Cleaning and Decontamination: A Review

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LEARNING OBJECTIVES

1. Discuss the point-of-use treatment process
2. Review the proper water quality for and chemicals used during the cleaning process
3. Discuss the cleaning and decontamination processes

Setting up devices for successful cleaning and decontamination processes begins during the procedure and is then completed in the decontamination area. The ability to effectively decontaminate and disinfect or sterilize any device depends on its proper treatment and cleaning. This lesson discusses appropriate cleaning and decontamination processes.

Objective 1: Discuss the point-of-use treatment process

Point-of-use treatment starts during the procedure when gross soil is removed from devices as they are used. After the procedure, point-of-use treatment steps include:

- Remove all disposable components from the trays and discard properly.
- Empty fluids from all containers.
- Separate reusable sharps to help prevent injuries.
- Flush lumens and channels.
- Tag or identify items that need repair.
- Place instruments in the correct tray, keeping items that belong in a set together, in a manner that will prevent damage.
- Separate used devices from unused devices using a surgical towel or tray liner, if available. *Note: Unused devices will still need to be processed.*
- Treat devices with either a spray or foam enzyme or surfactant product.
- Wear proper personal protective equipment (PPE) throughout this process no matter where it is performed.

The last step in point-of-use treatment is to safely transport the soiled items to the decontamination area. Instruments must be contained during transport to reduce the chance of cross-contamination. Items can be transported using closed or open carts or an approved container or biohazard bag. Closed carts are the method of choice, as they offer the most protection to both the devices and facility environment. If open carts are used, the cart should have a solid bottom shelf, and the cart and soiled devices should be completely covered using an approved reusable or disposable cover. Approved containers or biohazardous bags should be closed securely. Placing them inside a bin or cart will offer more protection. All

items should be secured to minimize movement and device damage.

If transporting soiled devices off-site or between campus buildings for cleaning, the U.S. Department of Transportation's (DOT's) regulations for transportation of biohazardous materials should be carefully followed. The applicable regulation is available from the DOT Hazardous Materials Regulations (HMR; 49 CFR Parts 100-180). State and local laws should also be checked to be sure items are transported in compliance with all requirements.

Temperature and humidity should be maintained within standards during transport. If devices are being transported in a vehicle, they should not be left in the vehicle without climate controls to prevent excessive heating, cooling or humidity. Transport vehicles must be on a cleaning schedule, with cleaning occurring between every soiled load that will be followed by a clean load. *Note: Soiled and clean items should be transported separately. If soiled and clean devices are being transported at the same time, they must be completely segregated.*

Objective 2: Review the proper water quality for and chemicals used during the cleaning process

It is essential to keep all soiled instruments moist until beginning the cleaning process in the decontamination area. Dried-on soil is more difficult and time-consuming to remove, and it may damage the surface of some devices. Therefore, gross soil must be removed as soon as possible after use.

Manufacturers' instructions for use (IFU) must always be followed when cleaning all devices. Manufacturers of reusable medical devices are responsible for ensuring that their devices can be effectively cleaned and disinfected or sterilized, if necessary. Device labeling should identify specific methods of cleaning that have been validated by the manufacturer. These instructions are reviewed by the U.S. Food and Drug Administration (FDA) and approved as part of the device's 510(k) premarket approval.

Cleaning devices in Sterile Processing (SP) is much more complex than cleaning dishes at home. At home, the choice of water is what comes out of the kitchen faucet and the chemical is the favorite dish detergent. Cleaning healthcare devices requires different types of water and specific cleaning chemicals. All healthcare cleaning chemicals do not work with all types of water or water temperature, and unlike dish detergent, the chemicals need to be properly measured. Before any cleaning process can be started, each device's IFU must be consulted to determine which type of water and chemical(s) are appropriate for the cleaning process.

Water is a very important component of the cleaning and decontamination processes. Using the wrong type of water or the wrong water temperature can deactivate the cleaning chemicals, damage the devices being cleaned and interfere with the sterilization cycle. It is necessary, therefore, that each device's IFU is carefully followed and the correct water for the process is used.

There are two types of water used in the medical device cleaning process: utility water and critical water. Utility water is water that comes from the tap, but depending on the quality of the potable (tap) water at the facility, additional treatment might be needed to meet its requirements, such as those outlined in the Association for the Advancement of Medical Instrumentation's ANSI/AAMI ST108:2023 *Water for the processing of medical devices*. Utility water is used for flushing, cleaning and intermediate rinsing.

