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## Learning Objectives

1. Understand flash sterilization best practices.
2. Discuss fundamental issues of flash sterilization.
3. Describe new guidance from TJC and CMS on flash sterilization.

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# Flash Sterilization: Exposing best practices in 2010

by Dorothy Larson

I'm sure it's no surprise to hear that there has been an increased focus regarding the practice of flash sterilization in health care facilities over the past several months. Why is flash sterilization under the microscope, and how confident are you that your facility is adhering to best practices? Let's take time to review some of the flash sterilization fundamentals from AAMI and AORN. We'll also discuss what The Centers for Medicare and Medicaid Services (CMS) and The Joint Commission (TJC) have to say about flash sterilization.

There may be some things you've been contemplating recently when running flash steam sterilization cycles, such as: Are we flashing too much? Have I selected the correct steam sterilization mode for the devices we're sterilizing? Are we monitoring our flash sterilization cycles properly? Where should we be placing internal chemical indicators in our flash containers? What documentation needs to be kept? Is our facility prepared for a Joint Commission survey? Let's take a closer look at these questions. Get ready for a quick, yet thorough review of flash steam sterilization. You won't want to miss any important steps!

## What is flash sterilization, and why the focus on flash sterilization today?

Flash sterilization is the process designed for the steam sterilization of patient care items for immediate use.<sup>1</sup> Flash sterilization involves a high temperature ranging from 270-275°F with minimal or no dry time. The sterilization process used may be either gravity or dynamic-air-removal cycles (e.g. prevacuum), and the type of packaging being used today includes perforated, mesh-bottomed, open surgical trays, rigid sterilization container systems, protective organizing cases; and single-wrapped surgical trays.

There is still a misconception that sterilizing in an open tray or rigid container using a prevacuum cycle is not consid-

ered flashing. If there is little or no dry time involved, and when an item cannot be stored for use at a later date, then it is a flash sterilization cycle.

Over the years, people have misused flash sterilizers, moving from flashing a single instrument to sterilizing entire instrument sets because of a lack of inventory and poor scheduling.

## How much flashing is acceptable?

You might be wondering if your facility is flashing too much, or just the right amount. There may not be a definitive answer to this question, however, you could start by assessing the amount of flash sterilization that's being done in your facility. You may already have taken appropriate measures to reduce the number of flash cycles you're running, and these types of efforts are encouraged. Or, your facility might be flashing all day long, every day! If the latter sounds familiar, then you probably should take a closer look at your process and explore areas for improvement.

Planning ahead, appropriate packaging, inventory management and cooperation with vendors can help decrease the need to flash sterilize instruments and implants.<sup>2</sup>

## The Joint Commission position

In 2009, TJC issued an updated position statement on steam. The intent was to de-emphasize the focus on the number of flash sterilization cycles a facility is running and instead focus on the entire sterilization process. The Joint Commission surveyors will be looking at all the critical processes included in steam sterilization, such as cleaning and decontamination, sterilization, and storage and return to the sterile field.

You can prepare for a survey by TJC by checking with staff to see if they can produce and demonstrate compliance with device manufacturer's written guidance on cleaning and sterilizing instruments, and that they are using biologi-

cal indicators (BIs) and chemical indicators (CIs) according to manufacturer's instructions. Also, ensure BI log books or electronic records are up-to-date. Finally, check to see that any flash sterilized instruments are protected as they travel from the sterilizer to the sterile field.<sup>3</sup>

**CMS on flash sterilization**

The CMS has provided recent clarification to state survey agencies for assessing whether flash sterilization is being conducted appropriately at ambulatory surgery centers (ASCs). Effective January, it has been suggested that surveyors ask these questions:

1. Is the sterilizer labeled for this cycle by the manufacturer?
2. What is the sterilizer manufacturer-recommended load for that cycle?
3. Is the containment device used labeled by its manufacturer for use in that cycle?
4. For what load is the containment device recommended by its manufacturer?
5. Is the CI used labeled for use in this cycle by its manufacturer?
6. If a BI is used, is it labeled for use for this cycle by its manufacturer?
7. If the cycle is used frequently, is it checked regularly with a BI?

While CMS stresses that flash sterilization is not inherently bad, "Sterilization of unwrapped/uncontained loads should not be routine practice in ASCs but should be used only for an urgent and unpredicted need for a specific device (e.g., when an instrument is dropped). Routine sterilization of unwrapped/uncontained loads continues to be inappropriate and should be cited as a violation of 42 CFR 416.51(a)."<sup>4</sup> Essentially, CMS sees flash sterilization as being acceptable as long as the devices are wrapped or containerized and that sterilization is conducted following all manufacturers instructions.

**Selecting the appropriate flash sterilization cycle**

A question that often gets asked is, "Should we flash sterilize using the prevacuum or gravity cycle?" However, the first question that should be asked is "What are the written recommendations of the device manufacturer?" To ensure patient safety, the reusable medical device manufacturer (MDM) is responsible for ensuring that the device can be effectively cleaned and sterilized.

