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## Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes

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### Acknowledgments

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### Preface

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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. These standards were originally developed to complement the 1996 position statement *Reprocessing of Flexible Gastrointestinal Endoscopes* published by SGNA and the American Society for Gastrointestinal Endoscopy (ASGE), and serve as the interpretive document for the 1994 guidelines of the American Society for Testing and Materials (ASTM) F 1518, *Standard Practice for Cleaning and Disinfection of Flexible Fiberoptic and Video Endoscopes Used in the Examination of the Hollow Viscera*. The current version complements SGNA's 2000 *Guidelines for the Use of High Level Disinfectants and Sterilants for Reprocessing of Flexible Gastrointestinal Endoscopes*.

Proper reprocessing of endoscopes and accessories is critical to the safe and successful treatment of patients. SGNA and ASGE support increased research in the areas of endoscope design and encourage manufacturers to develop flexible gastrointestinal endoscopes that can be easily disassembled for reprocessing and verification of cleaning and high level disinfection. The use of non-immersible endoscopes is no longer acceptable because endoscopes which cannot be completely immersed in liquid cannot be adequately cleaned and high-level disinfected.

### Personnel

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Only individuals who are able to read, understand, and implement instructions on the proper cleaning and high level disinfection of gastrointestinal endoscopes and accessories should be given the responsibility to reprocess such instruments. In addition, these individuals must meet annual competency standards for endoscope reprocessing. Temporary personnel should not be allowed to clean or disinfect instruments in either a manual or an automated reprocessing system.

## Education and Training

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All staff in any setting where gastrointestinal endoscopy is performed must adhere to infection control principles that will maintain a safe environment, free from the possibility of spreading disease to patients and coworkers. This is true regardless of the setting, that is, hospital, clinic, or office, or the variety of gastrointestinal (GI) procedures performed.

Infection control education is a critical part of the orientation and continuing education for all personnel, including physicians, nurses, and assistive personnel who work in the gastrointestinal endoscopy setting. Components of this education program should include the following: (1) universal precautions; (2) Occupational Safety and Health Administration (OSHA) rules on occupational exposure to bloodborne pathogens (OSHA Law 29 CFR part 1910); (3) reprocessing procedures for endoscopes and accessory equipment; (4) mechanisms of disease transmission; (5) maintenance of a safe work environment; (6) safe handling of high level disinfectants and sterilants; and (7) procedures for waste management. Additional training with documented competency must be done for new models of endoscopes or automatic endoscope reprocessors as they are introduced in the facility. Annual updates are recommended to ensure compliance with current standards and manufacturers' guidelines.

Decisions must be made in each endoscopy setting regarding the number and category of personnel who will be responsible for instrument reprocessing. All persons involved must be properly trained and their performance subject to periodic review and continuing education. All individuals who reprocess endoscopes and accessories require detailed knowledge of the instruments and specific methods required to produce an instrument safe for use. This knowledge is developed through repetition and the guidance of a preceptor. There should be documentation of completion of the initial infection control orientation/reprocessing competency and subsequent annual competency review and infection control update for each individual who reprocesses instruments. (See Appendices I and II, Sample Formats for Reprocessing Competency.)

## Quality Assurance

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Each setting where gastrointestinal endoscopy is performed must have an effective quality assurance program with special emphasis on cleaning and high level disinfection of flexible endoscopes. Elements of the quality assurance program include supervision, training, annual competency review, methods of assuring the availability of appropriate equipment and supplies, and procedures for reporting infections.

Supervisory personnel must be familiar with the principles and practices of instrument reprocessing if they are to properly train and monitor staff. Knowledgeable supervisors also serve to impress upon peer groups and subordinates the importance of these functions.

There must be a policy of invariable adherence to the reprocessing protocol. The protocol and its implementation should be reviewed periodically to assure that it is being followed routinely and that there is no new information that would require a modification. Modifications should be made with care. Consultation with an infection control advisor should be considered when modifications to the reprocessing protocol are made. The review process and protocol modifications should be documented.

