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Policy Area	Infection Prevention
Applicability	UNC Medical Center

Endoscope

I. Description

Describes the steps for cleaning, high-level disinfection, and sterilization of endoscopes

II. Rationale

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

III. Policy

A. Health Care Personnel (HCP) should adhere to guidelines found in the following policies:

1. High-Level Disinfection (HLD) - Manual Reprocessing of Reusable Semi-Critical Medical Devices
2. Sterilization of Reusable Patient-Care Items
3. Hand Hygiene and Use of Antiseptics for Skin Preparation
4. Exposure Control Plan for Bloodborne Pathogens
5. Personal Protective Equipment Requirements
6. Infection Control and Screening Program: Occupational Health Service

B. HLD Competency and Training

1. All health care personnel (HCP) who perform HLD activities are required attend the initial HLD class as soon as possible after assignment of HLD responsibilities to the HCP. Thereafter and at least 365 days, HCP is required to complete the HLD refresher module via LMS. Registration for the initial class and the refresher is via LMS. Contact Infection Prevention or LMS for classes.
2. Please see the Infection Prevention's Instrument Reprocessing website for the most current competency form for the HLD processes performed at your specific area and specific devices.
3. Initially, there are four elements that must be completed in order to meet UNCH's requirements for HLD competency:
    a. Training
        - HLD Class and on-the-job practice with a competent person
    b. Demonstration
        - Able to perform HLD with no assistance
    c. Observation
        - Competent person observes your entire process
    d. Documentation
        - Competent person completes your competency form
4. Yearly (at least every 365 days), three elements must be completed:
    a. Demonstration
    b. Observation
    c. Documentation
5. All HLD HCP must take the LMS module "Color Blindness for High-Level Disinfection Staff."
    a. Staff should receive hands-on training based on UNC Health policies and procedures for reprocessing critical and semi-critical devices.
    b. All work should be supervised by a competent staff member until competency is documented for each reprocessing task.
    c. Competency testing should be conducted by staff with a valid competency form on file at commencement of employment and at least annually thereafter. The approved competency form for UNC Medical Center facilities

is available on the Infection Prevention's Instrument Reprocessing website.

d. Completed competency forms will be kept at an immediately accessible location.

6. Temporary personnel should not be allowed to reprocess endoscopes until competency has been established.
7. 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.
8. Key personnel who are involved in staff education of cleaning/disinfection processes must have documented training by the company representatives 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.
9. 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.
10. 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.
11. For guidance on developing educational content, Infection Prevention should be consulted.

C. Summary – The Seven Steps for High-Level Disinfection of Flexible Endoscopes

1. For all steps of High-Level Disinfection, personnel will don appropriate PPE
2. It is strongly recommended to use disposable buttons, brushes and endotherapy instruments.
3. Refer to scope manufacturer's instructions for use when damaged scopes are reported.
4. Endoscopes should have periodic in-depth inspections by the manufacturer per the manufacturer's instructions for use.
5. 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 the section Training and Competency Testing.

b. All health care personnel involved in endoscope reprocessing should adhere to standard infection prevention and control recommendations to protect both patient and health care personnel.

c. Supplies and equipment:

i. Personal protective equipment including, but not limited to extended cuff gloves, full face protection to include eyes, nose, and mouth, impervious gown, and safety glasses/goggles must be worn.

ii. Leak testing equipment.

iii. Channel cleaning adapters per both the endoscope and automated endoscope reprocessor (AER) manufacturer's instruction for use.

6. Pre-Cleaning: Preparing the Endoscope for Cleaning

a. Pre-cleaning of flexible endoscopes and reusable accessories is done at point of use by following the scope manufacturer's instructions. Pre-cleaning may include the use of an enzymatic detergent. Perform immediately following completion of the endoscope procedure to help prevent the formation of biofilm.

b. Transport the scope and accessories to the reprocessing area in a leak-proof container with a Biohazard label on it.

c. Scopes needing reprocessing should be placed in a designated area used for dirty scopes only.

7. 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, follow the manufacturer's instructions for cleaning a damaged scope. Follow automated endoscope reprocessor (AER) instructions for AERs able to high-level disinfect damaged scopes.

