

1947

Sterilization in the Perioperative Setting



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AORN INDEPENDENT STUDY ACTIVITY
VIDEO AND STUDY GUIDE



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TABLE OF CONTENTS

PURPOSE/GOAL.....	i
OBJECTIVES.....	i
INTRODUCTION.....	i
ASEPTIC TECHNIQUE.....	1
DECONTAMINATION.....	2
ENVIRONMENT.....	4
MECHANICAL CLEANING.....	4
ASSEMBLY.....	5
PACKAGING.....	6
STERILIZATION.....	7
• Thermal.....	7
• Flash Sterilization.....	10
• Chemical.....	13
• Radiation.....	18
• Process Controls.....	18
LOANERINSTRUMENTS.....	21
STORAGE AND SHELF LIFE.....	21
TRANSPORTATION.....	22
POLICIES AND PROCEDURES.....	23
SUMMARY.....	23
GLOSSARY.....	24
BIBLIOGRAPHY.....	25
POST TEST.....	28
ANSWER SHEET.....	30

PURPOSE/GOALS

This activity was designed to provide the novice nurse with basic knowledge of the complete sterilization process and the expert nurse with an in-depth review of the sterilization process.

OBJECTIVES

After viewing the videotape and completing this study guide, the participant will be able to

- describe the process of preparing surgical equipment for sterilization,
- identify different sterilization methods,
- discuss storage and transportation of sterilized items, and
- identify the aspects of quality control.

INTRODUCTION

Specific standardized procedures, based on accepted principles and practices of aseptic technique, are necessary for the sterilization of all supplies and equipment used in invasive procedures regardless of where they are used.

The goal of each aseptic technique is to optimize primary wound healing, prevent surgical infection, and minimize the length of recovery from surgery. Aseptic practices are implemented perioperatively (preoperatively, intraoperatively, and postoperatively) to minimize wound contamination. All members of the surgical team must be knowledgeable about aseptic technique and practice strict adherence to aseptic technique principles. However, it is the perioperative nurse who monitors the implementation of aseptic techniques by all surgical team members and ensures that breaks in technique are corrected. To prevent serious complication to the already compromised surgical patient, it is essential that aseptic technique and sterile technique be practiced with absolute accuracy.

ASEPTIC TECHNIQUE

Aseptic technique includes a group of procedures that prevent contamination of microorganisms through the knowledge and principles of containment and control. Sterile technique comprises methods by which contamination of an item is prevented by maintaining the sterility of the item/area involved with the procedure.

As a means of preventing infection during any invasive procedure, AORN established recommended practices for basic aseptic technique as a guide for anyone, either directly or indirectly involved with patient care, who is present during the procedure. These recommendations are based on the knowledge of epidemiology and microbiology and can be applied to any area in which invasive procedures are being performed. For our purposes we are concerned with the AORN recommended practice that states that “items used within a sterile field should be sterile.”

All basic procedures of cleaning, sterilizing, disinfecting, and maintaining the sterility of supplies are based on our knowledge of bacteria. Microorganisms are in the food we eat, the air we breathe, the water we drink, the ground we walk on, and all things around us, including our bodies. Not all microorganisms are normally pathogenic or capable of causing disease. In fact, humankind generally enjoys a state of peaceful coexistence with most microorganisms.

The patient is a source of endogenous infection because of the large number of microorganisms found in and on the body. Because skin is the first line of defense against the entry of microorganisms into the body, when the skin is incised, the patient is exposed immediately to the risk of infection, and measures must be taken to minimize that risk.

Attempts to control equipment sources of infection include decontamination, sterilization, and disinfection. All supplies and instruments that are intended for use during any invasive procedure must have been decontaminated and sterilized or disinfected prior to use. Although many tasks involved in instrument cleaning and sterilization are assigned to ancillary personnel, it is important that perioperative nurses have a complete understanding of the processes involved, because they share accountability for determining whether an item is safe for use. Instruments, supplies, and other equipment must be readied according to acceptable practices through a group of processes. It is important that all personnel know how to execute these tasks correctly and safely, and be able to distinguish the processes that achieve sterility from those that merely provide high-level disinfection.

DECONTAMINATION

Decontamination is the first step toward reducing the potential hazards associated with direct contact with blood, fluids, or tissues on contaminated instruments. Decontamination refers to a process by which the bioburden is reduced and contaminants are removed, either by hand cleaning or mechanical methods. Bioburden is defined as the degree of contamination with microorganisms and organic debris. In health care, bioburden generally refers to microorganisms that may be capable of producing disease or infection. The greater the complexity of a device, the more difficult it is to decontaminate and terminally sterilize. Specific solutions (such as water with detergents or enzymatic products) and equipment are used to remove the blood and debris from the surface of an object or instrument, thereby making them safe to handle.

Once rendered safe for handling through a decontamination process, patient care items undergo a process of either disinfection or sterilization. Proper care and cleaning help ensure an instruments' effectiveness, reduce the likelihood of delays, and reduce the risk of infection and injury. The care and handling of surgical instruments should follow the manufacturers' recommendations.

PROCESS OF DECONTAMINATION

Cleaning and decontamination begins on the sterile field the moment an instrument is used in the operating/procedure room. The scrub person should wipe the gross soil from the instrument with a sponge moistened with sterile water to keep them free of gross soil during the surgical procedure. All instruments opened in the operating or procedure room should be decontaminated whether or not they have been used. This is necessary because scrubbed persons may touch instruments without being aware of it and used instruments also may come in contact with unused instruments.

All instruments should be kept free of gross soil during the surgical procedure. Instruments with lumens should be kept patent by irrigation with sterile water. Devices made of stainless steel or other metal should not be soaked in saline or sodium hypochlorite solution (household bleach) because the chloride ions in both substances will cause rapid corrosion of the metal.

