Surgical Instrument Decontamination: A Multistep Process

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ABSTRACT
Surgical instrument decontamination requires the collective input of facility leaders, OR staff members, and sterile processing department personnel. Individual accountability can ensure that instruments are cleaned according to the manufacturers’ written instructions for use, appropriate regulations, and facility policies. Information about the instrument decontamination process—from point of use to sterilization—should help enable perioperative nurses to advocate for and participate in the appropriate implementation of the necessary process steps. Sterile processing department leaders should develop policies and procedures for decontamination of surgical instruments and devices and the various accountabilities for the process steps. They also should help provide education for their staff members and complete required documentation. This article reviews the steps of instrument cleaning and decontamination and provides a framework to help perioperative leaders and educators facilitate these steps in their work environments, prevent instrument damage, and help ensure safe patient care.

Key words: sterile processing department, instrument cleaning, instrument decontamination, instructions for use, sterilization.

During accreditation reviews, surveyors from regulatory bodies (eg, The Joint Commission) examine processes that facility leaders have implemented for decontaminating and sterilizing instruments.1 The Joint Commission surveyors refer to standards and guidelines developed by the Association for the Advancement of Medical Instrumentation (AAMI) and AORN when inspecting instrument processing areas. In addition, surveyors refer to facility policies and manufacturer’s instructions to ensure that personnel are performing tasks correctly.1

POINT-OF-USE CLEANING AND TRANSPORTATION
The first step in cleaning instruments and devices begins during a procedure. The scrub person should wipe the instruments and devices with a sponge moistened with sterile water to remove gross soil (eg, blood and other body fluids, bone, eschar, microorganisms).2,3 The scrub person can soak instruments during the procedure in a basin of sterile water to facilitate the removal of tissue and other debris; he or she should irrigate any cannulated or lumened instruments with sterile water intraoperatively without creating aerosols. Saline is corrosive and the scrub person should never use it to remove soil from instruments. If he or she uses saline, the instrument or device should immediately be rinsed with sterile water to remove the saline.2

Biofilm comprises microorganisms and extracellular tissue. It adheres to instrument surfaces, and once dried, it is difficult to remove.4 Biofilm can form on the inner surfaces of endoscope channels and is prone to form when the internal channels become scratched or damaged. In a favorable environment, some microorganisms can reproduce in 4 to 20 minutes.5 To prevent biofilm formation and microbial growth, OR and sterile processing department (SPD) staff members should remove gross soil at the point of use and begin the
cleaning process as soon as possible after use (Figure 1). Some instrument and device manufacturers now indicate that their products should be cleaned immediately after use or within a specified time frame (eg, 30 minutes from the time of use). Prompt cleaning also decreases the instrument corrosion that may occur after contact with blood, saline, and other chemicals (eg, hemostatic agents) during the surgical procedure. When staff members do not remove gross soil from instruments at the point of use, it increases the SPD technician's workload and lengthens instrument cleaning times, which may negatively affect patient care.

Flexible Endoscopes
Flexible endoscopes (eg, cystoscopes, ureteroscopes, gastrointestinal [GI] endoscopes, bronchoscopes) used during procedures require point-of-use cleaning (ie, at the bedside) before they are sent to the SPD. The scrub person should remove organic soil and biofilm completely to help ensure the subsequent high-level disinfection or sterilization process is effective. Commercial products may reduce bioburden and keep soils moist on flexible endoscopes; however, the scrub person or SPD technicians should not use these products unless the manufacturer has validated that the chemicals in the product are acceptable for use with endoscopes. Scrub persons should perform point-of-care cleaning to prevent secretions and tissues from drying, adhering to the endoscopes, and creating biofilm, which makes cleaning difficult.

