ANSI/AAMI ST91:2021

Flexible and semi-rigid endoscope processing in health care facilities

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Flexible and semi-rigid endoscopes are a necessity and valuable equipment in the medical field; they are used in body cavities for diagnostic procedures. ST91 is a guide for everyone in health care facilities that face challenges with new devices being developed for patient care to follow and understand the policy on how to reprocess flexible and semi-rigid endoscopes. This standard will provide better understanding and guidance for cleaning and disinfecting/sterilizing flexible endoscopes.

Decontamination Workflow

When reprocessing flexible and semi-rigid endoscopes, the workflow should be from the decontamination room to the clean room to storage area with adequate workspace. Section 4.2.1 *Workflow General considerations* states, "counters, sinks and work surfaces should be height adjustable or positioned at heights that accommodate the average height of employees and the tasks to be performed at each location." Counter tops should have adequate space to place endoscopes on when performing dry leak testing. It is also recommended that a pass-through window from the decontamination room to the clean room be of counter height. Having an ergonomic workflow will help eliminate worker injury. Also, having anti-fatigue mats will help alleviate foot and leg pain from standing for long periods of time and wearing a back brace will help with lower back pain.

Healthmark's Autoclavable Anti-Fatigue Mat is a great addition to help in aiding back stress from long periods of standing. The Adjustable Back Brace helps with keeping the back erect and relieve lower back pain from bending over for long periods of time.

- **Autoclavable Anti-Fatigue Mat- (AFM-580)**

- **Adjustable Back Brace- (2886)**

After pre-cleaning has been completed in the procedure room, the endoscope is then transported to the decontamination area/room for manual cleaning. First, the endoscope needs to be manually cleaned and the endoscope should be taken to the processing area and placed in the AER for high

level disinfection. Section 4.2.2 *Physical separation* states, "An area should be defined for disinfection/sterilization that is separate from the manual cleaning/processing area. For manual processing, this area should include a designated area for the immersion of the device for disinfection followed by rinsing in accordance with the disinfectant manufacturer's written IFU. For automated processing, the AER, washer-disinfector, or sterilizer forms an essential barrier between the dirty and clean areas of the processing area." After the sterilization process, an area that is controlled for storage that is away from patient use should be determined to avoid possible risks of contamination to the flexible endoscopes.

When processing flexible and semi-rigid endoscopes, it is essential to have restricted areas for authorized personnel. It is necessary for employees and visitors to comply with facility policy prior to entering restricted areas such as the decontamination room and clean room. Section 4.2.3 *Traffic control* states, "Personnel and visitors can carry microorganisms into the processing areas, increasing the potential for environmental contamination in these areas."

The size of the department needs to be considered and this will affect how the personnel are able to function and work efficiently in the areas of processing, maneuvering and storage space available, terminal sterilization, manual HDL, and AER high-level disinfection or liquid chemical sterilization. Section 4.3.1.4 *Space requirements for manual high-level disinfection or manual liquid chemical sterilization* states "Space requirements can vary significantly depending upon the specific processing needs of the facility and are often underestimated during the planning process. Adequate space is needed for effective and safe endoscope processing."

When processing flexible endoscopes, at least two sinks should be used. One for leak testing and the other for manual cleaning with each having a faucet for attachments to flush the lumens. The sinks should be deep enough for the endoscope to be fully submerged for wet leak testing and manual cleaning and wide enough as to not over coil the endoscope.

Temperature, Relative Humidity, and Ventilation

The temperature in the processing area is important because employees are wearing PPE for long periods of time which consists of a bouffant cap, shoe covers, disposable bootlegs, lined sleeve gloves, mask, face shield, and gown. "Requirements for HCAC in the endoscope processing area should conform with the specifications of ANSI/ASHARE/ASHE that were in effect when the HVAC system was initially installed or last upgraded" according to section 4.3.7 *Heating, ventilation, and air conditioning (HVAC) operating parameters Temperature and relative humidity*. Ventilation of air flow is important for both the decontamination room which has negative pressure with 10 exchanges per hour and the clean room with positive pressure with 10 exchanges per hour. Section 4.3.7 states, "The health care facility should establish and implement systematic processes for monitoring HVAC performance parameters and a mechanism for identifying and resolving variances within the rooms throughout the facility where processing occurs."

Healthmark offers the T EMP-USB-TP for the Central Processing Department where temperature control is crucial.

- **Temp-USB-TP**

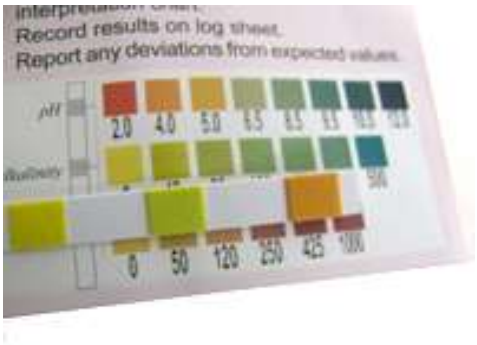
Good hand hygiene is essential and should be considered before the technician begins the processing of flexible and semi-rigid endoscopes. The sink, soap dispenser and towel dispenser should be hands-free and located away from the decontamination sinks as well as in the clean room where endoscopes are manually cleaned, high level disinfected and sterilized. The technician should wash their hands before donning PPE and after doffing PPE prior to leaving the decontamination room. On the clean side, hands should be washed before putting on gloves when handling endoscopes to prevent possible cross contamination. Section 4.3.9 *Hand hygiene facilities* states, "Conveniently located hand hygiene facilities and alcohol-based hand rub dispensers help to promote hand hygiene and increase compliance with hand hygiene policies and procedures." In keeping proper hand hygiene, fingernails should be kept short and polish free as this can hinder the technician from proper handling and inspecting an endoscope. The nails should be kept short and not longer than the tip of the finger. Nail polish is not to be worn due to possibility of it chipping and falling into the lumen/channel or in the tray, including acrylic nails, gels and extensions also should not be worn. Section 6.5 *Hand Hygiene* states "Policies and procedures on hand hygiene should be developed and communicated to employees. Careful attention to hand hygiene can minimize the potential for acquiring or transmitting diseases."

