

The Hot Issues of Flash Sterilization



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The Hot Issue of Flash Sterilization: Study Guide #1

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Description of Study Guide Topic

The use of flash sterilization is often misunderstood by healthcare professionals today. Effective flash sterilization requires professional knowledge, skill and judgment to ensure safety and quality patient care. This study guide is designed for nurses and anyone else involved in the development, management, performance and evaluation of flash sterilization and is intended to serve as an introduction to the key considerations surrounding flash sterilization. Information includes different flash sterilization cycles, time and temperature parameters, appropriate applications for flash sterilization, handling and preparation techniques, process monitoring and flash sterilization documentation.

Overall Purpose of Study Guide

To provide information on the process and application of flash sterilization.

Objectives

Upon completion of this study guide program, the participant should be able to:

1. Describe critical issues when performing sterilization of items using the flash method.
2. Review flash sterilization monitoring.

Intended Audience

This study guide is a self-study program intended for use by perioperative nurses, surgical technologists, endoscopy suite nurses and other staff members, sterile processing staff members, infection preventionists nurses and other healthcare professionals interested in this topic.

Introduction

This study guide focuses on the steam sterilization method called “flash sterilization,” a process that is sometimes misunderstood and inappropriately practiced.

Topics discussed in this study guide include:

- > Various flash sterilization cycles
- > Appropriate parameters for each cycle
- > Handling and preparation techniques prior to sterilization
- > Transfer of items to the point of use after flash sterilization
- > Chemical, biological and mechanical monitoring of flash sterilization
- > Documentation of the flash sterilization process

This same basic information is appropriate for use in hospitals, ambulatory surgery centers, medical and dental offices, or any facilities where flash sterilization is performed using large or small steam sterilizers. As with any sterilization process, confirm the cycle parameters required for a device with the manufacturer.

Flash Sterilization Cycles

The flash sterilization cycles that are currently available for use are the gravity displacement cycle, the prevacuum cycle and the single-wrap cycle (sometimes called the Express cycle).

Gravity Displacement Cycle

The gravity displacement cycle has been the most commonly used cycle for flash sterilization. Like other steam sterilization processes, it has three phases:

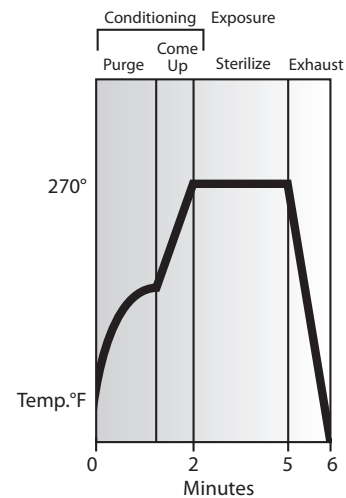
- > The conditioning phase
- > The exposure phase
- > The exhaust phase

Conditioning Phase

Though it differs by sterilizer manufacturer, the conditioning phase of the gravity displacement cycle generally proceeds as follows:

1. Steam comes from the source and enters the sterilizer jacket (the space between the sterilizer chamber wall and the outer shell).
2. Steam enters the sterilizing chamber from the jacket and forms a layer above the air.
3. As more and more steam is admitted, the air is pushed out through the chamber drain. (For chambers without jackets, steam directly enters the chamber.) It is very important that all of the air be removed, because it can prevent steam from contacting the surfaces that are to be sterilized. Remember, steam will only sterilize surfaces it can touch.
4. As air is pushed out, the load is heated and the chamber temperature is sensed by a temperature probe in the chamber drain line.
5. When all of the cool air is pushed out, the trap closes.
6. Pressure increases inside the chamber, allowing the chamber to achieve sterilizing temperature.

Once the preselected sterilizing temperature is reached, the exposure phase begins.



Exposure Phase

The exposure phase lasts for the amount of time that has been set for a particular item to be sterilized. Routine exposure parameters for gravity displacement cycles (AAMI ST79:2006) include the following:

- > The nonporous cycle is appropriate for surface sterilization of simple, routine, all-metal surgical instruments only. The minimum exposure time for non-porous flash sterilization in a gravity displacement sterilizer is three minutes at 270° F (132° C)
- > The porous cycle is used with items such as rubber and plastic

items, or those with lumens or multi-parts. The porous cycle is also used when metal instruments are combined with porous items. A longer exposure time is needed for adequate steam penetration of porous items. The minimum exposure time for a porous cycle in a gravity displacement sterilizer is 10 minutes at 270° F (132° C)

At the completion of the exposure phase, the exhaust phase begins.

