

2019

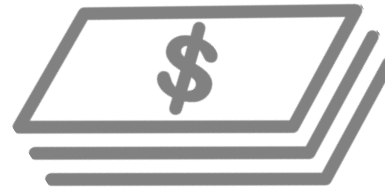
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APIC EDUCATION

Endoscope Reprocessing for the Infection Preventionist

Rebecca T. Alvino RN, MS, CNS, CIC, CNOR

- There are no financial disclosures to report.
- I am the Nurse Liaison/Infection Prevention Advisor for the California Central Service Association (CCSA) (volunteer board position).



Objectives for Today's Session

- Identify the basic anatomy of an endoscope.
- List some of the different published guidelines that are applicable to endoscope reprocessing.
- Describe the steps for endoscope reprocessing from point-of-use to storage.
- Identify some of the behaviors and practices that could indicate problems with endoscope reprocessing in your facility.

Endoscope Reprocessing: What's the Big Deal?

- ECRI Institute (2019) calls endoscopes one of the top 10 risks to patient safety
- Endoscopes are vital to providing clinical care through less-invasive procedures

Superbug outbreaks

“Complex, reusable instruments – such as endoscopes, cannulated drills, and arthroscopic shavers – are of particular concern.”

Contaminated Scopes Infect Patients

Study: Nearly three-quarters of commonly used medical scopes tainted by bacteria

Who Publishes the Information, Standards, and Guidelines That Influence, Educate, and Regulate Endoscope Reprocessing?

- AAMI (Association for the Advancement of Medical Instrumentation)
- AORN (Association of periOperative Registered Nurses)
- APIC (Association for Professionals in Infection Control and Epidemiology)
- ASGE (American Society of Gastroenterologists)
- CDC (Centers for Disease Control and Prevention)
- CMS (Centers for Medicare and Medicaid Services)
- DNV GL (Det Norske Veritas Germanischer Lloyd)
- FDA (US Food and Drug Administration)
- SGNA (Society of Gastroenterology Nurses and Associates)
- TJC (The Joint Commission)

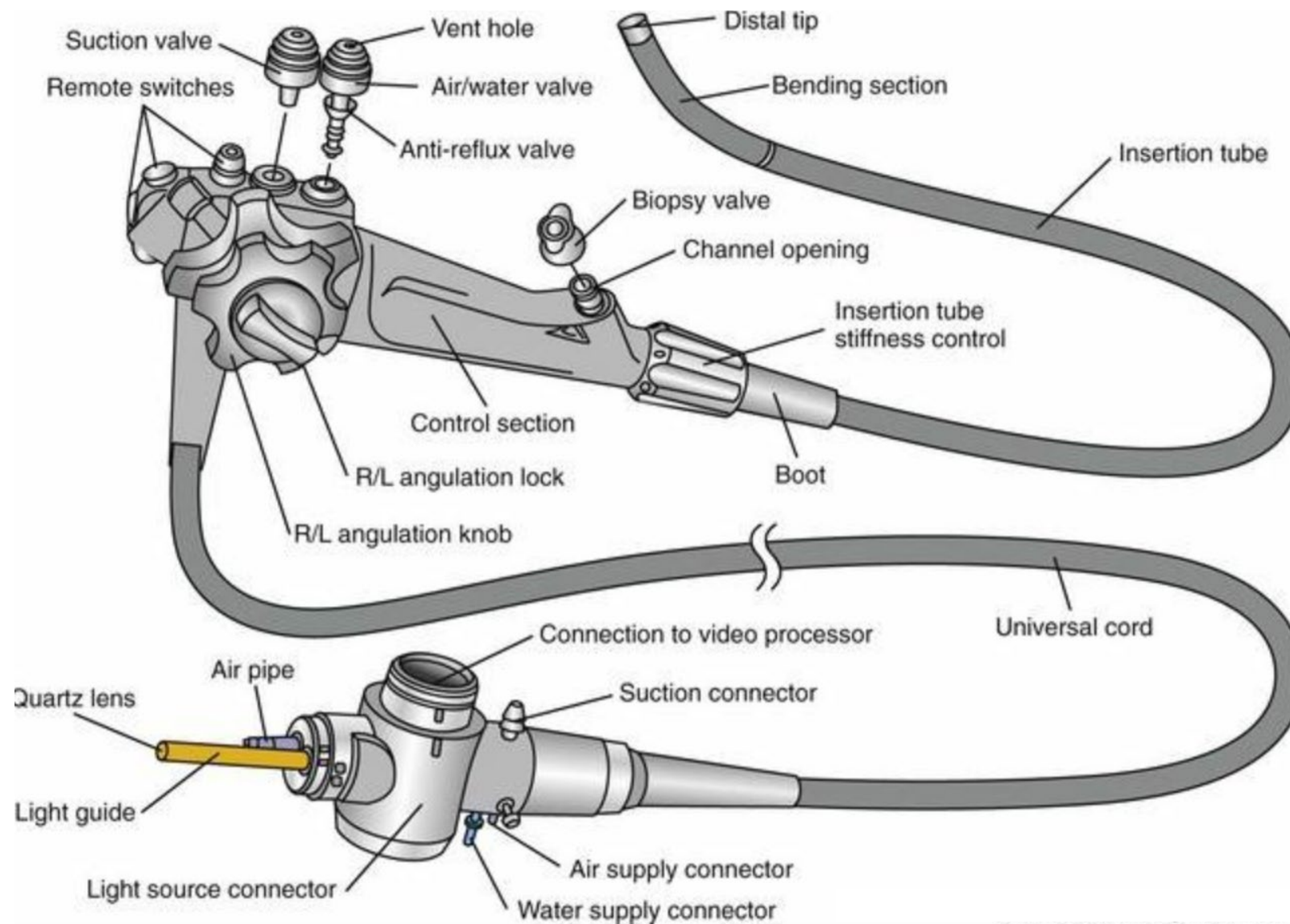


Essential Elements of an Endoscope Reprocessing Program

HICPAC (2017; 2015) outlined these essential elements:

- Administrative
- Documentation
- Inventory
- Physical Setting
- Education, Training, and Competencies
- Risk Assessment and Quality Assurance
- Disinfection/Sterilization Breach or Failure

Basic Anatomy of an Endoscope



Where Might Endoscopes Be Used?



