

3

Instrument Processing

LEARNER OBJECTIVES

1. Discuss the responsibilities of the perioperative nurse in processing instruments to prevent patient injury and surgical site infection.
2. Explain the partnership between perioperative personnel and the sterile processing department in instrument processing.
3. Describe responsibilities for cleaning surgical instruments at the point of use and transport to the sterile processing department.
4. Explain the relationship among cleaning, sterilization, and disinfection.
5. Identify the steps associated with inspecting, assembling, and packaging items for sterilization or disinfection.
6. Describe high- and low-temperature sterilization technologies.
7. Discuss responsibilities associated with sterilization monitoring.
8. Explain requirements for storage of sterile items.

LESSON OUTLINE

- I. Introduction
- II. Managing Instruments at the Point of Use
 - A. Instruments Exposed to Prions
 - B. Transporting Items from Point of Use to Sterile Processing Department
- III. Decontamination: Sterile Processing Department
 - A. Manual Cleaning
 - B. Mechanical Cleaning
 - C. Special Needs Instruments
 - i. Eye Instruments
 - ii. Flexible Endoscopes
 - iii. Robotic Instruments
 - D. Ultrasonic Cleaning
 - E. Lubrication
- IV. Preparation and Packaging
 - A. Inspection
 - B. Assembly and Packaging
 - i. Selection Criteria for Barrier Protection
 1. Woven Fabric
 2. Nonwoven Materials
 3. Pouches: Plastic/Paper, Plastic/Tyvek
 4. Rigid Container Systems
 - ii. Packaging Items for Steam Sterilization
 - iii. Packaging Items for Low-Temperature Sterilization
 - C. Monitoring: Chemical Indicators and Integrators
 - D. Labeling

- V. Sterilization and Disinfection
 - A. Sterility Assurance Level
 - B. Methods of Sterilization
 - i. High-Temperature Sterilization Technologies
 - 1. Steam Sterilization
 - 2. Gravity Displacement
 - 3. Dynamic Air Removal (Prevacuum Sterilizer)
 - 4. Extended Cycles
 - 5. Steam–Flush–Pressure–Pulse Sterilizer
 - ii. Immediate-Use Steam Sterilization (IUSS)
 - iii. Low-Temperature Sterilization Technologies
 - 1. Hydrogen Peroxide Plasma
 - 2. Vapor-Phase Hydrogen Peroxide
 - 3. Ethylene Oxide Gas (EtO)
 - 4. Liquid Chemical Sterilant Processing System
 - 5. Vaporized Hydrogen Peroxide and Ozone
- VI. Sterilization Monitoring: Quality Control
 - A. Physical Monitors
 - B. Chemical Indicators
 - C. Biological Monitors
- VII. Sterilization: Documentation
- VIII. Disinfection
 - A. Glutaraldehyde
 - B. *Ortho*-phthalaldehyde
 - C. Disinfection: Quality Control
 - D. Disinfection: Documentation
- IX. Reuse of Single-Use Devices
- X. Storage of Sterile Items
 - A. Shelf Life

Introduction

1. Postoperative wound infection/surgical site infection (SSI) is a complication of surgery with potentially dire consequences for the patient, including delayed recovery, increased length of stay, increased cost of care, increased pain and suffering, and even death.
2. According to the Centers for Disease Control and Prevention (CDC, 2015c), SSIs are a leading cause of hospital-associated infections (HAIs), accounting for 31% of all HAIs in hospitalized patients in a recent study. SSIs are associated with a 3% mortality rate and 75% of SSI-associated deaths are directly attributable to the SSI.
3. SSI reduction has been identified as a Phase One priority in the U.S. Department of Health and Human Services (HHS, 2013) Action Plan to Prevent Health Care-Associated Infections.
4. Intact skin is the body’s first line of defense against infection. Pathogenic microorganisms are capable of causing disease when they invade human tissue.
5. Surgical incisions interrupt skin integrity, providing a portal of entry for pathogenic microorganisms, which increases a patient’s risk of getting an infection by giving microorganisms a route into normally sterile areas of the body. Invasive drains, catheters, and monitors also alter skin integrity and contribute to the risk for infection.
6. Contaminated instruments are a known source of infection (Dancer, Stewart, Coulombe, Gregori, & Verdi, 2012; Saito et al., 2014). Every effort must be made to remove microorganisms from any items that contact human tissue during surgical interventions.
7. The nursing diagnoses of “increased risk for infection” and the outcome statement “free from injury” are pertinent when caring for patients undergoing invasive procedures.
8. Most instrument processing is performed in a separate sterile processing department (SPD). The perioperative nurse, however, is a partner in the process of preparing instruments and assumes varying levels of responsibility for cleaning, inspection, packaging, sterilization, and storage of sterile supplies.
9. As the patient’s advocate, the perioperative nurse strives to ensure that all instruments delivered to the sterile field have been appropriately prepared and processed and are in good working order. Instruments or supplies improperly prepared or processed can harbor microorganisms that can result in infection. Items that fail to function as intended can cause patient injury.
10. When disinfection and sterilization are accomplished within the operating room department, it is often the perioperative nurse who is responsible for the process.
11. No single method of instrument processing is appropriate for all instruments. Composition and configuration of an instrument determine its compatibility with the sterilization and disinfection processes available within the healthcare facility. Device and equipment manufacturers’ instructions for use (IFU) must be considered when purchasing and processing decisions are made.

Definitions

Antiseptics: Chemicals used to destroy microorganisms on body surfaces. The number and type of organisms killed are determined by the composition and concentration of the antiseptic and the amount of time the agent remains active.

Autoclave: A steam sterilizer.

Bioburden: A population of viable microorganisms on an item.

Biofilm: A collection of microscopic organisms that exist in a polysaccharide matrix that adheres to a surface and prevents antimicrobial agents such as sterilants, disinfectants, and antibiotics from reaching the cells.

Biological indicator: A sterilization monitor consisting of a known population of resistant spores that is used to test a sterilizer's ability to kill microorganisms.

Bowie-Dick test: An air-removal test designed to assure that the autoclave can remove air and noncondensable gases from the chamber of a dynamic air-removal autoclave and that steam can penetrate a specified pack.

Cavitation: In an ultrasonic washer, the process by which high-intensity sound waves generate tiny bubbles that expand until they collapse or implode, causing a negative pressure on the surfaces of the instruments that dislodges soil.

Chemical indicator: A device used to monitor one or more process parameters in the sterilization cycle. The device responds with a visible chemical or physical change (usually a color change) to conditions within the sterilizer chamber. Chemical indicators are usually supplied as a paper strip, tape, or label that changes color when the parameter or parameters have been met. Chemical indicators go on the outside and inside of each package to be sterilized.

Contaminated: (1) In the operating room environment, a term referring to items that are not sterile. Items soiled or potentially soiled with microorganisms are considered to be contaminated. Items that were opened for surgery, whether or not they were actually used during surgery and whether or not they are known to contain microorganisms, are also considered to be contaminated. (2) In the regulatory arena, a term referring to an item that has been in contact with an infectious agent.

Decontamination: The process that renders a previously contaminated item safe for handling. Decontamination may be accomplished manually or with an automated system. Decontamination is usually accomplished by cleaning followed with a thermal or chemical disinfection process.

Disinfectant: An antimicrobial agent used to destroy microorganisms on inanimate surfaces. The composition and concentration of the disinfectant and the amount of time an item is exposed to it determine the number and types of organisms that will be killed.

Disinfection: A process that kills all living microorganisms, with the exception of high numbers of spores.

- Low-level disinfection kills vegetative forms of bacteria, lipid viruses, and some fungi.
- Intermediate-level disinfection kills vegetative bacteria, mycobacteria, viruses, and fungi, but not spores.
- High-level disinfection kills vegetative bacteria, mycobacteria, viruses, fungi, and some spores.

Event-related sterility: A sterile item remains sterile until an event happens to render it unsterile.

IFU: Manufacturer's instructions for use; the U.S. Food and Drug Administration (FDA) requires that the manufacturer of every item validated for use in the operating room or sterile processing department must supply written instructions on how to use the item properly.

Immediate-use steam sterilization (IUSS): A steam sterilization process for sterilizing heat- and moisture-stable items that are needed immediately; previously known as "flash sterilization."

Manufacturer's IFU: Written instructions provided by the manufacturer of every validated medical device that details appropriate use and processing of the device.

Prion: An infectious protein particle responsible for rare and fatal diseases of the nervous system.

Spaulding's Classification: A system of categorization that determines the level of processing of an item based on its intended use.

Spore: An inactive or dormant, but viable, state of a microorganism, which is notably resistant to heat, drying, and chemicals and is difficult to kill. Sterilization methods are monitored by assessing their ability to kill a known population of highly resistant spores.

Sterile: Free of all viable microorganisms, including spores.

Sterility assurance level (SAL): The probability of a viable microorganism being present on an item after sterilization.

Sterilization: A process that kills all living microorganisms, including spores. Fiberoptic and robotic instruments costing many thousands of dollars are standard components of many procedures.

Strike-through: Passage of a liquid through a barrier product.

Treated water: Water from which additives such as chlorine, dissolved salts, naturally occurring minerals, organic contaminants, bacteria, and endotoxins have been removed.

Washer-disinfector, washer-decontaminator: Automated processing units used to decontaminate instruments. Cycles within these machines vary but always include washing and rinsing.

12. Selecting the appropriate method of processing instruments requires an understanding of the scientific principles involved in cleaning, inspection, packaging, sterilization, and storage of sterile instruments and supplies.
13. When immediate-use steam sterilization (IUSS) or high-level disinfection is required, the perioperative nurse may assume total responsibility for cleaning, inspection, and packaging, as well as for the sterilization or disinfection process. For instance, the perioperative nurse must understand why no instruments—not even a single instrument intended for IUSS—should ever be cleaned in a scrub sink.

Managing Instruments at the Point of Use

14. All instruments opened for a surgical procedure in the operating room or in an invasive procedure room are considered contaminated whether or not they are used.
15. During a surgical procedure, instruments should be kept as clean as possible; they should be wiped clean with a laparotomy sponge moistened with sterile water or immersed in sterile water to prevent debris from drying in serrations and crevices.
16. Instrument lumens should be flushed free of debris using a syringe filled with sterile water. Irrigation should take place below the surface of the water to prevent aerosolization of particles.
17. Sterile water, not saline, should be used for cleaning items during surgery. Blood and body fluids as well as saline are highly corrosive and can cause rusting and pitting (AORN, 2015, p. 615).
18. Instruments should be cleaned as soon as possible after use to prevent blood and other debris from drying in crevices or the surfaces of an instrument.
19. Bioburden that has been allowed to dry on instruments is difficult to remove and can interfere with the sterilization or disinfection processes by preventing the sterilizing or disinfecting agent from contacting every surface of the item.
20. Once an instrument is opened, it is considered contaminated whether or not it is actually used.
21. Instruments should be returned to their original containers so that sets are complete when they arrive in the SPD for processing.
22. Before instruments leave the operating room:
 - Remove blades and other sharps and discard them in a sharps container.
 - Remove drill bits and saw blades; if disposable, discard in a sharps container; if reusable, wipe clean and segregate them to prevent injury to SPD personnel.
 - Segregate sharp instruments, such as scissors and osteotomes, from other instruments.
 - Open instruments with box locks and joints.
 - Unless contraindicated by the manufacturer's IFU, disassemble devices with multiple components; keep the parts together.
 - Place heavy instruments in the bottom of the tray with lighter ones on top.
23. Preventing bioburden from drying on instruments facilitates effective cleaning in the SPD and helps to prevent corrosion, rusting, and pitting.
24. Instruments should be returned to the SPD as soon after surgery as possible.
25. To prevent the formation of biofilms, particularly within lumens, instruments should not remain in water for lengthy periods of time. Once formed, biofilm cannot be rinsed away and must be removed by mechanical means. If not completely removed, biofilm will prevent the sterilant from contacting all surfaces of the instrument (**Figure 3-1**).

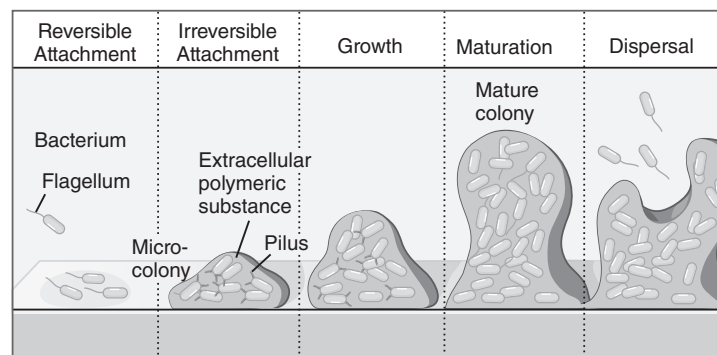


Figure 3-1 Biofilm.

26. Biofilms can pose a serious threat to health. In addition to compromising the disinfection and sterilization processes, biofilm can break free from the surface of a device inside the patient's body, resulting in a massive infusion of bacteria that can cause an infection that is difficult to treat. Because the biofilm lives within a self-made protective glycocalyx, it may be 500 times (or more) resistant to antibiotics (Center for Biofilm Engineering, 2011). Sterilant will not be able to reach the microorganisms protected within the glycocalyx.
27. To prevent the formation of biofilms and to prevent debris from drying on instruments, contaminated instruments should be kept moist until they are cleaned. Coat instruments with an enzymatic spray or gel intended for pretreatment. In some facilities, instruments may be covered with a moist towel or placed inside a package designed to maintain humid conditions.
32. Unlike bacteria, viruses, and fungi, prions are resistant to routine sterilization and disinfection procedures. Ideally, instruments used on tissue known or suspected to be contaminated with prions should be discarded. When it is not known whether the patient on whom the instruments were used has a prion disease, the instruments should be quarantined until the diagnosis is determined, and, if positive for prion disease, discarded.
33. When a patient has or is suspected of having a prion disease, instruments that are not discarded should be cleaned and sterilized according to special protocols:
- At the point of use, avoid mixing instruments exposed to high-risk tissue with instruments used on other tissue.
 - Keep instruments moist until cleaned or decontaminated.
 - Clean the instruments as soon as possible to minimize drying of tissue, blood, and body fluids on the instruments.

