THE FLASH DANCE IS OVER!  
IUSS IS OUR NEW PARTNER

LEARNING OBJECTIVES
1. Define “flash sterilization” and explain why it was replaced with the term “immediate-use steam sterilization” (IUSS)
2. Describe IUSS and discuss its proper use
3. Review steam sterilization methods for IUSS processing
4. Explain that IUSS training and education is critical
5. Identify inappropriate medical devices for IUSS processing
6. Explain the basics for an immediate-use steam sterilization policy

THE BEGINNING OF THE END OF THE “FLASH DANCE,” WHICH moved our profession from flash sterilization to immediate-use steam sterilization (IUSS), resulted from a 2010 meeting of numerous healthcare organization and regulatory and accreditation agency personnel. Organizations represented included the International Association of Healthcare Central Service Material Management (IAHCSMM); the Association of periOperative Registered Nurses (AORN); the Association for Professionals in Infection Control and Epidemiology Inc. (APIC); The Joint Commission (TJC); the Centers for Medicare and Medicaid Services (CMS); the Centers for Disease Control and Prevention (CDC); the Accreditation Association for Ambulatory Health Care (AAAHC); the American Dental Association (ADA); and the U.S. Food and Drug Administration (FDA).

Concerns were voiced about poor flash sterilization practices used by some facilities, and the need for process improvements to sterilize medical devices in surgery and other areas requiring quick instrument turnaround. Originally, flash sterilization was designed for single instrumentation that may have become contaminated during the surgical procedure; however, the process had evolved to become an all too common “remedy” for challenges, such as inadequate instrument inventories, untimely receipt of loaner instrumentation, and so on.

OBJECTIVE 1: DEFINE “FLASH STERILIZATION” AND EXPLAIN WHY IT WAS REPLACED WITH “IMMEDIATE-USE STERILIZATION” (IUSS)

Flash sterilization was defined as “the process by which unwrapped instruments are sterilized for immediate use when an emergency situation arises; the process of sterilizing an item that is not packaged.” Its replacement was necessary because, in many instances, the process was uncontrolled and critical steps were not correctly performed. For example, cleaning was inadequate, and sterilization was based on a gravity cycle with a 3- or 10-minute exposure, based on whether

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the item being sterilized was porous or non-porous. Devices were sometimes placed in open baskets for sterilization and, when the cycle was completed, they were removed and transported to the point of use unprotected, which contaminated the contents.

**OBJECTIVE 2: DESCRIBE IUSS AND DISCUSS ITS PROPER USE**

A position paper addressing the correct method to reprocess instrumentation between cases was endorsed by IAHCSSMM, AORN, APIC, AAAHC, and the ASC Quality Collaboration (ASCQC). Note: the ASCQC brings together leaders from the ambulatory surgery center industry and organizations that focus on healthcare quality and safety.

The position paper is applicable to all healthcare facilities that perform sterilization (not just hospitals) in the same way that ANSI/AAMI ST79 is directed to all healthcare facilities, including hospitals, nursing homes, extended-care facilities, free-standing surgical centers, clinics, and medical and dental offices.

The importance of following the IUSS position paper is demonstrated by the fact that surveying organization personnel, including those representing TJC, have been trained on IUSS techniques and may review logs to assess whether the process is appropriately used. For example, IUSS sterilization logs can be reviewed to determine if the same instrument or set is frequently undergoing IUSS due to inadequate instrument inventories.

IUSS is also addressed in TJC’s National Patient Safety Goal NPSG 07.05.01: Implement evidence-based practices for preventing surgical site infections. This is an important goal because a risk assessment to determine the reason(s) for IUSS may show ways to reduce it.

All instrumentation must be thoroughly cleaned according to applicable manufacturer’s Instructions for Use (IFU), and by adherence to best practices. Instrumentation must be disassembled, thoroughly cleaned, processed through the automated washing process (if permitted), and inspected. Personnel performing this task must wear the appropriate personal protective equipment (PPE). Note: required PPE for decontaminating medical devices are general-purpose utility gloves and a liquid-resistant covering gown with sleeves (example: a backless gown, jumpsuit, or surgical gown), liquid-resistant shoe covers, fluid-resistant facemask, and eye protection.

