**LEARNING OBJECTIVES**

1. Explain the value of standards and guidelines for a hospital’s reprocessing policies and procedures.

2. Discuss who comprises the surgical instrument protection team, and why.

3. Detail key standards and guidelines that should be incorporated into an effective instrument protection program.

**New tools, old ways?**

In spite of the many surgical advancements, there seems to be varying quality and consistency in the performance of evidence-based pre-cleaning in today’s surgical suites. For example, it is widely understood that surgical instruments need to be wiped down at the point of use, and that sterile water is the liquid of choice. Yet, when there is no sterile water available for scrub techs, I’ve observed them dampening laparotomy sponges with saline to wipe down the instruments. The “old” practice of using saline is not recommended by any standard or guideline, because evidence shows that the chloride ions in saline solutions can cause pitting and deterioration of metal surgical instruments (AST, 2009). Is saline use occurring because of a lack of information, misinformation, or habit? Are the scrub techs working independently of the SPD, or as part of an “instrument protection team,” dedicated to performing best practices that do no harm to instruments or patients?

Because they are tied together by the devices they both handle daily, and because they are both charged to prevent infections for the ultimate protection of patients, it is vitally important that OR scrubs and SPD personnel join forces. They must have a clear understanding of each other’s roles and responsibilities as part of the instrument protection team, so that each person can execute their practices optimally and help achieve the team’s goal.

**Best practices – provided for a reason**

Many of today’s reusable medical devices have lumens, nooks and crannies that create additional places for blood, tissue and body fluids to “hide,” or become lodged or dried and difficult to remove. Since antibiotic-resistant infections are emerging at an alarming rate, it is more important than ever before to follow the recommended sterilization and decontamination guidelines and standards offered by healthcare professional and regulatory agencies, which are evidence-based and considered to be the best available methods. They exist to provide a foundation for each hospital to incorporate into its own optimal...
cleaning, decontamination and sterilization processes and procedures. In this module we’ll discuss a number of reprocessing guidelines and standards that should inform your instrument protection and reprocessing procedures.

Protection point one: the OR

It’s not news to anyone that before we can achieve effective terminal sterilization, we must achieve effective decontamination, and to do this we must first perform effective cleaning, which begins with the removal of visible soil (organic and inorganic material) from channels and surfaces at the point of use. So, we define the instrument protection cycle as beginning at the point of use, with the first scrub person at the sterile field.

If the scrub person doesn’t protect the instruments as they are used in the OR, these reusable medical devices are at risk of transmitting contamination to the next patient. Residual bioburden may dry inside channels and on surfaces, and if not completely removed during reprocessing, can block sterilant from reaching that area of the instrument surface. In addition, the use of saline for cleaning may cause areas of damage and/or corrosion that can harbor biofilm. Poor point-of-use care also makes the cleaning and decontamination process much more difficult and time-consuming for the SPD team, which increases turnaround time back to the OR for that device.

Both the Association of periOperative Registered Nurses (AORN) and the Association of Surgical Technologists (AST) in their respective Recommended Guidelines/Standards of Practice endorse the practice of cleaning surgical instruments during the surgical procedure by removing gross soil from the surface of the instrument(s) with a sponge moistened with sterile water. They also state that instruments with lumens should be flushed with sterile water to remove blood and debris trapped within the lumens.

AORN and AST also recommend that a labeled basin of sterile water be made available at the sterile field for the purpose of cleaning instruments throughout the surgical procedure. Larger instruments, such as orthopedic reamers, may require a labeled basin of water positioned in a ring stand to allow for soaking, which will be more effective in removing gross soil (Lewellyn, 2016). Post-procedure, AST recommends that soiled instruments be soaked in a solution of sterile water and an enzymatic detergent. They refer you to the manufacturer’s instructions for use (IFUs) for the correct proportion of sterile water to enzymatic agent.

If instruments are to be transported to the SPD in the soaking solution, the guidelines require a splash-proof containment device to ensure the safety of healthcare workers. Another option is the application of a moisturizing agent and/or covering the instruments with a wet towel to prevent the drying of soils.

To sum up, the best practices for protecting reusable devices at the point of use include:

- Keep them clean and moist during the surgical procedure with a lap sponge moistened with sterile water, or by wiping them down and placing them in a basin of sterile water.
- Flush all lumens with sterile water to remove bioburden.
- Where appropriate, disassemble the devices into their component parts and moisten them before transporting them to the SPD.
- Send them for reprocessing as soon after the procedure as possible, in a splash-proof container, with a wet towel, enzymatic soaking solution, or moisturizing transport gel applied thoroughly over all components and instruments to maintain moisture.

