

## **Sterilization and Disinfection: Getting It Right**

### **Instructions**

1. Print the document. Read the activity and record your answers to the post test questions on the answer sheet.
2. A score of 80 is required to earn a contact hour certificate for 2.5 contact hours. If you are unsuccessful on your first attempt, you may retake and resubmit the test.
3. Document the time you spent on the activity (hours & minutes) including completing the post test and the evaluation.
4. Complete the activity evaluation.  
Be sure to include your email address – certificates will be e-mailed or you will be notified if you need to retake the post test.
5. Mail your answer sheet and your completed evaluation to  
eChapter Provider Unit  
PO Box 29133  
Dallas, TX 75229

## **Sterilization and Disinfection: Getting It Right 2.5 Contact Hours**

This CE activity is designed to provide the basic information in sterilization and disinfection that every perioperative nurse should know

### Objectives

1. Explain the importance of competence in sterilization and disinfection for perioperative nurses.
2. Describe the relationship of cleaning and inspection to effective sterilization or disinfection.
3. Compare/contrast the various sterilization technologies in terms of items sterilized, packaging, and monitoring
4. Compare the three levels of disinfectants, including application and monitoring techniques.
5. Describe the characteristics and application for each of the various types of sterilization monitors.

### Introduction

At one time instrument processing was relatively simple. Most instruments were made from stainless steel, were autoclavable, and there were few variations in recommended cycle times. The inventory of rigid endoscopes was small and demand for turnaround of heat and moisture sensitive devices was moderate at best. This changed with the advent of minimally invasive surgery and the proliferation of, and demand for, expensive, minimally invasive surgical instrumentation. This advanced technology resulted in an increased body of knowledge and the need for operating room personnel to regularly demonstrate competency to reflect understanding of the complex changes in instrument processing.

Factors related to minimally invasive surgery that increased the body of knowledge and need for increased competence in sterilization and disinfection for Operating Room personnel

- New sterilization technologies
- New instrumentation
- Variations in cycles
- Limited inventories of expensive heat sensitive devices
- Updated standards
- Increased focus on instrument processing

The experts in instrument processing are the personnel working in the Sterile Processing Department (SPD), also known as Central Sterile (CS), or Central Service. Because of the increased level of responsibility of this group of workers for patient safety, certification is now required in some areas of the country and may soon become a requirement throughout the United States.

There are times, however, when operating room personnel must assume full responsibility for processing instruments. To do the job correctly and to ensure that instruments are safe for patient use, requires in-depth knowledge of sterilization and disinfection principles and practices.

**The Operating Room Must Occasionally Assume Full Responsibility for Sterilization and Disinfection**

- When SPD is closed on an off-shift or weekend
- When instruments are needed immediately and none that are sterile are available
- When demand exceeds inventory and instruments are kept in the OR to facilitate rapid turnaround

## **CURRENT STANDARDS IN STERILIZATION AND DISINFECTION**

### ***Spaulding Classification***

How a device is used determines how it must be processed. The Spaulding Classification of medical devices, developed by Earle Spaulding in 1968 and adopted by the Centers for Disease Control and Prevention (CDC), is used to determine whether a device must be sterilized, disinfected, or merely cleaned. The three Spaulding classes are critical, semi-critical and non-critical <sup>1</sup>

Critical devices penetrate a mucous membrane and enter normally sterile areas of the body. Examples of critical devices include Metzenbaum scissors, hemostats, and scalpels. Critical devices require sterilization – a process that kills all microorganisms including high numbers of spores. Semi-critical devices, such as thermometers and endoscopes, contact intact mucous membranes but do not penetrate them. Semi-critical devices may be sterilized but require a minimum of high-level disinfection – a process that kills all microorganisms with the exception of high numbers of spores. Non-critical devices such as blood pressure cuffs and crutches contact intact skin. Non critical devices require low-level disinfection – soap and water cleaning.

**Spaulding Classification of Medical Devices**

- Critical: penetrate mucous membranes; enter normally sterile body cavities
- Semi-critical: contact intact mucous membranes
- Non-critical: contact intact skin

### ***Organizations providing guidance to the Operating Room (OR)***

In addition to the Spaulding classification of devices, guidelines for instrument processing may also be found at the CDC web site. Standards from various other organizations also provide guidance as to how a device must be processed and what the necessary steps are to accomplish this.

Organizations Providing Instrument Processing Recommendations and Standards Most Relevant to the Operating Room

**AORN**

The Association of periOperative Registered Nurses (AORN) publishes *Recommended Practices on Instruments and Powered Equipment – Care and Cleaning, Sterilization in the Perioperative Practice Setting and Disinfection, High-Level, and Packaging Systems – Selection and Use* (AORN, 2004). These documents are reviewed periodically and undated at least every five years.

**AAMI**

The Association for Advancement of Medical Instrumentation is a standard setting body that includes representatives from sterilization technology industry, consultants, scientists, and end users. The documents published by this organization are frequently referenced by other standard setting bodies and are considered to be “the” United States standards for sterilization and disinfection.

**ISO**

The International Standards Organization (ISO) is an international standard-setting body. Many of the ISO sterilization and disinfection standards are reflected in standards both in the United States and elsewhere around the world.

**SGNA**

The Society for Gastroenterology Nurses and Associates writes standards related to processing devices used in Gastrointestinal (GI) Endoscopy. Although most GI endoscopic procedures are performed in a department separate from the OR, there are times when these devices are used and processed in the operating room. Recent reports of patient infections resulting from improperly processed flexible endoscopes have underscored the need to process these devices adhering strictly to the published guidelines.

**Central Service Organizations that Drive Sterilization and Disinfection Practice**

**ASHCSP and IAHCMM**

Two organizations specifically designated for Sterile Processing personnel are the American Society for Healthcare Central Service Personnel (ASHCSP) and the International Association of Healthcare Central Service and Materials Management (IAHCMM). These organizations develop and participate in writing standards and promote certification for their members.

## STEPS INVOLVED IN INSTRUMENT PROCESSING

### *Cleaning*

Cleaning is the single most important step in instrument processing. Without the removal of debris and bioburden, it is impossible to guarantee the sterilization or disinfection process. Debris that adheres to an instrument can prevent contact with the sterilant; even though the sterilizer is working perfectly, the sterility of a device that is not clean cannot be insured.

The person in the scrub role should initiate cleaning during the surgical procedure, keeping instruments as free of debris as possible either by submerging them after use in a basin of sterile water (provided specifically for this purpose), or by wiping them with a sterile lap pad, moist or dry depending upon the amount of debris present. Lumened devices should be periodically submerged in water. Small lumened devices may require irrigation with a syringe to prevent debris from drying and adhering to the inside walls of the lumen.

Following surgery instruments should be covered and transported to a dedicated decontamination area. Instruments should be washed as soon as possible after surgery. A cold-water rinse may help to prevent blood from drying on the instruments. If a delay before washing is anticipated, the instruments should be coated with an enzyme spray, foam, or gel to prevent debris from drying.

#### Cleaning

- Cleaning is the most critical component of instrument processing.
- Inadequate cleaning can interfere with the sterilization process.
- The sterility of an item that has not been properly cleaned cannot be assured.
- You can clean without sterilizing; you cannot sterilize without cleaning!

### *Biofilm*

A biofilm is a collection of microscopic organisms that exist in a polysaccharide matrix that adheres to a surface and prevents antimicrobial agents from penetrating and contacting the microorganisms. A biofilm that is introduced into the patient can have severe infection consequences for the patient. Although biofilms can form on any surface they most commonly form in device lumens. Recent emphasis on the significance of biofilms in causing infection makes cleaning especially important for lumened devices.

#### Biofilm

- A collection of microscopic organisms adherent to a surface.
- Prevents sterilant from contacting instrument surface during sterilization.
- Infection caused by a biofilm can have severe patient implications.
- Especially large doses of antibiotic may be necessary to treat infection caused by a biofilm.
- Antimicrobials may not be able to penetrate into the cells.