Exhaust Phase

During the exhaust phase, the following sequence of events occurs:

1. Steam is removed from the chamber.
2. The sterilizer chamber is brought back down to atmospheric pressure and a small vacuum may be pulled to remove excess steam from the chamber.
3. Air is reintroduced through a filter that removes contaminants.
4. The end-of-cycle signal sounds, signaling that the chamber door can be opened.

Drying time is not commonly used during this cycle; however, some cycles permit a short drying time to be entered at the end of the cycle.

This same basic sterilizing cycle is similarly performed by tabletop steam sterilizers.

In general, the total cycle time from beginning to end will vary depending on:

- > The type and size of the sterilizer
- > The steam source
- > The type and quantity of items being sterilized

For example, sterilizers that generate their own steam may take longer in the conditioning phase than those directly connected to a steam distribution system.

Prevacuum Cycle

Flash sterilization can also be accomplished in sterilizers with prevacuum cycles, also known as “prevac” sterilizers. In a prevacuum cycle, air is mechanically pulled from the chamber during the conditioning phase and steam is actively pulled out during the exhaust phase at the end of the sterilizing cycle. Mechanical air removal is accomplished using a vacuum pump or an ejector system, which is more efficient than the gravity displacement method. During this process, there are several injections of steam. Each injection is followed by a chamber evacuation to remove both steam and air. Once the appropriate injections and evacuations are complete and the appropriate exposure temperature is reached, the steam pressure is held for the appropriate sterilizing time and then exhausted. A dry time may be used if desired.

Routine exposure parameters for prevacuum cycles include:

- > Compared to the gravity-displacement porous cycle, the porous cycle in prevacuum sterilizers can be shortened to a minimum of four minutes exposure at 270° F (132° C), because of the more efficient air removal, steam penetration and contact of steam with the product to be sterilized

Remember: Longer exposure times may be required by the manufacturers of some complex medical devices; times cited here are only minimum recommendations.

Flash Sterilization with Single Wrappers

Some prevacuum and pulsing gravity displacement steam sterilizers have a cycle that is designed to permit prevacuum flash sterilization using a single nonwoven or textile wrapper. The parameters for this sterilization cycle are established and/or preset by the sterilizer manufacturer and vary depending on the design of the sterilizer. This cycle is designed for flash sterilization of all-metal, nonporous items only (except for the wrapper), arranged on a perforated or mesh-bottom instrument tray. Items with lumens or complex medical devices can not be processed in this cycle because air removal and steam contact within them may not be achieved in this cycle, which has fewer prevacuum pulses than a regular prevacuum cycle.

On some sterilizers, this cycle is called the “Express” cycle. It operates basically the same as the prevacuum cycle in that it uses mechanical air removal; however, there are only two injections of steam and chamber evacuations before the exposure temperature is reached. Following the exposure time, steam is exhausted and a brief dry time is employed. The preset exposure time on sterilizers with Express cycles is four minutes at 270° F (132° C), followed by a three minute dry time. The total cycle time is about 12 minutes.

The single wrapper protects the sterilized items from environmental contamination that may be encountered en route from the sterilizer to the point of use. However, precautions must be taken to differentiate these single-wrapped flash-sterilized trays from sequentially double-wrapped trays that have been processed conventionally. Unlike double-wrapped, conventionally sterilized instrument trays, these single-wrapped packs must be used immediately. Handling a single-wrapped tray after sterilization will be discussed later in this study guide.

Applications of Flash Sterilization

Flash steam sterilization of medical devices was developed for unplanned or **emergency** reprocessing of individual items in an operating room setting when time is insufficient for use of the preferred wrapped or containerized sterilization procedure. Flash sterilization may be appropriate, for instance, in the following situations:

- > When a one-of-a-kind instrument has been contaminated and needs to be replaced to the surgical field immediately
- > When an item has dropped on the floor and is needed to continue a surgical procedure
- > When specific instruments are needed for an emergency procedure
- > When there is no other sterilization alternative

In recent years, flash sterilization has come to be improperly utilized more and more for the routine processing of patient-care items:

- > Medical devices for which inventory is inadequate
- > A surgeon’s personal instruments
- > Borrowed instruments
- > Surgical implants
- > Complete sets and power equipment

In each of these circumstances, the items should have been decontaminated, dried, wrapped and sterilized by the Sterile Processing Department according to the manufacturer's instructions instead of being flash sterilized.