- Channel cleaning brushes and sponges or lint-free cleaning cloths

8. Manual Cleaning

a. Manual cleaning should occur within the manufacturer's recommended time

frame. When cleaning is delayed beyond this interval, the manufacturer's directions for delayed processing should be followed. Placing the endoscope in a pack to maintain moisture, for example a Humipak® can prevent debris from drying out if an extended period of time is anticipated.

b. Meticulous manual cleaning is the most important step in removing the microbial burden from endoscopes, accessories, and instruments. Follow the endoscope manufacturer's instructions for cleaning. Include valve covers, channels, elevator channel assemblies, connectors, and all detachable parts. Retained debris may adversely affect the efficacy of the high-level disinfectant (HLD).

    i. Follow manufacturer's instructions for both the enzymatic detergent and endoscope.

    ii. Use fresh enzymatic cleaner solution for each endoscope to prevent cross contamination.

    iii. Discard disposable parts. The endoscope must be completely disassembled so all surfaces may be reached for thorough cleaning.

    iv. Use a digital timer to time soak duration.

    v. Use brushes appropriate for the size of the endoscope channel, parts, connectors, and orifices.

    vi. It is strongly recommended that only single use, disposable channel brushes be used. If reusable brushes must be used, the brush must follow the same disinfection procedure as the scope after each use of the reusable brush.

    vii. When applicable attach automated endoscope flushing aid (e.g., Scope Buddy™) for the type of scope being cleaned. Proceed per manufacturer's instruction for use.

    viii. For areas without an automated endoscope flushing aid, follow manufacturer's instructions for cleaning the specific scope make and model.

    ix. Reusable endoscopic/endotherapy instruments (e.g., biopsy forceps and other cutting instruments) that break the mucosal barrier should be cleaned and sterilized between each patient use following manufacturer's IFU.

    x. Ultrasonic cleaning of reusable endoscopic accessories and endoscope components may be used to remove soil and organic material from hard-to-clean areas.

xi. Certain models of endoscopes (i.e., duodenoscopes) require specialized cleaning and brushing of elevator channels. Refer to scope manufacturer's IFUs.

c. Automated flushing aid attachments facilitate cleaning with forced flow of fluids.

i. The exterior must be manually rinsed with water to remove residual debris and enzymatic cleaning.

ii. Dry the endoscope and accessories with a soft, lint-free cloth to prevent dilution of the high-level disinfectant if manually disinfecting.

d. For areas without an automated flushing aid attachment

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 if manually disinfecting. Follow AER IFU regarding drying the endoscope prior to placing in the AER.

9. Visual Inspection

a. After manual cleaning, visually inspect the endoscope and its accessories. Visual inspection provides additional assurance that the endoscope and its accessories are clean and free of defects.

b. Damage to the endoscope can prevent adequate cleaning and disinfection. If there are concerns for damage, the manufacturer should be contacted to determine if more detailed inspection should occur by the manufacturer.

10. High-Level Disinfection

a. Following cleaning and visual inspection perform HLD or sterilization in accordance with the manufacturer's IFU. Carefully review and adhere to the endoscope manufacturer's reprocessing instructions and to the IFU for chemicals or sterilants and any equipment (e.g., automated endoscope reprocessors) used for reprocessing to help ensure that effective disinfection occurs.

b. 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.

c. Use high-level disinfectants cleared by the FDA and compatible with the

endoscope per manufacturer's recommendations.

d. Comply with all applicable safety policies regarding exposure monitoring to minimize personnel exposure.

e. Prepare and verify minimum effective concentration of the high-level disinfectant (HLD) according to the manufacturer's labeling instructions.

f. Containers or basins used during manual high-level disinfection should be washed, with enzymatic detergent and water, rinsed and dried on a regular basis, e.g., daily for enzymatic detergent containers/basins and when the high-level disinfectant expires or fails minimum effective concentration.

g. High-level disinfectants must be approved by Infection Prevention prior to purchase. Refer to the Infection Prevention policy: High-Level Disinfection (HLD) - Manual Reprocessing of Reusable Semi-Critical Medical Devices for approved high-level disinfectant chemicals.

h. Special Considerations for Manual High-Level Disinfection (HLD)

    i. Completely immerse the endoscope, all removable parts, accessories, and instruments in a basin of properly prepared HLD solution. 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. The reprocessing area should have engineering controls to ensure good air quality.

    ii. To prevent damage to the endoscopes, scopes must be soaked one per container and never crowded. Do not soak any sharp instruments with the endoscope that may potentially damage the endoscope.

    iii. Soak the endoscope, instruments and accessories in the HLD for the specified time/temperature required to achieve high-level disinfection per the chemical manufacturer's instructions for use. Use a timer to verify soaking time.

    iv. Removable parts should be disinfected simultaneously.

    v. 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.

11. Rinse After Manual Disinfection

- Thoroughly rinse the exterior surfaces of the insertion tube with tap water.

Suction or perfuse 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.

12. 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.

    b. Dry all channels with instrument air. Avoid the use of excessively high air pressure, which may damage the internal channels of the flexible endoscopes. Review manufacturer's instructions for ideal and maximum psi to 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.