### ***Bioburden Reduction***

Studies have shown that cleaning reduces the bioburden (number of microorganisms) on instruments by approximately 4 logs.<sup>2,3</sup> One log represents a 90 percent reduction. For example, if a device had 1,000,000 microorganisms on it, a one log reduction would leave 100,000 microorganisms. After a 4 log reduction only 100 microorganisms would remain.

Most Central Processing departments utilize automated washing machines that control time and temperature and include wash, rinse, disinfection, lubrication and drying cycles. This equipment is rarely available in the operating room and washing is often performed manually under less than ideal conditions. A number of devices, such as powered drills, must be washed manually to prevent damage because of material composition or design. Manual cleaning is acceptable and effective only if done properly.

### ***Cleaning Products***

It is sometimes difficult to determine which, among the many cleaning products on the market, is the best product to use. Selection should be based upon a careful review of manufacturers' literature and after consultation with the infection control practitioner in the healthcare facility. Surgical instruments should be cleaned only with products specifically intended for this purpose. For example, it is not good practice to clean a device in the scrub sink using products intended for surgical hand antisepsis.

Detergents for cleaning instruments may include one or more enzymes. Enzymes break down fats, protein and carbohydrates: protease for protein, lipase for fat, amylase for starches. For instruments used on procedures where the bioburden consists primarily of fats a detergent product containing lipase may be appropriate. Instruments from vascular procedures might benefit from a detergent with a protease enzyme to break down bloody debris. Both alkaline and acidic solutions can be corrosive and damaging to instruments; therefore, a multi-enzyme product with a neutral pH is most often preferred in the United States.

Equally important to effective cleaning is how the detergent is mixed and used. Detergents should be used strictly according to the manufacturer's instructions. While it may be tempting to increase the concentration of the detergent mix when instruments are heavily soiled, this is poor practice and can compromise the sterilization or disinfection process. This is particularly true with flexible endoscopic instruments. Highly concentrated detergent cannot be rinsed easily and the resulting residual detergent can interfere with the disinfection or sterilization process. It is equally important to follow manufacturer's instructions if an automated system is used.

#### **Insure Proper Concentration for Manual Cleaning of Instruments**

A good suggestion for insuring proper detergent concentration when cleaning instruments manually is to place a mark on the sink at the desired water level and to post instructions indicating the specific amount of detergent to be added.

### ***Cleaning Supplies***

In addition to the proper detergent, it is important to use appropriate cleaning supplies. Brushes should be long enough to extend beyond the distal end of lumened devices. Brush diameter should be large enough for the bristles to touch all surfaces on the inside of the lumen, but not so large that they collapse completely when passed through the lumen. Pipe cleaners should be used for

ports and crevices. Brushes designed to remove debris from crevices are appropriate for heavily soiled devices with multiple serrations, such as vascular forceps and orthopedic rasps. Scrub brushes are not appropriate for cleaning instruments. It is important that cleaning brushes are well-maintained, cleaned and sterilized daily, inspected before each use, and replaced if worn.

All devices should be disassembled prior to cleaning. Disassembled devices (with the exception of powered instruments) should be immersed in a mixture of detergent and water and should be cleaned beneath the surface of the water to prevent aerosolization of microorganisms.<sup>4</sup> Devices should not be cleaned under running water where water and debris can splash. When a lumened device is cleaned with a brush, the brush should be passed from the proximal end of the lumen out beyond the distal end and while the brush is extended, it should be swished in the detergent to remove debris before being pulled back through the lumen. Following washing, instruments should be thoroughly rinsed by immersion in clean rinse water according to manufacturer's instructions; some detergents require more than one rinse by immersion in clean water.

Personnel washing instruments should wear personal protective equipment (PPE) whether one instrument or a whole set is being washed. Personal protective equipment includes a water-repellant apron or gown, cap, mask, goggles or mask with face shield, and gloves. The gloves should be sturdy and should extend up to the mid forearm.

#### Cleaning Tips

- Do not clean instruments in the scrub sink!
- Disassemble instruments before cleaning.
- Use warm water and detergent in the concentration indicated by the manufacturer.
- Manually clean instruments below the surface of the water.
- Pass the brush completely through a lumened instrument and swish to remove debris before bringing brush back through the lumen.

#### ***Ultrasonic Cleaning***

Instruments should be cleaned before being placed in an ultrasonic cleaner; the ultrasonic cleaner is not intended for the removal of gross debris. Ultrasonic machines clean through a process of cavitation. High frequency sound waves are converted into mechanical vibrations that pass through a solution and generate microscopic bubbles on the instrument. As these bubbles collapse inwardly or implode, they create tiny vacuums that draw debris from the instrument. Ultrasonic cleaners are especially useful for removing debris from small crevices and areas on the instrument that are not easily accessible such as box locks.

Ultrasonic cleaners are not appropriate for all devices. Lensed instruments, for example, should never be subjected to ultrasonic cleaning as the process can disrupt the integrity of the lens seal. Devices of dissimilar metals should not be placed together in the ultrasonic washer because electroplating can occur that can result in permanent discoloration and weakening of the instruments. Ultrasonic cleaners are, by themselves, not biocidal and instruments must be rinsed after ultrasonic cleaning.

#### ***Lubrication***

Instruments with moveable parts may be lubricated in a water-soluble lubricant intended for surgical instruments. Oil based lubricants should not be used except to lubricate internal mechanisms on

powered equipment such as drills and saws. Oil based lubricants can interfere with the sterilization process by coating bacteria and shielding them from contact with the sterilant. As always, consult the device manufacturer's instructions to determine the appropriate lubricant and appropriate use.

### ***Drying***

Instruments should be dried with a soft clean cloth before they are disinfected, packaged, or sterilized. Forced air may be necessary to dry lumens. The exception is instruments with lumens that will be steam sterilized. The lumens of devices to be steam sterilized should be moistened with distilled or demineralized water.<sup>5</sup> During the sterilization process, moisture in the lumen will become steam. Lumens in instruments that will not be steam sterilized might require drying with forced air.

#### Drying Instruments

With the exception of devices with lumens that require moistening with demineralized water in preparation for steam sterilization, instruments should be thoroughly dried prior to disinfection, sterilization, or storage.

### ***Inspection***

Instruments should be inspected for cleanliness and function prior to disinfecting, packaging, or sterilizing. An instrument that is not clean or that fails to function properly can cause a delay in surgery, frustrate the surgeon, or worse, result in patient injury. For example, if an insulated electrosurgical laparoscopic instrument whose insulation is not intact is used, the patient can suffer an inadvertent burn that can lead to peritonitis and even death.<sup>6</sup> Instruments should also be checked for proper alignment.

#### Tips for Inspection

- Inspect crevices, grooves and areas that are not readily accessible for cleanliness.
- Inspect box locks and joints for cracks and for ease of movement.
- Check tips and jaws of instruments for cracks - a crack is a sign of impending breakage.
- Inspect the base of holder jaws in particular for cracks.
- Inspect instrument jaws for proper alignment; tips should not overlap.
- Forceps should approximate and release smoothly. (If forceps with teeth do not readily open they are probably misaligned.)
- Clamps should be closed and held to the light; light shining through jaws indicates misalignment.
- Needle holders should hold a needle securely; you should not be able to rotate a loaded suture.
- Check chisels, scissors and osteotomes for burrs or nicks and for sharpness.
  - Scissors such as heavy Mayo scissors should cut easily through four layers of gauze.
  - Metzenbaum scissors and other delicate scissors should easily cut through two layers.

- Check light cables for broken fibers
- Hold one end of the cable to the light and inspect the other end for black dots that indicate broken fibers; the greater the number black dots the lower the illumination.
- Telescopes should be checked for lens clarity.
  - Hold the scope to the light and look through the eye-piece; the image should be crystal clear.
  - A cloudy or fuzzy image may indicate moisture penetration between lens and eyepiece.
- Inspect insulated instruments thoroughly to insure the insulation is intact.
- Inspect microscopic instruments under magnification; additional light may be necessary in the area where inspection is performed.