- Hospital (acute care) setting
- Ambulatory surgery or ambulatory endoscopy center
- Office-based setting
- Others?

Can Endoscopes Be Reprocessed Anywhere?

Some of the key AAMI ST91 (2015) Design Recommendations:

- Unidirectional workflow from dirty to clean to storage
- Physically separated from patient procedure rooms
- Defined decontamination, high-level disinfection/sterilization areas, and storage areas (physical separation by walls, doors, and/or pass-through windows is ideal) of sufficient space
- Sufficient space for leak testing to take place
- Designated drying area

Can Endoscopes Be Reprocessed Anywhere?

Some of the key AAMI ST91 (2015) Design Recommendations:

- Considerations for adequate lighting and ergonomics for staff
- Level floors that are monolithic or joint-free
- Walls and ceilings constructed of non-shedding, non-particulate materials that can withstand frequent cleaning
- Flush ceilings with pipes enclosed and fixtures recessed
- Decontamination areas (when physically separate) and single-space reprocessing areas should maintain negative pressure relationships to adjacent areas

Temperature, Humidity, and Air Exchanges Required for Endoscope Reprocessing Areas

AAMI (2015)

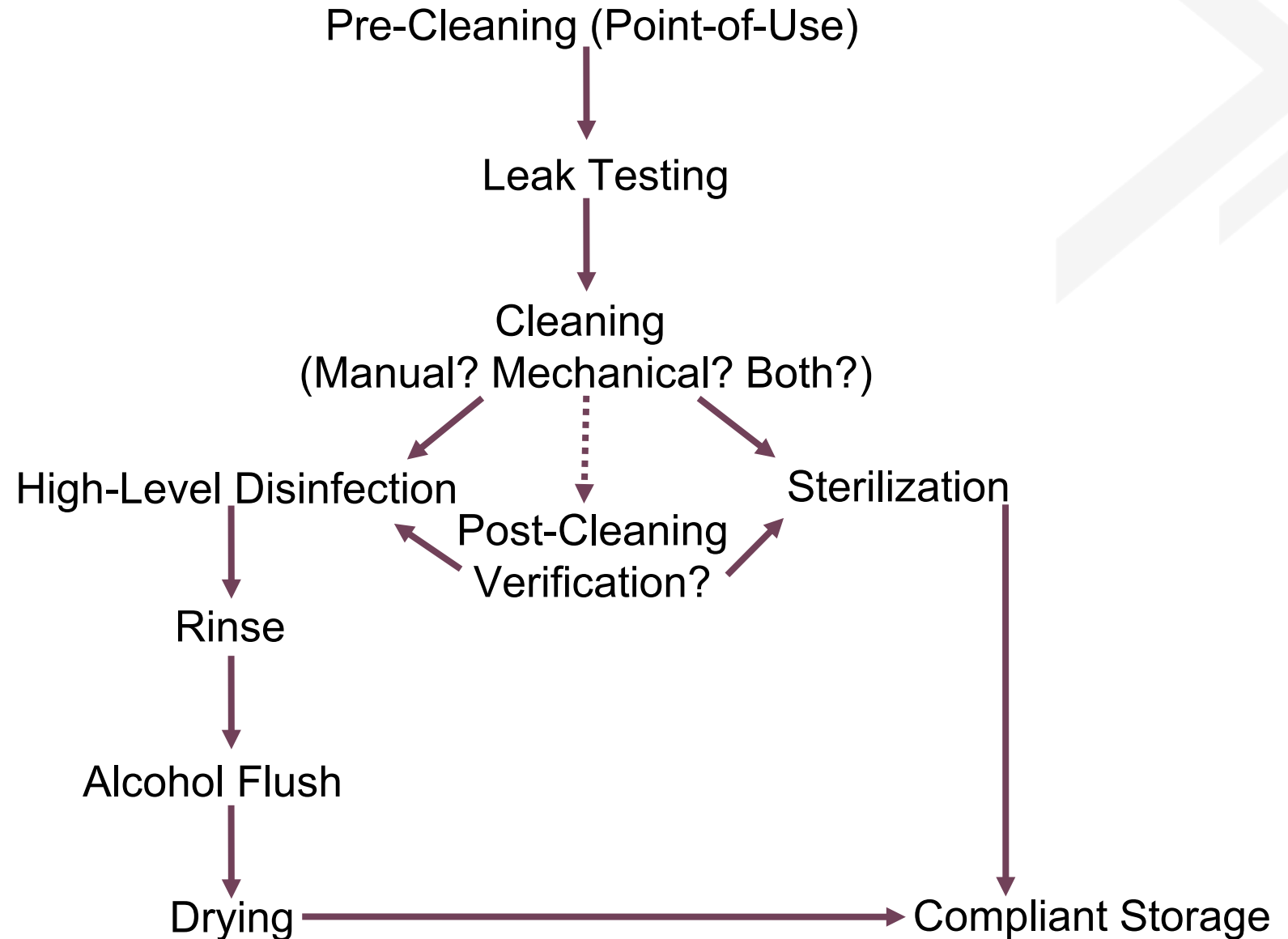
**ANSI/ASH
E/ASHRA
E
Standard
170
(2017)**

	Temp (F/C)	Humidity (%)	Air Changes per Hour (ACH)	Air Relationship to Adjacent Area
Decontamination Area/Single-Space Reprocessing Area	NR	NR	10	Negative
Clean Area	68-73 (20-23)	30-60%	10	Positive
Storage Area	Max 75 (24)	Maximum 60%	4	Positive

Endoscope Reprocessing Steps



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Endoscope Pre-Cleaning: How Important Is It?

It is *NOT* just a regulatory requirement, and it is *NOT* just a step in the IFU!

Putnam (2016) lists the general pre-cleaning steps as follows:

- Prepare fresh solution of the cleaning product;
- Wash exterior surfaces with a soft, lint-free cloth or saturated sponge;
- Suction the cleaning solution through device channels;
- Alternate flushing of channels with cleaning solution and air, finishing with air;
- Place the distal end of the endoscope into cleaning solution and suction through the endoscope;
- Visually inspect the endoscope for damage;
- Discard the cleaning solution and cloth/sponge after use.



