Is that really clean?

by Sarah Brown, MBA and Sandra Beauclair, BSN, RN, CNOR

Infection is already a risk. Prevention of healthcare-associated infections (HAIs), particularly surgical site infections (SSI), continues to be a top priority for the healthcare workforce and the facilities in which they work, or at least it should be. A recent article reported a seven-month-old infant who underwent surgery in which visible bioburden from a previous case was discovered on the surgical instruments. Fortunately, this particular case had a good outcome; no SSI or other ill effect developed. Sadly, this is not the outcome for many surgical patients.

In 2011, the Centers for Disease Control and Prevention (CDC) estimated that 157,500 surgical site infections occurred from inpatient surgeries. There are, of course, a number of variables that will put one patient at greater risk than another patient, such as older age, diabetes, obesity, smoking, a compromised immune system, and ischemia (poor blood supply) due to vascular disease or irradiation. Trauma, shock, blood transfusion, hypothermia (body temperature below 35° C), hypoxia (not enough oxygen reaching the tissues), and hyperglycemia (high blood sugar) are other physiological states that also increase the risk of SSI. A patient undergoing abdominal surgery or a contaminated or “dirty” procedure also has a higher risk of infection. With all these risks already facing surgical patients, there is no excuse for adding avoidable ones. Improperly reprocessed medical devices should never, ever be the cause of an SSI.

Patients trust that the healthcare workforce is properly trained and certified; that they know and understand the standards and guidelines that are in place for their particular area of responsibility. This may not always be the case. Furthermore, it’s not uncommon for healthcare department teams to function in isolation and not collaborate with one another. However, patients expect and deserve the absolute opposite. Our job then is to ensure that the care patients receive will keep them safe and cause no harm.

“Squeaky clean”

Obviously, we have no control over an SSI that is a direct result of a person’s health condition, but we do have control over how we perform healthcare tasks, and specifically how we pre-clean, clean and further process the instruments that are used to perform surgical procedures. The job of reprocessing reusable medical devices (including surgical instruments) is the responsibility of the entire “instrument protection team,” as discussed in the September 2016 HPN Self-Study Series article.

We know the process of cleaning is complex because of the intricacy of today’s advanced devices, and the detailed, time-consuming recommended steps needed to assure thorough cleaning and disinfection. It can be intensely challenging to achieve the desired perfect, “squeaky clean” result, but that shouldn’t stop us. To achieve complete sterilization, which is the removal of virtually all living microorganisms, reusable medical devices must be squeaky clean, with no exceptions. Any bioburden remaining on a device will prevent the surfaces beneath that bioburden from being sterilized, so the instrument protection team must ensure that reusable medical devices are squeaky clean.

It’s fair to say that today’s medical device cleaning process is more complex than the sterilization process that follows it. The new diagnostic and surgical tools in use today are delicate, and have lumens, serations or other hard-to-reach nooks and crannies that provide the perfect places for microorganisms to hide. Effectively cleaning these very expensive reusable instruments, and without causing damage, requires a deep knowledge of the device and its instructions for use (IFU), a thorough operator knowledge of today’s advanced automated cleaning equipment, and careful handling and attention to detail. This required level of diligence is much greater than ever before.

Just as there are different modalities for disinfection and/or sterilization (e.g., steam, dry-heat, liquid chemical sterilant, hydrogen peroxide, EO and high-level disinfection), there are also different modalities for cleaning reusable medical devices. However, the most critical factor in the cleaning process is the human one – it’s the protective role of each healthcare team member who handles the devices and the cleaning equipment during the cleaning process. Automated washer-disinfectors and ultrasonic cleaners are powerful cleaning tools, but the overall success of clean-
ing still depends on the people executing all the necessary steps correctly each and every time. There can be no margin for error or lapse in the cleaning process. Every nook, cranny and hard-to-reach spot on a reusable medical device must be made squeaky clean.

