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Learning Objectives

1. Explain the intended purpose of flash sterilization in healthcare settings as defined by FDA and guidance organizations
2. Discuss the three types of flash sterilization cycles, their phases, and their most appropriate uses
3. Explain the steps and documentation requirements for effective flash process management

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How do I flash thee ...

by Cynthia Joseph, CRCST, CCSMC, BSIT, MBA/HCM

Today's healthcare providers are required to make many decisions that impact patient and staff safety. Healthcare professionals must consider and balance the standards and recommended practices of respected professional organizations, state and federal safety and compliance requirements, and their own hospital policies. This can complicate the decisions that are made in critical areas such as sterile processing departments and surgical suites.

A facility's sterile processing and OR staffs, infection preventionists and risk management specialists, among others, are responsible for making critical perioperative and sterile processing decisions every day. One constant rule is that *all instruments must be sterile for all surgical procedures*. Flash sterilization has been a practice in hospitals and other healthcare facilities for many years, yet healthcare providers still have questions about when, why and how to flash.

What is flash sterilization?

According to the Free Dictionary, "flash" means "To appear or occur suddenly; to move or proceed rapidly." In the hospital this might be translated as, "to sterilize rapidly and to appear in the operating room ASAP!" Flash sterilization was originally cleared by FDA to process one instrument at a time. It was intended for emergency situations; for example, when a one-of-a-kind instrument fell from the sterile field and needed to be returned to the field immediately.

In the U.S., a hospital's policies and procedures related to processing surgical instruments are guided by, among others, the Association for the Advancement of Medical Instrumentation (AAMI), the Association of periOperative Registered Nurses (AORN), and the Joint Commission. According to AAMI ST37:1993; 2.12, flash sterilization is "a process designed for the steam sterilization of patient care items for immediate use."

AORN's Recommendation IV from the 2009 Edition of the "Perioperative Standards and Recommended Practices" adds parameters to the definition by stating, "Use of flash sterilization should be kept to a minimum. Flash sterilization should

be used only in selected clinical situations and in a controlled manner." This new recommendation also indicates that flash sterilization should take place within a validated container, following the manufacturer's recommendations, to prevent contamination during the container's transfer to the point of use. Containers must be made of materials that can withstand the repeated temperature changes during frequent flash cycles.

The Joint Commission expects each clinical/practice setting to follow the recommended standards and guidelines set by AORN and AAMI. They expect each healthcare facility that employs flash sterilization to develop and implement policies and procedures that are followed, documented and monitored. Joint Commission requires that you "document what you do" and "do what you document." They have also updated their position on steam sterilization, indicating that "you can flash as long as it's a part of a complete and effective process of sterilization."

Centers for Medicare & Medicaid Services (CMS) has indicated that flash and rapid sterilization cycles are acceptable as long as you have met the requirement for all steps in the process including: containment of contaminated items, decontamination, sterilization in accordance with manufacturer's recommendations, and transporting items back to the sterile field "point of use" in an aseptic manner. They are also looking for a continual education program/process for the staff and policies and procedures that reflect each step in the process.

Furthermore, CMS recently stated that *flash sterilization should not be the norm, but rather, should only be used in the event of an urgent and unpredicted need for a specific device, such as to clean an instrument that was dropped on the ground during a procedure. The guidelines, effective for fiscal year 2010, were revised following CMS consultation with the Centers for Disease Control and Prevention and the Food and Drug Administration (<http://www.aorn.org/News/Managers/October2009Issue/ASCFlash>).*

Needless to say, hospitals and ambulatory surgery centers are facing the challenge of eliminating or greatly decreasing the number of flash sterilization cycles.

Let me count the ways... three cycle options

There are three types of flash sterilization cycles; gravity, prevacuum and express. However, all flash sterilization cycles have these three phases:

- The conditioning phase, during which the steam enters and air is removed from the chamber. The pressure increases inside the chamber and the steam inside reaches the sterilizing temperature.
- The exposure phase, when the actual sterilization set time and temperature are achieved.
- The exhaust phase, during which air re-enters and steam is removed from the chamber, and the pressure inside the chamber returns to atmospheric pressure.

Each type of flash cycle is appropriate for specific types of surgical and diagnostic devices. It's important to note here that *the appropriate sterilization cycle for each surgical and diagnostic device must be determined and validated by the device's manufacturer.* The sterilizer manufacturer is not responsible for validating a cycle for specific devices.

Gravity, traditionally known as the "flash" cycle

Gravity flash sterilizers were the only type of sterilizers available in the operating room for many years. The gravity displacement cycle uses gravity in the conditioning and exhaust phases to displace the air and steam. It is the most commonly used flash sterilization cycle; when OR nurses talk about "flash sterilization" they are often referring to the gravity displacement cycle.

Both non-porous and porous items can be flash-sterilized in a gravity displacement sterilizer as long as the appropriate time and temperature are used.

Prevac cycles

The dynamic air removal (prevacuum) capability was added to flash sterilizers to make them useful for complex instruments and devices such as orthopedic and neurosurgical instruments and power equipment. Prevac cycles use mechanical means to inject and remove air and steam during the conditioning and exhaust phases. Many surgical nurses are unaware that steam sterilizers now have a prevacuum cycle that can be used to sterilize items for immediate use.