QUESTION FOR YOU!!



What are biofilms?

- A. Blood, carbohydrates, and other proteins left in their gross state on endoscopes and other surfaces after manual cleaning**
- B. An accumulated biomass of bacteria and extracellular material that is tightly adhered to a surface and cannot be removed easily**
- C. Population of viable microorganisms on a product and/or a sterile barrier system**
- D. What x-rays are developed and printed on**

Biofilms on instruments and environmental surfaces: Do they interfere with instrument reprocessing and surface disinfection? Review of the literature

Michelle J. Alfa PhD *

Department of Medical Microbiology, University of Manitoba, Winnipeg, Manitoba, Canada

- Traditional biofilm forms in conditions of continuous hydration (water pipes, showers, taps, sinks, etc.)
- Dry surface biofilms (Almatroudi et al., 2017) persist on hard and soft environmental surfaces, and represent a heterogenous accumulation of organisms and other material in a dry matrix
- Build-up biofilm (BBF) is the accumulation of material forms by repeated patient-exposure, cleaning and disinfection or sterilization and dry storage
- The major difference in these two: BBF undergoes repeated complete or partial fixation through exposure to chemicals (disinfectants or sterilants) or heat (sterilization) that fixate organic residuals onto medical device surfaces

Soiled Endoscope Transport: Just HOW Do the Endoscopes Get to their Next Stop?

- AAMI ST91 (2015) recommends a closed system for transport
- ONE endoscope and its accessories (reusable valves) per container. Container should be large enough to maintain a large coil diameter for the endoscope
- Forceps and other instrumentation should travel in a separate container
- The container must be leak proof, puncture resistant, and labeled as biohazardous as per OSHA 29 CFR 1910.1030



What Attire is Required in Endoscope Reprocessing Areas?

AAMI ST91 (2015)	AORN (2019)
Clean uniforms that are provided by and donned at the facility	Clean surgical attire and head coverings should be worn in the processing room (5: Benefits Balanced with Harms)
Change attire daily or more often as needed, such as when wet, grossly soiled, or otherwise contaminated	Scrub attire that has been penetrated by blood, body fluids, or other potentially infectious materials must be removed ASAP and replaced with clean attire (Regulatory Requirement)
Reusable uniforms should be laundered by a healthcare-accredited laundry	Launder scrub attire at a healthcare-accredited laundry facility, the healthcare organization according to state regulatory requirement OR according to CDC laundering recommendations (if no state requirements) (Recommendation)
All head and facial hair (except eyebrows and eyelashes) should be completely covered with surgical-type hair covering	Cover scalp and hair when entering semi-restricted and restricted areas (Recommendation); cover a beard when entering restricted areas and while preparing and packaging items in the clean assembly section of the sterile processing area (Recommendation); remove head coverings at end of shift or when contaminated (Recommendation)
Shoes worn in processing area should be clean, have non-skid soles, sturdy enough to prevent injuries from dropped items. Liquid-resistant shoe covers worn if potential for contamination and/or soaked with blood or other bodily fluids	Wear clean shoes when entering semi-restricted and restricted areas (Recommendation); fluid-resistant shoe covers or boots are worn in instances when gross contamination can be reasonably expected (Regulatory Requirement); shoe covers worn as PPE must be removed immediately after use, discarded, and hand hygiene performed (Regulatory Requirement)

PPE for Endoscope Reprocessing: Vital for the Work or a Fashion Faux Pas?

- Personal protective equipment (PPE) for cleaning flexible endoscopes requires gloves, eye and skin protection
 - AORN (2019): Surgical mask with eye protection, a fluid-resistant gown, general purpose utility gloves that extend beyond the cuff of the gown, and fluid-resistant shoe covers
- Assess PPE for breaches (saturated gown sleeves, saturated masks, holes in gloves, etc.)
- Reusable PPE decontaminated and integrity checked for breaches between uses



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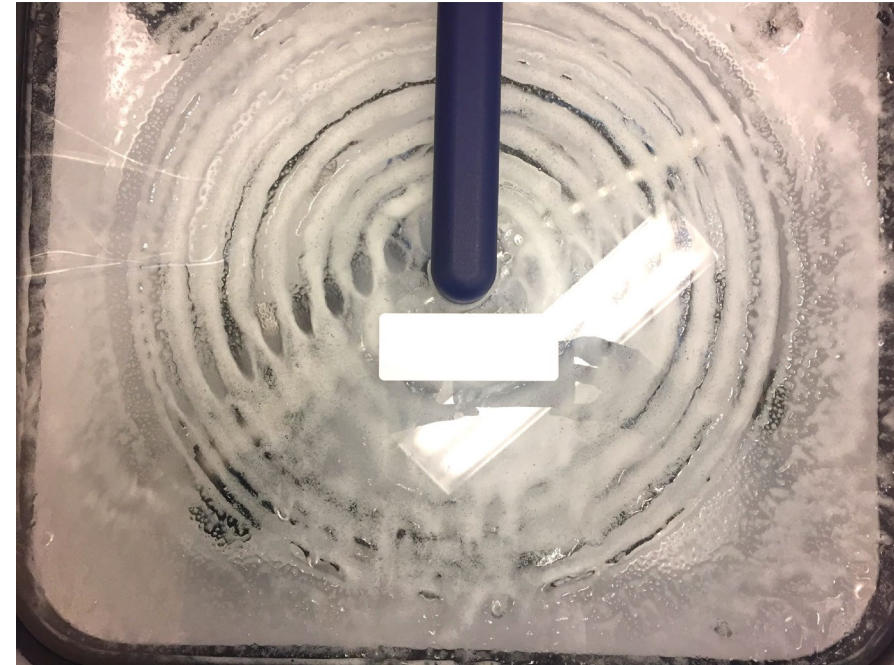
What is Leak Testing?



- Leak-testing checks the integrity of the endoscope using pressurization and air to identify leaks
 - Leaks in endoscopes = Damage to endoscopes
 - Without leak-testing, damaged endoscopes that are subjected to cleaning and reprocessing could further damage the endoscope to an unusable condition
 - How is leak testing performed at your facility: manually, with an automated process, or both?
-
- **DRY LEAK TEST FIRST!** If the endoscope passes, then proceed to the submerged (wet) leak test
 - If an endoscope **FAILS** a leak test, refer to the IFU for instructions for cleaning and preparation for repairs

Endoscope Cleaning: It is Vital to Reprocessing!

