

KEEPING PATIENTS SAFE : COMPLIANCE WITH STANDARDS FOR FLEXIBLE ENDOSCOPE PROCESSING

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Objectives

- To review the issues with processing flexible GI endoscopes
- To discuss the new AAMI Document (ST-91) and its components
- To discuss the FDA and CDC recommendations for processing ERCP (duodenoscopes) scopes

Issues with Flexible Endoscopes

- Valuable diagnostic and therapeutic tool
- Dealing with microbes that are more resistant than ever
- Endoscopes very expensive – pressure to book as many cases as possible
 - Reduced reimbursements
 - Listed in top ten technology hazards for patients for several years in a row (ECRI) including 2016; now # 1 hazard

Joint Commission Results First Half 2015

- Percentage of healthcare facilities that met the standards to reduce the risk of infections associated with medical equipment, devices and supplies:
 - 54% of Acute care hospitals
 - 46% of Ambulatory Care/Surgery facilities
 - 60% of Critical Access Hospitals

Need

- Microorganisms may be spread from patient to patient by contaminated or improperly processed flexible and semi-rigid endoscopes or malfunctioning equipment
- Microorganisms may be transmitted from patients to endoscopy personnel and/or from endoscopy personnel to patient

Risks

- Chemical substances can remain on devices from various chemicals used during the procedure or processing that can cause toxic reactions in subsequent patients.
- Devices may be damaged or rendered difficult to use due to mishandling or inadequate processing.

Help is on the Way!!!!

- “Flexible and semi-rigid endoscope processing in health care facilities”
- New document available from AAMI
- ANSI/AAMI ST 91:2015: *Flexible and Semi-Rigid Endoscope Processing in Health Care Facilities*



Need for ST-91 Document

- Developed by the AAMI Endoscope Reprocessing Working Group under the auspices of the AAMI Sterilization Standards Committee.
- This document is intended to provide comprehensive information and direction for health care personnel in the processing of these devices and accessories.
- Numerous guidelines causing confusion in workplace

Society Guidelines



U.S. Food and Drug Administration



ST-91

- Initially was proposed as a technical information report (TIR) that would synthesize existing guidance in the area of endoscope processing.

- As the draft was developed, the working group identified a need in the field for more extensive guidance, and proposed revising the document to be an American National Standard.

What Does the Document Cover?

- Functional and physical design criteria for endoscope processing areas;
- Education, training, competency verification, and other personnel considerations;
- Processing recommendations;
- Installation, care, and maintenance of automated processing equipment;
- Quality process improvement

Contents

- Design of Endoscope Processing area
- Personnel considerations
- Cleaning and high level disinfection
- Automated endoscope reprocessors
- Sterile endoscope sheaths
- Terminal sterilization by gaseous chemical sterilization processes

Contents

- Processing of endoscope accessories
- Storage of reprocessed endoscopes
- Transport of high level disinfected endoscopes
- Quality Control and Risk Assessment

Education, Training and Competency Assessments

- All personnel performing processing of endoscopes be certified as a condition of employment.
- **At a minimum, personnel should complete a certification exam.**
 - Note: The Certification Board for Sterile Processing (CBSPD) has an accredited "Certified Flexible Endoscope Reprocessor" examination. www.sterileprocessing.org.

CDC

Staff Training and Competency: Ensure personnel performing reprocessing of duodenoscopes have received appropriate training with competency verification for reprocessing procedures. Competencies should be assessed at initiation of employee duties and at least annually and anytime a breach is identified or when a new technique or equipment is introduced. Competency verification should include direct observation in addition to other assessments per facility policy (e.g., written tests). Personnel responsible for reprocessing endoscopes are encouraged to seek certification in flexible endoscope reprocessing.

Reference: Centers for Disease Control – Memo on "Interim Protocol for Healthcare Facilities Regarding Surveillance for Bacterial Contamination of Duodenoscopes after Reprocessing." Posted 3-11-15

Documentation

- Education, training, and competency verification activities should be provided and documented for
- All processing personnel on procedures for processing of all endoscopes and
- Use of all AERs and sterilizers in use at the facility.

Education, Training and Competency Recommendations

- Processing activities should be closely supervised until competency is verified and documented for each processing task, from cleaning through storage of the endoscope.

