 2013; AAMI, 2015; Petersen et al., 2011; Gastroenterological Society of Australia [GESA] & Gastroenterological Nurses College of Australia [GENCA], 2010):

1. Precleaning;
2. Leak testing;
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.

Note: Visual inspection is usually included within manual cleaning and not listed as a separate step. However, due to the recent issues with reprocessing, visual inspection warrants its own step. It may be considered a “time out” or safety stop to verify that the endoscope is at least visually clean before proceeding to HLD. It follows the rule that an item must be cleaned prior to HLD, with all endoscope surfaces coming in contact with the disinfectant solution, to ensure that all organic material is removed. Although more reliable methods are being developed to verify thorough cleaning, visual inspection remains an important step. This step is covered in detail below.

The nine steps are discussed in the following sections.

1. PRECLEANING

Precleaning 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. Precleaning 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. Precleaning should be performed at point of use, before bioburden has an opportunity to dry and before complete decontamination (Miner, 2013; Petersen et al., 2011).

a. Necessary supplies include:

- 1) Personal protective equipment (at a minimum gloves, eye protection, impervious gown, 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.
- b. 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. Note that the cloth/sponge should be disposed of, sterilized, or high-level disinfected between cases (Peterson et al., 2011; Rutala & Weber, 2004).
 - c. 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., 2011). Finish by suctioning air.
 - d. Flush and manipulate the forcep elevator of duodenoscope or EUS scope per the manufacturer's instructions.
 - e. Flush air and water channels in accordance with the endoscope manufacturer's instructions.
 - f. Flush the auxiliary water channel per the manufacturer's instructions.
 - g. Detach the endoscope from the light source and suction pump.
 - h. Attach protective video cap if using video endoscope.
 - i. Transport the soiled endoscope to the reprocessing area in a closed container that prevents exposing staff, patients, or the environment to potentially infectious organisms (Petersen et al., 2011). The transport container must be labeled to indicate biohazardous contents (ASGE, 2011; AAMI, 2015). Containers should be large enough to prevent damage to the endoscope by being coiled too tightly.

Note: THE FOLLOWING STEPS OCCUR IN THE REPROCESSING AREA

Have the following available:

- a. Personal protective equipment (at minimum gloves, eye protection, impervious gown, face shield, or simple surgical mask that will not trap vapors);
- b. Leak-testing equipment;
- c. Channel cleaning adapters (per the manufacturer's instructions);
- d. Large basin or sink;
- e. Detergent solution prepared according to the manufacturer's

instructions;

- f. Appropriate size channel cleaning brushes;
- g. Sponge and/or lint-free cloth;
- h. Automated flush pump device where applicable; and
- i. Magnifying glass, if desired.

2. LEAK TESTING

Leak testing detects damage to the interior or exterior of the endoscope. 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 manufacturer's 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. Note that the endoscope must be completely disassembled so that all surfaces may be reached for thorough cleaning. Literature suggests that reusable buttons and valves be reprocessed and stored together with the endoscope as a unique set for tracking purposes (British Society of Gastroenterology [BSG], 2014).
- 3) Attach the leak tester and pressurize the scope 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 scope in all directions, observing for bubbles. Depress the freeze and release buttons while observing the control head of the scope for bubbles. Check the insertion tube, distal bending section, and universal cord for bubbles coming from the interior of the scope.

- 6) Remove the endoscope from 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 removal of leak tester. Continue with the reprocessing steps when the test is complete unless a leak is detected.

If a leak has been identified or detected, follow the endoscope manufacturer's instructions on how to proceed.

3. MANUAL CLEANING

Manual cleaning of endoscopes is necessary prior to automated/manual high-level disinfection or sterilization. **This is the most important step in removing the microbial burden from an endoscope.** 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). Manual cleaning and thorough brushing of channels are required even when AER manufacturers claim that manual cleaning is unnecessary (FDA, 2009).

The composition of soil found on endoscopes includes proteins, fats, carbohydrates, and the various chemical salts that exist in blood and other body fluids. Ideally, a cleaning solution should have a broad spectrum of effectiveness against these various contaminants and not harm the device being cleaned. Enzymatic cleaning solutions use surfactants to break down and digest bioburden.

Manual cleaning follows these steps:

- a. Fill a sink or basin with freshly-made solution of water and a medical grade, low-foaming, neutral pH detergent formulated for endoscopes that may or may not contain enzymes (ASTM, 2007; Marion et al., 2006).
- b. Dilute and use the detergent according to the manufacturer's instructions. Note that:
 - 1) Freshly prepared detergent solution should be used for each endoscope to prevent cross-contamination.
 - 2) Low-foaming detergents are recommended such that the device can be clearly visualized during the cleaning process, preventing personnel injury and allowing for complete cleaning of lumen surfaces.
 - 3) Endoscopes exposed to synthetic lipids may require additional cleaning with a detergent formulated to remove synthetic lipids.
- 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 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.
- 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 endoscopy 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., 2011; 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 (EUS) 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. Note that reusable brushes should 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.
- k. Attach the endoscope manufacturer's cleaning adapters for suction, biopsy, air, and water channels. Note: 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 latest manufacturer's instructions for specific steps.