13. Storage

    a. Staff reprocessing endoscopes must ensure that users can readily identify that the endoscope has been reprocessed. Endoscopes ready for use are tagged with a "clean" tag. If a scope does not have a "clean" tag attached, the scope must not be used on a patient.

    b. Endoscopes should be stored in a manner that will protect the endoscope from contamination and damage.

        - To facilitate drying, the endoscope should be stored vertically with the distal tip hanging freely without a tip protector.

    c. Do not store in the carrying case. Carrying cases supplied by the manufacturer are not suitable for storage.

14. Documentation

    - Maintain documentation for each step every time an endoscope is reprocessed. Logs are posted on the Infection Prevention's Instrument Reprocessing website

D. Automated Reprocessing

1. Automated endoscope reprocessors (AER) standardize the disinfection process and decrease personnel exposure to disinfectants. Follow all steps for the mechanical cleaning of the endoscope before using an automated reprocessor. For AERs that are FDA validated to perform the cleaning process, follow the AER manufacturer's instructions for automated cleaning.
2. Compare the manufacturer's reprocessing instructions provided by both the endoscope and the AER manufacturer and resolve any conflicting recommendations.
3. The elevator channel assembly of duodenoscopes must be processed according to the scope's manufacturer's IFU and AER manufacturer's IFU.
4. Automated reprocessors must receive preventive maintenance by qualified personnel and this should be guided by manufacturer's recommendations.
5. Prepare and use the AER according to manufacturer's instructions for use.
6. Use correct adapters according to manufacturer's instructions.
7. Place valves covers and other removable parts into the appropriate container in the basin of the reprocessor.
8. Start the machine and allow it to complete all cycles/phases. If cycles/phases are interrupted, high-level disinfection cannot be ensured.
9. If a final alcohol rinse cycle is not included in the automated reprocessor, this step should be done manually.
10. Dry and store as described in manual disinfection.
11. If the automated endoscope reprocessor produces a print out, those print outs shall be kept on file for 5 years. For printer paper that fades, scan the print outs into a computer file that is accessible to staff.
    - Staff removing the scope from the AER must initial the printout immediately after each cycle finishes.

E. Disinfection of Water Bottles and use of Disposable Water Bottle Systems Which Provide Water via the Endoscope during Procedures

1. If a disposable tubing system and disposable water bottle are used, follow manufacturer's instructions for use and disposal.
    - A new disposable water bottle/tubing system must be used before every ERCP procedure. Sterile water should be used to fill the water bottles

2. If reusable water bottles are used, they must be washed, disinfected, and sterilized at the end of each day and/or before an ERCP procedure.

F. Flexible Lumened Endoscope Tracking

- Logs/records for flexible lumened endoscope should include the patient's identifier (i.e., MRN, CSN), date of procedure, and a scope identifier (e.g., serial number or other unique identifier). Document the endoscope's unique identifying number in the electronic medical record of the patient. This system allows for follow-up should there be a problem with the scope or processing procedures. Logs should be maintained for 5 years.

G. Additional Instructions for Duodenoscopes (ERCP Scopes)

- Flexible duodenoscopes must be double high-level disinfected after each use. It is not necessary to decontaminate the scope via the enzymatic detergent and brushing steps before the second run through the AER. The first AER cycle should be completed, printouts checked and initialed, and the cycle run a second time and printout checked and initialed as usual.

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

1. Pre-clean the endoscope per manufacturer's instructions for use.
    - Transport the scope to the area designated for cleaning dirty scopes in a covered container marked biohazard. 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 according to manufacturer's instructions.
4. Dry the endoscope and accessories.
5. High-Level Disinfection
    - After cleaning the scope, following manufacturer's instructions for use, immerse the scope in the HLD chemical, using a basin large enough to allow for total immersion and cover with a tight fitting lid.
6. Rinse the endoscope thoroughly with a large amount of clean water.
7. Dry the endoscope with a soft lint free cloth or towel.
8. Rinse or wipe the endoscope with 70% ethyl or isopropyl alcohol.

9. 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.

I. 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 container marked "biohazard" to reduce the risk of inadvertently confusing the scope as clean prior to returning it to the processing area.
2. When an endoscope is transported for use in another location, the used, dirty scope should be placed in a leak resistant covered container with a "biohazard" label and returned within 60 minutes in a designated cart or by hand to the scope reprocessing area.

J. Rigid Endoscopes

Endoscopes that normally pass through sterile tissues (e.g., arthroscopes, laparoscopes) are critical devices and should be sterilized after each use and maintained in a sterile condition via an appropriate wrap or tray until use.

