

# Flash Sterilization - What Sterile Processors Need to Know

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**\*\*This in-service has been Approved by the CBSPD, Inc. for 1 CEU.**

Editor's note: This Inservice is not being published to advocate flash sterilization but rather to explain how the technique is performed.

The sterilization process itself is not the concern but rather how the entire process is performed. John Perkins, PhD, in his publication Principles and Methods of Sterilization, states that "speed is a militant force against sterilization.<sup>1</sup> It is important to remember that sterilization is an event. It requires the maximum control of all variables so as to affect a minimum margin of doubt in the end result." Flash sterilization implies that we can achieve sterilization instantaneously (in a flash). However, many factors can adversely affect the outcome of effective sterilization.

## **Recommended Practices**

Immediate-use sterilizers are most often located in the OR and in ambulatory surgery centers, but can also be found in some labor and delivery departments. Immediate-use sterilization is appropriate in emergency situations, as when a one-of-a-kind item is dropped on the floor during surgery or otherwise becomes contaminated and is needed urgently. However, AORN does not support the use of immediate-use sterilization as a substitute for a sufficient inventory of surgical instrumentation. Major issues associated with immediate-use sterilization are insufficient time to correctly clean the devices before sterilization and the potential for contamination of the device after sterilization (because there is no packaging to protect it). Furthermore, many manufacturers no longer provide immediate-use sterilization instructions for their devices.

Immediate-use sterilization should not be attempted without the device manufacturer's written instructions for cleaning and sterilization. The sterilization instructions must be replicated exactly, meaning that if only a gravity-displacement immediate-use cycle was validated for the device, then the device must be sterilized in a gravity-displacement immediate-use cycle (not a dynamic-air-removal immediate-use cycle).

Immediate-use sterilization was usually performed with the device unwrapped and in a perforated, mesh-bottom, open tray. It is now often performed with the device in a containment device such as a rigid sterilization container. AORN recommends that items to be sterilized for immediate use be contained in a containment device validated for immediate-use sterilization cycles (AORN, 2011).

Immediate-use sterilization will quickly sterilize a device if there is no barrier (packaging) to impede air removal and steam penetration. Special "flash containers" have been developed to protect devices after sterilization and during transport to the OR. (These containers are not meant for storage of the sterile items; the items must be used immediately, not stored for future use or held from one case to another.) The use of such containers might necessitate a longer sterilization time than the unwrapped method. The container manufacturer's written instructions for cleaning, maintenance, and cycle exposure times should be followed.

The Joint Commission (JC) published new survey standards for steam sterilization, including immediate-use sterilization, in 2009 (Joint Commission, 2009). The JC discussed the issues associated with flash sterilization with “experts in the field, professional organizations, and government organizations.” The JC will now focus its survey efforts on the entire sterilization process, not just on the amount of flash sterilization performed: “. . . surveyors will review the critical steps of disinfection and sterilization to determine if the process is appropriate.” The JC announcement describes the three critical steps of reprocessing:

- 1) “Cleaning and decontamination. All visible soil must be removed prior to sterilization because steam and other sterilants cannot penetrate soil, particularly organic matter. Manufacturers’ instructions are available for all instruments; these include directions for the cleaning and decontamination process. Some smooth metal instruments may be easily brushed clean, while complex products may require disassembly and special cleaning techniques. Many manufacturers specify that an enzymatic soak be used as well.
- 2) “Sterilization. Most sterilization is accomplished via steam, but other methods are also available. Steam sterilization of all types, including flashing, must meet parameters (time, temperature and pressure) specified by both the manufacturer of the sterilizer, the maker of any wrapping or packaging, and the manufacturer of the surgical instrument. In addition to these instructions, parametric, chemical and biological controls must be used as designed and directed by their manufacturers.
- 3) “Storage or return to the sterile field. Each newly sterilized instrument must be carefully protected to ensure that it is not re-contaminated. For full steam sterilization cycles, packs of instruments are wrapped and sealed. Instruments subjected to steam sterilization using methods other than full cycle sterilization may be transported in ‘flash pans’ or other devices specifically designed for the prevention of contamination during and after the steam process.”