There should be a designated individual in the endoscopy setting assigned to monitor compliance with the reprocessing protocol. The understanding and performance of each individual involved in reprocessing should be reviewed at least annually.

Monitor reusable high-level disinfectants and sterilants for minimum effective concentrations at least each day of use. A log of results should be maintained. High-level disinfectants and sterilants must be changed when the solutions fail to meet minimum effective concentration or exceed the manufacturers' recommended use life, whichever comes first.

Document monitoring of high-level disinfectant and sterilant vapor levels annually and when a change in the disinfection phase of the reprocessing protocol occurs, when a different high-level disinfectant or sterilant is used, or when a staff member exhibits symptoms of overexposure. For details, refer to SGNA's Guideline for the Use of High Level Disinfectants and Sterilants for Reprocessing of Flexible Gastrointestinal Endoscopes.

A preventive maintenance plan should be in place for all automated reprocessors. Quality controls recommended by manufacturers should be adhered to and documented.

Report any suspected or identified infections to those responsible for infection control in the endoscopy setting. Performing routine cultures of endoscopes is not recommended but may be done in the event of an identified outbreak.

## Procedure Rooms

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To prevent cross-contamination in an endoscopic procedure room, 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.

Negative pressure rooms or rooms with air circulated through high-efficiency particulate air (HEPA) filters are recommended when endoscopy is performed on patients with known or suspected tuberculosis.

## Reprocessing Room

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Reprocessing of contaminated patient equipment should be done in an area designated and dedicated for this function. This should be a room separate from where endoscopic procedures are performed. Current local and state codes and federal guidelines should be incorporated in 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, handwashing 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. Bottled sterile water may be used.

Reagents needed for reprocessing include a low-sudsing, enzymatic detergent formulation recommended for endoscopes, a Food and Drug Administration (FDA)-cleared high-level disinfectant or sterilant, and 70% isopropyl alcohol. An EPA-registered hospital-grade disinfectant should be used for surface cleaning.

### High-Level Disinfectant or Sterilant Spill Containment Plan

Each endoscopy setting should have a spill containment plan specific for the high-level disinfectant or sterilant used. The information from the specific Material Safety Data Sheet should be incorporated into the plan. The plan should include written procedures for actions to contain the spill and deactivate the chemical, an intra- and inter-departmental communication plan, and an evacuation plan. Upon assignment to the department and annually thereafter, all persons working in the setting must be trained on 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.

## Accessories

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The FDA requires manufacturers of reusable devices to provide instructions for cleaning and high-level disinfection or sterilization. Refer to the manufacturer's guidelines for specifics on reprocessing of endoscopic accessories. Accessories which are classified as critical devices (break the mucus membrane and/or come into contact with sterile tissue or the vascular system) require sterilization. Critical items labeled for single-use should not be reprocessed and/or reused.

# Reprocessing Protocol

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The reprocessing protocol presented here outlines basic steps to clean and perform high level disinfection of gastrointestinal endoscopes. Manufacturers' instructions should always be consulted for design features unique to a particular instrument, which require specific reprocessing detail.

While this protocol specifically addresses gastrointestinal endoscopes, its steps may be applied to reprocessing other types of flexible endoscopes.

## 1. PREPARING THE ENDOSCOPE FOR CLEANING

The initial steps in the reprocessing protocol begin in the patient room immediately after removal of the insertion tube from the patient and prior to disconnecting the endoscope from the power source.

