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"OUR ENDOSCOPE IS BROKEN, BUT LUCKILY
NURSE HAS HER MOBILE PHONE CAMERA - IT'S
QUITE SMALL..."

Endoscopy Reprocessing

Education Review

March 2016

Endoscope Reprocessing

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Endoscope Reprocessing

Review of Terms

Biofilm – refers to a complex community of microorganisms that form a matrix of extracellular material composed of exopolysaccharides (EPS)

Automatic endoscope reprocessor(AER): a unit for mechanical cleaning, disinfecting, and rinsing of flexible endoscopes.

Reuse-life – refers to a statement by the manufacturer indicating the maximum number of days of a reusable high-level disinfectant / sterilant might be effective

Terminology

Cleaning-a process using friction, detergent, and water to remove organic debris; the process by which any type of soil, including organic debris, is removed. Cleaning removes rather than kills microorganisms.

Contaminated-the presence of potentially infectious, pathogenic organisms (blood, other potentially infectious material) on or in animate or inanimate objects.

Decontamination-a process that removes contaminating infectious agents and renders reusable medical products safe for handling.

Detergent-refers to a surfactant or mixture used for cleaning

Terminology

Disinfection-a process that kills most forms of microorganisms or inanimate surfaces. Disinfection destroys pathogenic organisms (excluding bacterial spores) or their toxins, or vectors by direct exposure to chemical or physical means.

Endoscope-refers to a tubular instrument used to examine the interior of the hollow viscera. In this document, "endoscope" refers only to flexible gastrointestinal endoscopes.

Enzymatic cleaner-a cleaner that uses enzymes to remove protein from surgical instruments.

High level disinfection-a process that kills all microorganisms with the exception of high numbers of bacterial spores and prions. High-level disinfectants have the capability to inactivate hepatitis B and C viruses, HIV, and *Mycobacterium tuberculosis*, but do not inactivate the virus-like prion that causes Creutzfeld-Jakob disease. Government-registered high-level disinfection agents kill vegetative bacterial, tubercle bacilli, some spores and fungi, and lipid and nonlipid viruses, given appropriate concentration, submersion, and contact time.

Terminology

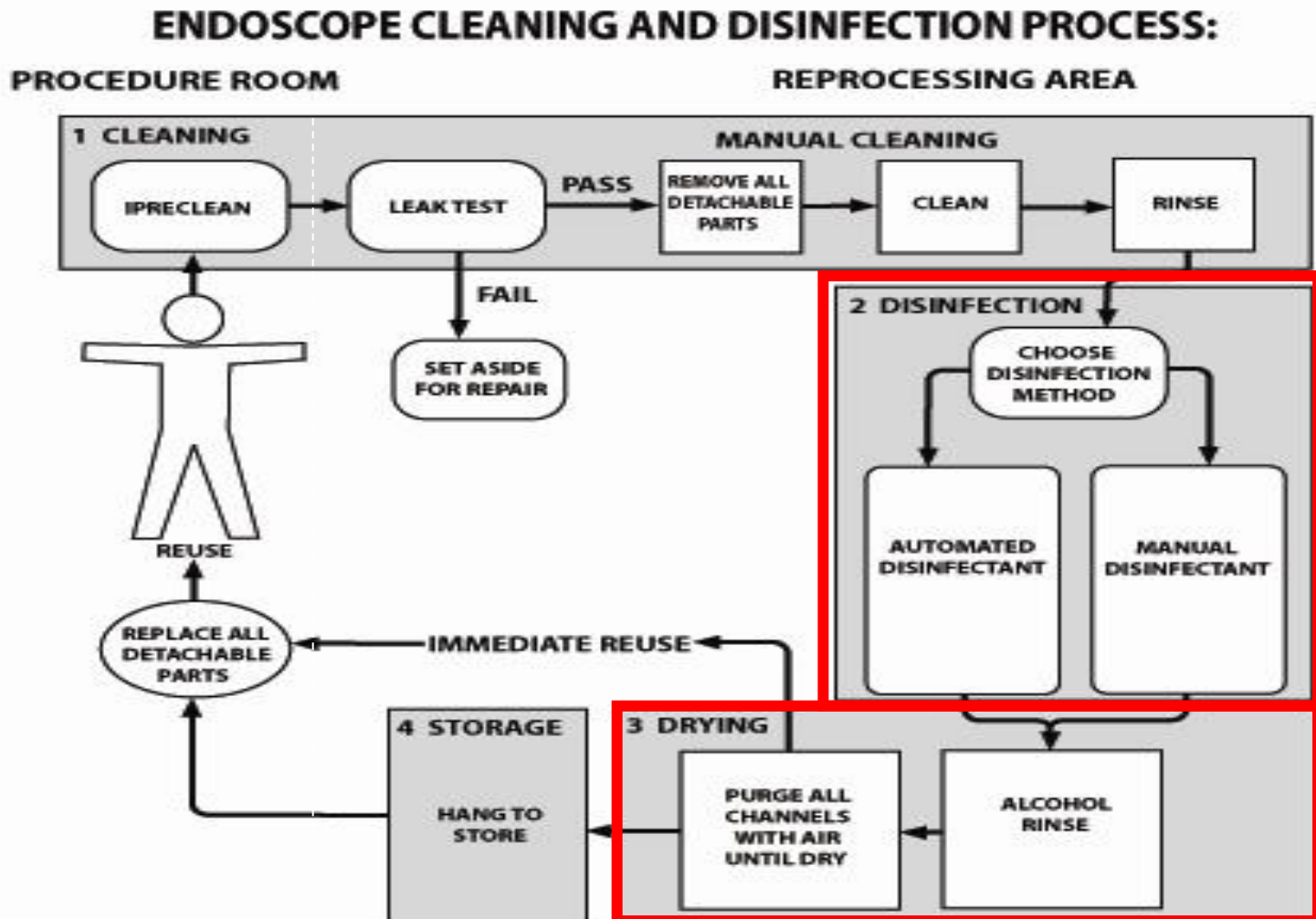
Reprocessing-refers to the validated process of cleaning then disinfecting, or sterilizing endoscopes and accessories. In relation to endoscopy, it includes all the steps from pre-cleaning to drying.

