


Infection Control Manual		
	Policy Name	Endoscope
	Policy Number	IC 0019
	Date this Version Effective	May 2015
	Responsible for Content	Hospital Epidemiology

I. Description

Describes the steps for cleaning and disinfection of endoscopes.

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II. Rationale

Inadequately cleaned and disinfected endoscopes may result in the transmission of infectious diseases. Strict adherence to the cleaning and disinfection guidelines in this policy and issued by your scope manufacturer is essential to eliminate the risk of endoscope-related infections.

III. Policy

A. Definitions

1. **Cleaning** – The physical removal of soil and organic material from objects, usually done with water and detergents or enzymatic products. Meticulous cleaning must precede disinfection and sterilization procedures, since materials that remain on the surfaces of instruments interfere with the effectiveness of these processes.
2. **Disinfection** – A process that eliminates all pathogenic microorganisms on inanimate objects but ordinarily not bacterial spores; disinfection may be accomplished with chemicals or wet pasteurization.

- a. A few disinfectants will kill spores if prolonged exposure time (6-10 hours) is used. These are called chemical sterilants.
- b. At similar concentrations, but with shorter exposure periods (≤ 45 minutes) these same disinfectants may kill all microorganisms with the exception of high numbers of bacterial spores. These disinfectants are called high-level disinfectants (HLD).
3. High-Level Disinfection - A process that eliminates all pathogenic microorganisms on inanimate objects with the exception of high numbers of bacterial endospores. Several factors influence the effectiveness of disinfection, including (1) the presence of organic matter, (2) proper choice of disinfectant for the object to be disinfected and (3) the concentration and exposure time of the disinfectant solution. Meticulous cleaning is required prior to immersion in the disinfectant. If glutaraldehyde (e.g., Cidex) is used, high-level disinfection is achieved by immersion for 20 minutes at 20°C (room temperature). If ortho-phthalaldehyde is used, high-level disinfection is achieved by immersion for 12 minutes at 20°C. See Appendix 1 for advantages and disadvantages of high-level disinfectants.
4. Sterilization – the complete elimination or destruction of all forms of microbial life. This may be accomplished in health care settings by steam under pressure, dry heat, ethylene oxide gas, hydrogen peroxide gas plasma, or liquid chemicals.
5. Critical Items are instruments or objects that contact normally sterile tissues or the vascular system. Because of the high risk of infection if such an item is contaminated with any microorganism, including bacterial spores, it is critical that they be sterile. Examples: surgical instruments, endoscope passing through a surgical opening.
6. Semicritical Items come into contact with mucous membranes or skin that is not intact. Intact mucous membranes are generally resistant to infection by common bacterial spores but are susceptible to other microorganisms. Semicritical items require at least high-level disinfection. This is usually accomplished by the use of liquid chemicals or wet pasteurization in healthcare settings. Examples: flexible and rigid fiberoptic endoscopes, anesthesia equipment (breathing circuits, laryngeal blades).
7. Non-critical Items touch only intact skin. These items may be cleaned with a quaternary ammonium compound (e.g., MetriGuard®, SaniCloths®). Surfaces exposed to blood and body fluids should be cleaned with an EPA registered disinfectant-detergent or a 1:10 dilution of household bleach. Examples: environmental surfaces (e.g., floors, bedrails), examination tables, IV poles, blood pressure cuffs

B. Summary – The Six Essential Steps for High-Level Disinfection of Endoscopes

1. Pre-Clean – Point-of-use (bedside): remove debris by wiping exterior and aspiration of detergent through air/water and biopsy channels.
2. Clean - Mechanically clean external surfaces, including brushing internal channels, flushing each internal channel with water and a detergent or enzymatic cleaner. This step also includes leak testing.
3. Disinfect – Immerse endoscope in high-level disinfectant and perfuse disinfectant into the suction/biopsy channel and air/water channel and expose for at least 20 minutes (or according to disinfectant manufacturer's instructions for use [IFUs]).
4. Rinse – The endoscope and all channels should be rinsed with sterile water, filtered water, or tap water.
5. Dry – The insertion tube and inner channels should be purged with air, flushed with alcohol (assists drying), purge channels with air and dry the exterior.

6. Store – The endoscope should be stored in a way that prevents recontamination (e.g., hung vertically in a clean location).