Surgical Implants

In the case of surgical implants, conventional wrapped sterilization is particularly important. Implants remain in the body and infections that involve them are significantly more difficult to treat and many times, require surgical intervention to remove the implant to resolve the infection. Therefore, the following agencies and organizations all recommend that implantable medical devices never be flash sterilized:

- > The Centers for Disease Control and Prevention (CDC)
- > The Association of Perioperative Registered Nurses (AORN)
- > The Association for the Advancement of Medical Instrumentation (AAMI)

CDC notes that implantable items require special handling before and during sterilization and that packs containing implants need to be clearly labeled as such. To guarantee a wide margin of safety, it is recommended that each load containing implantables be tested with biological monitors and that the sterilized item not be released for use until the spore test is negative. If it is not possible to process an implantable object with a confirmed spore test before use, CDC recommends that the unwrapped object receive the equivalent of full-cycle steam sterilization and not flash sterilization. Flash sterilization is not recommended for implantable items. The efficacy of the flash sterilization cycle is not in question but the ability to safely deliver the unwrapped sterilized implant to the sterile field without contamination is critical. Biological monitoring of the sterilization cycle only gives a better statistical assurance of cycle effectiveness.

Powered Surgical Instruments

Flash sterilization of powered surgical instruments also is not recommended by AORN (AORN, 2008). Traditional gravity displacement flash sterilization cycles are seen as inadequate for powered surgical instruments. There may be difficulty in air removal and steam penetration within the device using the gravity flash cycle. Sterilization times documented by the manufacturer of the medical device must be adhered to as they may be longer.

Handling and Preparing Items for Flash Sterilization

Despite these important restrictions, one must remember that only when flash sterilization is performed using valid sterilization cycle parameters, the process can be performed successfully.

Even when flash sterilization is performed appropriately though, problems can occur with medical devices before and after they are flash sterilized. Such problems may occur during:

- > Transporting, handling, cleaning and decontaminating items
- > Inspecting and preparing decontaminated items for flash sterilization
- > Aseptic transfer

Because flash-sterilized items are usually used immediately and before the biological testing results are available, it is particularly

important that everyone involved in this process perform each step correctly. AAMI recommends (AORN, 2008) that documentation of the premature release of implants be recorded. AAMI further recommends that an exception form for the Premature Release of Implantable Device/Tray accompany the implant to the operating room and be filled out by the operating room personnel.

Decontamination

Contaminated items must be subjected to a cleaning/decontamination process prior to flash sterilization.

Transport to the Decontamination Area

First of all, the handling of contaminated items from the operative field must be done in a way that will protect the transporter and the environment from direct contact with that item. This can be simply accomplished by putting on a pair of protective gloves before touching the item and then containing it in an impermeable bag, bin, or other covered container for transport to the cleaning/decontamination area. Care must be taken not to contaminate the outside of the container nor permit the covering to be released during transport. Reusable containers also should be suitably decontaminated after each use.

The Decontamination Area

Ideally, items to be flash sterilized should be transferred to an area specifically designed for decontamination that is separate from the clean preparation and sterilization area(s). The environment in the decontamination area should be carefully controlled, including the following:

- > Walls or partitions should be in place to separate the decontamination area from the clean preparation, sterilization and patient care areas. During cleaning, contaminated fluids can be splashed and aerosols created that can contact work surfaces, walls and personnel. In addition, contamination can spread from soiled to clean areas, instruments and persons, by the indiscriminate touch of a soiled, gloved hand
- > Floors and walls should be constructed of materials that can withstand frequent splashing, spills and the cleaning agents and methods that will contact them every day
- > Good ventilation must be available to prevent the spread of potentially dangerous microorganisms. Negative pressure in the decontamination room allows the air to flow into or toward the decontamination areas. Air should flow into or toward decontamination areas from the cleaner areas adjacent to them. There should be no less than 10 air exchanges per hour to effectively reduce environmental contamination by means of air dilution
- > Temperature and humidity should be controlled. The decontamination area should be comfortable for properly attired personnel. This means a temperature of 16-18° C (60-65° F) and a relative humidity of 30-60%. Higher temperatures and humidity can produce an environment conducive to microbial growth and thus increase the overall bioburden
- > Adequate lighting must be available for the proper performance of decontamination and preparation procedures

When separate processing areas are not available, spacial separation of the soiled, clean and sterilization functions can be made satisfactory by a combination of good:

- > Environmental control characteristics
- > Work-flow patterns
- > Work practices

To limit the possibilities of cross-contamination, everyone should be aware of the protocols and the boundaries that have been set. Performing soiled and clean work in the same room at the same time should be avoided whenever possible. It is preferable that the cleaning task be accomplished first, the area be cleaned and disinfected and then inspection and assembly tasks can follow.

