Guideline Summary: Processing Flexible Endoscopes

PURPOSE

To provide guidance to perioperative, endoscopy, and sterile-processing personnel for processing all types of reusable flexible endoscopes and accessories.

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#	Recommendation	Key Points
III	Flexible endoscopes and accessories should be precleaned at the point of use.	• Precleaning of flexible endoscopes and accessories at the point of use should occur 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. • When the precleaning process will be delayed (eg, an endoscope is used for intubation and remains in the procedure room for potential reuse), designated personnel (eg, RN circulator, scrub person) should wipe the external surfaces with a soft, lint-free cloth or sponge saturated with utility[a] or sterile water and should suction water through the channels.
IV	After precleaning at the point of use, contaminated flexible endoscopes and accessories should be transported to the endoscopy processing room.	• Contaminated flexible endoscopes and accessories should be transported to the endoscopy processing room as soon as possible after use. • Endoscopes and accessories should be kept wet or damp but not submerged in liquid during transport. • Contaminated endoscopes and accessories must be transported to the decontamination area in a closed container or closed transport cart. The container or cart must be leak proof, puncture resistant, and large enough to contain all contents. o The container should be of sufficient size to accommodate the endoscope when the endoscope is coiled in large loops. o The transport cart or container must be labeled with a fluorescent orange or orange-red label containing a biohazard legend. o Flexible endoscopes should be transported in a horizontal position and not suspended. • Endoscope accessories should accompany the endoscope but should be contained separately. • The processing of endoscopes and endoscope accessories should begin 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, the manufacturer's instructions for use (IFU) for delayed processing should be followed. o Flexible endoscopes should not be left soaking in enzymatic cleaning solutions beyond the endoscope manufacturer's designated contact time

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		unless this is recommended in the manufacturer's IFU for delayed processing. o A procedure should be developed and implemented for recording the times that the procedure is completed and cleaning is initiated.
V	Flexible endoscopes designed to be leak tested should be leak tested after each use; after any event that may have damaged the endoscope; and, if it is a newly purchased, repaired, or loaned endoscope, before use.	• Leak testing should be performed before manual cleaning and before the endoscope is placed into cleaning solutions. • When an endoscope fails a leak test, it should be removed from service and repaired or replaced (see recommendation VII, fourth bullet).
VI	After leak testing and before high-level disinfection (HLD) or sterilization, flexible endoscopes should be manually cleaned.	• Manual cleaning should occur as soon as possible after leak testing. • Manual cleaning should be performed using the type of water recommended by the endoscope manufacturer. • Manual cleaning should be performed using a cleaning solution recommended by the endoscope manufacturer. o Manual cleaning should be performed using a freshly prepared cleaning solution. Cleaning solutions should be changed before they become cloudy or discolored and before there are visible particulates in the solution. o Cleaning solutions should be changed when the temperature of the solution does not meet the temperature specified in the manufacturer's IFU. • The endoscope should be completely submerged in the cleaning solution during the cleaning process. Removable parts (eg, valves, buttons, caps) should be detached from the endoscope and submerged if this is recommended by the endoscope manufacturer's IFU. • All exterior surfaces of the endoscope should be cleaned with a soft, lint-free cloth or sponge saturated with the cleaning solution. • All accessible channels and the distal end of the endoscope should be cleaned with a cleaning brush of the length, width, and material recommended by the endoscope manufacturer. The endoscope valves should be manually actuated during cleaning. o The elevator mechanism and the recesses surrounding it should be cleaned and brushed with a cleaning brush of the length, width, and material recommended by the endoscope manufacturer. The elevator should be raised and lowered throughout the manual cleaning process. o A clean brush should be used for each endoscope cleaning. Brushes and other items used to clean endoscope channels should be visually inspected before use and should not be used if the integrity of the brush or other cleaning item is in question. o The accessible channels of the endoscope should be brushed multiple times until no debris appears on the brush. Debris should be removed from the brush before the brush is retracted through the channel and after each pass by swirling the brush in the cleaning solution and rinsing it. • The channels of the endoscope should be flushed with cleaning solution. A cleaning adapter or automatic flushing system may be used when it is compatible with the endoscope. • The exterior surfaces and internal channels of the endoscope should be flushed and rinsed with utility water until all cleaning solution and residual debris is removed. • The exterior surfaces of the endoscope should be dried with a soft, lint-free cloth or sponge and all channels purged with instrument air. • Reusable parts (eg, valves, buttons, port covers, tubing, water bottles), accessories (eg, forceps), and cleaning implements (eg, brushes, channel-cleaning adapters) should be cleaned, brushed, rinsed, and high-level disinfected or sterilized.