- What guides the cleaning process for each type of endoscope in your facility?
- Some cleaning steps in some complex endoscope IFUs (such as duodenoscopes) consist of 10+ pages of cleaning steps!
- Reusable valves should be disassembled from the endoscopes, but stay together through the reprocessing cycle. How are reusable valves cleaned?
- Are brushes single-use or reusable? If reusable, when should they be reprocessed? When should they be changed?
- How often are detergent solutions changed?

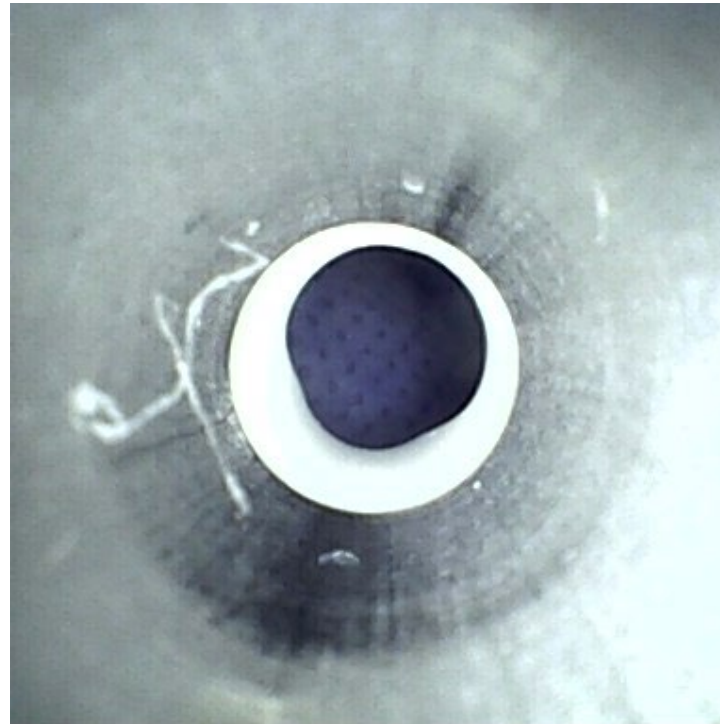
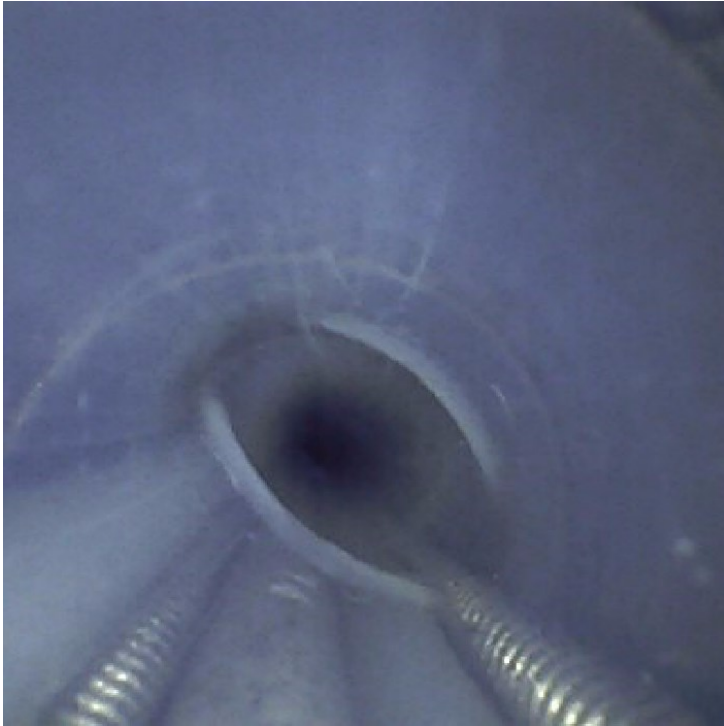


TIMELY Endoscope Cleaning is Vital to Reprocessing!



- How do your endoscope reprocessing teams address delays in reprocessing?
- Which IFUs contain explicit instructions around delayed reprocessing?
- Does delayed reprocessing implementation create new bottlenecks in cleaning for other soiled endoscopes?
- What is done by endoscope reprocessing teams to implement delayed reprocessing?
- What are end-users doing to make sure their devices do not require delayed reprocessing implementation?
- Conversely, is there such a thing as STAT reprocessing?

If It Isn't Clean, Can It Really Achieve High-Level Disinfection or Sterilization?



Post-Cleaning Verification: Because If It Isn't Clean...

- Visual inspection combined with other methods to allow assessment of external surfaces, internal housing, and internal channels
- Testing mechanical equipment cleaning efficacy
- Monitoring of key parameters, such as temperature, etc.
- Cleaning verification tests for users to measure levels of organic soil and microbial contamination on the cleaned device
 - Protein
 - Carbohydrate
 - Hemoglobin
 - Adenosine triphosphate (ATP)
 - Bacteria-specific enzyme



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QUESTION FOR YOU!!

True or False?

According to the FDA, testing for cleaning adequacy AFTER high-level disinfection is not appropriate.

FDA (2018)

High-Level Disinfection for Endoscopes

- What kind of high-level disinfectant(s) does your facility use?
- What is the contact time required by the IFU?
- Temperature requirements? How is temperature obtained?
- Locally exhausted or in a negatively-pressured space?
- Delivery by automated endoscope reprocessor or manual immersion?
- Quality testing of high-level disinfectant?