Issue: Cleaning

- Multiple studies in many countries have documented lack of compliance with established guidelines for cleaning and disinfection for all types of flexible endoscopes
- Failure to comply with scientifically-based guidelines has led to numerous outbreaks



Type and Level of Microbial Contamination

- Flexible endoscopes acquire high levels of bioburden (population of viable microorganisms on a product and/or a package – AAMI ST 79) because of the cavities they enter
- CDC reports that the bioburden found on flexible gastrointestinal endoscopes after use can be as high as 10,000,000,000 billion

Spaulding's Classifications

- **Semicritical items** contact intact mucous membranes or non-intact skin
- These medical devices should be free from all microorganisms; however, small numbers of bacterial spores are permissible
- This category includes endoscopes
 - Does not consider problems with reprocessing of complicated, heat sensitive devices

Steps in Reprocessing Flexible Endoscopes

- Precleaning**
- Leak Testing**
- Manual Cleaning**
- Visualization**
- High Level Disinfection**
- Rinsing**
- Drying**
- Storage**

High Level Disinfection - Best Practices

Point of Use

- pre-clean to prevent soil from drying.

Reprocessing Area

- perform leak test,
- manual cleaning & rinsing,
- visualization of scope
- high level disinfection (manual or automated),
- rinsing, drying and storage.

Quality Assurance

- documentation & record keeping.

Consistency

- All scopes should be cleaned and reprocessed in the same manner
- There are different levels of scopes and how they are used
 - Level one – scopes used in sterile procedures must be sterile
 - Level two – scopes used in non sterile procedures should be high level disinfected at a minimum

Cleaning

- Cleaning - removal of visible soil (e.g., organic and inorganic material) from objects and surfaces
- Can be performed manually or mechanically using water with detergents or enzymatic products



Cleaning

- Thorough cleaning is essential before high-level disinfection or sterilization
- Inorganic and organic materials that remain on the surfaces of instruments can interfere with the effectiveness of these processes
- HLD cannot make direct contact with all surfaces of the device if soil or other residue remains
- Why is there a discussion about returning to sterilization of ERCP scopes?

Microbial Contamination

- Highest levels found in the suction channels
- Studies have shown that proper cleaning reduces the level of microbial contamination by 4–6 log (safe to handle)
- Several investigators have shown that cleaning completely eliminates the microbial contamination on the scopes (CDC)



□ Reference: Centers for Disease Control: **Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008**

Microbial Contamination

- The larger the number of microbes, the more challenging the cleaning
- More time may be needed with the germicide to destroy all of them
- Reducing the number of microbes increases the margin of safety when the germicide is used according to the IFU



High Level Disinfection – HLD

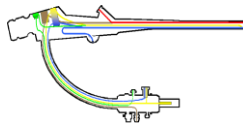
- A process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects
- Each of the various factors that affect the efficacy of disinfection can impact or limit the efficacy of the process
- Concentration of and exposure time to the germicide can affect outcome
- Temperature, pH, and chemical makeup of the disinfection process can also affect outcome

Sterilization

- Dependant on adequate cleaning, rinsing, and device preparation
- Low temperature sterilization methods
 - Liquid Chemical Sterilants (LCS)
 - Liquid Chemical Reprocessing (AER)
 - Ethylene Oxide Sterilizers
- Potential for steam sterilization?

Factors Impacting HLD/Sterilization

- Ineffective cleaning of the devices
- Type and amount of microbial contamination present
- Physical nature of the object (e.g., crevices, hinges, and lumens)
- Presence of biofilms
- Cross-contamination during rinsing or storage



An endoscope can contain many internal channels. Just like the outside of the endoscope, these internal channels can become contaminated with microorganisms.

More Factors Impacting HLD/Sterilization

- Design and functionality of the reprocessing system; manual? Automated?
- Collaboration between endoscope manufacturers and equipment providers
- **Training and competency of personnel**
- Process for follow-up on outbreaks or breaches in protocols
- Risk analysis

Factors Affecting Cleaning/HLD

- Location of microorganisms – many “nooks and crannies”
- Equipment such as endoscopes that have crevices, joints, and channels are more difficult to disinfect than flat-surfaced equipment
- Staff competencies are critical for proper processing

Education, Training and Competency Recommendations

- Personnel involved in endoscope processing should be provided education, training, and complete competency verification activities related to their duties
 - upon initial hire;
 - annually;
 - at designated intervals;
 - or whenever new endoscopic models, new processing equipment, or products such as new chemicals are introduced for processing.