Staff members who process flexible endoscopes need to follow the written instructions for use (IFU) from both the endoscope and cleaning solution manufacturers. Some endoscope manufacturers (especially those of flexible GI endoscopes) recommend that cleaning be performed no more than one hour after precleaning. Therefore, scrub persons should note the time that the precleaning was performed and relay this information to the GI or other endoscope technician of the time elapsed since the precleaning. If staff members do not begin manual cleaning within the specified time frame, they should follow the endoscope manufacturer's IFU for delayed reprocessing procedures. If staff members are not able to begin the cleaning process immediately because the endoscope is needed for repeat uses during a procedure, designated personnel (eg, RN circulator, anesthesia technician) should follow the manufacturer's IFU and complete point-of-use cleaning of external surfaces and clean internal channels with water.

End-of-Procedure Preparation for Transport
Surgical team members should consider any instrument or device that has been opened for a surgical procedure to be contaminated after it is removed from sterile packaging, even if the item was not used. Therefore, at the end of the procedure, the scrub person should open and disassemble (if multipart) all instruments and devices as directed by the manufacturers' written IFU. Additionally, AORN and AAMI do not recommend the restringing of instruments when sent to SPD. If stringers were used, they would need to be wide enough apart for the instruments to be sufficiently open so as to be adequately exposed to the detergent and water in the ultrasonic cleaner and mechanical washer. Additionally, when using

Figure 1. Orthopedic stems that were not pretreated and were left in the dirty utility room of the OR during a weekend (A). Sterile processing department technicians required 18 hours to clean them effectively. Photograph courtesy of Nancy Chobin. Instrument set that has had gross soil removed in the OR after use (B). Photograph courtesy of Case Medical, Inc, South Hackensack, NJ.
a stringer, SPD personnel would need to devise a method for keeping the instruments in an upright, vertical position for effective cleaning. This is not always feasible because of the design of most ultrasonic and mechanical washers. After cleaning, the SPD technician would need to remove the stringer from the instruments to inspect them.

At the end of the procedure, the scrub person must remove all disposable sharp objects from instruments and devices and place them in a sharps container to prevent SPD technicians from experiencing an occupational bloodborne pathogen exposure. The scrub person should place delicate items in a separate specialty container to prevent damage during transport (Figure 2). Many specialty containers provide secure holders to maintain the instruments’ positions during transport. The scrub person should place each instrument in its designated location in the container to prevent damage (Figure 3). The scrub person should have an easy way to notify SPD technicians when instruments require repair. One method is for the scrub person to apply an autoclavable tag to the instrument so the SPD technicians know to remove the instrument from service after they complete the cleaning process. In addition, staff members should take precautions to minimize instrument damage. This includes

- protecting tips and other parts of fragile instruments;
- separating and containing any reusable instruments that may cause injuries to SPD personnel;
- organizing the instrument container with the larger and heavier instruments on the bottom to protect the lighter and fragile instruments on top;
- avoid placing instruments in basins with solution because the solution can spill in transit or upon removal, contaminating personnel or the environment; and
- avoid separating used instruments from unused instruments.

Although staff members may want to expedite the room cleaning processes in anticipation of a subsequent procedure, when they place instruments in the wrong trays or do not protect them from damage, they can cause delays in instrument processing and preparation (Figure 4). In addition, the facility may incur significant costs to repair or replace instruments, and the number of available instruments in the tray may be reduced when instruments are not available because of damage.

Before sending the instruments to SPD, the scrub person is responsible for keeping the instruments moist to facilitate removal of organic soil, a major factor in cleaning. Scrub persons have three options to maintain the moisture of soils, which are listed as follows.

- Use an enzymatic product designed for pretreatment of instruments that does not aerosolize (ie, not liquids). This type of product varies in odor, may be a foam or gel, and varies in the length of time it maintains moisture.
(ie, 24 hours to several days). Scrub persons should follow the manufacturer’s IFU and apply the product to all surfaces of the instruments.

- Cover the instruments with a moist towel, place the instruments in a biohazard bag or puncture-proof biohazard container, and close the containment device to prevent the moisture from evaporating. Use water, not saline, to moisten the towel.

