Pre-treatment is a must; a wet storage story

by Ray Taurasi

Q We have an issue with the OR being resistant to pre-treating soiled instruments during the case breakdown prior to returning them to SPD. Quite often, the instruments are returned heavily soiled with blood and organic matter dried on. Dirty instruments are basically thrown in an instrument tray or basin and sent to SPD. This lack of point-of-use pre-treatment creates a challenge and extra work and longer reprocessing time for SPD staff. When I bring the problem up during joint meetings the OR manager says they will try to improve. However, it is not always possible as they are in a rush to get the room turned over and the next case started. He also claims that there is no requirement for pre-treatment with an enzyme detergent.

What is your recommendation on the pre-treatment with an enzymatic product prior to sending to SPD?

A Both AAMI and AORN Standards and recommendations do stress the importance of pre-cleaning instruments immediately after use in the OR. Pre-clearing includes the removal of gross soil. It is standard practice for the scrub nurse to keep all instruments on the sterile field free of gross soil throughout the surgical procedure. A soiled instrument should never be passed to a surgeon.

During case breakdown the OR staff is responsible for pre-cleaning all used instruments; at this point all instruments with lumens should be flushed with distilled water or as otherwise specified by the device manufacturer. While an enzymatic product may be used at this stage, it is not a requirement. It is essential that soiled instruments be maintained in a moist state before arriving in the SPD for cleaning as this will prevent the drying of surgical debris on or within the surgical instruments.

If organic matter is allowed to dry on instruments, as you have encountered, their removal during the cleaning process will become more difficult, adversely affecting the efficacy of the cleaning process. The pre-sterilization cleaning process in SPD should include the use of an enzymatic agent or other agent capable of breaking down organic matter. This will improve the efficiency of the cleaning process in the removal of visible and invisible soils. In all circumstances it is imperative that the medical device manufacturers' IFUs be followed relative to the cleaning processes and chemistries utilized.

Q We recently purchased several of the new closed sterilization containers for immediate use steam sterilization (IUSS) to aid in turnaround time by decreasing the number of trays for orthopedic cases. This container also has a thirty day post sterilization shelf life. We have found that these new trays retain an excessive amount of moisture after sterilization which we are very concerned about. In consultation with the manufacturer, they stated that the retained moisture and wetness is acceptable with this container and has been approved by FDA. We're conflicted and not sure we want to continue the use of these containers. Could you please comment on this new process.

A I am a believer that we must keep an open mind to new technologies and be receptive to the changes they may bring to practice. That said, as users, we must become well-informed and educated on any new technology, and every detail must be carefully assessed and analyzed. All technical data, IFUs, validations and related documents must be obtained, read, understood and verified. Obtain the appropriate FDA 510K and premarket clearance documents if applicable and read them very carefully.

The following are some questions you might want to consider in your assessment of this product and it's use in your facility:

- Do all documents support and correlate with the manufacturer's claims?
- Why would you want or need to use IUSS process when you plan to store an item? Wouldn't conventional terminal sterilization be more appropriate?
- Does the IFU comply with the recommendations of AAMI, AORN and other professional entities (e.g., CMS, APIC, CDC) regarding IUSS?
- Does this IUSS container follow the Multi-Society Statement on Immediate Use Steam Sterilization?
- Does the device's sterilization IFU and cycle parameters conform to the IFU of the various instrument manufacturers? What about implants?
- What effect would wet storage have on the instruments? Is there increased potential for rust, corrosion, and other damage?
- Will wetness inside of the containment device become a source of biofilm formation or other contamination?
- Is there any chance for barrier strike through or leakage?
- Does your OR have the appropriate facilities, processing equipment, environmental controls, and skilled professionals to appropriately reprocess and sterilize instruments in accordance with the same principles required of a Sterile Processing Department?
- This list is not meant to be all inclusive and I am sure you can add many items and questions that need answers relative to your unique situation. I would not rush into the utilization of any new technology until I felt 100 percent confident that all of my concerns were sufficiently addressed and satisfied.

Ray Taurasi is Principal, Healthcare CS Solutions. His healthcare career spans over three decades as an Administrator, Educator, Technologist and Consultant. He is a member of AORN, AHA, SGNA, AAMI and a past president of IAHCSMM. Taurasi has been a faculty member of numerous colleges teaching in the divisions of business administration and health sciences.