Initial decontamination of instruments should begin immediately after the completion of any invasive procedure to prevent the formation of biofilm. If items are soaked in water or an instrument cleaning solution at the point of use, the liquid should be contained or discarded before transport. A towel soaked with water, not saline, may be used to cover instruments to keep them moist. The Occupational

Safety and Health Administration (OSHA) requires that contaminated instruments be contained in a leak-proof container to minimize the risk of exposing personnel to contaminants during transport. Large quantities of items may be contained within a larger transport cart with doors or a plastic cover. Contaminated instruments should be transported to the decontamination area as soon as possible after completion of the surgical procedure. Cleaning is the single most important step in making a medical device ready for reuse. Debris on a device can interfere with its function or lead to a foreign body or pyrogen reaction in a patient if introduced into the body. There are five objectives in the cleaning process:

- Removal of visible soil, including blood, tissue, and bone
- Removal of invisible soil, such as microorganisms
- Removal of pyrogens
- Preparation of the surface of any item for sterilization or disinfection in order to allow direct contact with the agent
- Protection and safety of patients and personnel

Cleaning can be accomplished either by hand or mechanical methods. Regardless of the method chosen, some basic steps are required.

The first step should be a cool water rinse to get rid of gross debris. Cool water rinse will remove gross debris and help prevent coagulation of the blood present on instruments. If the device is heavily soiled with protein or fat, or if the soil has dried on, an enzymatic detergent might be helpful as the step after the cool water rinse.

Next, choose a detergent compatible with the materials in the device and suited for the type of soil. Consult the device manufacturer for recommendations of the type of detergent to be used. If cleaned by hand, the process must be done under the water level to prevent splash dissemination of harmful microorganisms.

When sorting instruments, consider the following:

- Type and amount of soil.
- What the instrument is made of.
- The decontamination process being used.

The detergent used during decontamination can influence the effectiveness of the cleansing process. Detergents, classified according to the amount of hydrogen ions (pH) they contain, help apply friction to the surface of the instrument, and the chemical interaction assists with the breakdown of debris.

ENVIRONMENT

Care must be taken to provide a suitable environment that is as free from contaminants as possible for the decontamination and sterilization process. Factors to be controlled in the environment include

- room temperature,
- humidity,
- ventilation, and
- physical separation of decontamination and sterilization processes.

It is important to keep the temperature within the recommended range of 65 to 70 degrees Fahrenheit. A relative humidity setting range between 30 and 60 percent helps control the bioburden in the area. The ventilation system for the instrument preparation areas should be set up so the air flows from clean areas into the decontamination area and then is exhausted outside. Bacteria and fungi thrive at warm temperatures; cooler temperatures may impede bacterial and fungal growth in the decontamination area. Regulated environmental controls in work areas are essential for the comfort of personnel wearing appropriate attire and Personal Protective Equipment (PPE). Organizations should monitor and record environmental controls in each area to ensure that, at minimum, recommended parameters are met and maintained.

All horizontal surfaces in the processing area should be cleaned daily and as needed with a hospital-grade germicidal solution. All other areas should be cleaned on a regular basis as dictated by the facility's policies and procedures.

STANDARD PRECAUTIONS

Each employee working with contaminated goods must adhere to standard precautions, required by the OSHA in accordance with the recommendations from the Centers for Disease Control and Prevention (CDC). Each facility must have the requirements and recommendations on PPE standard precautions, and hazardous materials available for personnel to review. OSHA requires that personnel wear skin and mucous membrane protection (ie, fluid-resistant or impervious gowns, gloves, and facial protection).

MECHANICAL CLEANING

Mechanical cleaning can be performed by using one of several types of machines.

Ultrasonic Washer

The ultrasonic unit (ie, a washer decontaminator sometimes referred to as a disinfectant) and the washer sterilizer are examples of machines that perform mechanical cleaning. All items must be cleaned first before being placed into the washer or the sound energy will be absorbed by the larger clumps of tissue or other debris, making the process ineffective.

Ultrasonic cleaners remove the fine debris from instruments using the energy from high-frequency sound waves created by transducers in the sides or bottom of a sink-like chamber filled with water.

A detergent can be added to the water to enhance the cleaning process. The water also can be heated. Upon completion of the cycle, the devices are rinsed under running water or placed in a second chamber for rinsing to prevent debris from re-adhering to the instruments.

Washer-Disinfectant

Washer decontaminators/disinfectors can be single- or multi-chamber tunnel units. The cycles in each type or model differ, but generally include a pre-rinse, followed by washing and a sustained rinse. The last portion of the sustained rinse uses very hot water—180 to 195 degrees Fahrenheit. Some units include a lubrication cycle. Upon completion of the programmed cycle, the instruments are rendered safe for handling. The chief advantage of this type of unit is that it allows totally hands-off processing.

Washer-Sterilizer

Washer sterilizers have been around for more than 30 years. They wash instruments or other devices, rinse them, and then go through a gravity steam sterilization process, usually at 270 degrees Fahrenheit. The instruments are **not** considered prepared for subsequent use. The washer sterilizer must have a cold cycle. If heat is

used during the process, gross bioburden must be removed or it will bake onto the item.

Regardless of the method chosen to clean the instruments, all items with detachable parts that can be separated need to be disassembled for cleaning, packaging, and sterilizing.

Decontamination is the critical step in breaking the chain of cross-infection between patient and patient and between patient and health care worker. Sterilization cannot be achieved if items are not thoroughly cleaned of the protein soil.