C. High-Level Disinfection of Flexible, Lumened Endoscopes, Accessories, and Instruments

1. Pre-Cleaning: Preparing the Endoscope for Cleaning
 - a. Pre-cleaning should be performed at the point of use, before bioburden has an opportunity to dry (within 20 minutes) and before complete decontamination. Pre-cleaning should remove visible debris by wiping the exterior of the endoscope /accessories with an appropriate detergent solution and aspiration of a large volume of detergent solution through the air/water and biopsy channels.
 - b. Appropriate personal protective equipment (PPE) must be worn to prevent staff exposure to blood and other potentially infectious materials (OPIM).
 - c. Transport the scope to reprocessing area covered. If the endoscope reprocessing area is not located in the immediate vicinity and transport is required, place scope and accessories in a plastic bag/container with a Biohazard label on it. If the bag is not transparent, label the bag “scope.”
 - d. A dirty scope should not be left in a clean area. Scopes needing reprocessing should be placed in a designated area used for dirty scopes only.
2. Prerequisites for Cleaning the Endoscope and Accessories in the Reprocessing Area
 - a. Only personnel who have been trained and competency tested may process endoscopes and their accessories. Refer to section 8: Training and Competency Testing.
 - b. All health care personnel involved in endoscope reprocessing should adhere to standard infection prevention and control recommendations (e.g., Standard Precautions), including those to protect both patient and health care personnel.
 - c. Have the following available:
 - i. Personal protective equipment (extended cuff gloves, full face protection to include eyes, nose, and mouth, impervious gown) must be employed during the entire cleaning and disinfection process.
 - ii. Leak testing equipment.
 - iii. Channel cleaning adapters (per endoscope and automated endoscope reprocessor [AER]) manufacturer’s recommendations).
 - iv. Channel cleaning brushes and sponge or lint-free cleaning cloths.
3. Leak Testing
 - a. Perform pressure/leak testing after each use and before formal reprocessing according to manufacturer’s instructions.
 - b. If a leak is detected or the endoscope appears damaged, the manufacturer’s recommendations for cleaning a damaged scope must be followed (see Appendix 3).
4. Cleaning: Meticulous mechanical cleaning is the most important step in removing the microbial burden from endoscopes, accessories and instruments. Endoscope manufacturer’s instructions for cleaning must be adhered to and these instructions vary from model to model and manufacturer to manufacturer. For example, manufacturer’s instructions for cleaning a duodenoscope are different from the instructions for cleaning other types of endoscopes. Include valve covers, channels, elevator channel assemblies, connectors and all detachable parts. Retained debris may inactivate or interfere with the

capability of the active ingredient of the high-level disinfectant (HLD) to effectively kill and/or inactivate microorganisms. Cleaning the endoscope and accessories according to manufacturer's instructions is necessary before automated or manual disinfection.

- a. Fill a sink or basin with freshly made solution of water and low-sudsing enzymatic cleaner compatible with the endoscope and dilute according to the manufacturer's instructions.
 - i. Depending on the enzymatic cleaner's manufacturer's instructions, a specific water temperature may be essential to activate the detergent solution.
 - ii. Use fresh enzymatic cleaner solution for each endoscope to prevent cross contamination. These solutions are not microbiocidal and will not retard microbial growth.
- b. Detach the suction and air/water valve covers, the biopsy channel cover, port covers, and the distal end hood, if present. Discard those parts that are designated as disposable. The endoscope must be completely disassembled so all surfaces may be reached for thorough cleaning.
- c. Clean the external surfaces and components of the endoscope using a soft cloth or sponge.
- d. Whenever practical, leave the endoscope submerged in the enzymatic cleaner solution when performing all subsequent cleaning steps to prevent splashing of contaminated fluid. The recommended soak time is 2 to 5 minutes or according to the enzymatic detergent manufacturer's instructions.
- e. Completely immerse the endoscope in the enzymatic cleaner. Brush all accessible channels. After each passage, rinse the brush, removing any visible debris in the detergent solution before retracting and reinserting it. Continue brushing until there is no debris visible on the brush. Use brushes appropriate for the size of the endoscope channel, parts, connectors and orifices (e.g., bristles should contact all surfaces for cleaning).
- f. Flush by repeatedly pressing the valve covers during the cleaning to facilitate solution access to all surfaces.
 - i. When applicable (e.g., GI Procedures and OR), attach Scope Buddy attachments appropriate for the type of scope being cleaned. Proceed per manufacturer's instruction for use.
 - ii. For areas without Scope Buddy – Suction at least 30 cc through each of the ports of the endoscope. Suction via the umbilicus (air inlet, water inlet, suction port) as well as the head of the endoscope (suction, air-water, and biopsy port) until the solution is visibly clean. Prolonged soaking of the channels in the enzymatic cleaner solution may be beneficial if there has been a delay in beginning the cleaning process.
- g. Remove the endoscope from the enzymatic cleaning solution.
- h. Reusable endoscopic/endothorapy instruments (e.g., biopsy forceps and other cutting instruments) that break the mucosal barrier should be mechanically cleaned as described previously and then sterilized between each patient use (high level disinfection is not appropriate since these accessories are critical devices).
- i. Ultrasonic cleaning of reusable endoscopic accessories and endoscope components may be used to remove soil and organic material from hard-to-clean areas.

- j. Attach adapters for suction, biopsy, air, water channels, and any adapters for special endoscope channels (e.g., elevator wire channel, auxiliary water channel, double-channel scopes).
 - i. To achieve adequate flow through all lumens, various adapters or channel restrictors may be required. Refer to the manufacturer's instructions.
 - ii. Certain models of endoscopes (i.e., duodenoscopes) require specialized cleaning and brushing of elevator channels. Refer to scope manufacturer's IFUs.
 - k. Remove the endoscope from the enzymatic cleaning solution.
5. Rinse and Dry After Enzymatic Detergent
- a. For areas using the Scope Buddy®
 - i. The Scope Buddy ® facilitates cleaning with forced flow of fluids.
 - ii. The exterior must be manually rinsed with water to remove residual debris and enzymatic cleaning.
 - iii. Dry the endoscope and accessories with a soft, lint-free cloth to prevent dilution of the high-level disinfectant used in subsequent steps.
 - b. For areas without the Scope Buddy®
 - i. Thoroughly rinse the exterior of the endoscope, all channels and lumens, and all removable parts with copious warm running water to remove residual debris and enzymatic cleaner.
 - ii. Dry the endoscope and accessories with a soft, lint-free cloth to prevent dilution of the high-level disinfectant used in subsequent steps.
6. High-Level Disinfection
- a. Endoscope and accessories that come in contact with mucous membranes are classified as semi-critical and should receive at least high level disinfection after each patient use.
 - b. Use high- level disinfectants cleared by the FDA and compatible with the endoscope per manufacturer's recommendations.
 - c. Comply with all applicable safety policies regarding exposure monitoring to minimize personnel exposure (e.g., glutaraldehyde).
 - d. Prepare the high-level disinfectant (HLD) according to the manufacturer's labeling instructions.
 - e. The use-life of a reusable HLD is related to several factors including, but not limited to, dilution, time, temperature of the solution (e.g., 20°C for glutaraldehyde), 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 microorganisms. This effective level of the HLD is the "minimum effective concentration" or MEC.
 - f. Test the HLD for minimum effective concentration (MEC) daily if the solution is used daily. If not used daily, check the MEC prior to use. Discard the solution according to the manufacturer's time frame (e.g., 14 vs. 28 days for glutaraldehyde) and whenever the chemical indicator indicates that the concentration is less than the MEC. If performing manual disinfection using basins to contain the HLD, a date should be placed on the container to indicate the date it expires.
 - g. Use the test strip specific for the brand and type of germicide (e.g., use 1.5% test strips with Cidex-Activated Dialdehyde Solution®).