If the same person performs both decontamination and sterilization, then the soiled protective apparel used during cleaning should be removed, the clothing beneath the soiled protective apparel should be checked to ensure that it is clean and dry and then thorough handwashing should be done before proceeding. Good work practices are essential and everyone who cleans contaminated items and prepares them for flash sterilization must follow them.

Attire

Whenever contaminated items are handled, personnel involved in decontamination and flash sterilization must wear appropriate attire, including the following:

- > Surgical attire, consisting of pants and a shirt tucked into the pant waistband or a close fitting tunic
- > A hair cover, including covering for all facial hair except for eyebrows and eyelashes
- > Clean, durable shoes with nonskid soles
- > A high-filtration-efficiency face mask

In addition to the attire specified above, personnel working in the decontamination area must wear:

- > A long-sleeved, fluid-resistant protective outer garment, such as a gown, apron or jumpsuit
- > Long, cuffed, fluid-resistant, protective gloves
- > Fluid-resistant shoe covers or boots, if extensive splashing is expected
- > Goggles or safety glasses or face shields for eye protection

To minimize the risk of transferring microorganisms from the healthcare facility to home and family, reusable protective attire should be laundered by the laundry facilities used by the healthcare institution for other surgical textiles.

Sometimes the scrub personnel are responsible for preparing medical devices for flash sterilization. They must be reminded to remove their contaminated scrub gowns before leaving the operating room for the cleaning area to limit the possibility of contamination along the way.

Decontamination

When cleaning/decontaminating medical devices prior to flash sterilization, these guidelines should be followed:

1. Consult the device manufacturer's instructions for cleaning.

2. Open and disassemble items as appropriate, retaining all parts together so that reassembly can be accomplished efficiently.
3. Use an initial cold water rinse and perhaps an enzymatic presoak to help remove blood tissue and gross debris. Mix per the manufacturer's instructions.
4. Clean all items manually or mechanically using warm water and a detergent appropriate for the items being cleaned.
5. Rinse all items thoroughly.

If the instruments are decontaminated by using a washer/sterilizer, the instruments are not ready for aseptic use after that process. They must be inspected for cleanliness and proper function before they are terminally flash sterilized for patient-care use.

Inspection and Assembly

The decontaminated instruments must be inspected for cleanliness, proper function and alignment, freedom from defects, sharpness of cutting edges, looseness of pins and chipping of plated surfaces.

An open, perforated, or mesh-bottom instrument tray should be used to contain instruments for flash sterilization.

The clean, open and/or disassembled instruments should be arranged so that air removal and steam contact can easily take place as follows:

- > Position instruments that have concave, broad, or flat surfaces so that water will not pool
- > Flush lumens of needles, suction tubes and catheters with sterile or distilled water so that air can be pushed out when the steam is created within. Remember that the presence of air will prevent steam contact
- > Open all hinged instruments and place them on instrument racks, pins, or stringers as needed
- > Disassemble all items with removable parts
- > Position heavy items in such a way that they will not damage more delicate items

Preferably, only a few instruments at a time are processed using flash sterilization, which is consistent with "emergency use" recommendations discussed below (AAMI 2006). Flashing full or multiple trays increases the time it takes to get the load to the sterilizing temperature so the total cycle time may be increased. A full tray is also more difficult to handle after sterilization without contaminating it.

The manufacturer of complex medical devices should be consulted for guidance in preparation for sterilization.

According to AAMI (2006), complete sets should NOT be flash sterilized unless:

- > There is an urgent need
- > The physical layout ensures direct delivery of the sterilized items to the point of use
- > Work practices ensure proper cleaning, decontamination, inspection and arrangement of instruments prior to sterilization

- > Procedures are developed and followed for aseptic handling and personnel safety during transfer of the sterilized items from the sterilizer to the point of use

Protective organizing cases designed for micro-surgery, orthopedic and air-powered instruments can be used only if they are specifically designed and tested for flash sterilization cycles. The manufacturer's instructions must be followed carefully.

Some rigid sterilization containers are suitable for flash sterilization. The manufacturer should provide scientific evidence to document that the container functions properly during the flash sterilization method, which cycles are appropriate and complete instructions for use of the container.

Sterilization

Once items have been properly decontaminated, inspected and assembled, the next step is flash sterilization.

The Sterilization Area

The steam sterilizer used for flash sterilization should be located in a restricted-access area where personnel are required to wear hair coverings, masks and complete surgical attire. The sterilization area should be immediately adjacent to, or part of, the area where the sterilized items will be used in patient care. The sterilizer should not be located near any potential sources of contamination, such as sinks or trash disposal areas. Handwashing facilities should be located conveniently near all areas in which instruments are decontaminated and prepared for sterilization so as to encourage and allow for good handwashing practices.