- **Have the following available:**
  - Personal protective equipment (gloves, eye protection, impervious gown, face shield or simple surgical mask that will not trap vapors).
  - Container with enzymatic detergent solution.
  - Sponge or soft, lint-free cloth.
  - Air and water channel cleaning adapters per manufacturer's instruction.
  - Protective video caps (if using video endoscopes).
- Immediately after removing the endoscope from the patient, wipe the insertion tube with the wet cloth or sponge soaked in the freshly prepared enzymatic detergent solution.
  - Dispose of the cloth/sponge between cases.
- Place the distal end of the endoscope into the enzymatic detergent solution. Suction the solution through the biopsy/suction channel until the solution is visibly clean. Alternate suctioning detergent solution and air several times. Finish by suctioning air.
  - Alternate suctioning of fluid and air is more effective than suctioning fluid alone in the removal of debris from internal lumens.
  - Immediate flushing of the biopsy/suction and air/water channels precludes drying of organic and inorganic debris on lumen surfaces and may remove large numbers of microorganisms.
- Flush or blow out air and water channels in accordance with the endoscope manufacturer's instructions.
- Detach the endoscope from the light source and suction pump.
- Attach protective video cap (if using video endoscope).
- Transport the endoscope to the reprocessing area in an enclosed container
  - Containers, sinks and basins should be large enough that the endoscope will not be damaged by being coiled too tightly.
  - A container will prevent contamination during transport.
  - Reprocessing should occur in a room separate from the procedure room.

## 2. CLEANING THE ENDOSCOPE IN THE REPROCESSING AREA

- Have the following available:
  - Personal protective equipment (gloves, eye protection, impervious gown, face shield or simple surgical mask that will not trap vapors)
  - Leak-testing equipment
  - Channel cleaning adapters (per manufacturer's instructions)

- Large basin of enzymatic detergent solution prepared according to manufacturer's instructions Channel cleaning brushes
- Sponge and/or lint-free cloth

### 3. LEAK TESTING

- Leak test the endoscope following manufacturer's instructions.
- Attach the leak tester and pressurize the scope before submerging it in water. Some manufacturers specify removing detachable parts prior to leak testing, some do not.
- With the pressurized insertion tube completely submerged, flex the distal portion of the scope in all directions, observing for bubbles. Submerge the entire endoscope and observe the head of the scope, the insertion tube, distal bending section and the universal cord for bubbles coming from the interior of the scope.
  - The leak test will detect damage to the interior or exterior of the endoscope. The leak test is done before immersion of the endoscope in reprocessing solutions in order to minimize damage to parts of the endoscope not designed for fluid exposure.
- Follow the manufacturer's instructions if a leak is detected or the endoscope appears damaged.

### 4. CLEANING

**Manual cleaning of endoscopes is necessary immediately after removing the endoscope from the patient and prior to automated or manual disinfection.** This is the first and most important step in removing the microbial burden from an endoscope. Retained debris may inactivate or interfere with the capability of the active ingredient of the chemical solution to effectively kill and/or inactivate microorganisms.

- Fill a sink or basin with freshly made solution of water and a low-sudsing enzymatic detergent compatible with the endoscope.
- Dilute according to the detergent manufacturer's instructions.
  - Depending on the detergent formulation used, a specific water temperature may be essential to activate the detergent solution.
  - Use fresh detergent solution for each endoscope to prevent cross contamination.
  - Low-sudsing detergents are recommended such that the device can be clearly visualized during the cleaning process to preclude personnel injury and to allow for complete cleaning of lumen surfaces. Excessive sudsing can inhibit good fluid contact with the device surfaces.
- Immerse the endoscope.
- Wash all debris from the exterior of the endoscope by brushing and wiping the instrument while submerged in the detergent solution. Whenever practical, leave the endoscope submerged in the detergent solution when performing all subsequent cleaning steps.
  - The instrument should be left under water during the cleaning process to prevent splashing of contaminated fluid.
- Detach the suction and air/water valves, the biopsy channel cover, the distal end hood, if present, and all other removable parts. Discard those parts that are designated as disposable.
  - The endoscope must be completely disassembled so that all surfaces may be reached for thorough cleaning.
- 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 of non-abrasive and lint-free cleaning tools will prevent damage to the endoscope
- Brush all accessible endoscope channels including the body, insertion tube and the umbilicus of the endoscope. Use a brush size compatible with each channel.