- h. Record on the test strip bottle the date opened and the expiration date. Manufacturer's instructions for use, storage, and expiration date must be followed.
 - i. Keep a log of test results (Appendix 4). Ideally, all endoscope processing locations should use the log in appendix 4.
 - j. Flexible Lumened Endoscope Tracking - A log/record (e.g., log book, computerized log system) should be kept for flexible, lumened endoscopes including the patient's name/medical record number, date of procedure and a scope identifier (e.g., serial number). This system is necessary for follow-up should there be a problem with the scope or processing procedures. Logs should be maintained for 5 years.
 - k. The FDA-cleared label claim for high-level disinfection should be used unless there are scientific studies that demonstrate an alternative exposure time is effective for disinfecting semicritical items. For example, if >2% glutaraldehyde is used, scientific data show that all immersible internal and external surfaces should be in contact with this high-level disinfectant for not less than 20 minutes at 20°C.
 - l. Containers or basins used during manual high-level disinfection should be washed with detergent and water. They should be rinsed and then dried with a clean towel. The water basin should then be wiped with a clean cloth dampened with alcohol. The containers should be placed upside down to dry. This should be done daily for the enzymatic detergent and water basins and between glutaraldehyde changes for the glutaraldehyde container.
 - m. The selection and use of disinfectants in the healthcare field is dynamic and new products may become available. High-level disinfectants used at UNC Healthcare must be approved by Hospital Epidemiology prior to purchase.
7. Manual High-Level Disinfection(HLD)
- a. Completely immerse the endoscope, all removable parts, accessories and instruments in a basin of HLD. The basin must be compatible with the HLD and of a size to accommodate the endoscope without undue coiling. HLD containers must have a tight-fitting lid to contain the vapors of the HLD. Lids must be kept on the containers except when placing an endoscope into and taking an endoscope out of the disinfectant. This helps contain vapors.
 - b. To prevent damage to the endoscopes, scopes should be soaked one to a container and never crowded. Do not soak any sharp instruments with the endoscope that may potentially damage the endoscope.
 - c. Using appropriate cleaning adapters, fill all channels of the endoscope with disinfectant until all air is removed from the channel and the disinfectant can be seen exiting the opposite end of each channel. Ensure that all channels are filled with HLD and that no air pockets remain within the channels. Pressure lock channels with a Luer lock syringe to retain the disinfectant for the amount of time recommended by the manufacturer. The plunger of the syringe should be pulled back enough to see the disinfectant in the syringe and left for the duration of the soak time. This ensures complete microbial destruction.
 - d. Because contact of the disinfectant with the inner surfaces of lumens and channels cannot be visually confirmed, perfusion of the disinfectant until a steady flow of solution is observed is necessary to ensure complete contact of the disinfectant with the surfaces of lumens and channels.

- e. Cover the HLD 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.
 - f. Soak the endoscope, instruments and accessories in the HLD for the time/temperature required to achieve high-level disinfection (i.e., for glutaraldehyde, at least 20 minutes at room temperature). Use a timer to verify soaking time.
 - g. Removable parts should be disinfected simultaneously.
 - h. Flush all channels completely with air before removing the endoscope from the HLD. This preserves the concentration and volume of HLD and prevents exposure from dripping and spilling.
8. Rinse After Manual Disinfection
- a. Thoroughly rinse the exterior surfaces of the insertion tube with tap water. Suction copious amounts of water through the biopsy and air/water channels to rinse all disinfectant from the interior surfaces of the scope. Discard the rinse water after each use/cycle.
 - b. Rinsing prevents exposure and potential injury of skin and mucous membranes from chemical residue.
9. Drying
- a. Flush all channels, including accessory channels, with alcohol until the alcohol can be seen exiting the opposite end of each channel.
 - i. Alcohol purges should be used even when sterile water is used for rinsing.
 - ii. 70-90% ethyl or isopropyl alcohol is used as a solvent to assist drying the interior channel surfaces. 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.
 - iii. Use fresh 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.
 - b. Dry all channels with forced air. Bacteria, such as *Pseudomonas aeruginosa*, a common contaminant of tap water, and fungi multiply in a moist environment. Avoid the use of excessively high air pressure, which may damage the internal channels of the flexible endoscopes (10 psi is ideal, though no more than 20 psi should be used). The length of channels in gastrointestinal endoscopes may require an extended drying time.
 - c. Remove all channel adapters if used.
 - 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 (valves, etc.) to the endoscope during storage. Storage of endoscope with the removable parts detached lowers the risk of trapping liquid inside the instrument and facilitates continued drying of the channels and channel openings.
10. Storage
- a. Staff reprocessing endoscopes must ensure that users can readily identify whether and when an endoscope has been reprocessed. For example, the clean endoscope may be covered with a clean paper sheath, or stored in a manner that denotes that the scope

has been high-level disinfected and is ready for use (e.g. clean utility cabinet/room or tagging/labeling system).

