OR Manager Inc

OR Manager
Vol. 28 No. 8
August 2012

Sterilization & Infection Control

Lumens and endoscopes: Meeting cleaning basics

Narrow-lumened instruments and endoscopes are one of your biggest reprocessing challenges. They have the highest risk of being improperly processed, notes Michelle J. Alfa, PhD, FCCM, a researcher in health care-associated infections. If the lumens and channels of endoscopes are not cleaned properly, high-level disinfection or sterilization may not be effective.

This column addresses the cleaning basics for lumens and endoscope channels. It should be noted that, in some cases, the design of the lumens and endoscopes makes them very difficult if not impossible to clean. In fact, AORN suggests using ophthalmic surgical instruments with single-use cannulae whenever possible because the lumens are so hard to clean.

Dr Alfa, who is a professor at the University of Manitoba, Canada, and medical director for the clinical microbiology discipline with Diagnostic Services of Manitoba, reviewed cleaning advice at the Association for Professionals in Infection Control and Epidemiology conference in San Antonio, Texas, in June 2012.

One of the clarion themes of the AAMI/FDA Medical Device Reprocessing Summit held in October 2011 was for medical device manufacturers to consider reprocessing requirements early in the design process so these devices can be effectively cleaned.

Follow instructions for use

Obtain the most up-to-date instructions for use (IFUs) and follow them. If the instructions say to process the instruments through 2 ultrasonic cycles, then do not just use 1 ultrasonic cycle to save time because you can bet that those instruments will not be clean.

IFUs can be obtained from corporate websites or by calling a company's sterility assurance or quality assurance services. Another option is the oneSource document site (www.onesourcedocs.com, 800/701-3560). For a minimal charge, this company will provide you with the most up-to-date IFUs. If the IFUs are not understandable or incomplete, talk to the manufacturer.

Review IFUs before purchase

ECRI Institute suggests reviewing the IFUs before purchasing an endoscope to determine if:

- the device is more difficult to process
- the facility has the equipment and tools to process the device
- it will take longer to process the device.

If the process will take longer, what effect will this have on the case schedule? Will the facility change the case schedule to allow proper processing of the endoscope? This same information could apply to more complex instrument sets that are usually loaned to a facility.

Technologies to aid cleaning

These technologies (probably not a complete list) may provide more effective cleaning of lumens and endoscope channels:

- Endoscope sheaths, which create a sterile barrier between the scope and patient by covering the exterior of the scope and providing a sterile, disposable channel for irrigation and tool passage
- Inserts for deep sinks or counter tops that replace syringes and internal brushing by pumping detergent and water through scopes, which reduces labor and errors
- Pull-through cleaning devices that provide a complete circumferential seal in the lumen tube
- Automated chemical delivery system/device or sink proportioner to ensure appropriate dilution of the cleaning agent
- Flushing aids used at the sink to provide continuous hands-free channel flushing
- Ultrasonic units with irrigation pumps for flushing cannulated instruments inside and outside
- Automatic endoscope reprocessors (AERs) with a cleaning claim.

Preclean instruments

The OR staff needs to preclean instruments as soon as possible after use and keep them moist by using a commercially available presoak product (eg, enzymatic) and/or a towel moistened with water (but not saline) before transferring them to sterile processing.

If instruments are not kept moist, blood and body fluids will dry on them within a short time, cause pitting, and will be hard to remove. This adds additional processing time to cleaning, which may, in turn, delay the return of instruments to the OR. This can have a big impact on OR workflow and customer service.

Manual cleaning

"Manual cleaning is not as reproducible and effective as automated cleaning," Dr Alfa notes, "but it does allow you to observe specific problem areas when cleaning."

Don't take short cuts in manual cleaning. Also, look at the instrument manufacturer's IFUs because they may say automated cleaning with a washer/disinfector alone may not be effective, which means manual cleaning should be done first.