ASSEMBLY

Once decontamination has been completed, the instrument can be assembled in preparation for sterilization. During the assembly process, all items received for sterilization must be inspected. Check for surface integrity (eg, staining, chipping, pitting, flaking, rusting, cracks); proper functioning (eg, opens and closes with ease, parts move together smoothly); completeness (eg, all parts of disassembled instruments are together); and dryness. Replace or repair any instrument that is damaged or not functioning correctly.

Instruments should be arranged in sets and placed in a tray with a mesh or perforated bottom or specifically designed container that permits the penetration of the sterilizing agent and prevents the

trapping of air. For steam sterilization, a towel or other absorbent material may be placed in the bottom of the tray to help absorb condensation that is formed during sterilization and help speed the drying process.

All instrument joints and hinges must be opened to ensure contact with the sterilizing agent. All instruments with detachable parts must be disassembled.

An absorbent towel or other porous material must separate items (eg, basins and medicine cups) that are nested. This allows for contact with the sterilizing agent on all surfaces.

PACKAGING

The next step in preparing items for sterilization includes packaging. Packaging systems should

- permit sterilization to take place,
- maintain sterility until the package is opened or the integrity of the package is compromised,
- be structured to provide for aseptic delivery of the contents onto the sterile field,
- be compatible with the sterilization process,
- be used according to the manufacturers' written instructions, and

- be labeled according to the policies and procedures of the practice setting and according to manufacturers' instructions.

Packaging materials include woven fabrics, nonwoven materials, peel pouches of plastic and/or paper, and rigid container systems. If the sterility of an item is to be considered event related, the packaging material should be strong enough to maintain its integrity following the sterilization process and to protect the item from contamination.

Manufacturers of packaging systems should be consulted for package preparation, configuration, and sterilization recommendations. Preparation and assembly procedures should address the type of surgical instruments, total set weight, and density. All packaging must contain a monitoring device and must be labeled according to facility policy. Labeling should include

- package contents,
- assembler's identification,
- sterilization date,
- sterilizer identification, and
- cycle number.

STERILIZATION

Sterilization is defined as the process by which all forms of microbial life - including bacteria, viruses, spores, and fungi - are destroyed to an acceptable sterility assurance level. There are three basic sterilizing (sterilant) categories.

1. Thermal – this category includes
 - a. saturated steam
 - b. hot air/dry heat
2. Chemical – this category includes
 - a. ethylene oxide (EO) gas
 - b. low-temperature hydrogen peroxide gas plasma
 - c. peracetic acid
 - d. ozone
3. Radiation (physical) – this category includes
 - a. Microwave (nonionizing)
 - b. X-ray (ionizing)

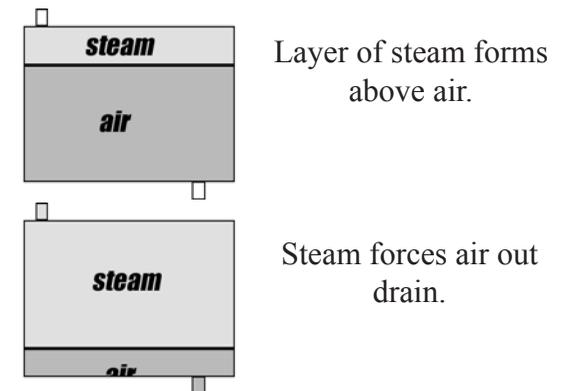
THERMAL STERILIZATION

Steam, at atmospheric pressure, is incapable of sterilizing an item. However, when steam is placed under pressure, the temperature rises, and the moist heat produced destroys the protein within the cell, rendering it harmless. Direct contact with the steam is required to ensure sterility. Steam under pressure is still the most commonly used and economical method for sterilization of heat-tolerant items. It is easily supplied and controlled. Steam does not leave any toxic residue. The basis of the steam sterilization process is direct saturated steam contact.

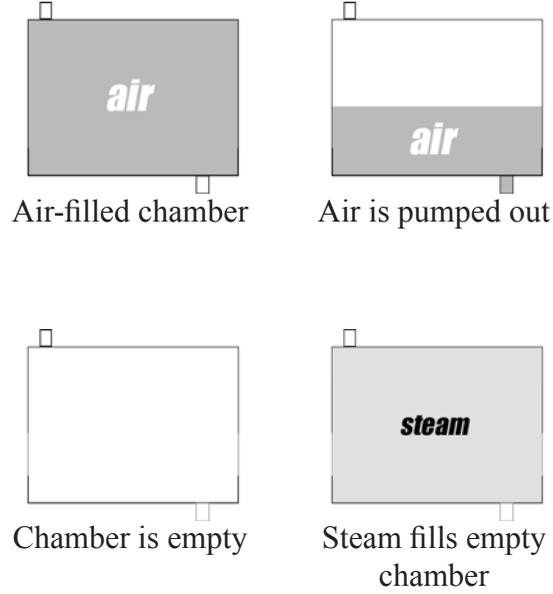
For steam to be effective, it has to penetrate every fiber and reach every surface of the items to be sterilized for a specified time at a required temperature. Exposure time depends on the size and contents of the load and the temperature within the sterilizer.

There are two types of steam sterilizers, gravity displacement and dynamic-air removal. The type of steam sterilizer is defined by the method of air removal it uses. Different sterilizing methods are often done through gravity displacement, dynamic-air removal, and flash or high-speed pressure. Each sterilizing unit must be monitored for correct loading, cycle parameters, cleaning, and mechanical upkeep.

Gravity displacement sterilizers rely on gravity to remove air, which is heavier than steam. Steam and air do not mix well; therefore, a layer of steam forms above the air. As more steam is introduced, the space in the chamber decreases and the air exits through the drain at the bottom of the sterilizer.



Dynamic-air removal (e.g. steam-flush pressure pulse and prevacuum) sterilizers are similar to gravity displacement sterilizers, except they are fitted with a vacuum pump to ensure that air is removed from the sterilizing chamber and from the load before the steam is injected. These sterilizers are considered more efficient in removing air than the gravity sterilizer.