Training and Competency

Competencies required for:

- All types of scopes used (e.g. different manufacturers, GI scope vs. bronchoscope)
- Leak Testing
- Manual cleaning and manual high level disinfection (HLD)
- Manual cleaning followed by automated cleaning and HLD
- Use of AER

Training and Competency

Competencies required for:

- Processing of all accessories
- Selection and use of detergents
- Selection and use of HLD
- Use of PPE when handling contaminated devices
- Transport of used scopes
- Storage and transport of HLD scopes

Training and Competency

- Surveyors focusing on who is performing the competencies
- Do they have the knowledge, skills and expertise to perform the assessments?

Pre-Cleaning of Used Scopes

- Endoscopes and accessories should be immediately cleaned after each patient procedure
- Pre-cleaning/flushing of biopsy channels helps prevent drying or organic and inorganic debris in lumens
- Need supplies for pre-cleaning (now available in kits)

Transportation of Used Scopes

- Transport to Processing room in enclosed container or biohazard bag (avoid tightly coiling scope in transit) – transport device must be labeled as biohazard
- Transport containers should be disinfected after each use
- Reprocessing should not take place in the procedure room

Scope Transfer Systems



Manufacturer's Instructions

- **NEVER** reprocess a scope without written instructions from the scope manufacturer
- Use the cleaning agents, cleaning implements and disinfecting/sterilizing agents **VALIDATED** by the manufacturer or an equivalent
- Copy the cleaning/HLD instructions; keep in scope processing room
- The reusable device manufacturer is responsible for ensuring that the device can be effectively cleaned, disinfected or sterilized

Common Errors in the Reprocessing of Flexible Endoscopes

Point of Use (Procedure Room)

- Not wearing proper PPE
- Not having MFR's IFUs
- Reprocessing delay (multiple procedures and/or with procedures performed at night or on the weekend)
- Failure to clean all channels (even if unused, fluid and debris can enter channels at the distal tip)
- Transporting without using a closed container and/or not labeled as biohazard



Environment

- Separate rooms for cleaning and HLD preferred
- Cleaning room
 - Hand wash sink
 - 2-well sink for cleaning/rinsing
 - Eyewash station for chemicals
 - Room for cleaning equipment
 - Cleaning chemicals and implements

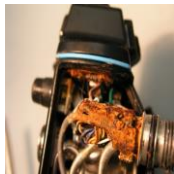
Leak Testing

- The single most effective means of preventing flexible scope damage due to fluid invasion
- Follow scope manufacturer's instructions for process
- Remove all detachable valves and apply fluid protective caps prior to testing
- Keep all valves and adapters with specific scope
- Insufflate (pressurize scope first)

Leak Testing

- Submerge in tap water
- Angulate bending section while immersed
- Massage and inspect all areas of scope
- Confirm there are no continuous series of bubbles in water
- Should take approximately 90 seconds

Damage from Fluid Invasion



Leak Testers in AERs

- **MAY NOT REPLACE MANUAL LEAK TESTING – check with AER manufacturer**
- Maintains a sufficient pressure so that if there is a small leak the scope can still be reprocessed before returning to the scope manufacturer
- If it is a major leak some machines will not run

Patient Safety Issues

Cross-patient infection breakout
e.g. Pseudomonas, Salmonella, HIV,
hepatitis B and C, Staph, et al



Major fluid invasion

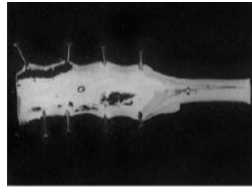


Fig 9. Interior surface of a flexible endoscope suction channel (2.8 mm in diameter) removed during leak repair. Holes in the

Interior surface of a flexible endoscope suction channel (2.8mm in diameter) removed during leak repair.