Cleaning solution

Follow the instrument manufacturer's IFUs to determine the type of cleaning solution to use. Follow the cleaning solution manufacturer's IFUs for the correct:

- dilution/concentration of the solution
- temperature of the water
- water quality to use for the dilution
- correct exposure time.

Test the accuracy of the dilution process, including the automated dispensing and measurement systems, to ensure you are correctly diluting the solution. The Joint Commission will be asking for this information during surveys.

The optimal temperature of the water should be in the range of 27ºC to 44ºC (80ºF to 110ºF) not to exceed 60ºC (140ºF). This temperature should be monitored and documented. The cleaning solution should be discarded when soiled.

Vertically soak instruments with lumens to prevent air bubbles from forming within the lumens, which will prevent the cleaning solution from contacting all surfaces of the lumens. Do not soak instruments horizontally. Thoroughly flushing lumens will also help with the solution contact.

Brushes

Brushing should be performed under water to avoid aerosolization of contaminants and splashing of infectious material while wearing the appropriate personal protective equipment (PPE). Cleaning brushes should be of the appropriate type, size (diameter and length), bristle type, and material. The brush should have the same diameter as the lumen or channel. If this information is not available in the medical device's IFUs, contact the manufacturer.

Don't be stingy with the brushes. Use either single-use brushes, or if using reusable brushes, decontaminate them at least daily. If you continue to use the same brush during the day, the bristles may become worn and no longer contact the sides of the lumen or channel. If dirty, the brush may add more bioburden than it is removing. Also, brushing is only effective if the brush is long enough to exit the lumen or channel completely. Otherwise, dirt is just pushed to the spot where you stop.

Water quality and rinsing

In general, tap water may be used for the initial rinse, but the final rinse should be performed with treated water (eg, deionized or distilled water or water treated by reverse osmosis) that does not stain or contaminate the instruments. The water treatment process needs to be maintained to eliminate pyrogens, and the water quality should be tested.

Mechanical cleaning equipment

Mechanical cleaning equipment includes:

- utensil and cart washers
- washer-sanitizers and pasteurization equipment
- washer-disinfectors and washer-decontaminators
- ultrasonic cleaners.

For mechanical cleaning, follow the IFUs for the instrument, the mechanical cleaning equipment, cleaning agents, and lubricants. This will ensure the correct dilution/concentration of the solution, water temperature, water dilution of the cleaning agent and rinsing, and correct exposure time.

Review and initial each cycle printout on the mechanical cleaning equipment to ensure the equipment is functioning. Workers need to understand how to correctly operate equipment for efficiency, worker safety, and successful outcomes of the process.

Perform the daily and preventive maintenance, such as descaling and cleaning the strainer, spray arms, and nozzles. Check the pumps and chemical feed rates and detergent feed lines to make sure that chemicals and detergents are being pumped into the system and ensure the correct chemicals and lubricants are being used. Check the cleaning solution between ultrasonic cycles and change if heavily contaminated. Degassing after filling with water may be recommended. Keep the lid in place to prevent aerosolization of contaminants.

Load instruments according to the IFUs from the instrument and mechanical cleaning equipment manufacturers to ensure the instruments are in contact with the cleaning agent. In general, remove instruments from containment devices and remove materials such as mats that could interfere with the cleaning agent con-

tacting the medical device. In an ultrasonic unit, fully submerge instruments with lumens to remove air so the cleaning solutions can contact all surfaces or correctly connect if an irrigation pump is available.

Verification of cleaning

Historically, the effectiveness of manual and mechanical cleaning has been verified by visual inspection. The problem with visual inspection is that instruments may look clean but still be contaminated with biofilm, microbes, or biological residues. In addition, visual inspection does not work for lumens or endoscopes. Some instrument manufacturers have suggested using cameras.

AAMI in its Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities (AAMI ST79 Annex D) discusses technologies available to verify the cleaning process by measuring levels of organic soil and microbial contamination. The most common methods test for adenosine triphosphate (ATP) or protein (sidebar, p 23).