Eyewash units are also important to have in the department in case of emergencies of eye irritation and should be located no further than 10 seconds from the location of chemical or storage area. Maintenance is required on a consistent basis to ensure the units are working properly and in good condition. Section 4.3.10 *Emergency eyewash/shower equipment* states, "Suitable eyewash units must be available for immediate use in all places where chemicals are used (29 CFR 1910.151C). The availability of eyewash units for immediate emergency use is required by OSHA. Maintenance of the eyewash units is necessary to ensure adequate performance and to prevent contamination."

Water quality is an important part of endoscope reprocessing. The correct water should be used throughout the entire cleaning process to which the user should review the manufacturer's IFU.

Section 4.3.11 *Water quality* states, “Using the correct water quality helps to prolong the life of medical devices, facilitates their effective functioning, and importantly, reduces the risk of medical device contamination.” Healthmark offers the AquaTest™ 3-in-1 Water Quality Test Strips that shows the water quality statistics: pH, Alkalinity and Hardness.

- **AquaTest™- (AT101)**



Environmental cleaning should be performed daily in areas of decontamination, the clean room and sterilization. All surfaces should be always kept clean to help eliminate dust from collecting in areas that house endoscopes, storage shelves, instrument storage cabinets and air ducts. Environmental cleaning supplies should be kept in separate storage areas for both the decontamination room and the clean room. Section 5 *Environmental cleaning* states “Special attention should be paid to the sequence of cleaning to avoid transferring contaminants from “dirty” to “clean” areas and surfaces.”

Education and training should be provided to employees for verification that is relative to the technician duties as well as completing competencies annually to ensure proper practice with new scopes and equipment and the use of new chemicals with correct dosage is being used. Section 6.3.1 *Education, training, and competency verification, General considerations* states, “All personnel performing endoscope processing shall complete formal training and competency verification in all aspects of endoscope processing prior to first assignment to perform these tasks independently.” It is essential that technicians maintain knowledge of current policies and procedures of manufacturer’s IFUs and regulated facilities’ policies. Healthmark offers a variety of topics for the staff and department for education offering CEU programs, as well as several online games for continuing education at https://www.hmark.com/index.php.

Personal Protective Equipment

Coming into the health care facility, the technicians must change into clean scrubs before starting work. If they are in the decontamination room and become grossly soiled or wet, the technician should doff the dirty scrubs and don clean scrubs before returning to work. No jewelry or watches should be worn, facial hair should be covered with a facial bouffant cover, and hair should be covered with a bouffant cap or scrub hat. Never leave the facility with scrubs on, as

they may contain gross soil or other contaminants and can come into contact with other people. Section 6.6.1 *Attire General considerations* states, Clean attire minimizes the introduction of microorganisms and lint from personnel to items being processed and to the environment."

Healthmark offers several different options of headwear to protect the technician's hair. One size fit's all, 100% cotton fabric custom imprinted reusable scrub hats and disposable bouffant and scrub hats are available.

● Custom-Printed Cotton Scrub Hats- (PRSC-WT)

● Custom-Printed Disposable Headwear- (PSC-WT, PBC-WT)

Personal Protective Equipment is a must in the decontamination area to protect the technician from gross soil, microorganisms, and sharp instruments. This is for the safety of the employee during the process of decontamination and all measures should be followed. The fluid resistant face mask covers the lower half of the face (nose, cheeks, mouth and underneath the chin area). The bouffant cap covers and protects the hair from getting wet and keeps the hair out of the way. Protective eye goggles are worn to prevent the eye from getting splashed. The face shield with a wide drape covers the entire face and protects from all angles. The gown protects the technician from getting gross soil and getting wet from water spray. The gown should be tied in the back to cover the technician's back to limit exposure to contaminants. The gloves should be placed over the gown arm cuff and up the arms to prevent from getting wet. If gloves become torn, wash hands before donning new gloves. Shoe covers are to protect the feet from getting wet; bootleg covers are also an option to keep the shoes and legs protected from getting wet or soiled. Section 6.6.2 *Personal protective equipment* states, "PPE will minimize the potential for employee exposure to bloodborne and other disease-producing organisms and chemicals used in the

processing of endoscopes. Wearing heavy-duty, waterproof gloves while handling contaminated items decreases the potential for puncture, limits microbial burden on hands, and decreases the risk of cross-contamination."

Healthmark has Long Sleeve Gloves to protect the technician from becoming wet during processing that are flexible, lightweight, and provide hand and arm protection with an elastic cuff to prevent slippage from the upper arm. The Wide Drape Face Shield provides extended coverage to the neck area to prevent accidental splashing from bloodborne pathogens coming into contact with the skin. Disposable Bootlegs keep legs and feet dry. Gowns with Thumb Loops provide coverage around the wrist and arm to ensure a secure fit to limit excess water from coming into contact with the skin. The Decontamination Gown will help protect the wearer from contamination when working in a decontamination area.

