Quality Assurance with Rigid Containers

Katrina Simpson, M.A., CST, CSPDT

Objectives:

Discuss various quality assurance issues regarding rigid containers.
Discuss measures CSS personnel can take to initiate infection control.
Discuss rigid container reprocessing concerns.
Discuss the components of the rigid container.

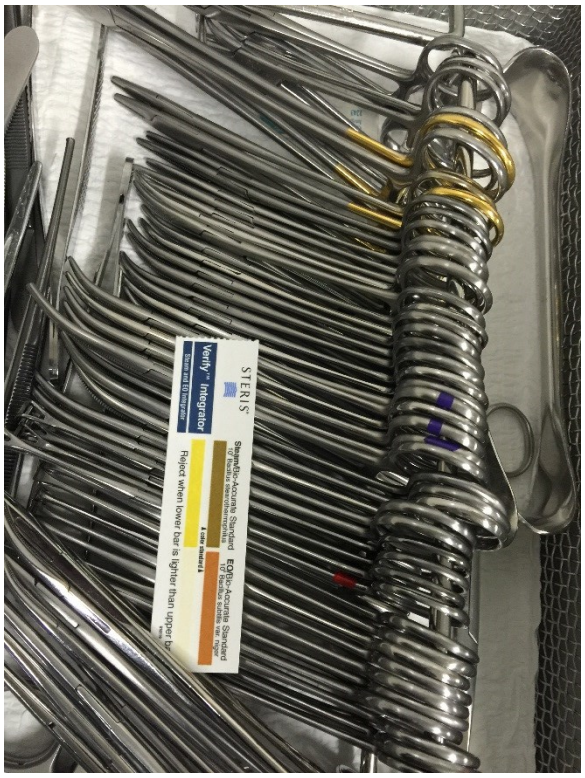
Where are my filters?

Look at the picture above. What is the first thing that you notice incorrect about this picture? You guessed it, no filter! Dr. Thompson, a prestigious vascular surgeon at New ABC Hospital brings in millions of dollars a year to the hospital. One day, a trauma comes through the operating doors, the OR has been busy with vascular procedures all day. The only "sterilized" AAA set that can be used for this

emergency procedure is sent up from the Sterile Processing Department to the operating room. The patient is intubated, put to sleep, and prepped for surgery. The scrub tech goes to reach for the "sterilized" AAA container, lifts the instruments out of the rigid container, and immediately realizes that the bottom filter is missing out of the container. What should the technician do? The patient is minutes away from a fatality. Should the operating room team proceed and use the unsterile instruments? There is no easy response to these questions. It would not be ideal for the technician to use these instruments on the patient because they could furthermore complicate any underlying issues the patient may have. "The use of inadequately sterilized critical items represents a high risk of transmitting pathogens, documented transmission of pathogens associated with an inadequately sterilized critical item" (Centers for Disease Control and Prevention, 2008, para 2). The best thing the technician could do in this situation is request similar instruments to get the case started, and utilize the Immediate Use Steam Sterilizer to process any additional instruments that may be needed for the case. The patient should always be the primary concern for the surgical team, and yes, that include sterile processing.

Other QA concerns

Unfortunately, missing filters are not the only concern regarding rigid containers. There are numerous components to the rigid container. The CS technician must be familiar with the anatomy of the rigid container before handling it. Rigid containers can have a solid or perforated bottom, a container lid, gasket, latching mechanism, ID tags, appropriate sized instrument basket, filter retention plates, two handles, and a load card holder (Chobin, 2013. Pp 197-198). It is important that all of these components are working appropriately to initiate effective sterilization. Rigid containers must be thoroughly cleaned and dried before allowing assembled surgical instruments to be placed within the tray. Excess moisture can contribute to wet loads, which furthermore, contribute to instrument recalls. To ensure effective sterilization, it is important for rigid containers containing both a perforated top and bottom to be sterilized in Ozone, Low-Temperature Gas Plasma, Ethylene Oxide or Gravity sterilization cycles. This is important to ensure adequate steam penetration and air-removal. Containers with a perforated top and solid bottom can be placed in Dynamic-Air removal cycles. All filters used must be of correct size. It is inappropriate to cut filters to fit the perforations on the container. Before sterilizing anything in a rigid container, the weight of the set should not exceed 25 pounds. "AAMI ST77:2005, "Containment devices for reusable medical device sterilization," addresses the weight issue of a containment device, the instruments, and any accessories or wrappers, and recommends that the combined maximum weight should not exceed 25 pounds" (Case Medical, 2006). Excessive weight within the tray can contribute to ineffective sterilization.