Protection point two: the SPD

SPD technicians are responsible for the lion’s share of the reprocessing function. They are responsible for all the complex cleaning, preparation, packing and disinfection/sterilization processes, which require precise activities and the management of numerous key variables. Their jobs require a grasp of many cleaning concepts and scientific facts that inform what they do every day. The American National Standards Institute (ANSI) and the Association for the Advancement of Medical Instrumentation (AAMI) standard, ST79 2010, Section 7.5.1, notes that SPD managers have the responsibility to make sure their staff understands the various factors that affect whether or not a cleaning and disinfecting process will be fully effective. These factors include:

- Water quality for rinsing and steam sterilization
- Optimal detergents and/or enzymatic cleaners for the devices
- The appropriate washing method (manual, mechanical or both)
- The right equipment/impliments for manual and mechanical cleaning
- Correct rinsing and drying procedures
- Proper preparation of devices for disinfection/sterilization

Pre-cleaning

Once the soiled instruments reach the SPD, it’s important to continue the cleaning process as soon as possible. Delays between any steps of the reprocessing procedure afford microbes the opportunity to grow, which makes subsequent cleaning and disinfection/sterilization steps more challenging (FDA, 2015).

More specifically, the longer a contaminated device sits waiting to be cleaned, the greater the chance of biofilm building. Biofilms are strong networks of interconnected microbes that set up house on or in a medical device. The microbes develop ties or connections that are tightly woven together as they attach to the surface. They especially love internal surfaces of lumens, and nooks and crannies of a device that are hard to reach or clean. Once established, they are not easily removed. They protect themselves by forming a barrier layer resistant to disinfectant penetration, which makes cleaning and decontamination even more challenging. Thorough and timely cleaning, while the device is still moist, decreases the opportunity for biofilm development, which reduces the opportunity for biofilm to interfere with the sterilization process by acting as a barrier to the chosen sterilant (steam, hydrogen peroxide, peracetic acid, or other sterilizing agent or process).

Bioburden, such as blood for example, has unique properties that make it particularly challenging to remove. In a liquid form, blood can ooze into difficult-to-clean cracks and crevices of a surgical instrument. Once it lands in these microscopic irregularities, it coagulates and dries. The fibrin filaments in coagulated blood cling to those microscopic irregularities, requiring rehydration and “elbow grease” or “chemical warfare” to remove it. The best weapons available to SPD technicians are: high pH detergents, enzymatic solutions, mechanical scrubbing, and high-pressure water sprayers. Neutral pH detergents are no match for fibrin filaments by themselves, but when combined with an enzymatic agent, they can work well.

The proteins in blood are another component that can be difficult to remove. Once denatured by heat or chemicals, they become even harder to remove. An initial cool water rinse can help prevent denaturing of watersoluble proteins such as albumin (Perkins, 1969 as cited by AAMI ST79).
The importance of the right chemistries

According to ANSI/AAMI ST79, 7.5.2, “The primary agent that affects cleaning is the detergent solution or the combination of detergent and enzymatic solution.” There are three main categories of detergents to know about: enzymatic presoaks and cleaners, neutral detergents, and alkaline detergents. Enzymatic products should be used when there is mostly organic soil (e.g., blood, body tissue and fat), and when there is no mechanical action being used, such as in an automated washer-disinfector. Enzymatics work well in an automated environment such as a washer-disinfector and in combination with neutral detergents. In locations/facilities where water quality is a problem (particularly hard water >200 parts per million), an alkaline detergent is a better option. SPD staff must refer to the detergent manufacturer’s, device manufacturer’s and washing equipment manufacturer’s instructions for use (IFU) to determine correct dilution amounts, water temperature, soak and wash times, and to verify device compatibility with each selected chemistry.

Manual Cleaning

ST79, 7.5.3.2 states, “Manual cleaning is often recommended for delicate or complex medical devices, such as microsurgical instruments and air-powered drills.” To prevent aerosolization, immersible devices should be cleaned while submerged under water. Non-immersible devices should be cleaned in a manner that prevents or will not produce aerosols, then should be rinsed and dried according to each manufacturer’s IFU. Use device manufacturer-recommended cleaning utensils (e.g., brushes). Following the cleaning process, thorough rinsing is required to assure the removal of all soil and detergent residues.

Mechanical Cleaning

According to ST79, 7.5.3.3, mechanical or automated cleaning and rinsing are functions performed by equipment intended to remove soil and microorganisms through the incorporation of mechanical action combined with thermal and/or chemical disinfectant processes. ST79 warns us that if blood remains on an instrument after the wash phase of a mechanical cleaning equipment cycle, the blood’s water-soluble proteins will be denatured in any subsequent heated process, such as the hot disinfection phase of a washer-disinfector or washer-sterilizer cycle or a steam sterilization process. Denatured proteins are much harder soils to clean the next time through the washing process. It is imperative that all traces of blood, body fluids, and debris be removed during the wash phase of a mechanical cleaning equipment cycle. Failure to do so could result in undetected bioburden that could pose a risk to employee health or result in a patient infection (2010).

Rinsing

Disinfection and sterilization efficacy can be affected if any residual soils or detergents remain following the final rinse. These residues can also result in adverse reactions in patients. It is equally important that the final rinse water is treated/filtered and free from contaminants (e.g., pyrogens) and is of a quality that will not stain the instruments (ST79, 2010, 7.5.4).