- b. Endoscopes should be stored in a manner that will protect the endoscope from contamination and damage.
 - i. Correct storage of the endoscope will prevent damage to the exterior of the device by protecting the device from physical impact.
 - ii. To facilitate drying, the endoscope should be stored vertically with the distal tip hanging freely.
- c. A storage cabinet with good ventilation will encourage continued air drying of the surfaces and prevent undue moisture buildup in the cabinet interior, thereby discouraging any microbial contamination of the cabinet surfaces.
- d. If a cabinet is not available the endoscope may be stored on the endoscope cart or other designated area in a clean location.
- e. Carrying cases supplied by the manufacturer are not suitable for storage.

11. Automated Reprocessing

- a. Automated endoscope reprocessors (AER) standardize the disinfection process and decrease personnel exposure to disinfectants. However, no currently available automated reprocessors provide adequate cleaning of endoscopes. It is necessary to follow all steps for the mechanical cleaning of the endoscope before using an automated reprocessor. See section C. 1 – 5.
- b. Compare the reprocessing instructions provided by both the endoscope's and the AER's manufacturer's instructions and resolve any conflicting recommendations.
- c. Currently, the elevator wire channel of duodenoscopes is effectively cleaned in UNCH's AERs (Olympus, personal communication, April 1, 2015, Ryan Primus, Olympus representative). However, users should obtain and review model-specific reprocessing protocols from both the endoscope and AER manufacturers and check for compatibility (Multisociety Guideline, 2011, category 1B).
- d. Automated reprocessors should receive preventive maintenance by qualified personnel and this should be guided by manufacturer's recommendations.
- e. Prepare and use the reprocessor according to manufacturer's guidelines.
- f. Place the endoscope in the reprocessor and attach all channel adapters according to manufacturer's instructions to ensure exposure of all internal surfaces with the high-level disinfectant.
- g. Place valves covers and other removable parts into the soaking basin of the reprocessor. Unless the reprocessor has a dedicated space for accessories, reprocess these items separately.
- h. If the machine has a cycle that uses detergent, it should be a product that is compatible with the reprocessor and the endoscope.
 - i. Improper amounts and dilution of the 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. Detergent residue may interfere with the action of the HLD.
- i. Set the machine for the appropriate time and temperature depending on the disinfectant used.

- j. Start the machine and allow it to complete all cycles/phases. If cycles/phases are interrupted, high level disinfection cannot be ensured.
- k. If a final alcohol rinse cycle is not included in the automated reprocessor, this step should be done manually.
- l. Follow final alcohol rinse with purging all channels with air. See section C. 9.
- m. Drying and storage are the same as described in manual disinfection (section C. 9 and 10).
- n. If the automated endoscope reprocessor produces a print out, those print outs shall be kept on file for 3 years. Some printer paper fades over time. If this is the case, scan the print outs into a computer file that is kept for at least 3 years and accessible to staff.

12. Disinfection of Water Bottles

- a. Water bottles, which provide water via the endoscope during endoscopic procedures, are to be emptied and disinfected at the end of each procedure day. However, water bottles used during ERCP are changed for each ERCP. Sterile water should be used to fill the water bottles. Follow manufacturer's recommendations.
- b. At the end of each day of use, or after each use for ERCP, empty the remaining water from the water bottle.
- c. Wash the exterior and interior of the bottle and cap using a soft clean cloth in fresh warm water containing enzymatic cleaner.
- d. Rinse the bottle and cap with running tap water.
- e. Fully submerge the bottle and cap in HLD per manufacturer's recommendation. Alternatively, caps and bottles can be steam sterilized for 10 minutes.
- f. Remove from HLD; rinse vigorously in a clean sink under running water.
- g. Set the bottle so as to drain any fluid contained in it; blow dry water pipe tubing of cap using compressed air.
- h. Once fully dry, place bottle and cap in open storage container in a clean area.

D. Additional Instructions for Duodenoscopes (ERCP Scopes)

Rationale: In response to evidence of outbreaks of disease in patients who have undergone ERCP procedures in healthcare facilities other than UNC Healthcare, UNC Healthcare is implementing the following additional step in reprocessing duodenoscopes:

- 1. Following completion of HLD for flexible duodenoscopes, submit the scope to Central Processing Department for ethylene oxide (ETO) sterilization.

E. High-Level Disinfection of Non-Lumened Flexible Endoscopes

- 1. Preclean the endoscope within 20 minutes of use to prevent drying of secretions on the scope.
 - a. Wipe the insertion tube, body of the scope and any accessories with a clean soft cloth or a gauze pad soaked with enzymatic detergent solution or clean water.
 - b. Transport the scope to the area designated for cleaning dirty scopes. Protect the scope by supporting the insertion tube and body of the scope.
- 2. Perform a leak test after each use. Follow the manufacturer's instructions.
- 3. Mechanically clean the scope.