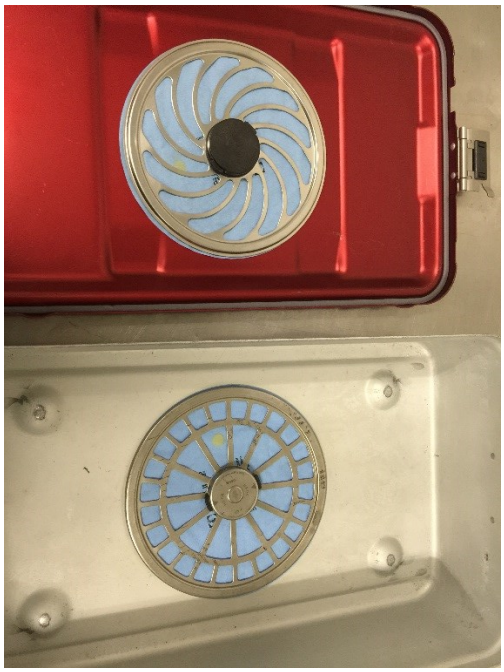


Is the appropriate chemical indicator contained within the set? It is not only important to check filters, but also inspect to verify that the appropriate chemical indicator is placed within the instrument set before the instrument is sterilized.

Technicians must also make sure that any packaging material that can be utilized to serve as a barrier and package for sterilized equipment is not contained within the rigid container, ex: single-use wrappers, paper-plastic pouches.

How do we fix these QA concerns?

There are often times within the sterile processing department in which the staff can get exceptionally busy and overwhelmed in which errors are increased. Regardless of how busy the Sterile Processing Department may become, it is never okay to take short cuts or allow even one error to occur. Central Sterile Processing is truly the heart of the hospital. One error can cause a sentinel event, and in rare cases death being the ultimate occurrence. Therefore, it is imperative for each CS department to have quality assurance policies in place to avoid such incidences. Look at the list below to see what measures CS technicians can take in order to ensure that filters and other mechanisms of the rigid container are checked before they get to the operating room.



- Have CS personnel place filters in rigid containers as soon as they are decontaminated and dried and double check that the filter retention plates are secured
- Add verification of filters for rigid containers on instrument inventory sheets
- Double check that the appropriate chemical indicator is within the set, ex: steam indicators for steam, gas chemical indicators for gas sterilization cycles
- Have the CS technician running the sterilizer verify that all rigid containers have filters on the top and bottom, when necessary, locking mechanisms, load card holders, and tray ID name tags before sterilization
- Verify that dents or other noticeable damage is not present in the containers (this can prevent proper sterilization by allowing air to enter the set)
- Ensure that all rigid containers being utilized have a 510(k) clearance administered through the FDA (This information can be verified through the manufacturer's instructions for the device)

It is imperative that the CS professional is aware and educated about various quality assurance issues regarding the usage of rigid containers. Rigid containers are ideal for sterilizing a large amount and variety of surgical instruments for various specialties. When processed correctly, they provide excellent barriers to pathogens, which can ultimately help to reduce the risk of a hospital acquired infection by utilizing improperly sterilized medical equipment to the surgical patient.

References

Case Medical Incorporated. (2006). *The Basics of Packaging.* Retrieved from

http://www.casemed.com/caseacademy/downloads/CASDF002.pdf .

Centers for Disease Control and Prevention. (2008). *Guideline for Disinfection and Sterilization in Healthcare Facilities.* Retrieved from http://www.cdc.gov/hicpac/Disinfection_Sterilization/13_0Sterilization.html.

Chobin, N. (2013). *The Basic of Sterile Processing, 5th Edition.* Lebanon, New Jersey: Sterile Processing University

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Post-Test 2015

1 It is recommended to use non-sterile instruments on the surgical patient in the case of an emergency.
TRUE FALSE

2 Items not sterilized can result in an increased risk of pathogen transmission.
TRUE FALSE

3 All components of the rigid container must be in working order and not damaged.
TRUE FALSE

4 Rigid containers containing both a perforated top and bottom must be placed in in Dynamic-Air removal cycles for sterilization.
TRUE FALSE

5 Instrument sets must exceed 25 pounds in order to be processed in rigid containers.
TRUE FALSE

6 It is necessary to package scissors in paper-plastic pouches before placing them into rigid containers.
TRUE FALSE

7 Missing filters are not the only quality assurance concern with rigid containers.
TRUE FALSE

8 Overwhelmed staff does not contribute to errors being made in CSS.
TRUE FALSE

9 It is okay to place a chemical indicator within a set, which is intended for steam sterilization in an ethylene oxide cycle.
TRUE FALSE

10 Rigid containers should have a 501 (k) clearance through the AAMI.
TRUE FALSE

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Lana Haecherl
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