Automated Endoscope Reprocessors

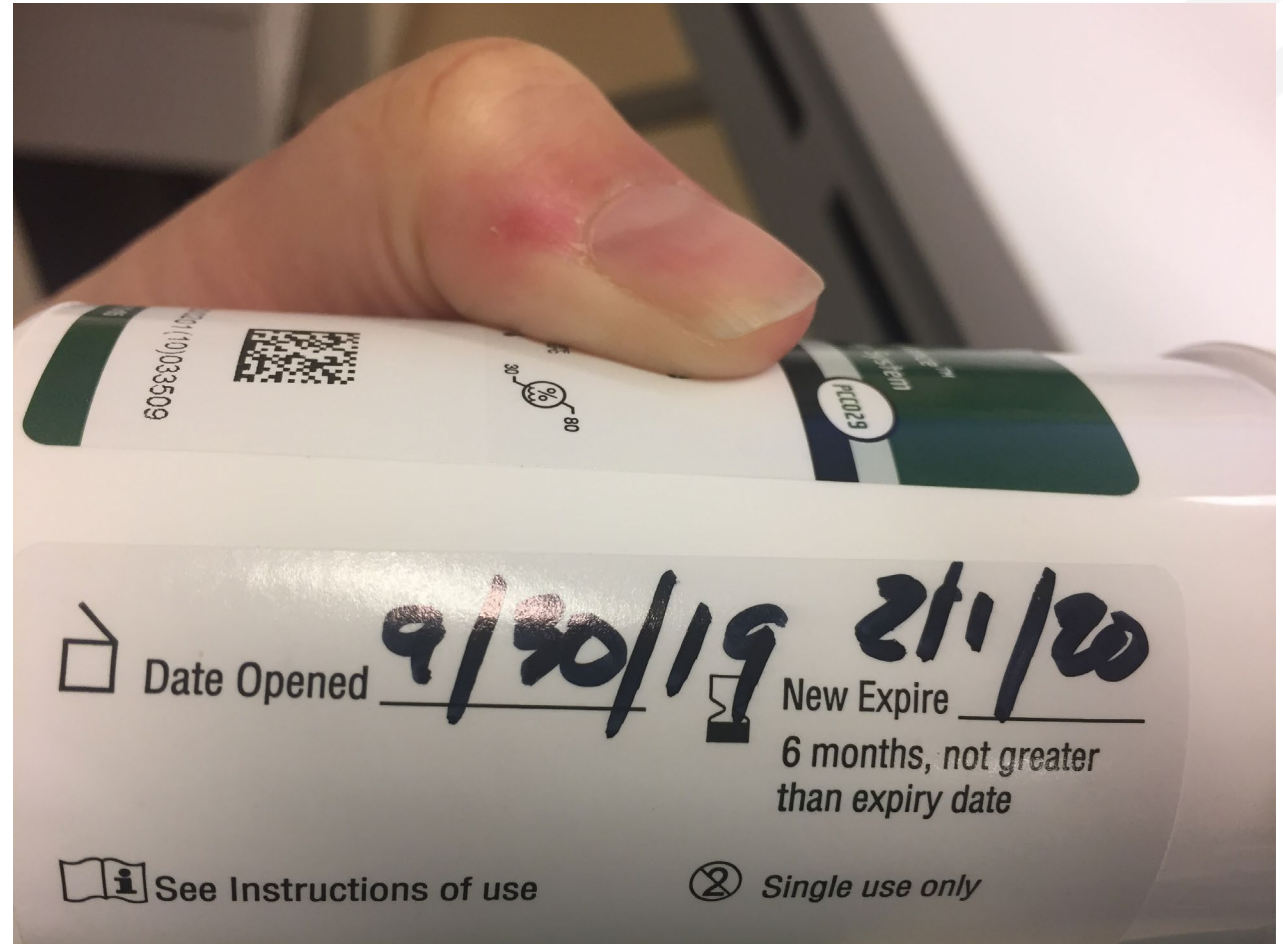
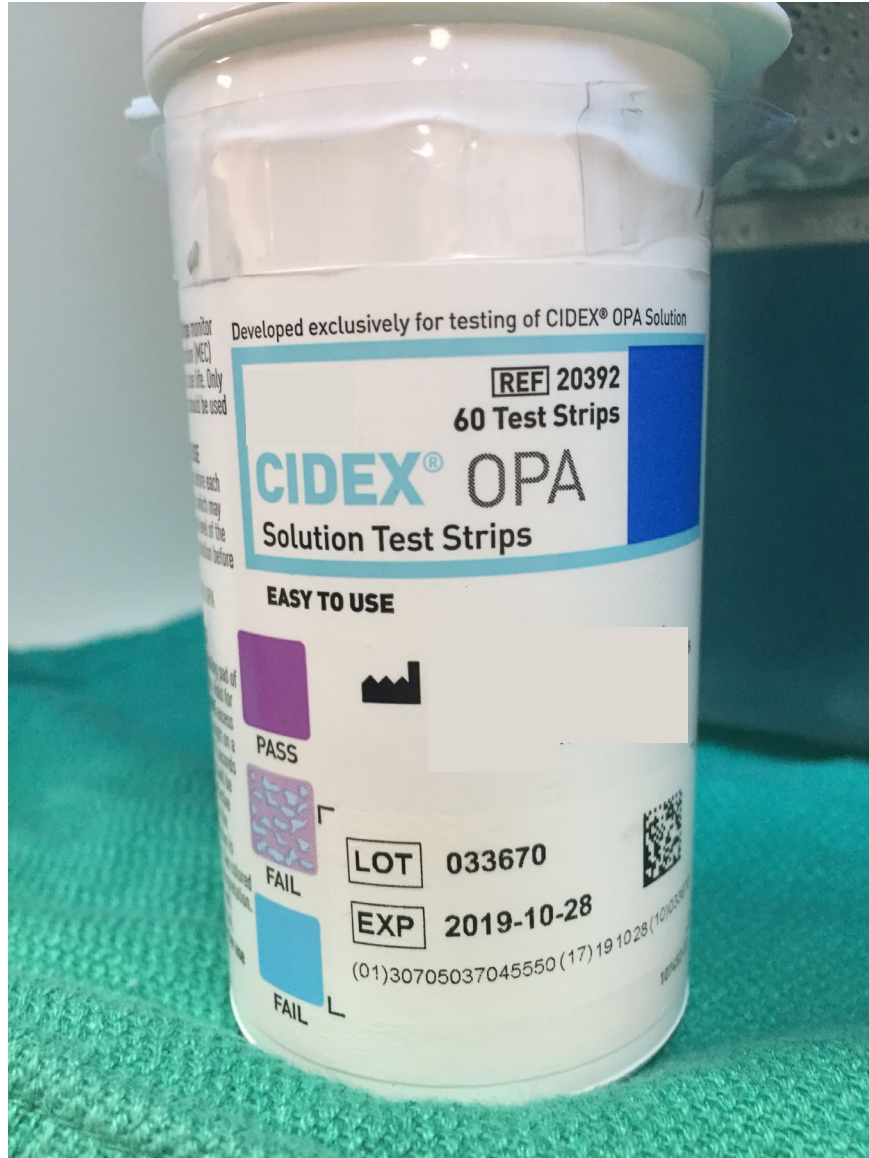
- If using automated endoscope reprocessor (AER), are the endoscopes reprocessed in the AER validated for this AER?
- How often is the AER cleaned?
- Connectors are available for each type of endoscope?
- Connectors are regularly cleaned? What does the IFU of the AER require/recommend?
- Are endoscope accessories able to be reprocessed in the AER?
- Is a validated high-level disinfectant used in the AER?
- Are endoscopes placed in the AER so all surfaces achieve contact with the high-level disinfectant?