[APIC Guideline for infection prevention and control in flexible endoscopy Volume 28, number 2, p.145]

Cleaning

- Follow scope manufacturer's instructions if leak detected
- **MANUAL** cleaning **MUST** be performed before any automated cleaning
- Must clean all surfaces, channels and ports whether they were used or not!!!!
- **EXCEPT** automated endoscope reprocessors validated for no manual cleaning
- Many recommending manual cleaning prior to AER

Cleaning Steps



- Fill sink with solution of enzymatic detergent (measure water and detergent!)
- Immerse scope and clean exterior surfaces using soft cloth or brush
- Detach suction and air/water valves, biopsy channel cover and other removable parts
- Keep with respective scope

Enzymatic Detergents

- **MAY BE AFFECTED BY:**
 - Water quality
 - Contact time
 - Expiration date
 - Activity at use dilution
 - Single or multiple enzymes
 - Multi-enzymatic cleaners are catalysts reducing reprocessing times and attacking various soils
- Rinse well and discard enzymatic cleaners or detergents after each use
 - They are not microbicidal
 - Will not retard microbial growth
- Not all scope manufacturers recommend enzymatic detergents

Cleaning

- All parts of the scope must be cleaned
- Use brushes of correct diameter and length to ensure thorough cleaning of all internal lumens
- **MUST use brushes of the diameter and length recommended by the scope manufacturer**
- After passing brush through channel, use fingers to remove debris from brush before pulling brush back into channel
- Continue cleaning until no debris left on brush

Brushing

- Only use brush for one scope and discard or clean/disinfect
- Some brushes are color-coded for ease of use and selection



Friction removes bioburden and debris

Automated Flushing

- Units available to facilitate flushing
- Eliminates human factor
- Units need to be tested daily for proper volume of water
- Units may require decontamination
- Tubing requires decontamination



Manual Flushing with Syringe

- Scope manufacturer's flushing protocol
- Each channel needs to be flushed with the same amount of fluid
- Use detergent solutions first and flushed 3 times
- Use rinse water second with 3 flushes



Common Errors in the Reprocessing of Flexible Endoscopes

Manual Cleaning

- Failure to fully submerge endoscope
- Failure to submerge for the required length of time (need timer)
- Neglecting to dilute the detergent per the MFR's IFU
- Using worn, damaged or improper brushes
- Failure to use MFR's validated cleaning adapters
- Damaged/improperly reprocessed cleaning adapters
- Failure to thoroughly rinse



Rinsing

- Rinsing endoscopes and flushing channels with sterile water, filtered water, or tap water will prevent adverse effects associated with disinfectant retained in the endoscope (e.g., disinfectant-induced colitis)
- Items can be rinsed and flushed using sterile water after high-level disinfection to **prevent contamination with organisms in tap water, such as nontuberculous mycobacteria, Legionella, or gram-negative bacilli such as Pseudomonas**

Accessories

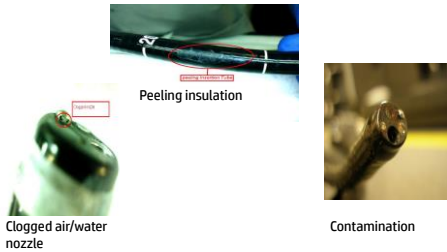
- Mechanically clean reusable accessories inserted into endoscopes that break the mucosal barrier and then sterilize these items between each patient after cleaning
- Use ultrasonic cleaning for reusable endoscopic accessories, such as biopsy forceps to remove soil and organic material from hard-to-clean areas

Inspection

- Incorporate visual inspections and testing of the equipment to identify conditions that may affect the cleaning or disinfecting processes, such as testing for leaks, examination for cracks, and checking the integrity of fiber optic bundles.
- Visual inspection alone may not be sufficient for assessing the efficacy of cleaning processes; the use of methods that are able to measure organic residues that are not detectable using visual inspection should be considered in facility cleaning policy and procedures.