1. Follow manufacturer's instructions for cleaning, rinsing, and drying prior to disinfection or sterilization
    a. Thorough cleaning, including exterior and interior channels and sheaths, must be performed prior to disinfection or sterilization.
        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 may be used with sufficient scrubbing action to remove gross soil.
        iii. Leak testing is not performed on rigid endoscopes.
        iv. After cleaning the exterior and interior channels and sheaths must be rinsed and then dried as much as able before immersing into a HLD liquid or placed into a sterilization container.
    b. High-level disinfection can be achieved by completely submerging the endoscope in disinfectant 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 to ensure complete microbial destruction.

c. Thoroughly rinse the exterior surfaces of the insertion tube with tap water. Suction or perfuse 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.

2. Drying High-Level Disinfected Rigid Endoscopes

    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, with 70-90% ethyl or isopropyl alcohol should be used even when sterile water is used for rinsing.

        ii. Use fresh alcohol that has been properly stored in a closed container between uses.

    b. Dry all channels with instrument air.

    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.

3. Storage: Staff reprocessing endoscopes must ensure that users can readily identify whether and when an endoscope has been reprocessed. Endoscopes ready for use are tagged with a "clean" tag.

    a. Endoscopes should be stored in a manner that will protect the endoscope from contamination and damage.

    b. A storage cabinet with adequate ventilation will encourage continued air drying of the surfaces and prevent undue moisture buildup in the cabinet interior.

        • Scope storage cabinets need to be maintained in a clean manner, with no dust/debris on the bottom and should be cleaned on a regular basis.

    c. If a cabinet is not available the endoscope may be stored on the endoscope cart or other designated area in a clean location.

d. Do not store in the carrying case.

K. 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. Clean, rinse, and dry per the Infection Prevention: Sterilization of Reusable Patient-Care Items.
    c. The instruments/accessories to be sterilized should be placed in an individual sealed pack such as a peel pack.
2. Methods of Sterilization – Endoscopes
    a. Steam sterilization should be used when indicated by scope manufacturer's cleaning instructions.
        - Scope manufacturer's IFUs for the sterilization process must be followed.
    b. Hydrogen peroxide gas plasma is generally not used for endoscopes because of restrictions on lumen diameter and length.
3. 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. Prior to sterilization, these items must be cleaned according to the device manufacturer's instructions.
        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.

4. Equipment not used internally, such as power sources, illuminators, insufflators, and suction devices should be cleaned according to manufacturer's instructions.

L. Environmental Services

- Cleaning and disinfection of reprocessing environment is performed daily with an EPA-registered disinfectant cleaning solutions.

M. Safety

1. Appropriate personal protective equipment should be readily available and used 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 health care workers and patients.
    - Air-exchange equipment (ventilation system, exhaust hoods, etc.) should be used to minimize the exposure of all persons to potentially toxic vapors as indicated in the Safety Data Sheet.
3. Infection Prevention will conduct rounds in reprocessing areas to ensure that reprocessing instructions are current, accurate, and correctly implemented.

N. Quality Assurance and Surveillance

1. ERCP scopes are cultured using the CDC specified guidelines for quality improvement purposes only. Cultures are not meant to monitor adequate cleaning and high-level disinfection of ERCP scopes.
2. If a cluster of endoscopy-related infections occurs or is suspected, an investigation will be initiated to determine the potential routes of transmission and reservoirs. Notify Infection Prevention (984-974-7500) for assistance with any questions or problems.

O. 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

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

Multisociety guideline on reprocessing flexible GI endoscope: 2016 update. Gastrointestinal Endoscopy.

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Healthcare Infection Control Practices Advisory Committee (HICPAC). Essential Elements of a Reprocessing Program for Flexible Endoscopes - Recommendation of the HICPAC. Centers for Disease Control and Prevention. Retrieved 02/2021

APIC Text. Chapter 56: Endoscopy. Association for Professionals in Infection Control and Epidemiology. Retrieved 02/2021

Food and Drug Administration - Duodenoscope Surveillance Sampling & Culturing: Reducing the Risks of Infection. https://www.fda.gov/media/111081/download. Retrieved 03/2021

V. Related Policies

Environmental Health and Safety Policy: Personal Protective Equipment Requirements

Infection Prevention Policy: Exposure Control Plan for Bloodborne Pathogens

Infection Prevention Policy: Hand Hygiene and Use of Antiseptics for Skin Preparation

Infection Prevention Policy: High-Level Disinfection (HLD) - Manual Reprocessing of Reusable Semi-Critical Medical Devices

Infection Prevention Policy: Infection Control and Screening Program: Occupational Health Service

Infection Prevention Policy: Sterilization of Reusable Patient-Care Items

Approval Signatures

Step Description	Approver	Date
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