The image shows a page from the '3M Sterilization Assurance Standards Practice' document. The main heading is 'FLASH Sterilization'. It includes a 'Definition' section, a 'Biological Indicator Testing of Flash Cycles' section, and a 'Recommended Practices for Monitoring of Flash Sterilization' section. The 'Recommended Practices' section lists several key points: 'Flash sterilization should be used only to select critical situations and a container name', 'Flash sterilization should be used for emergency situations', and 'Flash sterilization should not be used for implantable devices'. There is also a table with columns for 'Sterilization Type', 'Quality Requirements', and 'Approved or Noted (e.g., additional)'. The 3M logo is visible in the bottom right corner of the document image.

3M Sterilization Assurance Standards Practice

The device labeling should identify specific methods of cleaning and sterilization that have been validated by the manufacturer. You should follow their sterilization instructions even when the recommended times are longer than the cycles recommended by the sterilizer manufacturer. Note also that some container manufacturers specify exposure times longer than times recommended by the sterilizer or device manufacturer.

If you only use a certain programmed sterilization cycle because it's always been done that way, then this is a sign there's probably some work to be done in this area. Begin by making a list of all the items you're processing, and then obtain up-to-date written manufacturer's instructions. Once you have this information, you'll be able to select the appropriate steam sterilization parameters. These instructions should be kept in a file and then periodically reviewed. If your flash sterilizer is used to run both gravity and prevacuum cycles, ensure appropriate monitoring products are used.

**AAMI and AORN recommendations**

Current recommended practices (RP's) for sterilization from the Association for the Advancement of Medical Instrumentation (AAMI) and the Association for peri-Operative Registered Nurses (AORN) state that any healthcare facility that reprocesses medical devices must have an effective quality control program. This includes monitoring steam sterilization

cycles using physical monitors, chemical and biological indicators, having a product recall procedure and a continuous quality improvement program, maintaining appropriate documentation, and reporting practices that enable traceability of each facility-sterilized medical device to the patient.

AORN states that use of flash sterilization should be kept to a minimum and should be used only in selected clinical situations and in a controlled manner, and only when there is insufficient time to process by the preferred wrapped or container method. Flash sterilization should not be used as a substitute for sufficient instrument inventory.<sup>2</sup>

There are several necessary steps to help ensure a successful flash sterilization outcome, including:

- Properly cleaning and decontaminating surgical instruments;
- Following device manufacturer's written instructions for cycle type, exposure times, temperature settings, and drying times, if applicable;
- Using sterilization containers or trays validated for flash sterilization;
- Using Class 5 chemical integrating indicators within each sterilizer container or tray;
- Practicing aseptic technique during transport to the point of use;
- Using flash sterilized items immediately;
- Using representative process challenge devices (PCDs) to routinely monitor sterilizer efficacy;
- Using physical monitoring devices (e.g., printouts) to verify cycle parameters;
- Using a BI and Class 5 CI to monitor implant loads; and
- Documenting cycle information and monitoring results.

The AORN RP's are clear that implantable items should not be flash sterilized except in cases of emergency when other options are not available. When an emergency situation exists, the RP states that a rapid-action BI and a Class 5 CI should be run with the load. The implant should be quarantined until the rapid-action BI result is negative.<sup>2</sup>

AAMI ST79 also states that flash sterilizing implants is not recommended. (8.6.2.1) For routine monitoring of flash sterilization cycles, the following is recommended (10.7.4):

- Test each type of tray configuration routinely processed, such as a perfo-

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## SELF-STUDY from page 33

rated, mesh-bottomed, open surgical tray; a rigid sterilization container system; a protective organizing case, or a single-wrapped surgical tray. When running the same type of cycle for different exposure times, only the shortest cycle time needs to be tested.

- Place the BI(s) and CI(s) in the most difficult-to-sterilize area of the PCD. For rigid sterilization container systems, follow container manufacturer's recommendations.
- Place the PCD on the bottom shelf of an otherwise empty sterilizer, and in the area least favorable to sterilization, which is generally over the drain.
- For dynamic-air-removal sterilizers (prevacuum), run a Bowie-Dick test pack daily.

All of the physical monitors, chemical and biological indicators should produce acceptable results, indicating the flash cycle was correct and complete. Results of these monitoring devices should be interpreted by a qualified individual.

## Rigid sterilization containers

There has been a notable increase in the use of rigid containers for flash sterilization in the OR and, with that, increased questions about how to monitor. AORN recommends the use of rigid sterilization containers that are specially designed and intended for flash sterilization cycles. The reason for this is to reduce the risk of contamination during transport of items to the point of use, and for the ease of presentation to the sterile field.

When selecting the sterilization cycle to use for a specific rigid sterilization container, the following should be taken into consideration:

- The container system manufacturer's written recommendations; and
- The sterilizer manufacturer's recommendations.