In addition, the JC has advised that “surveyors will, among other activities

- “Observe instruments from the time they leave one operating room to when they are returned to the next.
- “*Ask health care workers to provide the manufacturers’ instructions for instrument sterilization, and to describe and demonstrate how instruments are being cleaned and decontaminated according to those written instructions.* [emphasis added]
- “Observe the cleaning of instruments. Rinsing is rarely enough to properly remove soil from instruments; meticulous cleaning is needed.
- “Verify that staff members are wearing appropriate personal protective equipment.
- “Observe the sterilization process. The surveyor will ask for the manufacturer’s instructions for the following items: the sterilizer, wrapping or pacing, and the instruments.
- “Review sterilization logs. Surveyors will ask about physical chemical and biological indicators.

- “Observe the return of instruments to the sterile field and verify that they are being protected from recontamination.”

These new JC survey requirements reinforce the need to perform immediate-use sterilization to the same standard as terminal (wrapped) sterilization.

Subsequent to the release of the new JC survey standards, a group published a multi-society position paper to further discuss immediate-use sterilization. This position paper is endorsed by AAMI, AORN, APIC, the Accreditation Association for Ambulatory Health Care (AAAHC), the Ambulatory Surgery Center Quality Collaboration (ASC QC), and IAHCMM. The paper states that “personnel involved in reprocessing should be knowledgeable and capable of exercising critical thinking and judgment, and should implement standardized practices.” Certification and the availability of standards and recommended practices are necessary for staff competency. The position paper stresses the importance of following the medical device manufacturer’s written instructions for reprocessing. If these instructions are unclear, incomplete, require a cycle not available in the facility, are not compatible with the sterilizer or container/wrapper instructions for use, the device manufacturer should be contacted for more information or guidance. The medical device manufacturer has the final word on the processing instructions. The position paper also stresses that implants should not be processed by immediate-use sterilization excepted in documented emergency situations. The multi-society statement is available from the Certification Board for Sterile Processing & Distribution, Inc. website at [www.sterileprocessing.org](http://www.sterileprocessing.org)

### **Steps in the Flash Sterilization Process**

Probably the two most important steps after proper cleaning are to confine and contain the device after sterilization to avoid contamination.

### **Getting the Devices Clean**

Transporting soiled instrument(s) to the decontamination (soiled utility room) area can present problems (e.g. a table cover is placed over the instruments; instruments are in a solution). Too often, instruments to be flash sterilized are “rinsed off”, washed in scrub sinks or any wash facility available. However, the decontamination process, which if done correctly removes all soils (visible and invisible), is essential to effective sterilization. Soiled surgical instruments should be transported to the decontamination area in a manner that prevents contamination of the person transporting them and the environment. A plastic bin that can be cleaned and disinfected works nicely for transport.

The area in which the instruments are decontaminated should be physically separated from the area in which the instruments are inspected and reassembled. Doors leading to the decontamination area should be kept closed. Personnel assigned to the decontamination area should wear personnel protective equipment (PPE) (i.e., head cover, shoe covers, impervious gown, gloves, face/eye protection) when cleaning surgical instruments. All PPE should be removed and hands washed when leaving the decontamination area.

### **Using enzymatic detergents aids in the decontamination process.**

Using enzymatic detergents aids in the decontamination process. All devices should be thoroughly cleaned and rinsed following the device manufacturers' written instructions. Proper cleaning agents are necessary to make the cleaning process more efficient and to protect the surgical instruments' finish. All detergents should be measured carefully and used in accordance with the manufacturers' instructions. Instruments with multiple parts should be disassembled for cleaning. Soft-bristle brushes should be used to clean the instruments, with particular attention paid to ratchets, serrations, and box locks (joints). Manual cleaning should be done while holding the instrument and the brush under the water level to prevent aerosolization

of bacteria. Always strictly follow the manufacturer's instructions for cleaning including the chemicals and the cleaning methods recommended (e.g. ultrasonic cleaning).

### **Preparing the Devices**

After decontamination, surgical instruments should be treated with a water-soluble lubricant (often referred to as instrument "milk" because of the white color). This lubricant protects the instrument's surface and can prolong its life. Follow the manufacturers' instructions for mixing and when the solution needs to be changed (expiration date). The lubricant should be allowed to air dry.

Items with multiple parts should be kept disassembled for sterilization to allow the steam to make contact with all instrument surfaces.

When preparing items for flash sterilization, all hinged instruments should be in the open position, multiple-part devices should be disassembled. According to AAMI ST-79, devices with lumens should only be flushed with distilled water immediately before sterilization if the device manufacturer recommends this process. Today, this is usually recommended for lumened devices being processed in a gravity displacement steam cycle, not a pre-vacuum cycle.

