
STERIS

Immediate Use Steam Sterilization:

What SP Technicians Must Know

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LEARNING OBJECTIVES

1. Describe the recommended practices for performing immediate use steam sterilization
2. Define restrictions for immediate use steam sterilization
3. Discuss methods to reduce immediate use steam sterilization

In the past, the process for sterilizing items needed immediately for a surgical case already in progress was called flash sterilization. In 2010, leaders from healthcare organizations, many employed by accrediting agencies, met to discuss this practice. The group determined that flash sterilization was often not used according to its intended purpose—for emergency use only. More importantly, the procedures followed by many healthcare organizations were inconsistent with best practices. In some cases, cleaning practices were questionable, including being performed in sub-sterile rooms without the appropriate cleaning implements or equipment, and personal protective equipment (PPE) was not worn consistently. The flash sterilization cycle was a 3- or 10-minute gravity cycle with no dry time, and cycle selection was based on whether or not an item was porous. Also, the manufacturers' instructions for use (IFU) were not always followed, and sterilization and transport containers were frequently misused.

From that meeting, the organizations released a statement, agreeing that flash sterilization was not only an antiquated term but also in need of new-and-improved practices. The name of the process was changed to immediate use steam sterilization (IUSS) to provide broader awareness of its core purpose and to promote best practices. Today, when IUSS is used judiciously for emergency situations and when all essential steps are followed correctly, the practice provides a safe device for patient use.

IUSS requires all instrumentation to be processed according to the instrument manufacturer's instructions for use (IFU). This lesson addresses how to safely process medical devices with IUSS, monitor the process, and ensure it is only used sparingly and appropriately.

Objective 1: Describe the recommended practices for performing immediate use steam sterilization

Communication between the Operating Room (OR) and Sterile Processing department (SPD) is crucial. SPD technicians must be aware of what will need to undergo IUSS so they can plan effectively. This awareness is essential because IUSS instrumentation will become a priority when the items are received in the decontamination area.

After use, the instrumentation is sent to a decontamination area for proper cleaning. The cleaning process should only be performed in a decontamination area where trained personnel and proper equipment are available. Cleaning should never take place in a hand wash or scrub sink. Instruments undergoing IUSS must be cleaned the same as devices that will be terminally sterilized.

Personnel working in the decontamination room must wear the appropriate personal protective equipment (PPE). The required PPE for cleaning medical devices is general-purpose utility gloves and a liquid-resistant cover gown with sleeves (e.g., a backless gown, jumpsuit or surgical gown); fluid-resistant shoe covers; head attire; fluid-resistant facemask; and eye protection/face shield.

Gross material, if remaining on instrumentation, should be removed, and the instruments should be disassembled and cleaned according to each device's IFU. Then, instruments that can withstand mechanical cleaning are loaded into the washer, and the correct cycle for those instruments is selected.

After thoroughly cleaning the instrumentation, the devices are inspected, tested and prepared following the IFU and best practices. Again, it is vital to ensure no steps are rushed or skipped.

A containment device validated for IUSS and cleared by the U.S. Food and Drug Administration (FDA) is the recommended packaging for instruments processed in an IUSS cycle. Approved IUSS packaging must facilitate the sterilization process, contain sterilized items during transfer to the procedure and allow for aseptic presentation of the included devices.

Since the implementation of IUSS, most sterilization container manufacturers have had validated testing performed on their containers to enable them to undergo IUSS. Before using sterilization containers for IUSS, it is imperative to obtain and review the IFU. The IFU will document whether the container can be used for IUSS, provide the proper sterilization cycle and identify any restrictions. The container IFU will include any supplies needed, including the appropriate filter. Packaged devices should be identified as a set intended for IUSS. Items undergoing IUSS must be used for the case in which they were sterilized and not held for another case. Having the set identified as IUSS alerts staff to return the set for reprocessing, which helps prevent the set from being used for a later procedure.

IUSS sterilization may occur in the SPD or another department with a sterilizer approved for the process and trained staff who can competently perform it. The sterilizer manufacturer's written IFU should include instructions for IUSS and proper transportation after sterilization. The selection of the sterilization cycle is based on the medical device IFU; in some cases, an extended cycle may be included in the IFU. When sterilizing with IUSS, there is little or no dry time. The items may be hot and wet, so caution must be followed during handling.