Critical water is water that has been highly treated to remove microorganisms and organic and inorganic material. Mineral deposits and high microorganism levels remaining on devices after a utility water rinse can interfere with the decontamination, disinfection and sterilization processes. Critical water, therefore, is used for final rinsing. *Note: Critical water is not free of bacteria. Distillation, deionization and reverse osmosis are the most common methods of treating critical water.*

When choosing water, pH is also important. Most chemicals require the use of neutral water, however, it is important to follow each chemical's IFU, as some detergents require slightly alkaline or acidic water. Utility water should have a pH of between 6.5 and 9.5, and critical water pH should fall between 5.0 and 7.5.

Water treatment equipment is frequently placed in or very near to the Sterile Processing department (SPD) and may need to be monitored by the SP team in collaboration with Biomedical Engineering staff or an outside contractor. Water quality needs to be monitored to help ensure the required parameters are met. Per ANSI/AAMI ST108, water quality should be tested monthly for critical water and quarterly for utility water.

Common cleaning chemicals used for cleaning medical devices

Today's cleaning processes have become much more technical. Since there are many types of chemicals available, choosing the correct cleaning chemical

is sometimes difficult or confusing. Each chemical has a specific purpose and must be used in accordance with its own IFU.

Enzymes are catalysts that can accelerate chemical reactions. Different enzymes are useful in removing specific types of organic matter. For example, protease breaks down blood, mucous and feces, while albumin and lipase help to remove fats. Removing or dissolving fats helps to loosen bone chips, which can be bound together by fat. Amylase is useful in removing starch. Enzymatic chemicals are frequently used for point-of-use treatment, presoaking instruments or combined with other chemicals to enhance their cleaning ability.

Temperature is a special concern when using enzymatic cleaning products. If the water temperature is too low, usually below 90°F (32°C), the enzyme will not activate. If the water temperature is too high, above 140°F (60°C), the enzyme will break down. Either temperature extreme, too hot or too cold, will make the detergent ineffective.

Detergents enhance water's ability to remove soil. Emulsifiers and chelating agents in detergents help remove organic soil, minimize formulation of insoluble deposits and prevent water spots. Detergents are formulated for different processes, such as manual cleaning or a specific type of mechanical cleaning, but most formulas used in healthcare are neutral pH.

Acidic and alkaline detergents are frequently used for specific types of soil removal but need to be closely monitored to avoid device damage. Alkaline detergents (pH 10 to 11.5) can effectively remove organic soils but may need to be neutralized with an acidic detergent rinse to avoid damage. Acidic detergents work well on inorganic soils and make stainless steel shine. Acidic descalers are used to remove mineral scale from devices and cleaning equipment.

When using either acidic or alkaline chemicals to remove stains or rust, it is imperative that the soak times do not exceed those specified in the IFU as damage to the device will occur. Careful rinsing of the instrument is also required to remove any trace of either acidic or alkaline detergents.

All devices need to be properly rinsed prior to further processing. Critical water is used as a final rinse for most devices. Rinsing with critical water most frequently occurs after rinsing with utility water, as critical water rinses away chemical residues, minerals and other debris remaining after a utility water rinse.

Objective 3: Discuss the cleaning and decontamination processes

Cleaning and decontamination are two separate and distinct processes. Cleaning refers to the removal of all visible and non-visible soil and foreign material. Decontamination is the process of removing or reducing infectious organisms and contamination to make a device safe for handling without PPE. Some devices are safe for handling after thorough cleaning, while others require decontamination or exposure to a microbiocidal process.

Cleaning

Cleaning is the first and most important step in the decontamination, disinfection or sterilization process. Bioburden left on medical devices can cause pyrogenic or foreign body reactions and create a breeding site for infection. Reducing bioburden through the cleaning process is essential to the success of the decontamination and subsequent disinfection or sterilization processes.

The manufacturer's IFU will state how each item can be properly manually or mechanically cleaned. Items should always be cleaned following their IFU. Device manufacturers are required to submit complete cleaning instructions to the FDA during the device's 510(k) premarket approval process. In general, mechanical cleaning is more effective and consistent than manual cleaning; however, some devices cannot be cleaned mechanically because either the device cannot be immersed or a mechanical process may damage it.

