

# Proper Care and Handling of Flexible Endoscopes

Flexible and semi-rigid endoscopes are complex instruments with many parts (e.g., insertion tubes, lenses, port covers, and valves) for use in various body cavities for diagnostic and therapeutic procedures. In the United States alone, at least 11 million gastrointestinal endoscopies are performed annually and the number of procedures is only expected to increase.<sup>1-3</sup>

Endoscopes are reusable devices and every patient represents a potential source of infection; therefore, all endoscopes must undergo rigorous reprocessing to ensure pathogenic microorganisms are removed before reuse. Risks associated with endoscopy procedures include: <sup>1</sup>

- Transmission of microorganisms from patient to patient by contaminated or improperly processed flexible and semi-rigid endoscopes or malfunctioning equipment.
- Transmission of microorganisms from the gastrointestinal tract through the bloodstream during the procedure.
- Transmission of microorganisms from patients to endoscopy personnel or personnel to patients.
- Residual chemical substances can remain on devices from the various chemicals used during procedures or processing that can cause toxic reactions in subsequent patients.
- Inadequate handling or processing can damage endoscopes and accessories.

Proper care, handling and processing of endoscopes is essential to minimize the above risks as well as ensure instrument longevity and functioning.

The Spaulding classification system is used to determine what type of disinfection or sterilization is appropriate for medical devices. The following three classes stratify risk of infection associated with each device: <sup>4</sup>

- Critical devices break the mucosal barrier and should be sterilized (e.g., reusable biopsy forceps)
- Semi-critical devices come in contact with mucosa or non-intact skin and should undergo sterilization or high-level disinfection (e.g., endoscopes)
- Non-critical devices come in contact with intact skin and should be cleaned with soap and water or disinfected with a germicide (e.g., blood pressure cuffs)

When possible and practical, flexible and semi-rigid endoscopes should be sterilized due to the greater margin of safety built into sterilization. High-level disinfection is a multi-step process and is expected to be able to inactivate *most* pathogenic bacteria, viruses, and fungi but may not reliably inactivate certain types of microorganisms including bacterial spores. When these devices are used in sterile tissue procedures, sterilization is recommended.<sup>1</sup>

There are several factors impacting the effectiveness of reprocessing endoscopes, which include: 4

- Endoscope-related factors:
  - Complex design making thorough cleaning difficult.



- o Variety of models available, each requiring different cleaning procedures or brushes.
- Age, frequent use/reprocessing, and repair can damage the internal surface leading to increased retention of residual organic material and microorganisms and potential infection risk.

### • Personnel-related factors:

- Inadequate training and/or knowledge.
- o Inadequate number of staff to support volume, workflow, and throughput.
- Frequent disruptions during reprocessing.
- Limited accountability.
- Time pressures for rapid endoscopic turn-around.
- Lack of mindfulness and underestimation of risk.

### Reprocessing-related factors:

- Numerous steps that must be meticulously followed
- Steps that are prone to human error.
- Delay in reprocessing.
- o Inadequate cleaning prior to high-level disinfection/sterilization.
- Inappropriate use of disinfectant (e.g., wrong concentration/temperature, expired, inadequate exposure time).
- Use of certain sterilants and disinfectants that may fixate.
- Inadequate drying prior to storage.
- Lack of quality control measures to monitor reprocessing.
- Equipment malfunction or contamination (e.g., flushing pumps or automated endoscope reprocessors).
- Use of incorrect connectors for flushing aids.
- Unrecognized issues with water supply affecting water quality.

All healthcare facility reprocessing programs must have an infrastructure that supports training and competencies, quality measurement, and management. To ensure safe and effective endoscope reprocessing requires a multidisciplinary team of clinical personnel, reprocessing personnel, infection prevention personnel, and leadership.<sup>4</sup>

#### Reprocessing personnel must:

- o Understand the rationale for each reprocessing step and strictly adhere to the protocol.
- o Readily access, read, and understand the manufacturer's instructions for use (IFU).
- Complete competency validation:
  - Initially upon hire and periodically as required by facility policy<sup>5</sup>
  - Demonstrate model-specific competency for all reprocessing steps annually,
     AND:
    - More frequently for specialty endoscopes used infrequently
    - Whenever a new model of endoscope, accessory, reprocessing equipment (e.g., automated endoscope reprocessor, leak tester), or chemical is purchased<sup>4,5</sup>
    - Whenever there are updates to the manufacturer's IFUs<sup>5</sup>