- **Lined Sleeve Gloves- (41380, 41480, 41580, 41680)**

- **Face Shield with Drape- (SLH-002)**

- **Face Shield- (SHL-001)**

● **Disposable Bootlegs- (BOOTLEG)**

● **Gowns with Thumb Loop- (42500)**

- **Decontamination Gown- (MN110 SMMD, MN110 LGXL, MN110 2X3X, MD110 4X**

It is also essential to stay cool underneath your PPE while working in the decontamination area. As the heat, humidity rises, wearing PPE causes body heat to rise which can lead to dehydration, and the body starts to slow down. Appendix A.3 *Protective attire* states, "The plastic or other fluid-resistant material provides an excellent barrier to bloodborne pathogens, but it does not allow for the body to dispense any excess heat that might build up." Wearing cooling devices in the decontam area will help avoid excess body heat and keep the body cool. Appendix A.4 *Alternative cooling methods for personnel working in the decontamination area/room* states, Cooling devices worn under PPE could provide additional comfort. Cooling devices can be reusable or single-use and include:

A. cooling bandanas, skull caps, or headbands
B. cooling neck scarfs or towels; and
C. cooling vests

Healthmark offers several types of Latex free Cool Aids that help to combat body heat while wearing PPE: Evaporating Cooling Neck Band, Cooling Skull Cap, Cooling Beanie, Single-use Cooling Vest, Hybrid Cooling Vest with Replaceable Cool Pak Inserts.

- **Cool Aids**

- **Single-Use Cooling Vest- (SUCV-001)**

Healthmark offers different types of compression socks to help with muscle fatigue in the lower legs and feet in four styles: Below Ankle, Ankle, Mid-Calf and Knee High.

- **Swanky Athletic Socks- (94737-M, 94699-M)**

- **Compression Socks**

Cleaning and High-Level Disinfection

Pre-cleaning endoscopes is done at the point of use. This is performed after the patient's procedure and before the flexible endoscope is transported to the decontamination room for manual cleaning and high-level disinfection. Donning fresh PPE is done before the technician begins pre-cleaning of the endoscope. Section 7.2.2 *Point of use treatment Procedure steps a-k* states, " Don PPE, the cleaning solution is prepared according to the IFU, wipe insertion tube with wet non-linting cloth or non-abrasive sponge from cleaning solution, suction the solution through the channel according to the manufacturer's IFU, raise and lower the forceps elevator three times by turning the elevator control level or per the manufacturer's IFU, then flush the air/water channels with solution using endoscope cleaning adapter or IFU-instructed air/water flow. Flush other channels with solution as directed in the manufacturer's IFU and until it is clear. Next, detach the endoscope from the light source and suction pump. Remove disposable accessories, if used. Attach a fluid resistant cap over any electrical components, and lastly

visually inspect the endoscope for damage." After all the steps of the pre-cleaning are completed, transport the flexible endoscope to the decontamination room for manual cleaning.

Healthmark's Non-linting Wipes are for use immediately after the item has been used, and prior to automated or manual disinfection to ensure items are dry. The Durasponge allows for safe cleaning of surgical instruments and surfaces.

● **Non-Linting Wipes**

● **Durasponge – (ESP905201, ESP904101)**

Endoscopes that are transported individually with the accessories in a closed system are considered contaminated. The container must be labeled "biohazard" and meet OSHA requirements; it must also be large enough to fit an endoscope so not to over coil the insertion or light guide tubes to prevent damage during transportation. Section 7.3.1 *Transport of contaminated endoscopes* states, "Improper containment and transport of contaminated endoscope represents a potential risk of infection transmission to staff and patients. Precleaned endoscopes are still considered contaminated and appropriate precautions and procedures should be followed."

Healthmark Products to Comply with Contaminated Transport

Round Soaker, SST Tray Systems and **Transport Trolley (2220, 2220 Trolley)**: Round soaker bin has a 20" diameter and is perfectly sized to allow a flexible endoscope to coil naturally and safely for transport or soaking. A lift off lid completely covers the tray. The Trolley can accommodate up to 5 round soaker trays simultaneously.

Clean/Dirty Scope Seal Kit (2220 LOK): Seals have clean/dirty tamper evident seals.

2 Part Clean/Dirty Label (AV-52482): This sticker is used to communicate whether the endoscope contained within a bin is clean or dirty

Biohazard signs (BIO3X3): Meet AAMI and OSHA requirements for labeling of contaminated items for transport

Humipak: Instrument manufacturers, AAMI, AORN and others generally recommend that decontamination of instruments begin within 30 minutes of use so that organic soils, particularly blood, do not dry. But often this is not possible. The Humipak consists of a layer of highly absorbent material sandwiched between two layers of water-proof film. To use, place individual instruments, or an entire instrument tray inside the Humipak, add the specified amount of water to the absorbent layer, and seal with the peel away adhesive strip. This creates a water-tight, moist atmosphere that will prevent organics from drying over an extended period of time.