Inspection Prior to HLD

- ALWAYS INSPECT SCOPE FOR DAMAGE/CLEANLINESS



High Level Disinfection

- Should be performed in a separate room from the cleaning
- Issues with cross contamination
- HLD accepted as the standard for GI scopes
 - More cost effective
 - Quicker turn around
- Need for sterilization of GI scopes due to *C. difficile* not substantiated by scientific evidence



AERs vs. Manual Process

- Automated endoscope reprocessors (AER) offer several advantages over manual reprocessing
 - Automate and standardize several important reprocessing steps
 - Reduce the likelihood that an essential reprocessing step will be skipped
 - Reduce personnel exposure to high-level disinfectants or chemical sterilants



Automated Endoscope Reprocessors

- Units can
 - Clean only
 - Disinfect only
 - Clean and disinfect
 - Sterilize only
- Check mfrs instructions before purchasing
- If a final alcohol rinse is not included in the automated reprocessor, this step should be done manually followed by purging all channels with air

AERs

- Need to document which AER used (if multiple units) or which chamber/bay used for traceability (if multiple bays)
- Develop procedures for processing scopes after hours (major issue)
- Scopes should be processed within one hour of use

Steris System 1E

- Uses S-49 liquid chemical sterilant inside a processor
- Has a chemical indicator specific to PA (peracetic acid)
- System has a BI but not required
- Must clean scope first and use correct quick connect adapter
- Scopes should then be used immediately or dried, alcohol flush, dried and stored
- Does one flexible scope at a time in about 26 minutes

Evo-Tech

- Provides HLD of GI scopes
- No manual pre-cleaning (except duodenoscopes)
- Uses Cidex OPA
- Performs all steps inside the AER from leak testing to alcohol flush
- Has 2 separate basins, one scope per basin
- Cycle time is app. 33 minutes

Custom Ultrasonics

- FDA recalled the units in early 2016 after company failed to respond to FDA requests for additional proof the system provided HLD for all scopes
- Now the FDA is backtracking.
- Custom Ultrasonics said in a notice posted on its website that it will send hospitals a label to affix to the washers. The label warns medical staff not to use the machines to clean duodenoscopes.
- Robert Blanchard, director of product management and sales for Custom Ultrasonics, said in an e-mail that the company declined to comment on the FDA letters.

Custom Ultrasonics

- It's not clear how many hospitals are still using Custom Ultrasonics devices.
- Nine out of 16 U.S. hospitals that had superbug cases linked to duodenoscopes were identified in the Senate staff report as using Custom Ultrasonics machines to clean them.

Other AERs

- Medivators
 - ▣ Self contained unit
 - ▣ Provides HLD with glutaraldehyde or non-glutaraldehyde-based chemicals
 - ▣ Computerized for entire process

Manual HLD

- **Only surfaces that directly contact the germicide will be disinfected**
 - There must be no air pockets -use a syringe to pull solution into all channels
 - The equipment must be completely immersed for the entire exposure period
 - Completely immerse the endoscope in the high-level disinfectant, and ensure all channels are perfused

Manual High Level Disinfection

- Rinsing - must be thoroughly rinsed
- Usually 3 separate rinses
- Do not re-use water. Fresh water for each rinse
- Sterile water preferred since tap water is not pure

Common Errors in the Reprocessing of Flexible Endoscopes

Manual HLD

- Using a sink or basin of insufficient dimensions
- Using a solution after it's expiration date
- Not MRC testing solution prior to each use



AER

- Failure to manually clean and/or rinse before using the Automated Endoscope Reprocessor (AER)

Delayed Reprocessing

- If reprocessing is delayed beyond one hour, extended soaking/cleaning protocols may be required
- Follow the scope manufacturer's instructions for delayed reprocessing
- Can occur when scopes are used on Nursing Units or ER during off hours

What is the process for ensuring these scopes get cleaned within an hour?

Sterilization of Flexible and Semi-Rigid Scopes

- Need to select packaging based upon the sterilization method being used
- Wraps, rigid containers, paper-plastic pouches, Tyvek pouches
- For delicate devices, a protective container is recommended



Drying/Storage

- Keep all adapters, valves with the respective scope
- Dry exterior of scope
- Rinse and dry all removable parts
- Flush all channels with alcohol
- Purge all channels with air (*P. Aeruginosa* loves to live in moist environment!)
- Use pressure recommended by scope manufacturer to avoid damaging sheath



Drying/Storage

- Store hung in a vertical position with no coils
- Affix tag or other device indicating scope was reprocessed.
- Mechanically ventilated cabinets best to reduce microbial growth.
- Must be maintained.
- Perform risk assessment