Both non-porous and porous items can be sterilized in prevacuum cycles if the appropriate time and temperature are used.

However, the manufacturers of more complex instruments must provide the recommended cycle and time to use for flash sterilization. If this information is not written in your owner's manual, contact the device manufacturer and request the information in writing.

Express cycles

Express cycles are preprogrammed into the equipment by the sterilizer manufacturer. According to AAMI, express cycles are considered to be single-wrapper cycles. The cycle has a five-minute conditioning time, four-minute exposure time @ 270° F (132° C), and a three-minute drying time, which results in a total cycle time of 12 minutes. Since this cycle has a short drying time, the single wrapper may still be damp when the cycle is complete. This is why it's important to remove the tray at the end of the cycle with sterile gloves and towels, using aseptic technique.

The express cycle is *only for non-porous items that are wrapped in only one wrapper.* The wrapper protects the sterilized items during transfer to the point of use. The express cycle is not intended for power equipment, unless the manufacturer of the equipment has validated the safety and effectiveness of the express cycle for that equipment.



Rigid sterilization container systems and orthopedic organizing boxes with trays of instruments cannot be used in this cycle (or any other flash cycle) unless the containers have been validated by the container manufacturer.

In addition, wrappers such as Kimberly-Clark One Step (double thickness) sterilization wraps cannot be used for express cycles unless the manufacturer has validated their use for this abbreviated prevacuum cycle.

Flashing "loaner" technology

Device manufacturers are constantly developing advanced instruments for surgeons' new breakthrough surgical procedures. When loaning expensive new instrument sets to a hospital for a surgeon's use, manu-

facturers may not be able to supply enough instrument sets to fully meet that surgeon's scheduling needs. This leaves OR staff and the sterile processing department to deal with the turnaround challenge.

Instruments are becoming more complex, and their containers are presenting sterilization challenges also. Manufacturers must be sure that all material components can withstand the intense temperature changes of repeated sterilization.

Hospital staff must research the manufacturer's flash sterilization recommendations for these loaner sets and adhere to them. This is not always easy to do. Some manufacturers will rely on the facilities' policies and procedures for flashing, while others have specific recommendations that can be contradictory to facility policy. For example, if hospital policy states that all items will be flashed using a closed container, in a gravity cycle, for 5 or 10 minutes, but the manufacturer recommends flash sterilization using a gravity cycle for 20 minutes, what should the facility do? What about the manufacturer who recommends a prevac flash cycle for their device and makes no recommendation for gravity cycles at all? How can staff choose and validate the most appropriate cycle and exposure time?

Several manufacturers have validated their product/device utilizing a specific cycle. Some will give you a formula to use if you are faced with a device that requires more or less exposure time. The question that many providers are faced with here is: who will take the responsibility for the outcome?

According to AAMI's recommendation, validation can be accomplished by testing and documenting results. *Validation* is a "documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications." (ANSI/AAMI ST79:2006 and ANSI/AAMI ST79/A1:2008(Consolidated Text) 2 Definitions and abbreviations 2.132)

Do I flash implants?

AAMI ST79: 2006 states, "Flash sterilization of implantable devices is not recommended; however, if it is unavoidable, full traceability to the patient shall be maintained."

AAMI and AORN also recommend that biological indicators should be included in

See **SELF-STUDY** on page 32

SELF-STUDY from page 31

every load containing an implant. Documentation should include the patient's name, surgeon, item being processed, cycle, date and all indicator results, including the results of the biological indicator.

The flash dilemma

The various guidance statements and clinical realities related to flash sterilization have caused a dilemma for facilities. Some have had to redefine 'flash sterilization,' calling it an 'emergency/early release cycle.' They complete all the required documentation for early release without the results of the biological indicator. Others have validated the use of Class 6 emulating indicators and added these to their protocols along with complete early release documentation and a BI. This has provided the added assurance of immediate, documented cycle-specific results at the completion of a cycle, which allows them to determine whether or not to release the load before having the result of

the BI (which they record after the required incubation time).

Manage the flash process well

The flash sterilization dilemma continues to be debated by professionals and guidance organizations. Until a definitive solution is developed, it's important that your facility's protocols follow the recommendations currently required by the governing and certification boards, and that they include all steps in the sterile processing function. These include the decontamination step, assembly and inspection step, sterilization process (according to manufacturer's recommendations) and the aseptic transport step.

All steps should be documented in the policies and procedures, and should be readily available to all staff members who perform this process. In addition, the following data should be documented for each cycle:

- Date
- Process used/cycle type
- Patient Name

- Surgeon Name
- Operator's Name
- Item being processed
- Reason for processing
- All testing results (CI, BI and indicators)

This data can be used to create a quality management program. Flash cycle data will indicate what, why and when you flash, and can help you determine how to improve and monitor the process. This information can also help to identify insufficient inventories of specialty items and areas that require additional staff education. Ultimately, the quality management program may help you to decrease the number of flash cycles you run and more closely approach best flash practices. **HPN**

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9. UPDATE: *The Joint Commission's Position on Steam Sterilization*, Joint Commission Perspectives, July 2009, Volume 29, Issue 7, <http://www.jcinc.com/common/PDFs/fpdfs/pubs/pdfs/JCReqs/JCP-07-09-S8.pdf>.
10. AORN Management Connections; *CMS outlines flash sterilization clarifications for ASC surveys*, October 2009 Vol. 5 Issue 10, <http://www.aorn.org/News/Managers/October2009/Issue/ASCFlash>.