- Comply with tracking and documentation required for each reprocessing phase.
- Immediately report any breaches in reprocessing.
- Support the identification and reporting of errors to promote a culture of safety.
- Understand the safety hazards of endoscope reprocessing and take appropriate actions to protect self and others.
- Follow manufacturers' guidelines for maintenance, repair, and replacement of endoscopes and equipment used for reprocessing, including loaner equipment.
- Temporary personnel should not reprocess endoscopes until competency established.
- Frontline leadership in the endoscopy setting should:<sup>4,5</sup>
  - Use a multidisciplinary team (i.e., physicians, nurses, reprocessing personnel, infection preventionists) to develop policies related to endoscope reprocessing in all practice settings where endoscopy is performed. Policies should:<sup>5</sup>
    - Address the following for endoscopes and accessories to ensure compliance with endoscope and reprocessing equipment manufacturer's IFU:
      - Selection
      - Use
      - Transport
      - Reprocessing
      - Storage
    - Include requirements for documentation of essential reprocessing steps, parameters regarding physical setting for reprocessing, staff education/training/competency assessment, ongoing quality assurance procedures, and procedures/protocols responding to equipment and high-level disinfection/sterilization failures or breaches. Documentation should include the following:5
      - Endoscope and patient identifiers for all reprocessing methods as tracking is essential in the event of a disinfection failure and/or for responding to device/product recalls
      - Procedure end time and manual cleaning start time
        - Recording these times allows reprocessing personnel to ascertain how long the endoscope has been waiting reprocessing, to prioritize reprocessing of specific endoscopes, to determine whether routine reprocessing within the manufacturer's time for cleaning is achievable, and if not, to implement the manufacturer's procedure for delayed processing.
      - Testing results for effective concentrations of chemical disinfectant
      - Expiration dates for test strips and chemical disinfectants
      - Preventive maintenance and repair of endoscopes and reprocessing equipment records (e.g., leak testers, automated endoscope reprocessors, sterilizers).



- Investigation of critical or potential critical events such as high-level disinfection or sterilization process failures or equipment failures
- Compatibility with each endoscope, automated endoscope reprocessor, and method of high-level disinfection.
- Maintenance of documentation of all reprocessing activities (e.g., AER maintenance records, test results verifying high-level disinfection concentration, reuse life, retired endoscopes, etc.).
  - Detailed records are essential for identifying: reprocessing errors, endoscopes affected by that error, and patients who are at potential risk.
  - Frontline leadership should monitor adequate documentation for all reprocessing stages.
- Include management of loaner endoscopes to ensure adherence to the same reprocessing standards as facility-owned equipment.
- Must be compliant with federal and local regulatory and relevant accrediting organization standards and requirements and take into consideration the standards and recommendations from professional organizations (i.e., American Gastroenterology Association, Association for the Advancement of Medical Instrumentation, etc.).
- Be reviewed on a regular basis and updated regularly when new equipment purchased or new information is published.
- Be competent in reprocessing endoscopes in order to train and verify staff competency.
- Ensure staff are compliant with the manufacturer's validated IFU for reprocessing.
- Follow manufacturer's guidelines for maintenance, repair, and replacement of endoscopes and reprocessing equipment.
- Have plan in place for replacing endoscopes.
- Ensure that the reprocessing protocol and related competencies are reviewed and updated based on current standards and manufacturer's guidelines.
- Consult with infection prevention and reprocessing personnel when considering modifications to current reprocessing protocol or purchase of new reprocessing equipment.
- Collaborate with infection prevention and quality to assess risk of disease transmission in the reprocessing environment.
- Provide timely corrective action plan for patient safety issues related to reprocessing.
- o Ensure availability of adequate staff to support meticulous and timely reprocessing.
- Allow adequate time for reprocessing to ensure adherence to all reprocessing steps recommended by the manufacturer's IFU.
- Have a protocol in place to ensure personnel can readily identify endoscopes that have been properly processed and ready for use.
- Observe staff for adherence to endoscope reprocessing policies and protocols, possibly using a checklist.
- o Promote a culture of safety so staff can be free to communicate concerns.