Suit Cases

- Never use the suit cases to transport/store scopes
- The interior surfaces are porous and cannot be cleaned.
- Only intended to send scope back for repair

Improper Storage of Scope



Scopes Stored Improperly



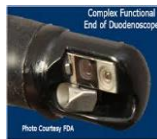
Duodenoscopes

- Flexible, lighted tubes that are threaded through the mouth, throat, and stomach into the top of the small intestine (duodenum)
- Used during ERCP procedures, a potentially life-saving procedure
- Application to diagnose and treat problems in the pancreas and bile ducts



Duodenoscopes

- Duodenoscopes are complex instruments that contain many small working parts.
- If not thoroughly cleaned and disinfected, tissue or fluid from one patient can remain in a duodenoscope when it is used on a subsequent patient.
- In rare cases, this can lead to patient-to-patient infection.



Duodenoscopes used in >500,000 ERCP procedures annually

Decontamination

- Very small lumens (ERCP scopes) cannot be cleaned properly in automated system alone
- Need to use 2-5ml syringe to flush out channels x 3 times
- Use brushes as recommended and clean x 3
- Despite adapters for automated systems still must be manually cleaned first



FDA Recommendations

- Follow manufacturer’s instructions for cleaning and processing. (Over 125 steps!)
- Adherence to general endoscope reprocessing guidelines and practices established by the infection control community
- Follow specific reprocessing instructions in the manufacturer’s labeling for each device.
- Reference “Design of Endoscopic Retrograde Cholangiopancreatography (ERCP) Duodenoscopes: May Impede Effective Cleaning”: FDA Safety Communication posted 2/19/2015

FDA Recommendations

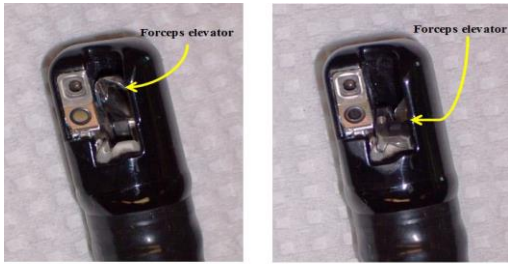
- Even though duodenoscopes are inherently difficult to reprocess, strict adherence to the manufacturer’s reprocessing instructions will minimize the risk of infection.
- The benefit of using cleaning accessories not specified in the manufacturer’s instructions, such as channel flushing aids, brushes, and cleaning agents, is not known.
- Deviations from the manufacturer’s instructions for reprocessing may contribute to contamination.

Reference “Design of Endoscopic Retrograde Cholangiopancreatography (ERCP) Duodenoscopes: May Impede Effective Cleaning”: FDA Safety Communication posted 2/19/2015

FDA Recommendations

- Follow these additional general best practices:
- Meticulously clean the elevator mechanism and the recesses surrounding the elevator mechanism by hand, even when using an automated endoscope reprocessor (AER).
- Raise and lower the elevator throughout the manual cleaning process to allow brushing of both sides. Clean 3 times in each position.
- Reference “Design of Endoscopic Retrograde Cholangiopancreatography (ERCP) Duodenoscopes: May Impede Effective Cleaning”: FDA Safety Communication posted 2/19/2015

Elevator Raised and Lowered



(a) Lowered/ closed forceps elevator

(b) Raised/ open forceps elevator

FDA Recommendations

- Implement a comprehensive quality control program for reprocessing duodenoscopes.
- Your reprocessing program should include written procedures for:
 - monitoring training
 - adherence to the program
 - documentation of equipment tests, processes, and quality monitors used during the reprocessing procedure.
 - ensure compatibility with your AER

Reference "Design of Endoscopic Retrograde Cholangiopancreatography (ERCP) Duodenoscopes: May Impede Effective Cleaning": FDA Safety Communication posted 2/19/2015

CDC Guidance March, 2015

- **Duodenoscope Reprocessing:** Facilities should review all steps in duodenoscope reprocessing **several times a year (e.g., quarterly)** and ensure strict adherence to the manufacturer's instructions, paying particular attention to the following:
 - **Manual cleaning:** Ensure that the elevator mechanism located at the distal tip of the duodenoscope is thoroughly cleaned and free of all visible debris.
 - **Inspection:** Visible inspection is to be done with the elevator in the "open/raised" position as well as with the elevator in the "closed/lowered" position to ensure there is no visible debris above or below the elevator mechanism
 - **Use of a lighted magnifying glass (e.g., 10x) to improve detection of residual debris around the elevator mechanism.**