After the endoscope has reached the decontamination room, a leak test should be performed before manual cleaning begins. The leak test will detect if there is damage to any part of the endoscope. Always follow the endoscope manufacturer's IFU before dry leak testing, wet leak testing, and manual cleaning. Fresh PPE should be donned before leak testing is done. Before leak testing begins, Section 7.4.3 *Manual (dry) leak testing* states to, "remove all detachable parts from the endoscope (e.g., single-use valves and biopsy port covers)." The wet leak testing is done under water to show if there is any damage to the endoscope. This will show a consistent stream of bubbles in the water if there is damage.

To test the endoscope with a mechanical dry leak tester, the endoscope is attached to the leak tester tubes with a fluid resistant cap attached. The technician then scans the endoscope and starts the leak tester cycle. Proceed to the cleaning process if the endoscope passes the test. If using an AER to do the leak test, follow the AER manufacturer's IFU. If a leak is found on the endoscope, begin the modified cleaning process, and follow the IFU instructions for the endoscope.

Once the leak test is completed, the technician can begin manually cleaning - always don fresh PPE when cleaning an endoscope. Section 7.5.1 *Cleaning General considerations* states, "Cleaning should begin as soon as possible after confirming that the endoscope does not have any leaks." If the cleaning process is delayed after use, read the manufacturer's IFU before manually cleaning any endoscope for delayed processing. Brush the valves and all channels thoroughly with an endoscope brush that is the correct size according to the endoscope manufacturer's IFU. Section 7.6 *Manual cleaning* states, "Use brushes of the length, width,

and material specified in the endoscope manufacturer's written IFU. Follow the brushing technique specified in the endoscope manufacturer's IFU to clean the endoscope, keeping the endoscope immersed at all times. Use cleaning brushes that are either single-use and dispose of after cleaning (preferred), or reusable and cleaned." When, cleaning multiple endoscopes, fresh water and solution should be used each time. After cleaning is completed, rinse to remove the solution with copious amounts of potable water. Make sure each lumen has adequate water flow and purge channels with air using a syringe to remove water. If using pressurized air, it should not exceed the recommended pressure by the endoscope manufacturer. Dry the exterior of the scope with a low linting cloth.

Healthmark offers the Leak Tester Tester which is designed to check the accuracy of air pressure provided by automated and handheld endoscope leakage testers.

- **Leak Tester Tester- (LTT-4000, LTT-1001, LTT-1002, LTT-1003, LTT-1004)**

Healthmark offers the One-Hour Indicator Label designed to be a visual reminder to healthcare workers of post-procedures.

- **Single-Use 1 Hour Indicator- (HTK-1H2)**

- **12 Day Indicator Hangtime Label-(HTK-12D)**

Healthmark offers single-use brushes. The elevator mechanism brush is designed for efficient scrubbing of endoscope elevator wires with an ergonomic handle. The endoscope brushes are designed to facilitate maximum cleaning that will ensure compatibility with the endoscope channel.

- **Elevator Mechanism Brush- (EMB-002)**

- **Endoscopes Brushes**

High level disinfection of endoscopes can be done in a soaking tub or automated endoscope reprocessor (AER). This is for reprocessing of semi-critical and critical heat-sensitive flexible and semi-rigid endoscopes. Section 8.2.1 *High-level disinfection* states, "High-level disinfection is the minimum level of processing for semi-critical endoscopes. Many liquid chemical sterilants (LCSs) and HLDs cleared by the FDA are labelled for use in both liquid processes."

When disinfecting endoscopes with liquid chemical sterilization/high level disinfection, always don fresh PPE and use a closed container to immerse the endoscope into the LCS/HLD solution. Section 8.2.4.1 *Manual processing procedure (a-g)* states, "Use only LCS/HLD solutions recommended by the endoscope manufacturer or that have been validated for use for both efficacy and compatibility and cleared by the FDA. Use a timing device to assure correct soak time, use a clean dry container, prepare the LCS/HLD product according to the manufacturer's written IFU, check expiration of solution before immersion and then immerse the endoscope in the LCS/HLD to ensure all surfaces are covered. Do not use LCS/HLD past their expiration date. Use a solution test strip or chemical monitoring device to test the concentration for the active ingredients before each use." Before manual rinsing, don fresh PPE and thoroughly rinse the surface, channels, and accessories. Manually dry the endoscope and channels for a specific period of time with medical grade air. Use 70-90% ethyl or isopropyl alcohol with the appropriate amount for each lumen with air until no moisture remains. Section 8.2.5.2 *Manual Drying* states, "Use pressure-regulated instrument air or HEPA-filtered air to dry the channels in accordance with the manufacturer's written IFU. Refer to the endoscope manufacturer's written IFU for guidance on correlating the force of air pressure to channel size and select the air pressure accordingly."

Healthmark has a variety of labels to accommodate specific items that state contaminated or sterile. The 7 Day Hangtime Label indicates the length of time the endoscope was last processed. Self-Looping label shows the necessary information of when the scope was

processed and by whom. Hangtime Labels track the day and month when scope was reprocessed and come in a variety of colors.

- **7 Day Hangtime Label- (HTK-7D2)**

- **Hangtime Labels- (403225 HTK)**

Automated Endoscope Reprocessors

Automated endoscope reprocessors are machines designed for cleaning and disinfecting endoscopes and accessories. The machine uses LCS/HLD solution for the disinfection process. These machines are designed to allow the flow of solutions into channels. Section 8.2.3.1 *Automated high-level disinfection/liquid chemical sterilization features* states, "The AER process can be more efficient and consistent than a manual process, resulting in less user exposure and avoidance of prolonged endoscope exposure to the toxic LCD/HLD." Be sure the AER is FDA cleared and can clean the endoscopes that are in the facility's inventory.