Sterile-refers to the state of being free from viable microorganisms (AAMI, 2015)

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

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

Endoscope Reprocessing



Manual Cleaning

Manual Cleaning

- Thorough and meticulous manual cleaning of all instruments must precede exposure to any high-level disinfectant or sterilant. This process significantly reduces the organic and microbial challenge to the high-level disinfectant or sterilant. An item that has not been cleaned cannot be assuredly disinfected or sterilized.
- Refer to endoscope manufacturers' guidelines for design features unique to a particular instrument

Personal Protective Equipment

- Should be used when reprocessing endoscopes. Gowns, gloves and protective eyewear are recommended when handling any high-level disinfectant / sterilant

Personal Protective Equipment

Personal Protective Equipment

Gowns – impervious to fluid, long sleeves that fit snugly around the wrist, and wrap to cover as much of the body as possible. Dispose of or launder gowns if they become wet or are exposed to contaminated material

Gloves – inspect for tears or holes before use. Gloves should be long enough to extend up the arm to protect the forearm or clothing from splashes or seepage. To prevent cross-contamination, change gloves and wash hands whenever moving from a dirty to clean task or environment

Eye and / or face protection are necessary – contact lenses are not sufficient eye protection. A face shield is recommended. Do not use high filtration masks since they may actually trap vapours.

Reprocessing Room Standards

- The process and products used for cleaning, disinfection and or/sterilization of endoscopes must be compatible with the equipment being used
- Each health care setting in which endoscopic procedures are performed should have written detailed procedures for the cleaning and handling of endoscopes
- Reprocessing of contaminated patient equipment should be done in an area designated and dedicated for this function
- This room should be separate from where endoscopic procedures are performed
- Ventilation must be capable of removing toxic vapours generated by, or emitted from, cleaning or disinfectant agents – the vapour concentration of the chemical disinfectant being used should not exceed allowable limits (eg. 0.05 ppm for glutaraldehyde)
- Minimum of 10-12 air exchanges per hour in the reprocessing area

Reprocessing Room Standards

- Tap water and / or water that has been filtered by passage through a 0.2micron filter or water of equivalent quality should be available in the reprocessing area
- Manual cleaning should include a medical grade, low-foaming, neutral pH enzymatic formulated for endoscopes that contain enzymes to digest all components of bioburden; including, blood, fat, carbohydrate, uric acid, starch

Accessories

- Accessories which are classified as critical devices (e.g. biopsy forceps) require sterilization. Critical items labeled for single-use should not be reprocessed and / or reused.

Transportation and Handling of Contaminated Endoscopes

- Covered containers with easily cleanable surfaces should be used for handling and transporting soiled endoscopes
- Soiled endoscopes should be transported by direct routes where cleaning will be performed
- Containers used to transport soiled endoscopes should be cleaned after each use and need to have a Biohazard sticker on the outside of the container.