Instruments Exposed to Prions (American National Standards Institute & AAMI, 2001, Annex C; AORN, 2015, pp. 635–340; Rutala & Weber, 2010)

28. A prion is an infectious protein particle responsible for transmissible spongiform encephalopathies such as Creutzfeldt-Jakob disease (CJD), a rare and always fatal disease of the central nervous system.
29. The brain, spinal cord, dura mater, and eye are considered high-risk tissue for transmission of prion disease.
30. The perioperative nurse should follow institutional policies and procedures, and conduct a patient assessment to identify those patients who are at high risk for prion disease and to identify those procedures with the potential to expose instruments to tissue contaminated with prions.
31. Information and protocols regarding prions are evolving. In addition to the Society for Hospital Epidemiology of America (SHEA) "Guideline for Disinfection and Sterilization of Prion-Contaminated Medical Devices" (Rutala & Weber, 2010), the CDC and the AORN should be consulted when developing protocols for instruments exposed to prions.
34. Use the following protocols for decontaminating the instruments:
- For instruments that are easily cleaned, steam autoclave them after thorough cleaning at 272°F (134°C) for 18 minutes in a prevacuum sterilizer or at 270°F (132°C) for 60 minutes in a gravity-displacement autoclave/cycle.
 - For instruments that are difficult to clean or have small lumens:
 - Discard the instruments
 - or
 - Immerse the instruments in 1NaOH for 60 minutes, then remove, rinse with water, and sterilize using one of the cycles already described
 - Once the instruments have been processed, proceed with conventional cleaning, packaging, and sterilizing.

Section Questions

1. What are some of the adverse implications of surgical site infections? [Refs 1–2]
2. How does a surgical procedure place a patient at risk for infection? [Refs 4–6]

(continues)

Section Questions (continued)

3. Describe the perioperative nurse's role in instrument processing. [Refs 8–13]
4. What instrument features influence compatibility with processing technologies? [Ref 11]
5. How does the scrub person reduce bioburden on instruments during a procedure? [Refs 15–16]
6. What is the rationale for choosing sterile water rather than saline to clean instruments on the sterile field? [Ref 17]
7. What is the rationale for keeping instruments clean during a procedure? [Refs 18–19]
8. How should instruments be managed following the procedure in preparation for their return to the sterile processing department? [Refs 21–22, 27]
9. What is a biofilm? [Ref *Definitions*]
10. When should instruments be returned to the sterile processing department? [Ref 24]
11. Why do biofilms present a greater challenge to cleaning than other bioburden? [Refs 25–26]
12. What implication do biofilms have for patient care? [Ref 26]
13. What is a prion? [Ref *Definitions*, 28]
14. What are the high-risk tissues for transmission of prion disease? [Ref 29]
15. What options are available for decontaminating hard-to-clean instruments that have been exposed to prions? [Refs 31–34]

Transporting Items from Point of Use to the Sterile Processing Department

35. Transport items from the point of use to the SPD as soon as possible.
36. Remove all trash and linen from sets. Any items returned to SPD that cannot be processed will be discarded when they arrive in the decontamination area.
37. Contain all instruments in a durable, leak-proof, labeled, or color-coded container that is closed before being removed from the work area to prevent personnel from contacting contaminated items during transfer (AAMI, 2013; Occupational Safety and Health Administration [OSHA], 2012a, 29CFR 1910.1030 (e) (2) (ii) (B)).
38. A biohazard label should be affixed to the cart before it is removed from the work area (OSHA, 2012a, 29CFR 1910.1030(g)(1)(i)(H)).

Decontamination: Sterile Processing Department**Manual Cleaning**

39. Instruments are received in the sterile processing department in an area specially designed

to contain contamination, often shortened to “decontam” for “decontamination.”

40. The “decontam” area is a negative air pressure environment. Negative pressure prevents microorganisms in the air from escaping into surrounding areas. AAMI recommends a minimum of 10 air exchanges per hour (AAMI, 2013, §3.3.6.4); the Facility Guidelines Institute (FGI, 2014) recommends a minimum of 6 air exchanges per hour.
41. In addition, personnel working in the decontamination area should wear the following personal protective equipment (PPE) for protection from exposure to contamination (AAMI, 2013, §4.5.1–4.5.2):
 - A liquid-resistant gown or apron with sleeves
 - Long-cuffed utility gloves
 - A mask
 - Eye protection (goggles or full-face shield)
42. All instruments returned to the SPD are cleaned whether they were used or not. Cleaning is the first and most important step in preparing items for sterilization. If an item is not thoroughly clean, it cannot be sterilized. Any debris remaining on an instrument will prevent sterilant from contacting the surface.

- Remember, an item can be clean but not sterile; but no item can be sterile if it is not clean.
43. For instruments and devices that are not sensitive to heat or moisture, mechanical cleaning in an automated system is preferable because the process is consistent. Manual cleaning can be equally effective if performed correctly.
 44. Some powered surgical instruments and heat-sensitive, delicate, or specialty items cannot tolerate mechanical washing. These items should be cleaned separately according to the device manufacturer's IFU.
 45. When instruments are manually cleaned, regardless of whether they are cleaned in the decontamination section of the SPD or in a decontamination area within the operating room, it is important for the process to be standardized. The following supplies and equipment should be readily available wherever items are processed:
 - Enzymatic detergent
 - Soft-bristle brushes of various sizes
 - Syringes for irrigation of lumens
 - Adaptors and accessories for specific devices as required by the manufacturer's IFU
 - Eyewash station
 - Medical grade compressed air
 - PPE
 46. Before washing with a detergent, instruments should be rinsed in cold water to remove gross debris. Hot water coagulates protein and makes the cleaning process more difficult.
 47. The detergent, usually containing one or more enzymes, should be specific for instrument cleaning. Detergent should be used strictly according to the manufacturer's IFU. For example, mixing detergents to a higher concentration because of heavy debris is not appropriate and may, in fact, impede rinsing that will subsequently interfere with sterilization or disinfection.
 48. Immersible items should be cleaned below the surface of the water to prevent aerosolization of debris. Lumens and cannulas should be flushed while submerged.
 49. Items that cannot be immersed should be cleaned in a manner that prevents aerosolization of debris. Soft-bristle brushes or pipe cleaners can remove soil from hard-to-reach places such as hinges and serrations.

50. Abrasive cleaners, scouring pads, metal brushes, or steel wool should not be used on surgical instruments unless indicated in the device's IFU.

Mechanical Cleaning

51. For mechanical cleaning in a washer-disinfector/decontaminator, instruments are arranged in trays with an open-mesh bottom and placed on shelves in the machine.
52. Washer-disinfector/decontaminators usually offer a variety of cycle options. Phases in the cycle may include cool-water rinse, enzymatic soak or rinse, detergent wash, ultrasonic cleaning, hot-water rinse (180–195°F/70–76°C), thermal or chemical disinfection, treated water rinse, and drying.
53. The washer-disinfector/decontaminator is built into the wall between the decontamination area and the clean areas where instruments are assembled and packaged. Instruments are placed into the machine in the decontamination area and are removed from the opposite end in the clean area.
54. Instruments that have been processed in a washer-disinfector/decontaminator or are manually washed and disinfected according to the IFU are considered clean and safe to handle, and are ready to be inspected, assembled, packaged, and prepared for patient use.

Special Needs Instruments

Eye Instruments

55. Although the principles for cleaning are similar for all instruments, eye instruments require special attention. They are delicate and cannot usually be cleaned in automated systems, so special care must be taken to ensure adequate cleaning.
56. It is essential to clean eye instruments in accordance with the manufacturer's IFU. Eye instruments are delicate and have extremely small lumens. Thorough cleaning of lumens immediately following use is essential to ensure the removal of debris that may be responsible for toxic anterior segment syndrome (TASS).
57. Improper processing of eye instruments has been associated with TASS, a noninfectious inflammation of the anterior segment of the eye that can lead to permanent vision impairment (Al-Ghoul et al., 2014).

58. Most cases of TASS occur when foreign material that was not removed during cleaning and sterilization is introduced into the anterior chamber of the eye. Endotoxins from Gram-negative bacteria in ultrasonic cleaners, viscoelastic solution used during eye surgery, and detergent and disinfectant residue have all been associated with TASS (AAMI, 2013, p. 229).
59. Several organizations have established guidelines that should be referenced for detailed instructions on processing ophthalmic instruments:
 - AORN (2015, p. 630)
 - American Society of Cataract and Refractive Surgery (ASCRS) and American Society of Ophthalmic Registered Nurses (ASORN; Henning, 2011)

Flexible Endoscopes

60. Flexible endoscopes are complex instruments; cleaning them is a multistep process. The manufacturers' IFU provide the specific information required to process each device.
61. Personnel responsible for cleaning and disinfecting these devices should refer to the following:
 - American Society for Gastrointestinal Endoscopy (ASGE) and SHEA (Petersen et al., 2011)
 - AORN (2015, p. 589)
 - Society of Gastroenterology Nurses and Associates (SGNA, 2013)
 - CDC (2015b)
 - The endoscope manufacturer's IFU for cleaning and disinfection or sterilization
62. Personnel responsible for endoscope reprocessing should have demonstrated competence for this complex task.

Robotic Instruments

63. Robotic instruments are complex and have lumens and difficult-to-clean components. It is essential to follow the device manufacturer's IFU for cleaning, inspection, and processing.
64. Pay special attention to cleaning the ports and articulating areas on robotic instruments. Flush ports while rotating the articulating component of the device through its full range of motion. Flush until the water runs clear.

Failure to flush effectively may result in incomplete removal of debris that can dry and harden, making cleaning more difficult and impeding effective sterilization.

Ultrasonic Cleaning

65. The purpose of ultrasonic cleaning is to dislodge and remove tenacious debris from instruments with hard-to-reach nooks and crannies.
66. Ultrasonic cleaning is not suitable for lensed instruments, powered instruments, or instruments that are chrome plated or made of plastic or rubber. Consult the instrument manufacturer's IFU to determine whether ultrasonic cleaning is compatible with a specific instrument.
67. High-intensity sound waves generate tiny bubbles that expand until they collapse or implode (cavitation), creating negative pressure that dislodges soil from hard-to-reach crevices. Ultrasonic cleaning is especially beneficial for items with box locks, serrations, lumens, and crevices.
68. Follow both the detergent and the ultrasonic manufacturers' IFU when adding detergent to the water in the ultrasonic cleaner. The IFU will also indicate if and when the water needs to be degassed.
69. Before placing instruments in the ultrasonic washer, ensure that they are free of gross soil.
70. Place instruments in a specially designed instrument basket or tray. Instruments should not rest on the bottom of the unit because that will prevent cavitation on the part of the instrument not in contact with water.
71. Attach adaptors that flush cleaning solution through the lumens of cannulated instruments.
72. Only instruments of the same kind of metal should be placed in the ultrasonic machine at one time. If instruments constructed of dissimilar metals are combined in the ultrasonic cleaner, etching and pitting may occur as a result of ion transfer from one metal to another.
73. To prevent aerosolization of contaminants, the lid on the ultrasonic cleaner should remain closed during use.
74. If an automated rinse phase is not included in the ultrasonic cycle and instruments are not placed in an automated washer using treated water, instruments should be manually rinsed with treated water.

75. The solution in the ultrasonic washer should be changed at least daily or whenever it is visibly soiled. The manufacturer's IFU will have instructions for changing the solution.
76. Most facilities use an ultrasonic cleaner following initial decontamination and prior to manual cleaning. Some facilities use ultrasonic cleaning for most instruments; others use it exclusively for specialty or difficult-to-clean instruments. Some washer-disinfectors/decontaminators include an ultrasonic cycle.

Lubrication

77. Instruments with movable parts should be lubricated according to the device manufacturer's IFU with an antimicrobial, water-soluble lubricant that protects against rusting and staining. Because the lubricant is usually white, it often called *instrument milk*.
78. The lubricant must be water soluble to allow penetration of steam during sterilization. The residue from oil-based lubricants can prevent penetration of the steam.

Section Questions

1. How does OSHA require that contaminated materials be transported to a decontamination site away from the work area? [Refs 37–38]
2. What is the purpose of the negative pressure in the “decontam” area of the SPD? [Ref 40]
3. How many air exchanges per hour are required in the decontamination area? [Ref 40]
4. What PPE is required for personnel in the “decontam” area? [Ref 41]
5. Why is cleaning the most important step in preparing items for sterilization? [Ref 42]
6. Why is it preferable to use a mechanical washer rather than to clean manually? [Ref 43]
7. What items might require manual cleaning? [Ref 44]
8. What supplies and equipment should be readily available wherever items are cleaned? [Ref 45]
9. Why is hot water not used to rinse contaminated instruments? [Ref 46]
10. How can mixing detergents in a higher concentration than recommended interfere with sterilization? [Ref 47]
11. Describe the methods employed to prevent aerosolization from occurring. [Refs 48–49]
12. In what area do items enter the washer, and where do they exit? [Ref 53]
13. What causes TASS and how can it be prevented? [Refs 56–58]
14. What resources should be consulted when preparing to clean endoscopes? [Ref 60–61]
15. Why are robotic instruments difficult to clean? [Refs 63–64]
16. What is the purpose of ultrasonic cleaning? [Ref 65]
17. Explain how cavitation dislodges soil. [Ref 67]
18. What instruments should not be subjected to ultrasonic cleaning? [Refs 66, 72]
19. What determines the amount of detergent to use and the frequency of changing the solution? [Refs 68, 75]
20. What type of lubricant is used for surgical instruments? [Refs 77–78]

Preparation and Packaging

Inspection

79. When instruments arrive in the clean area of the SPD, sometimes called the “prep and pack” area, any remaining moisture should be dried, and instruments should be inspected for

cleanliness, integrity, alignment, sharpness of edges, and proper function.

80. It is critical that items that do not function as intended be removed from service and either discarded or sent for repair. At the point of use, there is very limited opportunity to check each instrument for function; therefore, it is

imperative that careful inspection and checking for function occur prior to packaging. An instrument that fails in surgery can be the direct cause of an injury to the patient.