Housekeeping practices for the sterilization area should include daily cleaning of floors and horizontal work surfaces and regular cleaning of other surfaces. Special attention should be given to the sequence of cleaning to avoid transferring contaminants from dirty to clean areas or surfaces.

The temperature, humidity, lighting and ventilation in the sterilization area should be controlled as described for the decontamination area.

Traffic in the area where flash sterilization takes place should be restricted to authorized personnel. Good traffic control practices limit opportunities for contamination of the flash-sterilized items during removal from the sterilizer and transfer to the point of use.

Personnel

An initial orientation and on-the-job training should be provided for all personnel involved in flash sterilization processing, including:

- > Basic microbiological principles
- > Decontamination of medical devices
- > Preparation of items for flash sterilization
- > Instruction in sterilizer operation
- > Parameters of steam sterilization
- > The institution's infection-control policies and procedures (particularly those relating to sterility maintenance of flash sterilized items during transport from the sterilizer to the point of use)

Continuing education programs should be offered at regular intervals so that workers can review and update their knowledge and skills.

The Sterilization Process

For flash sterilization, always load the tray flat in the sterilizer, not only to keep the instruments in order and protect them from damage, but also to facilitate good air removal, steam contact and drainage.

The parameters described earlier should be followed for gravity-displacement, prevacuum, or the single wrap (Express cycles).

Transfer to the Point of Use

Once the sterilization cycle is complete, the next challenge begins; that is, to get the sterilized items to the sterile field for use without contaminating them. A study conducted by Harris (1992) confirmed that flash-sterilized items that are hot and wet can be contaminated by airborne particles during transport. The more metal mass of instrumentation in a tray, the more likely they will be wet after steam sterilization. It is difficult to deliver flash-sterilized devices aseptically.

If a proper container or single wrapper is not available, contaminants that are present in high-traffic areas and the aerosol sprays created at scrub sinks must be avoided. AAMI states procedures for transferring the items from the sterilizer to the point of use should be based on the assumption that condensate will be present with the containment device (as is typical of flash sterilization). The containment items should not be placed on a non-sterile surface and these procedures should be developed in consultation with the supervisor of the department and the infection control preventionist, with the objective of ensuring the best practice possible for aseptic transfer within the physical constraints of the facility (ANSI/AAMI ST79:2006).

Users should adhere to aseptic technique for flash-sterilized items during transport to the point of use. It is important that sterilization processing be carried out in a clean environment and that flash-sterilized devices are transferred to the point of use in a manner that prevents contamination. Rigid sterilization containers designed and intended for flash-sterilization cycles should be used (AORN 2008).

Rigid flash-sterilization containers:

- > reduce the risk of contamination during transport to the point of use
- > facilitate ease of presentation to the sterile field
- > protect sterilized items during transport

The person doing the transport must be alert to all sources of potential contamination. The scrubbed person for a surgical procedure should transport items only in areas where strict traffic control is enforced.

The same guidelines apply for the removal of a single wrapped tray after the completion of the Express cycle. Although the outer wrapper may be dry, expect to find condensation within the tray, as is often seen when using the unwrapped method. This moisture can strike through the wrapper, so care must be taken to avoid contamination by contact with nonsterile surfaces. The wrapped tray should never be placed on unsterile surfaces. The sterilized tray should be placed on a sterile, impervious drape or on a surface separate from the working sterile field so that the wrapper can be opened by the circulator. The sterile items may then be removed from the tray by the scrub person and taken to the sterile field. The items sterilized using the Express cycle must be used immediately as with any other flash cycle. This wrapped tray can not be stored for later use.

Monitoring Flash Sterilization

To ensure that appropriate sterilization cycle parameters have been achieved, flash sterilization is monitored by chemical, biological, mechanical and Bowie-Dick type indicators.

Chemical Indicators

Chemical indicators are sterilization process monitoring devices that respond with a characteristic chemical or physical change to one or more of the physical conditions in the sterilizing chamber. Chemical indicators are intended to detect potential sterilization failures that may result from personnel errors or sterilizer malfunctions. They do not prove that sterilization was achieved.

A chemical indicator should be chosen based on the manufacturer's data on reliability, safety and performance characteristics. Written information should be obtained on how to interpret indicator results, the sterilization conditions that the indicator will detect, the storage requirements and shelf-life of the indicator.