Manual Immersion High-Level Disinfection

- Where is the manual immersion HLD located?
- Are immersed endoscopes non-channeled or channeled? How are channels filled with disinfectant?
- Is high-level disinfectant within temperature?
- Solution tested for potency/quality assurance at each use?
- QA materials for solution are not expired, either per policy or per manufacturer?
- Documentation of QA process?
- Is endoscope fully submerged?
- Air bubbles on the surface of the endoscope? After flushing channels with disinfectant?
- How long is the soak time for the disinfectant?
- What is the rinsing process? Where is the endoscope rinsed? What is the water quality required per IFU?
- Is fresh PPE donned for manual immersion?

Are These Test Strips OK to Use Today?



Rinse Water Quality Matters!

- AORN (2019) recommends critical water for reprocessing flexible endoscopes
- AAMI (2015) recommends potable water (see AAMI TIR34) for manual rinsing after cleaning. Refers to endoscope IFU for rinse water quality post-HLD
- SGNA (2018) recommends clean water
- **Fresh water for each rinse cycle!**

Critical Water Quality (AORN, 2019)

Hardness: <1mg/L
calcium carbonate

pH 5 to 7

Chloride <1mg/L

Bacteria <10 CFU/mL

Endotoxin <10
endotoxin units (EU)/mL

Drying Endoscopes: Because Moist Endoscopes Aren't Cool



- Drying is critical to maintaining the quality of the reprocessed endoscope!
- Instrument air is necessary for drying endoscopes!
- Alcohol flush are currently recommended in the US by AAMI (2015) and required by SGNA (2018); AORN (2019) recommends performing a multi-disciplinary risk assessment
- APIC (2019) lists alcohol flush with 70-90% ethyl or isopropyl alcohol
- When it comes to performing alcohol flushes, what do the IFUs of the endoscopes say?
- Is an endoscope in storage not yet dry? SGNA (2018) says it must be reprocessed before patient use

Yes, You CAN Sterilize (Some) Endoscopes!



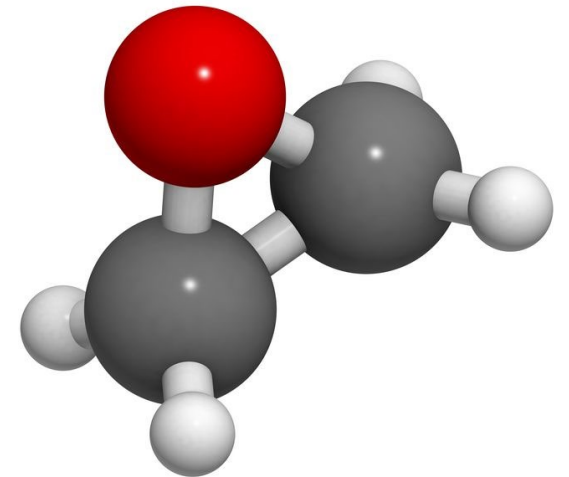
- Sterilization: Complete elimination or destruction of all forms of microbial life
- AAMI (2015): Sterilization is the only option in sterile environments
- Instruments that enter sterile tissue (such as biopsy forceps, sphincterotomes, etc.) **MUST** be sterilized

- Which packaging materials are validated for use by the endoscope manufacturer?
- Not all endoscopes can be sterilized, and not all sterilizable endoscopes can be sterilized using the same sterilization modalities!



Ethylene Oxide (EO) Sterilization of Endoscopes

- Sterilization modality for heat and moisture-sensitive materials
- Certain packaging materials can be used in EO sterilization
- Toxic! Permissible exposure limits of 1 part per million airborne EO in the workplace—employee exposure monitoring is critical to safety AND a regulatory requirement
- Items undergoing EO sterilization (including lumens) must be dry prior to sterilization
- EO sterilization and aeration should be assigned to qualified personnel with demonstrated competence in all areas of sterile reprocessing
- Items that undergo EO sterilization (including flexible endoscopes) must undergo aeration, usually for several hours



Endoscope Storage: Horizontal? Vertical? In a Container? Tucked Away In an Office? Stored in a Foam-Lined Suitcase?



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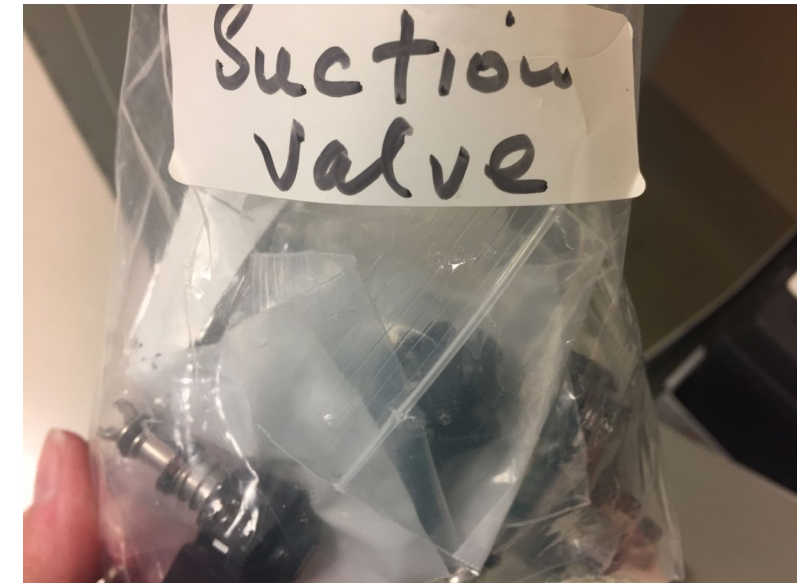


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- Reprocessed endoscopes should hang vertical in a cabinet that is well-ventilated, clean, and provides enough space for endoscopes to not coil or contact other endoscopes
- Caps, valves, and other detachable components should be stored with endoscope but not on endoscope
- Drying cabinets? AORN (2019) recommends, but does not require
- Retrieve and handle clean endoscopes with clean, gloved hands
- How long can high-level disinfected endoscopes be safely stored before reprocessing?
- Should endoscopes be stored in procedure rooms?