AORN no longer recommends that steam sterilization for immediate use Flash sterilization ~~can~~ be performed with the device unwrapped (most common – called the open pan method) or with a single wrapper. (One manufacturer of steam sterilizers offers a special flash sterilization cycle in which a single wrapper is used to help contain the device as it is transferred from the sterilizer to the point of use after sterilization.) In addition, flash sterilization containers are available that totally contain the instrument during and after sterilization. The AAMI recommends that flash sterilization containers be tested in your facility's sterilizers to verify that sterilization can be achieved when used in your particular sterilizers. The process for container validation is described in the AAMI document. It is important that the manufacturer of the containers provide written, scientific documentation that its containers are suitable for the flash sterilization process.

### **Sterilization**

Steam sterilization for immediate use (SSIU) can be performed in gravity displacement or pre-vacuum sterilizers that are equipped for such cycles. Some individuals get confused with the cycles. Gravity displacement is usually referred to as "flash" and pre-vacuum cycles as pre-vacuum. However, in flash sterilizers, they are both flash cycles, it is the manner in which air removal takes place that differs. The pre-vacuum cycle has mechanical removal of air while the gravity cycle uses gravity to remove air. It is important to remember that in SSIU cycles, there is little to no drying time, this is the major difference in a SSIU cycle and a wrapped cycle.

The minimum flash exposure times are detailed in Figure 1. However, it is important to understand that device manufacturer's should be contacted for their specific flash sterilization instructions and this information reconciled with the standard cycle times. Many device manufacturers no longer give flash sterilization instructions.

Most Operating Rooms have high speed gravity flash sterilizers that operate at 270°F. Today ORs are replacing their high speed gravity flash sterilizers with pre-vacuum flash sterilizers which can also operate as high speed gravity units. The pre-vacuum flash sterilizers also operate at 270°F.

The pre-vacuum flash sterilizers require a Bowie-Dick- test daily. This test measures the sterilizer's ability to remove all the air from the chamber in a pre-determined period of time. Look for a uniform color change in the test sheet; otherwise air has been detected in the pack.

It is essential that the test be performed according to the test manufacturer's instructions. Usually the test is placed on the bottom shelf over the drain line (coldest spot in the sterilizer and the most difficult location to heat-up) and the cycle set for 3 to 3 ½ minutes exposure with 0-1 minute dry time.

Some sterilizers are pre-set for a Bowie-Dick test cycle. If the sterilizer's cycle cannot be adjusted, a 4-minute exposure is also acceptable. Some sterilizers also include a one-minute dry cycle. The Bowie-Dick test must be negative before the sterilizer is placed into use. If the sterilizer fails the test a repeat test should be performed. If the repeat test is still positive, a service call should be placed. If the sterilizer is pre-vacuum and has a gravity displacement cycle, the gravity displacement cycle can still be used while waiting for the pre-vacuum cycle to be corrected.

### **Chemical Monitoring**

Characteristics – these devices are sterilization process monitoring devices. They are designed to respond with a characteristic chemical or physical change to one or more of the physical conditions within the sterilizer chamber. The chemical indicator (CI) is intended to detect potential sterilization failures that could result from personnel errors or sterilizer malfunctions. The “pass” response of a CI does not prove that the item accompanied by the CI is sterile.

When selecting chemical indicators, obtain data from the manufacturers regarding their reliability, safety and performance characteristics. The CI manufacturer should be required to provide written information how to interpret the CI results.

The CI manufacturer should be required to provide information on the sterilization conditions the CI will detect; the storage requirement for CI and the shelf life of the CI (expiration date). Chemical indicators should be selected that do not bleed, flake or otherwise adulterate devices being sterilized.

A chemical indicator should be used in each tray or container being processed. After the sterilization cycle has been completed interpret the CI results in accordance with the written instructions of the manufacturer.

### **Biological Testing**

The biological testing should reflect the type of sterilization performed and the conditions under which flash sterilization are performed. If flash sterilization is performed using pre-vacuum cycles in an open pan, then a pre-vacuum BI should be placed in an open mesh pan. Place the BI vial in the pan and run on the shortest cycle used for pre-vacuum (usually 3 minutes). If flash sterilization is performed using high speed gravity in an open pan, then a flash (gravity) BI should be placed in an open mesh pan (as noted above) and the BI test run on the shortest cycle used for gravity (usually 3 minutes). If a flash container is used (e.g. Riley Flash Pak) then the BI should be placed inside the Riley container and run on the cycle usually selected for the Riley Flash Pak. As you can see, multiple BI tests may be needed depending on the manner in which flash sterilization is performed. Some of the newer rapid response BIs require a minimum 4-minute exposure time; check with the BI manufacturer for exposure times for BI testing.