There are four parameters that affect the steam sterilization process:

- steam saturation,
- pressure,
- temperature, and
- time.

In general, the exposure time required to sterilize wrapped items is 30 minutes at 250 degrees Fahrenheit (121 degrees Centigrade) in a gravity displacement sterilizer or 4 minutes at 270 degrees Fahrenheit (132 degrees Centigrade) in a prevacuum sterilizer.

Steam sterilized items must be allowed to cool thoroughly before handling or removing them from the sterilizer cart. Items might still contain steam vapor and condensation. If handled, there is a potential for compromising the barrier properties of the packaging materials.

TYPICAL MINIMUM CYCLE TIMES FOR GRAVITY-DISPLACEMENT STEAM STERILIZATION ¹					
Item	Exposure time at 250° F (121° C)	Minimum drying time	Exposure time at 270° F (132° C)	Minimum drying time	Exposure time at 275° F (135° C)
Wrapped instruments	30 min	15 to 30 min	15 min	15 to 30 min	10 min
Textile packs	30 min	15 min	25 min	15 min	10 min
Wrapped utensils	30 min	15 to 30 min	15 min	15 to 30 min	10 min

1. Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST79:2006 Comprehensive Guide to Steam Sterilization and Sterility Assuring in Health Care Facilities. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2006. Reprinted with permission.

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FLASH STERILIZATION

Flash sterilization is steam sterilization at 270 degrees Fahrenheit (132 degrees Centigrade) by the **unwrapped** method. Professional organizations recommend using flash sterilization only when there is insufficient time to sterilize an item by the preferred packaged method or when the surgical suite has been specifically designed to incorporate the flash sterilization of instrumentation.

An example of a suitable suite would be one in which the steam sterilizers open into each procedure room, and decontamination facilities are designed in accordance with local, state, and federal guidelines.

According to the Association for Advancement of Medical Instrumentation (AAMI), nonporous metal items without lumens can be flashed in a gravity displacement sterilizer for 3 minutes, whereas, porous items or items with lumens should be sterilized for 10 minutes in a gravity displacement sterilizer or in a prevacuum sterilizer for 4 minutes.

The exposure phase for flash sterilization has as much lethality as the regular steam sterilization cycle. Problems arise if items are not cleaned and decontaminated properly or when they are contaminated as they are being transported from the sterilizer to the sterile field.

Flash sterilization of implants is discouraged because the result of the biological monitoring may not be available before implantation. Implantable devices should be sterilized with a biological indicator and a chemical integrating indicator and documented according to the Federal Drug Administration (FDA) guidelines. The implantable device should be quarantined and not released until the rapid-action biological indicator provides a negative result.

EXAMPLES OF TYPICAL FLASH STEAM STERILIZATION PARAMETERS¹

Type of sterilizer	Load configuration	Time	Exposure Temperature	Drying Times
Gravity displacement	Metal or nonporous items only (ie, no lumens)	3 minutes	270° F - 275° F (132° C - 135° C)	0 to 1 minutes
	Metal items with lumens and porous items (eg, rubber, plastic) sterilized together. Complex devices (eg, powdered instruments requiring extended exposure times). Manufacturer instructions should be consulted.	10 minutes	270° F - 275° F (132° C - 135° C)	0 to 1 minute
Dynamic air-removal (prevacuum)	Metal or nonporous items only (ie, no lumens)	3 minutes	270° F - 275° F (132° C - 135° C)	N/A
	Metal items with lumens and porous items sterilized together	4 minutes 3 minutes	270° (132° C) 275° F (135° C)	N/A

- The Sterilizer manufacturer’s instructions for use of express cycles should be followed. One sterilizer manufacturer provides an express flash cycle that permits flash sterilization with a single-ply wrapper to help contain the device to the point of use. This cycle is not recommended for devices with lumens. Express cycles should only be used if the sterilizer is designed with this feature.
- Steam-flush pressure-pulse: See manufacturers’ written instructions for time and temperature.
- This table does not include specific instructions for rigid flash sterilization containers. The container manufacturer’s instructions should be followed.

REFERENCE

1. Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST79:2006 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2006:60-72. Adapted with permission.

Advantages of Steam Sterilization

- Steam sterilization is the easiest, safest, and surest method of on-site sterilization. Heat- and moisture-stable items that can be steam sterilized without damage should be processed with this method.
- Steam is the fastest method; it has the shortest cycle time.
- Steam is the least expensive and most easily supplied agent. It is piped in from the facility's boiler room. An automatic, electric-powered steam generator can be mounted beneath the sterilizer for emergency standby when steam pressure is low.
- Most steam sterilizers have automatic controls and recording devices to eliminate the human factor from the sterilization process as much as possible when operated and cared for according to the manufacturers' recommendations.
- Many items such as stainless steel instruments can withstand repeated processing without damage.
- Steam leaves no harmful residue.

Disadvantages of Steam Sterilization

- Precautions must be used in preparing and packaging items, loading and operating the sterilizers, and drying the load.
- Items must be clean, free of grease and oil, and heat tolerant.

- Steam must have direct contact with all areas of an item. It must be able to penetrate packaging material, but the material must be able to maintain sterility.
- Timing of the cycle must be adjusted for differences in materials and sizes of loads; these variables are subject to human error.
- Steam may not be pure. Steam purity refers to the amount of solid, liquid, or vapor contamination in steam. Impurities can cause wet or stained packs and stained instruments.

The sterilization cycle parameters recommended by device manufacturers should be reconciled with the sterilizer manufacturer's written instructions for the specific sterilization cycle and load configuration. Certain types of equipment and implants may require prolonged exposure times or drying times.

