by Chuck Hughes

Manual HLD of Flexible Endoscopes

BEST PRACTICES SHOULD BE adhered to in any profession because they reflect the values and standards of that profession. In healthcare, adherence to sterilization and high-level disinfection (HLD) best practices is critical to ensure patient safety, as one of our greatest threats is healthcare-associated infections (HAIs).

In the U.S., instrument reprocessing best practices are documented in the Association for the Advancement of Medical Instrumentation (AAMI) Standards, the Association for periOperative Room Nurses (AORN) Standards and Recommended Practices, along with other documents, such as the Society of Gastrointestinal Nurses Association's (SGNA) Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes. Flexible endoscopes are some of the most challenging instruments for healthcare facilities to reprocess due to their unique design and complex reprocessing steps.

HLD is recognized as the standard for reprocessing flexible endoscopes by SGNA, AORN and many other organizations. In 2012, SGNA updated its Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes for use in all settings where endoscopy is practiced. This article reviews the reprocessing steps covered in the updated SGNA Standard, which is available at www.sgna.org. *It is important to consult and follow the endoscope manufacturer's validated Instructions for Use (IFU) as design features unique to a particular instrument may require specific reprocessing details.* The basic steps to clean and perform HLD on flexible endoscopes include: Pre-cleaning, leak testing, manual cleaning, HLD (manual or automated), drying, and storage. *Note: Appropriate personal protection equipment (PPE) should be worn at all times.*

Pre-cleaning should be done immediately after removing the endoscope from the patient. This is done by wiping the insertion tube with a wet cloth or sponge soaked in freshly prepared detergent solution. Place the distal end of the endoscope into an appropriate detergent solution and suction a large volume of detergent through the scope until clear. Finish by suctioning air. Flush air and water channels, in accordance with the endoscope manufacturer's IFU. Detach the scope from the light source and suction lamp. Attach the protective video cap (if using a video scope). Transport the soiled endoscope to the reprocessing area in a closed container.

Containers, sinks and basins should be large enough that the endoscope will not be damaged by being coiled tightly. In the reprocessing area, the following supplies should be available: PPE; leak detection equipment; channel cleaning adapters, per the manufacturer's IFU; large basin or sink; detergent solution prepared per the manufacturer's IFU; appropriate size channel cleaning brushes; and a sponge or lint-free cloth.

Leak testing detects damage to the interior or exterior of the endoscope and is done before immersion into reprocessing solution to minimize damage to parts not designed for fluid exposure. Manual leak testing steps: remove suction valves, air water valves, and biopsy valves. Discard those parts that are disposable. *Note: Disposable valves can be used to eliminate the meticulous cleaning required for reusable valves.* Attach the leak tester and pressurize the scope before submerging it in clear water. Be sure to refer to the manufacturer's IFU to determine if any other parts should be removed prior to leak testing. With the pressurized scope submerged, flex the distal portion of the endoscope in all directions, observing for bubbles. Depress the freeze and release buttons while observing the control head of the endoscope for bubbles. Check the insertion tube and distal bending section, as well as the universal cord for bubbles coming from the interior of the endoscope. Remove the endoscope from the sink or basin, and turn off the leak tester and disconnect from video cap. Allow the endoscope to depressurize and ensure the video cap is secure and has not loosened with removal of leak tester. If no leak is detected, continue with the reprocessing steps. Computerized leak testing steps: remove suction valves, air water valves and biopsy valves. Attach the leak tester to computer. Input data, including scope ID and user. Move knobs and depress the freeze and release buttons when indicated. Continue with reprocessing steps if no leak is detected. If a leak or high humidity is detected or if the endoscope appears to be damaged, follow the manufacturer's IFU.

Manual cleaning of endoscopes is necessary prior to automated or manual disinfection and is the most important step in removing bioburden. Fill a sink or basin with a freshly-made solution of water and a medical grade, low-foaming, neutral pH detergent formulated for endoscopes that may or may not contain enzymes. Dilute and use according to the detergent manufacturer's IFU and only do not reuse the solution for another scope, as this can cause cross contamination. Ensure that the video cap is secure and immerse the scope. Wash all debris from

the exterior by brushing and wiping the scope while submerged in the detergent solution. Use a small, soft brush to clean all removable parts, including inside and under the suction valve, air and water valve, and biopsy port cover and openings. Brush all accessible channels, including the body, insertion tube and the umbilicus of the scope. Use a brush size compatible with each channel. After each passage, rinse the brush in the detergent solution to remove any visible debris before retracting and reinserting it. Continue brushing until there is no debris visible on the brush.