### **Monitoring the Sterilization Cycle**

All flash sterilization cycles should be monitored to verify the effectiveness of the process. Administrative controls, such as charts, printouts, and gauges, should be monitored and interpreted (and initialed by the sterilizer operator) for correlation with the proper cycle times and temperatures for items being processed. Each type of method used in immediate-use sterilization (e.g., open pan, container) and each type of sterilization cycle used (e.g., gravity-displacement, dynamic-air-removal) should be monitored at least weekly, preferably daily, with a BI and a Class 5 integrating indicator (AORN, 2011). For containers designed for immediate-use sterilization, product testing should be performed when the container is purchased and on an ongoing basis to ensure the effectiveness of the sterilization process.

Chemical indicators should be used in each cycle to verify that all sterilization parameters have been met. It is important to verify with the manufacturer that the chemical indicators being used have been tested and are recommended for flash sterilization cycles.

Biological monitoring is recommended at least weekly and preferably daily (depending on the volume of sterilization). The organism used to test for steam sterilization is *Geobacillus stearothermophilus*. The manufacturer of the biological monitor being used should provide documentation that the product has been tested and is indicated for flash sterilization cycles. Additional BI testing is recommended whenever an implant is included in the cycle (NOTE: it is not recommended by AAMI, AORN or the Centers for Disease Control to flash sterilize implants unless an emergency). Whenever a new sterilizer is installed, an existing sterilizer is relocated or after a major repair to the sterilizer (not routine preventive maintenance), three BI tests should be run, back-to-back. If the flash sterilizer is a pre-vacuum unit, then three BI tests should be run, back-to-back, followed by 3 BI tests on the flash gravity cycle (if used) followed by three consecutive Bowie-Dick tests. All testing must be negative before the sterilizer is placed back into use. Conventional steam biological monitors require 48 hours of incubation at 55-56 degrees Celsius (131-132.8°F.) for pre-vacuum flash and 24 hours for gravity flash cycles. The tests are self-contained and can easily be performed in the surgical suite or an office setting. There are also biological tests available that provide a reading within 1 hour (for gravity flash cycles) and three hours for a pre-vacuum flash cycle. An unsterilized control vial is required to validate that the organisms were viable. It is essential that the control vial and the BI vial both have the same lot number. The lot control numbers should be documented on the BI log form.

### **Record Keeping**

All items that are flash sterilized should be documented on a flash sterilization log (Figure 2). A log should be maintained at each flash sterilizer and changed daily. The logs are necessary to meet the requirements to be able to trace items to the patient in the event of a sterilizer malfunction. All sterilization logs should be maintained with the charts and/or printouts for each day so they can be easily retrieved for reference.

It is also essential that all results of BI testing be documented within the time frame specified by the BI manufacturer (e.g. one hour after testing). All control vial results also must be documented.

### **Continuous Quality Improvement**

It is important that the flash sterilization process be monitored for improvements. All sterilizer operators should receive initial training and continuing education to ensure proper use of the sterilization equipment and how to perform all BI and other testing. All biological and chemical monitoring should be interpreted by the operator of the sterilizer and verified before the instruments are used. Sterilization and BI records should be periodically reviewed for accuracy and completeness.

### **In Summary**

In today's managed health care environment, practitioners must ensure that all patient outcomes are favorable. The ideal conditions would include sufficient surgical instrumentation to allow for proper decontamination and terminal sterilization. However, if SSIU (flash) sterilization must be performed, the proper protocols, as detailed in this In-service, should be followed by all personnel. Flash sterilization can be performed safely if all of the necessary steps are taken. However, it is prudent to remember that flash sterilization is often performed under constraints such as stress and lack of time that increase the risk of errors.

Remember the words of Dr. Perkins: "Speed is a militant force against sterilization." We as practitioners must ensure that policies and procedures are developed to ensure that all steps in the flash sterilization process are followed correctly and that continuous quality improvement monitors are developed to verify the efficacy of the process. Without these processes in place, both patient and practitioner are at risk.