**Let’s get this cleaning started**
Where does the cleaning process begin? It starts in the surgical suite, at the point of use, with the scrub nurse or surgical technologist. The scrub person has primary responsibility for pre-cleaning all reusable medical devices during a procedure. They are also responsible for pre-treating the devices immediately after the procedure, to maintain moisture until they are transported to protection point two, the decontamination area of the sterile processing department (SPD).

The surgical technologists must remove all visible soil (organic and inorganic material) from channels and surfaces. This can be done during the procedure. Before the used instruments are sent to the SPD, they can be covered with a sterile water-soaked towel or treated with a product designed to adhere to instrument surfaces, to keep them moist and loosen bioburden. The surgical technologist should send soiled instruments to the SPD as soon as possible, to prevent soils from drying on device surfaces.

The sterile processing technician in the SPD relies heavily on the effectiveness of the pre-cleaning process performed in the surgical suite. The decontamination team spends time at the sink pre-cleaning the instruments while also inspecting them for damage and visible soil. Well-cleaned and moistened instruments and devices can save time during inspection and pre-cleaning.

The full pre-cleaning process in the SPD involves soaking, inspecting, priming, brushing, flushing and rinsing the instruments, following the manufacturer’s IFU and all appropriate recommended guidelines and standards. Unless medical devices are limited to manual cleaning only in their IFU, pre-cleaned devices can then be placed in an ultrasonic cleaner and/or a washer-disinfector (WD). Both are means to automate the cleaning of surgical instruments and utensils in a reliable and repeatable manner.

**The power of ultrasonic cleaning**
A reusable device may take a detour into an ultrasonic cleaning system or ultrasonic irrigation system before it goes into a WD. This step is another opportunity to remove bioburden and prevent biofilm build-up. The cleaning mechanism used in an ultrasonic process is fairly simple, but extremely effective. Small microscopic implosions are induced by high frequency pressure (sound waves) that collide with soils adhering to metals and plastics, which removes them from the instrument’s surface. The frequency of the waves dictates the size of the implosions and the size of the contaminant removed, and which crevices it is removed from. This method can remove bioburden on reusable devices very effectively in a short period of time. However, the instruments still require additional cleaning and thorough rinsing after being processed in an ultrasonic cleaner.

Generally speaking, the advantage of an automated mechanical cleaning method is that it cleans much more efficiently and consistently than a human being. Automated washers often out-perform their human counterparts because they are able to thoroughly clean entire batches of instruments at a greater speed, while also accessing hard-to-reach surfaces. This, in turn, improves productivity and cleaning quality. According to ANSI/AAMI ST79 7.5.3.3, mechanical cleaning equipment removes both soil and microorganisms through an automated cleaning and rinsing process; it may also include a thermal disinfection process that is capable of destroying various types of microorganisms.

Before placing any reusable medical device into an automated system, it’s always important to consult the medical device manufacturer’s IFU to determine which cleaning method(s) and chemistries are appropriate. This not only assures maximum cleaning effectiveness, but helps to avoid unnecessary and expensive damage to the instruments.

**All trays matter**
The SPD pre-cleaning technician’s performance can also affect the efficacy of each WD or ultrasonic cleaner cycle. After the initial manual cleaning, the technician’s next step is to place the instruments in the appropriate tray and then load the tray into the washing system.

Tray design plays a very important role in the efficacy of a WD’s cycle. The tray design must allow the cleaning chemistry and mechanical cleaning action to reach the devices. The height of the tray itself and the height of the loaded instruments are both very important considerations. The height of the tray, with or without instruments loaded, should allow the washer spray arms to operate and rotate freely. When the spray arm does not rotate, chemistry and water are not reaching the devices effectively. The same principles apply to automated cleaning equipment as they do to sterilization: The chemistry and water will not clean the devices if it cannot reach them. Furthermore, if the tray has been loaded to resemble a stainless steel replica of Mt. Everest, or the tray is solid on all four sides, it is likely that the water and chemistries will not reach all of the devices.