Manual Cleaning

Manual cleaning follows point-of-use cleaning and removes the remaining gross soil from devices. Manual cleaning should be performed prior to any mechanical process to remove heavy soil. If not removed, the debris can circulate and deposit onto other devices. Some devices, like some complex or delicate items, rely on manual cleaning as they would be damaged by a mechanical process. Lumened devices should undergo an effective manual cleaning process prior to any mechanical cleaning.

Tools used during manual cleaning need to be those identified in each device's IFU. Using the correct brush diameter and cleaning cloth material is important to perform the cleaning process effectively.

The basics of proper cleaning include:

- Disassembling multipart instruments.
- Correctly mixing and using cleaning solutions according to the detergent's IFU.

- Using the proper cleaning tools as identified in the IFU.
- Brushing items under the surface of the water to avoid the formation of aerosols that could spread contaminants.
- Using vertical containers (if available) for soaking lumened devices.
- Cleaning each device following the grain of the metal surface.
- Using the correct brush diameter for cleaning lumened items: Too small a diameter will prevent the bristles from making proper contact to remove the soil. Too large a diameter could flatten in the lumen, damaging the bristles or device and failing to remove the soil properly.
- Changing cleaning solutions frequently per guidelines, standards, and the facility's policies and procedures.
- Rinsing all items, even those undergoing a mechanical cleaning process.

Mechanical Cleaning

There are several types of mechanical cleaners, including ultrasonic cleaners, washer-disinfectors and cart washers. All mechanical cleaners should be operated and tested per their specific IFU. Equipment should not be used if it does not successfully pass the assigned test.

All items should be precleaned prior to mechanical cleaning. Multipart instruments should be disassembled, and cleaning solutions used per the IFU. Instruments should be secured in the open position and placed so the cleaning solution can reach all areas of each device. Equipment should be loaded per its IFU, and care should be taken to avoid overloading.

Ultrasonic Cleaners

Ultrasonic cleaners are used to clean hard-to-reach areas. Ultrasonic cleaners use a process called cavitation which is the creation of tiny air bubbles using vibrations in the solution. The bubbles continue to grow until they implode (collapse), removing the soil from areas like box locks and hinges. Ultrasonic cleaning solution should be changed frequently, with the solution emptied and the ultrasonic bay rinsed. ANSI/AAMI ST79 recommends changing the cleaning solution after each use with "a use" defined by the healthcare facility. The rationale is that changing the solution will minimize cross-plating and cross-contamination. The chamber should also be cleaned and disinfected per its IFU and facility protocols.

Some materials, such as glass, plastic, cork, chrome and rubber, cannot undergo ultrasonic cleaning. Always consult a device's IFU to determine if it can withstand ultrasonic cleaning.

Most ultrasonic cleaners do not have the ability to decontaminate. Some newer models do have a decontamination process, so consult the ultrasonic's IFU.

Items may require further mechanical cleaning after ultrasonic cleaning. Be sure all of the ultrasonic cleaning solution is rinsed from the devices before placing them in another type of mechanical cleaner.

Washer-Disinfectors

Washer-disinfectors are frequently single chamber units with multiple phases to each cycle; however, there are multiple chamber washer-disinfectors available, so it is important to be familiar with the model(s) in use in one's department.

Most automated instrument washers use impingement: a spray-force action of pressurized water against the instruments to physically remove bioburden. Washer-disinfectors rely on a combination of water temperature, detergent and spray-force action to remove soil from instruments during processing. Automated instrument washers use several steps in each wash process including a:

- Pre-rinse cycle to wet the instruments
- Detergent cycle with higher temperature water
- Lubrication cycle
- Rinse cycle(s)
- Dry cycle

Most washer-disinfectors are sold with preset factory-installed cycles. Loading the washer correctly is very important for the proper operation of the washer. Carefully follow the specific washer-disinfector's IFU. General rules include:

- Placing small items in approved baskets
- Opening all instruments and disassembling multipart instruments
- Not overcrowding the manifold (cart) racks
- Using hold-down screens to keep lightweight devices in place
- Removing all lids and covers from the trays
- Separating all multilayered trays
- Be sure the proper washer cycle is used for all devices as all instruments cannot tolerate all phases of the washer.

Cart Washers

Cart washers are used to wash large items such as carts, basins and instrument containers. Cart washers operate in a manner similar to automated instrument washers but on a larger scale. High-temperature water and detergent are

delivered under high pressure, followed by rinse and drying cycles. Newer model cart washers may have the option to clean surgical instruments. If an instrument cycle is used, it must be tested daily like the washer-disinfectors.