- Physical setting of the reprocessing area should:<sup>5</sup>
  - Be separate from the patient procedural area.
  - Ensure a "one way" work flow separates the contaminated work spaces from the clean work spaces.
  - Ensure directional airflow that maintains a negative pressure within the manual cleaning room relative to adjoining spaces, if a separate room.
  - Ensure heating, ventilation, and air conditioning parameters are appropriate for the chemicals and equipment in use.
  - Have a handwashing sink that is separate from the reprocessing sink(s).
  - Have an eyewash station, either plumbed or self-contained. Eyewash stations should not be installed in a location that requires flushing the eyes in the decontamination sink.
  - Have a designated space to enable access to IFUs and Safety Data Sheets for chemicals used to reprocess flexible endoscopes. Access to these files could be per computer or hard copy binder.
- Risk assessment or comprehensive gap analysis should be conducted periodically and whenever new endoscopes are purchased, IFUs change, or professional/regulatory guidance changes. The assessment should ensure the following:<sup>5</sup>
  - Meet and maintain all essential steps of reprocessing.
  - Flexible endoscopes are pre-cleaned at the point of use and transported safely to the reprocessing area.
  - Staff competencies are verified.
  - Sufficient numbers of reprocessing personnel are available when routine and/or emergency endoscopic procedures are performed.
  - Manufacturer's IFUs are readily available and followed.
  - Necessary reprocessing equipment and supplies are available.
  - Adequate physical space for reprocessing.
  - Heating, ventilation, and air conditioning parameters are monitored and controlled.
  - Appropriate storage for endoscopes.
  - Maintain documentation for complete traceability.

### **Essential Steps for Effective Endoscope Reprocessing:**

### 1. Pre-Cleaning:4-7

- a. Pre-cleaning removes organic material (e.g., blood, body fluids, feces) and decreases bioburden, making it more likely for the subsequent reprocessing steps to be more effective.
- b. Perform pre-cleaning immediately following endoscope removal from patient (or completion of procedure) at *point of use* and before organic material has dried on the surface or in the channels of the endoscope.
- c. If the pre-cleaning process is delayed (e.g., endoscope used for intubation and remains in the room for potential re-use), designated personnel (e.g., RN circulator/scrub



- person) should wipe the external surfaces with a single-use, soft, lint-free cloth/sponge saturated with sterile water and should suction sterile water through the channels.<sup>6</sup>
- d. Pre-clean flexible endoscopes and reusable accessories per device manufacturer's instructions for use (IFU).
- e. Necessary supplies for point of use pre-cleaning include:4
  - Personal protective equipment (PPE) at a minimum of gloves, eye protection, impervious gown, face shield or surgical mask
  - Container with detergent solution
  - Single-use soft, lint-free cloth/sponge
  - Air and water channel cleaning adapters per manufacturer's instructions
  - Protective video caps if using video endoscopes
  - Transport bin/container
- f. *After Point of Use Pre-Cleaning*, transport contaminated endoscope and accessories to the endoscopy processing room as soon as possible after use.
  - Have the following supplies available:<sup>4</sup>
    - PPE at a minimum of gloves, eye protection, impervious gown, face shield or surgical mask
    - 2. Leak testing equipment
    - 3. Channel cleaning adapters (model-specific)
    - 4. Large basin or sink
    - 5. Detergent solution prepared according to manufacturer's instructions
    - 6. Appropriate size channel cleaning brushes, consider disposable singleuse when available
    - 7. Single-use, soft, lint-free cloth/sponge
    - 8. Automated flush pump device where applicable
    - 9. Lighted magnification
  - Always transport endoscopes one at a time.<sup>7</sup>
  - Keep wet/damp but not submerged in liquid during transport.<sup>6</sup>
  - Must transport in a closed container or closed transport cart.<sup>6</sup>
    - 1. The container/cart must be leak proof, puncture resistant, and large enough to contain all contents.
    - 2. The container should be large enough to accommodate the endoscope coiled in large loops.
    - 3. Must label container/cart with orange-red biohazard label.
    - 4. Transport in horizontal position and not suspended.
  - Endoscope accessories should accompany the endoscope but contained separately.<sup>6</sup>
  - Do not stack or place an endoscope on a counter, sink or basin as-is while waiting for reprocessing.<sup>7</sup>