Endoscope

- a. Fill a sink or basin with a solution of water and low-sudsing enzymatic cleaner compatible with the endoscope. Dilute according to the manufacturer's instructions.
- b. Immerse the scope. While the scope is submerged, wash all debris from the exterior of the endoscope with a soft brush or lint-free cloth. This will help avoid splashes.
4. Thoroughly rinse the endoscope and all removable parts with clean water.
5. Dry the endoscope and accessories.
6. High-Level Disinfection
 - a. After cleaning the scope, immerse the scope in the HLD chemical, using a basin large enough to allow for total immersion. The basin must be covered with a tight fitting lid to minimize chemical vapor exposure. High-level disinfection with glutaraldehyde requires 20 minutes of contact at this temperature. Do not soak longer than this unless recommended by the manufacturer.
7. Rinse the endoscope thoroughly with a large amount of clean water.
8. Dry the endoscope with a soft lint free cloth or towel.
9. Rinse or wipe the endoscope with 70% ethyl or isopropyl alcohol.
10. Store the scope in an area/cabinet designated for clean endoscopes.
 - a. If a water-resistant cap is used for processing these scopes, it should be left off during storage to allow the endoscope to breathe.
 - b. If storing in a scope cabinet, the distal end of the scope should not touch the bottom of the cabinet.

F. Transporting Endoscopes

1. When a cart is used to transport an endoscope to perform a procedure in another area, the dirty scope will be placed back on the cart in an impervious bag marked "biohazard" to reduce the risk of mistaking the dirty scope for a clean scope prior to returning it to the processing area.
2. To prevent accidental contamination of a clean and reprocessed endoscope, endoscopes should not be transported or stored in the carrying case.
3. When an endoscope is transported for use in another location, the used, dirty scope should be placed in a leak resistant container (e.g., plastic bag or tub) with a "biohazard" label and returned within 20-30 minutes in a designated cart or by hand to the scope reprocessing area. The carrying case should not be used to transport the contaminated scope.

G. Rigid Endoscopes (RE)

Endoscopes that normally pass through sterile tissues (e.g., arthroscopes, laparoscopes) should be subjected to a sterilization procedure after each use.)

1. Cleaning, rinsing, drying prior to disinfection or sterilization
 - a. Thorough cleaning, including exterior and interior channels and sheaths, must be performed prior to disinfection or sterilization following the appropriate elements of section C above.
 - i. Non-integral parts (e.g., biopsy valve and tip cover) of the endoscope should be removed, according to the manufacturer's recommendations, and processed separately.

- ii. Any enzymatic surgical instrument cleaning solution (e.g., Valsure®) may be used with sufficient scrubbing action to remove gross soil.
 - iii. Note that leak testing is not performed on rigid endoscopes.
 - iv. Rinsing the exterior and interior channels and sheaths, followed by drying must follow cleaning.
- b. High-level disinfection can be achieved by completely submerging the endoscope in disinfectant (i.e., 2% glutaraldehyde) solution with all trapped air removed. Using appropriate cleaning adapters such as syringes, fill all channels of the endoscope with disinfectant until it can be seen exiting the opposite end of each channel. Ensure that all channels are filled with HLD and that no air pockets remain within the channels. Pressure lock by leaving the syringe attached to the channel to retain the disinfectant for the amount of time recommended by the manufacturer. This ensures complete microbial destruction.
- c. Glutaraldehyde exposure time should be a minimum of 20 minutes at 20°C.
- d. Rinse thoroughly with tap water following the details in section C. 8 above.
- e. Dry thoroughly prior to storage following the relevant details in section C. 9 above.
- f. Storage: Staff reprocessing endoscopes must ensure that users can readily identify whether and when an endoscope has been reprocessed. For example, the clean endoscope may be covered with a clean paper sheath and stored in a manner that indicates that the scope has been high-level disinfected and is ready for use (e.g. clean utility cabinet/room or tagging/labeling system).
- g. Endoscopes should be stored in a manner that will protect the endoscope from contamination and damage.
- h. Correct storage of the endoscope will prevent damage to the exterior of the device by protecting the device from physical impact.
- i. A storage cabinet with good ventilation will encourage continued air drying of the surfaces and prevent undue moisture buildup in the cabinet interior, thereby discouraging any microbial contamination of the cabinet surfaces.
- j. If a cabinet is not available the endoscope may be stored on the endoscope cart or other designated area in a clean location.
- k. Carrying cases supplied by the manufacturer are not suitable for storage.

H. Sterilization of Endoscopes, Accessories, and Ancillary Equipment Used Internally

1. General Information

- a. Instruments that contact sterile tissues or the vascular system must be sterile. Examples include endoscopes passing through a surgical opening, biopsy forceps, and cytology brushes.
- b. Thorough cleaning, rinsing and drying as described in section C. 1 – 5 above must precede sterilization.
- c. The instrument/accessories to be sterilized should be placed in an individual sealed pack such as a peel pack.
- d. Personnel involved with sterilizing items should be familiar with the Infection Control Policy: “Cleaning, Disinfection and Sterilization – Patient-Care Items.”