Endoscope Reprocessing Protocols

Basic steps to clean and perform high-level disinfection of gastrointestinal endoscopes

- 1) Pre-cleaning
- 2) Leakage testing
- 3) Cleaning
- 4) Rinsing
- 5) Disinfection
- 6) Rinsing
- 7) Drying
- 8) Storage

Endoscope Reprocessing Protocols

A. Pre-cleaning

- 1) Immediately after removal of the insertion tube from the patient and prior to disconnecting the endoscope from the power source

Prepare for bedside cleaning:

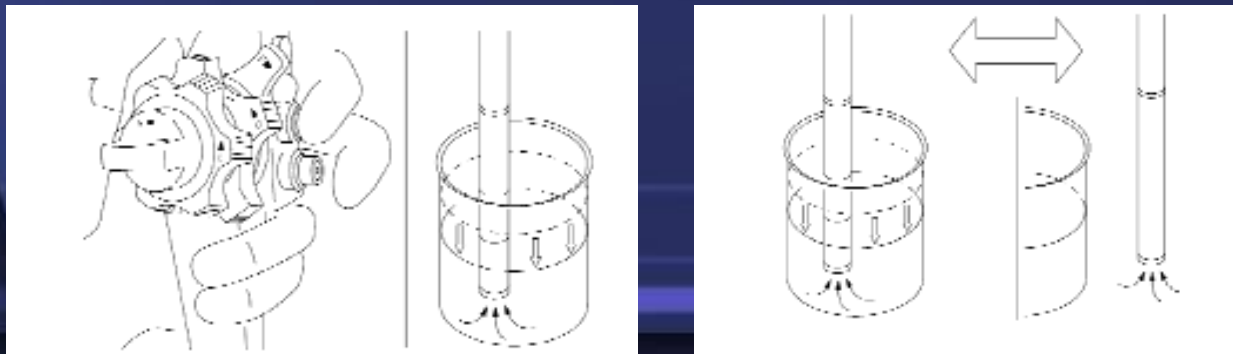
- ✓ PPE
 - ✓ Container with enzymatic
 - ✓ Sponge or lint-free cloth
 - ✓ Air and water channel cleaning adapters per manufacturer's instruction
 - ✓ Protective video cap
- 2) Wipe the insertion tube with the wet cloth or sponge soaked in the freshly prepared enzymatic solution. Note that the cloth / sponge should be disposed of between cases

Endoscope Reprocessing Protocols

A. Pre-cleaning

- 3) Place the distal end of the endoscope into the enzymatic solution. Suction the solution through the biopsy / suction channel, alternate suctioning enzymatic solution and air several times until the solution is visibly clean – Finish by suctioning air

Note: *Alternate suctioning of fluid and air is more effective than suctioning fluid alone in the removal of debris from lumens – immediate flushing of the biopsy/suction and air/water channels precludes drying of debris on lumen surfaces*



Endoscope Reprocessing Protocols

A. Pre-cleaning

- 4) Flush or blow out air and water channels in accordance with the endoscope manufacturer's instructions
- 5) Flush the auxiliary water channel
- 6) Detach the endoscope from the light source and suction pump
- 7) Attach protective video cap if using a video endoscope
- 8) Transport the Endoscope to the reprocessing area in an enclosed container

Note: *Containers, sinks, and basins should be large enough that the endoscope will not be damaged by being coiled too tightly*

Endoscope Reprocessing Protocols

B. Cleaning the Endoscope in the Reprocessing Area

Prepare the following:

- ✓ PPE
- ✓ Leakage testing equipment
- ✓ Channel cleaning adapters
- ✓ Large basin of endoscope detergent solution
- ✓ Channel cleaning brushes
- ✓ Sponge or lint-free cloth

C. Leak Testing

- Leak Testing detects damage to the interior or exterior of the endoscope
- The leak test is done before immersion of the endoscope in reprocessing solutions to minimize damage to parts of the endoscope not designed for fluid exposure.

Endoscope Reprocessing Protocols

C. Leak Testing

1. Manual Leak Testing

- Remove suction valves, air water valves, and biopsy valves
- Attached the leak tester and pressurize the scope before submerging it in water
- 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, observing the control head of the scope, depress the freeze and release buttons.
- Check the insertion tube and distal bending section as well as the universal cord for bubbles coming from the interior of the scope

Endoscope Reprocessing Protocols

D. Cleaning Solutions

- Composition of soil found on endoscopes includes, proteins, fats, carbohydrates and the various chemical salts that exist in blood and other body fluids.
- Ideally, a cleaning solution should have a broad spectrum of effectiveness against these various contaminants and not harm the device being cleaned
- i) Enzymatic cleaning solutions use surfactants to breakdown and digest bioburden. They are specifically selected to have a negligible effect on surface tension while still suspending soil particles. This feature provides easy rinsability.