Attach the scope manufacturer's cleaning adapters for suction, biopsy, air and water channels. If using an automated pump, refer to the pump manufacturer's IFU for compatibility and use. Attach the scope manufacturer's cleaning adapters for special endoscope channels (e.g. elevator channel, auxiliary channel, and double channel scopes). Flush all channels with detergent solution to remove debris. Soak the scope and internal channels for the period of time specified by the label, if using an enzymatic detergent. *Caution: Do not allow endoscope to soak too long (i.e., no longer than 60 minutes).* Next, thoroughly rinse the endoscope and all removable parts with clean water to remove residual debris and detergent. Purge water from all channels using forced air. Dry the exterior with a soft, lint-free cloth.

HIGH-LEVEL DISINFECTION (HLD)

The HLD or sterilant should be used in accordance with the manufacturer's IFU. Glutaraldehyde has been widely used for a long time in healthcare facilities as a HLD for reusable medical devices. Most solutions are acidic and must be activated to become sporicidal. Ortho-phthaladehyde (OPA) has demonstrated superior mycobactericidal activity compared to Glutaraldehyde and requires no mixing or activation. OPA has been shown to last longer before reaching its MRC and the concentration of the active ingredient does not decrease with age along. *Note: Until recently, there have been only two OPA manufacturers with FDA-cleared 14- day solutions that provide a 12-minute manual soak time. A third OPA manufacturer now has FDA clearance with a 28-day reuse life and 10-minute manual soak time.* Other solutions that are FDA- cleared for HLD include: hydrogen peroxide, peracetic acid and sodium hypochlorite in a variety of concentrations and combinations. The FDA website has a listing of manufacturers, active ingredients and contact conditions for each cleared solution.

HLD requires appropriate temperature, contact time and length of use following solution activation. Always follow the manufacturer's IFU when preparing disinfectant solutions, calculating expiration dates, and labeling solution soaking containers. Prior to each use, test the solution for minimum recommended concentration (MRC) according to the product-specified test strip IFU and record results. The MRC should never be used to extend the reuse life claim of the solution and the MRC may never be used beyond the date specified on activation.

Completely immerse the endoscope and all removable parts in a basin of HLD. Flush HLD into all channels of the endoscope until it can be seen exiting the opposite end of each channel. Take care that all channels are filled with the HLD and that no air pockets remain within the channels. Cover the soaking basin with a tight-fitting lid to minimize chemical vapor exposure. Soak the endoscope for the time and temperature stated in the manufacturer's IFU. Purge all channels completely with air before removing the endoscope. Thoroughly rinse the endoscope and all removable parts with clean water to remove residual debris and HLD. Purge water from all channels using forced air and then dry the exterior with a soft, lint-free cloth.

DRYING AND STORAGE

Flush all channels with alcohol until the alcohol can be seen exiting the opposite end of each channel. Purge all channels with air and remove all channel adapters. Dry the exterior of the endoscope with a soft, clean lint-free towel. Thoroughly rinse and dry all removable parts. Hang the endoscope in a vertical position to facilitate drying (with caps, valves and other detachable components removed, per the manufacturer's IFU). Be sure the storage area is clean, well ventilated and dust-free. *Note: SGNA makes no recommendation for length of storage; however, AORN Standards and Recommended Practices states that "flexible endoscopes should be reprocessed before use if unused for more than five days."* Storage cabinets should be cleaned and disinfected with an EPA-registered disinfectant when visibly soiled and on a weekly or monthly schedule. Endoscopes should not be stored in the original shipment cases.

IN CONCLUSION

Flexible endoscopes are some of the most challenging instruments for healthcare facilities to reprocess due to their unique design and complex reprocessing steps. But through strict adherence to standards and best practices, such as those set forth by AAMI, AORN and SGNA, healthcare facilities and those responsible for the cleaning, disinfection and overall management of the delicate and challenging instruments can feel confident that quality and patient safety will not be compromised.

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