Often perioperative nurses who are preparing instruments in the operating room are doing so in preparation for flash sterilization because the device or set is needed immediately. It may seem that inspection is not a priority; however, it is important that careful inspection be completed before processing.

### ***Packaging***

Prior to sterilization, items may be packaged in pouches, trays, or rigid containers. They may be wrapped in single use polypropylene wrap, paper, or with reusable fabric. Appropriate packaging and loading of the sterilizer is specific to each sterilization technology.

### ***Prions – Special Processing Procedures***

A prion is an infectious protein particle responsible for causing prion diseases such as Creutzfeldt-Jakob disease (CJD), a fatal neurological disease. Prions are resistant to most sterilization modalities and to the routine sterilization cycles used in healthcare facilities. Because of the unique nature of prions, every institution should have a policy that identifies patients who are diagnosed with CJD or who are suspected to be infected. A policy and procedure should also be in place for processing instruments used on those patients. Good communication among surgeons, perioperative nurses, anesthesia, and SPD is essential to identify, isolate, and process CJD-contaminated instruments appropriately.

In the operating room, standard precautions are sufficient to protect personnel from exposure to prions. During surgery, debris should not be allowed to dry in or on instruments or devices, and they should never be flash sterilized. Instruments should be processed as soon after surgery as possible, and should not be processed in the operating room. They should be processed only in a dedicated decontamination and sterilization area staffed by personnel familiar with the protocols. Processing personnel should be informed when known or suspected prion infected patients are scheduled for surgery and instruments used on these patients should be identified as such. Processing personnel should also be notified when surgery is complete so that they can plan to receive these instruments and to begin the decontamination process.

Protocols for processing instruments exposed to prions is evolving and related policies and procedures should be reviewed and modified as needed at least annually. Two sources of information related to processing instruments exposed to prions are the CDC and the World Health Organization (WHO).

## STERILIZATION TECHNOLOGIES

### ***Sterilization***

Sterilization is a process that kills all living microorganisms. It is measured by the probability of viable microorganisms being present on a device after sterilization. This probability is referred to as a sterility assurance level (SAL), and is expressed in mathematical terms. The standard for sterilization in the healthcare industry is  $10^{-6}$ . This is a mathematical expression that means there is less than, or equal, to a one in a million chance that any viable microorganism can remain on a device after sterilization.

Before a sterilizer can be introduced to the market, the manufacturer must demonstrate to the Food and Drug Administration (FDA) that the sterilizer can kill microorganisms with an SAL of  $10^{-6}$ . Device manufacturers must demonstrate to the FDA that their devices can be sterilized with a  $10^{-6}$  SAL. All sterilization technologies, e.g., steam, ethylene oxide, peracetic acid, and hydrogen peroxide gas plasma must deliver an SAL of  $10^{-6}$ .

Industries other than the medical industry often have a lower SAL such as  $10^{-3}$ . This does not mean that their product sterility is questionable; it means that the standard for sterilization of medical devices is exceptionally high. It is important, however, to remember that no matter how robust and lethal the sterilization process, the sterility of items processed in the sterilizer is dependent upon how well they were cleaned, inspected, and packaged prior to sterilization.

### ***Sterilization Technologies - Overview***

Sterilization modalities found in healthcare facilities in the United States include steam under pressure, ethylene oxide, hydrogen peroxide gas plasma, liquid peracetic acid, and dry heat. Steam is appropriate for instruments that are stable in the presence of heat and moisture. Because most surgical instruments are made from stainless steel, steam sterilization is the modality of choice for the majority of surgical instruments. Ethylene oxide and hydrogen peroxide gas plasma are appropriate for devices that are sensitive to heat and moisture, such as cameras and lensed instruments. Liquid peracetic acid is appropriate for devices that can tolerate moisture but not high temperatures. Dry heat is appropriate for sterilization of anhydrous oils, petrolatum products, and powders; however, since the majority of these products are provided sterile by commercial manufacturers, dry heat is rarely used in medical facilities.

Three terms are often associated with sterilization: *terminal sterilization*, *flash sterilization*, and *point-of-use sterilization*. Terminal sterilization refers to sterilization of wrapped items – items that can be stored in a sterile state following the sterilization process if not used immediately. Terminal sterilization may be accomplished in a steam, ethylene oxide, or hydrogen peroxide gas plasma sterilizer. Terminally sterilized items remain sterile until the package is opened or until the package integrity is compromised or contaminated. Terminal sterilization is the preferred method.

Flash sterilization refers to steam sterilization of unwrapped items. Items that are flash sterilized cannot be stored in a sterile state and must be used immediately. Flash sterilization is one point-of-use method since the items are processed in a sterilizer located adjacent to the operating room in which the device will be used and the device must be used right away.

Flash sterilization is discouraged by standard-setting bodies such as state health departments and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).<sup>7</sup> The sterility of flashed items is heavily dependent upon the technique of the personnel handling them, and there is ample opportunity for contamination in the process of delivering the item to the sterile field. However, time constraints, limited instrument inventories, and immediate need sometimes necessitate flash sterilization. Liquid peracetic acid sterilization is also a point-of-use technology.

Many facilities have drastically reduced the amount of flash or point-of-use sterilization by purchasing additional instruments and using alternate sterilization technologies.

#### Terminal vs. Point of Use Sterilization

- Terminal sterilization is sterilization of a wrapped package. Items that are terminally sterilized can be stored in a sterile state until use.
- Point-of-use sterilization is sterilization of an unwrapped item for immediate use; the item cannot be stored in a sterile state.
- Flash steam sterilization and peracetic acid are point-of-use approaches.

#### ***Steam Sterilization - Overview***

There are two types of steam sterilizers; gravity displacement and dynamic air removal. Dynamic air removal sterilizers are either vacuum assisted or steam-flush-pressure-pulse. The differences relate to the manner in which air is removed from the sterilizer chamber. In a gravity-displacement sterilizer, the air in the sterilizer chamber is replaced with steam through gravity. Dynamic air removal steam sterilizers use either a vacuum pump to remove air from the chamber prior to the entry of steam, or a series of repeated steam-flush and pressure pulses above atmospheric pressure to remove the air in the chamber. All steam sterilizers are referred to as autoclaves.

Gravity displacement sterilizers are typically found in small clinics and physician's offices or ambulatory surgery facilities. They were very common in operating rooms at one time but have largely been replaced by dynamic air removal sterilizers that can be programmed with either a vacuum cycle or a gravity displacement cycle.

The critical parameters of steam sterilization are time, temperature, and steam saturation or moisture. Steam saturation refers to the amount of water contained in the steam - the higher the temperature, the greater the steam saturation. Steam saturation should be between 97 and 100 percent. Effective sterilization is dependent upon an appropriate relationship of the three parameters. There is an inverse relationship between temperature and time; cycles at higher temperatures are shorter than cycles at lower temperatures. The minimum temperature for sterilization is 250<sup>0</sup> F (123<sup>0</sup>C). At atmospheric pressure, steam temperature is 212<sup>0</sup>F (100<sup>0</sup>C) which is insufficient to achieve sterilization. With the addition of 15 to 17 pounds of pressure per square inch, the steam will reach the required temperature. Sterilizers operate at temperatures between 250<sup>0</sup> F (121<sup>0</sup>C) and 274<sup>0</sup> F (134<sup>0</sup>C).

Exposure times range from three minutes up to an hour depending upon the type of sterilizer used and the device being sterilized. Exact time and temperature are determined both by the sterilizer manufacturer and the device manufacturer. It is critical that the sterilizer operator consult the manufacturer's instructions.

### Steam Sterilization Parameters

- Successful sterilization by steam is a function of an appropriate relationship of temperature, time, and steam pressure.
- The correct combination of temperature, time, and pressure is determined both by the type of autoclave and the item being sterilized.
- It should never be assumed that there is a single “correct” temperature or “correct” exposure time or “correct” combination that is appropriate for all devices.