- After each passage, rinse the brush in the detergent solution, removing any visible debris before retracting and reinserting it.
- Continue brushing until there is no debris visible on the brush.
- Clean and high-level disinfect reusable brushes between cases.
  - 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.
- Attach the manufacturer's cleaning adapters for suction, biopsy, air and water channels.
- Attach the manufacturer's cleaning adapters for special endoscope channels (e.g., elevator channel, forward water jet, double-channel scopes).
  - In order to achieve adequate flow through all lumens, various adapters or channel restrictors may be required. Refer to the manufacturer's instructions.
  - Because the elevator channel of duodenoscopes is a small lumen, force greater than can be generated by an automated reprocessor is needed to force fluid through it. This channel requires manual reprocessing (all steps) using a 3- to 5-milliliter syringe. Although the elevator channel of these scopes have channel adapters that may be made to fit reprocessors, this channel must be manually reprocessed.
- Flush all channels with the detergent solution to remove debris.
- Soak the endoscope and its internal channels for the period of time specified by the label of the enzymatic detergent. Prolonged soaking of the channels in the enzymatic detergent solution may be beneficial if there has been a delay in beginning the cleaning process.

## 5. RINSE AFTER CLEANING

- Thoroughly rinse the endoscope and all removable parts with clean water to remove residual debris and detergent.
- 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 liquid chemical germicide used in subsequent steps.

## 6. HIGH LEVEL DISINFECTION

High level disinfection (HLD) is recognized as the standard for reprocessing of gastrointestinal endoscopes by the SGNA, ASGE, the American College of Gastroenterology (ACG), the American Gastroenterological Association (AGA), the Association for Professionals in Infection Control and Epidemiology (APIC), and ASTM. Agencies such as the Centers for Disease Control and Prevention (CDC) and the Joint Commission on Accreditation of Health Care Organizations (JCAHO) recognize HLD as appropriate for gastrointestinal endoscopes. The only circumstance where sterilization of the endoscope is required is for use in a sterile, operative field.

HLD destroys all vegetative microorganisms but not necessarily all bacterial spores. The high-level disinfectant or sterilant used should be prepared in accordance with manufacturer's directions. Because most high-level disinfectants/sterilants are typically reused, they must be tested to assure that they remain above their minimum effective concentration (MEC). Refer to the *Guideline for the Use of High Level Disinfectants and Sterilants for Reprocessing of Flexible Gastrointestinal Endoscopes* for additional information on this topic.

In 1995, ACG, AGA, APIC, ASGE and SGNA adopted the following position on use of non-surfactant 2% glutaraldehyde products: after meticulous cleaning, high-level disinfection is achievable with a 20-minute soak at room temperature using a 2% glutaraldehyde solution that tests above its minimum effective concentration.

Follow manufacturer's recommendations to achieve high-level disinfection for all other high-level disinfectants and sterilants.

## 7. USING HIGH-LEVEL DISINFECTANTS AND STERILANTS

- Prepare the product according to manufacturer's label instructions.
- Test the product for the MEC on each day of use and more frequently as dictated by the number of endoscopes being reprocessed.

- The use-life of a reusable high-level disinfectant/sterilant is related to several factors including, but not limited to: dilution, time/temperature and number of uses. It is essential that the level of active ingredient be at or above that required to kill and/or inactivate the desired microorganisms.
- In each facility a quality study is recommended to assist in determining guidelines for your particular circumstances.
- The MEC may not be used to extend the use-life claim of the product.
- Use a product-specific test strip and keep a log of the test results.

## 8. MANUAL DISINFECTION

- Completely immerse the endoscope and all removable parts in a basin of high-level disinfectant/sterilant. The basin must be of a size to accommodate the endoscope without undue coiling and must have a tight-fitting lid to contain the chemical vapors.
  - In order to prevent damage to the endoscope, do not soak any sharp instruments with the endoscope that could potentially damage the endoscope.
- Inject 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.
  - Complete microbial destruction cannot occur unless all surfaces are in complete contact with the chemical.
  - Since internal contact cannot be visually confirmed because of scope design, perfusion until a steady flow of solution is observed is necessary.
- 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 should have engineering controls to ensure good air quality.
- Soak the endoscope in the high-level disinfectant/sterilant for the time/temperature required to achieve HLD. Use a timer to verify soaking time.
- 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.