- Place instruments into a commercial self-sealed pouch that will keep soils moist (Figure 5).

Surgical Instruments and Known or Suspected Creutzfeldt-Jakob Disease (CJD) Patients

Creutzfeldt-Jakob disease is caused by prions, which are infectious proteinaceous materials that are very difficult to remove from instruments. Because prion transfer has been shown to take place during neurological surgeries, only those instruments used on patients at an increased risk for CJD who are in direct contact with high-risk tissue (eg, spinal cord; posterior eye or brain procedures, including pituitary) are of concern. Any reusable instruments that contact high-risk tissue should be designed to be easily cleaned, and SPD leaders should have validation from the manufacturer that the instruments can tolerate exposure to extended sterilization cycles. Single-use instruments are available for CJD procedures (eg, single-use brain biopsy sets), and SPD leaders should collaborate with surgeons and perioperative leaders to ensure the instruments meet the needs of the surgical team. The SPD technicians can use cleaning processes that have been shown to reduce prion infectivity safely to process devices contaminated with low-risk tissue (eg, cerebrospinal fluid; tissue from lymph nodes or organs, including kidney, liver, spleen, or lung) or no-risk tissue (eg, urine, feces, blood, bone marrow). These methods include steam sterilization and hydrogen peroxide gas sterilization.

After use, the scrub person should identify all instruments or devices that require special prion processing and place those items in rigid containers. The scrub person should

- keep instrument soils moist using one of the three methods previously described,
- immediately send the instruments to SPD for reprocessing to help facilitate prion removal from the instruments, and

Figure 4. An example of the incorrect way to gather instruments at the end of a procedure (A). Robotic, laparoscopic, and other instruments are mixed together without organization; sharp tips and expensive instruments are not protected. Photograph courtesy of Nancy Chobin. An example of a set of separated instruments that have been pretreated and placed in their respective locations in the basket (B). Photograph courtesy of Case Medical, Inc, South Hackensack, NJ.

Figure 5. Pretreated surgical instruments in a self-sealed pouch to maintain moisture. Photograph courtesy of Healthmark Industries Company, Inc, Fraser, MI.
identify the instruments with a special label (eg, SPECIAL PRION PROCESSING) attached to the container or bin.2

As a precaution, surgical and SPD team members should treat all loaner spinal and neurological instruments received from a vendor representative as though contaminated with prions.9 Because the history of the loaned instruments is unknown, the SPD technicians should clean the instruments according to the manufacturer’s IFU and sterilize them by using extended cycles as recommended by the AAMI.3

Transporting Contaminated Instruments

Surgical personnel must contain contaminated items in closed bins or carts to prevent accidental contamination when transporting them from the procedure area to the decontamination area in the SPD.2,3,8 If SPD technicians are responsible for collecting the used instruments in multiple procedure areas, the SPD leaders should design the collection schedule to limit the transport time efficiently and avoid high-traffic areas.3 Sometimes staff members may use a dirty and clean dumbwaiter system to send and receive instruments. The Occupational Safety and Health Administration requirement for transport mandates that any container with a contaminated item must be identified (eg, red bag, biohazard label), puncture resistant, closeable, and leakproof (ie, sides and bottom).8 All transport containers should be cleaned and disinfected after each use. Therefore, facility leaders should provide only carts or bins that have IFU for decontamination (eg, cleaning in a washer, using a cart washer, disinfecting with an approved disinfectant).2,3

Safety in the Decontamination Area

The SPD technicians may be exposed to a variety of hazardous materials, including microorganisms, chemicals, and sharps. In addition to usual surgical attire, personnel assigned to the decontamination area wear personal protective equipment (PPE) consisting of