### ***Gravity Displacement Sterilizer***

In a gravity-displacement sterilizer, steam enters the chamber and replaces the air through gravity. The air is evacuated through a discharge port located in the floor of the chamber near the front. The port is actually the beginning of a filtered waste line. A thermometer located within this line detects when the steam has reached the required temperature. When this temperature is reached, actual sterilization begins. This is the exposure phase in the cycle. The temperature will remain at this level for a pre set amount of time. When exposure is complete the steam will be exhausted, and if the items are wrapped, a drying phase will begin. If items are flashed or unwrapped, drying is not included and the cycle will end once steam is exhausted.

Gravity-displacement sterilizers typically operate at a temperature of 250<sup>0</sup> F (121<sup>0</sup> C) for a period of three to ten minutes. Usual exposure times are three minutes for stainless steel instruments without a lumen, and ten minutes for stainless steel instruments with a lumen. However it is the manufacturers' instructions that determine the appropriate exposure time for the sterilizer and its contents. For example some powered equipment may require extended exposure time of more than 30 minutes in a gravity displacement sterilizer or gravity displacement cycle. Some instruments require gravity displacement cycles as indicated in the device manufacturer's instructions for processing. Gravity displacement cycles are also used to sterilize liquids. Because air removal is dependent upon gravity, and because air that is trapped in the sterilizer can interfere with the sterilization process, gravity-displacement sterilizers or cycles should only be used when sterilizing liquid or when specified by the device manufacturer.

### ***Dynamic Air Removal Sterilizer***

Dynamic air removal sterilizers provide a greater assurance of air removal than gravity displacement sterilizers. In a dynamic air removal cycle the air is mechanically removed from the chamber. The most common method of air removal is a vacuum pump. When the cycle starts, air is pumped out of the chamber prior to the entry of steam. The benefit of this is instant contact of the device to be sterilized with the steam as it enters the chamber, and the prevention of air pockets that can compromise the sterilization process. Dynamic air removal sterilizers are typically operated at a temperature of 270<sup>0</sup>F (134<sup>0</sup>C) with an exposure time of 4 minutes. Because steam contact is not dependent upon gravity, the cycle times are shorter than in a gravity displacement cycle. A powered drill that may require an exposure time of 30 minutes in a gravity-displacement cycle can be sterilized in 4 minutes in a dynamic air removal sterilizer. Sterilizers in which air is removed with a pump are referred to as pre-vac or high-vac sterilizers.

Because of its many advantages and wide application, steam is the most commonly used sterilization technology within healthcare facilities.

Steam sterilization:

- Is economical
- Is readily available
- Is rapid
- Is compatible with most surgical instruments
- Leaves no toxic residue
- Is safe for the environment

### ***Packaging and Loading***

Packaging materials, packaging techniques, and sterilizer loading can all affect the ability of the sterilizer to sterilize its contents. Packaging must allow for penetration of the sterilant and must be able to withstand the conditions inside the sterilizer. Items intended for steam sterilization may be packaged in paper, reusable textile, polypropylene, or in rigid containers intended and validated by the packaging or container manufacturer for this process. Tyvek® mylar pouches cannot be used for steam sterilization because the Tyvek® will melt and adhere to the instrument when subjected to high temperatures.

Steam is a contact sterilant and as such, the steam must be able to make contact with every surface of each item. All devices should be disassembled and packaged in their open position. Rubber sheeting such as an Esmarch wrap, should not be folded upon itself. Layers should be separated by a sheet of gauze or suitable textile. Cups and basins should not be stacked one inside the other unless separated by suitable textile such as a towel. Pouches should not be placed within trays or containers.<sup>4</sup>

There is no magic number of instruments or weight that is acceptable for trays. Trays should not be so heavy that they are difficult to carry or lift. Trays with too much metal mass can result in wet instruments at the end of a cycle, even though they were subjected to a drying cycle. When loading the sterilizer it is important to position items so that the steam can enter and exit the package equally. Basins and cups should be placed on their side to permit steam exit and entry. Packages should be positioned to prevent the formation of air pockets within the sterilizer.

### ***Flash Sterilization***

Although steam sterilizers in the operating room may be used for terminal sterilization, most terminal sterilization is accomplished in the sterile processing department. Steam sterilizers in the operating room are often used for flash sterilization – i.e. steam sterilization of an unwrapped item. Processing of an unwrapped item takes considerably less time than sterilization of wrapped packages. The cycle is shorter because the item is exposed directly to the sterilant and drying is not required. Terminal sterilization is the gold standard; flash sterilization should be reserved only for those items that are needed immediately and for which there is not a terminally sterilized and wrapped replacement.

The *AORN Recommended Practice for Sterilization in Perioperative Practice Settings* states, “Flash sterilization should only be used in carefully selected clinical situations when certain parameters are met.”<sup>5</sup> The CDC states, “... flash sterilization is not intended to be used for either reasons of convenience or as an alternative to purchasing more instrument sets or to save time.”<sup>8</sup>

Unfortunately it is not uncommon for a facility to flash sterilize a whole set of instruments when there is only one set and it is needed for back to back procedures. Typically the instruments are manually cleaned in the operating room rather than in an automated system in the sterile processing department. Instruments are placed unwrapped in a tray, flash sterilized, and transported to the back table in the operating room where the scrub person removes them from the tray. Although containers specific for flash sterilization decrease the potential for contamination, every effort should be made to avoid flash sterilization. The concerns surrounding flash sterilization do not relate to the ability of the sterilizer to sterilize but rather to the preparation or cleaning, packaging, and transport of the devices being sterilized.

- Some facilities have virtually eliminated flash sterilization by purchasing additional instruments.
- Maintaining an inventory of individually wrapped sterile instruments that are most apt to be needed during a procedure.
- Scheduling cases based on inventory and sterilization requirements.
- Switching to alternate sterilization technology.

If flash sterilization cannot be avoided the following guidelines should be followed:

- Refer to the device manufacturer's instruction for use to determine if the device is suitable for flash sterilization. If instructions do not identify flash sterilization as appropriate, the device should not be sterilized using this method.
- Instruments with removable parts should be disassembled.
- Instruments should be cleaned in a soiled utility or decontamination room with a hospital approved detergent intended for cleaning of surgical instruments. Instruments should never be cleaned in a scrub sink.
- The detergent must be mixed and used according to the detergent manufacturer's instructions. When instruments are heavily soiled it is tempting to use additional detergent. This is inappropriate and may actually compromise the sterilization process if detergent residues are not adequately rinsed.
- Brushes and other cleaning supplies should be available and used as needed, e.g. for cleaning lumens, box locks, serrations and other hard to reach areas of devices. Scrub brushes are not appropriate for cleaning instruments.
- Instruments should be thoroughly rinsed.
- Personal protective equipment, e.g., mask, fluid proof gown, gloves, and eye protection must be worn during the cleaning process.
- The instrument should be dried.
- The device manufacturer instructions should be consulted to determine the required cycle and exposure time. With the increasing diversity of instruments the "routine" 4 minute 270° F cycle may not be appropriate.
- Instruments should be disassembled and in the open position and placed in open mesh trays or in a container specifically designed for flash sterilization. Instruments should not be pouched within trays. If a flash container is used it must have been determined through a validation process that the device can be appropriately sterilized in the container.
- If a gravity-displacement sterilizer or a gravity cycle is selected and the device has a lumen the lumen should be moistened with sterile water.
- The cycle type, exposure time, and dry time, if desired, should be selected and the cycle started.

- At the completion of the cycle the devices should be transported in a manner to prevent contamination. (In some facilities the sterilizer opens directly into the operating room and risk of contamination during transport may be reduced.)

If the device manufacturer does not provide instructions for flash sterilization do not assume the device has been validated for flash sterilization.

Implants should not be flash sterilized.