These tools can be used to monitor both the manual and mechanical processing of instruments and the cleaning of endoscope channels. The monitoring is done after the cleaning step and before high-level disinfection or sterilization. Dr Alfa notes that if the monitoring is done after high-level disinfection or sterilization, the material left from inadequate cleaning will be fixed into the lumen or scope channel. The rapid test result may be negative even if cleaning was not effective, simply because the sampling method could not remove the fixed-on residuals.

AORN recommends evaluating manual cleaning when new types of instruments are reprocessed and periodically as determined by the health care organization. AAMI ST79 states: "Mechanical cleaning equipment should be tested upon installation, weekly (preferably daily) during routine use, and after major repairs."

Testing cleaning

AORN or AAMI do not have recommendations for testing of endoscopes. But because of the infection outbreaks associated with incorrect processing, hospitals are starting to test the cleaning process; in fact, some test each endoscope.

Monitoring tools include:

- thermometers and remote sensing equipment to monitor water temperature (ie, to check if the water and detergent from the washer is contacting all surfaces)
- devices to verify sonic activity or effective cavitation
- devices to verify cleaning effectiveness of equipment, instrument surfaces, lumens, and endoscope channels (ie, ATP or a protein test).

AORN and AAMI advise documentation of the entire cleaning process, as they do for the sterilization process.

How often to test?

How often should you test the effectiveness of the manual or mechanical cleaning of lumens and endoscope channels? A hospital I visited tested the lumen irrigation pump used in the ultrasonic unit for the DaVinci instruments and discovered the pump was not working. They did not know when the last lumen test was run. How many DaVinci instruments were not properly cleaned and used on patients? Do you want to risk that in your facility?

As with biological-indicator monitoring of sterilizers, the more often you monitor the effectiveness of the manual and mechanical cleaning processes, the sooner cleaning failures are detected and corrected, and the fewer patients are placed at risk. No matter which technology is used, cleaning will improve because you will have a tool to establish a cleaning baseline and measure the effectiveness of cleaning before and

after education and training.

Conclusion

Follow the medical device, mechanical cleaning equipment, and cleaning solutions IFUs. Without thorough cleaning and rinsing, it is not possible to achieve high-level disinfection or sterilization of medical devices. Be sure to monitor the manual and mechanical cleaning processes to determine if they are effective.

Ensure the competencies of those processing instruments and endoscopes by improving training, education, and certification. Review IFUs before you purchase medical devices to ensure you have the equipment, tools, and time to follow the IFUs. Patient safety is the top priority. ❖

—Martha Young, MS, CSPDT
President, Martha L. Young, LLC, providing SAVVY Sterilization Solutions for Healthcare
Woodbury, Minnesota

Martha Young is an independent consultant with long experience in medical device sterilization and disinfection.

References

Alfa M. Monitoring and Improving Effectiveness of Cleaning Medical and Surgical Devices. Presentations. Association for Professionals in Infection Control and Epidemiology. San Antonio, TX, June 2012.

AORN. Recommended Practices for Cleaning and Care of Surgical Instruments and Powered Equipment. Perioperative Standards and Recommended Practices. Denver, CO: AORN, 2012. www.aorn.org

Association for the Advancement of Medical Instrumentation. Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities. ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 (Consolidated text). Arlington, VA: AAMI, 2010. www.aami.org

Association for the Advancement of Medical Instrumentation. Reprocessing 2011 Summit: Priority Issues from the AAMI/FDA Medical Device Reprocessing Summit. www.aami.org/reprocessing/Materials/PDF/2011_Reprocessing_Summit_publication.pdf

ECRI Institute. Top 10 technology hazards for 2012. Health Devices. 2011:40(11). www.ecri.org/Products/Pages/Top-10-Hazards-Resources.aspx

Schulz R. Inspecting Surgical Instruments: An Illustrated Guide. Chicago, IL: International Association of Healthcare Central Service Materiel Management (IAHCSMM), 2005.