

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 work space. Section 3.2.1 *Workflow General considerations* states, “counters and work surfaces should be height adjustable or positioned at heights that take into account 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 work flow 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 processing area and placed in the AER for high level disinfection. Section 3.2.2 *Physical separation* states, “An area should be defined for

disinfection/sterilization that is separate from the manual cleaning/processing area. 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 3.2.3 *Traffic control* states, “Personnel and visitors can carry microorganisms into the processing areas, increasing the potential for environmental contamination in these areas.”

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, shoes covers, disposable bootlegs, lined sleeve gloves, mask, face shield, and gown. The temperature should be between 60°F and 73°F with relative humidity not exceeding 60% which can cause microbial growth according section 3.3.7.1 *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 3.3.7.2 *Ventilation* states, “The decontamination room air flows in the area and exhausted to the outside and never enters the clean room.” This is to have air flow from areas with positive pressure to areas with negative pressure.

Healthmark offers the TEMP-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 3.3.9 *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.

Environmental cleaning should be performed daily in areas of decontamination, the clean room and sterilization. All surfaces should be kept clean at all times 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 3.3.11 *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. 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 www.hmark.com.

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 4.6.1 *Attire General considerations* states, “Employees should change into street clothes when they leave the health care facility or when traveling between buildings located on separate campuses. This will minimize the introduction to microorganisms.”

Healthmark offers several different options of headwear to protect the technician's hair. One size fits 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.

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.

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



- **Wide Drape Face Shield- (1800W-100, 18000-100)**



- **Disposable Bootlegs- (BOOTLEG)**



- **Gowns with Thumb Loop- (42500)**



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 5.2 *Pre-cleaning at the point of use steps a-k* states, "The cleaning solution is prepared according to the IFU, wipe insertion tube with wet non-linting cloth or sponge from cleaning solution, suction the solution through the channel

according to 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, and flush with the minimally prescribed volume of solution and ensure channels are not blocked. Place distal end of the endoscope in the solution and suction it through the endoscope until it is clear. Next, detach the endoscope from the light source and suction pump. 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 Lint-Free Disposable Wipes 9” x 9” are for immediate use after surgical equipment has been used and are used for cleaning endoscopes prior to being reprocessed again after processing. The Durasponge allows for safe cleaning of surgical instruments and surfaces.

- **Lint-Free Disposable Wipes 9” x 9”- (CC555)**
- **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 overcoil the insertion or light guide tubes to prevent damage during transportation.

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 5.4.2 *Manual (dry) leak testing* states to, "remove all valve and biopsy port cover and keep with the endoscope throughout the cleaning process." 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. Manual cleaning should begin as soon as the leak test is completed so soil does not dry and interfere with the further processing. 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 5.5 *Manual cleaning* states, "Cleaning brushes should either be single-use and disposed of or reusable and receive high-level disinfection or sterilization after each use, according to the IFU." 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 One-Hour Indicator Label designed to be a visual reminder to healthcare workers of post-procedures.

- **Single-Use 1 our Indicator- (HTK-1H)**



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 5.7.2 *High-level disinfection* states, "The solutions that can be used are cleared by the FDA are "glutaraldehyde, orthophthaldehyde, peracetic acid, chlorine and hydrogen peroxide."

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.

Follow the IFU of the LCS/HLD to prepare the solution and contact time and temperature, test the MRC before each use with a test strip, and immerse the endoscope into the solution with the scopes accessories following the endoscope manufacturer's IFU. Document date, time, and endoscope information that was placed in the solution, along with the operator, date, and time the endoscope was removed. 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 70-80% ethyl or isopropyl alcohol with the appropriate amount for each lumen with air until no moisture remains.

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-7D)**



- **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. The AER is not to take the place of manual cleaning - it is still required before placing endoscopes into the AER. 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. Section 8.4 *Hydrogen peroxide* states, "Hydrogen peroxide can burn exposed skin, the technician should take extra care to avoid contact and can cause fire when it comes into contact with certain material."

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.

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**



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. 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.

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-7D)**



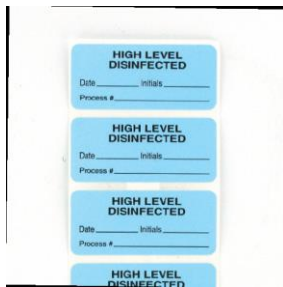
- Self-Looping Information Label- (404225-351-GI)



- 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 10.4.2 *Existing guidelines*, according to AORN guidelines, the length of time that a high-level disinfected endoscope should be left in the storage cabinet before it is used is five days. If not used in that time period, it should be reprocessed before use. A risk assessment should be done by the facility to determine the length of time an endoscope is in storage before it is reprocessed. The facility should develop a policy and procedure to determine the maximum storage time and define conditions that may occur. Also, a policy should be in place for endoscopes that have exceeded the time in storage before the next patient use.

When retrieving an endoscope from the storage cabinet Section 11 *Transport of high-level disinfected endoscopes* states, “don new exam gloves.” 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 12.1 *Quality control general considerations* states, "quality control involves verification and monitoring of personnel performance and work practices and adherence to established policies and procedures."

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 12.2 *Product identification and traceability* states, "Record-keeping is needed for both epidemiological tracking 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 12.3.1 *Documentation and record-keeping Documentation* states, "Documentation helps ensure monitoring of the process as it is occurring, verifies that critical cycle parameters have been met, and establishes accountability."