Dry Heat/Hot Air Sterilization

Dry heat sterilization is used primarily to sterilize anhydrous items that can withstand high temperatures (eg, anhydrous oils, petroleum products, and talcum powder) that steam and ethylene oxide gas cannot penetrate. In the absence of moisture, higher temperatures are required to destroy microorganisms through a very slow process of heat absorption by conduction.

Advantages of Dry Heat Sterilization

- Hot air penetrates certain substances that cannot be steam or gas sterilized.
- Dry heat is the only acceptable on-site method for sterilizing talcum powder.
- Dry heat can be used in laboratories to sterilize glassware.
- Dry heat is a protective method of sterilizing some delicate, sharp, or cutting-edge instruments.
- Instruments that cannot be disassembled may be sterilized in hot air.
- Carbon steel does not become corroded or discolored in dry heat as it may in steam.

Disadvantages of Dry Heat Sterilization

- A long exposure period is required because hot air penetrates slowly and possibly unevenly.
- Time and temperature vary with different substances.
- Overexposure may ruin some substances.
- It is destructive to fabrics and rubber goods.

CHEMICAL STERILIZATION

Peracetic Acid

Peracetic acid is a liquid chemical sterilization method that uses low temperatures of 122 to 131.9 degrees Fahrenheit (50 to 55.5 degrees Centigrade) and is as efficient as steam and EO sterilization. It requires the use of a special unit designed for this type of sterilization.

The process begins with the chemical sterilization unit that uses a buffered solution of peracetic acid. The unit automatically dilutes the peracetic acid to a concentration of approximately 2000 ppm. The items to be processed are exposed to the solution for 12 minutes at 122 to 131.9 degrees Fahrenheit (50 to 55.5 degrees Centigrade). Afterwards, the processed items are rinsed 4 times with sterile water provided by tap water that is passed through a membrane filter. This filter must meet the United States Pharmacopoeia criteria for sterilization of pharmaceuticals by membrane filtration.

An internal self-diagnostic and monitoring system produces a printed document confirming that all sterilization parameters have been met during each cycle. Peracetic acid is a very effective sterilant and may be the most universally potent antimicrobial agent.

Advantages of Peracetic Acid Sterilization

- The processor has a rapid cycle time.
- The products (e.g., peracetic acid, oxygen, water) are environmentally friendly.
- Peracetic acid is compatible with a wide variety of materials and instruments that are moisture tolerant and heat sensitive.

Disadvantages of Peracetic Acid Sterilization

- The potential exists for material incompatibility (eg, aluminum anodized coatings become dull).
- It is unsuited for moisture-sensitive instruments.
- Peracetic acid occasionally causes a noxious odor similar to vinegar.
- Items must fit within one of the processing trays and containers provided, which limits the number of items that can be processed at one time.
- Processed items must be used immediately.

Ethylene Oxide (EO)

Ethylene oxide is a colorless, flammable, explosive gas that commonly is used to sterilize heat and moisture-sensitive items. It is also a carcinogen and mutagen. It is extremely hazardous when inhaled or when it comes in contact with the eyes or skin.

Ethylene oxide has been proven to be more effective than other agents due to its ability to penetrate packaging materials, device lumens, and medical devices with complex geometry. It is effective against virtually all microorganisms including bacterial spores, molds, yeasts, and viruses.

Ethylene oxide reacts exoterically with compounds that possess a labile hydrogen atom (e.g., water). Alkylation reaction interferes with the nucleophilic cellular components leading to interruption and/or termination of the metabolic and reproduction capabilities, causing injury or death to the cells. In the past, EO was mixed with chlorofluorocarbons (CFCs) to reduce fire and explosion hazards. Because of concerns about the effect of CFCs on the ozone layer, they are no longer being produced for general use. New technologies using 100% EO, EO/carbon dioxide, or EO/hydrochlorofluorocarbon (HCFC) mixtures are becoming available.

Achieving complete sterilization using ethylene oxide is dependent upon four primary variables:

- proper time – 2 to 5 hours
- temperature – 98.6 to 145.4 degrees Fahrenheit (37 to 63 degrees Centigrade)
- chamber humidity of 45 to 75 percent
- use of the gas concentration required by the system being used

Failure of any one of these variables affects the probability of achieving sterilization.

Items sterilized using EO must be aerated for the prescribed amount of time in order to protect the health care workers and patients. EO residue cannot be removed by rinsing in water or other liquids. When EO mixes with water, ethylene glycol (ie, antifreeze) is formed.

If EO contacts the patient's blood anaphylaxis can occur. There has been at least one recorded cardiac arrest related to EO exposure. Reported injuries to health care workers include chemical burns, cataracts, neurologic damage, leukemia, chromosomal aberrations, and spontaneous abortions. Use of EO requires training, strict workplace guidelines, and periodic evaluation of exposures.

Advantages of EO Sterilization

- It is an effective substitute to use with most items that cannot be sterilized by heat.
- It provides an effective method of sterilization for items that steam and moisture may erode.
- It is noncorrosive and does not damage items.
- It completely permeates all porous materials.
- Automatic controls preclude human error by establishing proper levels of pressure, temperature, humidity, and gas concentration.

Disadvantages of EO Sterilization

- EO sterilization can be a complicated process that must be carefully monitored.
- EO sterilization is a long and slow process (longer than steam sterilization).
- EO requires special, expensive equipment.
- Items that absorb EO during sterilization, (eg, rubber, polyethylene, or silicone) require an aeration period.
- Toxic byproducts can be formed in the presence of droplets of moisture during EO exposure to some plastics, particularly polyvinyl chloride.
- Repeated sterilization can increase the concentration of the total EO residues in porous items, which can be hazardous unless gas can be dissipated.
- EO is a vesicant in contact with skin and mucous membranes.
- Inhaled EO gas can be irritating to mucous membranes. Overexposure causes nasal and throat irritation. Prolonged exposure may result in nausea, vomiting, dizziness, difficulty breathing, and peripheral paralysis.
- Long-term exposure to EO is known to be a potential occupational carcinogen, causing leukemia.