# FIGURE 1.

## REQUIRED TESTING OF FLASH STERILIZERS

### HIGH SPEED GRAVITY FLASH

			METHOD	FREQUENCY**
High Speed Gravity	270oF	3 minutes	Empty chamber	Weekly. Preferably daily
Flash Container	270oF	exposure time per container		
		mfrs instructions	Empty chamber	Weekly. Preferably daily

### Bowie-Dick (PRE-VACUUM) FLASH

Bowie-Dick (Dynamic Air Removal) Test	270oF	3-4 minutes	Empty chamber	Daily
Open Mesh Pan BI	270oF	3 minutes - Pre-vac cycle	Empty chamber	Weekly. Preferably daily
Open Mesh Pan BI	270oF	3 minutes - High Speed		Weekly. Preferably daily
		Gravity cycle	Empty chamber	Weekly. Preferably daily
Flash Container	270oF	per container mfrs instructions - if using both pre-vac and gravity cycles should test container on both cycles	Empty chamber	Weekly. Preferably daily
Express Cycles	270oF	as directed by sterilizer mfr	as directed by sterilizer mfr	Weekly. Preferably daily

\*\* and with all cycles containing implants

**ALL BI TESTING IS TO BE PERFORMED WITHOUT ANY INSTRUMENTATION IN THE PAN OR CLOSED CONTAINER**



## POST TEST QUESTIONS: Flash Sterilization - What Sterile Processors Need to Know

This in-service is Approved by the CBSPD for 1 CEU. Complete this post test and follow the directions at the end of the test for payment and results.

1. A major cause of excessive flash sterilization is:
  - A) Too many cases
  - B) Insufficient instruments
  - C) Lack of trust of SPD
  - D) Lack of sterilization equipment in SPD
2. According to AORN and AAMI, it is acceptable to use flash sterilization when
  - A) the surgeon insists
  - B) insufficient instruments available
  - C) in a documented emergency
  - D) too many cases are booked back-to-back
3. After cleaning the two most important steps in the flash sterilization process are:
  - A) contain and transport
  - B) transport and use
  - C) use and contain
  - D) confine and contain
4. The correct location for cleaning of soiled instruments prior to flash sterilization is
  - A) scrub sink
  - B) sub-sterile room sink
  - C) soiled utility room (Decontamination room) sink
  - D) basin of water in OR room
5. To prevent contamination of personnel or the environment, the best way to transport instruments from the OR room to the soiled utility room (Decontamination room) is:
  - A) in a basin of water
  - B) in a basin of enzyme detergent
  - C) on a table covered with plastic
  - D) in a tote bin, impervious bag or cart
6. The spore used to biologically monitor steam flash cycles is
  - A) bacillus atropheus
  - B) bacillus stearothermophilus
  - C) geo bacillus stearothermophilus
  - D) bacillus subtilis

7. The Bowie-Dick test measures
- A) the drying cycle
  - B) the sterilizer's ability penetrate into a pack
  - C) the sterilizer's ability to remove air from the chamber and packages
  - D) the quality of the steam
8. The Bowie-Dick test should be performed
- A) daily on all high speed gravity sterilizers
  - B) daily on all pre-vacuum sterilizers
  - C) weekly on all high speed gravity sterilizers
  - D) weekly on all pre-vacuum sterilizers
9. Biological testing of flash sterilizers is recommended
- A) weekly preferably daily
  - B) daily
  - C) every other day
  - D) at least monthly
10. A new pre-vacuum flash sterilizer has been installed in the OR. You are asked to test it before placing into use. What testing is needed?
- A) -Bowie-Dick test following by a BI test
  - B) Three consecutive BI tests on the pre-vac and gravity cycles
  - C) Three consecutive Bowie-Dick tests followed by three BI tests
  - D) Three consecutive BI tests on the pre-vacuum and gravity cycles followed by three Bowie-Dick tests

### **Directions for Payment and Results**

This in-service = \$10

Re-do's = \$10 each

**No refunds (all sales are FINAL), prices subject to change.**

Payment is accepted in the form of a Credit Card, Facility Check, or Money Order only.  
Sorry, no personal checks.

Upon passing this in-service, your certificate will be mailed to you within 7-10 business days.

Please fill out the form below and submit it with your payment and the quiz to:

**Sterile Processing University, 59 Allerton Road, Lebanon, NJ 08833.**

More on next page

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If you have any questions, please email [heidi@spdceus.com](mailto:heidi@spdceus.com). Thank you!