What About the Endoscope Accessories?

- Instruments that enter sterile tissue **MUST** be sterilized
- Reusable valves must remain with their originating endoscope through reprocessing—but not **IN** the endoscope during reprocessing
- Disposable valves may be an option for some endoscopes
- Water bottles and connecting tubes must also undergo validated HLD or sterilization (or be single-use) at least daily or according to manufacturer's IFU
- Sterile water should be used during procedures

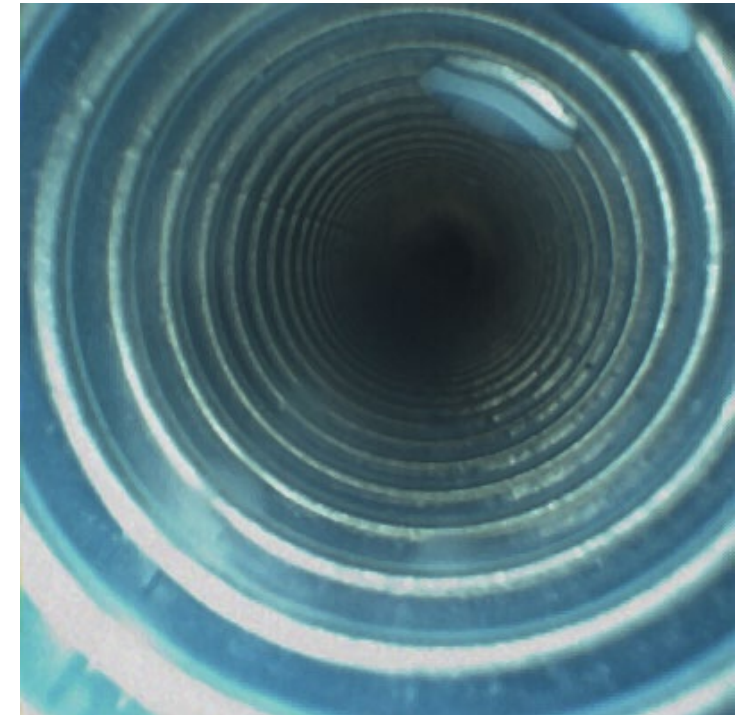


What's Wrong with This Picture?



Post-Cleaning Verification Technologies are NOT “Plug-and-Play” Technologies

- Borescopes: What does the user identify? Does everyone see and interpret the same things in the same way? How are users trained?
- Biomarker assessments: What is a “failure”? What do users do with these results?
- Implementation strategy: Every endoscope? Every x endoscope? Only certain types of endoscopes?
- Do failing results require repeat verification? Recleaning? Both?
- How many rounds of repeat verification and repeat cleaning are acceptable before escalation of concerns (contaminated endoscope, assessment of staff competency in cleaning device)?
- How will findings impact endoscope reprocessing throughput?



The FDA Continues to Remind Facilities of the Importance of Following Duodenoscope Reprocessing Instructions: FDA Safety Communication

Recommendations for a Comprehensive Quality Control Program

- Written procedures to monitor training and adherence to the quality control program
- Documentation of equipment tests, processes, and quality monitors during reprocessing
- Follow manufacturer IFU for leak testing, inspection, and maintenance of the device
- Incorporate the use of quality monitors during reprocessing procedures

FDA (April 12, 2019)



Supplemental Measures to Enhance Duodenoscope Reprocessing: FDA Safety Communication

- Quarantine duodenoscopes until culture-negative
- Use of liquid chemical sterilization for reprocessing
- Additional high-level disinfection cycle
- Ethylene oxide sterilization
- FDA-cleared low-temperature sterilization

Enhanced Reprocessing of Duodenoscopes: Surveillance Microbiological Culturing

- FDA (2018) *Duodenoscope Surveillance Sampling & Culturing: Reducing the Risks of Infection*
 - Preceded by the CDC (2015) interim microbiological culturing guidance



- Two-person process for culturing channels in order to maintain aseptic handling, conduct brushing steps, open packages, and handle upsampled areas of the duodenoscope
- Minimum of two samples should be obtained: 1) Instrument channel sample using flush-brush-flush technique, 2) Sample from elevator recess through flush-and-brush technique. Third sample should be obtained if elevator wire channels are open (unsealed).
- PPE of sufficient quantity for each sampled endoscope, including sterile gowns and gloves
- The 58-page protocol can be found at <https://www.fda.gov/media/111081/download>

Enhanced Reprocessing of Duodenoscopes: Surveillance Microbiological Culturing

- Design of surveillance culturing protocol must include IP, laboratory staff, endoscope reprocessing staff, and other stakeholders
 - Considerations for frequency: every duodenoscope? Every x duodenoscope? A timed cadence?
 - Hold duodenoscopes until results return: is there enough inventory to support clinical needs?
 - Who will complete these surveillance cultures?
 - What is done with these results? Are results to be reported to a committee? Leadership structure? Only positive results reported? What actions are generated from positive results?

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QUESTION FOR YOU!!