- a fluid-resistant face mask and eye protection (eg, goggles, full-length face shields) that protects the wearer from splashes,
- a fluid-resistant gown or jumpsuit with sleeves (may be backless),
- utility-type gloves that cover the cuff of the gown and are fitted at the wrist to prevent contact of contaminated solutions with the technician’s skin, and
- fluid-resistant shoe covers.2,3

After instruments and devices arrive in the decontamination areas, technicians are responsible for sorting them to identify contaminated sharps and delicate items that need to be segregated to prevent damage.10 When working to identify any remaining sharps, staff members in any area should never blindly reach into a basket of instruments. Some SPD leaders may require SPD technicians to use a sponge stick to sort through the instruments in search of a sharp item that could cause a puncture injury and exposure. The technicians should separate any basins and any microsurgical instruments from the general instruments.10 They should remove nonimmersible items (eg, power equipment) and items to be cleaned manually (eg, rigid endoscopes) from the tray. Finally, they should remove any silicone mats or other protective devices for separate cleaning.
CLEANING AND DECONTAMINATION

When cleaning and decontaminating instruments, the SPD technicians should follow the manufacturer’s IFU for each instrument. Many specialty instruments (e.g., orthopedic, spinal, robotic) have complex cleaning protocols that need to be followed, and current IFU should be easily accessible in the decontamination area for the SPD technicians. The cleaning process includes four general steps.

1. Verify that all hinged instruments are in the fully opened position.
2. Disassemble any multipart instruments for cleaning (if recommended by the device manufacturers).
3. Thoroughly rinse the instruments to remove any enzymatic foam or gel product that might have been used to pretreat the instruments. If another method was used to keep the soils moist (i.e., self-sealed pouch), then the instruments should be thoroughly rinsed to remove gross soil.
4. Manually soak the instruments in a neutral-pH enzymatic detergent for the amount of time specified by the detergent manufacturer unless otherwise specified by the device manufacturer.

The SPD technicians may use enzymatic solutions (e.g., proteases) to help remove organic debris from instruments. These enzymes work on the proteins that are common in blood and tissue. The technicians also may use cleaning solutions that contain lipases and amylases to break down fats and starches. Some solutions contain one enzyme; others contain more than one. These enzymatic cleaners are not disinfectants and may be inactivated by germicides. After the technicians use the enzymatic solutions on the instruments, it is important that they rinse the instruments to remove the solution and associated debris to prevent proteinaceous residue and adverse reactions (e.g., fever). Enzymatic detergents can be temperature sensitive, and SPD technicians should follow the detergent manufacturer’s IFU for water temperature and monitor the water temperature during the cleaning process.

Because most detergents are not microbicidal, SPD technicians should change the manual detergent solution after each use as specified by applicable polices. The AAMI also states that facilities should determine what constitutes a “use.” They should dilute the detergents according to the IFU and thoroughly rinse the detergent from the instruments using tap water after the enzymatic presoak.

The SPD technicians require nonlinting cloths to clean instruments and different sizes of cleaning brushes to clean the lumens of instruments according to the manufacturer’s IFU. Although the technicians may use reusable cloths, they should be clean, nonlinting, and changed frequently. Brushes can be reusable or single use; the technicians should clean reusable brushes after each use and should either disinfect or sterilize them daily. It is important to purchase brushes that have IFUs for cleaning, disinfection, or sterilization. The SPD technicians should continually inspect reusable brushes for damage or wear and verify that they are in good condition and can effectively clean the instruments. The technicians should discard single-use brushes after use.

Manual Cleaning

The SPD technicians should perform manual cleaning of all instruments if mechanical cleaning equipment is not available or not operational and when the manufacturer’s IFU requires it (e.g., microsurgical instruments, rigid endoscopes, power equipment). Unless otherwise directed by the device manufacturer’s IFU, they should use low-foaming, neutral-pH enzymatic detergents or neutral-pH manual-cleaning detergents that prevent instrument damage and allow the technician to see what they are cleaning. The SPD technicians should submerge the soiled instrument in the detergent solution to decrease aerosolization of contaminants and thoroughly rinse the item after manual cleaning. The sink area should have three wells to facilitate this process: one for soaking and washing, one for rinsing, and one for the final rinse. If required by the manufacturer’s IFU, the technicians should perform the final rinse with treated water (e.g., reverse osmosis water).