- m. Flush all channels with the detergent solution to remove debris.
- n. Soak the endoscope and its internal channels for the period of time specified by the label.

Note: All steps should be completed sequentially and immediately following the procedure. **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 AER's that provide this feature.

5. VISUAL INSPECTION

Visual inspection is recommended to make sure the endoscope is visibly clean (AAMI, 2015; Rutala et al., 2008). It 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).
- c. Repeat manual cleaning step(s) if not clean.

Note: It is impossible to visualize internal channels. 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 high-level disinfection (Visrodia et al., 2014). If the tool results are positive, this allows

for the re-cleaning of the endoscope prior to disinfection. The frequency of the testing should be determined by the individual institutions (Alfa et al., 2013, 2014; AAMI, 2015; ASGE, 2014).

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), and ASTM International. Agencies such as the Centers for Disease Control and Prevention (CDC) and the Joint Commission (JC) recognize HLD as appropriate for gastrointestinal endoscopes. Sterilization of endoscopes is indicated in the rare occasions when it is used as a critical medical device, where there is potential for contamination of an open surgical field (Petersen et al., 2011) or per individual institutional policy.

HLD destroys all viable microorganisms, but not necessarily all bacterial spores (Rutala & Weber, 2013).

The effectiveness of the high-level disinfectant depends on:

- Effective precleaning, manual cleaning, and rinsing to decrease the organic load and microbial content of the endoscope;
- Drying after rinsing to avoid diluting the HLD; and
- Proper preparation and use (in accordance with the manufacturer's directions).

It is essential that the level of active ingredient in the HLD 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). Because most high-level disinfectants/sterilants are typically reused, they must be tested to assure that they remain above their minimum effective concentration (MEC) (AAMI, 2015; Rutala et al., 2008).

Test and monitor the disinfectant before each load/use by following 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. The MEC may never be used beyond the date specified on activation (AAMI, 2015; Rutala et al., 2008). High-level disinfectants and sterilants must be changed when the solutions fail to meet minimum effective concentration or exceed the high-level disinfectants' manufacturer's recommended reuse life, whichever comes

first (AAMI, 2015; AORN, 2015; ASGE, 2008; Petersen et al., 2011). Follow the manufacturer's instructions when the MEC of the product has failed by test strip.

Use a product-specific test strip to test the MEC and follow the directions on the test strip container. Some chemical test strips recommend the use of quality-control procedures to ensure the strips perform properly; if recommended, the user should follow the manufacturer's instructions (Rutala et al., 2008).

In addition, there should be an established program for monitoring occupational exposure to regulated chemicals (e.g., formaldehyde, EtO), which adheres to state and federal regulations (Rutala et al., 2008). For additional information, refer to SGNA's *Guideline for the Use of High Level Disinfectants and Sterilants for Reprocessing of Flexible Gastrointestinal Endoscopes* (2013). Maintain MSDS for all chemicals used for cleaning and disinfection. It is recommended that MSDS sheets be used for training staff on each chemical's safe use (ASGE, 2014).

HLD can be achieved either manually or automated 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 HLD.

- 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) and must have a tight-fitting lid to contain the chemical vapors (AAMI, 2010; Peterson et al., 2011).
 - 2) To prevent damage to the endoscope, 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. Take care that all channels are filled with the chemical and that no air pockets remain within the channels. Note that:
 - 1) Complete microbial destruction cannot occur unless all surfaces are in complete contact with the chemical (FDA, 2009).
 - 2) Since internal contact cannot be visually confirmed because of scope design, purging until a steady flow of solution observed is

necessary.

- c. Cover the soaking basin with a tight-fitting lid to minimize chemical vapor exposure. Note that:
 - 1) Exposure to chemical vapors may present a health hazard.
 - 2) The reprocessing area should 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 (e.g. leaving a scope to soak overnight).
- e. Purge all channels completely with air before removing the endoscope from the high-level disinfectant/sterilant. Note that purging the channels preserves the concentration and volume of the chemical, and prevents exposure from dripping and spilling.
- f. Go to reprocessing step #7 **RINSE AFTER HIGH LEVEL DISINFECTION** to complete this process, followed by drying, alcohol flush, and storage.

6B. AUTOMATED REPROCESSING

Endoscope reprocessors standardize the disinfection process and decrease personnel exposure to high-level disinfectants (ASGE, 2010; Kovaleva et al., 2013).