Assembly and Packaging

Selection Criteria for Barrier Protection

81. Packaging materials and systems are intended to maintain the sterility of items until their intended use.
82. Packaging material must be appropriate for both the item and the sterilization process. Not all packaging materials are compatible with every sterilization process; however, all packaging materials must:
 - Provide a barrier to microorganisms.
 - Permit penetration and exit of the sterilant.
 - Allow for adequate air removal.
 - Be intact; resist tears, punctures, and abrasions.
 - Permit complete and secure enclosure of the contents.
 - Be fluid resistant.
 - Be free of toxic ingredients and non-fast dyes.
 - Provide adequate seal integrity.
 - Be large enough to evenly distribute the contained mass.
 - Permit identification of the contents and/or labeling to identify contents.
 - Maintain sterility of items until package is opened.
 - Allow for aseptic delivery of contents to the sterile field.

(AAMI, 2013, §8.2; AORN, 2015, pp. 652)
83. A wide variety of types of packaging systems is available:
 - Woven fabrics
 - Nonwoven materials
 - Paper
 - “Peel packs” (plastic/paper and plastic/Tyvek pouches)
 - Rigid container systems

Woven Fabric

84. Reusable wrappers constructed of cotton and polyester blend fabrics that have been treated to be water resistant have been largely

replaced by disposable, nonwoven fabrics. Woven wrappers:

- May produce lint.
- Do not exhibit “memory,” a characteristic that causes material edges, when the package is opened, to return to their original folded position.
- Are compatible with steam and ethylene oxide (EtO) sterilization but may not be used with hydrogen peroxide or ozone.
- Must be inspected between uses for pinholes and tears. Damaged wrappers must be repaired with heat-sealed patches or discarded.
- Must be laundered between uses to prevent superheating and deterioration of the fabric. They should be maintained for a minimum of 2 hours at room temperature (i.e., 68–73°F [20–23°C]) and at a relative humidity of 30% to 60% (AAMI, 2013, §8.3.1).
- Lose their water-resistant properties over time and must be retreated or discarded.
- Usually require two wrappers (four layers) to protect sterile contents.
- Packages may be wrapped:
 - Sequentially: Two wrappers are folded one at a time to create a package within a package.
 - Simultaneously: Two wrappers at once: The item is folded into two wrappers at the same to create a single package.
 - Single-layer wrap: Items may be wrapped in a single layer of material when the single-layer wrap meets the same barrier protection requirements as two layers of traditional material.
- The manufacturer’s IFU will describe the number of layers required and the method of folding for each type of wrapping material.
- The facility’s policy for wrapping must be driven by the ability of the wrap available to maintain items in a sterile state.

Nonwoven Materials

85. Nonwoven wrappers are made of a combination of cellulose and/or other synthetic materials.
86. Nonwoven, cellulose-based wrappers are compatible with steam and EtO, but are not

- compatible with hydrogen peroxide (H_2O_2) sterilization technologies. Polypropylene wrappers are designed for items to be sterilized with H_2O_2 and with EtO and steam. The manufacturer's IFU will determine the compatibility of each wrapper with each sterilization technology.
87. Nonwoven wrappers are single use, disposable, almost entirely lint free, and tear resistant; they provide excellent barrier protection against dust, airborne microorganisms, and moisture.
 88. Items wrapped in nonwoven material are wrapped according to the manufacturer's IFU. Some nonwoven wraps require two layers; others require only a single wrap that is equivalent to a sequential double wrap.
 89. Nonwoven wrappers eliminate the need for washing, inspecting, and patching. Quality is consistent because wrappers are used only once and then discarded.
 90. Nonwoven wrappers may display undesirable memory, because wrapper edges try to return to their original fold when packages are opened. This creates the potential for contamination of package contents when a wrapper edge that has been handled folds back into the package and contaminates the sterile contents.
 91. Some nonwoven packaging products may require a longer sterilization time than woven packaging materials. This information must be supplied by the manufacturer.
 92. Packages are secured with pressure-sensitive tape that also serves as a process indicator. Select process indicator tape that is specific to the intended sterilization method. (See Ref 133.)

Pouches: Plastic/Paper, Plastic/Tyvek

93. Pouches (also called "peel packs") constructed from plastic and paper or plastic and Tyvek (a material made from high-density polyethylene fibers) may be used for packaging items for sterilization. The plastic/paper combination is appropriate for steam or EtO sterilization. Tyvek/plastic combinations contain no cellulose and are compatible with H_2O_2 and EtO sterilization, but not with steam.
94. The plastic film is fused to the paper or Tyvek so that one side is clear and the other opaque. The sterilant penetrates the opaque paper or Tyvek portion of the pouch, while the plastic portion permits visualization of the item inside.

95. Advantages of peel packs:
 - Inexpensive
 - Permit visualization of the contents
 - Lint free
 - Provide an effective barrier against airborne microorganisms
 - Suitable for packaging multiple small items and individual lightweight items
96. Disadvantages of peel packs:
 - Provide little resistance to punctures
 - Tendency to display memory
 - Limited to packaging items that can be delivered aseptically to the sterile field
97. Items can be packaged in a single pouch; or the sealed pouch containing the item can be placed within another pouch (double pouched). Double pouching is only permissible if the manufacturer's IFU indicate that the pouch has been validated for that option.
98. When double pouching, the inner pouch should fit inside the outer pouch without being folded (AAMI, 2013; see **Figure 3-2**), and the pouches should be oriented in the same direction (plastic faces plastic, and paper faces paper; AAMI, 2013, p. 73). The contents of the inner pouch will be visible.
99. Pouch material is available in many sizes, and pouches are manufactured as individual pouches or on a continuous roll that can be cut into desired lengths.
100. Pouches are either self-sealing or can be fused with a heat sealer. Self-sealing often provides the most secure seal. When heat sealers are used, consult the manufacturer's IFU to establish the appropriate temperature setting. Sealing at the incorrect temperature may result in a weak or incomplete seal.

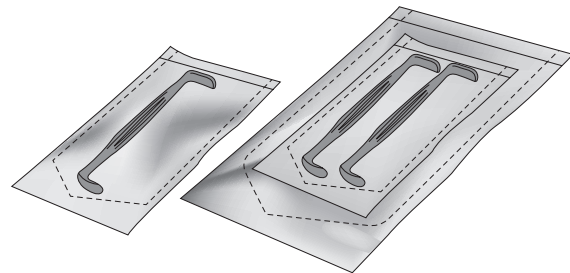


Figure 3-2 Single and double-packaging with paper/plastic pouches.

Reprinted from ANSI/AAMI ST79:2010 & A1: 2010 & A2:2011 with permission of Association for the Advancement of Medical Instrumentation, Inc. © 2011 AAMI www.aami.org. All rights reserved. Further reproduction or distribution prohibited.

101. Remove as much air as possible from the pouch before sealing. Air expands when it is heated and can burst the pouch seams during sterilization.
102. Once a pouch has been opened, the item may not be resealed without being reprocessed. The package seal must not permit resealing once the pouch has been opened.
103. Pouches should be positioned for sterilization on edge (vertically) and all facing in the same direction to promote penetration and evacuation of sterilant. Occasionally, racks are used to facilitate proper positioning.
104. Peel packs should never be placed inside instrument sets because they cannot be maintained in a vertical position (AAMI, 2013, p. 73). Paper bags, foam pouches, and other supplies have been validated for use within sets to contain multiple small items and protect delicate instruments (Figure 3-3).



Figure 3-3 Arrange small items in sets in paper bags, foam, and small containers validated for that purpose. Courtesy of Medical City Dallas, Dallas, TX.

Rigid Container Systems

105. Rigid container systems are packaging receptacles that have an outer case (often called a *casket*) constructed of aluminum, stainless

steel, heat-resistant plastic, or a combination of materials. Each system has one or more wire mesh baskets that fit inside to hold instruments (Figure 3-4).



Figure 3-4 Rigid Containers and Accessories. Courtesy of Case Medical, Inc., South Hackensack, NJ.

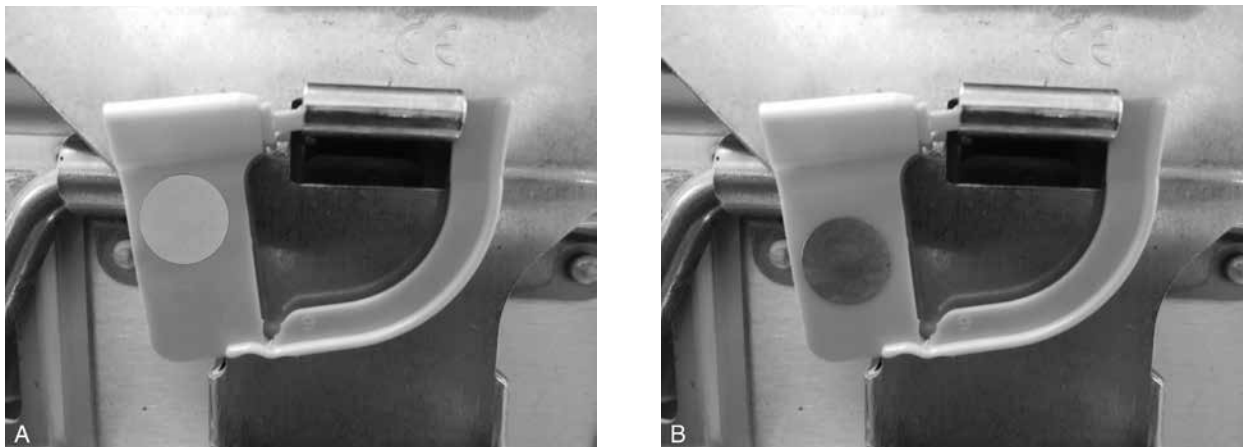


Figure 3-5 Tamper-proof container lock is also a process indicator: (A) Before sterilization and (B) After sterilization. Courtesy of Medical City Dallas, Dallas, TX.

106. Information about compatibility with sterilization technologies and cycles, arrangement of instruments within containers, sealing, labeling, temperature, exposure times, and cleaning instructions must be obtained from the manufacturer's IFU.
 107. Container systems have gaskets to promote a secure seal and either a valve or filter system to permit penetration and evacuation of sterilant.
 108. After rigid containers have been manually or mechanically cleaned, the gaskets, valves, and filter retainers must be inspected for integrity.
 109. Unless the IFU indicates that filters are intended to be used multiple times, a new filter(s) is placed in a container each time one is prepared for use.
 110. The lid and base of the container are held together by a latch mechanism.
 111. The container is locked with a tamper-evident seal (**Figure 3-5**). Once opened, the contents of the container should be used immediately.
- The container cannot be resealed. The seal may also contain a process indicator.
112. Advantages of rigid containers:
 - Durable; provide more protection for instruments than wrapped packages
 - Baskets often have pegs or posts to protect instruments and organize them efficiently
 - Do not require wrapping
 - Can stack for efficient storage
 113. Rigid containers can be heavy; an empty container can weigh as much as 10 pounds.
 114. If condensation occurs within the container, it is referred to as a "wet pack." When the scrub person opens a container in preparation for surgery and discovers a "wet pack," the instruments are not considered sterile and must not be used. (Note: consult the manufacturer's IFU to see if the container has been FDA cleared to permit moisture while retaining sterility.) An uncleared "wet pack" should be returned intact to the SPD with an explanation of the problem.

Section Questions

1. What do you look for when inspecting surgical instruments? [Ref 79]
2. Why is it important to inspect instruments before they are processed for use? [Ref 80]
3. What characteristics must all packaging materials have? [Ref 82]
4. Explain the concept of "memory" in relation to wrapping materials. [Ref 84]
5. Differentiate between sequential and simultaneous double wrapping. [Ref 84]

(continues)

Section Questions (continued)

6. What determines the number of layers of wrapping material required and the method of folding? [Ref 84]
7. Describe nonwoven wrappers. [Refs 85–87]
8. What differentiates peel packs appropriate for steam sterilization from those for H₂O₂ sterilization? [Ref 93]
9. Describe advantages and disadvantages of peel packs. [Refs 95–96]
10. When is double pouching permissible? [Ref 97]
11. What is the proper protocol for using two pouches to contain an instrument? [Ref 98]
12. Why is it wise to remove air from the pouch before sealing? [Ref 101]
13. Why are pouches constructed so that they cannot be resealed? [Ref 102]
14. How must pouches be arranged on the sterilizer shelf? [Ref 103]
15. Why can't peel packs be used to organize small instruments within instrument sets? [Ref 104]
16. Identify the components of a container system. [Refs 105, 107]
17. Where are the instructions for appropriate sterilization technology and cleaning? [Ref 106]
18. Describe the purpose of the gaskets, valves, and filters. [Ref 107]
19. What is the purpose of the tamper-evident seal that is part of the container's locking system? [Ref 111]
20. Describe advantages and disadvantages of container systems. [Refs 112–113]

Packaging Items for Steam Sterilization

115. Instruments and other items are arranged in container baskets or a perforated or mesh-bottom tray that permits steam to penetrate and also prevents air from being trapped (Figure 3-6).
116. Unless contraindicated by the container manufacturer, a lint-free absorbent towel or tray liner may be placed in the bottom of the tray to help absorb condensate that is formed during sterilization and to help speed the drying process (Figure 3-7).

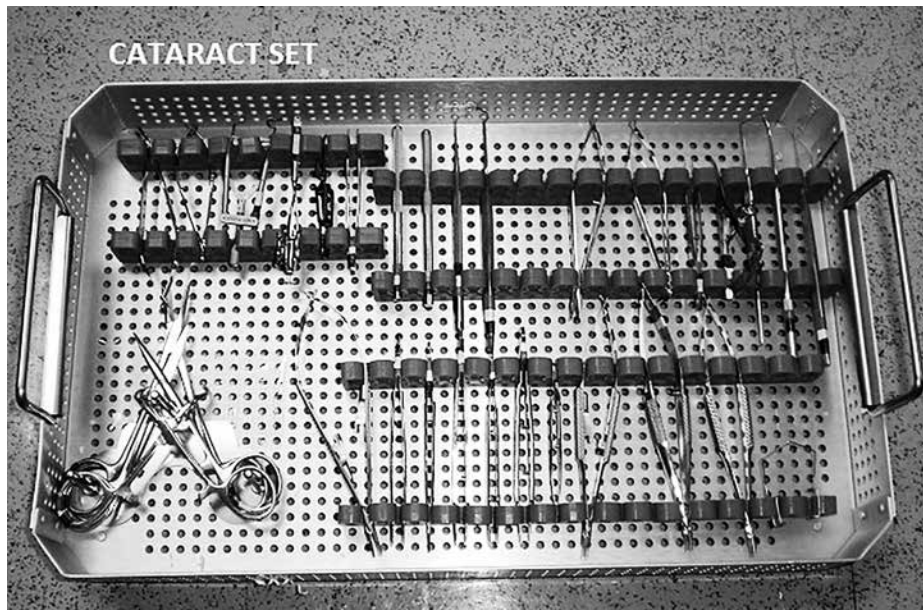


Figure 3-6 Instrument set arranged for sterilization.