- Processing of endoscope and accessories should occur as soon as possible after transport to endoscopy processing room or within the manufacturer's recommended time to processing.<sup>6</sup>
  - 1. When it is not possible to initiate cleaning within the manufacture's recommended time for cleaning, follow the manufacturer's instructions for use (IFU) for *delayed processing*.
  - Should not leave flexible endoscopes soaking in enzymatic cleaning solutions beyond the manufacturer's designated contact time unless this is recommended in the manufacturer's IFU for *delayed processing*.
- Develop process to record time of procedure completion and time of cleaning initiation.

## 2. Leak-Testing:<sup>2,4-6</sup>

- a. For endoscopes that require leak testing, perform leak test using manufacturer's IFU:6
  - · After each use
  - After any event that may have damaged the endoscope
  - Before use of newly purchased, repaired, or loaned endoscope
- b. Leak testing detects damage to external surfaces and internal channels that can lead to inadequate disinfection and further damage the endoscope. 4,5
- c. Perform leak testing *before manual cleaning* and *before placing into cleaning solutions* to minimize damage to endoscope parts that are not designed for fluid exposure.<sup>4,6</sup>
- d. Use a basin or surface large enough to ensure the endoscopes is not tightly coiled, which could mask holes or damage the endoscope.<sup>2</sup>
- e. When the endoscopes fail the leak test, remove from service and repair/replace.<sup>4,6</sup>

### 3. Manual Cleaning (most critical step in removing microbial bioburden from endoscopes):<sup>2,4-6</sup>

- a. Manual cleaning is the *most critical step in the disinfection process* since retained residual organic material contributes to bioburden development, which interferes with the ability of high-level disinfectants to kill/inactivate microorganisms. Therefore, *manual cleaning is necessary prior* to automated/manual high-level disinfection or sterilization.<sup>4,5</sup>
- b. Recommend personnel don fresh personal protective equipment (PPE) for manual cleaning.<sup>2</sup>
- c. Must follow the manufacturer's time frame for completing manual cleaning and if any delay occurs, follow the *delayed cleaning protocol* in the manufacturer's IFU.<sup>4</sup>
- d. Manual cleaning of complex components such as elevators requires optimal lighting and may benefit from magnification.<sup>4</sup>
- e. Manual cleaning should occur as soon as possible after leak testing using the manufacturer-recommended *type of water and cleaning solution*.<sup>6</sup>

## f. Manual Cleaning Steps:4

• Fill sink or basin with freshly made solution of water and medical-grade low-foaming, pH-neutral detergent formulated for endoscopes.



- 1. Recommend low-foaming detergents to clearly visualize the device during the cleaning process.
- 2. Dilute and use the detergent according to manufacturer's instructions.
- 3. Freshly prepared solution should be used for *each* endoscope to prevent cross-contamination.
- 4. Cleaning solutions should be changed:<sup>6</sup>
  - a. Before they become cloudy/discolored
  - b. Before there are visible particulates in solution
  - c. When solution temperature does not meet the temperature specified in the manufacturer's IFU.
- Ensure video cap is secure (if applicable) and completely submerge endoscope in cleaning solution.
- Wash all debris from endoscope exterior by brushing and wiping the instrument while submerged.
- Keep endoscope submerged in the detergent solution when performing all subsequent cleaning steps to prevent splashing of fluid and aerosolization of bioburden.
- Use a cleaning brush recommended by the endoscope manufacturer (for length, width, and material) to clean all reusable, removable parts, including inside and under the suction valve, air/water valve, and biopsy port cover and openings.
   Refer to manufacturer's instructions for additional steps and brushes to adequately clean elevator channels.
  - 1. Use brush size compatible with each channel and brush all accessible channels, body, insertion tube, and umbilicus of endoscope.
  - Visually inspect brushes and other items used to clean endoscope channels *prior to use* and do not use if the integrity of the brush or other cleaning item is in question.<sup>6</sup>
  - 3. Use a clean brush for each endoscope.
- Refer to manufacturer's instructions for brushing and flushing instructions.
- Brush accessible channels multiple times until no debris appears on the brush.
- After each passage, rinse brush in detergent solution removing any visible debris prior to retracting and reinserting.
- Flush all endoscope channels with detergent solution and soak for the appropriate time specified by the detergent manufacturer's instructions.
  - 1. A cleaning adapter or automatic flushing system may be used if compatible with endoscope. Refer to manufacturer's instructions and attach endoscope manufacturer's cleaning adapters.
- Inspect, clean, and high-level disinfect reusable brushes between cases.
  - 1. Replace any reusable brushes that are worn, frayed, or bent.



