



Ensuring automated instrument cleaning, sterile packaging and surgical mask disposal

by Ray Taurasi, Principal, Healthcare CS Solutions.

Q I understand that hinged, ring-handled and movable part instruments are supposed to be left opened during the cleaning process, however, for many devices like roggeurs, this isn't feasible or possible when using automated washers. Manufacturers' instructions for use (IFU) state the devices should be opened but they provide no directions as to how this can be done. If we don't follow the IFU we are liable if the instruments aren't clean. Since there is no way to keep these instruments opened in a washer, we are spending far too much time on manual precleaning measures and often this leads to inadequate cleaning. Do you have any suggestions?

A When instruments are closed, they are closed to cleaning. Water and detergent cannot reach all the surfaces of the instruments. It is these more complex instruments that are more likely to harbor organic matter, which can lead to cross-contamination and possible infection. Device manufacturers, AAMI, AORN and others, strongly recommend that instruments be kept in an open position when being cleaned. Open instruments will allow for the maximum exposure to cleaning agents and the mechanical action that dislodge and remove soil. There are various instrument spreaders available, which are designed to keep such instrumentation open during the automated cleaning process. (see figures 1 and 2)

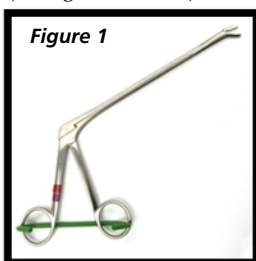


Figure 1

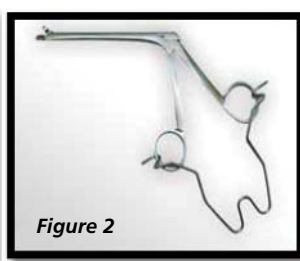


Figure 2

Q Our packaging wrappers have an expiration date on the box they come in. Our department follows an event related sterility maintenance policy. Do we need to follow the expiration date on the box?

A As you know, event related sterility maintenance (ERSM) means that a sterilized item will remain sterile until an event occurs that compromises the sterile integrity

of the sterile package. Common examples of such events include package damage, tears, holes, wetness, mishandling, suspicious staining, broken closures and locks. Professional guidelines, such as AORN, state that an expiration date (when applicable) should also be considered an event.

It is imperative that you fully understand what the date on the manufacturer's box means. Does it mean that once the packaging material has been utilized to contain an item that has been sterilized, that the package will maintain sterility forgoing any adverse events until the expiration date on the box? If that is the case, then each package would require an expiration date on it.

It is important to note that shipping cartons or internal storage boxes may have an expiration date on them. That date may be a best-use date, which relates to pre-sterilization shelf life. It is essential that you obtain and follow the manufacturer's IFU and that you obtain documentation of all validations relating to sterilization performance, sterility maintenance, and sterile shelf life/ERSM.

Q I am the nurse manager for Sterile Processing Services for a large acute care hospital. We sometimes find tiny tears that penetrate one layer of the instrument set wrapper. Some of the OR and SPS staff feel that it is okay to use the set if the tear hasn't penetrated all layers of the wrapper. Others believe that if any tears are found, the set must be considered contaminated and not used. Those in favor of using the set argue that it is similar to using the inner package of a peel pouch that is double pouched. I frankly am undecided. I can see the rationale of both arguments. What are your thoughts?

A I believe that if any compromise in sterile packaging integrity is found, that the set must be considered unsafe for use, broken down and completely reprocessed. You cannot compare the peel pouch scenario to flat wrap. Packaging materials are class 2 medical devices and for FDA clearance, they must demonstrate specific bacterial barriers, sterilization compatibility and the ability to

maintain sterility until the point of use. Your IFU for the flat wrap gives specific directions for wrapping and use of the product in accordance with product validations. The appropriate use ensures that the packaging material will provide the required barrier to microbial penetration; that means that all layers must be intact. For FDA clearance, peel pouches have demonstrated that their maternal composition provides the specified and validated microbial barrier with single pouch packaging. If there was a tear or hole in a peel pouch, you would consider the contents contaminated. For cases in which you might double pouch with the intent to dispense the inner pouch onto a sterile field, if the outer pouch is compromised or if the inner pouch has a tear, then the inner pouch must be considered unsterile and should not be passed off to the scrub nurse or placed on a sterile field.

Q I am the nurse manager at a doctor-owned ambulatory surgery center. We have a few surgeons who leave their face mask hanging off their neck when they finish a case. They go to the lounge while the room is being turned over for their next case, and then they return to the OR wearing the same mask. They feel it's an unnecessary waste of money to change their mask between cases, unless it's visually soiled. Clinically, I do not agree with this, but I have been unable to locate anything in writing to support my concerns. Do you have any references?

A The first place you might want to look for support is the mask manufacturer's IFU. You will find the disposable surgical mask identified as a single use item. Standards state that a single use item, such as a surgical mask, can only be used once, for one patient, at one time. Professional standards specifically note a mask should be changed between cases and not worn dangling around the neck. **HPN**

References:

- AORN's recommended practice on surgical attire: 2019 edition, page 1014-1015
- American College of Surgeons: <https://www.facs.org/about-ac/s/statements/87-surgical-attire>
- From the Association of Surgical Technologists: http://www.ast.org/uploadedFiles/Main_Site/Content/About_Us/Standard_Surgical_Attrire_Surgical_Scrub.pdf