Courtesy of Case Medical, Inc., South Hackensack, NJ.

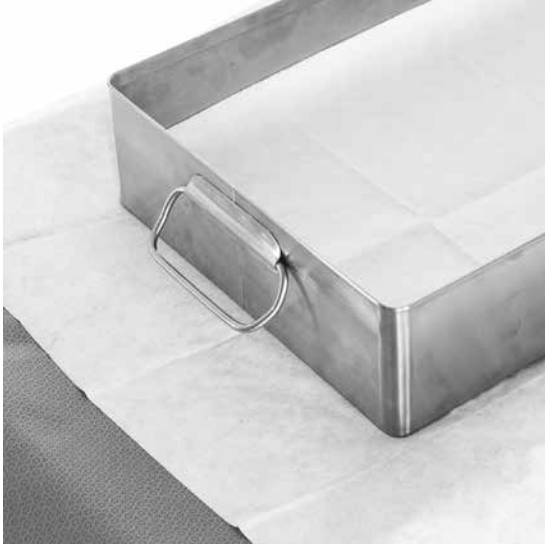


Figure 3-7 Tray liner in instrument tray.
© 2005 Kimberly-Clark Worldwide, Inc. Used with permission.

117. Instruments must be positioned so that every surface of each item will be exposed to the sterilant (**Figure 3-8**).
118. Joints and hinges of instruments must be opened and detachable parts disassembled unless the manufacturer provides validated

instructions for sterilization when the device is assembled (AORN, 2015, p. 654). Racks, pins, or stringers may assist in organizing instruments and securing them in an open position.

119. To prevent damage, heavy instruments are placed on the bottom of the tray, and delicate instruments are placed on top. If a container has two baskets, heavier items go into the bottom tray, lighter items in the top.
120. The combined weight of an instrument set, including the container, tray, and/or wrapper, should not exceed 25 pounds (AAMI, 2013, §8.4.2). Sets heavier than 25 pounds should be divided into two sets. In addition to employee safety concerns, instrument sets that are too heavy may concentrate too much metal mass and compromise drying.
121. Basins, bowls, and cups can be nested one inside the other if they are separated with gauze or an absorbent towel. The porous material permits entry of the sterilant, sterilant contact with all surfaces, and exit of the sterilant, and it facilitates the drying process.
122. Basins, bowls, and cups should be positioned vertically in the steam sterilizer to prevent water from pooling in them and to prevent wet packs.

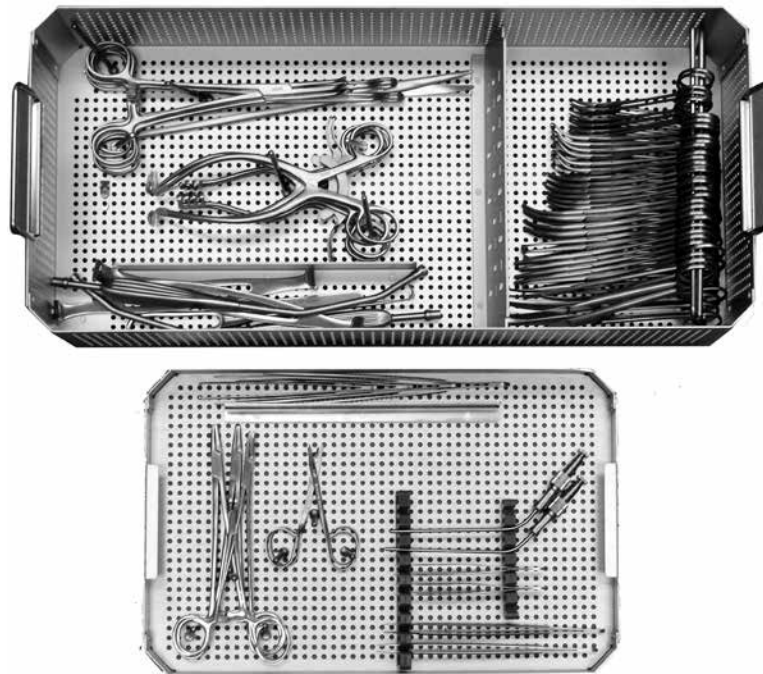


Figure 3-8 Instrument set arranged for sterilization. Note that ringed instruments are held open on a stringer, pins hold larger instruments in place. Heavy instruments are in the larger bottom tray; more delicate instruments are arranged in a separate tray that fits on top.

Courtesy of Case Medical, Inc., South Hackensack, NJ.

123. Nested items should be placed facing in the same direction to prevent air pockets, allow circulation of the steam, and permit condensate to drain out.
124. Rubber sheeting (e.g., Esmarch bandage) or other impervious material cannot be folded on itself or wrapped tightly in a roll for sterilization. The resulting density of the item prevents adequate circulation of the sterilant. (Note: Multiple alternate spellings of *Esmarch* are frequently used, including Eschmark and Esmark. The term is from the German surgeon Johann F. A. von Esmarch.)
125. Open the item and cover with a porous material (e.g., gauze) of the same size, roll or fold loosely, then wrap. This approach promotes sterilant contact with the entire surface of the rubber or other impervious material. Esmarch that is supplied sterile by the manufacturer is preferred.
126. Lumened items, such as cannulas and ventricular and irrigation needles, must be cleaned, rinsed, and dried thoroughly before packaging for sterilization.

Packaging Items for Low-Temperature Sterilization

127. For H₂O₂ or H₂O₂/ozone sterilization systems:
 - All items must be thoroughly dry; lumens should be blown dry with compressed air.
 - If any moisture is present on the objects, the sterilizer cannot achieve a vacuum and the cycle aborts (CDC, 2008).
 - Appropriate packaging includes polypropylene wrap or rigid container systems validated for this sterilization method. The sterilizer manufacturer's and device manufacturer's IFU must be followed when selecting trays and containers.
 - Cellulose-based materials (e.g., paper, gauze, linen, or towels) absorb hydrogen peroxide and cannot be included within the load.
128. For EtO sterilization:
 - Materials used to package items for steam sterilization are also appropriate for EtO sterilization.
129. Items prepared for gas sterilization must be thoroughly dry. Lumens should be blown dry with compressed air. EtO in contact with water forms ethylene glycol, a toxic residue.
 - Oil-based lubricants may not be used, because ethylene oxide cannot penetrate the film left by these lubricants.

Monitoring: Chemical Indicators and Integrators

130. Parameters of the sterilization process are conditions that must be met in order for sterilization to occur:
 - Steam sterilization: time, temperature, and steam quality
 - EtO sterilization: time, temperature, gas concentration, and relative humidity
 - H₂O₂ sterilization systems: H₂O₂ concentration, pressure, time, and temperature
131. Chemical indicators demonstrate a visible change when exposed to parameters of sterilization; indicators differ in the parameter(s) to which they are sensitive.
132. Process, or Class 1, indicators demonstrate only that items have been exposed to the physical conditions within the chamber that are monitored by the indicator.
133. Process indicators include heat-sensitive tape, labels, or strips that are placed on the outside of a package to distinguish between processed and unprocessed units (Figure 3-9).

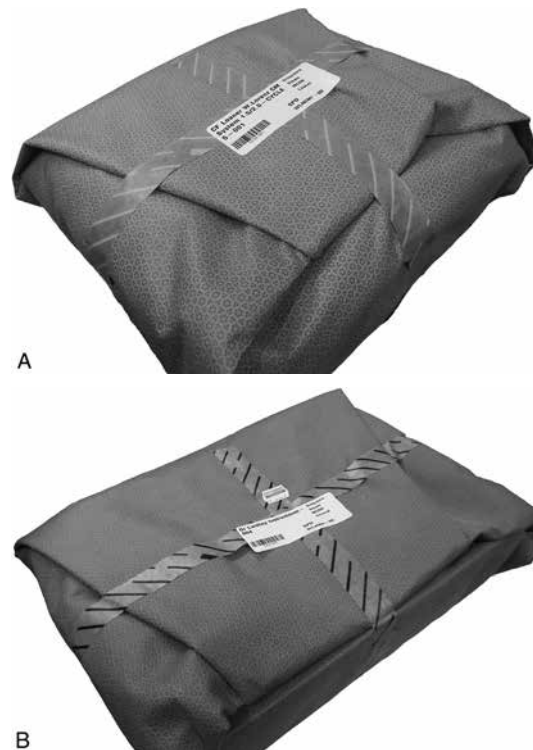


Figure 3-9 Process indicators change color when exposed to the sterilization process: (A) wrapped item waiting to be sterilized; process indicator stripes are white (B) item that has been removed from the sterilizer; process indicator stripes are black.

Courtesy of Medical City Dallas, Dallas, TX.

Packaging materials such as peel packs and rigid container locking devices often have an integrated process indicator.

134. When there is no visible indicator, the package must be considered contaminated.
135. In addition to the process indicator on the outside of each item, one or more chemical indicators should be placed inside of each package or set (AORN, 2015, p. 655).
136. The manufacturer's IFU will identify the most challenging location(s) within a set or container to determine the most effective placement of the internal indicator. An indicator should be placed in each layer of multilevel sets.
137. Single-variable indicators (Class 3) and multi-variable indicators (Class 4) respond to one or more of the critical parameters of sterilization. Class 3 and Class 4 indicators are rarely used in the surgical setting.
138. Integrators (Class 5) react to all critical parameters of the sterilization process. This is the most common internal indicator used in the healthcare setting (Figure 3-10).
139. Emulators (Class 6) also react to all critical parameters of the sterilization process and are cycle specific; each steam sterilization cycle has a specific emulator; emulators are not interchangeable (Figure 3-11).
140. Chemical indicators are designed specifically for either high-temperature or low-temperature sterilization and are not interchangeable. It is important to select the proper indicator for the sterilization technology being used.

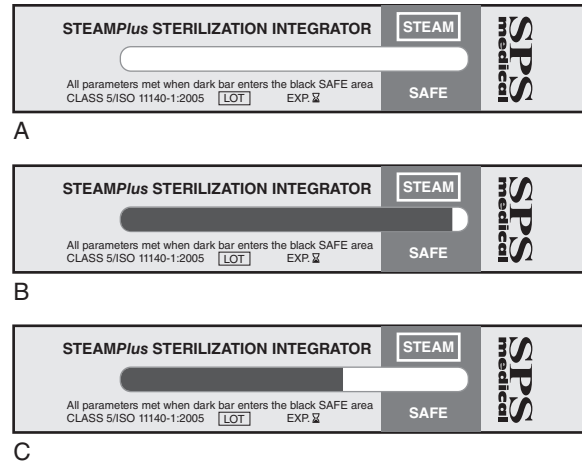


Figure 3-10 Class V integrators change color when exposed to all of the critical parameters of sterilization: (A) unexposed (B) Pass (C) Fail.

Courtesy of SPSmedical, Rush, NY.

Labeling

141. Items packaged for sterilization should be clearly labeled with the contents and initials of the package assembler (Figure 3-12).
142. Indelible, nonbleeding, and nontoxic markers may be used to mark packages. Marking on peel packs should be on the plastic side of the pouch (AORN, 2015, p. 658).
143. Before being placed into the sterilizer, a lot control sticker is placed on each package (Figure 3-13).

The lot control number indicates the sterilization date, sterilizer used, and cycle or load



Figure 3-11 Class Six emulating indicators are designed for specific steam sterilization cycles: (A) 270°F/132°C 4 minute cycle (B) 275°F/135°C 3 minute cycle (C) IUSS 3 and 10 minute cycles.

Courtesy of Steris Corporation, Mentor, OH.

number. Lot control numbers, in conjunction with computerized instrument tracking systems, facilitate inventory control, stock rotation, and retrieval of items in the event of sterilization or sterilizer failure.



Figure 3-12 Each package is clearly labeled with the contents and identifies the individual who assembled the package.
Courtesy of Medical City Dallas, Dallas, TX.



Figure 3-13 Lot control sticker.
Courtesy of Medical City Dallas, Dallas, TX.

Section Questions

1. Why do trays that hold instruments for sterilization have perforated bottoms? [Ref 115]
2. What purpose(s) does a towel in the bottom of an instrument tray serve? [Ref 116]
3. How must instruments be positioned in the tray for sterilization? [Refs 117–119]
4. What is the maximum recommended weight of an instrument set? [Ref 120]
5. How are hollow items such as basins and bowls positioned to prevent the accumulation of condensation? [Refs 121–123]
6. Describe preparation of an Esmarch bandage for sterilization. [Refs 124–125]
7. What effect will instruments that have not been thoroughly dried have on an H₂O₂ sterilization cycle? [Ref 127]
8. What packaging materials are appropriate for H₂O₂ sterilization? [Ref 127]
9. Identify the parameters associated with steam, EtO, and H₂O₂ sterilization technologies. [Ref 130]
10. How does a chemical indicator work? [Ref 131]
11. What is the purpose of a Class 1 chemical indicator? [Refs 132–134]
12. How do we determine where to put the chemical integrators inside of an instrument set? [Ref 136]
13. Explain the difference between a chemical integrator and an emulator. [Refs 138–139]
14. What information should be visible on every sterile package? [Refs 141, 143]
15. What is the purpose of a lot control number or lot control sticker? [Ref 143]

Sterilization and Disinfection

-
144. Sterilization and disinfection processes destroy microorganisms and are among the cornerstones of infection prevention. Protecting

the patient from surgical site infection requires the perioperative nurse to understand and apply the principles and practices of sterilization and disinfection.

