





Medical Device Cleaning: Back to Basics

BY PATTI KONCUR, CRCST, CHMMC, ACE -- IAHCSSM EDUCATION SPECIALIST

This series of self-study lessons on CS topics was developed by the International Association of Healthcare Central Service Materiel Management (IAHCSSM). Purdue University's Extended Campus and IAHCSSM both offer grading opportunities.

Earn Continuing Education Credits:

Online: Visit www.iahcsmm.org for online grading (complimentary to members; nominal fee for non-members).

By mail: For written grading of individual lessons, send completed quiz and \$15 to:
Purdue University - Online Learning
Young Hall, Room 526
155 S. Grant Street
West Lafayette, IN 47907

Scoring: Each online quiz with a passing score is worth 2 contact hours toward your CRCST recertification (12 hours).

Subscription Series: Purdue Extended Campus offers an annual mail-in or online self-study lesson subscription for \$75 (six specific lessons worth 2 points each toward CRCST recertification of 12 hours). Call 800.830.0269 for details.

For More Information:

IAHCSSM provides online grading service for any of the Lesson Plan varieties. Purdue University provides grading services solely for CRCST and CIS lessons. Direct any questions about online grading to IAHCSSM at 312.440.0078. Questions about written grading are answered by Purdue University at 800.830.0269.

LEARNING OBJECTIVES

1. Review the importance of the cleaning process
2. Describe proper point-of-use procedures and their importance to the cleaning process
3. Identify key steps in the cleaning and decontamination process

Cleaning is the most important task any Sterile Processing (SP) technician will be assigned. The instrument cleaning process is essential to successful outcomes and patient safety. Failure to properly perform any step in the cleaning process will result in a device that may be unsafe to handle with ungloved hands and a failed decontamination/disinfection/sterilization process. Ultimately, the patient may be negatively affected with a healthcare-associated infection (HAI), which can be life threatening.

Many technicians consider the cleaning and decontamination to be a single process; however, it is really comprised of two distinct and separate processes. Cleaning is the removal of visible and non-visible soil from medical devices. Decontamination, on the other hand, is the process of reducing contamination by infectious organisms to an acceptable level. Cleaning must be performed prior to decontamination or the decontamination process will not be effective.

The US Food and Drug Administration (FDA) requires manufacturers to provide comprehensive, detailed instructions,

also known as instructions for use (IFU), on how to perform the cleaning process effectively. As medical devices have become more complex, so have the processes that must be followed to effectively clean them. Today, some devices require more than an hour to clean properly.

This lesson will address the cleaning processes, beginning with point-of-use treatment. While general information is covered in this lesson, it is important to note that manufacturers' IFU must be reviewed and carefully followed for each device processed.

Objective 1: Review the importance of the cleaning processes

Adequately cleaning medical devices is challenging for many SP technicians; however, instrument cleaning is the first and most important step in the instrument processing cycle. Properly cleaning instruments is critical for providing safe, decontaminated, disinfected or sterilized instrumentation for patient use.

Improperly cleaned devices may become damaged and fail to perform as expected, which can result in case



delays or cancellations. Unclean instruments will cause an ineffective decontamination, disinfection and sterilization process which, in turn, may potentially lead to one or more of the following negative outcomes:

- Healthcare-associated infections (HAIs)
 - » According to the Center for Disease Control and Prevention (CDC), approximately one of every 25 inpatients acquire an HAI. More than 700,000 patients are affected annually and more than 100,000 HAI-related deaths occur each year (more than automobile accidents, AIDS and breast cancer combined).
 - » The average cost of treating a single HAI is \$21,000, totaling at least \$20 billion dollars in extra healthcare costs annually.
 - » 31% of surgical site infections (SSIs) are due to HAIs.
- Post-operative fever caused by endotoxins (a toxin present inside a bacterial cell that is released when the cell disintegrates)
- Negative public perception and increased liability risk
 - » Heightened media coverage (on televised news and in social media) is making the public increasingly aware of the risks associated with poorly cleaned medical devices. This can result in the public's lack of trust in the healthcare facility, which can result in fewer procedures and an increased risk for litigation.