Mechanical Cleaning

Although there are many types of mechanical cleaning equipment available for SPD use, ultrasonic cleaners and mechanical washers are the most common. The SPD technicians should refer to the manufacturer’s IFU for specific information related to equipment in their facility.

Ultrasonic cleaning

Ultrasonic cleaning is an effective way to remove soils from all surfaces, including hard-to-reach areas such as ratchets and box locks. The SPD technicians can use this method after soaking and rinsing instruments to remove gross soils.
Ultrasonic cleaning uses a generator to supply high-frequency sound waves to a tank filled with a diluted aqueous cleaning solution. Different types of ultrasonic cleaners are intended for use with different instruments.\(^2,3\) The ultrasonic waves create areas of varying pressure; during low pressure, they create microscopic bubbles that are imploded during high pressure. This process is called cavitation, and it disrupts the bonds holding the particulate matter to the instrument in every area that the solution touches.\(^2,3\) Generally, there is no bactericidal component to this process. Although many manufacturers recommend ultrasonic cleaning, SPD technicians should only use it when specified in the IFU for a specific device.

After filling the ultrasonic unit with detergent and water (in larger units, the detergent is automatically dispensed), the SPD technicians should follow the manufacturer’s IFU and run the appropriate cycle to release trapped air in the solution, a process called degassing.\(^2,3\) When air remains in the solution, the cavitation process is ineffective.

Ultrasonic cleaning cycles vary in length and generally range from 5 to 20 minutes; the cycles depend on the instrument manufacturer’s recommendations. These cleaners are effective only when used properly. The SPD technicians should not place plastic trays inside the unit because plastic absorbs the sound waves and interferes with the cleaning process.\(^10\) They also should not stack trays (Figure 6)\(^10\) or mix different types of metal instruments in the same load because this may cause instrument damage.\(^2\) Generally, detergents used in the ultrasonic cleaner are not microbicidal; therefore, SPD technicians should change the solution in the ultrasonic cleaner frequently and the SPD leader should determine the schedule for changing it.

After the ultrasonic cycle is complete, SPD technicians should thoroughly rinse the instruments with tap water before the next step (usually mechanical washing) begins. If the final cleaning step is the ultrasonic cleaning, the technicians should use critical water that has been treated to remove microorganisms and organic or inorganic materials for the final rinse.\(^3\) The SPD technicians should test the ultrasonic cleaner daily to verify that the unit is functioning properly and document the results of the testing.\(^2,3\)

**Mechanical washer**

Cleaning and decontamination are different processes; cleaning does not remove pathogenic microorganisms from instruments or make them safe to handle, use, or discard.\(^3\) Therefore, SPD technicians usually need to use an additional method to achieve decontamination. Often, a mechanical washer is appropriate for the next instrument processing step (if not contraindicated by the instrument manufacturer). Many facilities have a washer-decontaminator that cleans and decontaminates instruments so they are safe to handle without the need for personnel to wear PPE in the preparation and packaging area.

Washers may have operational malfunctions, so SPD technicians should perform a daily check of the washer before use and document the findings.\(^2,3\) The technicians

![Figure 6. Incorrectly stacked instrument trays in the ultrasonic cleaner (A). Photograph courtesy of Nancy Chobin. Ultrasonic cleaner loaded correctly with lumened devices (B). Photograph courtesy of Ultra Clean Systems, Inc, Oldsmar, FL.](image-url)
may need to verify the spray arms move freely and are not clogged and clean the drain strainers (ie, remove any small items that might have accumulated inside). The manufacturer's IFU should specify all required checks.