145. Advances in surgical techniques and technology have created a proliferation of complex, sophisticated, and expensive surgical instrumentation, including endoscopic, fiberoptic, and robotic instruments that require special handling.
146. The appropriate method of cleaning, disinfecting, and sterilizing an item is determined by its composition and configuration, and its compatibility with the sterilization and disinfection methods available within the healthcare facility. It is wise to consult the manufacturers' IFU for processing of instruments and devices when purchasing and processing decisions are made.
147. Whether an item is disinfected or sterilized depends on its intended use. The Spaulding classification of devices, developed in 1968 by Earle Spaulding and adopted by the CDC, categorizes devices as critical, semicritical, or noncritical and determines whether an item must be sterilized or if disinfection is sufficient (Exhibit 3-1).
148. The process of sterilization provides the greatest assurance that items are sterile (i.e., free of known and unsuspected microorganisms).
149. Critical items used in surgery must be sterilized with a sterility assurance level (SAL) of 10^{-6} . This mathematical expression means that there is equal to, or less than, one chance in 1 million that any viable microorganism will be present on an item after sterilization. This is a very high SAL compared to industries where an SAL of 10^{-3} (one chance in 1,000) might be acceptable.
150. In addition to the high level of sterility assurance, a sterilizer must be capable of killing 1 million spores in half the time for which the sterilizer is programmed for hospital use (Favero & Bond, 2001, pp. 885–886). For example, if the exposure phase in the sterilization cycle is 4 minutes, the sterilizer manufacturer must demonstrate that 1 million spores are killed in 2 minutes.
151. Certain pathogenic bacteria such as *Clostridium tetani* (that produces tetanus), *Clostridium peridens* (that causes gas gangrene), and *Clostridium difficile* (that causes serious infections) are capable of developing spores. Spores are the hardiest form of a bacterium; they are more resistant to heat, drying, and chemicals, and can remain alive for many years. When conditions are favorable for growth, such as when the spore gains entry into the body, the spore will germinate to produce a vegetative cell.
152. Disinfection kills all living microorganisms, with the exception of high numbers of bacterial spores. Disinfection does not provide the margin of safety associated with sterilization. Disinfectants vary in their ability to destroy microorganisms and are classified according

Sterility Assurance Level (SAL)

148. The process of sterilization provides the greatest assurance that items are sterile (i.e., free of known and unsuspected microorganisms).
149. Critical items used in surgery must be sterilized with a sterility assurance level (SAL) of 10^{-6} . This mathematical expression means that there is equal to, or less than, one chance in 1 million

Exhibit 3-1 Spaulding Classification System.

Minimum preparation of items is determined by the risk of infection involved with use	
Critical Item	<ul style="list-style-type: none"> • Device enters normally sterile tissue or the vascular system • Device should be sterilized to destroy all microbial life. • Examples: surgical instruments, cardiac and urinary catheters, implants, and ultrasound probes used in sterile body cavities
Semicritical Item	<ul style="list-style-type: none"> • A device that contacts intact mucous membranes and does not ordinarily penetrate sterile tissue. • Minimum level of processing is high-level disinfection to destroy all vegetative microorganisms, mycobacterium, small or nonlipid viruses, medium or lipid viruses, fungal spores, and some bacterial spores. • Examples: respiratory therapy and anesthesia equipment, some endoscopes, laryngoscope blades,²⁴ esophageal manometry probes, cystoscopes
Noncritical	<ul style="list-style-type: none"> • A devices that does not ordinarily touch the patient or touches only intact skin. • Such devices should be low-level disinfected. • Examples: blood pressure cuffs, OR bed safety strap, positioning equipment, computers, environmental surfaces

Data from Centers for Disease Control and Prevention. Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. Last updated December 29, 2009. http://www.cdc.gov/hicpac/Disinfection_Sterilization/2_approach.html

to their cidal activity (i.e., their ability to kill microorganisms).

153. Only sterilization can render an item free of all microorganisms, including spores.

Methods of Sterilization

154. The choice among methods of sterilizing an item depends on its compatibility with the sterilization technology, the configuration of the item, packaging of the item, available technologies, length of time of the sterilization process, and safety factors.
155. Steam is a high-temperature technology that is the least expensive and most common sterilization modality available in hospitals.
156. Two other accepted methods of sterilization, dry heat and ionizing radiation, are not found in U.S. healthcare facilities.
157. Equipment, safety, and cost considerations confine ionizing radiation to industrial settings where it is used for bulk sterilization of commercially prepared items.
158. Dry heat is appropriate for powders, oils, and petroleum products that cannot be penetrated by steam or ethylene oxide or other sterilizing agents. Dry heat sterilization is rarely used in hospitals in the United States because most of these products are supplied sterile from the manufacturer.
159. Heat- and moisture-sensitive items require low-temperature sterilization technologies.
160. EtO, approved for medical device sterilization in the late 1950s, was the first low-temperature technology. Because of the toxicity of EtO and the stringent restrictions for installation and use, it has largely been replaced with H₂O₂ sterilization technologies.
161. Hydrogen peroxide gas plasma was introduced in the 1990s; H₂O₂ vapor and H₂O₂ vapor plus ozone were introduced in the early 2000s. Advantages and disadvantages are associated with all sterilization technologies.

High-Temperature Sterilization

Steam Sterilization

162. Moist heat in the form of saturated steam under pressure is an economical, safe, and effective method of sterilization used for the majority of surgical instruments. Sterilization by this method is accomplished in a steam sterilizer, often called an *autoclave*.

163. For an item to be sterilized, steam must penetrate every fiber of the packaging and contact every surface of the item inside. In addition, the critical parameters of moisture, temperature, and time must be met.
164. Saturated steam contains the greatest amount of water vapor possible. Heated to a sufficient temperature, it is capable of destroying all living microorganisms, including spores, within a relatively short period of time.
165. Saturated steam destroys microorganisms through a thermal process that causes denaturation and coagulation of proteins or the enzyme protein system contained within the microorganism's cell.
166. Steam at atmospheric pressure has a temperature of 212°F (100°C), which is inadequate for sterilization. The addition of pressure to increase the temperature of the steam is necessary for the destruction of microorganisms.
167. An increase in pressure of 15 to 17 pounds per square inch will increase steam temperature to 250–254°F (121–123°C). Twenty-seven pounds of pressure per square inch will increase steam temperature to 270°F (132°C).
168. The minimum generally accepted temperature required for sterilization to occur is 250°F (121°C; Perkins, 1969, p. 161). Typical temperatures for the operation of steam sterilizers are in the range of 270–275°F (132–135°C), although 250°F (121°C) is also used (AAMI, 2013, §8). Steam sterilization is a function of time and temperature. Sterilization at 250°F (121°C) requires more time than sterilization at 270°F (132°C).
169. Steam sterilization has many advantages. Steam:
- Is readily available (most often supplied from the healthcare facility boiler).
 - Is economical.
 - Enables fast sterilization—destruction of most resistant spores occurs quickly.
 - Is compatible with most in-house packaging materials.
 - Leaves no toxic residue and is environmentally safe.
 - Is suitable for a wide range of surgical instrumentation. The majority of items used for surgery are made from stainless steel and can withstand repeated steam sterilization without sustaining damage.

170. Steam sterilization is also associated with several disadvantages, though preset cycles on more modern autoclaves minimize these challenges.
- A variety of instruments and devices used in surgery cannot withstand high-temperature sterilization.
 - A temperature of 270°F is not appropriate for all items. A reduced temperature of 250°F may be necessary for a specific item being sterilized. A temperature higher than 270° may be needed to comply with the manufacturer's IFU.
 - Timing of the sterilization cycle must be adjusted based on the type of cycle, variances in materials, device configuration, and size of the load.
171. Efficacy of steam sterilization depends on attention to detail. Improper preparation of items or improper placement within the autoclave can interfere with steam circulation, draining of condensate, or proper drying, any of which can cause the process to fail.
172. A steam sterilizer, sometimes called an *autoclave*, generally consists of a rectangular metal chamber and a shell. Between the two is an enclosed space referred to as a *jacket*. When the autoclave is ready to use, steam and heat fill the jacket and are maintained at a constant pressure, keeping the autoclave in a heated, ready state (Figure 3-14).
173. Items are placed in the chamber, the door is shut tightly, and the sterilization cycle is initiated. Steam enters the chamber and displaces all the air from both the chamber and the items in the load. As the pressure rises, steam penetrates the packaging and contacts all surfaces of the items within. The steam forces the air out of the chamber through a discharge port outlet at the bottom front of the autoclave.
174. It is essential that all the air in the chamber be displaced by steam. Trapped air will act as an insulator that interferes with heating and prevents steam contact with every surface of every item.
175. Proper loading of the autoclave is critical. Items must be placed so that steam can circulate freely throughout the chamber and can contact all surfaces. Placement of items must also promote drainage of condensate to prevent water from collecting within items. For example, items such as cups or basins must be placed on their side to facilitate drainage.



Figure 3-14 Steam Sterilizer.
Courtesy of Steris Corporation, Mentor, OH.

176. The discharge port outlet is the beginning of a filtered waste line. Beneath the filter is a thermometer. This is the coolest part of the autoclave.
177. The actual exposure or sterilization time does not begin until the thermometer senses that the steam has reached the necessary preset temperature.
178. If air is not trapped and the parameters of time, moisture, and temperature have been met, microbial destruction will occur.
179. When the exposure time is complete, the steam is exhausted through the outlet port and a drying cycle follows. A drying cycle is required for wrapped items.
180. Wrapped packages and instrument containers should be allowed to cool on the sterilizer rack. They should not be touched while they are cooling. Rigid containers can be hot enough to burn skin. Grabbing a hot package may result in strikethrough, causing condensate that has not yet evaporated to penetrate the wrapper. The package would then be considered contaminated and would need to be reprocessed.

181. A minimum drying time of 30 minutes is recommended, although some instrument sets may require as much as 2 hours to cool adequately (AAMI, 2013, §8.8.1).
182. Warm packages must not be placed on cool surfaces because condensate will form, causing the package to become damp. Microorganisms are capable of penetrating wet materials; therefore, moist packages that contact an unsterile surface must be considered contaminated.
183. Two types of steam sterilizers or autoclaves are in use today: the older gravity displacement and newer dynamic air removal technologies (high vacuum, prevacuum, and pulse pressure). These autoclaves differ in how air is removed from the chamber during the sterilization process.
184. Sterilizers vary in terms of their design and performance characteristics. Some sterilizers offer both a gravity-displacement and a dynamic air-removal cycle; some offer only one type of cycle.
185. The nature of the items and the container in which they are sterilized determine the necessary time and temperature for sterilization. No single setting is appropriate for all items. The manufacturers' IFU for the items and for the autoclave must be consulted to determine the correct cycle settings.

Section Questions

1. How is the method of cleaning, disinfecting, and sterilizing an item determined? [Ref 146]
2. Differentiate the need for sterilization versus high-level disinfection. [Ref 147]
3. What level of processing is required for crutches, thermometers, and hemostats? [Ref Exhibit 3-1]
4. What is the significance of a sterility assurance level of 10^{-6} ? [Ref 149]
5. Why are spores important when determining the efficacy of a sterilizer? [Refs 150–151]
6. Disinfection and sterilization both kill pathogens. How does sterilization differ from disinfection? [Refs 152–153]
7. What factors must be considered when choosing a sterilization technology to process an item? [Ref 154]
8. Why are there both high-temperature and low-temperature sterilization technologies in healthcare? [Refs 155, 159]
9. What must occur inside the autoclave for an item to be sterilized? [Ref 163]
10. Why does an autoclave require steam under pressure to achieve sterilization? [Refs 166–167]
11. List advantages and disadvantages of steam sterilization. [Refs 169–170]
12. Describe how a steam sterilizer works to achieve sterilization. [Refs 172–179]
13. What factors can keep sterilization from occurring? [Ref 178]
14. Describe reasons for allowing packages to cool following sterilization. [Ref 180]
15. How can strikethrough cause a sterilized item to be considered contaminated? [Ref 180]

Gravity Displacement

186. In a gravity-displacement cycle or autoclave, steam replaces the air in the chamber by gravity.
187. As steam enters from a port located near the top and rear of the chamber, it is deflected upward. Air is heavier than steam; thus, by the force of gravity, the air is forced to the bottom while the steam rides on top of the air. The steam rapidly displaces the air under it and forces the air out through the discharge outlet port (Figure 3-15).
188. Most gravity-displacement autoclaves are operated at temperatures between 250°F and 274°F (121–134°C) with a 10- to 30-minute exposure time. For example, a wrapped instrument set requiring 30 minutes at 250°F (121°C) might require a 15-minute exposure at 270°F (134°C; AAMI, 2013, §8.6.1).

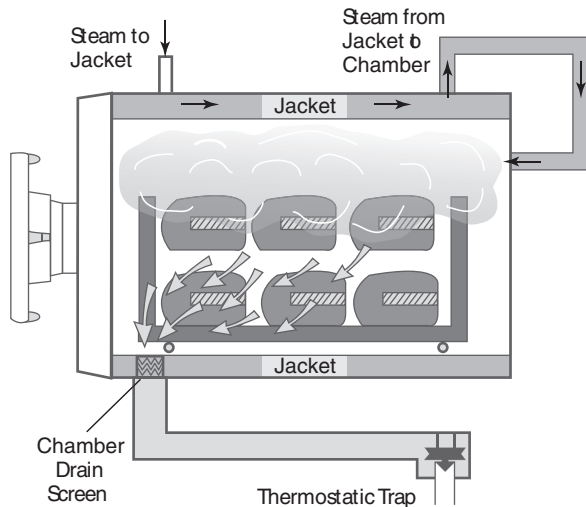


Figure 3-15 Steam sterilizer – Steam entry and air removal. Courtesy of AMSCO International, Inc.