### ***Ethylene Oxide Sterilization***

Ethylene oxide (EtO) sterilization is rarely, if ever, performed in the operating room and EtO sterilizers are normally located in the sterile processing department. Ethylene oxide is suitable for items that cannot tolerate high temperatures or moisture – e.g., cameras, endoscopes, and electrical cables. The critical parameters for EtO sterilization are gas concentration, temperature and humidity, and exposure time.

EtO gas may be supplied in small individual cartridges of 100% concentration, in large tanks combined with hydrochlorofluorocarbon (HCFC), or in combination with carbon dioxide. EtO is flammable and explosive, and the addition of these gases eliminates these hazards.

Items intended for sterilization in ethylene oxide may be packaged in polypropylene, Tyvek®, paper, reusable textile or containers intended and validated by the packaging manufacturer for this purpose.

Sterilization with EtO is a lengthy process with exposure times between three and six hours, followed by an eight to twelve hour aeration period. Aeration is necessary because ethylene oxide is toxic and carcinogenic; residuals must be removed to insure that the sterilized items are safe for patient use and employee handling.

The Occupational Health and Safety Administration (OSHA) has identified a number of requirements to protect employees who work with and around ethylene oxide.<sup>9</sup> Among them are 1) an exposure limit of 1 part per million over an eight hour work period, 2) a requirement to post a warning sign indicating that ethylene oxide is a cancer and reproductive hazard, 3) periodic monitoring of employee exposure, 4) a detection and alarm system for discovering a leak, 5) and other administrative and engineering controls. As a result of the safety and regulatory concerns related to EtO, many facilities have either reduced their dependence upon, or eliminated its use altogether by using alternate low temperature sterilization technologies and by purchasing instruments that do not require EtO sterilization.

### Ethylene oxide

- Is an excellent penetrator.
- Is suitable for heat and moisture sensitive items.
- Is toxic and carcinogenic.
- Is highly flammable and explosive in large concentrations.
- Is highly regulated.
- Sterilization is a lengthy process.
- Sterilization is a terminal process.

Perioperative nurses in the operating room are rarely responsible for ethylene oxide sterilization, however they may be impacted by the lengthy cycle time. Instruments processed exclusively in ethylene oxide can only be used once a shift and may be in the aerator when they are needed for a surgical procedure. Although it is very unlikely that sterile processing personnel would interrupt an ethylene oxide cycle to accommodate the OR schedule, for safety reasons perioperative nurses should never request premature release of items.

Never request interruption of an aeration cycle to retrieve items that have been sterilized with EtO

### ***Hydrogen Peroxide Gas Plasma***

Hydrogen peroxide gas plasma is a relatively new technology that was introduced to the marketplace in 1993. It is especially suitable for devices that cannot tolerate high heat or moisture. Items typically sterilized in hydrogen peroxide gas plasma include cameras, endoscopes, batteries, and devices with electronic components. Hydrogen peroxide gas plasma sterilizers can be located in either the sterile processing department or the operating room.

Because of the wide range of compatibility and the short cycle time as opposed to ethylene oxide, hydrogen peroxide gas plasma sterilization is often the method of choice for devices that cannot tolerate high temperatures or moisture.

This technology currently operates with a single cycle time for each model, which, depending upon the model, is between 45 and 74 minutes long. With this technology a vacuum is created; hydrogen peroxide liquid enters the chamber and is converted into a vapor that is effective at killing microorganisms. The hydrogen peroxide gas is charged with electrical energy to create a plasma. In the plasma state hydrogen peroxide vapor is converted into a highly reactive species that effectively remove hydrogen peroxide residuals from the sterilized devices. At the end of the cycle, the high energy species recombine into oxygen and water vapor leaving no toxic residuals, hence

no aeration is required. Because the water vapor is in the form of humidity, packages are dry at the end of the cycle.

Items intended for sterilization in hydrogen peroxide gas plasma may be packaged in polypropylene, combination Tyvek® mylar pouches, or containers intended and validated by the packaging or container manufacturer for this purpose. Items that are wet or that are made from cellulosic materials such as gauze, paper and cloth cannot be processed in hydrogen peroxide gas plasma.

In addition, there are very small diameter and or very long lumened devices that cannot be processed in this technology. The sterilizer operator should consult the operator's manual to determine those lumens that cannot be sterilized in this technology as the lumen size limits will vary with the sterilizer model. The operator should also confirm with either the device or the sterilizer manufacturer that the device intended to be sterilized is compatible with hydrogen peroxide gas plasma technology.

#### Hydrogen peroxide gas plasma

- Is suitable for sterilization of heat and moisture sensitive devices.
- Is rapid.
- Leaves no toxic or carcinogenic residuals.
- Is safe for patients and employees.
- Does not require the operator to determine or set cycle time.
- Sterilization is a terminal process.
- Is not suitable for cellulosic materials.
- Is not suitable for very small (less than 1 mm diameter) or very long lumens.

#### ***Liquid Peracetic Acid***

Liquid peracetic acid sterilization is a point-of-use technology that is suitable for devices that cannot tolerate high heat but can tolerate moisture. The devices most commonly sterilized with this technology are rigid and flexible endoscopes. This approach uses a table-top sterilizer that is almost always located in the operating room or in an area adjacent to the operating room itself.

During the sterilization process, a buffered solution of peracetic acid and hydrogen peroxide circulates around and through the devices being sterilized. This is followed by a sterile water rinse. At the end of the cycle the devices are wet and cannot be stored. If the device is not used upon completion of the cycle it must be sterilized again just before use. As with any sterilization technology, operators who use liquid peracetic sterilization should check with device manufacturers to determine compatibility with this technology.

Because of the short cycle time of approximately 25 minutes many facilities have used this technology to facilitate rapid turnaround of endoscopes rather than tie up a device in ethylene oxide where it will not be available for reuse for many hours. However, because the process is a just-in-time, or point-of-use technology, and not a terminal process after which items can be stored, many facilities have increased their inventory of endoscopes and/or converted to an alternative rapid terminal process such as hydrogen peroxide gas plasma.

#### Liquid peracetic acid

- Is suitable for sterilization of devices that are heat sensitive but can tolerate immersion.
- Is rapid.
- Leaves no toxic residuals.
- Is not a terminal process – devices are wet at the end of the cycle.

### ***New/Emerging Sterilization Technologies***

Super oxidized water is popular in several countries outside of the United States. Its primary application is for flexible endoscopes. It is a just-in-time sterilization process in which sodium chloride is treated by electrolysis and converted to a mixture of oxidants which are effective at killing microorganisms. At the end of the cycle the device is wet and cannot be stored in a sterile state.

Ozone has just recently been introduced to the market and is not widely used. With this technology, oxygen, water, and electricity are used to generate ozone which is effective at killing microorganisms. Operators of this technology should consult the operator's manual to determine device compatibility.

## **DISINFECTION TECHNOLOGIES**

### ***Overview***

Disinfection is used to kill microorganisms on *inanimate* objects such as surgical instruments and floors and is accomplished with liquid chemical germicides. Disinfectants vary in their ability to kill microorganisms and are categorized as high-level, intermediate-level, and low-level. Disinfectants are not interchangeable.

#### Disinfectants are NOT Interchangeable

##### High-level disinfectants

- kill all microorganisms with the exception of high numbers of spores
- used on surgical instruments or devices, such as gastroscopes, cystoscopes, and thermometers that contact a mucous membrane but do not penetrate the membrane or enter into a sterile area of the body

##### Intermediate-level disinfectants

- kill viruses, some fungi, vegetative bacteria, and the tubercle bacilli
- used on floors, walls and for other general housekeeping tasks.

##### Low-level disinfectants

- kill viruses, some fungi and vegetative bacteria
- used on floors, walls and for other general housekeeping tasks.

Only high-level disinfectants with a tuberculocidal claim that are cleared by the FDA for use as a high-level disinfectant may be used to disinfect surgical instruments. High-level disinfectants are effective in 5 to 45 minutes depending upon the chemical, the concentration, the temperature of the solution, and whether or not it is used in an automated or manual system.

