

HICPAC Sample Policy Template: Reprocessing Flexible Endoscopes

Administrative Approval

Date Created: _____

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Approval signature(s) with title and date of signature:

Signature	Title	Date
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Purpose: Facilities can use this sample policy template to develop a facility-specific policies that reflects the endoscopes and evidence-based practices employed by the facility. The policy document will provide guidance to personnel for processing all types of reusable flexible endoscopes and accessories.

Policy

It is the policy of **[insert name of facility]** that:

- All personnel involved in the reprocessing of endoscopes receive ongoing education, training and assessment of competency.
- Ongoing periodic audits of facility reprocessing protocols will be conducted to ensure quality assurance, monitor compliance, and the completeness of documentation.
- Flexible endoscopes and accessories will be precleaned at the point of use.
- Flexible endoscopes designed to be leak tested will be leak tested after each use, after any event that may have damaged the endoscope, and before use of a newly purchased, repaired, or loaned endoscope.
- After leak testing and before high-level disinfection (HLD) or sterilization, flexible endoscopes will be manually cleaned.
- Flexible endoscopes, accessories, and associated equipment will be visually inspected for cleanliness, integrity, and function before disinfection or sterilization.
- Chemicals and solutions used for cleaning and reprocessing flexible endoscopes and endoscope accessories will be handled in accordance with local, state, and federal regulations and the manufacturer's IFU.
- Flexible endoscopes and accessories will be stored in a manner that minimizes contamination and protects the device or item from damage.
- Records of flexible endoscope processing and procedures that enable traceability in the event of a processing failure will be completed and maintained.
 - o Records will be maintained for **[insert facility-specific time period]**.

Procedure Interventions

Precleaning

- Preclean flexible endoscopes and accessories at the point of use as soon as possible after the endoscope is removed from the patient (or the procedure is completed) and before organic material has dried on the surface or in the channels of the endoscope.
- Perform precleaning in accordance with the endoscope manufacturer's IFU and by
 - o preparing a fresh solution of the cleaning product with properties recommended by the manufacturer;
 - o washing the exterior surfaces of the endoscope with a soft, lint-free cloth or sponge saturated with the cleaning solution;
 - o suctioning the cleaning solution through the suction and biopsy channels;
 - o placing the distal end of the endoscope in the cleaning solution and suctioning the solution through the endoscope;
 - o flushing the air, water, and other channels of the endoscope alternately with the cleaning solution and air, finishing with air;
 - o visually inspecting the endoscope for damage; and
 - o discarding the cleaning solution and cleaning cloth or sponge after use.

Transporting

- Transport contaminated flexible endoscopes and accessories to the endoscopy processing room as soon as possible after use.
- Keep the endoscope wet or damp, but not submerged in liquid, during transport.
- Transport contaminated endoscopes and accessories to the decontamination area in a closed container or closed transport cart.
 - o Use a container that is leak proof, puncture resistant, and large enough to contain all contents.
 - o Use a container that is of sufficient size to accommodate the endoscope when the endoscope is coiled in large loops.
- Label the transport cart or container with a biohazard legend.
 - o Securely affix the biohazard label to the cart or container.
- Transport the accessories with the endoscope but contain them separately from the endoscope.
- Begin processing flexible endoscopes and accessories as soon as possible after transport to the endoscopy processing room or within the manufacturer's recommended time to processing.
 - o When it is not possible to initiate the cleaning process within the endoscope manufacturer's recommended time to cleaning, follow the manufacturer's IFU for delayed processing.
 - o Do not leave flexible endoscopes soaking in enzymatic cleaning solutions beyond the endoscope manufacturer's designated contact time unless this is recommended in the manufacturer's IFU for delayed processing.

Leak Testing

- Perform leak testing before manual cleaning and before the endoscope is placed into cleaning solutions.
- Perform leak testing in accordance with the endoscope and leak-testing equipment manufacturers' IFU and by
 - o removing all port covers and function valves;
 - o placing the endoscope in a loose configuration;
 - o pressurizing the endoscope to the recommended pressure;
 - o manipulating all moving parts, including the elevator, and angulating the bending section of the distal end;
 - o actuating video switches; and
 - o maintaining pressure and inspection for a minimum of 30 seconds.

- When an endoscope fails a leak test, remove it from service and send for repair or replacement per facility policy and procedure.

Manual Cleaning

- Perform manual cleaning in accordance with the endoscope manufacturer's IFU.
- Perform manual cleaning using the type of water and cleaning solution recommended by the endoscope manufacturer.
- Perform manual cleaning using a freshly prepared cleaning solution.
- Follow the cleaning solution manufacturer's IFU for
 - o water quality, hardness, and pH;
 - o concentration and dilution;
 - o water temperature;
 - o contact time;
 - o conditions of storage; and
 - o use life and shelf life.
- Completely submerge the endoscope in the cleaning solution during the cleaning process.
 - o Detach removable parts (e.g., valves, buttons, caps) from the endoscope and submerge them if recommended by the endoscope manufacturer's IFU.
- Clean all exterior surfaces of the endoscope with a soft, lint-free cloth or sponge saturated with the cleaning solution.
- 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.
- Manually actuate the endoscope valves while cleaning.
- Clean and brush the elevator mechanism (if present) and the recesses surrounding it with a cleaning brush of the length, width, and material recommended by the endoscope manufacturer.
 - o Raise and lower the elevator channel throughout the manual cleaning process.
- Use a clean brush for each endoscope cleaning.
 - o Visually inspect brushes and other items used to clean endoscope channels before use and do not use if the integrity of the brush or other cleaning item is in question.
- Brush the accessible channels of the endoscope multiple times until no debris appears on the brush.
 - o Remove debris from the brush before the brush is retracted back through the channel and after each pass by swirling the brush in the cleaning solution and rinsing it.
- Flush the channels of the endoscope with cleaning solution.
- Flush and rinse the exterior surfaces and internal channels of the endoscope with tap water until all cleaning solution and residual debris is removed.
- Dry the exterior surfaces of the endoscope with a soft, lint-free cloth or sponge and purge all channels with air.
- Clean, brush, rinse, dry, and high-level disinfect or sterilize all reusable parts (e.g., valves, buttons, port covers, tubing, water bottles), accessories (e.g., forceps) and cleaning implements (e.g., brushes, channel cleaning adapters).
 - o High-level disinfect or sterilize water and irrigation bottles at least daily.
 - o Do not allow any residual water or moisture to remain in the water bottle assembly.
 - o Use sterile water to fill water and irrigation bottles.
- Discard single-use parts, accessories, and cleaning implements after each use and do not reprocess.