The FDA has approved labeling some AERs as washer-disinfectors, which do not require prior manual cleaning and channel brushing. While the introduction of automated, brushless washing of endoscope channels represents a potentially significant advancement, the existing multi-society guideline (Petersen et al., 2011) and other international standards emphasize that manual cleaning and brushing are still necessary when a washer-disinfector is used in order to assure the overall efficacy of HLD. The redundancy achieved by adding an automated washing step following manual cleaning can undoubtedly provide an extra level of safety. Users are cautioned about dispensing with manual cleaning endoscope reprocessing and brushing steps before the capabilities of the new machines are confirmed in independent studies and in clinical practice (Alfa, Olson, & DeGagne, 2006; ASGE, 2008). Further studies in clinical settings are warranted for these technologies (Petersen et al., 2011).

If an automated endoscope reprocessor (AER) is used, ensure that the endoscope and endoscope components can be effectively reprocessed with the AER (e.g., because the elevator wire channel of duodenoscopes is not effectively disinfected by most AERs, this step 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. Follow the manufacturer's instructions to ensure exposure of all internal surfaces with the high-level disinfectant solution.

If the machine has a cycle that uses enzymatic detergent, it should be a product that is compatible with the reprocessor and the endoscope. Note that 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 or sterilant.

If the AER cycle is interrupted, HLD or sterilization cannot be ensured; therefore, the cycle should be repeated (Peterson et al., 2011). A preventive maintenance plan should be in place for all automated reproprocessors, equipment, and accessories used to reprocess endoscopes. Quality controls recommended by manufacturers of AERs 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.

In addition, a method to automatically store or print data verification of cycle completion is desirable.

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.
 - 1) The elevator channel of a duodenoscope has a very small lumen.

Since most automated reprocessors cannot generate the pressure required to force fluid through the lumen, a 2 ml-5 ml syringe must be used to manually reprocess (all steps) the elevator channel (Rutala & Weber, 2011; Rutala et al., 2008) unless the AER is validated to perfuse this channel.

- 2) Users should check with their endoscope manufacturer for model-specific information such as the elevator position on duodenoscopes during HLD.
- d. 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.
- e. Set the machine for the appropriate time and temperature, depending on the chemical used.
- f. Start the machine, and allow it to complete all cycles/phases. Note that, if cycles/phases are interrupted, HLD cannot be ensured and the full cycle must be repeated.
- g. 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 elevator and elevator channel must be manually flushed and dried per the manufacturer's instructions.

Do not allow the endoscope that has completed reprocessing 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 manufacturer's recommendations. Note that:

- a. Rinsing prevents exposure and potential injury of skin and mucous membranes from chemical residue.
- b. Fresh clean water should be used for each rinse of the endoscope.
- c. Rinsing is required for manual high level disinfection but may be completed in the AER. Refer to the manufacturer's instructions.

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). Drying the endoscope after every reprocessing cycle, both between patient procedures and before storage, is a requisite practice crucial to the prevention of bacterial transmission and nosocomial infection. Drying is as important to the prevention of disease transmission and nosocomial infection as cleaning and HLD (Kovaleva et al., 2013; Muscarella, 2006).

Alfa and Sitter (1991) demonstrated that endoscopes that had been dried with compressed air for 2 minutes were colonized with over 10 million units of gram-negative bacteria after 48 hours of storage, but endoscopes that had undergone 10 minutes of forced air drying had no microbial growth after 48 hours.

Alcohol will displace 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.

In order to ensure that endoscopes are thoroughly dried, they must be flushed with 70% to 90% isopropyl alcohol and dried with pressurized, filtered, air (either by AER or manually) (Kovaleva et al., 2013; Peterson et al., 2011; Rutala et al., 2008). Follow the manufacturer's instructions for specific AER, endoscope model, and channel.

- a. Flush all channels with 70% isopropyl 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. Note that

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. Once there is confirmation that an endoscope has been properly reprocessed, it is suggested that a system exist for identifying scopes that are clean and ready to use (CDC, 2015).

9. STORAGE

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 by physical impact. Endoscopes should be stored in accordance with the endoscope and storage cabinet manufacturers' IFU.

Two major types of storage cabinets exist: conventional cabinets and drying cabinets. Conventional cabinets are favored in the United States, and drying cabinets are used mainly in Europe and Australia.

Drying cabinets are designed to control air quality and humidity, and access to endoscopes (Courné & Geyssens, 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.

Length of storage is a controversial issue. 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 recent systematic review concluded that endoscopes can be stored for 7 days if they have been effectively reprocessed to remove all pathogens and almost all other microorganisms, 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 disinfected.
- 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. Literature suggests that reusable buttons and valves should be reprocessed and stored together with the endoscope as a unique set for tracking purposes (BSG, 2014).
- 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.

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;
- Most efficient drying methods;
- Water quality, and
- Standardized quality monitoring to validate effective cleaning and reprocessing.

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