2. Methods of Sterilization – Endoscopes

- a. Ethylene oxide gas sterilization is an enhancement for reprocessing duodenoscopes after the complete HLD process.
 - i. Flexible fiberoptic endoscopes (FFE) – Ethylene oxide gas sterilization should be performed at a temperature less than 135°F (57°C) and a pressure less than 20 pounds per square inch (psi). Aeration should be for 12 hours at 122°F (60°C) and a pressure less than 20 psi.
- b. Steam sterilization should be used when indicated by scope manufacturer's cleaning instructions.
 - i. Scope manufacturer's IFUs for the sterilization process must be followed.
 - ii. Steam sterilization cannot be utilized for flexible fiberoptic or video endoscopes.
- c. Hydrogen peroxide gas plasma is generally not used for endoscopes because of restrictions on lumen diameter and length.

3. Methods of Sterilization – Accessories and Ancillary Equipment Used Internally

a. General Information

- i. Biopsy forceps, cytology brushes and other cutting instruments that contact the vascular system must be sterilized after first cleaning with enzymatic detergent per manufacturer's instructions for use, followed by an ultrasonic cleaning, rinsing, drying and packaging in an individual sealed pack. Ethylene oxide or steam sterilization is recommended.
 - ii. Packaging and labeling of items for sterilization
 - Items to be sterilized should be prepared and packaged so sterility can be achieved and maintained to the point of use.
 - Sterilized items should be labeled with: a load number that indicates the sterilizer used; the cycle or load number; and the date of sterilization.
 - Sterile packages should be evaluated before use for loss of integrity (e.g., torn, evidence of moisture, punctured).
 - Sterilized packs may be used (unless labeled with an expiration date) unless the integrity of the packaging is compromised.
 - iii. Sterile items should be stored so that the packaging is not compromised (e.g., punctured, bent).
4. Equipment not used internally, such as power sources, illuminators, insufflators, and suction devices should be cleaned at frequent, regular intervals with gauze dampened with soap and water, then with 70% alcohol or SaniCloths®.

a. Steam Sterilization

- i. Steam sterilization may be performed on equipment such as a biopsy forceps and cytology brushes. Manufacturer's instructions should be consulted.
- ii. Maximum temperature should not exceed 132°C (270°C) for a period of time not to exceed 10 minutes.

b. Chemical Sterilization

- i. Chemical sterilization may be performed on non-spiral configuration accessories and instruments (e.g., guidewires) with FDA-cleared chemical sterilant. After cleaning

the instrument it should be soaked for the time specified by the manufacturer. It should then be thoroughly rinsed with sterile water and stored to maintain sterility. (If sterility is not desired, it may be stored as are disinfected instruments).

I. Safety

1. Appropriate personal protective equipment (e.g., extended cuff gloves, full face protection to include eyes, nose, and mouth, respiratory protection devices, etc.) should be readily available and should be used, as appropriate, to protect workers from exposure to chemicals or microorganisms (e.g., HBV).
2. Facilities where endoscopes are used and disinfected should be designed to provide a safe environment for healthcare workers and patients.
 - a. Air-exchange equipment (ventilation system, exhaust hoods, etc.) should be used to minimize the exposure of all persons to potentially toxic vapors (e.g., glutaraldehyde). Please see the Safety Policy entitled "Glutaraldehyde Control" for details.
 - b. Where endoscopes are reprocessed manually, covered containers should be used to minimize dispersion of potentially toxic vapors.
3. Hospital Epidemiology will conduct infection control rounds in high-risk reprocessing areas to ensure that reprocessing instructions are current and accurate and that they are correctly implemented.

J. Training and Competency Testing

1. All individuals given the responsibility for cleaning, disinfection and sterilization of endoscopes must be familiar with the physical characteristics of the endoscope and with this policy. They must receive device-specific reprocessing instructions. Comprehensive and intensive training for all staff assigned to reprocess semicritical and critical items is essential to ensure that they understand the importance of meticulous care when reprocessing instruments. To achieve and maintain competency, each member of the staff that reprocesses semicritical and/or critical instruments will be trained as follows:
 - a. Staff responsible for high level disinfection of channeled endoscopes shall attend the UNCH High Level Disinfection workshop provided by the Infection Prevention department. The workshop is offered approximately every other month at various locations. Contact Infection Prevention for details and to register.
 - b. Hands-on training based on UNC Health Care policies and procedures for reprocessing critical and semicritical devices.
 - c. All work should be supervised until competency is documented for each reprocessing task.
 - d. Competency testing should be conducted at commencement of employment and at least annually thereafter. The approved competency test form for UNC Health Care facilities is attached to this policy as Appendix 2.
 - e. Review the written reprocessing instructions regularly to ensure they are compliant with the scientific literature and the manufacturer's instructions.
2. Temporary personnel should not be allowed to reprocess endoscopes until competency has been established.
3. Personnel who infrequently reprocess endoscopes (e.g., once every 3 or more months) will require review and may need repeat competency testing more frequently than annually.
4. Key personnel who are involved in staff education of cleaning/disinfection processes must have documented training by the company representative prior to newly purchased

endoscopes being used or processed. These personnel may now educate other staffs who have the responsibility of teaching reprocessing of endoscopes to others in their area.

5. All endoscopy personnel must be educated about the biologic and chemical hazards present while performing or assisting at endoscopic procedures and during the reprocessing of endoscopic equipment.
6. The quality assurance program for endoscopes should emphasize cleaning, sterilization and disinfection procedures, supervision, training and annual competency review. Untrained personnel should not be allowed to clean or disinfect instruments either manually or via an automated reprocessing system. Personnel for whom competency has not been documented will not be allowed to clean or disinfect instruments.
7. For guidance on developing educational content, Hospital Epidemiology should be consulted.