Most mechanical washers have several cleaning and decontamination cycles that vary with the make and model of the washer. Cycles may include a cold-water rinse, wash, rinse, instrument lubrication cycle, and drying. Mechanical washers use several chemicals that may include an enzymatic detergent, a mechanical cleaner, and an instruments lubricant (if applicable). The SPD leader should follow instrument manufacturer recommendations when selecting the detergents to be used in their washers. Many surgical instrument manufacturers recommend a neutral-pH detergent for cleaning, and some orthopedic instrument manufacturers specify that their instruments should not be subjected to alkaline detergents.

Many washers have a variety of preprogrammed cycles that are specific for utensils (eg, basins, bowls), instruments, delicate instruments, or instruments with heavy soil (eg, orthopedic instruments). Some implant manufacturers specify that their implants (eg, screws) should not be subjected to instrument lubricant, and many washers can be programmed for this requirement.

The SPD technicians need to know how to load the washer correctly because the detergent and water should be able to contact all surfaces of the instruments. The SPD technicians should not place bowls, cups, and other similar items on top of instruments because they could prevent the detergent from reaching some of the surface areas. They should separate the trays of multilevel sets and place the individual trays in the washer separately and remove all instruments from their sterilization containers during cleaning. If SPD technicians do not adhere to the manufacturer's requirements for loading the washer, a cleaning failure may occur.

**POLICIES AND PROCEDURES**

Sterile processing department leaders are responsible for developing appropriate policies for their areas. Two important policies for the decontamination area of the SPD address accountability for surgical instruments and the steps and processes involved in the decontamination of surgical instruments. The accountability policy describes the steps to be taken at the end of the surgical procedure in the OR and transportation of the used instruments to the decontamination area in the SPD. The second policy details the steps and equipment needed for the effective decontamination of instruments and devices. Without well-written policies and procedures, accountability and consistent processes do not exist. The SPD leaders should develop the facility's policies and procedures with input from infection preventionists using national practice guidelines (eg, AAMI, AORN, Occupational Safety and Health Administration) and should include references to the relevant standards or guidelines used in their development.
leaders who interface with the SPD (eg, OR, labor and delivery, interventional radiology, cardiac catheterization laboratory) should be involved in the policy approval process and share appropriate information on the policies with their staff members. The SPD leaders should review and update their policies as specified by facility policy or state regulations.

**EDUCATION AND DOCUMENTATION**

If possible, the SPD leader should work with the perioperative educator to develop and maintain a record of staff members’ onboarding education, ongoing education, and competency assessment and verification of the ability to successfully complete tasks related to their roles. The leader may need to have documentation of a competency assessment and verification for the cleaning of complex instruments or devices. The SPD leader also should provide education and competency verification activities for their staff members on the use of washers, including correct cycle selection.

The SPD leader also should have a written plan for routinely verifying and documenting that the facility’s cleaning equipment can properly clean instruments and devices after they are manually cleaned. Testing the cleaning effectiveness of mechanical cleaning equipment is an important part of the overall sterilization process improvement plan, and the AAMI recently changed their recommendation on the frequency of equipment testing from weekly to every day the equipment is used. This change reflects the importance of verifying that the equipment used to clean instruments (eg, ultrasonic cleaner, mechanical washer) is functioning correctly. The SPD leaders should review the documentation for all required testing and follow up on any adverse results.

**CONCLUSION**

Instrument cleaning and decontamination begins in the OR or procedure area; it is a critical multistep process that affects the end goal of sterilization. Surgical, procedural, and SPD team members should comply with manufacturer’s IFU and applicable regulations to complete cleaning and decontamination effectively. When staff members complete point-of-use instrument cleaning activities, adhere to requirements for transporting the instruments to the decontamination area, and complete the appropriate instrument cleaning and decontamination processes, they can facilitate instrument sterilization and safe patient care.

**REFERENCES**


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