AAMI's recommended flash sterilization parameters

Minimum cycle times for gravity-displacement steam sterilization cycles				
8.6.1 Sterilization parameters for wrapped or containerized items				
Item	Exposure time at 121°C (250°F) in minutes	Exposure time at 132°C (270°F) in minutes	Exposure time at 135°C (275°F) in minutes	Drying times in minutes
Wrapped Instruments	30	15		15-30
Wrapped Instruments			10	30
Textile packs	30	25		15
Textile packs			10	30
Wrapped utensils	30	15		15-30
Wrapped utensils			10	30
Unwrapped non-porous items (instruments)		3		0-1
Unwrapped non-porous and porous items in mixed loads		10	10	0-1

NOTE: These tables represent the variations in sterilizer manufacturers' recommendations for exposure at different temperatures. The stated parameters are only intended to be general guidelines. For a specific sterilizer, consult only that sterilizer manufacturer's recommendations.

Minimum cycle times for dynamic-air-removal steam sterilization cycles			
8.6.2 Flash sterilization parameters			
Item	Exposure time at 132°C (270°F) in minutes	Exposure time at 135°C (275°F) in minutes	Drying times in minutes
Wrapped Instruments	4		20-30
Wrapped Instruments		3	16
Textile packs	4		5-20
Textile packs		3	3
Wrapped utensils	4		20
Wrapped utensils		3	16
Unwrapped non-porous items (instruments)	3	3	NA
Unwrapped non-porous and porous items in mixed loads	4	3	NA

8.6.2.1 General Consideration: This table provides cycle times and temperatures for currently available flash sterilization cycles. The stated parameters are only intended to be general guidelines. The sterilizer manufacturer's written instructions and the device manufacturer's written instructions should always be followed. The sterilizer manufacturer has validated the parameters for the particular sterilization cycle provided by the sterilizer. For certain devices, the exposure time might have to be extended; therefore, the device manufacturer's written instructions should also be consulted and followed.

See **SELF-STUDY** on page 34

How do I flash thee ...

Circle the one correct answer:

1. Who is responsible for knowing how the flash sterilization process is conducted?
 - a. OR and CS Managers
 - b. CS, OR staff, ICP and Risk Mgmt Specialist
 - c. All staff members who perform the operation of flash sterilization
 - d. All of the above
2. Flash sterilization was originally cleared by FDA to process one instrument at a time in emergency situations.
 - a. True
 - b. False
3. Which guidance organizations have recommendations and guidelines for flash sterilization cycles?
 - a. AAMI and AORN
 - b. AAMI/ANSI, AORN and Joint Commission
 - c. AORN, AAMI, CMS and Joint Commission
 - d. None of the above.
4. There are six sterilization cycle options that can be utilized for flash sterilization; gravity, prevac, express, exposure, exhaust and conditioning.
 - a. True
 - b. False
5. Flashing implantable devices is acceptable if the items processed are fully traceable to the patient and all information related to the implant is maintained.
 - a. True
 - b. False
6. What steps are the governing and certification boards expecting facilities to include in their flash sterilization policies and procedures?
 - a. Decontamination process
 - b. Assembly and inspection process
 - c. Sterilization process according to manufacturer's recommendations
 - d. Transport to point of use
 - e. Disposal
 - f. a through d
7. The same documentation data required for each flash sterilized item can also be used to:
 - a. Indicate what, why and when you flash
 - b. Establish a quality management program
 - c. Identify insufficient inventories of specialty items
 - d. Decrease the overall use of flash sterilization
 - e. Identify areas that require additional staff education
 - f. a through c
 - g. All of the above
8. Centers for Medicare & Medicaid Services (CMS) has indicated that flash and rapid sterilization cycles are acceptable as long as you have met the requirement for all steps in the process including:
 - a. Containment of contaminated item
 - b. Sterilization in accordance with manufacturer's recommendations
 - c. Aseptic transport back to the sterile field
 - d. Decontamination
 - e. All of the above
 - f. b, c and d
9. Regarding implants, AAMI and AORN have stated that:
 - a. Flash sterilization of implantable devices is not recommended
 - b. Documentation include the patient's name, surgeon, item being processed, cycle, date and all indicator results, including the results of the biological indicator
 - c. If it is unavoidable to flash an implant, full traceability to the patient must be maintained
 - d. Biological indicators be included in every load containing an implant
 - e. All of the above
 - f. a, b, and d
10. According to AAMI, validation:
 - a. Can be accomplished by testing and documenting results
 - b. Is a documented procedure
 - c. Obtains, records and interprets the results required to establish that a process will consistently yield product complying with predetermined specifications
 - d. Can't be done
 - e. a through c

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