Cleaning Verification

Before HLD/sterilization of flexible endoscopes, cleaning verification steps are performed to verify the cleaning process was effective. 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. Training staff to adequately perform the cleaning verification test are documented and the technicians are “consistently achieving the expected level of cleaning.” 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. Use the magnifier to enhance visibility in hard to see tight spaces and crevices.

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.

- **ChannelCheck™- (UCC-101)**- For testing blood, protein and carbohydrates



- **EndoCheck™**- for blood (EDH-110, EDH-200, EDH-270, EDH-350, EDH-420, EDH-470)
- **EndoCheck™**- for protein (EDP-110, EDP-200, EDP-270, EDP-350, EDP-420, EDP-470)

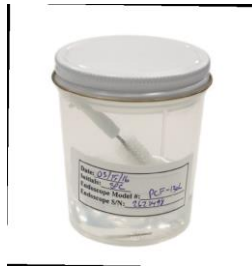
- **FlexiCheck™ - (FLEXCHECK-101, FLEXCHECK-102)**



- **ScopeHolder- (SCPH-102)**



- **Flexible Endoscope Sampling Kit- (CK-250, CK-374)**



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



- **Flexible Inspection Scope- (FIS-005)**



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 12.7.3 *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 12.9.3 *Qualification testing 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.” 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 after report the issue to the shift supervisor with the sterilizer number, cycle it was ran on, lot number, the results of the BI, and load contents.

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 come into contact with the items in question. Health care facilities should have a recall procedure in place to ensure the safety of patients. Section 12.10.1 *Product recalls* states, “compliance with the user facility reporting requirements of the FDA’s and MDR regulations, and identification and retrieval of items suspected to be unsterile.” 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 12.10.2. 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 12.11.2 *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 analysis consist of risk assessment that identifies a source of failure, how the facility will handle the failure, or that a fail will occur should be assumed. Risk management will determine which failures need to be monitored and then take action to ensure that the problem will be controlled. 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.

References

1. 3.2.1 Work flow General considerations. © 2015 Association for the Advancement of Medical Instrumentation ■ AAMI ST91:2015.
2. 3.2.2 Physical separation. © 2015 Association for the Advancement of Medical Instrumentation ■ AAMI ST91:2015.
3. 3.2.3 Traffic control. © 2015 Association for the Advancement of Medical Instrumentation ■ AAMI ST91:2015.
4. 3.3.7.1 Temperature, relative humidity, and ventilation. © 2015 Association for the Advancement of Medical Instrumentation ■ AAMI ST91:2015.
5. 3.3.7.2 Ventilation. © 2015 Association for the Advancement of Medical Instrumentation ■ AAMI ST91:2015.
6. 3.3.9 Hygiene facilities. © 2015 Association for the Advancement of Medical Instrumentation ■ AAMI ST91:2015.
7. 3.3.11 Environmental cleaning. © 2015 Association for the Advancement of Medical Instrumentation ■ AAMI ST91:2015.
8. 4.6.1 Attire General considerations. © 2015 Association for the Advancement of Medical Instrumentation ■ AAMI ST91:2015.
9. 5.2 Precleaning at the point of use, steps a-k. © 2015 Association for the Advancement of Medical Instrumentation ■ AAMI ST91:2015.
10. 5.4.2 Manual (dry) leak testing. © 2015 Association for the Advancement of Medical Instrumentation ■ AAMI ST91:2015.
11. 5.5 Manual cleaning. © 2015 Association for the Advancement of Medical Instrumentation ■ AAMI ST91:2015.
12. 5.7.2 High-level disinfection. © 2015 Association for the Advancement of Medical Instrumentation ■ AAMI ST91:2015.
13. 8.4 Hydrogen peroxide gas sterilization. © 2015 Association for the Advancement of Medical Instrumentation ■ AAMI ST91:2015.

14. 10.2 Storage of high-level disinfected endoscopes. © 2015 Association for the Advancement of Medical Instrumentation ■ AAMI ST91:2015.
15. 11 Transport of high-level disinfected endoscopes. © 2015 Association for the Advancement of Medical Instrumentation ■ AAMI ST91:2015.
16. 12 Quality control General considerations. © 2015 Association for the Advancement of Medical Instrumentation ■ AAMI ST91:2015.
17. 12.2 Product identification and traceability. © 2015 Association for the Advancement of Medical Instrumentation ■ AAMI ST91:2015.
18. 12.3 Documentation and record-keeping. © 2015 Association for the Advancement of Medical Instrumentation ■ AAMI ST91:2015.
19. 12.7.3 Nonresponsive or inconclusive chemical indicators. © 2015 Association for the Advancement of Medical Instrumentation ■ AAMI ST91:2015.
20. 12.9.3 Qualification testing acceptance criteria. © 2015 Association for the Advancement of Medical Instrumentation ■ AAMI ST91:2015.
21. 12.10.1 Product recalls General considerations. © 2015 Association for the Advancement of Medical Instrumentation ■ AAMI ST91:2015.
22. 12.10.2 Recall procedure. © 2015 Association for the Advancement of Medical Instrumentation ■ AAMI ST91:2015.
23. 12.11.2 Risk analysis. © 2015 Association for the Advancement of Medical Instrumentation ■ AAMI ST91:2015.

Rev: 05/24/2018