# g. Rinse After Manual Cleaning:<sup>4,6</sup>

- Thoroughly rinse and flush exterior endoscope, internal channels, and all movable parts with utility water until to remove all residual debris and detergent.
- Purge water from all channels using forced instrument air.
- Dry exterior surfaces with a soft, lint-free cloth/sponge to prevent dilution of the high-level disinfection in subsequent steps.
- Rinsing may be performed in automated endoscope processors (AERs) that provide this feature.
- Reusable parts (e.g., valves, buttons, port covers, tubing, water bottles), accessories (e.g., forceps), and cleaning implements (e.g., brushes, channel-cleaning adapters) should be cleaned, brushed, rinsed, and undergo high-level disinfection/sterilization.<sup>6</sup>
- i. Single-use parts, accessories, and cleaning implements should be discarded after use and not reprocessed.<sup>6</sup>

### 4. Visual Inspection:<sup>4-6</sup>

- a. Visual inspection provides additional assurance that the endoscope and reusable accessories are clean and free of defects. Visually inspect and evaluate endoscopes, accessories, and associated equipment for:
  - Cleanliness (e.g., retained debris)
  - Missing parts
  - Clarity of lenses
  - Integrity of gaskets and seals
  - Moisture
  - Physical/chemical damage (e.g., cracks, corrosion, discoloration)
  - Function
- b. All endoscopes and reusable accessories should be visually inspected during all stages of handling and reprocessing:
  - Prior to use
  - During endoscopy procedure
  - After endoscopy procedure
  - During and after manual cleaning
  - Before disinfection/sterilization
- c. Visually inspect and process all new, repaired, refurbished, or loaned endoscopes, accessories, and other equipment according to the manufacturer's IFU.
- d. Use lighted magnification to inspect endoscopes and accessories for cleanliness and damage.
  - May use endoscopic camera/borescope to inspect internal channels.
- e. Visual inspection does not guarantee decontamination from manual cleaning but serves as a "time out" to ensure that the endoscope is visually clean before proceeding to high-level disinfection.



- f. Repeat manual cleaning if not visually clean and remove defective endoscopes, accessories, and equipment from service for repair/replacement.
  - Decontaminate medical equipment being sent for repair to the fullest extent possible and attach a biohazard label prior to transportation.