Sterilizing endoscopes by ethylene oxide or hydrogen peroxide gas requires packaging that will allow the sterilant to penetrate through it and onto the endoscope. The material compatibility should be referred to by the manufacturer's IFU before wrapping the endoscope to be sterilized. Pouches used for ethylene oxide are plastic/paper and only plastic/Tyvek® is used for gas plasma. Rigid container systems are another method of containment for sterilization which have been cleared.

Healthmark has a variety of pouches and packaging for EO and other low-temperature sterilization methods that are available in heat seal, self-seal and roll packaging. Also, the EO Sterilization Basket for Flexible Endoscopes built from high-quality stainless steel with drop down handles.

● **Steriking® Self Seal Pouches**

● **Steriking® Tyvek® Self Seal Pouches**

● **EO Sterilization Basket- (75.0068.4)**

The sterilization method for flexible endoscopes and semi-rigid endoscopes is most often EO sterilization. The endoscope should be packaged in material compatible for EO sterilization and cycle to be used. For vaporized hydrogen peroxide (VHP) sterilization, read the endoscope manufacturer's IFU for compatible sterilization cycles. Section8.3.5 *Hydrogen peroxide and Hydrogen peroxide-ozone sterilization* states, "Acceptable packaging material may include: non-cellulose-based peel pouches, polypropylene wrap and rigid sterilization container systems cleared for use in the specific type of hydrogen peroxide or hydrogen peroxide-ozone sterilizer."

When processing the accessories to the endoscopes, remove all valves and submerge into the clean solution. Flush and brush all areas around the valves until no visible soil remains. The valves can go into an AER for HLD if it has been cleared and in accordance with AER IFU. Keep the accessories together with the endoscopes as a unit. Section 10.1 *Processing of endoscope accessories* states, "Processing certain reusable endoscope components, such as air/water and suction valves, biopsy port covers, water bottles, and tubing, requires the same level of inspection, cleaning, and high-level disinfection or sterilization as the endoscopes themselves."

Healthmark offers the Green Mesh Valve Bag which helps keeps reusable valves and scope together as a unit.

- **Endoscope Valve Bag- (VB604 GN, VB604 WT) Green or White mesh bag**

- **Secure Mesh Bag- (VB604 WT)**

Reprocessed endoscopes should be hung vertically in a ventilated storage cabinet with the distal tip hanging freely. This will prevent any kinking and allow any remaining moisture to drain out of the distal tip, helping to decrease any potential microbial growth in the scope. Keep all valves disconnected from the endoscope for drying. Section 11.2.2.1 *Endoscope drying cabinets* states "Endoscope drying cabinets are closed cabinets designed for storage of flexible endoscopes that circulate HEPA-filtered or instrument air through the cabinet and each endoscope channel at continuous positive pressure." When hanging the endoscope in the storage cabinet, it is necessary to attach a label to the scope with the date, time, and technician that processed the endoscope. Endoscopes that have been sterilized should remain in the container or packaging until use. Section 11.2.4 *Maximum safe storage time for high-level disinfected endoscope General considerations* states, "The accepted maximum safe storage time for processed endoscopes before they can no longer be considered safe for patient use is not well defined." It is essential to dry endoscopes to remove any residual moisture which will lead to bacteria growth in a short period of time. Annex K.2 *Importance of drying* states, "Because bacteria can double in population every 20- to 30 minutes, an inadequately dried endoscope contaminated with only one or two viable bacteria can, after eight hours of storage, be contaminated with tens of thousands to millions of bacteria magnifying the risk of transmission of infectious organisms to the next patient Alfa, et al. [73]."

Healthmark has a variety of labels to accommodate specific items that state contaminated or sterile. The 7 Day Hangtime Label indicates the length of time the endoscope was last processed. The Self-Looping Label shows the necessary information of when the scope was

processed and by whom. The Hangtime Label tracks the day and month when the scope was processed and come in a variety of colors.

● High-Level Disinfected Labels- (HM-52483-HLD)

● 7 Day Hangtime Label- (HTK-7D2)

● Self -Looping Information Label- (404225-351-GI)

● Hangtime Labels- (403225 HTK)

● HLD Labels- (DC-100214-71-BL)

● Green Mesh Valve Bag- (VB604-GN, VB604-WT)

Storage of High-Level Disinfected Endoscopes

Section 11.2.4 *Maximum safe storage time for high-level disinfected endoscopes General considerations* states, "The available data suggest that the risk of contamination is reduced when storage is performed according to the endoscope and storage cabinet manufacturer's written IFU." A risk assessment should be done by the facility to determine the length of time an endoscope is in storage before it is reprocessed. A policy and procedure should be to determine the maximum storage time and define conditions that may occur as well as endoscopes that have exceeded the time in storage before the next patient use. Section 11.2.4.2 *Risk assessment* states, "A multidisciplinary team that can include infection preventionists, endoscopy RNs, endoscopy processing personnel, endoscopists, risk management, and other personnel should conduct the risk assessment." When storing endoscopes, they should be kept clean and dry. The storage area should prevent scopes from being too close to the ceiling to prevent fire hazards and violating fire codes, off the floor to allow for cleaning and away from the outside walls. Section 11.3.2 *Storage area* states "Adequate space is needed around sterile materials to allow for air circulation in the room, to prevent contamination during cleaning of floors, and to prevent contact between sterile items and the condensation that might form on the interior surfaces of outside walls." Annex J. *Endoscope storage risk assessment* list the steps a-m that should be taken when storing endoscopes:

A. Endoscopes are stored so that residual fluid does not remain in the channels
B. Endoscopes are stored, with their detachable parts dismantled, in a manner that keeps them secure and together with the endoscope as a unique set
C. Endoscopes are stored suspended vertically in a cabinet designed for flexible endoscope storage, or horizontally, if so, instructed within the cabinet manufacturer's written IFU
D. Tracking is available for each endoscope, including last episode of HLD
E. If a storage cabinet is used, all manufacturer's written IFU should be followed and documented
F. Endoscope internal channels receive additional drying by flushing with instrument quality air or HEPA filtered air even after AER processing or they are mechanically dried, verified to be dry or stored in drying cabinet.
G. Non-linting cloths used to dry external surfaces
H. Processed endoscopes are appropriately tagged with eh date last processed
I. Storage cabinet is kept closed
J. If storage cabinets fulfill the standard EN 1644-2015 [28], the cabinet manufacturer recommends a maximum safe storage time based on validated test methods
K. Processed endoscopes are handled with new, clean, non-latex gloves when moved fro AER, to drying, to hanging and to the procedure room
L. A method of air circulation (HEPA filter, instrument air, drying cabinet, etc.) is used
M. Endoscope are transported to the storage cabinet in accordance with Section 11

When retrieving an endoscope from the storage cabinet Section 12 *Transport of processed endoscopes* states, "perform hand hygiene and don new clean, non-latex gloves, according to the facility's policy, unless otherwise specified by the procedure or the endoscope manufacturer's written IFU." Transporting an endoscope that has been high-level disinfected should be contained in a closed container with a clean plastic bag with a clean label on the container. The container should be of adequate size to accommodate the endoscope, so it is not tightly coiled and becomes damaged. This will ensure that the endoscope does not become re-contaminated by a technician's hands or touch any surfaces while being handled.

Healthmark Products that Comply with Clean Transport

- **Round Soaker and Transport Trolley (2220, 2220 Trolley):** Round soaker bin has a 20" diameter and is perfectly sized to allow a flexible endoscope to coil naturally and safely for transport or soaking. A lift off lid completely covers the tray. The Trolley can accommodate up to 5 round soaker trays simultaneously.

- **Clean/Dirty Scope Seal Kit (2220 LOK):** Seals have clean/dirty tamper evident seals.

2 Part Clean/Dirty Label (HM-52483-HLD): This sticker is used to communicate whether the endoscope contained within a bin is clean (HLD) or dirty.

- **Clean Label (CLN4X4):** Label is used to communicate whether the instruments contained within a bin or cart are clean.

- **Liners (SST-CCD-LNR):** Eliminate confusion between reprocessed and soiled medical devices with color-coded SST Liners. The single-use liners assist with identification, temporary storage, and transportation of medical equipment by providing an enclosed environment for instruments.

●**Decontam Gloves- (DSK-1, DSK-2, DSK-3, DSK-4, DSK-5)**

Quality Control

When processing flexible endoscopes and semi-rigid endoscopes, quality control is essential to the process. Healthcare facilities should implement a quality and safety program for all employees to adhere to when processing endoscopes. Healthcare facilities should have a tracking system and procedures in place for each endoscope and for the personnel handling the endoscope. This is to identify every endoscope, the serial number, and accessories. Also, this will help verify that visual inspection of the endoscope and scheduled maintenance is performed. In addition, all personnel should be trained and documented with the verification of processing the endoscopes. If there are any discrepancies, follow the facility's policy and perform an investigation to determine the cause of damage or lapse in the processing of the endoscope. Section 13.1 *Quality Control general considerations* states, "The health care facility should establish a multidisciplinary, comprehensive, written quality assurance and safety program for all aspects of endoscope processing."

Traceability is key when processing endoscopes as well as the date and the cycle number of the sterilizer. All endoscopes have a serial number as does the AER. This accounts for any technician that has reprocessed endoscopes manually and with the AER. A label is associated with the endoscope with the date, time, and operator to identify when it was processed and how long it has been in the storage cabinet. Section 13.3 *Product identification and traceability* states, "Quality control record-keeping is critical and relies heavily on historical data, especially where quality control measures yield conflicting evidence. Record keeping is needed for both epidemiological tracking and ongoing assessment of the reliability of chemical sterilization and high-level disinfection processes." Record keeping for chemical sterilization or high-level

disinfection should be maintained with the lot number of the AER, the procedure, physician, date, and time of cycle with the technician's name. Keep records of the BI and report positive BI results to the department supervisor. Section 13.4.1 *Documentation* states, "Documentation helps ensure monitoring of the process as it is occurring, verifies that critical cycle parameters have been met, and establishes accountability. Also, electronic records of process monitoring results, including specific load item identification, are recommended because of their better legibility, accuracy, traceability, security, and data integrity."

