Reprocessing in the ambulatory surgery center setting

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When a patient has surgery in an ambulatory surgery center their expectations are that the care they get will be the same as the care they would get if they were in a traditional hospital setting. To meet the patient’s expectations, the instrumentation needs to be processed following the same standards used in a hospital setting. This is confirmed in the ANSI/AAMI ST79 Comprehensive guide to steam sterilization and sterility assurance in health care facilities introduction overview, which states “This recommended practice encompasses steam sterilization in all health care facilities, including ambulatory-care and office-based facilities.”

Processing environment

The processing environment is an important part of infection prevention. The processing environment needs to be clean to prevent contamination of the instrumentation, provide employee safety and maintain sterility. It must also prevent confusion as to whether or not an item has been cleaned. For this reason, there are best practices for this area. According to AAMI ST79, the sterile processing area should have a one-way directional flow to prevent cross-contamination. Physical separation by walls is the best practice, however, in office-based facilities physical separation may not be possible. In that case, spatial separation could be acceptable, but it must be supplemented with a one-way directional workflow pattern, appropriate airflow characteristics, and good work practices.

The directional flow should begin in the area where contaminated items are received. The workflow should ensure that contaminants are contained. Work area design also should allow adequate space for all functions and should promote efficiency by minimizing distances between related areas. Containing contaminated instrumentation helps ensure employee safety.

Processing personnel need training and education to perform the critical task of instrument processing. Hiring a certified CSS Tech provides a distinct advantage as they have the foundation of medical device processing knowledge. As staff are on-boarded it is important that they are shown how to operate all of the processing equipment, perform all of the quality monitoring tasks, and perform packaging duties. They should also be informed of safety practices, be taught how to do instrument decontamination, preparation, inspection, packaging, and sterilization and be informed of facility storage policies and procedures. Processing staff should receive training for all new instrumentation and processing equipment. Annual competencies should be performed especially for the high-risk tasks such as processing flexible endoscopes, instrument decontamination and sterilization. The training should be documented and the records maintained.

There should be policies and procedures based on best practices developed and available for staff.

Point of use

Processing instrumentation is a team effort. It begins at the point of use to prevent the formation of biofilm. It is at the point of use that debris can begin to dry. Techniques used to keep debris moist are to place a towel moistened with water over the instrument, placing the instrument inside a package designed to maintain humid conditions, or using a pretreatment instrument spray. After the instrumentation has been treated, they need to be safely transported to the decontamination area.

Transport

Before being transported, the contaminated instrumentation needs to be contained and marked as being biohazardous. This is true even if the instrumentation is being transported across the hallway. The method of transport is not determined upon distance, it is determined by the contamination. According to the OSHA Bloodborne Pathogens...
Standard, contaminated instrumentation that is sharp must be transported completely covered in a closed container, or in a cart that is puncture-resistant, leak-proof and labeled as biohazardous. Non-sharp contaminated items can be transported in a leak proof container marked as biohazard. The acceptable labeling methods required by OSHA are the biohazard label or a red bag.

**Decontam room**

Instrumentation should only be cleaned in the decontamination room, including loaner instrumentation. The decontamination room should have all of the necessary decontamination equipment, cleaning implements and cleaning chemistries to thoroughly clean instrumentation. Personnel must wear the required personnel protective equipment (PPE) to be protected from biohazardous material. (See figure 1.) The standard PPE is:

- Hair covering/cap
- Fluid-resistant face mask
- Fluid-resistant gown with sleeves (for example, a backless gown, jumpsuit, or surgical gown)
- Eye protection
- Utility gloves that are durable to prevent tearing and leaking
- Liquid-resistant shoe covers should be worn if there is possibility of shoes becoming contaminated with bodily fluids.

Instrumentation should be cleaned following the instrument manufacturer’s instructions for use (IFU) in conjunction with the detergent’s IFU and processing equipment IFU.

Best practices recommend that instrumentation is disassembled and opened as it goes through the cleaning process. All lumened items should be brushed and flushed using the correct size and type of brush until the lumen is cleaned. Only clean, lint free cloths, sponges and brushes are used. Once these cleaning implements become soiled, they should be replaced. The cleaning solution is changed frequently such as after each instrument set or as the solution becomes soiled.

The cleaning solution should be prepared and maintained following the detergent manufacturer’s IFU. Detergents have recommended dilution and some detergents, such as enzymatic detergents, have recommended temperatures that must be maintained.

After instrumentation is thoroughly cleaned, it must be thoroughly rinsed to remove residues. The quality of rinse water is very important, as the rinse water should not leave any residues on the instrumentation.

Drying should be performed using clean lint-free cloths and instrument-grade air.

Instrumentation that has areas with difficult to reach areas such as lumens, joints or crevices should undergo ultrasonic cleaning. Ultrasonic cleaning is designed for fine cleaning and only used after the gross soil has been removed. Instruments should be disassembled and in the open position. Instrumentation should be placed in metal baskets with enough holes to allow for the ultrasonic cleaning action to get to all areas of the instrument. Just as the cleaning solution in sinks needs to be changed frequently, so does the ultrasonic cleaner. The ultrasonic manufacturer’s IFU should be followed.