Inspecting

- Visually inspect and evaluate endoscopes, accessories, and equipment for
 - o cleanliness,

- ☐ missing parts,
- ☐ clarity of lenses,
- ☐ integrity of seals and gaskets,
- ☐ moisture,
- ☐ physical and chemical damage, and
- ☐ function.
- Use lighted magnification to inspect endoscopes and accessories for cleanliness and damage, as needed.
- Remove defective endoscopes, accessories, and equipment from service and send for repair or replacement per facility policy and procedure.

High-Level Disinfection or Sterilization

- Manually clean the endoscope and accessories before mechanical or manual HLD or sterilization.

Mechanical methods

- Check the expiration date of the high-level disinfectant or liquid chemical sterilant before each use.
- Use a test strip or other US Food and Drug Administration (FDA)-cleared testing device specific to the disinfectant or liquid chemical sterilant and minimum effective concentration of the active ingredient for monitoring solution potency before each use.
- Perform mechanical processing in accordance with the endoscope manufacturer's IFU and the mechanical processor's IFU.
 - ☐ Verify compatibility between the endoscope and the mechanical processor before processing.
 - ☐ Position the endoscope 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 the mechanical processor are connected correctly.
 - ☐ Monitor the mechanical processing cycle to verify it is completed as programmed.
 - If a mechanical processing cycle is interrupted, repeat the entire cycle.
- Perform mechanical processing using the cleaning, disinfectant, and sterilant solutions and chemicals recommended by the endoscope manufacturer and the mechanical processor manufacturer.
 - ☐ Know the location of the safety data sheet for each chemical used.
 - ☐ Know the location of the chemical spill kit.

Manual methods

- Check the expiration date of the high-level disinfectant before each use.
- Use a test strip or other US Food and Drug Administration (FDA)-cleared testing device specific to the disinfectant and minimum effective concentration of the active ingredient for monitoring solution potency before each use.
- Completely immerse the endoscope in the high-level disinfectant solution for the designated time according to the device and high-level disinfectant manufacturer's IFU.
- Flush and fill lumens and ports with the high-level disinfectant solution then completely immerse the items in the disinfectant solution for the designated time.
- Following disinfection, thoroughly rinse the endoscope and all of its channels and ports with water that meets the manufacturer's specification or as recommended by professional organizations.
 - ☐ Rinse all removable parts and endoscope accessories.

May be required for both mechanical and manual methods

- Flush endoscope lumens with 70% to 90% ethyl or isopropyl alcohol according to the endoscope manufacturer's IFU.
- Dry the exterior surfaces of the endoscope with a soft, lint-free cloth or sponge.
 - Purge the endoscope channels with air.
 - Dry all removable parts and endoscope accessories.

Sterilization

- Package and sterilize endoscopes and endoscope accessories in accordance with the manufacturers' IFU.

Storing

- Store flexible endoscopes in accordance with the endoscope and storage cabinet manufacturers' IFU.
 - Do not store flexible endoscopes in their original shipment cases.
 - Store flexible endoscopes with all valves open and removable parts detached, but stored with the endoscope.
- Wear clean, low-protein, powder-free, natural rubber latex gloves or latex-free gloves when handling processed flexible endoscopes and when transporting them to and from the storage cabinet.
- Identify processed endoscopes with the facility-specific visual cue.
- Visually inspect endoscopes and storage cabinets for cleanliness before placing endoscopes into or removing them from the cabinet.
- Store sterile items in a sterile storage area per facility policy and procedure.

Records

- Records related to flexible endoscope processing will include the
 - date and time,
 - identity of endoscope and endoscope accessories,
 - method and verification of cleaning and results of cleaning verification testing,
 - number or identifier of the mechanical processor or sterilizer and results of process efficacy testing,
 - identity of the persons performing the processing,
 - lot numbers of processing solutions,
 - disposition of defective items or equipment, and
 - maintenance of water systems, endoscopes and endoscope accessories, and processing equipment.
- Records related to flexible endoscopy procedures will include the
 - date and time,
 - identity of the patient,
 - procedure,
 - identity of the licensed independent practitioner performing the procedure, and
 - identity of the endoscope and endoscope accessories used during the procedure.
- Records related to annual training and competency audit will include the
 - date and time of training and competency verification
 - name of personnel taking training/ competency verification
 - results of competency verification
 - results of audit tool
- Records related to facility audits should include the
 - date and time
 - facility name

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[Insert facility name or a header]

- ☐ completeness of inventory and repair log
- ☐ gap analysis
 - actions taken
- ☐ risk assessment
 - actions taken

Available from: <https://www.cdc.gov/hicpac/recommendations/flexible-endoscope-reprocessing.html>