Processing Rooms or Areas

- Perform endoscope processing in a room where only processing activities are performed and that is physically separated from locations where patient care activities take place.
- Wear personal protective equipment that includes a 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.
- Maintain a unidirectional workflow from the decontamination area or room to the clean area or workroom and then to the clean storage location.
- Keep processing room doors closed.
- Maintain relative humidity and temperature within the heating, ventilation, air conditioning (HVAC) design parameters.
- Monitor performance of the HVAC system and report a variance in parameters according to the health care organization’s policy and procedure so that designated personnel can perform a risk assessment to determine whether corrective measures should be taken.

Precleaning

- Preclean flexible endoscopes and accessories at the point of use as soon as possible after the endoscope is removed from the patient.
- When precleaning will be delayed (eg, an endoscope is used for intubation and remains in the procedure room for potential reuse), wipe off the external surfaces and suction water through the channels.
- Follow the manufacturer’s instructions for use (IFU) for precleaning.
- Use a fresh cleaning solution.
- Wash the exterior surface of the endoscope with a soft, lint-free cloth or sponge saturated with cleaning solution.
- Suction cleaning solution through the suction and biopsy channels.
- Flush the air, water, and other channels, alternating with cleaning solution and air, finishing with air.
- Discard the cleaning solution and cloth or sponge after use.

Precleaning flexible endoscopes at the point of use eases and improves the cleaning process and helps reduce the formation of biofilm, which can interfere with subsequent high-level disinfection or sterilization.
TRANSPORTING

- Transport contaminated endoscopes and accessories to the decontamination area or room as soon as possible.
- Keep endoscopes moist but not submerged in liquid during transport.
- Transport endoscopes in a closed container or closed transport cart.
- The container must be leak proof and puncture resistant and should be large enough to contain all contents with the endoscope coiled in large loops.
- Label the transport cart or container with a biohazard legend.
- Keep accessories with the endoscope but contained separately.
- Process endoscopes and endoscope accessories as soon as possible after transport to the endoscopy processing room or within the manufacturer’s recommended time to processing.
- When it is not possible to initiate the cleaning process within the endoscope manufacturer’s recommended time to cleaning, follow the manufacturer’s instructions for delayed processing.
- Implement a process for recording the times when the procedure is completed and the cleaning is initiated.
- Clean and disinfect transport carts.

Transporting the contaminated endoscope as soon as possible facilitates expeditious initiation of the cleaning process and helps prevent organic material from drying on the surface or in the lumens. Keeping accessories with the endoscope helps prevent them from being lost or damaged and facilitates traceability of the endoscope and accessories as a single unit.

LEAK TESTING

- For flexible endoscopes designed to be leak tested, perform a leak test after each use, after damage may have occurred, and before use of a new, repaired, or loaned endoscope.
- Perform the leak test before manual cleaning and before the endoscope is placed into the cleaning solution.
- Perform leak testing in accordance with the endoscope and leak-testing equipment manufacturers’ IFU.
- Remove all port covers and function valves.
- Pressurize the endoscope to the recommended pressure.
- Place the endoscope in a loose configuration.
- Manipulate all moving parts; angulate the bending section of the distal end.
- Actuate video switches while testing.
- Maintain pressure and inspect the endoscope for a minimum of 30 seconds.
- When an endoscope fails a leak test, remove it from service and send for repair or replacement.

Leak testing can reduce damage and repair costs and decrease the potential for patient infection or injury that might result from use of an endoscope that is not completely sealed.
MANUAL CLEANING

• Manually clean the flexible endoscope as soon as possible after leak testing.
• Follow the endoscope and cleaning solution manufacturers’ IFU.
• Use a freshly prepared cleaning solution compatible with the endoscope and do not add other products to the cleaning solution unless recommended by the manufacturer.
• Completely submerge the endoscope and accessories.
• Clean the exterior surfaces of the endoscope with a soft, lint-free cloth or sponge.
• Clean all accessible channels and the distal end of the endoscope with a cleaning brush of the length, width, and material recommended by the endoscope manufacturer.
• Actuate the endoscope valves while cleaning.
• Clean and brush the elevator mechanism and the recesses surrounding it.
• Raise and lower the elevator throughout the manual cleaning process.
• Use a clean brush for each endoscope cleaning.
• Brush the accessible channels of the endoscope until no debris appears on the brush.
• Remove debris from the brush before retracting the brush back through the endoscope.
• Flush the endoscope channels with cleaning solution.
• Flush and rinse exterior surfaces and internal channels of the endoscope with utility water until all cleaning solution and residual debris is removed.
• Dry the exterior surfaces and purge all channels with instrument air.
• Clean, brush, and rinse reusable parts, accessories, and cleaning implements.
• Use only single-use parts, accessories, and cleaning implements that are compatible with and approved by the endoscope manufacturer and discard them after use.

The effectiveness of the cleaning process can vary based on a number of factors, including the type of device being cleaned, the design of the device being cleaned, the person performing the cleaning, the amount of time spent cleaning, and the site where the device is being cleaned. Cleaning is the most important step in the processing of flexible endoscopes.

INSPECTING

• Inspect all new, repaired, refurbished, and loaned endoscopes and accessories before processing.
• Inspect and evaluate endoscopes and accessories for:
  - cleanliness
  - missing parts
  - clarity of lenses
  - integrity of seals and gaskets
  - physical or chemical damage
  - moisture
  - function
• Use additional illumination and magnification for inspection.
• Inspect internal channels using a camera or bore-scope, if available.
• Remove defective endoscopes, accessories, and equipment from service and send them for repair or discard them.
• Decontaminate equipment to be sent for repair and attach a biohazard label to the transport container before transport.