189. Certain powered equipment may require prolonged exposure times of as much as 55 minutes when sterilized in a gravity displacement sterilizer.
190. Sterilization at a higher temperature requires less time than at a lower temperature. A temperature of 270°F (132°C) will accomplish sterilization more rapidly than a temperature of 250°F (121°C). All recommended cycles achieve an SAL of 10^{-6} .
191. The disadvantages of a gravity-displacement process are the length of time required for sterilization and the dependence on gravity to remove air. A prevacuum or steam–flush–pressure–pulse cycle offers a greater margin of safety with regard to air removal.
192. Gravity-displacement cycles should not be used when a prevacuum or steam–flush–pressure–pulse cycle is available, nor when the item manufacturer’s IFU recommend a dynamic air-removal cycle.
193. Gravity-displacement sterilizers are common in dentist and physician offices, clinics, and small surgicenters. Sterilizers that permit only a gravity-displacement cycle can still be found in healthcare facilities; however, most sterilizers sold today for hospitals and large ambulatory surgery centers run dynamic air-removal cycles (though they may also offer gravity-displacement cycles).
194. Some medical devices, because of their design, may require a gravity-displacement cycle. The device manufacturer’s IFU will determine the cycle type, time, and temperature.
- Dynamic Air Removal (Prevacuum Sterilizer)**
195. The prevacuum autoclave is equipped with a vacuum pump that evacuates almost all air from the chamber prior to the injection of steam. The evacuation process, which takes approximately 5 minutes, essentially creates a vacuum within the chamber. When the steam enters the chamber, the force of the vacuum causes instant steam penetration and contact with all surfaces of the contents regardless of the size of the package or load.
196. Following the prevacuum phase, an exposure time of 3 to 4 minutes at 270°F to 275°F (132–135°C) is usually recommended for accomplishing sterilization (AAMI, 2013, §8.6.1). It is imperative that the device manufacturer’s instructions for use be consulted before selecting the cycle time and temperature.
197. A dynamic air-removal (prevacuum sterilization) cycle has several advantages:
- Incorrect placement of objects within the chamber will have less effect upon air removal than in a gravity-displacement cycle.
 - The entire load will heat rapidly and more uniformly than with a gravity-displacement autoclave; therefore, the exposure time is shorter.
 - Loading the autoclave is more efficient, allowing more supplies to be sterilized within a given time.
198. The disadvantage of a dynamic-air-removal (prevacuum) sterilizer is that in the event of a leak, such as in the door seal, an air pocket can form that will inhibit sterilization.
- Extended Cycles**
199. With proliferation of the number and types of surgical devices, the variety of cycle times has likewise increased. We cannot assume that a 4-minute exposure at 270°F (132°C) is always appropriate.
200. Although a 4-minute exposure time is typical, exposure times of 5, 8, and 15 minutes are not uncommon. These cycles are commonly referred to as *extended cycles*. Temperature requirements vary from 270°F to 275°F (132–135°C). The manufacturer’s IFU for sterilization of any instrument will determine the

correct cycle length and temperature. If a device calls for an extended cycle or temperature variation, other devices that require less time should not be included in the load unless they have been validated by the device manufacturer for these extended cycles.

201. An extended cycle of 18 minutes at 270°F (134°C) minutes is also required for instruments exposed to prions (AAMI, 2013, Annex C).

Steam–Flush–Pressure–Pulse Sterilizer

202. Instead of creating a vacuum to remove air from the chamber, a sterilizer may use a repeated sequence of steam, flush, and pressure pulses above atmospheric pressure. Because a vacuum is not drawn, a Bowie-Dick test or daily air-removal test is not required for this type of sterilizer.
203. A variety of cycle times can be selected, based on the nature of the items to be sterilized.
204. The advantage to a steam–flush–pressure–pulse sterilizer is that sterilization is not affected in the event of an air leak into the sterilization chamber.

Immediate-Use Steam Sterilization (IUSS)

(AORN, 2015, pp. 671–673; AAMI, 2013, §8.6.2)

205. IUSS has replaced the term *flash sterilization*, derived from “sterilization in a flash,” a quick way to sterilize an unwrapped item.
206. IUSS is appropriate only for processing an item needed urgently and for which there is no sterile replacement immediately available. For instance, IUSS might be used to sterilize a one-of-a-kind item that was contaminated during surgery and is essential to complete the procedure.
207. IUSS should not be used for routine sterilization of instruments and was never intended for sterilizing whole sets of instruments.
208. IUSS should be used only in carefully selected, urgent clinical situations and should not be used to sterilize implantable devices (AORN, 2015, p. 673). Use of IUSS is discouraged by a number of standards-setting organizations.
209. According to the CDC, IUSS is not intended to be used for convenience, as an alternative to purchasing additional instrument sets, or to save time (CDC, 2008).
210. Cleaning is absolutely critical to proper instrument processing, because inadequate cleaning

will compromise the sterilization process. At no time is it appropriate to rinse or clean an item in the scrub sink.

211. An item intended for IUSS must be cleaned in the same manner that it would be cleaned in the SPD. In many instances, instruments prepared for IUSS are cleaned and prepared under less-than-ideal conditions. Many operating rooms do not have the processes and resources in place that are available in the SPD. In addition, a separate decontamination area for cleaning instruments may not exist in the operating room.
212. Regardless of where instruments are cleaned, the cleaning process should be consistent and in compliance with accepted standards. Appropriate PPE is required for personnel, regardless of what is being cleaned or where cleaning is done. A scrub sink is not appropriate for cleaning instruments.
213. Items subject to IUSS should be sterilized in containers specifically validated for IUSS. These containers facilitate aseptic delivery of the item to personnel at the sterile field. Some containers used for IUSS have also been cleared by the FDA, for terminal sterilization that allows storage of sterilized items for later use. There are some new rigid containers designed specifically for IUSS that allow for an item to be stored for a short period of time. Rigid containers *not* intended specifically for IUSS should not be used for this process.
214. Although it is recommended that items sterilized via IUSS be placed in a dedicated container, a single wrapper may be used for certain types of instruments if the sterilizer IFU indicate this is appropriate.
215. IUSS may be done in a gravity-displacement or a dynamic air-removal (prevacuum or steam–flush–pressure–pulse) sterilizer. The cycles for IUSS are preset by the sterilizer manufacturer.
216. Exposure times for IUSS can vary by more than 30 minutes and are determined by factors such as the nature and configuration of the item, the type of sterilizer, and whether a dedicated container is available. For example, at 270°F (134°C), a 3-minute exposure is appropriate in both a gravity-displacement and a prevacuum sterilizer for most metal or nonporous or non-lumened items only. However, for metal items with a lumen, a 10-minute cycle in a gravity-displacement sterilizer is required. In a prevacuum sterilizer, metal items with a lumen might

- require only 4 minutes. If a dedicated IUSS container system is used, the exposure time and temperatures may vary further. For this reason, it is critical that sterilizer, container, and device manufacturer guidelines be followed.
217. Because there is little or no dry time with an IUSS cycle, items may be wet or moist at the end of the process. IUSS cannot be used to terminally sterilize wrapped or containerized items intended for storage.
 218. When a device manufacturer does not provide instructions for IUSS, the item should not be sterilized in this manner. Perioperative nurses should always refer to the manufacturer's IFU when selecting the cycle type, time, and temperature. Inconsistencies between the device manufacturer's and the sterilizer manufacturer's IFU should be resolved before sterilization.
 219. If IFU are not available within the operating room, the perioperative nurse should consult with personnel from the SPD. In the absence of instructions, IUSS should not be used to sterilize the item. It is important to refer to the most recent manufacturer's IFU, because instructions for sterilization continue to evolve.
 220. Another disadvantage of IUSS is that, following sterilization, aseptic transfer of the item from the autoclave to the sterile field may be challenging. Sterilizers are often located at a distance from the operating room, increasing the risk of contamination during transport.
 221. Using the special containers designed for use with IUSS reduces the risk of contamination during transfer from the autoclave to the sterile field.
 222. Ideally, a sterilizer used for IUSS would open directly into the operating room. This configuration facilitates transport without contamination.

Section Questions

1. What is the relationship between time and temperature for steam sterilization cycles? [Ref 190]
2. What are the disadvantages of gravity-displacement steam technology? [Ref 191]
3. What is the typical exposure time and temperature for a dynamic air-removal sterilizer? [Ref 196]
4. List some advantages of a dynamic air-removal sterilizer over a gravity-displacement sterilizer. [Ref 197]
5. What determines when an extended cycle might be necessary? [Refs 200–201]
6. What advantage does steam-flush-pressure-pulse technology have over the prevacuum autoclave? [Ref 202]
7. What differentiates an IUSS cycle from a regular steam sterilization cycle? [Ref 205]
8. For what circumstance is IUSS intended? [Ref 206]
9. What are some identified situations for which IUSS should *not* be used? [Refs 207–209]
10. Under what circumstances is it acceptable to clean instruments in the scrub sink? [Ref 210]
11. Why is cleaning an instrument prior to IUSS difficult in the operating room? [Refs 211–212]
12. In what type of autoclave can IUSS be done? [Ref 215]
13. What is the length of time associated with an IUSS sterilization cycle? [Ref 216]
14. When can an item *not* be sterilized in an IUSS cycle? [Refs 218–219]
15. Why is the location of the sterilizer a factor in safe IUSS sterilization? [Refs 220–222]

Low-Temperature Sterilization Technologies

Hydrogen Peroxide Plasma

223. Plasma is a state of matter that is produced through the action of a strong electric or magnetic field. In low-temperature hydrogen peroxide plasma sterilization, a plasma state is created by the action of radiofrequency or electrical energy on hydrogen peroxide vapor within a vacuum (**Figure 3-16**).
224. Items to be sterilized are placed in a sterilizing chamber, a vacuum is established, and liquid



Figure 3-16 Hydrogen peroxide plasma sterilizer – Sterrad 100NX.

Courtesy of Advanced Sterilization Products, division of Ethicon, Inc.

hydrogen peroxide is injected into a cap and enters the chamber in a vaporized or gas form. Hydrogen peroxide vapor is effective in killing microorganisms. The hydrogen peroxide gas is charged with radiofrequency energy that creates plasma. The levels of residual hydrogen peroxide are removed, and at the end of the cycle the reactive species recombine to form oxygen and water vapor. The water vapor is in the form of humidity and cannot be felt.

225. Monitoring includes a special chemical indicator designed to change color in the presence of H_2O_2 and a biological indicator containing the spore *Geobacillus stearothermophilus*.
226. Packages are dry at the end of the cycle and may be used immediately or stored for future use.
227. Advantages of low-temperature hydrogen peroxide gas plasma sterilization include:
 - Gas plasma offers an efficient alternative to EtO sterilization, no toxic chemicals are retained, and no aeration is required. Because there are no toxic byproducts, PPE or monitoring of the environment is not required.
 - The sterilization cycle is short (approximately 30 minutes to more than 1 hour depending up the sterilizer model).
 - The sterilant is compatible with most metals and plastics.
228. Disadvantages of low-temperature hydrogen peroxide gas plasma include:
 - The sterilizer is simple to operate. Cycle times are preset and temperature does not require adjustment.
 - There is no plumbing, no drain, nor other fixed requirements. Because the sterilizer connects to an electrical outlet, it can easily be relocated if the need arises.
229. In a vapor-phase hydrogen peroxide sterilizer, H_2O_2 is added to the sterilization chamber through a vaporizer under low pressure, creating a vapor that fills the sterilization chamber. As the H_2O_2 diffuses and contacts surfaces, an oxidative process inactivates microorganisms. Byproducts of the process are oxygen and water vapor in the form of humidity, so no additional aeration is required.
230. Programmed cycles address specific parameters for sterilizing instruments of different types: instruments with and without lumens and instruments with diffusion-restricted spaces (e.g., hinges, ratchets, box locks) and single- or dual-channel flexible endoscopes or other features.
231. For both vapor and plasma H_2O_2 , all items to be sterilized must be thoroughly cleaned, rinsed, and dried before being packaged and loaded into the chamber.
232. Items should be arranged in a single layer with minimal overlap to ensure proper diffusion of sterilant vapor throughout the load.
233. Cycle phases include:
 - Conditioning: Sterilant fills the reservoir and a vacuum pulse removes air and moisture from the chamber, filtered dry air is introduced, and the load is tested electronically for acceptable moisture content.

Vapor-Phase Hydrogen Peroxide

- Sterilization: A series of four pulses creates a vacuum and introduces sterilant vapor and filtered air into the chamber.
 - Aeration: The sterilant vapor is evacuated from the chamber. When the aeration phase is complete, the chamber pressure is brought to atmospheric level and the chamber door unlocks.
234. Monitoring includes a special chemical indicator designed to change color in the presence of H₂O₂ and a biological indicator containing the spore *Geobacillus stearothermophilus*.
235. Advantages of low-temperature hydrogen peroxide vapor sterilization include:
- Vaporized H₂O₂ offers an efficient alternative to EtO sterilization; there are no toxic byproducts, only water vapor and oxygen.
 - The sterilant is compatible with most metals and plastics, glass, and silicone.
 - The sterilizer is simple to operate. Cycle times are preset and temperature does not require adjustment.
 - There is no plumbing, no drain, nor other fixed requirements. The sterilizer connects to an electrical outlet and can be relocated easily if necessary.
236. Disadvantages of vaporized hydrogen peroxide include:
- Hydrogen peroxide vapor is not compatible with liquids, linens, powders, and cellulose materials such as linen, gauze, and paper.
 - Packaging materials are limited to nonwoven polypropylene wraps, Tyvek and Mylar pouches, or specific container systems.

Ethylene Oxide Gas (EtO)

237. EtO is a toxic gas used to sterilize items that cannot tolerate the temperature and moisture of steam sterilization. Ethylene oxide achieves sterilization by interfering with protein metabolism and cell reproduction.
238. Because OSHA (2012b) identifies EtO as a human carcinogen, the sterilizers must be housed in a location that is closely monitored and vented.
239. OSHA requires specific training, PPE, exposure monitoring, and warning signs. Exposure to EtO can cause eye irritation, nausea, dizziness, vomiting, nasal and throat irritation, shortness of breath, tissue burns, and hemolysis.

Insufficiently aerated items may cause patient or personnel injury (OSHA, 2012b, 29CFR 1910.1047 (j)(2)(i)(A)).

240. Because of safety issues and prolonged aeration time, most healthcare facilities have significantly reduced or eliminated the use of EtO, replacing it with newer low-temperature sterilization technologies that do not have the same safety issues, lengthy process, and aeration time.
241. Because EtO is toxic and a variety of materials can absorb EtO, items must be thoroughly aerated following sterilization to remove vestiges of the chemical from the packaging and the sterile items.

Liquid Chemical Sterilant Processing System

242. Peracetic acid is acetic acid (vinegar) plus hydrogen peroxide that provides an extra oxygen atom. Peracetic acid disrupts protein bonds and the extra oxygen atom inactivates cell systems and causes immediate cell death.
243. Liquid peracetic acid is a low-temperature, nonterminal process that can be used to prepare reusable heat-sensitive devices such as endoscopes and their accessories that cannot be processed using steam.
244. The items to be processed are placed in a dedicated container, then placed into the tabletop unit (Figure 3-17). The sterilant circulates through the container and tray, contacting all surfaces of the items. Items are then rinsed with filtered and UV-treated water.
245. Items with internal lumens are connected to irrigator adapters to ensure sterilant contact within the lumens. It is important to ensure that devices with lumens are fitted with the appropriate irrigator adapters prior to processing.



