

Sterilization & Infection Control

Are you up to speed on flash sterilization?

Flash sterilization is a fact of life in operating rooms—an item is dropped during a case, a surgeon brings a special instrument that needs to be sterilized, and so on. Professional organizations recommend keeping flash sterilization to a minimum. If it must be done, it must be done properly.

The Association for the Advancement of Medical Instrumentation (AAMI) says, “When performed correctly, flash sterilization is safe and effective.” Emphasis is on the word “correctly.”

Use this checklist to see if your practice is consistent with the latest recommendations.

You’re familiar with guidelines and standards for flash sterilization

— Association of periOperative Registered Nurses (AORN). Recommended practices for sterilization in the perioperative practice setting. In *2006 Standards, Recommended Practices, and Guidelines*. www.aorn.org

— Association for the Advancement of Medical Instrumentation. *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. ANSI/AAMI ST-79, September 2006. www.aami.org.

AAMI recommends that flash sterilization be considered only if:

- The facility can clean and decontaminate, inspect, and arrange the instruments into the recommended tray or container.
- The physical design of the area permits delivery of the sterilized devices directly into the procedure room.
- The facility has developed procedures that are followed and audited to ensure proper handling of devices and safe delivery to the point of use.
- The item is needed for use immediately after sterilization.

Your facility does not flash sterilize implants

AAMI and AORN say implants should not be flash sterilized. If flash sterilization must be done in an emergency, you have reviewed their recommendations for monitoring the process.

Flash sterilization is as well controlled and rigorous as sterilization for wrapped loads

Among issues to consider:

- You follow a multistep process as recommended by AAMI, including cleaning, decontamination, and preparation. Sterilization will not compensate for poor or inadequate cleaning!
- All devices are thoroughly cleaned and rinsed following the manufacturer’s instructions.
- Instruments are cleaned in a dedicated soiled utility room with negative pressure and 10 air exchanges per hour. Personnel who clean instruments wear the proper personal protective equipment.
- In an emergency, if a single item must be cleaned in a substerile room, all precautions to prevent cross-contamination are taken.

— You've planned how to transport flash-sterilized items to the point of use to minimize the potential for contamination.

If the flash sterilizer is in a substerile room adjacent to the OR, the open-mesh pan method is sufficient as long as precautions are taken to protect the device while transferring it from the sterilizer to the OR. Many facilities use flash sterilization containers to contain items during and after sterilization. It is best to standardize to one flash sterilization method—open pan vs container—to reduce the amount of sterilizer testing.

— If flash sterilization containers are used, you have written, scientific documentation from the manufacturer that the containers are suitable for this purpose.

— You've tested the containers in your sterilizers as recommended by AAMI.

— Your facility does not flash sterilize items in cases, such as loaner orthopedic instruments, without written verification that the cases are compatible with flash sterilization.

— The staff selects the appropriate sterilization cycle for flash sterilization as recommended by AORN and AAMI.

You perform quality monitoring

The quality monitoring process includes:

Physical parameters

Physical monitoring includes time, the temperature and pressure recorder, computer printouts, and gauges.

— Competencies for all sterilizer operators have been verified, including operation and use of sterilizers, interpretation of printouts, and installation of paper rolls.

— At the end of each cycle, the sterilizer operator:

- reviews the chart or printout
- verifies that the correct temperature was achieved and maintained for the correct amount of exposure time
- signs the recording document before items are removed.

Sterilizer efficacy testing

— Prevacuum steam sterilizers are tested on installation and routinely to ensure the vacuum system adequately removes air during the sterilization process. This is termed the Dynamic Air Removal Test (DAR), formerly called the Bowie-Dick test.

— For routine testing and when the sterilizers remain on all the time (steam supply is not shut off), the DAR test is performed at the same time daily (usually the first cycle of the day).

— If the sterilization equipment is shut off, the DAR test is performed as the first cycle of the day before the sterilizer is used for any other purpose. (Some sterilizer manufacturers recommend that a warmup cycle be performed first.)