Instrumentation processed through the washer disinfectant should have the gross debris removed and be in the open position, placed so that the water can access all areas of the instrument. Multi-level instrument sets should be placed separately in the washer. Instruments should not be crowded. The spinning arms should be checked for obstruction.

The detergents used should be compatible with both the washer and instrumentation.

Cleaning equipment should be tested at least weekly; preferably daily to assure it is performing correctly using cleaning verification tests. There are numerous variables that can affect the cleaning ability of mechanical washers; to assure they are functioning properly verification testing is recommended. In addition, the mechanical cleaning equipment IFU should be reviewed and followed. Some manufacturers recommend routine preventative maintenance be performed.

**Preparation & sterilization**

After instrumentation has been cleaned it is ready for inspection and assembly. Preparation and packaging are performed in a clean environment. There should not be any instrumentation that has not undergone the cleaning process in this area. Instrumentation is inspected for functionality and cleanliness. Lighted magnification should be available. Instrumentation must be dry. If absorbent material must be used it must be nonlinting. Lumened instruments should be dried using instrument grade air.

Instrument sets should be assembled so that the sterilant can reach all surfaces. The sets should not be too dense and the tray weight should not weigh more than 25 pounds. All jointed instruments should be in the open or unlocked position, multi-part instrumentation should be disassembled, unless the IFU states otherwise. Plastic-peel pouches should not be placed in instrument sets. Before double pouching with plastic peel-peel pouches, the manufacturer IFU should be consulted to assure they have been validated for this practice. Type 4, 5, or 6 chemical indicators are placed in the areas most resistant to the sterilization process, which may not necessarily be the center of the instrument set.

Instrumentation is packaged using packaging that has been validated for the method of sterilization to be used. To differentiate processed from unprocessed packages, a Type 1 chemical indicator is placed on the exterior of each package, unless the interior chemical indicator is visible such as in a peel-pouch package.

The sterilization method selected is based on the instrument IFU. It is important to completely review the IFU as some items may require a specific type of cycle such as a dynamic air removal or an extended sterilization cycle.

The sterilizer is loaded so that adequate space is left between items to allow for air removal, penetration of steam into each package, and steam evacuation. Basins and solid bottom pans should be positioned in the same direction and in a manner that allows for easy drainage. Plastic-peel pouches should be placed on their sides. If the load contains an implant, a biological process challenge device (PCD) which also contains a Type 5 chemical integrator is processed with the load to indicate that conditions for sterilization were met. The implant should be quarantined until the biological indicator results are known. Non-implant loads are monitored using a Type 5 or Type 6 chemical indicator or biological indicator PCD. All items in each load are assigned a lot control number and each item is labeled with that lot control number. A record with these lot control numbers is kept for all of the items in each load.

The sterilization cycle is selected and the cycle begins. At the end of the cycle the...
Physical parameters in the form of the sterilizer print out are reviewed to assure all of the sterilization parameters have been met. If so, the printout is signed by the sterilizer operator indicating that the sterilization parameters have been reviewed and met. If the sterilization parameters are not met, the sterilization load cannot be released and the supervisor needs to be contacted.

The load is allowed to cool before being handled. The external chemical indicators are checked to assure they changed. If a chemical indicator PCD is used, it should be checked to assure the endpoint has been reached. The biological indicator is incubated according to the manufacturer’s IFU.

Immediate use steam sterilization

Immediate use steam sterilization (IUSS) is a method used for instrumentation that is needed immediately. All of the processing steps described earlier are followed, except for the packaging and sterilization dry time. IUSS should not be used for implants unless it is an emergency. IUSS should not be a common method of sterilization to compensate for low inventories. Instrumentation should be packaged using a container that has been validated for IUSS and labeled as such to avoid confusion. The correct cycle must be used, monitored and documented. IUSS dry time is one minute or less. At the completion of the cycle, instrumentation will be hot and wet, so care must be taken to prevent burns. As the term implies, these instruments are expected to be used “immediately” and not placed on a shelf for future use.

Sterile storage

It is important to maintain the sterility of the sterile packages. Sterility is based on events; contamination is an event that compromises the sterility of the package. An event could be improper handling, transport or storage. A package is no longer considered sterile once it has been opened, punctured or becomes wet. To protect the integrity of the sterile packages, they must be stored in controlled conditions. The area must be clean and the traffic should be restricted. The environmental conditions should be maintained at a temperature below 75°F, relative humidity should not go above 70 percent and there should be at least four air exchanges per hour. The packages should be stored far enough away from the floor, the ceiling, and outside walls to allow for adequate air circulation, at least 2 inches from an outer wall and at least 8 to 10 inches above the floor. Fire codes should be followed. The packages should not be crowded or stored in an area that may be wet.

Quality monitors and verification tests

Throughout all phases of the sterilization process quality monitors are used to verify that the processes being used are effective. Quality monitoring begins with the decontamination processes. The automated mechanical washers (i.e., washer-disinfectors and ultrasonic washers) should have verification testing performed weekly, preferably daily, during routine use and upon installation, after major repairs, and when evaluating or changing to a new type of cleaning chemistry. These quality monitoring results should be documented.