Figure 3-17 Steris Liquid Chemical Sterilant Processing System 1E.

Courtesy of Steris Corporation, Mentor, OH.

- The manufacturer of each device should be consulted to determine if the device is validated for processing in a liquid peracetic acid processing system. Both the device manufacturer's and the liquid chemical sterilant processor manufacturer's IFU should be consulted to determine the appropriate irrigator adaptor(s).
246. Contact time is standardized at 6 minutes at a temperature of 45.5°C to 60°C (113.0–140°F). A rinse period follows the contact period; the rinse time depends on the water temperature and fill time. An entire cycle takes less than 30 minutes.
 247. Following processing, the circulating nurse opens the lid, retrieves the tray, transports it to the operating room, and opens it. The sterile scrub person removes the items (which are wet) from the tray and places them on the sterile field.
 248. Processing using liquid chemical peracetic acid is a “just in time” process. Processed items must be used immediately; they cannot be packaged and stored for later use. Processed items that are not delivered to the sterile field are hand dried and returned to storage for future processing; these stored items are not considered sterile.
 249. The system uses microprocessors to ensure that the required parameters are met.
 250. Monitoring includes a special chemical indicator designed to change color in the presence of peracetic acid. Biological monitoring is performed with a spore strip containing *Geobacillus stearothermophilus*.
 251. Advantages of liquid chemical peracetic acid processing include:
 - The cycle is less than 30 minutes and offers quick turnaround time.
 - Peracetic acid is combined with anticorrosive and buffering agents that prevent corrosion of instruments and render the sterilant nontoxic to personnel and the environment.
 - Liquid chemical peracetic acid processing is compatible with many materials that cannot withstand high-temperature sterilization.
 252. Disadvantages of liquid chemical peracetic acid processing include:
 - The size of the tray used for processing does not permit large loads to be processed. Only one flexible scope can be processed at a time.
 - Only immersible items that fit within the dedicated tray may be processed.
 - Items are wet at the end of the cycle.
 - Processed items must be used immediately. The nature of the process permits point-of-use processing but not storage. Processed items must be used immediately or dried and returned to storage for later processing; they cannot be left in the system to be used at a later time.

Vaporized Hydrogen Peroxide and Ozone

253. Combined vaporized hydrogen peroxide and ozone sterilization have recently been introduced to the market. Ozone is an emerging low-temperature technology.
254. Manufacturer's IFU should be consulted to determine the appropriate application of this technology.

Section Questions

1. What are the end products of H₂O₂ plasma sterilization? [Ref 224]
2. What are the advantages and disadvantages of H₂O₂ sterilization compared to EtO and steam technologies? [Refs 227–228, 235–236]
3. How should items be arranged in the sterilizer to promote successful sterilization? [Ref 232]
4. Why has EtO sterilization been largely replaced with other low-temperature technologies? [Refs 237–240]
5. Why is aeration of items sterilized with EtO so important? [Ref 241]
6. What items are appropriate for processing with peracetic acid? [Ref 243]
7. Why is peracetic acid considered a nonterminal process? [Ref 248]
8. How are chemical and biological monitoring done with peracetic acid?
9. Describe the advantages and disadvantages of a liquid chemical sterilant processing system. [Refs 251–252]
10. What additional low-temperature processes have been introduced to the market? [Ref 253]

Sterilization Monitoring: Quality Control

255. Items that have been sterilized for patient use cannot, themselves, be tested for sterility; the packages would have to be opened for testing and the items would no longer be available for patient use. Hence, we must assume that if a sterilizer is performing properly, it is, in fact, sterilizing the contents of each load. We assume the sterility of the contents if we can demonstrate that the sterilizer has performed properly.
256. Assumption of sterility is based on the following:
- Chemical and mechanical process indicators insure that all of the required parameters of sterilization have been met.
 - Biological indicators provide proof that microorganisms that are the most difficult to kill have, in fact, been destroyed.
257. Depending upon where sterilizer monitoring is done, the circulating nurse, the scrub person, and SPD personnel all share responsibility for checking these monitors.

Physical Monitors

258. Physical monitors include temperature and pressure recorders, digital printouts, and gauges that record activities within the chamber during the sterilization cycle.
259. A digital printout record correlates the exact times, temperatures, and pressures achieved during the conditioning, exposure, and exhaust phases of the sterilization cycle. The operator who opens the sterilizer at the end of the load should verify that the cycle was complete and correct. The printout includes space for the operator to initial and include the load identification (Figure 3-18).
260. Gauges on the autoclave may register pressure and temperature within the jacket and the chamber. Gauges on the EtO sterilizer may register temperature, gas concentration, and humidity.
261. With liquid peracetic acid, a diagnostic cycle is run to check electricity supply, filters, temperature, pressure, and system integrity at the beginning of each day, and a printout of the results is filed. A microprocessor system will abort the cycle if parameters are not met.

Chemical Indicators

262. A Class 2 chemical indicator, the Bowie-Dick or daily air-removal test (DART), is run each day before the first processed load to

```

=====
===== P R E U A C =====
=====
CYCLE START AT 8:43:23A
                ON 2/16/98

CYCLE COUNT      20
OPERATOR _____
STERILIZER       UAC 00

STER TEMP = 270.0F
CONTROL TEMP = 273.0F
STER TIME = 4 MIN
DRY TIME = 20 MIN

- TIME          T= F    U=inHg
                P=psia

C 8:43:35A 196.6    0P
C 8:44:35A 251.0   10P
C 8:45:42A 222.2   16V
C 8:46:13A 265.7   26P
C 8:47:31A 198.1   26V
C 8:47:57A 256.8   26P
C 8:49:13A 215.3   26V
C 8:49:40A 260.0   26P
C 8:50:57A 216.5   27V
S 8:51:33A 270.0   28P
S 8:52:33A 273.3   32P
S 8:53:33A 272.6   31P
S 8:54:33A 272.8   31P
S 8:55:33A 273.3   31P
E 8:55:33A 273.3   31P
E 8:55:54A 234.4   3P
E 9:15:55A 198.5   27V
Z 9:16:41A 200.1   2V

LOAD              021607

TEMP MAX=273.9F
TEMP MIN=270.0F

CONDITION        = 7:58
STERILIZE         = 4:00
EXHAUST           =21:08
TOTAL CYCLE      =33:06

PRINTOUT CHECKED BY:

=====
=  READY TO UNLOAD  =
=====

* NOT READY      9:32:56A
DOOR OPEN
=====

```

Figure 3-18 Steam sterilizer cycle printout.
Courtesy of Steris Corporation, Mentor, OH.

demonstrate that air is being eliminated from the chamber of each dynamic air-removal autoclave effectively enough to achieve steam penetration of a standard load (AAMI, 2013).

263. The Class 2 indicator contains a commercially prepared sheet of paper with various patterns of heat-sensitive ink that is contained in a commercially prepared package or placed in a specially constructed pack of towels. The Bowie-Dick or DART is placed over the drain in an otherwise empty autoclave.
264. Following the cycle, a uniform color change indicates that the air-removal process was successful (Figure 3-19).

Biological Monitors

265. Biological monitoring determines whether or not microorganisms have been destroyed and is, therefore, the most accurate method

of ensuring that the conditions necessary for sterilization have been achieved.

266. Biological indicators (BI) are available as capsules that contain a known, living, and highly resistant spore population; spore strips; and ampoules with spores suspended in the culture medium (Figures 3-20 and 3-21).
267. *Geobacillus stearothermophilus* spores are used to test steam autoclaves and hydrogen peroxide sterilizers. Ethylene oxide sterilizers are tested with *Bacillus atrophaeus* spores. Both types of spores are highly resistant non-pathogenic microorganisms.
268. A BI should be run in each steam sterilizer at least weekly and preferably every day that the sterilizer is in use (AAMI, 2013, §10.5.3.2).
269. A BI should be run in every sterilizer load containing an implant. In some facilities, a BI is run with each sterilizer load (AAMI, 2013, §10.5.3.2).
270. Implants should not be released for implantation until the results of biological monitoring are known to be negative for growth.
271. EtO sterilizers should be tested with every load (AORN, 2015, p. 674).
272. Hydrogen peroxide sterilizers should be tested daily and preferably with every load (AORN, 2015, p. 676).

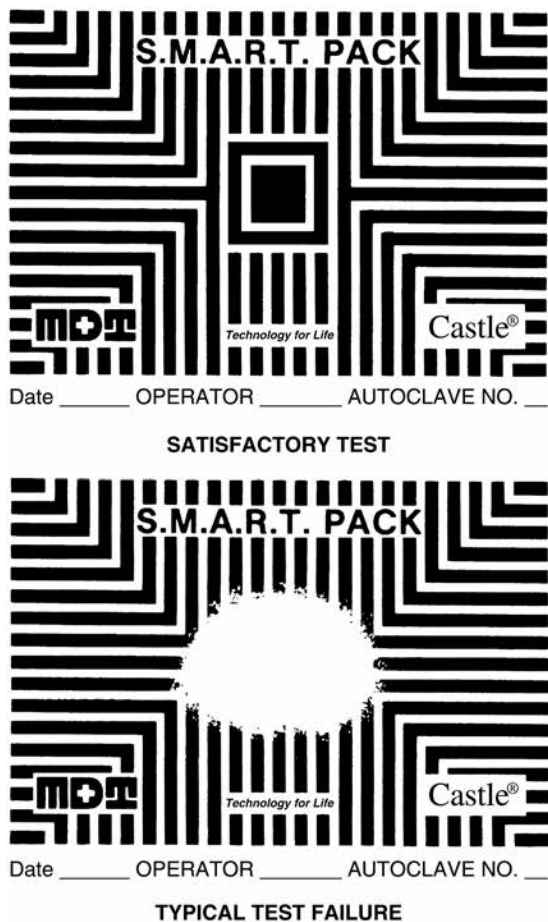


Figure 3-19 Air removal test.
Courtesy of MDT Biologic Company, Rochester, NY.



Figure 3-20 Rapid Readout Biological Monitor.
Courtesy of 3M, St. Paul, MN. The image is reproduced herein with permission. © 3M, 2013. All rights reserved.

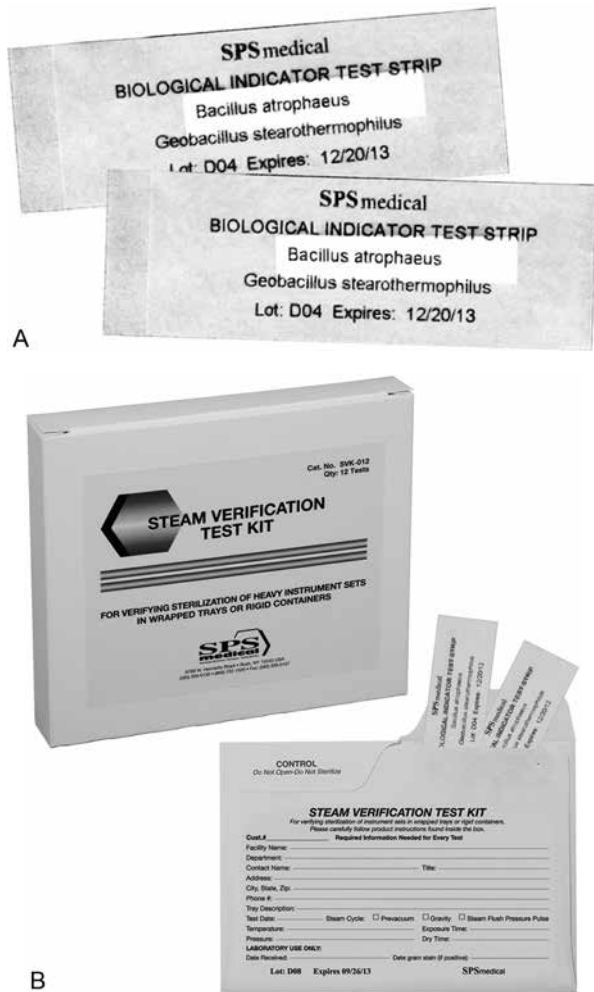


Figure 3-21 Biological indicator spore strips - dual (steam, EtO, dry heat, and chemical vapor): (A) Hospitals sometimes send spore strips to an outside validation lab for third party verification; (B) Clinics and office-based surgery often use a biological indicator mailing system.
Courtesy of SPSmedical, Rush, NY.

273. To routinely test the ability of the sterilizer to operate effectively, one or two strips, ampoules, or capsules containing the spores are placed at a specific location within the chamber (determined by the manufacturers' IFU), and a sterilizer cycle is run.
274. For cycles used for terminal sterilization, the biological monitor should be contained within a process challenge device (PCD). A PCD represents a defined challenge to the sterilization process. Most PCDs used are commercially prepared, but a PCD may be assembled by the user. Commercially prepared PCDs are equivalent in performance to an AAMI BI test pack (Figure 3-13).

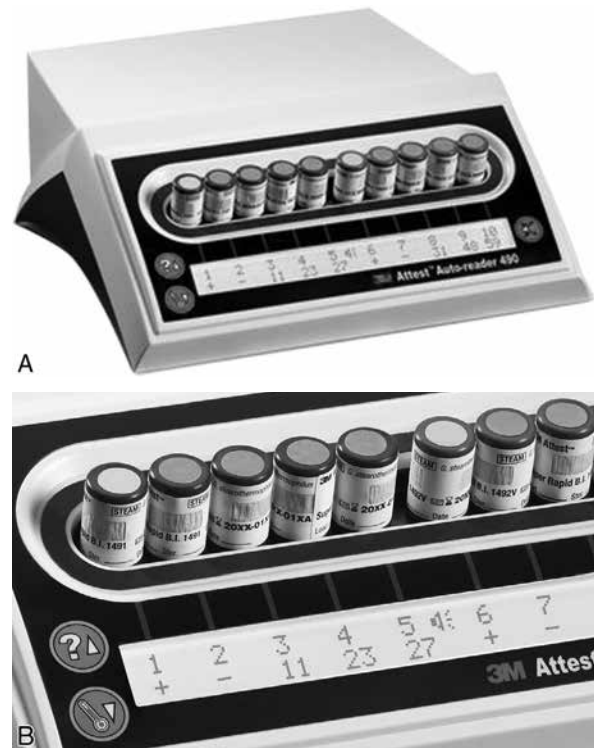


Figure 3-22 Rapid readout biological indicator incubation system (A) Incubator and (B) The + sign in well #1 indicates growth (the spores in the ampoule have not been killed); the – sign in well #2 indicates that there has been no growth after incubation for the required time (the spores in the ampoule have been killed); the 11, 23, and 27 in wells #3, 4, and 5 indicate the number of minutes left before incubation time is reached. At the end of that time, the numbers will be replaced by a + or a – sign.
Courtesy of 3M, St. Paul, MN. The image is reproduced herein with permission. © 3M, 2013. All rights reserved.