Another important consideration is the weight of the tray and its contents. The weight of a loaded tray should be manageable for staff to handle, and should also be manageable for the automated cleaning equipment to handle. The chamber capacity of an ultrasonic cleaner or a WD is limited to a particular weight, and most models specify what that is. The weight capacity guidelines help establish the total load size that is cleaned most effectively by that system.

Here are some of the best practices to keep in mind when loading trays for washers:
- The number of instruments in a tray and total weight of the tray should follow the washer’s IFU.
- Hinged devices should be opened and placed on stringers.
- The use of silicone positioning or hold-down screens helps to ensure proper device position and prevents obstruction of spray arm rotation.
- Trays used to hold the devices should not have solid sides or bottom; the design should allow water and chemistry to pass through freely.
- Devices should be positioned to minimize the collection of moisture.

**No strain, no pain**
The reprocessing function should protect more than the hospital’s instruments; it must also protect another highly valuable asset—its personnel. In 2010, the Occupational Safety and Health Administration (OSHA) reported that over 50 percent of healthcare worker days away from work were caused by strains and sprains. These strain and sprain injuries were not isolated to healthcare staff who provided direct patient care. The weight of instrument sets, from minor general surgery sets to heavy orthopedic sets, can potentially cause harm to the staff members who are most responsible for handling them. Any opportunity to reduce the risk of avoidable injury to healthcare workers is worth considering.
To mitigate the risk of injury while loading and unloading trays of instruments, proper body mechanics should be encouraged and the workflow should facilitate minimal handling. The less often a person has to pick up, carry, and put down a tray filled with instruments, the less chance of personal injury. Washer racks should be securely positioned on a transportation cart, to make loading and transferring the load to the WD more ergonomic. Some washer rack designs allow staff to continuously load the racks from one side, which further decreases the risk of injury because the person loading the rack is not required to walk around the rack to place the tray down securely.

In addition to the rack design, automating the transport process to the WD can further improve staff safety. This conveyor-based method of transferring racks from the sink to the WD minimizes the handling of heavy sets, which improves worker safety and enhances productivity at the same time.

The cycle counts
Once a rack has been properly loaded into the WD, the appropriate cycle must be selected by the operator. The reusable device’s IFU should specify which washing and thermal disinfection parameters and chemistry are recommended.

Most WDs come pre-programmed with commonly used cycles for reusable devices, such as Standard Instruments, Gentle, Orthopedic, or Utensils. Some may also include cycles for minimally invasive surgical (MIS) instruments and/or robotic devices. Some WDs offer the ability to customize a cycle to specific parameters required for a particular reusable device or for a healthcare facility’s protocol. The choice of cycle has a direct impact on the cleaning result, because the parameter settings (level of impingement, length of wash phases, rinsing phases, and the type of chemistry injected) will vary with each type of cycle.

Bioburden is removed by the washer’s mechanical impingement, which means “strike against.” The washer spray arms deliver a measured mixture of water and chemistry (detergent) that removes soils from the items in the load. Higher impingement levels deliver the liquid from the spray arms with greater pressure, to strike and remove bioburden very effectively. However, high impingement may not be suitable for all types of reusable medical devices. A low impingement cycle may need to be selected to send a less forceful stream of water and chemistry onto instruments that are more delicate.

The cycle can be selected in two ways: the operator can manually select the cycle for each load placed, or the washer can select it with information from a scanning technology. The use of automated scanning significantly reduces the likelihood of operator error. Here are the best practices when it comes to cycle selection:

- Use the chemistry recommended by the device manufacturers’ IFU.
- Select or program the cycle parameters to optimize cleaning for the specific devices in the load.

The 411 on drying
Instruments should be dry before they go to the prep-and-pack area on the clean side of the SPD. This makes them easier for staff to handle, but more importantly, for sterilization methods commonly used in the SPD (e.g., ethylene oxide, hydrogen peroxide, or steam sterilization), the absence of moisture is required for effective sterilization. For this reason, WDs also automate the drying process, to provide a repeatable, consistent, lint-free drying method and to reduce the workload for staff.

