SUBMIT YOUR QUESTIONS: **editor@hpnonline.com**

Sterilizing bone not a function of sterile processing; flush testing endoscopes after processing

by Ray Taurasi

Q I am the sterile processing manager at my facility and the OR supervisor recently asked me to sterilize a wedge of bone from a patient's skull for reimplantation a few days post-op. I advised her that this is something I could not do but she insisted it was an acceptable practice and that other facilities where she's worked have done it. I asked her for documentation, but she could not provide anything about the protocols for this. I told her I would not sterilize the bone without the documentation. She later returned with a signed, scribbled note from the surgeon stating that he authorized and insisted that I sterilize the bone immediately. I reluctantly complied with his orders and then learned later that the sterile bone was never used. The whole incident troubles me. I was not comfortable carrying out the surgeon's orders, but he is my superior and I figured he knows what he is doing. Should I have done differently?

A You were placed in an unfortunate situation and became a victim of hierarchy coercion. The fact that it was the surgeon's order to sterilize the bone would not necessarily be a sound defense for you if there was an adverse patient outcome which ended up in litigation. There is nothing in a surgeon's education that instructs them on the principles and methods of sterilization or the reprocessing of medical devices. The surgeon probably would be the first to point the finger at you if something did happen, stating you never advised him of potential problems and that you should have known better than to try to sterilize the bone. As the manager of sterile processing, you are ultimately responsible and accountable for the quality of all sterilization processes. Furthermore, if you are a licensed or certified professional in the field of sterile processing your credentials are testimony of your education and knowledge. One is expected to then practice accordingly; failure to do so could result in professional negligence and be subject to legal action. Fortunately, in this case the questionable item was not used.

I have worked with many healthcare systems dealing with very similar issues. It is quite likely you will encounter many unusual requests and demands throughout your career. You need to be prepared on how to deal legitimately with such serious matters. Unfortunately, I see far too many sterile processing managers that do not have the authority in balance with their responsibility, nor do they have the administrative support needed to make decisions. I would recommend that you discuss this issue and your concerns with your administrator and together consult with the hospital risk management and legal teams. I have provided some information below regarding the sterilization of bone. This may be a good springboard that leads to an acceptable protocol on how to handle situations like this in the future.

Generally, bone tissue should not be subjected to the steam sterilization process unless there is a specific clinical indication that warrants it should be done. The steam sterilization process could severely damage the bone composition and structure, as it denatures proteins. This would increase the potential of the resorption of the implanted bone. In other words, the body's own cells could eat away, and dissolve implanted sterile bone. Rejection may also be heightened as the changed and unfamiliar autologous sterile bone would now be a foreign body. It should also be noted that subjecting the bone to the steam sterilization process would also be considered a form of manufacturing requiring your facility to register with the FDA as a tissue bank.

The risk management and legal team can format sound legal forms including informed consent which requesting clinicians and surgeons can sign. You'll want to be proactive in obviating such stressful confrontations in the future. I would prepare a list of scenarios and unusual events that may occur and develop response protocols, complete with official authorization documents. You could also form an ongoing task force with representatives from risk management, nursing, OR, infection prevention, and administration for future surveillance.

References:

1. Guideline for autologous tissue management. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc.

2. Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/ Ps). Silver Spring, MD: US Food and Drug Administration; 2012.

Q Each morning in the endoscopy unit we test the instrument channels of processed scopes as they are removed from the storage racks. We utilize sterile water to flush the channels and the water is tested for the presence of blood, protein or carbohydrates. Should we repeat the alcohol disinfection flush after the testing?

A I believe the test that you are using is a cleaning verification test, which should be done following the manual cleaning process prior to disinfection or sterilization. The removal of residual soils, such as those you mention, is essential to allow the required intimate contact between the scope and disinfectant or sterilant. I suggest that you review your manufacturer's IFU for the use of your testing product. Also, alcohol flush in the channels is primarily to help facilitate drying of channels and not for disinfection.

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.