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HIGH-LEVEL DISINFECTION, LIQUID CHEMICAL STERILIZATION, OR PACKAGING AND STERILIZATION

- Mechanically clean and process flexible endoscopes and accessories by exposure to a high-level disinfectant or a liquid chemical sterilant, or mechanically clean and sterilize them.
- Follow both the endoscope and mechanical processor manufacturers’ IFU.
- Position endoscopes and accessories within the mechanical processor in a manner that ensures contact of the processing solutions with all surfaces of the endoscope.
- Ensure all connectors between the endoscope and mechanical processor are connected correctly.
- Perform mechanical processing of flexible endoscopes using critical water.
- Use cleaning, disinfectant, and sterilant solutions and chemicals recommended by the endoscope and mechanical processor manufacturers.
- If recommended by the mechanical processor manufacturer, use a test strip to monitor solution potency.
- After disinfection of the endoscope and accessories, mechanically rinse them with critical or sterile water.
- Form a multidisciplinary team to conduct a risk assessment to determine whether endoscope lumens should be flushed with 70% to 90% ethyl or isopropyl alcohol.
- Dry the exterior surfaces and removable parts of the endoscope.
- Dry the endoscope channels by purging with instrument air or by mechanically drying with a mechanical processor drying system.
- Package and sterilize endoscope accessories that enter sterile tissues or the vascular system.

STORING

- Place flexible endoscopes in a drying cabinet.
- If a drying cabinet is not available, store endoscopes in a closed cabinet with HEPA-filtered air that provides positive air pressure and allows air circulation around the flexible endoscopes.
- Do not store flexible endoscopes in their original shipment cases.
- Store mechanically processed flexible endoscopes in a cabinet that is either designed and intended for horizontal storage of flexible endoscopes or is of sufficient height, width, and depth to allow the endoscopes to hang vertically, without coiling and without touching the bottom of the cabinet.
- Store flexible endoscopes with all valves open and with removable parts detached but stored with the endoscope.
- Provide a distinct visual cue to clearly identify flexible endoscopes that are processed and ready for use.
- Visually inspect storage cabinets and flexible endoscopes for cleanliness before placing into or removing the endoscope from storage.
- If there is any evidence of contamination of the endoscope (eg, soil, moisture) the endoscope should be reprocessed before use.
- Wear clean gloves when handling and transporting processed flexible endoscopes to and from the storage cabinet.
- Clean and disinfect storage cabinets when they are visibly soiled and on a regular basis.
- Form a multidisciplinary team to establish a policy to determine the maximum storage time that processed flexible endoscopes are considered safe to use without reprocessing.

The Spaulding system classifies items as critical, semicritical, or noncritical. Items such as flexible endoscopes that come in contact with nonintact skin or mucous membranes are considered to be semicritical and should be processed by sterilization or, at a minimum, by high-level disinfection.

Effective storage of flexible endoscopes protects the endoscope and endoscope accessories from damage and reduces contamination to help ensure devices are safe for patient use.
RECORDING

- Keep records related to flexible endoscope processing that include:
  - date and time
  - identity of the endoscope and endoscope accessories
  - method and verification of cleaning and results of cleaning verification testing
  - number or identifier of the mechanical processor and results of processor efficacy testing
  - identity of the persons performing the processing
  - lot numbers of processing solutions
  - disposition of defective items or equipment
  - maintenance of water systems, endoscope and endoscope accessories, and processing equipment

- Keep records related to flexible endoscope procedures that include:
  - date and time
  - identity of the patient
  - procedure
  - identity of the licensed independent practitioner performing the procedure
  - identity of the endoscopes and accessories used during the procedure

- Specify in your policy and procedures how long records should be kept.

QUALITY MANAGEMENT

- Review and evaluate flexible endoscope processing to verify compliance and identify the need for improvement.
- Form a multidisciplinary team to establish a policy regarding processes for monitoring and auditing facility water quality to ensure compliance with requirements for endoscope processing as specified in the endoscope, processing equipment, and processing products manufacturers’ IFU.
- Form a multidisciplinary team to collaborate with manufacturer service personnel to determine schedules for preventive maintenance of flexible endoscopes, mechanical processors, and other equipment (eg, the drying cabinet) used for processing flexible endoscopes.
- Verify manual cleaning of flexible endoscopes by using cleaning verification tests when new endoscopes are purchased and at established intervals (eg, after each use, daily).
- Form a multidisciplinary team to evaluate the need to implement a program for regular microbiologic surveillance cultures of flexible endoscopes and mechanical processors.

Records provide data for the identification of trends and demonstrate compliance with regulatory requirements and accreditation standards.
PERSONNEL

- Ensure cleaning and processing is conducted by individuals who have received education and completed competency verification activities related to endoscope processing.
- Implement procedures to verify that processing of flexible endoscopes is performed in the same manner in all processing locations.
- Ensure sufficient time and numbers of personnel are provided to permit thorough cleaning and processing of flexible endoscopes.
- Schedule endoscopy procedures to allow sufficient time for cleaning and processing flexible endoscopes.
- Maintain an inventory of flexible endoscopes and accessories sufficient to meet the anticipated demand.
- Establish policies and procedures requiring that flexible endoscopes used for procedures performed at the bedside or outside of normal operating hours are processed in the same manner as endoscopes used during normal operating hours.

★ Having individuals who have received education and demonstrated competency process flexible endoscopes and accessories helps reduce the risk for errors and cross contamination.