Objective 2: Describe proper point-of-use treatment and its importance to the cleaning process

The instrument cleaning cycle begins with point-of-use treatment – and its steps begin during the procedure. Blood,

body fluids and other debris should be wiped from the device and lumens should be irrigated during the procedure to keep these contaminants from drying on the instrument. Sterile water should be used to wipe and irrigate as saline will corrode the instruments. *Note: Point-of-use treatment does not replace the cleaning that will take place in the SP area.*

Numerous guideline- and standards-making organizations, including the Association for the Advancement of Medical Instrumentation (AAMI) and the Association of periOperative Registered Nurses (AORN), recognize the importance of point-of-use treatment processes and have outlined the tasks that should occur at the point of use. Recently, The Joint Commission (TJC) announced heightened inspections of some of the cleaning and disinfection processes, including point-of-use tasks.

At the end of the procedure, staff preparing soiled devices for transport to SP should wear personal protective equipment (PPE) while handling the instruments. Using sterile water, gross soil should be removed from the instruments, and lumens should be irrigated before sending the instruments to SP. It's important to recognize that the removal of gross soil does not mean the instruments will arrive in the SP decontamination area clean and debris free.

All waste material and disposable items should be discarded in the appropriate container. Biohazardous waste, such as surgical drapes, should be discarded in the appropriate container or bag.

Multi-part instruments should be disassembled, and sharps should be segregated and placed in a container/area to protect both the sharp devices and employees.

Instruments should be placed in their appropriate container for transport. All instruments opened in

the procedure area should be sent to the decontamination area, even if they do not appear used or soiled.

Improperly loading instruments into their container can damage the instruments and container. Instruments should be protected from damage when placing them inside the tray. Delicate instruments should be placed on top of heavier instruments. Instrument tips should not be allowed to poke through the mesh wire or allowed to rest on the upper edge of the tray where they can fall from the tray or become damaged by the lid.

Instruments should be sprayed with a product whose purpose is to keep instruments moist, such as an enzymatic spray or gel, or moisturizing product. The use of a water-moistened towel is also acceptable.



Figure 1: Spraying instrument

Soiled medical devices should be contained for transport to the SP department (SPD) as soon as possible after the conclusion of the procedure. A closed case cart or container is the preferred method of transport.

Objective 3: Identify key steps in the cleaning and decontamination process

Instruments should be inspected and sorted in the decontamination area as soon as possible after they are received. Pre-sorting includes the sorting of



items that must only be hand processed, items that require special cleaning (e.g., eye instruments) and sorting of devices comprised of different metals. Chrome-plated, silver-based devices and those made of other metals should not be processed with stainless steel instruments, for example, because instruments of different metals can become damaged.

Some factors that could influence the cleaning process include:

- **The type of soil to be cleaned from the device.** Chemicals used to clean protein matter may not be suitable for cleaning fats, dyes and mineral deposits. Also, soil that is allowed to dry on devices may require additional soaking or cleaning time.
 - **Water quality (pH, water hardness).** Mixing a cleaning chemical in hard water when a neutral pH or softened water is required may deactivate the cleaning solution. Water quality in the decontamination area should be routinely monitored.
 - **Temperature.** Different temperatures are required at various stages of cleaning. The cleaning chemical IFU may require a specific temperature range for the product to be effective. If water temperature and pH are not at the recommended parameters, the cleaning chemicals will become ineffective. Water temperature in sinks and basins should be monitored.
 - **Preparation.** Instruments that are not properly prepared for cleaning (e.g., opened, disassembled), will not be thoroughly cleaned.
 - **Time.** Solutions must be allowed to react with the soil, and the time required for this to happen varies by
- chemical. Failure to allow the proper soak time will make the cleaning process more challenging.
- **Method of cleaning.** Use chemicals as directed by the IFU. If a chemical is formulated for manual cleaning, it may not be effective in a mechanical washer.
 - **Equipment performance.** Malfunctioning equipment will cause the cleaning process to fail. Equipment should be checked at least daily to ensure it is functioning as expected. Verification testing should be performed and documented, in accordance with the current standards.
 - **Brushes.** Brushes recommended for use by the chemical and the medical device's IFU should be used. The appropriate size, as recommended by the manufacturer, is important because using a brush that is too small will not clean properly and a brush that is too large may damage the instrument. Any cleaning cloths should be lint free. Abrasives should be avoided, unless specifically recommended in the IFU.