K. Quality Assurance and Surveillance

1. Quality Assurance - A representative sample of all scopes processed at UNC Healthcare is cultured on a quarterly basis in order to ensure that adequate cleaning and disinfection protocol are being performed and achieved.
2. If a cluster of endoscopy-related infections occurs or is suspected, an investigation will be initiated to determine the potential routes of transmission (e.g., person-to-person, common source) and reservoirs. Notify Hospital Epidemiology (984.974.7500) for assistance with any questions or problems.

L. Implementation

The Medical Director and supervisor of each department or his/her designee will identify persons responsible for supervising the implementation of this policy.

IV. References

Society of Gastroenterology Nurses and Associates, Inc.; Standards for Infection Control and Reprocessing of Flexible Gastrointestinal Endoscopes; (SGNA 2004).

Rutala, WA. APIC guidelines for selection and use of disinfectants. Am J Infect Control 1996; 24:313-342.

American Society for Gastrointestinal Endoscopy and the Society for Healthcare Epidemiology of America. Multi-society guideline for reprocessing flexible gastrointestinal endoscopes. Infection Control Hospital Epidemiology 2011; June 32:527-537.

Rutala, WA; DJ Weber and The Healthcare Infection Control Practices Advisory Committee. CDC Guidelines for Disinfection and Sterilization in Healthcare Facilities, MMWR. 2008

V. Reviewed/Approved by

Hospital Infection Control Committee

VI. Original Policy Date and Revisions

Revised on Aug 2004, Sept 2006, May 2009, May 2012, April 2015

Appendix 1: Summary of Advantages and Disadvantages of Chemical Agents Used as Chemical Sterilants¹ or as High-Level Disinfectants

Sterilization Method	Advantages	Disadvantages
Peracetic Acid/Hydrogen Peroxide	<ul style="list-style-type: none"> • No activation required • Odor or irritation not significant 	<ul style="list-style-type: none"> • Materials compatibility concerns (lead, brass, copper, zinc) both cosmetic and functional • Limited clinical experience • Potential for eye and skin damage
Glutaraldehyde	<ul style="list-style-type: none"> • Numerous use studies published • Relatively inexpensive • Excellent materials compatibility 	<ul style="list-style-type: none"> • Respiratory irritation from glutaraldehyde vapor • Pungent and irritating odor • Relatively slow mycobactericidal activity • Coagulates blood and fixes tissue to surfaces • Allergic contact dermatitis
Hydrogen Peroxide	<ul style="list-style-type: none"> • No activation required • May enhance removal of organic matter and organisms • No disposal issues • No odor or irritation issues • Does not coagulate blood or fix tissues to surfaces • Inactivates <i>Cryptosporidium</i> • Use studies published 	<ul style="list-style-type: none"> • Material compatibility concerns (brass, zinc, copper, and nickel/silver plating) both cosmetic and functional • Serious eye damage with contact
Ortho-phthalaldehyde	<ul style="list-style-type: none"> • Fast acting high-level disinfectant • No activation required • Odor not significant • Excellent materials compatibility claimed • Does not coagulate blood or fix tissues to surfaces claimed 	<ul style="list-style-type: none"> • Stains skin, mucous membranes, clothing, and environmental surfaces • Repeated exposure may result in hypersensitivity in some patients with bladder cancer • More expensive than glutaraldehyde • Eye irritation with contact • Slow sporicidal activity
Peracetic Acid	<ul style="list-style-type: none"> • Rapid sterilization cycle time (30-45 minutes) • Low temperature (50-55°C) liquid immersion sterilization • Environmental friendly by-products (acetic acid, O₂, H₂O) • Fully automated • Single-use system eliminates need for concentration testing • Standardized cycle • May enhance removal of organic material and 	<ul style="list-style-type: none"> • Potential material incompatibility (e.g., aluminum anodized coating becomes dull) • Used for immersible instruments only • Biological indicator may not be suitable for routine monitoring • One scope or a small number of instruments can be processed in a cycle • More expensive (endoscope repairs, operating costs, purchase costs) than high-level disinfection • Serious eye and skin damage (concentrated

Endoscope

	<p>endotoxin</p> <ul style="list-style-type: none"> • No adverse health effects to operators under normal operating conditions • Compatible with many materials and instruments • Does not coagulate blood or fix tissues to surfaces • Sterilant flows through scope facilitating salt, protein, and microbe removal • Rapidly sporicidal • Provides procedure standardization (constant dilution, perfusion of channel, temperatures, exposure) 	<p>solution) with contact</p> <ul style="list-style-type: none"> • Point-of-use system, no sterile storage
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Modified from Rutala

¹ All products effective in presence of organic soil, relatively easy to use, and have a broad spectrum of antimicrobial activity (bacteria, fungi, viruses, bacterial spores, and mycobacteria). The above characteristics are documented in the literature; contact the manufacturer of the instrument and sterilant for additional information. All products listed above are FDA-cleared as chemical sterilants except OPA, which is an FDA-cleared high-level disinfectant.

Appendix 2: UNCHC Endoscope Reprocessing Competency

I have read the UNCHC Endoscope Infection Control Policy and the Safety Policy on Glutaraldehyde Control before presenting for competency review.