Low-Temperature Gas Plasma Sterilization

Plasma is a fourth state of matter that consists of a cloud of ion, electrons, and neutral particles. It can be produced through the action of either an electric or magnetic field. Neon lights are an example of common man-made plasma. Low temperature hydrogen peroxide gas plasma technologies have been developed that may be used to sterilize heat- and moisture-sensitive items. The process begins with injection of hydrogen peroxide and water into a vacuum chamber. An aqueous solution of hydrogen peroxide is vaporized in the chamber surrounding the items to be sterilized. Then a radio frequency-induced electrical field accelerates electrons and other particles that collide with each other, creating a plasma cloud. The plasma cloud interferes with the cell membranes, enzymes, and nucleic acids to disrupt the life functions of the microorganisms.

The efficacy of the cycle is monitored by several methods. The sterilizer runs on a fixed, automatic cycle controlled by a microprocessor. At the end of each cycle, a record of the process parameters is printed and if any process parameter does not meet its acceptable limit, the cycle is cancelled. Biological and chemical indicators also are used to monitor sterilization.

Advantages of the Plasma System of Sterilization

- Turnover time is reduced because the total processing time is approximately 74 minutes, and no lengthy aeration is required.
- The end products are oxygen and vaporized moisture, thus preserving the environment. Therefore, no exhaust monitoring is required.
- Gas plasma does not leave a toxic residue.
- Plasma is noncorrosive, allowing rigid endoscopes, fiberoptic cables, defibrillator paddles, metal, and hinged instruments to be processed.
- The plasma system uses low temperatures.
- Items are wrapped in specific materials and can be stored for future use.
- Because of its size, the gas plasma unit can be installed and relocated easily.

Disadvantages of the Plasma System of Sterilization

- The rapid cycle of low-temperature gas plasma sterilization system precludes the use of cellulose (paper), linens, and liquids.

- Lumen sizes and the material composition of the item will also dictate whether an item can be processed by this system. The manufacturers' recommendations should be consulted as the limits of sterilization depend on whether the item is stainless steel, Teflon, or polyethylene.

Ozone sterilization

For moisture- and heat- sensitive items, ozone sterilization can be used. This sterilization process is accomplished using only oxygen and water, which is generated within the sterilizer. No aeration of the sterilized items is necessary, as the by-products of oxygen and water are nontoxic.

All devices sterilized by this method should comply with the manufacturer's specifications for lumen length and diameter. Items processed by ozone should be packaged in nonwoven pouches or reusable rigid sterilization containers. Cellulose-based packaging materials and products are **not** suitable for ozone sterilization.

Glutaraldehyde

Another chemical disinfectant, 2% alkaline glutaraldehyde, is used for high-level disinfection. It is also capable of sterilizing an item when immersed for 10 hours. Because of the time required to sterilize an item, using a chemical disinfectant is not recommended.



RADIATION STERILIZATION

Microwave

The **nonionizing** radiation of microwaves produces hyperthermic conditions that disrupt life processes. The heating action interferes with the cell membranes and affects the water molecules. This process uses low-pressure steam with the radiation to produce localized heat. The temperature is lower and the cycle is shorter than conventional steam. Small tabletop units are available and can be used for rapid sterilization of single instruments.

Gamma Ray

Commercial products are sterilized by irradiation using beta particles and gamma rays. **Ionizing** radiation produces ions by knocking electrons out of atoms. The ionic energy that results is converted to thermal and chemical energy. This energy kills microorganisms by disrupting the DNA molecule that prevents cellular division and propagation of biologic life. The rays have a very low temperature, and the process is dry. Ionizing radiation is the most effective sterilization method and there is no residual radiation generated. The process is monitored by using *Bacillus pumilus*; however, the product is released for use on the basis of the measurement of the radiation dose without the required quarantine period for biologic testing.

PROCESS CONTROLS

Process controls are those that ensure the physical conditions intended are present everywhere within the sterilizer. Methods for measuring sterilization parameters include recording charts and graphs, chemical indicators, temperature specific indicators, integrators, and daily function tests.

Recording Charts and Graphs

Recording charts and graphs are permanent records of both the sterilizing time and the temperature attained in the exhaust line of the sterilizer. The charts and graphs must be dated, identified by sterilizer number, and carefully examined after each sterilizer run and again before refilling.

Chemical Indicators

Chemical indicators are physical or chemical devices employed to monitor one or more sterilization parameters for detecting failures in packaging, loading, sterilizer performance or steam characteristics. The indicator gives instant, visual assurance that proper conditions for sterilization were present and an item has been subjected to one or more parameters of the sterilization process. *They do not prove the sterility of an item.* The chemical indicator is placed in the center of packages, among instruments in a tray, or other locations where it is necessary to ensure steam penetration and correct temperature attainment.

Temperature Specific Indicators

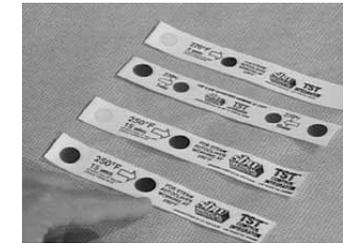
Temperature-specific indicators are designed to reveal the attainment of a specific minimum temperature at its location within the sterilizer chamber or load. These indicators do not require the presence of moisture. Temperature-specific indicators can consist of chemically treated paper indicators which change colors when exposed. Autoclave tape is one example, and is useful in identifying packages and articles that have been processed.