Personal protective equipment

Wearing the proper personal protective equipment (PPE) is not only an important component of employee safety but also required by the Occupational Safety and Health Administration (OSHA). PPE should be worn whenever soiled instruments are handled. Everyone entering the decontamination area should know the proper PPE to wear and the correct order of donning (putting on) and doffing (taking off) is important. Each person who will be handling soiled instruments should be trained and competency documented prior to handling soiled devices.

Instruments should be inspected and sorted in the decontamination area as soon as possible after they are received. Pre-sorting includes the sorting of items that must only be hand processed, items that require special cleaning (e.g., eye instruments) and sorting of devices comprised of different metals.

Sorting and pre-cleaning

With proper PPE in place, soiled devices should be sorted. Many devices can be mechanically processed; however, some devices can only be hand processed. Others, such as ophthalmic instruments, have special processing needs. Presorting the instruments helps avoid processing errors. Note: It is important that all manufacturer's instructions for use (IFU) be accessible to and used by instrument processing personnel. IFU specific to each device being processed, as well as the chemicals and equipment used, should be consulted to ensure the correct cleaning measures are used.

Most instruments should be soaked or pre-cleaned prior to mechanical cleaning. While some soil is easy to see and remove, it is difficult to see all the soil on medical devices. Pre-cleaning or soaking



instruments helps remove some of the difficult-to-see soil while preparing the instruments for a mechanical process. It is also important to follow each device's IFU for the proper solution, water type, concentration and temperature needed to pre-clean or soak the device. All devices should be pre-cleaned or soaked prior to any type of cleaning, especially mechanical cleaning, as most mechanical equipment was not made to clean gross soil or dried debris.

Manual cleaning

After pre-cleaning/soaking, the devices can move to the next phase of the process. Devices that are grossly soiled and still have dried debris can now be manually cleaned.

Again, it is important to consult the IFU for the proper cleaning solution and tools needed for manual cleaning. Ensure instruments are cleaned below the water's surface to protect the environment from aerosols. Serrations, jaws, hinges, lumens and crevices should be cleaned using the recommended type and size of cleaning brush. Each device should be carefully inspected to ensure it is clean. From there, the device should be rinsed in accordance with the device's IFU. If flushing is recommended, follow the recommendations for the proper pressures to apply during the flushing process. Note: All instruments must be properly rinsed after each step of the

cleaning process because not all cleaning solutions are compatible.

Mechanical cleaning

Mechanical cleaning should be used whenever possible. The use of mechanical equipment can improve cleaning effectiveness, increase productivity and promote standardization of the cleaning process. SP technicians need to verify their department's mechanical cleaning equipment operation daily (each day of use).

Commercially prepared tests are available to test the effectiveness of the mechanical equipment used in the decontamination area. These include:

- Tests to verify the cavitation process of the ultrasonic cleaners;
- Tests to verify the cleaning ability of the washer-disinfectors; and
- Tests to ensure proper water flow in cart washers.

All required verification testing for each type of mechanical cleaner will be documented in the IFU. The specified tests should be run, and test results should be documented daily (each day of use).