Disinfectants are more rapidly effective when they are heated however heating increases vapor pressure and the potential of increased employee exposure to harmful chemicals. Some high-level disinfectants are approved for use as a sterilant as well as a high-level disinfectant; however, this application is rare. Sterilization requires approximately 8 to 10 hours of immersion in the disinfectant, depending upon the solution. The time required for sterilization makes this approach impractical.

Items intended for high-level disinfection must be thoroughly cleaned and dried prior to disinfection. Items that are wet can dilute the disinfectant and render it ineffective. Detergents used for cleaning should be mixed and used exactly according to the manufacturer's instructions for use. It is particularly important to thoroughly rinse items after cleaning. Residual detergent can compromise the efficacy of the disinfectant.

#### Disinfectants vs. Antiseptics

- Disinfectants are used only on inanimate objects.
- Antiseptics are used on skin.
- Disinfectants and antiseptics are *not* interchangeable.
- Skin preps and surgical hand scrubs are antiseptics.

The most common high-level disinfectants used in the operating room

- solutions of 2% - 3.2% alkaline glutaraldehyde
- solutions of 55% ortho-phthalaldehyde

#### **Glutaraldehyde - Safety**

Glutaraldehyde is irritating to mucous membranes and is a sensitizer that can result in an allergic reaction. It should only be used under very controlled conditions. OSHA has set an exposure limit of 0.2 parts of glutaraldehyde to one million parts of air during any part of the work-day.<sup>10</sup> The highest risk of exposure occurs during mixing, immersion and removal of instruments, and when pouring or discarding solutions. Although OSHA does not require employee monitoring of exposure, monitoring should be instituted whenever high levels of exposure are suspected.

Safety precautions for glutaraldehyde include the following:

- Glutaraldehyde solutions should be mixed and used in a well-ventilated area or room with a minimum of 10 air exchanges an hour
- Whenever possible, glutaraldehyde solutions should be used under a ductless fume hood or local exhaust hood.
- Glutaraldehyde solutions should be stored in a closed container and solutions should be covered except when immersing and removing items.

- Personnel using glutaraldehyde should wear personal protective equipment, e.g., protective eye wear, nitrile gloves or two pairs of latex gloves, mask and fluid repellent gown or apron.
- Use of glutaraldehyde should be confined to as few places within the operating room as possible
- Personnel whose work exposes them to glutaraldehyde should receive yearly inservice on safe use.
- Every facility using glutaraldehyde should have a spill team and plan for cleanup Employees should not attempt to clean up a large spill.
- An eyewash station should be within 10 seconds of any area where glutaraldehyde is used.

In some operating rooms devices that have traditionally been high-level disinfected are now sterilized in alternate technologies and glutaraldehyde use is sometimes confined to the endoscopy department.

### **Ortho-phthalaldehyde**

Ortho-phthalaldehyde is a non-glutaraldehyde, high-level disinfectant that has achieved widespread use in a very short time. Because it has a very low vapor pressure, there is no odor associated with its use, and irritation of mucous membranes is less likely than with glutaraldehyde. Ortho-phthalaldehyde, however, is a sensitizer and as with glutaraldehyde, should be handled with caution. Personal protective equipment (e.g., a fluid-resistant gown or apron, eye protection and nitrile or a double set of latex gloves) should be worn during handling and use. It should be used in a well-ventilated area or under a ductless fume hood with a filter that will absorb ortho-phthalaldehyde from the air.

One of the outstanding characteristics of ortho-phthalaldehyde is that it will stain protein. If a device is not adequately cleaned and any protein remains on that device it will stain grey upon immersion in ortho-phthalaldehyde. It is important to follow the instructions for use, particularly with regard to rinsing. While it is tempting to rinse a device by pouring water over it, the instructions for use call for three separate immersion rinses in a large volume of water. Some practitioners regard the staining property as a marker to indicate proper cleaning and a signal to improve cleaning processes. Proper use will eliminate the potential for unintentional staining of surfaces in the area of use.

Because there are fewer instances of mucous membrane irritation, and because it is effective in a shorter time than glutaraldehyde, ortho-phthalaldehyde has largely replaced glutaraldehyde.

## **MONITORING THE STERILIZATION AND DISINFECTION PROCESS**

### ***Competency Program***

Every facility should have a competency based education program with periodic competency review for personnel who are responsible for instrument processing. These programs should be individually tailored to meet the practice expectations within that institution. The facility should

determine the content of the program, the frequency of education, and the competency assessments.

OR Personnel responsible for sterilizing instruments, including flash sterilization should demonstrate competency in

- Instrument disassembly
- Instrument cleaning
- Instrument drying
- Instrument inspection
- Instrument packaging
- Loading of the autoclave
- Autoclave cycle selection
- Sterilizer operation
- Quality control
- Selection and use of appropriate PPE

### ***Sterilization – Quality Control***

In addition to individual personnel competence, certain quality control measures or monitoring of the sterilization and disinfection processes should be conducted routinely to provide the highest assurance possible that the equipment is functioning properly and that the process is effective.

Quality control assesses all aspects of the sterilization process. Mechanical indicators measure the extent to which the parameters of the sterilization process are achieved. Chemical indicators are used to detect sterilization failures that could result from incorrect packaging, loading, or malfunction of the sterilizer. Biological indicators are used to detect failure of the sterilization process.

### ***Mechanical Monitoring***

In order for a sterilizer to sterilize with an SAL of  $10^{-6}$ , certain parameters must be achieved. For example: for steam, these parameters are time, temperature and steam saturation. One way to determine whether these parameters have been met is to check the printout that is provided at the end of the cycle. The printout will detail the temperature that was achieved, the pressure and the length of exposure time. This check should be done after every cycle and before instruments are placed into circulation. The printout should be filed for future reference. Ideally, the printout will contain information that will facilitate recognition of the instruments that were processed, and for which procedure/patient they were used. The printout is an example of a mechanical monitor.

### ***Chemical Indicators***

There are five classes of chemical indicators.

Class I indicator – (process indicator). A class I chemical indicator is typically configured as a tape, strip of paper or label, that changes color during sterilization. Class I indicators are used only to distinguish between processed and unprocessed items.

Class II indicator – (Bowie-Dick test). This indicator is designed for a specific test. For example in a high or pre-vac steam sterilizer a Bowie-Dick test is used to test the sterilizer's ability to create a vacuum. If the vacuum is incomplete steam may not penetrate into a package. Most facilities use a commercially prepared Bowie-Dick or air removal test. An uneven color change indicates possible air leak. A Bowie-Dick test should be run every day.

Class III indicator – (single-parameter indicator). This indicator is designed to react to one of the critical parameters of sterilization at a stated value of that parameter.

Class IV indicator – (multiple-parameter indicator). This indicator is designed to react to two or more of the critical parameters of sterilization at a stated value of the chosen parameters.

Class V indicator – (integrating indicator). This indicator is designed to react to all of the critical parameters over a specified range of sterilization cycles.<sup>4</sup>

A class I indicator should be visible on the outside of every package. For pouched items where one side of the pouch is clear, a chemical indicator placed inside that is visible from the outside of the pouch is acceptable. Before any item is delivered to the sterile field, the person dispensing the item must check the external indicator to ascertain that the package has been subjected to a sterilization process.

A chemical indicator should be placed on the inside of every package that is sterilized. A class I, class II, or class III, indicator may be used for this purpose. Indicator selection should be based on the complexity and contents of the pack. A class V integrating indicator, indicates a "pass" or successful cycle only if all the parameters have been achieved, and therefore provides a greater level of assurance than a class I, III, or IV chemical indicator. The internal chemical indicator should always be checked by the scrub person before items are accepted for use or before items are placed on the sterile field.

Chemical indicators are not a guarantee of sterility; they indicate only that the device has been exposed to one or more of the parameters of the sterilization process.

### ***Biological Indicators (BI)***

Biological indicators determine the efficacy of the sterilization process. A biological indicator is configured as a strip, capsule, or ampoule that contains at least a million known living and highly resistant spores. If the spores are killed during the sterilization process, it can be inferred that the process was effective.