Decontamination

Decontamination is performed after cleaning is completed and can be accomplished using a chemical or thermal process. Cart washers, washer-sterilizers and some ultrasonic cleaners have a programmed thermal decontamination phase after the cleaning and rinsing phases. Items that cannot undergo a thermal decontamination process may be chemically decontaminated following the device's specific IFU. *Note: It is important to follow the IFU as some devices are safe to handle after proper thorough cleaning.*

Conclusion

Reusable medical devices must be adequately cleaned and decontaminated before being prepared for packaging and subsequent sterilization. These processes are simple for some devices but very complex and time consuming for others. The manufacturer's IFU for a particular device must always be followed exactly. Failure to do so may yield a device that is not adequately cleaned and, therefore, cannot be disinfected or sterilized. P

RESOURCES

Association for the Advancement of Medical Instrumentation, ANSI/AAMI ST108:2023 *Water for the processing of medical devices.*

ANSI/AAMI ST79:2017 (with 2020 Amendments) *Comprehensive guide to steam sterilization and sterility assurance in health care facilities.*

Healthcare Sterile Processing Association. *Sterile Processing Technical Manual,* ninth edition, Chapter 8. HSPA, 2023.

CIS Self-Study Lesson Plan Quiz
Cleaning and Decontamination: A Review

Lesson No. CIS 303 (Instrument Continuing Education – ICE) · Lesson expires June 2027

1. Point-of-use treatment should begin:
   a. Within 24 hours of a device's use
   b. Upon the device's arrival in the decontamination area
   c. During the procedure
   d. In the procedure room, with direct oversight from the Sterile Processing manager or liaison

2. Items need to be contained during transport to:
   a. Prevent viewing of debris that may be disturbing to patients and visitors
   b. Prevent theft or unnecessary handling of the items
   c. Minimize contact or airborne spread of microorganisms
   d. Confirm they are not clean

3. If it is necessary to transport soiled items between buildings or campuses, one must consult the requirements of:
   a. The Occupational Safety and Health Administration (OSHA)
   b. The Department of Transportation (DOT)
   c. The Joint Commission (TJC)
   d. The Environmental Protection Agency (EPA)

4. Until cleaning can begin, it is most important to:
   a. Sort instruments according to the cleaning process that will be used
   b. Remove gross soil by wiping it off the items
   c. Discard all disposable items
   d. Keep instruments moist

5. Cleaning instructions must be:
   a. Verified by the FDA
   b. Verified by the manufacturer
   c. Validated by the FDA
   d. Validated by the manufacturer

6. Critical water is used for final rinsing of instruments because water impurities can:
   a. Protect microorganisms
   b. Leave a greasy residue on device surfaces
   c. Impede cleaning and decontamination processes
   d. Prevent detergents from contacting device surfaces

7. All cart washers:
   a. Clean large items
   b. Have instrument cycles
   c. Have a pasteurization cycle
   d. All the above

8. Enzymes are useful for:
   a. Removing specific types of organic matter
   b. Removing certain stains
   c. Dissolving some minerals
   d. Dissolving bone chips

9. Emulsifiers and chelating agents in detergents help:
   a. Remove organic soils
   b. Dissolve fats
   c. Minimize formulation of insoluble deposits
   d. Make stainless steel shine

10. When loading a washer-disinfector:
   a. Mixed loads should be avoided
   b. Lumened devices need to be connected to the irrigation tubing
   c. Multilevel trays should be separated
   d. Rigid containers need to be placed on the bottom shelf

11. The purpose of decontamination is to:
   a. Minimize cellular inflammation
   b. Render devices safe for handling without personal protective equipment (PPE)
   c. Ensure devices are functioning properly
   d. Expose devices to a microbiocidal process

12. Which machine is used to remove debris from hard-to-reach areas such as box locks and hinges?
   a. Cart washer
   b. Water pistol
   c. Washer-disinfector
   d. Ultrasonic cleaner

13. The solution used in an ultrasonic washer should be:
   a. Low pH
   b. Mixed with critical water
   c. Changed daily
   d. Changed frequently

14. Most automated instrument washers work on the principle of:
   a. Agitation
   b. Impingement
   c. Chemical reaction
   d. Thermal disinfection

15. Cart washers operate in a manner similar to a/an:
   a. Ultrasonic cleaner
   b. Automated endoscope reprocessor
   c. Automated instrument washer
   d. Pasteurizing machine

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