Are you correctly using rigid sterilization containers for IUSS?

Although immediate-use steam sterilization (IUSS) is a safe method to sterilize emergently contaminated instruments, inappropriate use may lead to an increased risk for surgical site infection, according to a study in the American Journal of Infection Control. This study stated the only acceptable indicator for use of IUSS based on recommended practices is intraoperative contamination.

AORN states that rigid sterilization containers that have been validated for IUSS and cleared by the US Food and Drug Administration (FDA) for this purpose should be used. Always follow the written instructions for use (IFU) issued by the manufacturer of the instrument and rigid sterilization container.

Cleaning/decontamination

The rigid sterilization container should be cleaned after each use with the cleaning solution, tools, water quality, and methods recommended in the rigid sterilization container written IFU.

Components that should be removed for cleaning include the container lid, the filter protector/holder/retention plate from both ends, the disposable filter, interior baskets, chemical indicators (CIs), disposable labels, locks, and posts/dividers. Cleaning the valve-type closures (reusable filters) usually requires removal and reassembly. Load the container into the mechanical washer according to the container manufacturer’s written IFU (eg, remove the lid and retention plate) to ensure contact of the cleaning solution and water with all surfaces.

If you are manually cleaning containers in the OR, use a soft lint-free cloth and a neutral-pH detergent. Cleaning solutions such as quaternary ammonium, phenolic germicidal detergents, or alcohol are not recommended, and the container’s warranty may be voided if the wrong type of cleaning solution is used. Do not use abrasive cleaners, scratch pads, or metal brushes. Thoroughly rinse to remove all detergent.

Inspection

Inspect rigid sterilization containers after each use. The AORN Recommended Practice for Packaging states inspections should ensure the:

• mating surfaces and edges of container and lid are free of dents and chips
• lid and container fit together properly and securely
• filter retention mechanisms and fasteners are secure and not distorted or burred
• latching mechanisms are functioning as they should
• handles are in working order
• integrity of the filter media is not compromised
• gaskets are pliable, securely fastened, and without breaks or cuts
• valves are in working order.

Inspect single-use or reusable filters and valve systems to ensure they are secure and in proper working order before sterilization.
Preparation

Packaging
Do not add materials such as mats or towels to the rigid sterilization container unless recommended in the container manufacturer’s written IFU. For effective sterilization, follow the container manufacturer’s written IFU to ensure the density of materials, weight, distribution, and lumen limitations are followed.

Do not place cassettes or organization trays with instruments inside the rigid sterilization container, and do not transfer a set of instruments provided in their own cassette/organization tray to a rigid sterilization container to avoid torn wrappers unless this procedure is described in the instrument/cassette/organization tray device manufacturer’s written IFU. These changes may not have been validated by the original instrument manufacturer, so they should not be made unless the instrument/cassette/organization tray device manufacturer provides written information to do so. It is the ultimate responsibility of the instrument manufacturers to provide the IFU for effective sterilization of their medical devices.

Instruments should be positioned into the rigid sterilization container according to the instrument and container manufacturer’s IFU to allow sterilant contact with all surfaces. Disassemble instruments if required, position instruments with concave or convex surfaces to prevent retention of water, and use racks or a stringer to open or unlock instruments. The total weight of instrument containment devices, including the contents, should not exceed 25 lb.

Placement of chemical indicators
According to AAMI ST79 and AORN’s Selection and Use of Packaging Systems for Sterilization, chemical indicators (CIs) should be placed in an area of the rigid sterilization container that presents a challenge for air removal and sterilant contact. Consult with the manufacturer of the rigid containers for the appropriate number of CIs and placement. This information should be provided in the container manufacturer’s written IFU. The AORN Recommended Practice for Sterilization states to use either a Class 5 or Class 6 internal CI. Remember that Class 6 CIs are cycle-specific and “should be used only in the specific cycles for which they are labeled.” A Class 1 CI should be placed on the outside of each rigid container to identify that the container went through the IUSS cycle.

Package labeling
Assign a lot number to each IUSS load, and record that in a load record system used for each cycle. Small record cards that attach to the rigid sterilization container are available, and some will provide space for a lot identification sticker.

Sterilization parameters
The sterilization parameters in the instrument and rigid sterilization container manufacturer’s written IFU should be used. If they do not agree, follow the instrument manufacturer’s IFU since it is the manufacturer’s responsibility to validate the sterilization cycle for their instruments/instrument sets. Do not use a cycle that is shorter than the cycle recommended by the rigid sterilization container manufacturer. If no IUSS cycle is listed, contact the instrument manufacturer to determine if that cycle can be used. Do not be surprised if the answer is no. With IUSS there is no dry time, so instruments are wet on the inside and outside after the cycle. This condensation, with repetitive use of IUSS, may cause instruments to rust, which reduces their use life and increases costs because they must be replaced.

Do not eliminate the dry time unless recommended by the instrument manufacturer, and do not shorten the recommended sterilization time. The same sterilization
parameters should be used for IUSS as for terminal sterilization, except that IUSS has a 0 or reduced dry time. Some powered instruments may have a slightly longer dry time for IUSS to minimize the chance of condensation inside the powered instruments. Do not change the sterilization or dry time recommended for the IUSS cycle.

After the sterilization cycle, examine the integrity of filter plates. Do not use the contents of the container if the filters are not intact or if they are damp, dislodged, or have holes, tears, or punctures.

Read the physical monitors and external CI before the container is transferred to the sterile field or opened. If either result suggests inadequate steam sterilization processing, do not use the contents of the rigid sterilization container.

**Transfer of instruments to sterile field**

The Multi-society Immediate-Use Steam Sterilization statement states that “immediate use” is broadly defined as the shortest possible time between a sterilized item’s removal from the sterilizer and its aseptic transfer to the sterile fields. The sterilized item is:

- used during the procedure for which it was sterilized
- used in a manner that minimizes its exposure to air and other environmental contaminants
- not stored for future use
- not held from 1 case to another.

Read the internal CI before the rigid sterilization container is transferred to the sterile field. If the CI suggests inadequate steam sterilization processing, do not use the contents. This process will keep you from having, at a minimum, to remove the entire instrument set or any other instruments that came in contact with the contaminated instrument from the sterile field and change gloves if any team member touched the contaminated items.

As soon as the rigid sterilization container is transferred to the sterile field, remove the instruments so they are not stored for future use or held for the next case. Rigid sterilization containers cleared by the FDA for IUSS do not have a claim for sterile storage because they are wet. In addition, if the wet instruments are stored, the instruments are not considered sterile and may rust, posing a patient safety problem.

If you are not correctly using rigid sterilization containers for IUSS, it’s time to follow the recommended practices and IFU to protect your patients. ✤

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**References**