Endoscope Reprocessing Protocols

E. Cleaning

Manual cleaning of endoscopes is necessary immediately after removing the endoscope from the patient and prior to automated or manual disinfection

- Performed as 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

Endoscope Reprocessing Protocols

E. Cleaning

1. Fill a sink with freshly prepared solution of water and a medical grade, low-foaming, neutral pH detergent formulated for endoscopes – Enzymatic detergent must be discarded after each use.
2. Dilute and use according to the detergent manufacturer's instructions.
3. Immerse the endoscope
4. Wash all the debris from the exterior of the endoscope by brushing and wiping the instrument while submerged in the detergent solution. Note that the instrument should be left under water during the cleaning process to prevent splashing of contaminated fluid and aerosolization of bioburden

Endoscope Reprocessing Protocols

E. Cleaning

5. 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.
6. Brush all accessible endoscope channels including the body, insertion tube and the umbilicus of the endoscope – brushes used for cleaning lumens should be of an appropriate size, inspected before and after use and discarded or cleaned, high-level disinfected and dried following use
7. After each passage, rinse the brush in enzymatic solution, removing any visible debris before retracting and reinserting it
8. Continue brushing until there is no debris visible on the brush
9. Cleaning items should be disposable or thoroughly cleaned and minimum of high-level disinfected between cases.

Endoscope Reprocessing Protocols

E. Cleaning

10. Attach the endoscope cleaning adapters for suction, biopsy, air, and water channels

Note: *Automated pumps are available for this step that eliminate the manual flush*

11. Attach the manufacturer's cleaning adapters for special endoscope channels (dual channel, elevator channel, auxilliary channel)

- i. To achieve adequate flow through all lumens, various adapters or channel restrictors may be required
- ii. The elevator channel of a duodenoscope is a small lumen, this channel requires manual reprocessing using a 2-5mm syringe

12. Flush all channels with the detergent solution to remove debris

13. Soak the endoscope and its internal channels for the period of time specified by the label

14. **If immediate reprocessing is not possible the endoscope should be leak-tested, flushed, brushed, and allowed to soak in a enzymatic solution until it can be thoroughly reprocessed**

Endoscope Reprocessing Protocols

F. Rinse After Cleaning

- Thoroughly rinse the endoscope and all removable parts with clean water to remove
- 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

G. High Level Disinfection

- Recognized as the standard of reprocessing for endoscopes by:
 - ✓ CSGNA / SGNA
 - ✓ ASGE – American Society for Gastrointestinal Endoscopy
 - ✓ ACG - American College of Gastroenterology
 - ✓ AGA - American Gastroenterological Association
 - ✓ APIC - Association for Professionals in Infection Control and Epidemiology
 - ✓ CDC – Centers for Disease Control and Prevention

Automated Endoscope Reprocessing

- Ensure that the endoscope and endoscope components are compatible with the automated endoscope reprocessor (AER)
- Follow the OEM instructions for use in the AER
- AER provide a method by which a permanent record of endoscope use and reprocessing can be monitored and validated
- Some AER have a system capable of tracking endoscopes and patients. For each procedure the patients name and record number, the date and time of procedure, type of procedure, the endoscopist and the serial number of the endoscope are recorded and stored to assist in outbreak investigation.

Endoscope Reprocessing Protocols

F. DRYING

- Purge all channels with air until dry
- Flush all channels, including accessory channels, with alcohol until the alcohol can be seen exiting the opposite end of each channel
 - i. 70% isopropyl alcohol is used to assist in drying the interior channel surfaces
 - ii. 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
 - iii. 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

Endoscope Reprocessing Protocols

F. DRYING

- 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 to the endoscope during storage as this lowers the risk of trapping liquid inside the instrument

Endoscope Reprocessing Protocols

F. DRYING

Drying the endoscope after every reprocessing cycle, both between patient procedures and before storage is a requisite practice crucial to the prevention of bacterial transmission

Drying is as important to the prevention of disease transmission as cleaning and high level disinfection

G. STORAGE

- Hang the endoscope vertically, with the distal tip hanging freely in a clean, 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
- Caps, valves and other detachable components should be removed during storage and reassembled before use
- Colonoscopes have a minimum shelf life of 7 days, if stored dry