# 5. High-Level Disinfection and Sterilization: 2,4-6

- a. Recommend personnel don fresh PPE for high-level disinfection and perform the process in a closed, sealed, and appropriately-labeled container.<sup>2</sup>
- b. High-level disinfection effectiveness is dependent on:4
  - Effective pre-cleaning, manual cleaning and rinsing to decrease organic material and microbial content.
  - Drying after rinsing to avoid dilution of the high-level disinfectant.
  - Proper preparation and use of disinfectant according to the manufacturer's instructions.
  - Should not use the following products in processing flexible endoscopes:<sup>6</sup>
    - 1. Skin antiseptics
    - 2. Hypochlorites
    - 3. Phenolics
    - 4. Quaternary ammonium compounds
- c. High-level disinfectants/sterilants are generally reused and must be tested to ensure they remain above their minimum effective concentration (MEC).<sup>4</sup>
  - Test and monitor high-level disinfectants according to manufacturer's testing instructions and keep a test result log.
  - High-level disinfectants/sterilants must be changed when the solutions fail to meet MEC or exceed the high-level disinfectants' manufacturer's recommended re-use life, or whichever comes first.
- d. High-level disinfection can be performed manually or by using an automated endoscope reprocessor (AER).<sup>4</sup>
- e. Manual High-Level Disinfection Steps:4
  - Ensure endoscopes have been purged with air and dried externally prior to immersion in disinfectant to minimize dilution of high-level disinfectant.
  - Completely immerse endoscope and all removable parts in a basin of high-level disinfectant/sterilant.
    - 1. Basin must be of adequate size to accommodate endoscope without undue coiling.
    - 2. Must have sufficient ventilation due to chemical vapors.
    - 3. Do not soak endoscope with sharp instruments that could potentially damage the endoscope.
  - Flush disinfectant into all channels until seen exiting the opposite end. No air must remain in the channel.
  - Cover soaking basin with tight-fitting lid to minimize chemical vapor exposure.



- Soak endoscope in the high-level disinfectant/sterilant for the time and temperature required per manufacturer's instructions.
  - 1. Use a timer to verify soaking time and do not exceed the manufacturer's recommended soaking time.
- Purge channels with air prior to removing endoscope from the high-level disinfectant/sterilant.
- Thoroughly rinse all surfaces and removable parts and flush all channels of the endoscope and removable parts with clean water according to the disinfectant and endoscope manufacturer's instructions.
  - 1. Recommend personnel to don fresh PPE.<sup>2</sup>
  - 2. Use fresh clean water for each rinse.
    - a. Multiple rinses may be required.<sup>2</sup>
  - 3. Rinsing is required for manual high-level disinfection.
- f. Automated Endoscope Reprocessing (AER):4
  - Endoscope reprocessors standardize the disinfection process and decrease personnel exposure to high-level disinfectants.
  - Verify compatibility between the endoscope and AER prior to processing.<sup>6</sup>
  - Manual cleaning and brushing are still necessary even when using an AER.
  - Use critical water (i.e., water that has been extensively treated to remove microorganisms and other materials) when performing mechanical processing of endoscopes.<sup>6</sup>
  - Use cleaning, disinfectant, and sterilant solutions and chemicals recommended by the endoscope and mechanical processor manufacturers.<sup>6</sup>
  - If the machine has a cycle that uses enzymatic detergent, ensure the product is compatible with both the reprocessor and the endoscope.<sup>4</sup>
  - If the AER cycle is interrupted, high-level disinfection/sterilization cannot be ensured; therefore, repeat the cycle.<sup>4</sup>
  - Should have a preventive maintenance plan in place for all AERs, equipment, and accessories.<sup>4</sup>
  - Adhere to and document quality controls recommended by AER manufacturers.<sup>4</sup>
  - Automated Reprocessing Steps:<sup>4</sup>
    - 1. Prepare endoscope reprocessor according to the manufacturer's instructions.
    - 2. Place endoscope in reprocessor and attach all channel adapters according to manufacturer's instructions.
      - a. Position endoscope and accessories within the AER in a manner that ensures contact of processing solution with all endoscope surfaces.<sup>6</sup>



- Place valves and other removable parts into the reprocessor soaking basin unless the reprocessor has a dedicated space for accessories.
- 3. Must strictly comply with duodenoscope reprocessing guidelines.
  - Institutions may determine to enhance high-level disinfection by including one or more of the following supplemental measures:
    - i. Microbiological culturing
    - ii. Repeat high-level disinfection
    - iii. Ethylene oxide sterilization
    - iv. Liquid chemical sterilization
- 4. Set the machine for the appropriate time and temperature (dependent on chemical used).
- 5. Start machine and complete all cycles. If the cycles are interrupted, high-level disinfection cannot be ensured and must repeat the full cycle.
- 6. If a final alcohol rinse cycle is not included, perform this step manually followed by purging all channels with air until dry.
- 7. Should not allow endoscope to sit in reprocessor for long periods following reprocessing (i.e., overnight).
- Must manually flush and dry the elevator and elevator channel of duodenoscopes and linear echoendoscopes per manufacturer's instructions.