For flash sterilization, an appropriate chemical indicator should be placed next to the item being sterilized in the instrument tray or container. At the completion of the cycle, the indicator should be examined for the appropriate color change. Inadequate and/or incomplete reaction of the chemical indicator could indicate improper preparation of the tray for sterilization, operator error, or a sterilizer malfunction. In any event, the item must be reprocessed before use. A chemical indicator is not considered a porous item for the purpose of determining cycle time.

Biological Indicators

Biological indicators (BI's) are used to test the ability of a sterilization cycle to kill microorganisms. BI's used for steam sterilization typically contain spores of *Geobacillus stearothermophilus*, a microorganism that will not produce disease in humans but is very resistant to being killed by steam sterilization. Several BI products are available for flash sterilization. Some biological indicators used for other types of steam sterilization may be too resistant so the appropriate biological indicator must be chosen for the type of flash sterilization cycle being used.

When choosing a biological indicator, some of the information to request from the manufacturer regarding the BI includes:

- > Reliability
- > Safety
- > Performance characteristics
- > Proper storage, handling and use

Before using a new lot or box of BIs, one of the BI's should be removed for the control test. This control BI must not be sterilized but must be handled and incubated according to manufacturer's instructions. The control will show positive growth if the test microorganisms are alive and ready for test. If the control does not show positive growth, retest it according to the manufacturer's instructions.

All steam sterilizers, including flash cycles, must be biologically tested with three consecutive test runs upon installation of a new sterilizer and after major repairs to assure the effectiveness in sterilizing medical and surgical items.

If a particular sterilizer provides several flash sterilization cycles (e.g., gravity displacement, prevacuum and Express cycles), each

one of these modes and each type of tray configuration (e.g., open surgical tray, single wrapped surgical tray, protective organizing case, or rigid sterilization container) must be biologically monitored if used. Care must be taken to use the correct biological test for the gravity cycle and for the prevacuum cycle. For routine testing, the following steps should be followed:

1. Place one biological indicator and one chemical indicator, by themselves, into a perforated or mesh-bottom unwrapped instrument tray. The test is run without instruments to minimize the lethality of the process. A filled tray takes longer to heat to sterilizing temperature, which increases lethality of the process. We want to prove we can kill the test microorganism using lesser lethality.

NOTE: Other routinely used configurations must also be tested. For instance, if rigid sterilization containers are used, they must be tested with a biological indicator. The Express cycle must also be tested.

If the empty tray test comes out negative and the rigid container test comes out positive on the same day in the same sterilizer, the "empty tray" test results indicate the cycle is operating as designed to kill microorganisms. The positive results with the rigid container tells you that it is probably inhibiting air removal and sterilant penetration. In this case, the "open tray" method of flash sterilization is theoretically safe to use. The rigid container should not be used until it passes the test.

2. Position the biological indicators so that, when the tray is placed on the bottom shelf of the otherwise empty sterilizer, they will be as close as possible to the sterilizer drain, since that is usually the coolest part of the chamber.
3. Run a nonporous cycle according to the sterilizer manufacturer's instructions.
4. At the end of the cycle, carefully handle the test tray with protective gloves.
5. Allow the biological indicator to cool. Handle it carefully according to the manufacturer's instructions.
6. Incubate the BI according to the manufacturer's instructions, generally at 131° F (55° C). (*Geobacillus stearothermophilus* will not grow as efficiently at lower temperatures and it should grow readily if the sterilization cycle was ineffective.)
7. Interpret the results; evidence of a properly functioning sterilization cycle is no growth of the test microorganism.

If positive growth is identified after incubation, the sterilizer should be taken out of service and reported to the supervisor, who should take the following steps:

- > Check the mechanical and chemical indicators to see if they indicate a faulty process
- > Determine the root cause of the failure, if any, with the sterilizer maintenance personnel
- > Ask the lab to identify whether the *Geobacillus bacterium* is growing or whether it's a microorganism that might have contaminated the specimen after sterilization
- > Retest the sterilizer with biological indicators

- > If a sterilization failure did occur, recall all items sterilized since the last good biological test
- > Notify the infection control officer so that appropriate patient follow-up and surveillance can be determined and initiated

All results of BI's (including those used as positive controls), should be interpreted by qualified personnel and should be included in the sterilizer records. Biological testing is considered satisfactory if the test BI is negative (no microbial growth) and the control BI is positive (microbial growth).

Bowie-Dick Type Tests

When the prevacuum or Express cycles are used, a Bowie-Dick type test must be performed upon installation and on a daily basis before the first load or use of the sterilizer. The objective of Bowie-Dick type tests is to assure that the mechanical air removal device efficiently removes air from the chamber and detects any air leaks into the chamber during the sterilization process.