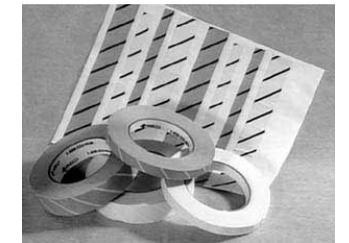
Chemical Indicators



Indicators placed in peel packs prior to sterilization cycle.



Temperature indicators



Autoclave tape changes color when exposed to sterilization process

Integrators

Integrators are multiparameter indicators that have been designed to provide an integrated response to defined combinations of temperature, time, and presence of steam. They are sterilant-specific. Integrators are based on a chemical and/or physical change that also results in a color change or migration of a chemical along a wick. This is a more sophisticated and accurate test of the sterilization process.

Daily Function Tests

A daily function test or a Bowie-Dick test must be performed daily on high-vacuum/pre-vacuum sterilizers. The purpose of this test is to determine the adequacy of the mechanical air removal during the pre-vacuum stage. The test pack should always be placed into an empty sterilizer over the drain (not in a pan). The test results must read in accordance with the manufacturer's recommendations. Failure of this test requires checking the sterilizer, identifying the cause of the malfunction, and correcting it before the sterilizer can be returned to service.

Recording Charts and Graphs

Biological monitoring is used to document the efficacy of specific sterilization cycles, not the sterility of the item. A biologic indicator is a preparation of living spores that are resistant to the sterilizing agent. If sterilization has occurred, the processed biologic unit will not grow any microorganisms. Biological indicators (BI)

are known populations of microorganisms in or on a carrier that has a specific resistance to the mode of sterilization being monitored.

The *Bacillus stearothermophilus* organism is used for steam, dry heat, and low-temperature gas plasma and peracetic acid sterilizers. *Bacillus subtilis* is used for ethylene oxide sterilization.

After exposure to the sterilization cycle and incubation, the absence of growth indicates that the appropriate parameters have been met. No growth, no color change, or no fluorescence demonstrates a negative response.

A positive response is demonstrated by the appearance of cloudy (turbid) growth, medium, colony-forming units, a color change, or fluorescence. A positive BI indicates a possible sterilization process failure. All products processed since the last negative BI should be recalled. An investigation must take place to determine which condition(s) caused the failure before the sterilizer can be used and the load either released for use or reprocessed. Retesting of the sterilizer is required if any sterilizer repairs occur.

Sterilization records for all sterilizers are maintained for each cycle for the time indicated by the state's statute of limitations. Recordkeeping includes results of daily function tests, results of biological monitoring, autoclave charts and graphs, and records indicating load contents and load control numbers.

LOANER INSTRUMENTS

Loaner instruments and implants should be managed by established processes and practices that include the following:

- Coordinating requests for loaner instrumentation in sufficient time for loaner items to be processed by conventional sterilization methods.
- Receiving inventory lists with each item.
- Obtaining manufacturer's written instructions for care, cleaning, and sterilization.
- Cleaning, decontaminating, and sterilizing borrowed instrumentation at the receiving facility (all loaner instruments should be considered contaminated upon arrival).
- Flash sterilization should not be used as a substitute for late delivery of loaner instrumentation.
- Implantable devices should be sterilized with a biological indicator and a chemical integrating indicator and documented according to the Federal Drug Administration (FDA) guidelines. The implantable device should be quarantined and not released until the rapid-action biological indicator provides a negative result.
- Cleaning and decontaminating loaner instrumentation prior to returning to the healthcare industry representative.
- Maintaining records of all transactions.

STORAGE AND SHELF LIFE

According to the AORN recommended practices, "the shelf life of a packaged sterile item is event related." Shelf life is defined as the period of time that sterility is generally maintained and is related to the capability of the packaging material and the storage conditions to protect the sterility of the packaged item after sterilization. Shelf life should be considered event related, not time related. Handling and storage are no less important than any other part of the sterilization process. Correct quantity and quality of supplies should be readily available to meet demands. Stock rotation should follow the principles of FIFO (first in/first out). Airborne bacteria and dust can be forced into a package by incorrect or excessive handling, poor storage facilities, or improper techniques. An aerosol or bellows effect occurs by the squeezing action of the hands each time the package is handled or by dropping a package onto the floor or hard surface. Bacteria can enter packages through ruptured seals, small breaks, and tears not easily detected. Moisture can be absorbed into pervious packages if a package is placed on a wet or damp surface, by carrying a package tightly under the arm where it can contact a warm, wet armpit, and by handling the package with wet or sweaty hands.

To help avoid an event that may compromise package content sterility, the following recommendations should be followed:

- Storage areas must be kept clean and free of dust, lint, dirt, and vermin. Routine cleaning procedures must be followed for all areas.
- All sterile items should be stored under conditions that protect them from extremes of temperature and humidity. Prolonged storage in a warm environment at high humidity can cause moisture to condense inside packages and thus destroy the microbial barrier of some packaging materials.
- Packages should be allowed to cool to room temperature before being put into storage to avoid condensation inside the package.
- Woven fabric and paper-wrapped items may be stored in closed cabinets and in enclosed or covered carts for up to 30 days, or on open shelving for up to 21 days.
- For open shelving, the highest shelf should be at least 18 inches below the ceiling and the lowest shelf should be 8 to 10 inches above the floor.
- Sterile storage areas should have controlled traffic patterns.

The length of time an item is considered sterile depends on factors that include the following:

- type and configuration of packaging materials used,
- number of times a package is handled before use,
- number of personnel who may have handled the package,
- storage on open or closed shelves,
- condition of the storage area (eg, cleanliness, temperature, humidity), and
- use of dust covers and method of sealing.