Visual Inspection

Visual inspection should be conducted to detect any remaining soil, using magnification is best where the naked eye cannot see inside lumened components such as using a borescope to visually inspect internal channels. Inspect the entire exterior of the scope, pay close attention the control knobs and distal tip for residual soil. Additionally, identifying any damage to the scope which can compromise the safety of the patient and the integrity of the scope. Annex E.4 *Visual inspection process* states, "Magnifiers and borescopes are used to inspect where the unaided eye cannot see, including assessment for defects in functionality, damage including pitting, stains, repair needs, missing or damaged components, imperfections, retained items, compromised integrity of materials and seals, residual moisture in or on the endoscope." Use the magnifier to enhance visibility in hard to see tight spaces and crevices. Section 13.5.2 *Visual inspection after manual cleaning* states, "Careful visual inspection should be conducted to detect the presence of any residual soil. Inspection using magnification and additional illumination will identify residues and/or damage more readily than the unaided eye."

Cleaning Verification

Before HLD/sterilization of flexible endoscopes, cleaning verification steps are performed to verify the cleaning process was effective. Annex F.1 User *verification of cleaning processes General considerations* letters a and b states,

A.) defining a cleaning process that can be accomplished with comprehensive personnel training and verified through observation that it can be followed consistently; and
B.) implementing a testing system that verifies adequate, consistent results.

The healthcare facility should develop a routine that every endoscope goes through a cleaning verification test after cleaning is completed, and the results are then recorded. Section 13.5.1 *Verification and monitoring of the cleaning process general considerations* states, "Cleaning verification tests are performed following cleaning and re used to verify the effectiveness of a cleaning process in removing or reducing to an acceptable level the clinical soil that occurs during the use of an endoscope." During the cleaning process of endoscopes, it is essential to remove the organic and inorganic material to ensure that disinfection or sterilization are achieved. Training staff to adequately perform the cleaning verification test are documented and

the technicians are "consistently achieving the expected level of cleaning." To determine the cleanliness of endoscopes markers are useful for benchmarking purposes such as, protein, carbohydrate, hemoglobin, ATP. When performing the tests, the "facility should determine whether the benchmarks pertain to the tests they intend to use based on the endoscope type, component tested, and whether the units or measurements are applicable" Annex F.2 *Markers (analytes)*. The tests that are performed on endoscopes should be easy to perform and not require the scope to be recleaned after testing has been completed and that it will not compromise the integrity of the scope. "Cleaning tests for in-use verification of medical device processing should be:

A. rapid
B. easy to perform
C. sensitive (i.e., meet realistic benchmarks)
D. accurate
E. repeatable
F. free of interfering substances and
G. robust (i.e., do not require exacting conditions or time constraints that cannot be achieved in routine processing areas)" Annex F.3 *Cleaning verification tests for users.*

Manual cleaning steps are also important when cleaning endoscopes. Each step must be done in-order to achieve cleanliness prior to HLD or sterilization. Steps that are skipped in the manual cleaning process will not ensure the scope has been effectively cleaned. The department can create a program for verifying efficacy to ensure manual cleaning steps are correct and consistently should be part of the quality control program. Annex F.4 *A program for verification of the efficacy of the manual cleaning during endoscope processing: An example* states, "A manual cleaning verification program has two goals: 1) Quality control- is each endoscope effectively cleaned before HLD or sterilization? 2) Process control- is the manual cleaning process under control?" Remember by creating this type of program does not take away the other control measures that take into account for verifying the efficacy of the manual cleaning process. This contain six components: "1) Establish policies and procedures; 2) Identify which endoscope types will be routinely monitored; 3) Determine test points for each type of endoscope; 4) Determine pass/fail thresholds; 5) Frequency of testing; 6) Data analysis," Annex F.4.

SGNA 2018 position statement on Endoscopic Accessories, Valves, and Water and Irrigation Bottles in the Gastroenterology Setting states, "a comprehensive quality control program for reusable medical devices should be implemented and include, but not limited to the following":

A. A visual inspection and equipment testing to identify conditions that may affect the cleaning or disinfection process (Ofstead et al., 2017; FDA, 2009). Damaged reusable items should be removed from use. Follow facility protocol for returning device.
B. Procedures for monitoring the useful life of medical devices that include visual inspection, scheduled maintenance, and removal of equipment from use based on manufacturer's guideline (FDA, 2009; CDC, 2015; Ofstead et al., 2017).

C. Protocols to ensure valves and other detachable reusable accessories are provided and identified as ready for use.
    1. Documentation should include the date of HLD; person(s) who performed reprocessing or sterilization; and may be cross-referenced with other records that can track the patient, date, type of procedure (British Society of Gastroenterology, 2017).
    2. Comprehensive training for staff to ensure they understand the methods and the importance of standard infection prevention measures and device-specific reprocessing instructions to carry out cleaning and high-level disinfection or sterilization procedures (Alfa et al., 2014; Muscarella, 2014; SGNA, 2015b).
    3. The high-level disinfection or sterilization process may affect the device; therefore, the device's integrity and functionality must be visually inspected during all phases of care. If the medical device is damaged, it should be removed from service immediately (ASGE, 2017).

Healthmark Cleaning Verification Methods that help in aiding the detection of residual blood, protein, and carbohydrate and optical inspection devices help with visual inspection to improve post cleaning inspection.

● **EndoDolly™ - (110405-SP)-** To hold endoscopes and allow them to hang properly while conducting active drying, quality assurance testing and transportation procedures.

● **EndoWally™- (EWALLY-001)-** To hold endoscopes on the wall, while conducting drying procedures or quality assurance.