Reference: Centers for Disease Control - Memo on "Interim Protocol for Healthcare Facilities Regarding Surveillance for Bacterial Contamination of Duodenoscopes after Reprocessing." Posted 3-11-15

CDC Guidance March,2015

- **Drying:** Ensures that the channels of the duodenoscope and elevator mechanism are thoroughly dried prior to storage.
- This should include an alcohol flush followed by forced air drying if these procedures are compatible with the duodenoscope per the manufacturer’s instructions.
- If channels and the elevator mechanism are not completely dry, bacterial growth can occur, forming a biofilm that is difficult to remove and could result in persistent contamination.

CDC Guidance March,2015

- **Use of Duodenoscope Culturing - Surveillance: Although routine culturing of endoscopes is not part of current U.S. guidelines, recent outbreaks associated with duodenoscopes have led some facilities to consider regular monitoring to assess the adequacy of duodenoscope reprocessing**
- **Recommended intervals ranging from every month to annually or after every 60 procedures, after reprocessing, following each use.**

The optimal frequency of surveillance cultures has not been established

Check with CDC And FDA

FDA Guidance August 2015

- **Hospitals and health care facilities that utilize duodenoscopes can, in addition to meticulously following manufacturer reprocessing instructions, take one or more of these additional steps to further reduce the risk of infection and increase the safety of these medical devices.**

FDA – August, 2015

- Not all health care facilities can implement one or more of these measures, which require specific resources, training, and expertise.
- Critical that staff responsible for reprocessing duodenoscopes have
 - the manufacturer's instructions readily available to promote strict adherence to the reprocessing instructions in the device labeling
 - understand the importance of their role in reprocessing the device
 - maintain proficiency in performing these reprocessing tasks.

FDA – August, 2015

- While the risk of infection transmission cannot be completely eliminated, **the benefits of these devices continue to outweigh the risks in appropriately selected patients.**
- Reprocessing is a detailed, multistep process to clean and disinfect or sterilize reusable devices, and can result in infection transmission if reprocessing instructions are not followed in every step of the process.

FDA – August, 2015

- Duodenoscopes are complex instruments that contain many small working parts.
- Proper cleaning and disinfection of the elevator mechanism is of particular concern.
- The moving parts of the elevator mechanism contain microscopic, hard-to-reach crevices.
- If not thoroughly cleaned and disinfected, tissue or fluid and residual bacteria from one patient may remain in device crevices of a duodenoscope, exposing subsequent patients to risk of infection.

FDA - August, 2015

- The FDA is aware of instances of persistent bacterial contamination even following strict adherence to manufacturer reprocessing instructions.
- Because of this, FDA recommends that facilities and staff that reprocess ERCP duodenoscopes establish and implement a comprehensive quality control program for reprocessing duodenoscopes

FDA – August, 2015

- Supplemental Measures for Facilities and Staff that Reprocess Duodenoscopes to Consider:
 - Microbiological Culturing
 - Ethylene Oxide Sterilization
 - Use of a Liquid Chemical Sterilant Processing System
 - Repeat High-Level Disinfection

CDC

- CDC is not recommending to move from high level disinfection to sterilization,” says Alexander Kallen, MD, MPH, a medical epidemiologist and outbreak response coordinator in the CDC Division of Healthcare Quality Promotion.
- “Our main recommendation is that facilities review their practices to make sure they adhere to exactly what the manufacturer recommends.”

FDA Alert August 4, 2015

- <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm454766.htm>
- Another outbreak from tainted scopes suspected at an L.A.-area hospital (8/21/15)
- The pseudomonas uncovered at the Pasadena hospital is a common cause of infections, but some strains of the bacteria are resistant to all antibiotics. That can make it deadly for some patients.
- No definitive link, still investigating

CDC and FDA Alert 9-11-15

- CDC and FDA are alerting healthcare providers and facilities about the public health need to properly maintain, clean, and disinfect or sterilize reusable medical devices.
- Recent infection control lapses due to non-compliance with recommended reprocessing procedures highlight a critical gap in patient safety.