Ultrasonic cleaning

After manual preparation or cleaning,



Figure 2: Irrigating instruments

many devices need to go through an ultrasonic cleaner. Once again, check the IFU for the proper chemical, dilution, time and the proper loading process for that device. Ensure the item is recommended for ultrasonic cleaning as some devices, such as chrome and laser-plated instruments, mixed metals and glass items, can be damaged by this process. Wood, cork, some plastics and other materials are also not recommended for ultrasonic cleaning.

Loading the ultrasonic cleaner is as important as loading a washer-disinfectant or a sterilizer. If not properly loaded, the items will not be properly cleaned. Care should be taken not to overload instrument trays. Overloaded trays interfere with the cavitation process because they make it more difficult for the solution to reach all instrument surfaces. Always follow the ultrasonic manufacturer's IFU for proper loading instructions.

If using an irrigating sonic, be sure the instruments are properly connected and the solution flows through the device. Ultrasonic cleaners are not designed to clean grossly soiled items; therefore, it is essential to never skip the pre-cleaning/soaking process.

The ultrasonic cleaner is operated with the lid closed to prevent aerosols and other contaminants escaping into the environment. All items must be properly

Mechanical cleaning should be used whenever possible. The use of mechanical equipment can improve cleaning effectiveness, increase productivity and promote standardization of the cleaning process. SP technicians need to verify their department's mechanical cleaning equipment operation daily (each day of use).



rinsed following ultrasonic cleaning, even if the items are to be placed into a washer-disinfector. It is important to ensure all ultrasonic cleaners are cleaned, maintained and tested per manufacturer's IFU, and that test results are properly documented.

Washer-disinfectors

After the devices have been properly prepped (and if recommended by the IFU) the devices can be placed into the washer-disinfector for cleaning. As with ultrasonic cleaners, the manufacturer's recommendations for chemicals, temperatures, cycles and loading processes must be carefully followed. When placing items into trays it is essential to:

- Place delicate instruments on top of heavier instruments. Improper loading of trays may cause instrument damage.
- Place instruments in a configuration that will allow the cleaning action to contact all surfaces of each item.
- Position items that may hold water in a way that allows them to drain.
- Confine or contain small parts that may become lost.
- Load each tray and washer basket in a manner that will allow the mechanical washing energy to contact all items to be cleaned.
- If using an irrigator tray, be certain that connections are properly attached.

Ensure instrument trays are properly loaded on the washer manifolds and adhere to the following practices for best outcomes:

- Trays with multiple layers should be separated.
- Trays should not be stacked and should have enough room between other trays to allow for proper circulation of solutions.
- Ensure spray arms are able to turn freely and will not hang up on an instrument.

It is essential that all washer-disinfectors are cleaned, maintained and tested according to the manufacturer's IFU and that test results are properly documented.

Cart Washers

Cart washers were originally designed to specifically clean carts and other large items, but not instrumentation. Some new cart washers now have validated instrument cleaning cycles programmed at the factory. Such an instrument cycle should be tested each day of use and the test results should be properly documented. Items should be loaded into the trays in the manner as they are loaded into the trays in the washer-disinfector, unless otherwise stated in the IFU. Always use the cart designed to hold instrument sets; do not place instrument sets on the carts designed to hold basins and containers.

All cart washers must be cleaned, maintained and tested according to the manufacturer's IFU and test results should be properly documented.

Conclusion

Consistently following proper cleaning procedures is one of the most important functions SP technicians perform. Diligence during these processes and careful adherence to IFU will help ensure items are not only safe to handle but are properly prepped for a successful disinfection or sterilization process. 

RESOURCES

International Association of Healthcare Central Service Materiel Management. 2016. *Central Service Technical Manual*, 8th Edition, Chapter 8.

Association of periOperative Registered Nurses. 2019. *Guidelines for Perioperative Practice, Guideline: Sterilization and Disinfection: Instrument Cleaning*.

Association for the Advancement of Medical Instrumentation. 2017. ANSI/AAMI ST79:2017, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. Sections 6 and 7.