Chemical indicators

Chemical indicators (CIs) are designed to respond with a chemical or physical change to one or more of the physical conditions in the sterilizer chamber. Their main function is to detect potential sterilization failures that could result from personnel errors or sterilizer malfunctions. Important: the "pass" response of a CI does not prove that the item accompanied by the CI is sterile.

— When selecting CIs, you have obtained data from the manufacturer on reliability, safety, storage, and performance characteristics.

— A CI is used in each tray or container being processed as recommended by AAMI and AORN.

— After the sterilization cycle has been completed and before the item is used, the staff interprets the CI results in accord with the manufacturer's written instructions.

— The device or tray is not used if the CI fails to produce the correct change.

Biological indicators

Biological indicators (BIs) consist of a standardized viable population of bacterial spores known to be resistant to the mode of sterilization being monitored. BIs are intended to demonstrate whether the conditions were adequate to achieve sterilization.

- ___ Only BIs specifically validated and recommended for use in flash sterilization cycles are used.
- ___ The BI manufacturer has provided written instructions for use of the BI.
- ___ The BI manufacturer has provided data on the reliability, safety, performance characteristics, type of cycles, and sterility assurance level (SAL) of its product.
- ___ Routine BI testing is performed at least weekly and preferably daily, as recommended by AAMI and AORN. The frequency depends on the age and dependability of the sterilization equipment as well as the frequency of flash sterilization.
- ___ For routine BI testing, the biological challenge test tray is the same type of tray routinely processed through the flash sterilizer, as AAMI recommends. If single instruments are usually flash sterilized, the test tray could be a single instrument placed inside the tray or container. One or more BIs are placed inside the tray or container for the test.
- ___ BI testing is performed for each type of cycle (eg, gravity, flash). The shortest cycle should always be the cycle tested because it represents the greatest challenge to the sterilizer. Be sure to read the package insert to ensure the BI being used is compatible with the cycle (gravity versus prevacuum) and to see if there are any limitations. For example, one type of flash sterilizer may require the minimum exposure time to be set for 4 minutes rather than 3 minutes. In this case, it is important to set the sterilizer's exposure time to 4 minutes to prevent the staff from selecting the 3-minute cycle.
- ___ If a positive BI occurs, all devices processed in the affected sterilizer are considered nonsterile, back to the last known negative BI.
- ___ BI testing is also performed for sterilizer installation or relocation testing, after any major repairs, and with any loads containing implantable devices (though flash sterilization of implants is not advised).

Flash sterilization containers

- ___ Flash containers are biologically monitored as recommended by AAMI.
- ___ If your facility uses a prevacuum flash sterilizer for open-pan and flash-container flash sterilization cycles, recommended testing includes:
 - DAR test
 - BI for prevacuum cycle (in open mesh pan)
 - BI for gravity cycle (in open mesh pan)
 - BI in flash sterilization container (for cycle usually used).

Flash sterilization is documented

- ___ Documentation includes, at a minimum:
 - date
 - sterilizer number
 - patient ID number
 - surgeon
 - device
 - documentation that device was cleaned (can be a check mark)
 - CI included in load
 - BI run (to document first BI of the day as well as any implant cycles).
- ___ Audits of flash sterilization records are performed monthly and any deficiencies noted. (Initially, audits may be required weekly or even daily.) Followup corrective action is taken.
- ___ Audit results are reported to the infection control and risk management departments. ❖

—Nancy Chobin, RN,
AAS, ACSP, CSPDM
Corporate Consultant/Educator
St Barnabas Health Care System
West Orange, NJ

Nancy Chobin is a member of the AAMI Steam Sterilization Standards Committee and the AAMI Steam Sterilization Hospital Practices Working Group.

A sample flash sterilization log is in the OR Manager Toolbox at www.ormanager.com.

What will Joint Commission ask?

The Joint Commission may look at the entire process for flash sterilization. Some questions surveyors may ask:

- How is flash sterilization performed?
- Does flash sterilization practice comply with the facility's policy?
- Is the documentation correct?
- Can flash-sterilized devices be tracked to the patient?
- Are implants flash sterilized?
- Most important, are items being routinely flash sterilized because of insufficient instrumentation or poor scheduling?