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		o Water and irrigation bottles should be high-level disinfected or sterilized at least daily. There should be no residual water or moisture remaining in the water-bottle assembly. • Single-use parts, accessories, and cleaning implements should be discarded after use and should not be reprocessed.
VII	Flexible endoscopes, accessories, and associated equipment should be visually inspected for cleanliness, integrity, and function before use, during the procedure, after the procedure, after cleaning, and before disinfection or sterilization.	• Before use, all new, repaired, refurbished, or loaned endoscopes, accessories, and other equipment should be visually inspected and processed according to the manufacturer's IFU. • Endoscopes, accessories, and equipment should be visually inspected and evaluated for o cleanliness, o missing parts, o clarity of lenses, o integrity of seals and gaskets, o moisture, o physical or chemical damage, and o function. • Lighted magnification should be used to inspect endoscopes and accessories for cleanliness and damage. o Internal channels of flexible endoscopes may be inspected using an endoscopic camera or borescope. • Defective endoscopes, accessories, and equipment should be removed from service and repaired or replaced. o Medical equipment being sent for repair must be decontaminated to the fullest extent possible and a biohazard label attached before transportation.
VIII	After manual cleaning and inspection, flexible endoscopes and endoscope accessories should be high-level disinfected or sterilized.	• A multidisciplinary team that includes infection preventionists, endoscopy and perioperative RNs, sterile-processing personnel, endoscopists, and other involved personnel should conduct a risk assessment to determine whether items that secondarily enter sterile tissue or the vascular system (eg, via a mucous membrane) should be sterile. • After manual cleaning and when it is compatible with the endoscope manufacturer's IFU, flexible endoscopes and accessories either should be mechanically cleaned and mechanically processed by exposure to a high-level disinfectant or a liquid chemical sterilant or should be mechanically cleaned and sterilized. o After precleaning and leak testing, and when directed by the mechanical processor manufacturer's IFU, mechanical processing may be accomplished without manual cleaning. • Mechanical processing should be performed in accordance with the endoscope manufacturer's IFU and the mechanical processor manufacturer's IFU. o Processing personnel should verify compatibility between the endoscope and the mechanical processor before processing. o Flexible endoscopes and accessories should be positioned within the mechanical processor in a manner that ensures contact of the processing solutions with all surfaces of the endoscope. o Processing personnel should ensure all connectors between the endoscope and the mechanical processor are connected correctly. o Processing personnel should monitor mechanical processing cycles to verify they are completed as programmed. If a mechanical processing cycle is interrupted, the entire cycle should be repeated. • Mechanical processing of flexible endoscopes should be performed using critical water.[b]

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		• Mechanical processing should be performed using cleaning, disinfectant, and sterilant solutions and chemicals recommended by the endoscope manufacturer and the mechanical processor manufacturer. o The following products should not be used for processing flexible endoscopes: ■ skin antiseptics, ■ hypochlorites, ■ phenolics, nor ■ quaternary ammonium compounds. • After disinfection, the endoscope and endoscope channels should be mechanically rinsed and flushed with critical or sterile water. o Endoscope accessories and removable parts should be rinsed with critical or sterile water. • A multidisciplinary team that includes infection preventionists, endoscopy and perioperative RNs, endoscopy processing personnel, endoscopists, and other involved personnel should conduct a risk assessment to determine whether endoscope lumens should be flushed with 70% to 90% ethyl or isopropyl alcohol. • After mechanical processing, the exterior surfaces of the endoscope should be dried with a soft, lint-free cloth or sponge. The endoscope channels should be dried by purging with instrument air or mechanically dried with a mechanical processor drying system. Removable parts and endoscope accessories should be dried. • A multidisciplinary team that includes infection preventionists, endoscopy and perioperative RNs, endoscopy processing personnel, endoscopists, and other involved personnel should conduct a risk assessment to determine the potential harms compared with the benefits of initiating one or more enhanced methods for processing duodenoscopes. Enhanced methods for processing flexible duodenoscopes may include implementing HLD followed by o endoscope quarantine until the duodenoscope is culture-negative, o a liquid chemical sterilant processing system, o a second HLD, o ethylene oxide sterilization, or o US Food and Drug Administration—cleared low-temperature sterilization.
IX	Flexible endoscopes and endoscope accessories should be stored in a manner that minimizes contamination and protects the device or item from damage.	• Cabinets used for the storage of flexible endoscopes should be situated in a secure location in the clean workroom of the endoscopy processing area in a two-room design or in a separate clean area close to, but not within, the endoscopy procedure room. o Storage cabinets should have doors and should be located at least 3 ft (0.9 m) from any sink. • Flexible endoscopes should be stored in a drying cabinet. o If a drying cabinet is not available, flexible endoscopes may be stored in a closed cabinet with HEPA-filtered air that provides positive pressure and allows air circulation around the flexible endoscopes. • Flexible endoscopes that have been mechanically processed should be stored in a cabinet that is either o designed and intended by the cabinet manufacturer for horizontal storage of flexible endoscopes or o of sufficient height, width, and depth to allow flexible endoscopes to hang vertically without coiling and without touching the bottom of the cabinet. • Flexible endoscopes should be stored with all valves open, and removable parts should be detached but stored with the endoscope. • Flexible endoscopes should be clearly identifiable, with a distinct visual cue, as processed and ready for use.