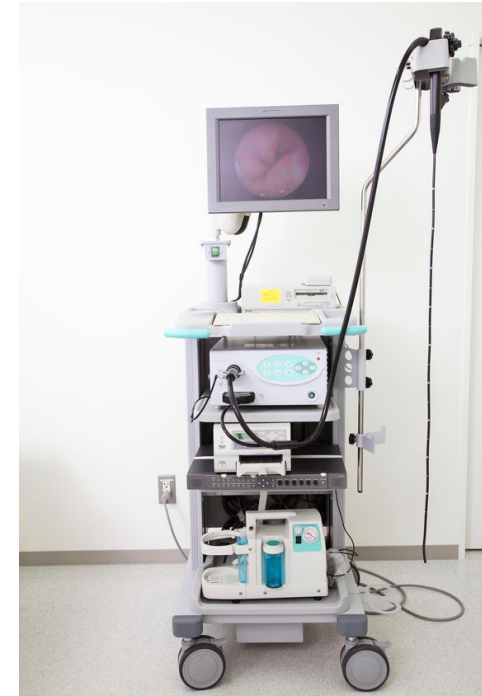
True or False?

According to the FDA, ATP testing could be used in lieu of endoscope sampling and culturing after high-level disinfection.

FDA (2018)

What's the Deal with Simethicone? (And cooking sprays? And infant drops?)

- Simethicone and infant gas relief drops may be used as defoaming agents during clinical use of endoscopes
- Cooking sprays and other lubricants may be used on endoscopes to aid in lubrication for passage of the insertion tubes
- SGNA (2018), citing FDA (2015) and Ofstead et al. (2017), states that if simethicone must be used, it must be used according to the endoscope IFU and at the lowest concentration feasible
- Residual simethicone promotes an environment protective of microorganisms and the formation of biofilm
- Ofstead et al. (2019) suggests that defoaming agents, lubricants, and tissue glues are not effectively removed during endoscope reprocessing
 - Can appear inside the working channels or as an oily substance on the exterior of the endoscope



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Documenting Each Endoscope Reprocessing Cycle

- Assigned lot number, including chemical sterilizer, AER, or soaking container identification and cycle number
- Specific contents of the lot or load, including quantity, reprocessing area, and item descriptions
- Patient's name and unique patient identifier
- Procedure, physician, and serial number or other identification of the item (if available)
- Shelf life date (if applicable), lot number, and date that container of LCS/HLD was opened; the use life of the open container; date product was activated or diluted; date that the ready-to-use solution was poured into the secondary container; reuse-life of the solution

Documenting Each Endoscope Reprocessing Cycle

- Exposure time and temperature, if not provided on the physical monitors
- Date and time of cycle
- LCS/HLD type and concentration
- Name and/or initials of the operator
- Results of BI or spore test strip (for sterilization modalities); result of chemical indicator testing, if applicable; results of solution monitoring strip, if applicable; results of the quality control of test strips, if applicable
- Any reports of positive BIs or spore test strips; inconclusive chemical indicators; low MRC or MEC testing results (as indicated by solution test strips or chemical monitoring device)
- Reports of positive microbial contamination testing



QUESTION FOR YOU!!

True or False?

Patient traceability of each endoscope and its use is not important nor recommended.

AAMI ST91 (2015); SGNA (2018)

What's Wrong with This Picture?



Suspect an Endoscope-Related Outbreak?

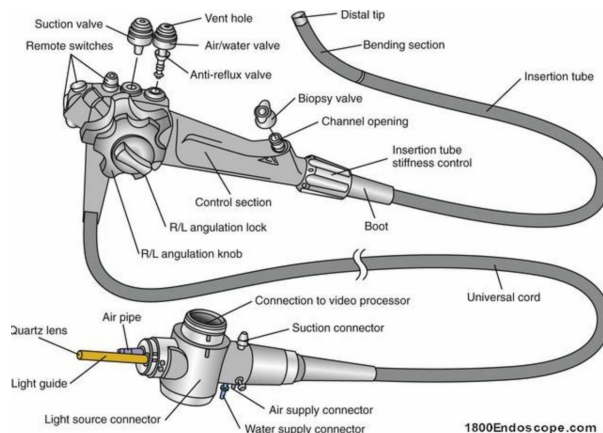
Notify, notify, NOTIFY!

Infection Prevention	Physician(s) responsible for care of patient(s)	Local health authorities	FDA
CDC	Endoscope manufacturer	Disinfectant/sterilant manufacturer	AER manufacturer

- Quarantine device(s) of concern
- If equipment is suspected to be source, remove from service
- Obtain isolates to investigate source or reservoir of infection, mechanism(s) for transmission and effectiveness of control measures, evaluate potential points for cross-contamination during collection, transport, and specimen handling in laboratory
- Thoughtfully consider environmental sampling for outbreak investigation
- Evaluate endoscopic practices and procedures, handling of devices, and practitioner techniques

Did We Meet the Objectives for Today's Session?

- Identify the basic anatomy of an endoscope.
- List some of the different published guidelines that are applicable to endoscope reprocessing.
- Describe the steps for endoscope reprocessing from point-of-use to storage.
- Identify some of the behaviors and practices that could indicate problems with endoscope reprocessing in your facility.

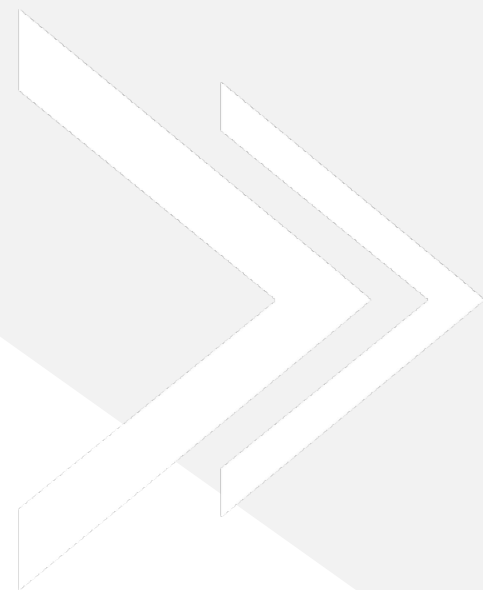


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- Pre-cleaning
- Transport to reprocessing
- Leak testing
- Cleaning
- Post-cleaning verification, including inspection
- High-level disinfection or sterilization
- Rinse (post-HLD)
- Alcohol Flush (post-HLD)
- Drying (post-HLD)
- Compliant Storage

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QUESTIONS?





Endoscope Reprocessing for the Infection Preventionist