## 9. RINSE AFTER MANUAL DISINFECTION

- Thoroughly rinse all surfaces and removable parts, and flush all channels of the endoscope and its removable parts with copious amounts of clean water.
  - Rinsing prevents exposure and potential injury of skin and mucous membranes from chemical residue.
  - Use fresh water for each endoscope.

## 10. DRYING

- Purge all channels with air.
  - Bacteria such as *Pseudomonas aeruginosa* have been identified in both tap and filtered water, and may multiply in a moist environment.
  - Avoid the use of excessively high air pressure. High pressure air can damage the internal channels of flexible endoscopes.
- Flush all channels, including accessory channels, with alcohol until the alcohol can be seen exiting the opposite end of each channel.
  - 70% isopropyl alcohol is used to assist in drying the interior channel surfaces.
  - Use alcohol that has been properly stored in a closed container between uses. Alcohol, when exposed to air, rapidly evaporates, and if below the recommended percentage level, cannot be relied upon to assist in the drying process.

- Alcohol flushes should be used even when sterile water is used for rinsing.
- Purge all channels with air.
  - Alcohol mixes with the remaining water on the channel surfaces and acts to encourage evaporation of the residual water as air flows through the channel.
- Remove all channel adapters.
- Dry the exterior of the endoscope with a soft, clean lint-free towel.
- Thoroughly rinse and dry all removable parts. Do not attach removable parts (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.

## 11. STORAGE

- Hang the endoscope vertically with the distal tip hanging freely in a well-ventilated, dust-free area.
  - A storage area with good ventilation will encourage continued air drying of the surfaces and prevent undue moisture build-up thus discouraging any microbial contamination.
  - Correct storage of the GI endoscope will prevent damage to the exterior of the instrument by protecting it from physical impact. Padding the lower portion of the storage area with non-porous material may prevent damage to the distal end of the scope.

## 12. AUTOMATED REPROCESSING

Endoscope reprocessors standardize the disinfection process and decrease personnel exposure to high-level disinfectants and sterilants. No currently available automated reprocessors provide adequate cleaning of endoscopes. It is necessary to follow all steps for the manual cleaning of the endoscope prior to using an automated reprocessor.

An automated endoscope reprocessor should have the following features: (1) the machine should circulate fluids through all endoscope channels at an equal pressure without trapping air; (2) the detergent and disinfectant cycles should be followed by thorough rinse cycles and forced air to remove all used solutions; (3) the disinfectant should not be diluted with any fluids; (4) the machine should be self-disinfecting; (5) no residual water should remain in hoses and reservoirs; and (6) cycles for alcohol flushing and forced air drying are desirable.

- Prepare the endoscope reprocessor according to manufacturer's guidelines.
- Place the endoscope in the reprocessor and attach all channel adapters according to manufacturer's instructions.
  - The elevator channel of most duodenoscopes is a very small lumen. Since most automated reprocessors cannot generate the pressure required to force fluid through the lumen, a 3-5 ml syringe must be used to manually reprocess (all steps) the elevator channel. Users should check with their endoscope manufacturer for model-specific information.
- 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.
- 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 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.
- Set the machine for the appropriate time and temperature depending on the chemical used.
- Start the machine and allow it to complete all cycles/phases.

- o If cycles/phases are interrupted, HLD cannot be ensured.
- If a final alcohol rinse cycle is not included in the automated reprocessor, this step should be done manually followed by purging all the channels with air.
- Drying and storage are the same as described in manual disinfection.

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SGNA's videotape *Reprocessing of Flexible Gastrointestinal Endoscopes* (2000), the cleaning chart *Steps Necessary to Thoroughly Clean and High Level Disinfect Immersible GI Flexible Endoscopes* (2000) and *Guideline for the Use of High-Level Disinfectants and Sterilants for Reprocessing of Flexible Gastrointestinal Endoscopes* (2000) are companion pieces to this document.

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