The sterilizer manufacturer's operator's manual should be consulted for cleared exposure times, temperatures, and drying times. And keep in mind there are specific types of medical equipment, such as some air-powered equipment, that might require prolonged exposure times. (ST79, section 8.6.3)

ST79 recommends that users conduct a pre-purchase evaluation of rigid sterilization container systems to verify sterilization efficacy in their facility, using their sterilizers and steam supply. The correct cycle parameters should be

selected and verified based on the results of product testing.(10.10.3.2.1)

## Chemical indicators/integrators

The AORN Recommended Practices for Selection and Use of Packaging Systems for Sterilization, Recommended Practice IX, provides this specific guidance for the placement of internal chemical indicators:

- Two chemical indicators/integrators should be placed inside rigid containers, one in each of two opposite corners of the inside basket;
- Multi-level containers should have a chemical indicator/integrator placed in two opposite corners (e.g., one in each of two corners) of each level.<sup>5</sup>

AAMI ST79 recommends a Class 3, 4, or 5 internal chemical indicator be used in the routine monitoring of items being sterilized, and placed in the area of the package, tray, or containment device considered to be least accessible to steam penetration. For a containment device, consult the manufacturer's instructions for placement of the CI. This location might or might not be the center of the package, tray, or containment device. (10.5.2.2.2)

## Documentation

Record keeping documents the materials that have been processed and the results of the sterilization process monitoring. The AORN RP for Sterilization states, "Documentation of cycle information and monitoring results should be maintained in a log (electronic or manual) to provide tracking of the flashed item(s) to the individual patient." A log or data base to trace sterilized items used on patients should include the following information for each load:

- Item(s) processed;
- Patient receiving the item(s);
- Cycle parameters used (e.g., temperature, duration of cycle);
- Date and time cycle is run;
- Operator information;
- Reason for flash sterilization.

This level of detail is necessary to allow the sterilized items that are used on patients to be traced.

## Summary

It is everyone's responsibility to help ensure that flash sterilized items are being properly processed for the safety of every patient! Are your policies and procedures up-to-date? Following written recommendations is the basis for a

department's policies and procedures. Create an inventory of all the manufacturer's instructions for the devices you flash sterilize, and make sure that you have those "flash" sterilization instructions on file. Conduct a mock survey of departments doing flash sterilization to ensure compliance. This could be done by following an instrument from the time it leaves the O.R. to when that same instrument is returned to the next O.R.

Take the time to assess your flash sterilization practices to see if there are gaps that still exist. Think positively! Start with a list of everything you are doing correctly today, and then identify any shortcomings, such as educational needs, lack of necessary equipment or instruments, poor documentation compliance, getting loaner instruments delivered on time, etc. Ensure the appropriate monitoring is being done with the use of physical monitors, chemical and biological indicators, and that everything that needs to be recorded gets documented. Make sure personnel are wearing appropriate PPE when decontaminating instruments. A better understanding of flash sterilization best practices can expose ways of improving routine flash sterilization practices. Following best practices will help lead to best patient outcomes! **HPN**

*Dorothy Larson, CSPDT: For over 10 years Dorothy Larson was the voice on the end of the 1-800-441-1922 3M Healthcare Tech Line for sterilization products. Larson spends her days solving sterilization process failures, answering technical questions, and providing technical information and documentation as requested. Larson is a Technical Service Representative for the 3M Infection Prevention Division, St. Paul, MN. She is certified as a Sterile Processing and Distribution Technician and a member of IAHCSSM.*

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**Flash Sterilization**  
**Exposing best practices in 2010**

Circle the one correct answer:

1. Flash sterilization is the process designed for the steam sterilization of patient care items for immediate use.  
A. True      B. False
2. Sterilizing in a rigid container using a prevacuum cycle with little or no dry time is not considered flashing.  
A. True      B. False
3. Planning ahead, inventory management and cooperation with vendors can help decrease the need to flash sterilize instruments and implants.  
A. True      B. False
4. Follow MDM's sterilization instructions even when the recommended times are longer than the cycles recommended by the sterilizer manufacturer.  
A. True      B. False
5. Both AORN and AAMI endorse the routine use of flash sterilizing implantable items.  
A. True      B. False
6. For routine monitoring of flash sterilization cycles, only one type of tray configuration routinely processed needs to be tested.  
A. True      B. False
7. Monitoring the sterilization process using physical monitors, CIs, and BIs is an important part of a quality control program.  
A. True      B. False
8. When an emergency situation exists and an implant must be flashed, AORN suggests a rapid-action BI and a Class 5 CI should be run with the load, and the implant should be quarantined until the rapid-action BI result is negative.  
A. True      B. False
9. AORN recommends two chemical indicators/integrators be placed inside rigid containers, one in each of two opposite corners of the inside basket.  
A. True      B. False
10. Maintaining documentation of cycle information and monitoring results is necessary to provide tracking of the flashed item(s) to the individual patient.  
A. True      B. False

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