Instruments sterilized by IUSS may be susceptible to contamination due to environmental exposure and handling by personnel transporting the sterile devices to the point of use. Therefore, it is crucial that sterilization processing is performed in a clean environment and that IUSS devices are transferred to the point of use in a manner that prevents contamination. Therefore, instrumentation must be contained from the sterilizer to the point of use.

All items sterilized by IUSS must also be documented. The IUSS record should include the following:

- Item(s) processed
- Date and time the item was processed
- Patient name or identifier
- Type of cycle used
- Monitoring results
- Name of the person(s) who initiated the sterilization cycle and unloaded the sterilizer
- Reason for IUSS

Objective 2: Define restrictions for immediate use steam sterilization

There are restrictions to IUSS that SP technicians must remember—most notably that IUSS should only be used for urgent situations, never out of convenience. When many of the same tray(s) will be used in a single day, patient procedures should be scheduled to allow adequate processing time to clean, inspect, package, terminally sterilize, and cool the trays. Surveying agencies will check for multiple days where the same tray was exposed to IUSS. It is important to review which instruments are used in the set and create smaller sets, using only those needed devices. Doing so helps prevent the purchase of larger sets that contain instruments that will not be used.

It is prudent to check the IFU of medical devices and packaging systems before deciding to sterilize them using IUSS because some medical devices (including many common devices) and

sterilization containers are not validated for IUSS. *Safe IUSS requires that all best practices are followed every time a device is sterilized; shortcuts are never acceptable.*

According to the Association of periOperative Registered Nurses (AORN) *Guideline for Sterilization*, IUSS should not be used for implantable devices, except in cases of defined emergency when no other option is available. Implants are foreign bodies and pose an increased risk of surgical site infection. AORN recommends careful planning, packaging, and inventory management, in cooperation with suppliers, to prevent IUSS of implantable medical devices. *Note: There may be situations in which IUSS of an implant is unavoidable. In such a circumstance, the sterilization cycle selection should be determined by the device manufacturer's written IFU. A biological indicator (BI) must be run with every implant sterilized, and the BI results should be read before using the implant. When an implant is used before the BI results are known, and the BI is later determined to have a positive result, the surgeon and infection preventionist(s) must be notified as soon as the results are known.* Record keeping for implants includes the patient's name or identification, surgeon, date and factors that could have prevented IUSS.

Instrumentation used on patients with suspected or confirmed Creutzfeldt–Jakob disease (CJD) or similar disorders and devices labeled for single use should not undergo IUSS.

Objective 3: Discuss methods to reduce immediate use steam sterilization

Although no standard exists that recommends a specific target metric for monitoring IUSS, surveyors are looking for an ongoing reduction of IUSS; this requires a monitoring process to gather data and reduce IUSS. While monitoring shows the amount of IUSS being performed, it also helps identify specific cases, physicians, days, reasons, insufficient inventories, and patterns driving the need for expedited steam sterilization. Analysis of this data can then be used to prevent further occurrences. If the data shows that late-arriving loaned instruments caused IUSS, the loaned policy must be reviewed, revised and enforced. A policy should be developed and implemented if the facility does not have one regarding loaned sets. IUSS of implants can be reduced by creating small sets or peel packs with slow-moving inventory and the most-used items. It is also important to note that many implants may be purchased sterile.

When seeking a reduction in IUSS, SP professionals should work closely with OR staff and infection preventionists. Adopting change is easier when the three departments work together to identify the reasons behind IUSS use and determine how to address them to prevent improper use of the practice. User departments should receive training on the cleaning and sterilization process and the length of time these processes take to ensure items are received in the SP area with enough time to allow safe, appropriate processing. Creating a priority list for instruments and sets used daily or seldomly is also imperative. In addition, SP professionals can request help from user areas to audit existing instrument sets and remove unneeded or unused devices.

Conclusion

SP, OR and IP professionals must all work together to reduce IUSS. When current practices are monitored and analyzed—and factors contributing to IUSS are addressed such as insufficient instrument inventories to meet procedural volume—a plan can be implemented to reduce the prevalence of IUSS. P