CDC and FDA Alert 9-11-15

- Healthcare facilities (e.g., hospitals, ambulatory surgical centers, clinics, and doctors' offices) that utilize reusable medical devices are urged to immediately review current reprocessing practices at their facility to ensure they (1) are complying with all steps as directed by the device manufacturers, and (2) have in place appropriate policies and procedures that are consistent with current standards and guidelines.

CDC and FDA Alert 9-11-15

- Healthcare facilities should arrange for a healthcare professional with expertise in device reprocessing to immediately assess their reprocessing procedures.
- This assessment should ensure that reprocessing is done correctly, including allowing enough time for reprocessing personnel to follow all steps recommended by the device manufacturer.

CDC and FDA Alert 9-11-15

- **Training**
- Healthcare facilities should provide training to all personnel who reprocess medical devices.
 - Training should be required and provided:
 - Upon hire or prior to provision of services at the facility
 - At least once a year
 - When new devices or protocols are introduced, including changes in the manufacturer's instructions for use during the device's life cycle

CDC and FDA Alert 9-11-15

- Personnel should be required to demonstrate competency with device reprocessing (i.e., trainer observes correct technique) prior to being allowed to perform reprocessing independently.
 - Healthcare facilities should maintain current documentation of trainings and competencies.
 - If the healthcare facility hires a contractor for device reprocessing, the facility should verify that the contractor has an appropriate training program and that the training program includes the specific devices the healthcare facility uses.

FDA Alert 9-18-15

- FDA Safety Communication: Reprocessed flexible bronchoscopes risk of infection
- While not every medical device report contains information sufficient to definitively identify the factors contributing to persistent device contamination or device-associated infection, FDA analysis to date has identified two recurrent themes:
- Failure to meticulously follow manufacturer instructions for reprocessing
- Continued use of devices despite integrity, maintenance and mechanical issues.

Multi-Society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes, 2011

- Interval of storage after which endoscopes should be reprocessed before use
 - Data suggest that contamination during storage for intervals of 7-14 days is negligible, unassociated with duration, occurs on exterior of instruments and involves only common skin organisms
 - Data are insufficient to recommend a maximal outer duration for use of appropriately cleaned, reprocessed, dried and stored endoscopes
 - Frequency for replacement of clean water bottles and tubing for insufflation of air and lens wash water, and waste vacuum canisters and suction tubing

Unresolved Issues:

- Shelf life when stored
- Replacement of Supplies

Multi-Society Guideline on Reprocessing Flexible GI Endoscopes, 2011, Infection Control and Hospital Epidemiology, June 2011, vol. 32, no. 6, ASGE - SHEA Guideline.

Accessories

- Never reprocess accessories in an AER unless the accessory and AER manufacturer validated this process

Documentation

Maintain log with the following information:

- Name of Patient/Medical Record #
- Serial # of the scope with traceability to the patient
- Document scope cleaned
- Document the HLD/sterilization process
- Documentation of the final alcohol rinse
- Procedure

Quality Assurance

New products for cleaning efficacy and protein detection

- AAMI recommends cleaning verification should be performed weekly, preferably daily.
- Product capable of testing virtually any lumened instrument for residual organic soils, including flexible endoscopes, no matter the channel size
- Tests for three common organic soils at once: blood, protein and carbohydrates.
- ATP is another option as a verification marker
- Test all ERCP scopes after cleaning?

Cleaning Effectiveness Test

- First product capable of testing virtually any lumened instrument for residual organic soils, including flexible endoscopes, no matter the channel size.
- Tests for three common organic soils at once: blood, protein and carbohydrates



Quality Assurance



- Test object simulates a flexible endoscope channel
- Use for monitoring the cleaning efficiency of endoscope washers with channel irrigation system
- Two separate test soils demonstrating the removal of blood and polysaccharides



In Summary

- Follow all scope manufacturer's instructions for use carefully
 - Keep on file in processing area
- Follow the HLD/sterilant manufacturer's instructions for use
 - Water quality
 - Soak time
 - Temperature of solution/concentration
- Verify competencies
 - Perform annual competency check on all scope processing personnel
- Encourage certification for processing personnel



QUESTIONS?