Mechanical Indicators

Physical or mechanical monitors include real-time records of chamber temperature and pressure, displayed on various types of recording charts, computer printouts and gauges. Mechanical monitoring is useful for the early detection of malfunctions, so that alternative procedures can be used in the event of sterilizer failures.

Mechanical monitors must be checked before, during and after each sterilization cycle to verify that appropriate parameters for sterilization have been reached and maintained for the correct exposure time. All persons responsible for operating the sterilizer should fully understand how to interpret the information provided by these devices.

The recording chart or computer printout must be signed by the operator before items are removed from the sterilizer. These charts and computer printouts should be maintained with other sterilizer records for as long as is required by state or local statutes and by the policies of the individual institution.

Recordkeeping for Flash Sterilization

For maximum safety, accurate and complete records of each sterilization cycle and routine and preventive sterilizer maintenance activities should be maintained.

Load Recordkeeping

For each sterilizer load, the following should be recorded: the evidence of the sterilization cycle performance and biological results and a record that indicates how the item was handled throughout the flash sterilization process. The load record keeping should allow a specific load to be traceable back to the patient that had those flashed items used in his or her case. A log should be created for each cycle that indicates the:

- > Date
- > Name of the person who decontaminated the item
- > Name or number of the sterilizer used
- > Sterilization load number
- > Type of sterilization cycle used
- > Load contents

- > Sterilization time and temperature
- > Operating room number
- > Patient's name
- > Time the load entered and was removed from the sterilizer
- > Person(s) responsible for loading and unloading
- > Results of chemical, biological and Bowie-Dick type testing, if applicable and any follow up actions taken

This type of recordkeeping is essential for both epidemiological tracking and for ongoing assessment of the reliability and effectiveness of the sterilization process.

Maintenance Records

Excellent sterilizer maintenance and recordkeeping of this service are essential. The sterilizer manufacturer should be consulted for information regarding daily and preventive maintenance requirements.

A maintenance record should be kept for each sterilizer. Enough information should be provided to identify the steam sterilizer and to establish a continuous history of all scheduled and unscheduled service, including at least the following:

- > Date on which service was requested
- > Model number and serial number of the sterilizer
- > Location of the sterilizer
- > Person who requested and authorized the service
- > Reason for the service request
- > A description of the service performed
- > Types and number of parts replaced
- > Name of the person who performed the service
- > Date the work was completed
- > Signature/title of the person acknowledging completion

Summary

AAMI has a document titled "Comprehensive guide to steam sterilization and sterility assurance in health care facilities." This document can be referenced along with other resources cited in the bibliography to help improve flash sterilization practices in healthcare facilities.

Healthcare professionals are responsible for understanding and utilizing appropriate flash sterilization processes when flash sterilization is employed within healthcare environments.

Glossary

Biological Indicator

A calibrated population of bacterial spores (of high resistance to the mode of sterilization being monitored) on or in a carrier, put up in a package which maintains the integrity of the inoculated carrier and which is of convenience to the ultimate user, that serves to demonstrate whether sterilization conditions were met.

Bowie-Dick Type Test

A diagnostic test of a dynamic-air-removal (prevacuum) steam sterilizer's ability to remove air from the chamber and prevent air re-entrainment.

Chemical Indicator

A physical or chemical device employed to monitor one or more process parameters of the sterilization cycle in order to detect failures in packaging, loading, or sterilizer function. The chemical indicator usually consists of a sensitive chemical or ink dye that may vary in sensitivity from product to product.

Cleaning

The removal, usually with detergents, mechanical action, of all adherent visible soil (e.g., debris) from the surfaces, crevices, serrations, joints and lumens of instruments, devices and equipment by a manual or mechanical process that prepares the items for safe handling and/or further decontamination.

Decontamination

According to OSHA (1992), "the use of physical or chemical means to remove, inactivate, or destroy blood-borne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use or disposal." (29 CFR 1910.1030)

Exposure Time

The period during which items are exposed to saturated steam at the specified temperature.

Flash Sterilization

A steam sterilization cycle designed for the sterilization of patient-care items for immediate use. Items processed by means of this cycle must always be used immediately, since sterility assurance can not be maintained.

Gravity Displacement

A type of sterilizer in which incoming steam displaces residual air through a port or drain located in or near the bottom (usually) of the sterilizer chamber.

Mechanical Indicator

A device that indicates sterilization cycle conditions, including time, temperature and pressure. Also known as a physical indicator.

Personal Protective Equipment

Specialized equipment or clothing used by persons decontaminating medical devices for flash sterilization to protect themselves from direct exposure to blood or other potentially infectious materials include: fluid-resistant gloves, gowns, aprons, head and foot coverings high filtration surgical masks and eye protection (goggles/ face shield).