Verification of clean

The cleaning verification process is the final step and, as the others, is extremely important to the assurance of patient safety. This last step in the cleaning/decontamination process has three stages: 1) visual inspection (with the naked eye); 2) visual inspection aided by magnification equipment; and 3) other methods that measure organic residues. There are three types of verification indicators available that will detect the following organic material: ATP, hemoglobin, and protein. Indicators should be easy to use, sensitive, accurate, rapid, free of interfering substances, robust and repeatable.

Successful disinfection and sterilization are absolutely required to ensure patient safety and minimized HAI/SSI rates. The cleaning process, therefore, must also be successful. “Professionals in the field ought to seek out whatever means are available and practical to verify this function...whether the process is accomplished by hand or mechanically” (ST79, 2010, 7.5.5).

Protection point three: the Team

In a hospital, every healthcare professional will tell you they have their own job to do and are pressed for time. This may well be true; each professional in the OR and SPD certainly has important and specific duties and responsibilities he or she must execute. However, although they are segregated in different areas of the hospital, the OR and the SPD are “tied at the hip.” They depend on each other to achieve safe, successful surgical and diagnostic procedures that bring benefits to the patient and revenue to the hospital. Members of these two departments comprise the core of the surgical instrument protection team because they handle the same tools and serve the same “customers”; the surgical patients and the surgeons, within the same admission periods. In addition, “turnovers” are critical for both the OR and the SPD. ORs must turn cases efficiently to maximize the number of procedures that can be completed in a day; SPDs are under pressure to turn over (reprocess) instruments quickly enough to keep up with the daily surgery schedule and the available instrument inventory. In other words, they are basically on the same team anyway.

There is no excuse for these trained professionals not to collaborate to develop solutions for suboptimal processes that put patients, staff and instruments at risk, and that have the potential to cost the hospital reimbursement income and even its reputation. In fact, both departments can, and should, be committed to providing “continuity of care” for all expensive and delicate reusable medical devices.

Elimination of all risk is not realistic, but there are two things both departments can do to mitigate it. The first is to learn, understand and respect each other’s roles and responsibilities related to instrument care and reprocessing, and the reasons for them. The second is to jointly develop steps that improve the quality and consistency of care for their reusable medical devices. These efforts will certainly result in an increased level of safety for the patients and healthcare staff, as well as prolonging the useful life of expensive advanced devices.

The bottom line is this: the work of the surgical instrument protection team matters. As a functional and ethical unit, this team must establish and maintain close relationships among its members. Furthermore, team members must establish and maintain the kind of regular communication that anticipates issues and addresses them before they result in negative consequences. By doing this, they will be actively contributing to their hospital’s reputation and bottom line.
The Surgical Instrument Protection Team

Circle the one correct answer:

1) What should the foundation be for the development of cleaning, decontamination and sterilization processes and procedures?
   a. The number of instruments sets being processed daily and the number of washer-disinfectors available.
   b. Evidence-based recommended decontamination and sterilization guidelines and standards offered by healthcare professional and regulatory agencies.
   c. The rapid pace of emerging antibiotic-resistant infections.
   d. AORN guidelines.

2) Effective cleaning is initiated at the point-of-use. Which two organizations recommend the practice of cleaning surgical instruments during surgical procedures?
   a. AORN and ANSI/AAMI
   b. FDA and AST
   c. CDC and AORN
   d. IAHCSMM and AST
   e. AORN and AST

3) Which section of ANSI/AAMI ST79 2010 notes that Sterile Processing Department (SPD) managers have the responsibility to make sure their staff understands the various factors that affect whether or not a cleaning and disinfecting process will be fully effective?
   a. Section 7.5.5.
   b. Section 7.5.1
   c. Section 7.5.3

4) The FDA explains that delays between any steps of the reprocessing procedure afford microbes the opportunity to grow, which makes subsequent cleaning and disinfection/sterilization steps less challenging.
   a. True
   b. False

5) There are three key instrument protection points. At which point within the cycle of protection does the initial removal of visible soil begin, and with whom?
   a. At the point of use with the surgical assistant
   b. At the point of use with the circulating nurse
   c. At the point of use with the perioperative scrub
   d. At the point of use with the surgeon

6) It’s an acceptable practice to use sterile saline in the OR as a solution for cleaning surgical instruments.
   a. True
   b. False

7) It is extremely important for SPD technicians, who are responsible for the vast majority of complex cleaning, preparation, packing and disinfection/sterilization processes, to be knowledgeable in:
   a. Instrument cleaning concepts
   b. Scientific facts related to cleaning
   c. Instruments’ instructions for use
   d. All of the above
   e. a only

8) The three main categories of detergents are enzymatic presoaks and cleaners, neutral detergents, and alkaline detergents. Of these three, which one should be used when there is mostly organic soil and when there is no manual action being used?
   a. Neutral detergent
   b. Alkaline detergent
   c. Enzymatic presoaks and cleaners
   d. All of the above

9) What are the unique properties of blood that make it particularly challenging to remove?
   a. It coagulates and dries
   b. It oozes into difficult-to-clean cracks and crevices
   c. The fibrin filaments in coagulated blood cling to microscopic irregularities
   d. All of the above

10) Efficient instrument turnover is a critical function for:
    a. OR and Environmental Services
    b. OR and SPD
    c. SPD and Environmental Services

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