#### 6. **Drying:**<sup>4</sup>

- a. All channels and surfaces of endoscopes must be thoroughly dried prior to storage as moisture allows microorganisms to survive and multiply.
- b. To ensure the endoscope is thoroughly dry, must flush with 70-90% ethyl or isopropyl alcohol prior to being dried with pressurized, filtered air either by AER or manually.
  - Alcohol mixes with water on the channel surfaces aiding evaporation or residual water as air flows through the channel.
- c. Drying Steps:
  - Flush all channels with alcohol until alcohol can be seen exiting the opposite end.
  - Purge all channels with compressed, filtered air.
    - 1. Avoid use of excessively high air pressure that can damage internal channels.
  - Remove all channel adapters
  - Dry the endoscope exterior with a soft, lint-free cloth.
  - Thoroughly rinse and dry all removable parts.
  - Ensure a system is in place to identity endoscopes that have been reprocessed and ready for use (e.g., tagging system).



## 7. Storage:4-7

- a. After reprocessing is complete, store endoscopes and accessories in a manner to prevent contamination, protects equipment from damage, and promotes drying.<sup>5</sup>
- b. Transport clean scopes by hand with the distal end held to prevent accidental impacts.<sup>7</sup>
- c. Key considerations for storage of endoscopes and accessories:
  - Use storage cabinet made of a material that can be cleaned and disinfected with an EPA-registered hospital-grade disinfectant.<sup>4</sup>
    - 1. Cleaning frequency should be performed on a regular basis (e.g., daily, weekly) and when visibly soiled.<sup>6</sup>
  - Storage cabinets should:<sup>6</sup>
    - 1. Be located in a secure location in the clean workroom of the endoscopy processing area in a two-room design, **OR**
    - 2. Be located in a separate clean area close to but not within the procedure room.
    - 3. Be located at least 3 feet from any sink.
    - 4. Have doors
  - For conventional storage cabinet:<sup>4</sup>
    - Sufficient height, width, and depth to allow flexible endoscopes to hang vertically without coiling or touching the bottom of the cabinet or another endoscope.
    - 2. Caps, valves and other detachable components are removed to prevent moisture accumulation and subsequent microbial growth.
  - When using a drying cabinet, follow the manufacturer's instructions. Since drying does not rely on gravity, endoscopes can be stored horizontally or vertically, depending on cabinet design.<sup>4</sup>
  - Store flexible endoscopes with all valves open and removable parts detached and stored with the endoscope.<sup>6</sup>
    - 1. Many products are available to keep valves and adapters with the endoscope as a unique set (e.g., mesh bags, valve storage cages).<sup>2</sup>
  - Consider use of distal tip protector that does not trap moisture to reduce distal tip damage.<sup>4</sup>
  - Flexible endoscopes should be clearly identifiable with a distinct visual cue as processed and ready for use.<sup>6</sup>
  - Each facility should determine a method of documentation and traceability of the endoscope and reusable accessories.<sup>4</sup>
    - 1. Traceability documentation should include the following:
      - a. Patient identifier
      - b. Date
      - c. Procedure type
      - d. Person performing endoscope reprocessing



- d. Staff should wear clean, powder-free gloves when handling processed endoscopes and when transporting them to/from the storage cabinet.<sup>6</sup>
- e. An endoscope that is not dry must be reprocess prior to use.<sup>4</sup>
- f. The hang time of an endoscope is controversial with no consensus between organizations. The Society of Gastroenterology Nurses and Associates (SGNA) supports a 7-day storage interval for reprocessed endoscopes, only if processed and stored per professional guidelines and manufacturer instructions.<sup>4</sup>

### **FDA Updated Recommendations by Discipline**

# Flexible Bronchoscopes: June 25, 2021 FDA Safety Communication Flexible Bronchoscopes

- Consider using a single-use bronchoscope in situations of:
  - Increased risk of spreading infections
  - o Immunocompromised patients or those with history of prior disease
  - o Multidrug resistant micro-organisms
  - No support for immediate reprocessing of the scope
- COVID-19 patients
  - AABIP (American Association for Bronchology & Interventional Pulmonology)
     <u>recommendations</u>

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