Prevacuum Sterilizer

A type of steam sterilizer that depends upon one or more pressure and vacuum excursions at the beginning of the cycle to remove air. This method of operation results in shorter cycle times for wrapped items because of the rapid removal of air from the chamber and the load by the vacuum system, the usually higher operating temperature (132° C to 135° C. {270° F to 275° F) the shorter exposure time and the accelerated drying of fabric loads.

Rigid Container System

Specifically designed heat-resistant metal, plastic, or anodized aluminum receptacles used to package items, usually for sterilization of surgical instruments. The lid and/or bottom surface contain a steam-or-gas-permeable, high efficiency microbial filter.

Sterilization

A process designed to remove or destroy all viable forms of microbial life, including bacterial spores, to an acceptable sterility assurance level.

References and Suggested Readings

Association for the Advancement of Medical Instrumentation. "Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities." ANSI/AAMIST79:2006 8.85 Flash cycles with sealed containment devices, Arlington, VA: ANSI 2006 AAMI, 1998.

Association of Perioperative Room Nurses. "Perioperative Standards and Recommended Practices." 2008 edition, RP Sterilization, Denver: AORN 2008.

Harris, MH. "Flash sterilization: Is it safe for routine use?" AORN Journal 55 (June 1992): 1547-51.

Occupational Safety and Health Administration. "Occupational Exposure to blood-borne pathogens." Code of Federal Regulations, Title 29, Part 1910.1048.

Perkins J. Principles and Methods of Sterilization in the Health Sciences. 2nd ed. Springfield, IL: Charles C. Thomas, 1980.

Reichert M, and Young JH., "Sterilization Technology for the Health Care Facility," 2nd edition. Gaithersburg, MD: Aspen Publishers Inc. 1997.

The International Association of Healthcare Central Service Materiel Management. "Central Service Technical Manual" 7th edition, Chapter 14, Point of Use Processing, Chicago: IAHCSSM 2007.

Review Questions

1. The flash sterilization process by which air is forced out of the chamber by the incoming steam is the:
 - A. gravity displacement cycle
 - B. prevacuum cycle
 - C. express cycle
 - D. single-wrapped cycle
2. The sterilizer chamber is brought back to atmospheric pressure during the:
 - A. conditioning phase
 - B. come-up phase
 - C. exposure phase
 - D. exhaust phase
3. For gravity-displacement sterilization of nonporous items, the minimum exposure time is:
 - A. 10 minutes
 - B. 6 minutes
 - C. 3 minutes
 - D. 4 minutes
4. The porous flash sterilization cycle is more effective in prevacuum sterilizers than in gravity displacement sterilizers because prevacuum cycles:
 - A. are hotter
 - B. have more efficient air removal
 - C. achieve higher pressures
 - D. do not require a conditioning phase
5. Flash sterilization was designed for:
 - A. unplanned or emergency situation only
 - B. any unwrapped items
 - C. implants
 - D. air-powered instruments
6. The process that is designed to render any contaminated item safe for handling, but not necessarily for patient use, is called:
 - A. cleaning
 - B. disinfection
 - C. decontamination
 - D. sterilization
7. When loading a tray for flash sterilization, it should always be:
 - A. positioned on edge
 - B. laid flat
 - C. wrapped with a single wrapper
 - D. upside down so that moisture does not become trapped
8. For flash sterilization, a chemical indicator should be used:
 - A. in every load
 - B. daily
 - C. weekly
 - D. for installation testing only
9. Why is routine biological testing of a flash sterilizer performed in an empty chamber?
 - A. The lethality of the flash process is minimized in a chamber with no instruments.
 - B. The chamber heats up more slowly when empty.
 - C. The lethality of the process is greater in an empty chamber.
 - D. The chamber cools off faster when empty.
10. Bowie-Dick type indicators test for complete air evacuation in:
 - A. gravity displacement cycles
 - B. prevacuum cycles
 - C. express cycles
 - D. B and C

1. A (Gravity Displacement Cycle) & (Glossary)
2. D (Gravity Displacement Cycle)
3. C (Gravity Displacement Cycle)
4. B (Prevacuum Cycle)
5. A (Applications of Flash Sterilization)
6. C (Decontamination)
7. B (The Sterilization Process)
8. A (Chemical Indicators)
9. A (Biological Indicators)
10. D (Bowie-Dick Type Tests)

Answers to Review Questions & Section Sources:

Evaluation Form

Study Guide #1: The Hot Issues of Flash Sterilization

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Non-RN: License or Social Security Number

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