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#	Recommendation	Key Points
		• Flexible endoscopes and storage cabinets should be visually inspected for cleanliness before endoscopes are placed into or removed from storage. • Personnel should 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. • A multidisciplinary team that includes infection preventionists, endoscopy and perioperative RNs, endoscopy processing personnel, endoscopists, and other involved personnel should establish a policy to determine the maximum storage time that processed flexible endoscopes are considered safe to use without reprocessing. o The multidisciplinary team should establish a policy for removing and reprocessing the endoscope before use if the maximum storage time has been exceeded. • Storage cabinets used for flexible endoscopes should be cleaned and disinfected with an Environmental Protection Agency–registered hospital-grade disinfectant when they are visibly soiled and on a regular (eg, daily, weekly) basis. o A multidisciplinary team that includes infection preventionists, endoscopy and perioperative RNs, endoscopy processing personnel, endoscopists, and other involved personnel should establish a policy to determine the cleaning frequency of the storage cabinet.
X	The health care organization should maintain records of flexible endoscope processing and procedures.	• Records related to flexible endoscope processing should include the o date and time, o identity of the endoscope and endoscope accessories, o method and verification of cleaning and results of cleaning-verification testing, o number or identifier of the mechanical processor or sterilizer and results of process efficacy testing, o identity of the person(s) performing the processing, o lot numbers of processing solutions, o disposition of defective items or equipment, and o maintenance of water systems, endoscopes and endoscope accessories, and processing equipment. • Records related to flexible endoscope procedures should include the o date and time, o identity of the patient, o procedure, o identity of the licensed independent practitioner performing the procedure, and o identity of the endoscope and endoscope accessories used during the procedure.
XIII	The health care organization's quality management program should evaluate the processing of flexible endoscopes.	• A multidisciplinary team that includes facility engineers, endoscopy processing personnel, infection preventionists, and other involved personnel should establish a policy to determine 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. Water quality and water filtration systems should be assessed at established intervals and after major maintenance to the water supply system. • A multidisciplinary team that includes facility engineers, endoscopy processing personnel, infection preventionists, and other involved personnel should collaborate with manufacturer service personnel to determine schedules for preventive maintenance of flexible endoscopes, mechanical

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		processors, and other equipment (eg, the drying cabinet) used for processing flexible endoscopes. • Manual cleaning of flexible endoscopes should be verified using cleaning-verification tests when new endoscopes are purchased and at established intervals (eg, after each use, daily). o A multidisciplinary team that includes infection preventionists, endoscopists, endoscopy processing personnel, and other involved individuals should establish the type of cleaning-verification test to be performed. • A multidisciplinary team that includes infection preventionists, endoscopists, endoscopy processing personnel, microbiologists, laboratory personnel, risk managers, and other involved individuals should evaluate the need to implement a program for regular microbiologic surveillance cultures of flexible endoscopes and mechanical processors. o The multidisciplinary team should establish the methods and frequencies for microbiologic surveillance culturing of flexible endoscopes and mechanical processors. o If a cluster of suspected or confirmed endoscopy-related infections is identified, the infection preventionist should initiate an investigation in consultation with a health care epidemiologist and the multidisciplinary team.

[a] *Utility water: Water that was obtained directly from a faucet and that has not been purified, distilled, or otherwise treated. Synonym: tap water.*
[b] *Critical water: Water that has been extensively treated to remove microorganisms and other materials.*

Reference
1. *Guideline for processing flexible endoscopes. In:* Guidelines for Perioperative Practice. *Denver, CO: AORN, Inc; 2016:675-758.*

AORN has developed this Guideline Summary as a service to AORN members. The summary is intended to be an adjunct to the complete guideline upon which it is based and is not intended to be a replacement for that document. Individuals who are developing and updating organizational policies and procedures should review and reference the full guideline.