Central Service (CS) personnel have the expertise to correctly and consistently perform instrument cleaning tasks. When surgical personnel performed cleaning tasks for flash sterilization, their time was inefficiently used, and instrumentation was not processed in a dedicated decontamination room. Instead, it was hasty cleaned in a surgical area, often without the appropriate cleaning implements, PPE, water quality, decontamination equipment, and expertise.

Instrument cleaning is an extremely important step in instrument sterilization, and there can be no shortcuts or missed steps. Thorough cleaning requires the use of an ultrasonic washer, medical grade air, and detergents designed for cleaning medical devices. As well, there are specific water quality requirements, and the correct size and type of brushes, among other cleaning tools and supplies, are also essential.

All critical steps must be performed. For example, the correct type of detergent must be used with the correct cleaning solution preparation, and lumened devices must be properly brushed and flushed. For thorough cleaning, instruments must be disassembled, and instruments requiring ultrasonic cleaning must be processed with this equipment. Also, the final rinse should be done with treated water (examples: deionized, reverse osmosis, and distilled). Drying requires the use of lint-free cloths or medical-grade air.

After decontamination, devices are moved to the preparation and packaging area. It’s here where they are inspected for cleanliness and functionality, and prepared for sterilization following best practices and the manufacturer’s IFU.

The purpose of packaging is to ensure that sterilization occurs and then to maintain item sterility as it is transported to the point of use and presented to the sterile field. Instruments are packaged for IUSS sterilization with a Class 5 chemical indicator in the package. Note: the packaging process should provide an easy method to identify that the containerized set is intended for IUSS, so the set will not be used for a later surgery case.

Sterilization will occur near the point of use in an IUSS process, typically in the surgical department. Since the implementation of IUSS, most sterilization container manufacturers have performed validation testing on their containers to enable their use in the IUSS process; however, some require new types of container filters. Before using sterilization containers for IUSS, the IFU must be carefully reviewed to ensure that they can be used for this purpose and will indicate the proper sterilization cycle. Note: one benefit to using sterilization containers is that instrumentation can be completely prepared in CS. The instrument set is thoroughly cleaned, inspected, assembled, and packaged, just as is done for sets undergoing terminal sterilization, and the container provides aseptic transportation and presentation.

After use, the instruments and container should be returned to CS for cleaning. Cleaning instrument containers before each use is recommended by AAMI ST 79. Therefore, sterilization containers for IUSS must also be cleaned in the CS department in-between uses.
OBJECTIVE 3: REVIEW STEAM STERILIZATION METHODS FOR IUSS PROCESSING
The use of several critical steps is required to produce a product that is sterile and safe for patient care. First, the sterilization cycle used in the IUSS process must be based on the medical device manufacturer’s IFU, just as when sterilization is done in the CS department.

With IUSS processing, the manufacturer’s IFU will dictate the cycle to be used. For example, the IFU for most medical devices requires a dynamic air removal cycle, and instruments requiring extended sterilization cycles in CS departments also need these cycles with IUSS. Since there will be little to no dry time with IUSS processing, the items may be hot and wet after sterilization, and caution is required. Also, since the package contains moisture, it cannot be stored or used for a later surgical case, and must be returned to CS for reprocessing.

Upon completion of the sterilization cycle, the sterilization parameters must be reviewed to ensure they were met. Also, the sterilizer printout must be signed to indicate that the parameters were reviewed and attained. All healthcare steam sterilizers must be tested weekly (preferably daily, as is done in most hospitals) with a biological spore of Geobacillus stearothermophilus in a process challenge device (“test pack”). The processing cycle used is the one to be tested. If a facility uses gravity and dynamic air removal cycles, both must be tested. Test results must be recorded and the records should be retained.