● **ChannelCheck™- (UCC-222)-** For testing blood, protein, and carbohydrates

● **Scope Sleeve- (SSLV-003, SSLV-004, SSLV-005)-** Manufactured of material comprised of 80% cellulose and 20% polypropylene, the single use Scope Sleeve are designed to cover and protect insertion tubes after reprocessing, during transportation and storage.

● **FlexiCheck™ - (FLEXCHECK-101, FLEXCHECK-102)**

● **ScopeHolder- (SCPH-102)**

● **Flexible Endoscope Sampling Kit- (FESK-200-200, FESK-230-400, FESK-230-600, FESK- 230-900)**

- **Interchangeable Magnifier- (MAG-225, MAG-LENS, MAG-L5D, MAG-L8D, MAG-L12D, MAG-L15D)**

● **Table-Top Lighted Magnifiers- (26501-DSG, 26505-SIV, 82400-4BL, 42400-4 RD)**

● **Flexible Inspection Scope- (FIS-005)-** Designed with a blue handle that includes a distal tip composed of a light source and camera lens at the end of a 110cm flexible blue shaft, which feature white graduation marks.

● **Flexible Inspection Scope- (FIS-006)-** Designed to inspect internal channels of 1.3mm in diameter or larger, the FIS-006 is the ideal tool to visually inspect potentially soiled or damaged items.

● **Flexible Inspection Scope- (FIS-007)-** Has modular design with interchangeable flexible inspection scope attachments available in diameters of 1.06mm and 1.9mm

Chemical Indicators and Biological Indicators

Chemical indicators are used to assist in detecting sterilization failures such as incorrect loading into the sterilization or the wrong wrap or packaging was used or the failure of the sterilizer. The chemical indicator is placed inside the wrap or package to be sterilized and placed in an area where the indicator can be challenged. Section 13.8.3 *Nonresponsive or inconclusive chemical indicators* states, "If a CI is nonresponsive or inconclusive, it is possible that the entire load is non-sterile." Biological indicators are monitoring devices with microorganisms that can be resistant to sterilization.

Section 13.9.1 *Biological indicators General considerations* states, "Biological indicators are the only sterilization process monitoring devices that provide a direct measure of the lethality of the process." Each day a routine test with BIs is performed with the lot number, cycle, and sterilizer number on the PCD. Remove the BI from the PCD and place in the incubator with the control BI. After the incubation is completed, read, and record the results. If the BI comes back as positive, report the issue to the shift supervisor with the sterilizer number, cycle it was run on, lot number, the results of the BI, and load contents. Section 13.10.2 *Qualification test procedure and acceptance criteria* states, "All monitoring results, including results from BI controls, should be interpreted by a qualified individual, and should be included in the sterilizer records."

Healthmark offers Chemical indicators for Ethylene Oxide (EO) and Biological Indicators for EO for monitoring ethylene oxide sterilization.

● **CROSS CHECKS EO Ethylene Oxide Sterilization Monitor- (CI-106)**

● **EZTest® Biological Indicators– (EZG-6)** for EtO

Product Recalls

Recalling items that have been stored that were processed with liquid chemical sterilization or high-level disinfection should be reported to the infection prevention professional as well as the shift supervisor and other personnel to contact all patients that have encountered the items in question. Health care facilities should have a recall procedure in place to ensure the safety of patients. Section 13.12.1 *Product recalls General considerations* states, "Establishing recall procedure can help ensure patient safety, compliance with the user facility reporting requirements of the FDA's and MDR regulations, facilitate the identification and retrieval of items suspected to be unsterile or incorrectly high-level disinfected, and provide for adequate follow-up actions (e.g., quarantine of the sterilizer or automated processing equipment, notification of physicians and affected areas, surveillance of patients)." The procedure should contain the circumstances of the recall, the person that is authorized to issue the recall, the person responsible for the recall order. Section 13.13 *Outbreak report* states, "The recall is to be reported to the appropriate departments, FDA, the local health department and State Board of Health, and CDC, the device manufacturer, and the chemical sterilant manufacturer."

Risk Analysis

Endoscopes that are disinfected are not sterile, but one that has been high-level disinfected, is free of viable pathogens. Section 13.14.2 *Risk analysis* states, "The Spaulding Classification of the device will define the level of disinfection or sterilization required." Semi-critical devices that come into contact with mucous membranes do require high-level disinfection. Risk analyses consist of the following:

A. Risk assessment- that identifies a source of failure, how the facility will handle the failure, or that a failure will occur should be assumed.
B. Risk management- will determine which failures need to be monitored and then take action to ensure that the problem will be controlled.
C. Risk communication- is interaction with sterile technicians and OR staff, endoscope technicians and the infection prevention professionals to inform patients of the items that have been recalled.

Identifying problems in the decontamination room that could cause a potential risk to patients or staff should be monitored to ensure the problem is corrected. Audits in the department help identify possible risks then follow through with the departments policy and procedure to make the necessary corrections. This will provide data to be assessed for the effectiveness and the make adjustments where they are needed.

SGNA 2018 position statement on Endoscopic Accessories, Valves, and Water and Irrigation Bottles in the Gastroenterology Setting also states, "Infection prevention principles should be a guiding factor in selecting medical devices because cross-contamination can transmit infection."

"There are advantages and disadvantages in using disposable or reusable medical devices. Facilities should make these decisions with the infection prevention team based on":

- A risk assessment of the device design, labeling, and handling after single use:
- Evidence-based practice.
- Policy, procedure, and regulatory requirements.
- Waste stream management guidelines.
- Unit feasibility and financial impact.

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