TRANSPORTATION

Transportation of sterile items should also be controlled. Transportation procedures of sterile items can help prevent damage and preserve the quality and integrity of the processed items until the time of use. Sterile items should be transported to a storage area in covered or enclosed carts that can protect the items from environmental contaminants along the transportation route. An evaluation should be conducted to determine the conditions of the transportation route.

POLICIES AND PROCEDURES

Policies and procedures establish authority, responsibility, and accountability, and serve as operational guidelines. Personnel must follow manufacturers' written instructions for the operation and maintenance of sterilization equipment, as well as for creating an awareness of the hazards that different sterilants may pose to patients, coworkers, and the environment. These policies and procedures should pertain to the following:

- decontamination, terminal sterilization, and cleaning of all reusable items and the disposal of disposable items;
- packaging and labeling of items;
- loading and unloading all sterilizers;
- operation of the sterilizers;
- monitoring and maintenance of sterilization cycle records;
- preventive maintenance of equipment;
- transportation and storage of sterile items;
- handling of sterile items; and
- tracking and recall of items deemed unsafe for use.

SUMMARY

Creating and maintaining a sterile environment before and during the surgical procedure reduces the patient's risk of acquiring a postoperative infection. The most important measure in preventing postoperative infection is the flawless application of aseptic technique principles. It is important that everyone understands his or her role in reducing the risk of infection to the patient.

Prevention of infection begins in the central supply department with the decontamination, assembly, preparation, and sterilization of surgical items and continues with the surgical team as they monitor the implementation of aseptic practices in the operating suite.

GLOSSARY

Anhydrous: Items that are free of water.

Bioburden: The degree of microbial load; the number of viable organisms contaminating an object.

Biofilm: A thin coating containing biologically active organisms that have the ability to grow in water, solutions or in vivo and that coat the surface of structures (e.g. teeth, inner surfaces of catheters, tubes, implanted or indwelling devices, instruments, other medical devices).

Decontamination: Any physical or chemical process that removes or reduces the number of microorganisms or infectious agents and renders reusable medical products safe for handling or disposal;

Disinfector: An agent, mechanical, chemical, or physical, which destroys all microorganisms with the exception of some bacterial spores.

Dynamic air removal: Mechanically assisted air removal from the sterilization chamber of prevacuum and steam-flush pressure-pulse steam sterilizers.

Event related sterility: Loss of sterility of a packaged sterile item. An event that occurs in which the sterile packaged contents become compromised while being stored and/or handled.

Endogenous: A source from the patient (e.g., skin).

Exoterically: Capable of being understood by, or suited for, many.

Gravity displacement: A cycle during sterilization in which the incoming air displaces the residual air through a port or drain near the bottom of the sterilizer chamber.

Pyrogens: Substances capable of increasing body temperature; they may be of microbial origin, often polysaccharides, and may contaminate distilled water.

Rigid container systems: Specifically designed heat-resistant, metal, plastic, or anodized aluminum receptacles used to package items, usually surgical instruments, for sterilization. The lids and/or bottom surfaces contain steam or gas-permeable, high-efficiency microbial filters.

Sterilization: The destroying of all forms of life, especially microorganisms, by heat, chemical, or other means.

Terminal sterilization: The packaging and sterilization of an item(s) intended for later use, and, therefore, stored.

Vesicant: A highly reactive chemical that causes tissue blistering.

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Washer decontaminator: A processing unit that cleans by a spray-force known as, impingement. This machine combines a vigorous agitation bath with jet-stream air to create underwater turbulence. These cycles are intended to render the items safe to handle by persons who will inspect and prepare the instruments for terminal sterilization.

Washer sterilizer: A processing unit that mechanically cleans surgical instruments through a series of cycles similar to the washer decontaminator. The cycles end in sterilization.

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POST TEST

1. The first step toward reducing the potential hazards associated with contaminated instruments is:
 - a. sterilization
 - b. assembly
 - c. aeration
 - d. decontamination
2. Cleaning and decontamination of instruments should begin when:
 - a. the instruments are taken to the sterile processing department
 - b. the instruments are selected for the procedure
 - c. the instrument is first used
 - d. the instrument falls off the sterile field
3. Each employee working with contaminated goods must adhere to standard precautions as required by:
 - a. FDA
 - b. The Joint Commission
 - c. OSHA
 - d. EPA
4. Which of the following are approved methods for mechanically cleaning contaminated instruments?
 - a. ultrasonic washer
 - b. washer-disinfector
 - c. washer sterilizer
 - d. all of the above
5. Sterilization can be accomplished by several methods. Which of the following are acceptable sterilization methods?
 - a. Thermal
 - b. Chemical
 - c. Radiation
 - d. all of the above
6. Which is the most economical and commonly used sterilization method for heat-tolerant items?
 - a. steam
 - b. ozone
 - c. low temperature gas plasma
 - d. none of the above
7. Flash sterilization of implants is discouraged because the result of the biological monitoring is not available before implantation.
 - a. True
 - b. False
8. All loaner instruments should be considered _____ and should be _____ before use.
 - a. sterile; examined
 - b. contaminated; sterilized
 - c. sterile; re-sterilized
 - d. contaminated; flashed
9. Implants are foreign bodies and they increase the risk of surgical site infection. Therefore, implants should be _____ and not released until the rapid-action biological indicator provides a _____ result.
 - a. quarantined; status quo
 - b. sterilized; dynamic
 - c. quarantined; negative
 - d. sterilized; positive
10. The shelf life of a packaged sterile item is considered:
 - a. event related
 - b. sterile forever
 - c. sterile for 30 days
 - d. none of the above

Sterilization in the Perioperative Setting

POST TEST ANSWER KEY

1. D
2. C
3. C
4. D
5. D
6. A
7. A
8. B
9. C
10. A

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