COMPETENCY CRITERIA:

Circle appropriate outcome measure:

Competencies

Met	Not Met	N.A.	Verbalizes knowledge of cleaning and disinfecting solutions used, labeling, length of effective use life and soak times.
Met	Not Met	N.A.	Documents concentration of high-level disinfectant appropriately (e.g., if used daily, test daily).
Met	Not Met	N.A.	Wears personal protective equipment, including gown, gloves, eyewear.
Met	Not Met	N.A.	Demonstrates initial gross decontamination of exterior of scope and accessories. Wipes exterior of scope with clean cloth soaked in detergent or enzymatic cleaner.
Met	Not Met	N.A.	Leak tests scope.
Met	Not Met	N.A.	Demonstrates the process of manual washing and brushing all channels, ports and valves covers with appropriately prepared detergent or enzymatic cleaner.
Met	Not Met	N.A.	Uses suction to fill channels with detergent or enzymatic cleaner (or Scope Buddy)
Met	Not Met	N.A.	Brushes lip of biopsy port.
Met	Not Met	N.A.	Uses suction to rinse interior until fluid is clear, ends by suctioning air to clear fluid from scope (or Scope Buddy) and rinses exterior of scope.
Met	Not Met	N.A.	Fills interior channels with high-level disinfectant and immerses completely to prevent air bubbles. Utilizes manufacturer's recommended immersion time (or AER machine)
Met	Not Met	N.A.	Demonstrates the proper use of the automatic processor. Verbalizes knowledge of test cycles before and after use.
Met	Not Met	N.A.	Uses appropriate test strips and records results.
Met	Not Met	N.A.	Avoids contaminating clean and/or disinfected items with dirty gloves. Washes hands after removing dirty gloves. Dons clean gloves prior to removing scope/accessories from glutaraldehyde.
Met	Not Met	N.A.	Rinses scope with either sterile water, filtered water, or tap water. Uses "clean" suction (or AER machine).
Met	Not Met	N.A.	Uses forced air to dry the scope followed by alcohol to assist in drying. Then purge scope with forced air (or AER machine).
Met	Not Met	N.A.	Demonstrates proper cleaning, high-level disinfection, rinsing and drying of all accessories.
Met	Not Met	N.A.	Demonstrates proper cleaning and sterilization of biopsy forceps and other cutting instruments, which enter sterile body sites.
Met	Not Met	N.A.	Labels or packages disinfected scopes/accessories to indicate disinfection has been done.
Met	Not Met	N.A.	Is able to state conditions indicating a scope has not been disinfected (e.g., if not labeled or packaged, scope is considered contaminated and requires high-level disinfection prior to use).
Met	Not Met	N.A.	Properly stores scope/accessories in a clean location.
Met	Not Met	N.A.	Empties and disinfects water bottles.
Met	Not Met	N.A.	Disinfects brushes if reusable; discards disposable brushes after use.
Met	Not Met	N.A.	Empties and cleans pans or sink as indicated.
Met	Not Met	N.A.	Removes personal protective gear and discards appropriately.
Met	Not Met	N.A.	Washes hands before leaving reprocessing room.

I certify that this individual has met all competencies for reprocessing endoscopes.

Signature: _____ Date: _____

Print Name: _____ Title: _____

Appendix 3: Recommendations for Cleaning and Disinfecting Broken/Damaged Scopes

If, during routine reprocessing of an endoscope, a leak or damage is detected please follow the following procedure to get scope cleaned, sterilized, and repaired:

1. Contact scope manufacturer for specific instructions on returning a damaged scope. Manufacturer's instructions may differ from those below.
2. Leave scope attached to leak tester
3. Continue with normal manual cleaning and brushing as described above in Section C numbers 4 and 5.
4. Following manual cleaning of the scope, and send scope to Central Processing for ETO gas sterilization and notify immediate supervisor (manager or charge nurse) and the CPD Supervisor or Educator of a damaged scope. If scope is not taken immediately to CPD, please label it as damaged and segregate if from other scopes.
5. After sterilization, the scope should be sent out for repair following departmental procedures.
6. Alternatively, in areas with the DSD Edge, the scope may be put through the AER for high level disinfection rather than using ETO sterilization (if the leak is small and can be appropriately covered with tape prior to reprocessing.)

Appendix 4: High-Level Disinfectant Minimum Effective Concentration (MEC) Log

UNC Healthcare								
High Level Disinfection LOG								
Clinic Name: _____								
Chemical Used: _____								
Staff Initials	Test Date	Chemical Temp	Test Strip Brand (3M* or Cidex*?)	Test Strip Lot #	Date Test Strips Expire	This column is for Cidex® Brand** Test Strips ONLY: Test Strip QC Pass or Fall See note below**	Date Solution Expires	Solution MEC* Test: Pass or Fail
			3M Cidex			Pass Fail		Pass Fail
			3M Cidex			Pass Fail		Pass Fail
			3M Cidex			Pass Fail		Pass Fail
			3M Cidex			Pass Fail		Pass Fail
			3M Cidex			Pass Fail		Pass Fail
			3M Cidex			Pass Fail		Pass Fail
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			3M Cidex			Pass Fail		Pass Fail
			3M Cidex			Pass Fail		Pass Fail
			3M Cidex			Pass Fail		Pass Fail

*MEC = Minimum Effective Concentration

** Cidex® brand test strips require quality control (QC) when opening a new bottle of test strips. INSTRUCTIONS ARE ON LABEL.

Initials	Signature	Initials	Signature