Biological indicators contain a minimum of 1,000,000 spores most resistant to the technology for which it is indicated.

***Geobacillus stearothermophilus*** spores – monitor steam, hydrogen peroxide, and liquid peracetic acid sterilizers

***Bacillus atropheaus*** spores monitor ethylene oxide.

Biological indicators are **not** interchangeable.

The biological indicator is processed in the sterilizer, and upon completion of the cycle is placed in an incubator. Length of incubation varies with the product – from rapid read-out products to those requiring a minimum of 24 hours. If there is no growth after the prescribed incubation time, the indicator is considered “negative” and it may be assumed that the sterilizer is functioning effectively.

Enzyme-only-based indicators do not contain spores, but are comprised of multiple interactive enzymes. Reaction of the enzymes during the sterilization process correlates well with the activity of a BI and is considered highly reliable. The benefit of enzyme-based indicators is that the results can be obtained soon after the process. There is an enzyme indicator that also contains spores, giving the user the option of incubating the indicator for an added measure of security.

The AORN Recommended Practice for Sterilization prefers daily monitoring of steam sterilizers with a BI, but recommends a minimum of weekly BI testing. They make a similar recommendation for monitoring of peracetic acid. Biological monitoring of ethylene oxide sterilizers requires a BI in every load. AORN recommends consulting the manufacturer of the hydrogen peroxide gas plasma sterilization system to determine monitoring schedule<sup>3</sup>; the manufacturer recommends daily monitoring.

It is important to choose the correct BI for monitoring purposes. For example there are different BIs available for monitoring the different types of steam sterilization cycles. Monitor selection must be based on the type of cycle being tested. If a sterilizer is used for more than one type of cycle it must be monitored for each type of cycle. Results of testing should be readily available and consulted before sterilizer use.

### ***Disinfection – Quality Control***

Disinfectants should be labeled with the date of activation (the date the solution is mixed), the expiration date (product label will indicate how long after activation the product can be used), and the name or initials of the person who mixed the solution. The disinfectant should be routinely tested to determine for minimum effective concentration (MEC) – the concentration below which the product is considered ineffective. When a solution fails the MEC test it should be discarded. The MEC takes precedence over the expiration date identified when the solution was activated. For example, a disinfectant label may indicate the solution can be used after 14 days; however, if the MEC drops below the stated limit before 14 days the solution should be discarded immediately.

It is important to consult the manufacturer's recommendations for testing the MEC. Some manufacturers specify that MEC testing should be performed before each use. Only those test strips approved for use by the disinfectant manufacturer should be used to test the product. MEC test strips are not interchangeable. The most frequent reasons for MEC test failure are dilution of the solution from water on instruments and high volume use

In addition to the MEC test, a quality control test should be performed upon activation of the solution. This test is done to determine that the solution is effective. The product instructions for use detail how the test must be conducted. In recent years the JCAHO has asked to see documentation of the quality control test to insure facility compliance with manufacturer requirements.

Results of MEC testing should be documented. The dates of testing and the name/signature of the person(s) performing the test should be included. Individual institutional policies may vary with regard to documentation requirements.

#### Minimum Effective Concentration (MEC)

The concentration below which a disinfectant is considered ineffective

MEC takes precedence over expiration date; when the MEC fails, the solution must be discarded regardless of expiration date.

MEC test strips are NOT interchangeable; only the test strip indicated by the manufacturer should be used to test a solution.

#### **SUMMARY**

Although sterilization and disinfection should be performed in the sterile processing department where personnel have been specifically trained, there are many instances in the operating room where OR personnel must assume responsibility for cleaning and disinfecting or sterilizing instrumentation and devices. It is essential that OR personnel are well educated in these processes.

The OR must have a comprehensive, competency-based program to prepare OR personnel for the responsibilities associated with sterilization and disinfection. OR personnel must be able to determine appropriate processing procedures required for critical, semi-critical, and non-critical instruments and devices. They must realize that cleaning is essential to effective disinfection or sterilization and know how to clean instruments and devices properly. Personnel must be able to demonstrate the ability to select the proper mode of sterilization, prepare instruments and devices properly, operate the sterilizer(s) correctly, and monitor sterilization and disinfection processes effectively.

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## Sterilization and Disinfection: Getting It Right Post Test

**A score of 80 is required to earn a Certificate for 2.5 Contact Hours**

1. According to the Spaulding classification, which of the following statements is TRUE?
  - a. Semi-critical devices penetrate mucous membranes, enter normally sterile body cavities, and require high level disinfection.
  - b. Critical devices penetrate mucous membranes, enter normally sterile body cavities, and require high level disinfection.
  - c. Non-critical devices penetrate mucous membranes , enter normally sterile body cavities, and require high level disinfection.
  - d. Critical devices penetrate mucous membranes, enter normally sterile body cavities, and require sterilization.
  
2. Medium level disinfection kills all forms of bacteria including high numbers of spores.

True                      False
  
3. The most important step in the processing of instruments is
  - a. Sterilization
  - b. Cleaning
  - c. Packaging
  - d. High level disinfection
  
4. Which of the following statements about the cleaning of instruments used in surgical procedures is FALSE?
  - a. Can reduce bioburden by 4 logs.
  - b. Should be accomplished under running water.
  - c. If inadequate can interfere with the sterilization process.
  - d. Should begin in the operating room.
  
5. Which of the following statements about biofilms is FALSE?
  - a. Biofilms are collections of microorganisms that are impossible to remove from the surfaces of dirty instruments.
  - b. Biofilms cause particularly difficult-to-treat infections.
  - c. Preventing the formation of biofilms is one goal of good pre-cleaning of contaminated surgical instruments.
  - d. Biofilms develop most frequently in lumened instruments.

6. Which of the following statements about instrument cleaning is TRUE?
- a. Instruments may be cleaned in the scrub sink with the proper detergent before flash sterilization.
  - b. All types of instruments can be disassembled and all parts can be immersed in detergent and cleaned beneath the surface.
  - c. A brush should be passed completely through a lumen and swished to remove debris.
  - d. Instruments should be rinsed thoroughly under running water.
7. Which of the following statements about cleaning is FALSE?
- a. Personnel cleaning instruments must wear appropriate PPE including face protection, apron or gown, and gloves that come to the mid forearm.
  - b. Ultrasonic cleaners can cause electroplating of devices with dissimilar metals that results in discoloration and weakening of instruments.
  - c. Ultrasonic machines clean by cavitation; microscopic bubbles implode creating a vacuum that draws debris from the instrument.
  - d. There are ultrasonic cleaners appropriate for all types of devices; each different type of machine requires a specific detergent.
8. Which of the following statements about drying instruments is FALSE?
- a. After cleaning and rinsing, instruments must be completely dry before disinfection, sterilization, or storage.
  - b. Water on instruments that have not been dried can dilute a disinfectant and reduce its effectiveness.
  - c. The lumens of instruments that will be steam sterilized must contain water that becomes steam during the process of sterilization.
  - d. Very small or very long lumens may require forced air for drying.
9. Which of the following statements about inspection is FALSE?
- a. The black dots in a fiberoptic cable that is held up to the light for inspection represent debris that has not been removed during cleaning.
  - b. Instruments should be checked for alignment, cracks, ease of movement, and integrity of insulation (when applicable).
  - c. Telescopes with a fuzzy or cloudy image may indicate that moisture has penetrated behind the lens.
  - d. A suture in the jaws of a needle holder should not be able to be rotated.
10. Which of the following statements about prions is FALSE?
- a. A prion is an infectious protein particle responsible for causing prion diseases such as CJD and every facility should have a protocol for managing prion-contaminated instruments and devices.
  - b. Good communication among surgeons, perioperative nurses, anesthesia, and SPD is essential to identify, isolate, and process CJD-contaminated instruments appropriately.
  - c. Standard precautions are sufficient to protect personnel from exposure to prions.
  - d. Instruments should be processed in the OR immediately following a procedure on a CJD patient.