Verification tests are also available for instrumentation that undergoes manual cleaning. The methods available are adenosine triphosphate (ATP) and protein monitors. Both methods require that outer surfaces be swabbed for testing. Luminated instrumentation can either be swabbed or flushed with water. In the case of water sampling, the water is tested for ATP or protein levels.

When using an ATP verification test, contaminated surfaces show high levels of ATP, clean surfaces show low ATP levels. The ATP collected on a swab is converted to a light signal, which is measured using a specific type of luminometer. These results are quantitative. ATP bioluminescence is measured in Relative Light Units (RLU), which provide a metric for measurement.

A protein test can also be used to detect protein residues left on surgical instruments due to inefficient cleaning. The protein comes from body fluids. This test shows a color change. There are no numeric values.

To assure sterilizers are working effectively, quality monitoring is performed on a routine basis. All sterilizers should be tested with biological indicators. Biological indicators are considered the “gold standard” for sterilization monitoring. The reason being biological indicators are the only sterilization monitors that provide a direct measure of the lethality of the process. These indicators are used to show that the conditions were adequate to achieve sterilization. When using these tests it is important to follow the biological indicator manufacturer’s IFU. Included in the IFU is information on the sterilization modality, how to perform the test, along with incubation instructions. Each day that the test is performed, a control from that same lot should be incubated in the same incubator.

The biological and control lot number must match and be documented. Biological monitoring should be done at least weekly, but preferably every day that the sterilizer is in use and in every load containing implants. Implants should not be used until the results of the BI testing are obtained. As was stated earlier, biological indicators should be used within PCDs.

When using a dynamic air removal sterilizer, a Bowie-Dick test should be run daily, before the first processed load. A Bowie-Dick test is used to detect air leaks, inadequate air removal, inadequate steam penetration, and noncondensable gases. This test can be run without a dry time and should be run in the first load of the day. As ambulatory surgery centers don’t run 24/7, running at least one empty chamber cycle to heat up the sterilizer before doing the Bowie-Dick test can help prevent false failures. The Bowie-Dick test pack should be placed horizontally in the front, bottom section of the sterilizer rack, near the door and over the drain, in an otherwise empty chamber. The manufacturer of the Bowie-Dick test will provide information on how to perform and interpret the results of the test.

Qualification testing is performed for sterilizers that have been relocated, had major repairs, malfunctions, sterilization failures and after installation. The testing order differs for qualification testing than the routine monitoring. Three consecutive cycles should be run, one right after the other, with a biological indicator PCD. For dynamic air removal sterilizers three consecutive cycles should then be run, one right after the other, with the Bowie-Dick test.

Conclusion

Sterilization is a complex process. All of the processes should be performed following the best practices as described in this article to provide the highest level of sterilization assurance. HPN

References:

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Circle the one correct answer:

1. The instrument workflow should function in the following manner
   a. Process the expensive instruments first
   b. One-way directional flow
   c. Clean and contaminated instruments can be mixed so long as they are labeled
   d. Place the utensils on the front of the line.

2. Recommended training for personnel performing instrument processing includes:
   a. Certification with annual competencies
   b. A nursing degree
   c. Listening to a former employee
   d. Radiology school

3. Cleaning begins:
   a. In the decontam room
   b. After the instruments have been sorted
   c. At the point of use
   d. At the sink

4. Covering contaminated instruments for transport should be performed
   a. For all contaminated items
   b. When the transport needs to go down a second hallway
   c. Only for sharp items
   d. Only in hospitals

5. Standard PPE for the decontam room are:
   a. Utility gloves, plastic apron and face shield
   b. Yellow gown, utility gloves, face shield
   c. Utility gloves, fluid resistant mask, water impermeable gown with impermeable sleeves, hair covering, eye protection
   d. Face mask, gloves, gown

6. At the end of the sterilization cycle
   a. The door is opened and instrument are used
   b. The sterilization parameters are checked to assure the sterilization parameters have been met.
   c. Instruments have water on them so they are left to dry
   d. Instruments are wrapped

7. Cleaning verification of automated washers should be performed:
   a. Weekly, preferably daily
   b. When the instruments have debris on them
   c. Monthly
   d. With eye instruments

8. Sterilizers should be tested with a biological indicator PCD
   a. When the surgeon requests
   b. When infections occur
   c. Weekly, preferably daily and with all implants
   d. If instrumentation couldn’t be cleaned

9. A Bowie-Dick test is performed in a dynamic air removal sterilizer
   a. The first load of the day in an empty chamber
   b. In the same load as the biological indicator
   c. Weekly preferably daily
   d. With implants

10. The ANSI/AAMI ST79: Comprehensive guide to steam sterilization and sterility assurance in health care facilities is for
    a. Only hospitals
    b. Member hospitals
    c. Only outpatient surgery centers
    d. All healthcare facilities including ambulatory centers

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