Automated drying can be an effective and time-saving option. The drying phase in WDs can be lengthened or shortened, depending on the requirements of the reusable devices. The drier the instruments are when they are removed from the WD, the less manual drying is required of the SPD technician in the prep-and-pack area. Furthermore, hand-drying instruments with a cloth increases the risk of leaving lint on the instrument, which in turn has the potential of interfering with sterilization and thereby increasing the risk of SSI.

ANSI/AAMI ST79 recommends the use of a non-linting cloth or textile if additional hand drying is needed. As with the other parameters of the WD cycle, it is important to consult each device manufacturer’s IFU. In some cases, manually drying the device with a non-linting cloth may be required instead of using the drying function of a WD. An important exception to most drying recommendations concerns reusable medical devices with lumens, which may instead require moistening with deionized or distilled water before the sterilization process (ANSI/AAMI ST79: 7.5.6).

The design of a washer’s drying system will affect how efficiently moisture is removed or is minimized on instruments. Some systems recirculate HEPA filtered water inside the chamber, which reduces the overall time required to dry the instruments. Other systems introduce filtered air from outside the chamber that requires heating as it is drawn into the chamber. Air can also be circulated through the washer rack itself, forcing moisture away from the devices in the chamber.

Best drying practices include:

- Review the device manufacturers’ IFU to determine if automated drying is recommended.
- Use lint-free textiles if manual drying is needed.

If it isn’t clean, it won’t be sterile
This will forever be a guiding statement for all who reprocess medical devices. And the follow-up should be “if it isn’t sterile it can’t be used on a patient.” The assurance of sterilization is, in fact, dependent upon a completely clean device (squeaky clean). A completely clean device, in turn, is absolutely dependent on the level of diligence exercised by the surgical instrument protection team (surgical staff and SPD staff). This team must be well trained, well informed, well equipped, and resolute in their efforts to do no harm to patients or each other.

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References
Is that really clean?

Circle the one correct answer:

1) There are a number of considerations when cleaning reusable medical devices; of these, the most critical is:
   A. Reaching the lumens, serrations, and hard-to-reach nooks and crannies.
   B. Their complex design.
   C. The delicate nature of the instrument.
   D. The protective role of each healthcare team member.

2) How well surgical instruments are kept free of gross soil during a surgical procedure has no impact on instrument turnaround time.
   A. True
   B. False

3) Until they are transported to the SPD, covering soiled instruments with a towel moistened with saline is an acceptable option when transport gel spray or a splash-proof container with an enzymatic solution is not available.
   A. True
   B. False

4) At protection point two, the SPD technician will continue the cleaning process by soaking, inspecting, priming, flushing and rinsing reusable medical devices per the manufacturer’s IFU. Following this manual process all reusable medical devices will be conveyed to the WD.
   A. True
   B. False

5) What are two of the mechanical modalities used in the SPD decontamination area?
   A. Washer-disinfector and ultrasonic cleaner
   B. Dishwasher and ultrasonic cleaner
   C. Three-basin sink and ultrasonic washer

6) WDs come with cycles such as:
   A. MIS, Robotics, Standard Instruments
   B. Gentle, Orthopedic, Utensils
   C. Custom cycle
   D. a and b
   E. All of the above

7) Automated washer-disinfectors use _________ as a mechanism for cleaning, and ultrasonic cleaners use __________.
   A. Scrubbing, vibration
   B. Circulation, ultrasound
   C. Impingement, microscopic implosion
   D. All of the above

8) The design of a washer tray must allow the _________ and __________ to reach the devices.
   A. Cleaning chemistry and mechanical action
   B. Height of the tray and the spray arm
   C. A and B
   D. None of the above

9) Generally, instruments should be dry before they go to the prep-and-pack area because:
   A. It makes them easier for staff to handle
   B. Devices intended for gas or steam sterilization must be fully dry before they can be sterilized
   C. a and b
   D. None of the above

10) In 2010, OSHA reported that over 50 percent of healthcare worker days away from work were caused by strain and sprain injuries of only the healthcare staff who provided direct patient care.
    A. True
    B. False

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