11. Which of the following statements about managing prion-contaminated instruments is FALSE?
- Standard precautions will protect OR personnel from prion contamination
  - Debris should not be allowed to dry in or on instruments or devices
  - Flash instruments from prion or prion-suspected cases before transporting to SPD
  - Instruments should be processed immediately after surgery in SPD by personnel familiar with the protocols.
12. Sterility Assurance Level (SAL) for sterilization of medical devices and instrumentation in the United States is ...
- $10^{-6}$  (the probability of equal to or less than one chance in a million that any viable microorganism will remain on a device following sterilization)
  - Indication that 90% of microorganisms will be killed during the process.
  - The same for steam, EtO, peracetic acid, and hydrogen peroxide plasma technologies.
  - a and c
13. Which of the statements about flash sterilization is FALSE?
- Flash sterilization is point of use sterilization.
  - Flash sterilization can be accomplished with steam, EtO, peracetic acid, or hydrogen peroxide plasma.
  - Flash sterilization is discouraged by all standard-setting bodies.
  - Items that are flash sterilized cannot be stored in a sterile state.
14. Which of the following statements about steam sterilization is FALSE?
- Effective steam sterilization is based upon an appropriate relationship between time, temperature, and steam saturation.
  - The correct combination of time, temperature, and saturation is 10 minutes at 274° with 100% saturation.
  - Time and temperature for effective sterilization are determined by the autoclave manufacturer and the device manufacturer.
  - None of the above (all of the above are true statements)
15. Which of the following statements about steam sterilizers is FALSE?
- There are both gravity displacement and dynamic air displacement sterilizers in the U.S. today.
  - Steam penetrates items more efficiently in a gravity displacement sterilizer.
  - In pre-vac or high-vac sterilizers, air is removed dynamically with a vacuum pump.
  - Cycle times are shorter in dynamic displacement sterilizers than in gravity displacement sterilizers.
16. Which of the following statements about packaging and loading is FALSE?
- Packaging and loading impact the effectiveness of the sterilization process.
  - Packaging materials must permit penetration of the sterilant to all surfaces of the item/device.

- c. Reusable linen and Tyvek® are universal packaging materials, appropriate for all types of sterilization
- d. The appropriate maximum weight of a sterilized package is determined by each individual facility.

17. Which of the following statements about ethylene oxide (EtO) is FALSE?
- EtO is appropriate for items that cannot tolerate high heat or moisture.
  - Critical parameters for EtO sterilization are temperature, gas concentration humidity and exposure time
  - EtO is flammable, corrosive, toxic, and a carcinogen and therefore is closely regulated by OSHA. (Don't think manufacturer **regulates** guidelines for use
  - Aeration for a period of 24 hours is required to evacuate toxic residue from sterile items and packages.
18. Which of the following statements about hydrogen peroxide plasma sterilization is FALSE
- Hydrogen peroxide plasma sterilization is best suited to items that are intolerant of high heat and moisture, especially cameras, scopes, batteries, and devices with electronic components.
  - The best wrapping materials for hydrogen peroxide plasma sterilization are reusable linen wrappers and Tyvek®-mylar pouches.
  - Items that are wet cannot be processed with hydrogen peroxide plasma, nor can some very small diameter or very long lumened items.
  - Hydrogen peroxide plasma sterilization often replaces peracetic acid and EtO sterilization because it is fast, non-toxic, safe, and sterile items can be stored for later use.
19. Liquid peracetic acid sterilization is
- A terminal sterilization process.
  - A flash sterilization process.
  - A point-of-use sterilization process.
  - Appropriate for scopes that will be stored overnight.
20. Which of the following statements about disinfection is FALSE?
- Disinfection is the killing of microorganisms on both inanimate surfaces and skin.
  - Disinfectants are not interchangeable; the organisms they kill are dependent upon the type of disinfectant.
  - Heating increases the effectiveness of a disinfectant but also increases employee exposure to harmful chemicals.
  - Some disinfectants might be FDA approved as sterilants but the time required for sterilization is prohibitive.
21. Which of the following statements about disinfection is FALSE?
- The concentration of a disinfectant can be lowered by water from rinsed instruments and high volume of use.
  - Once disinfectants are activated they should be labeled with an expiration date.
  - If the MEC test strip fails before the expiration date, the disinfectant must be discarded.
  - The most commonly used disinfectants are glutaraldehyde 2% - 3.2% and 10% chlorine.

22. Which of the following statements about glutaraldehyde and ortho-phthaldehyde is FALSE?

- a. Glutaraldehyde should be mixed in a well-ventilated room with a minimum of 10 air exchanges.
- b. Ortho-phthalaldehyde is less irritating and less sensitizing than glutaraldehyde and therefore does not require the same PPE.
- c. Ortho-phthalaldehyde has a low vapor pressure and therefore has minimal odor associated with it. (Some folks claim they smell something – don't want to have to defend the statement).
- d. Ortho-phthalaldehyde stains protein.

23. Which of the following statements about chemical indicators is FALSE?

- a. Class I indicators only distinguish between processed and unprocessed instruments or packages.
- b. Class II (Bowie Dick) indicator assesses the autoclave's ability to evacuate the air from the chamber.
- c. Class III and IV indicators respond to specific parameters of the sterilization process and an indicator should be placed inside every package that is sterilized (The way I read it without change is that both a III and IV should be placed in every package).
- d. Class V (integrators) respond to all parameters of the sterilization process and therefore can guarantee sterility.

24. Which of the following statements about biological indicators is TRUE?

- a. Both standards and manufacturers recommend daily biological monitoring for each type of sterilizer.
- b. Biological indicators contains at least one million spores of a microorganism known to be highly resistant to a specific method of sterilization.
- c. *Geobacillus stearothermophilus* spores are used to monitor steam, peracetic acid, and ethylene oxide sterilization.
- d. Biological indicators are typically read after 36 hours of incubation and if negative (no spore growth), the sterilizer is assumed to be functioning effectively.

25. Enzyme-based indicators correlate well with biological indicators and have the advantage of a more rapid readout.

TRUE or FALSE

## Sterilization and Disinfection: Getting It Right

### Answer Sheet

[A score of 80 is required to earn 2.5 contact hours.]

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**STERILIZATION & DISINFECTION: GETTING IT RIGHT**

Name of evaluator: \_\_\_\_\_

E-mail address \_\_\_\_\_

Mailing address \_\_\_\_\_

Preferred phone (indicate day or evening) \_\_\_\_\_

**Purpose:**

This activity will address the information required for a perioperative nurse to attain competence in the processes of cleaning, disinfecting, and sterilizing instruments and devices.

**1 = Not At All            2 = Somewhat            3 = Almost Completely            4 = Completely**

- |   |  |
|---|--|
| <p><b>1. To What Extent were the following objectives achieved?</b></p> <p><b>A. Explain the importance of competence in sterilization and disinfection for perioperative nurses</b></p> <p><b>B. Describe the relationship of cleaning and inspection to effective sterilization or disinfection.</b></p> <p><b>C. Compare/contrast the various sterilization technologies in terms of items sterilized, packaging, and monitoring</b></p> <p><b>D. Compare the three levels of disinfectants, including application and monitoring techniques.</b></p> <p><b>E. Describe the characteristics and application for each of the various types of sterilization monitors.</b></p> <p><b>2. Rate the effectiveness of the teaching/learning resources.</b></p> <p><b>3. How well did the objectives relate to the overall purpose?</b></p> | <p>1   2   3   4</p> <p>1   2   3   4</p> <p>1   2   3   4</p> <p>1   2   3   4</p> <p>1   2   3   4</p> <p>1   2   3   4</p> <p>1   2   3   4</p> |
|---|--|

Document the total amount of time (hours and minutes) you spent completing this activity, including the test \_\_\_\_\_ hours \_\_\_\_\_ minutes

**Your comments/suggestions/recommendations are very important.**