As with all sterilization processes, record-keeping is required, and the following information should be maintained:
• Name of person initiating the sterilization cycle and unloading the sterilizer.
• The reason for IUSS

OBJECTIVE 4: EXPLAIN THAT IUSS TRAINING AND EDUCATION IS CRITICAL
Training and education is vital to ensure effective IUSS. Personnel performing the reprocessing must be knowledgeable about all details and be able to demonstrate competencies, including:
• Decontamination of instrumentation to prepare it for sterilization
• Steam sterilization best practices
• Obtaining and complying with the manufacturers’ IFU
• Packaging items for IUSS
• Selecting correct quality monitors
• Decontaminating rigid sterilization containers, if used
• Transporting sterilized items from the sterilizer to the point of use

Certification is a demonstration of competency. Continuing education on medical device processing further assures that the required competencies are met. In addition, processing personnel must possess critical thinking skills. IAHCSMM provides a comprehensive training program for all aspects of medical device processing. The Certified Registered Central Service Technician (CRCST) training program prepares personnel to effectively reprocess medical instrumentation, and CRCST certification demonstrates the required competencies. CRCST personnel are integral members of the healthcare team that is responsible for decontaminating, inspecting, assembling, disassembling, packaging, and sterilizing reusable surgical instruments or devices in a healthcare facility. IAHCSMM offers a course that prepares candidates for the CRCST certification exam. This course is designed to measure the understanding of general CS- and infection prevention-related topics. Candidates must also successfully demonstrate skills through completion of hands-on work experience, and those holding the CRCST designation must recertify annually by completing continuing education requirements.

In addition, Certified Instrument Specialist (CIS) technicians ensure that all instruments, including those used for IUSS, are thoroughly cleaned and properly packaged and sterile. They also learn how to examine equipment for defects and report problems, test autoclaves and record the results, order supplies, assemble instrument trays, distribute supplies, and ensure that sterile supplies are within their expiration date.

OBJECTIVE 5: IDENTIFY INAPPROPRIATE MEDICAL DEVICES FOR IUSS PROCESSING
Disposable items and instrumentation used on Creutzfeldt-Jakob disease (CJD) cases are not recommended for IUSS. Further, non-emergency implants should not be subjected to IUSS when any other option is available.

AAMI ST79 addresses IUSS for implants in section 10.3: IUSS of implantable devices is not recommended; however, if it is unavoidable, full traceability to the patient should be maintained. Sterilizing implants increases the risk of a surgical site infection because they are considered a foreign body. When sterilizing implants, a biological monitor and Class 5 chemical indicator must be included. To ensure it is safe, the implant should not used until the final result is available showing negative growth. Should an implant be used and the biological monitor show positive growth, the surgeon and the facility’s infection prevention committee must be contacted immediately.

Record-keeping for implants should include the patient’s and surgeon’s name, date, and the reason IUSS was required.
Reviewing and analyzing this information can identify patterns to help prevent further occurrences. For example, records may show a pattern of IUSS on a specific day; identify instrument shortages, reveal the overscheduling of cases that are not supported with current instrumentation, and identify late-to-arrive loaner sets. If late-arriving loaners create the need for IUSS, the loaner policy and applicable procedures must be reviewed and revised. If the facility does not have a loaner policy, one must be developed and implemented. All stakeholders should be involved in policy development, including infection prevention, quality, CS, safety committees, administration, and surgery (including the department’s manager). Policy support must be provided by administrative personnel and the Supply Chain Director. The loaner policy must be shared with vendor representatives to ensure that they know about and realize the consequence of not complying with it. Note: IAHCSMM developed a position paper and policy template on loaner instrumentation.4 It is available on IAHCSMM’s website (under “News” and 2011 archives). In March 2014, IAHCSMM also released a Loaner Instrument Receipt Document, a template form facilities can use to better manage and document the receipt of loaner instrumentation. This is also available in the News section of IAHCSMM’s website.

**OBJECTIVE 6: EXPLAIN THE BASICS FOR AN IUSS POLICY**

Each facility using IUSS should have an applicable policy with a statement of purpose and procedures that are consistently followed. The procedures should be clearly stated and must be understood by all applicable personnel. The policy should be reviewed by the infection prevention and surgical safety committees, and should address all critical IUSS steps, including:

- Decontamination
- Preparation
- Packaging selection and use
- Selection of sterility monitor
- Selection of sterilization cycle
- Transport to point of use
- Documentation
- Guidelines for emergency implant sterilization using IUSS

**IN CONCLUSION**

IUSS has replaced flash sterilization, and all critical instrument cleaning, inspection, preparation, packaging, and sterilization steps must now be followed. IUSS should be minimized and not used for implants, unless in an emergency situation. Personnel should be trained and competent to perform IUSS according to the applicable policy and procedures, and record-keeping is needed to yield information about its use.  

**REFERENCES**


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