275. For IUSS cycles, the biological monitor is placed directly in the tray/container to be used, because the tray/container is considered to be the PCD.
276. Rapid-readout BIs whose growth is visible in 3 hours, 1 hour, or as little as 30 minutes, have largely replaced the traditional BI that took 24–48 hours before bacterial growth was visible (Figure 3-22).
277. It is essential to select the biological monitor specific to each sterilizer technology and cycle.
278. The traditional biological indicator must be incubated before results can be read. Before the BI is placed in the incubator, it is crushed in order to expose the spores to the growth medium in the capsule. A control BI (one that has *not* been through a sterilization cycle) must be incubated at the same time. The

- microorganisms in the control BI are alive and will grow when they are exposed to the growth medium. As the bacteria grow, the medium exhibits a distinct color change. Microorganisms in the BI from the sterilizer should be destroyed and therefore will not grow when exposed to the growth medium and no color change will occur. At the end of the incubation period, a distinct difference in color between the control and the test BI indicates a “negative BI” and successful sterilization.
279. Rapid-readout BIs must also be incubated. However, they detect the presence of *Geobacillus stearothermophilus* by recognizing the activity of alpha-glucosidase, an enzyme present within the organism. The presence of the enzyme is detected by reading fluorescence produced by the enzymatic breakdown of a nonfluorescent substrate. This creates a fluorescence change, which is detected by the auto-reader. A fluorescence change indicates a steam sterilization process failure.
 280. A positive BI reading (demonstrating bacterial growth) indicates that sterilizing conditions have not been met, indicating a “failed load.”
 281. A positive BI should be reported immediately to the appropriate supervisor, the load quarantined, and the sterilizer taken out of service until the cause is determined.
 282. With rapid-readout BIs, the length of time between sterilization and available BI results is short enough that items in the “failed load” will most likely not have been used for patient care.
 283. In addition to sterilizer malfunction, a positive reading can indicate incorrect packaging, an incorrect cycle, items incompatible with the process, or incorrect placement of items within the sterilizer.
 284. When the cause of the sterilizer failure can be immediately identified and the failure is confined to one load or one item within the load, corrective action is taken, the sterilizer is returned to service, and the load is reprocessed.
 285. When the cause of failure is unknown, all items from the failed load must be recalled, as well as any items processed between that load and the last load with a negative BI.
 286. The sterilizer is returned to service after repair and subsequent BI testing is negative.
 287. If a traditional BI is used, the incubation time may be lengthy and sterilized items might be sent to the operating room before the results of the biological testing are available, and a portion of the contents of the sterilizer may have been used.
 288. Identification of items to recall is made from the load list/lot number. The SPD advises the operating room staff if any items to be recalled have been delivered to the operating room.
 289. It is essential that all of the items from the sterilizer be accounted for. When items have been opened for procedures and patient exposure is known, facility policy determines the notification process that usually involves infection prevention staff and the operating surgeon.

Sterilization: Documentation

-
290. The following records for each sterilizer should be filed daily and kept as a permanent record (Figure 3-23):
 - Results of Bowie-Dick/DART
 - Results of biological monitoring
 - For each sterilizer load:
 - List of all contents of the load
 - Load lot control sticker (sterilizer number, sterilizer load, date)
 - Chemical monitor included in load
 - Biological monitor results if implant included in load
 - Sterilizer printout, initialed by the operator for verification of cycle parameters (if one person puts in a load and another removes it, both persons should initial the document)
 - Sterilizer failure results (if applicable)
 291. IUSS records should be fully traceable to the patient on whom the sterilized item was used.


```

=====
=== DART TEST ===
=====
CYCLE START AT 1:01:56A
                ON 1/28/15

CYCLE COUNT    13132
OPERATOR -----
STERILIZER     VAC 04

STER TEMP = 270.0F
CONTROL TEMP = 272.0F
STER TIME = 3.5 MIN
DRY TIME = 1 MIN
    
```

Bowie-Dick Plus Test Sheet
AIR REMOVAL



Site: MCDH
 Load #: 1

	TIME	T= F	U=inHg P=psia
C	1:02:17A	118.0	0.4P
C	1:03:48A	230.6	13.4P
C	1:05:10A	176.0	13.4U
C	1:06:39A	261.5	26.1P
C	1:08:17A	182.3	16.3U
C	1:09:28A	264.6	26.0P
C	1:11:04A	185.1	18.8U
C	1:12:10A	264.3	26.0P
C	1:13:46A	190.4	19.6U
S	1:16:32A	270.0	28.9P
S	1:17:32A	271.8	29.9P
S	1:18:32A	271.2	29.6P
S	1:19:32A	271.1	29.6P
E	1:20:02A	271.2	29.7P
E	1:20:40A	221.1	3.6P
E	1:21:40A	198.3	19.0U
Z	1:23:07A	191.0	2.0U

Quantity	Deliv Loc
1	
1	

No.: 4 Init.: ~~T~~LM

```

LOAD          012801

TEMP MAX=272.1F
TEMP MIN=270.0F

CONDITION    =14:15
STERILIZE    = 3:30
EXHAUST      = 3:05
TOTAL CYCLE  =20:50
    
```

PRINTOUT CHECKED BY:
 TUM

=====

B

Figure 3-23 (B) Bowie Dick test documentation; note that the Bowie Dick test is listed on the envelope as the first load of the day.
 Courtesy of Medical City Dallas, Dallas, TX.

Sterilizer Load Contents

Sterilizer: Stm04
 Time Opened: Wed 28-Jan-2015 2:17:57 pm
 Cycle: Cycle 2 PV 270.6.36
 Employee: Thomas Thomas
 Comments:

Site: MCDH
 Load #: 6



Set Type	Index	Unique ID	Site	Quantity	Deliv Loc
Biological Indicator	000		MCDH	1	
ENT NSR Set	002		MCDH	1	
ENT Tympanoplasty Set	001		MCDH	1	
General Laparoscopy Instruments	015		MCDH	1	
Neuro Midas Electric Drill	005		MCDH	1	
New Ortho Lami Retractor Pan	002		MCDH	1	
New Ortho Lami Set	001		MCDH	1	
Ortho De Mayo Knee Positioner - Base	004		MCDH	1	
Ortho De Mayo Knee Positioner - Boot	004		MCDH	1	
Pediatric Set	005		MCDH	1	
PL Debridement Set	004		MCDH	1	
Plastic Minor Set	001		MCDH	1	
PN Irrigating Bipolars	001		MCDH	1	
PP Ortho	000		MCDH	1	
Robot Camera Pan	000		MCDH	1	
Robot Camera Pan	002		MCDH	1	
Robot Camera Pan	004		MCDH	1	
Robot Camera Pan	008		MCDH	1	
				18	

=====
 ===== P R E V A C =====
 =====
 CYCLE START AT 2:18:09P
 ON 1/28/15

CYCLE COUNT 13137
 OPERATOR _____
 STERILIZER UAC 04
 STER TEMP = 270.0F
 CONTROL TEMP = 272.0F
 STER TIME = 6 MIN
 DRY TIME = 36 MIN

	TIME	T= F	U=inHg	P=Psi
C	2:18:30P	112.4	0.2P	
C	2:20:01P	217.5	7.7F	
C	2:21:18P	180.0	10.1U	
C	2:23:44P	263.7	26.0P	
C	2:25:42P	202.7	10.0U	
C	2:27:27P	264.8	26.1P	
C	2:29:27P	205.2	10.1U	
C	2:31:07P	264.8	26.1P	
C	2:33:06P	207.4	10.4U	
S	2:36:46P	270.0	29.2P	
S	2:37:46P	271.9	30.5P	
S	2:38:46P	271.5	30.1P	
S	2:39:46P	271.0	29.8P	
S	2:40:46P	271.1	29.9P	
S	2:41:46P	271.2	29.9P	
E	2:42:46P	271.2	29.9P	
E	2:43:52P	217.9	3.7P	
E	3:19:53P	163.8	27.6U	
Z	3:22:02P	126.9	2.0U	



LOAD 012806
 TEMP MAX=272.1F
 TEMP MIN=270.0F
 CONDITION = 0:18:15
 STERILIZE = 0:06:00
 EXHAUST = 0:39:16
 TOTAL CYCLE = 1:03:31

PRINTOUT CHECKED BY:

 = READY TO UNLOAD =

Sterilizer: Stm04 Load #: 6 1/28/2015 Julian:28

Wednesday January 28, 2015 14:19

Page 1 of

* NOT READY 3:22:33P
 DOOR OPEN

Figure 3-23 (C) Documentation for each load includes a load list, chemical indicator, lot number, and sterilizer load printout.

Courtesy of Medical City Dallas, Dallas, TX.

Section Questions

1. Explain why items sterilized for patient use cannot be tested to insure their sterility. [Ref 255]
2. On what methods do we base our assumption of sterility of the contents of a sterilizer? [Ref 256]
3. Describe the physical monitors used to assess the performance of sterilizers. [Refs 258–260]
4. What is the purpose of a Bowie-Dick test or DART? [Ref 262]
5. When is the Bowie-Dick test (or DART) run and how is the package placed in the autoclave? [Ref 262–263]
6. How do we determine that the Bowie-Dick test or DART has either passed or failed? [Ref 264]
7. What is the purpose of a biological monitor? [Ref 265]
8. What spores are used to test each type of sterilization technology? [Ref 267]
9. When should BIs be run? [Refs 268–279]
10. At what point are implants released after sterilization? [Ref 270]
11. How frequently are H₂O₂ sterilizers tested with a BI? [Ref 272]
12. Why is the BI contained within a PCD? [Ref 274]
13. How do rapid-readout BIs compare to traditional BIs? [Ref 276]
14. Describe the process of incubating a BI. [Ref 278]
15. Explain the purpose of using a control when incubating a BI. [Ref 278]
16. How can you tell if an incubated BI is positive or negative? [Refs 278–279]
17. What reasons might there be for a failed BI? [Ref 283]
18. What process must follow a failed BI? [Refs 284–285]
19. What documentation should be captured for every sterilizer load? [Ref 290]
20. What additional documentation is required for IUSS? [Ref 291]

Disinfection

292. Disinfection is a process that destroys pathogenic microorganisms through the use of a liquid chemical germicide.
293. A disinfectant is an agent that destroys vegetative forms of harmful microorganisms. Some disinfectants kill some spores; however, disinfectants do not kill high numbers of spores.
294. Liquid chemical disinfectants are used to destroy pathogens on inanimate objects such as walls, tables, small equipment, and surgical instruments.
295. Disinfectants must be selected according to their intended use. Disinfectants suitable for housekeeping purposes such as cleaning walls and surfaces are not suitable for disinfection of surgical instruments. Likewise, the most appropriate disinfecting agent for surgical instruments is not the most suitable for housekeeping.
296. Examples of disinfectants include alcohol, chlorine and chlorine compounds, formaldehyde, glutaraldehyde, hydrogen peroxide, iodophors, *ortho*-phthalaldehyde, phenolics, and quaternary ammonium compounds.
297. Disinfectants vary in their ability to destroy microorganisms, and they are not interchangeable. Disinfectants are categorized as high level, intermediate level, and low level.
298. Factors that influence the efficacy of a disinfectant include the type of chemical, concentration and temperature of the chemical, amount and types of microorganisms present, configuration of the item to be disinfected, adequacy of prior cleaning, and exposure time.
299. High-level disinfectants kill all microorganisms, including vegetative bacteria forms, the tubercle bacilli, viruses, and fungi. They do not kill large numbers of spores, although some high-level disinfectants can achieve sterilization after prolonged exposure of 8 hours or

more. Because waiting for such a long period of time is impractical, high-level disinfectants are not used for sterilizing instruments. Disinfectants used for disinfecting instruments and medical devices are not used on environmental surfaces.

300. Intermediate- and low-level disinfectants are formulated to be used on environmental surfaces and are never to be used on instruments and medical devices.
301. Intermediate-level disinfectants inactivate most vegetative bacteria, the tubercle bacillus, fungi, and viruses, but not necessarily bacterial spores.
302. Low-level disinfectants kill most vegetative bacteria, some fungi, and some viruses; they do not kill the tubercle bacillus.
303. For instrument disinfection, only high-level disinfection is appropriate. The most frequently used high-level disinfectants are solutions of 2% to 3.2% alkaline glutaraldehyde or 0.55% *ortho*-phthalaldehyde.
304. Following exposure to the solution, the device must be thoroughly rinsed, preferably in sterile water. It is important to refer to the manufacturer's IFU, because some disinfectant products require as many as three separate rinses.
305. To avoid dilution of the disinfectant and compromising the disinfection process, all items to be disinfected should be thoroughly cleaned, rinsed, and dried prior to immersion.

Glutaraldehyde

306. Glutaraldehyde is a commonly used high-level disinfectant. High-level disinfection is achieved in minutes, although the exact number of minutes varies with the concentration and temperature of the solution. The manufacturer's IFU and institutional policy describe the exact required immersion time.
307. Glutaraldehyde is irritating to mucous membranes and can irritate skin, eyes, throat, and nasal passages. It should be mixed in a well-ventilated room with a minimum of 10 air exchanges per hour. Local exhaust ventilation located at the level of the point of discharge is the preferred method of preventing vapor from escaping. Self-contained workstations with a fume hood should be installed where glutaraldehyde is used. Glutaraldehyde should always be stored in a closed container.

308. Protective eyewear, nitrile gloves or a double set of latex gloves, a mask, and a repellent gown should be worn during use of glutaraldehyde. Exposure varies with the activity. Mixing and discarding the solution and immersing and retrieving items from the solution are the activities that pose the greatest risk of exposure.
309. Like all disinfectants, glutaraldehyde must be mixed and used strictly according to the manufacturer's IFU and standards of practice. Information regarding mixing instructions, temperature, use, immersion time, toxicity, and length of effectiveness can be found on the product's label.
310. The current OSHA ceiling threshold limit value for exposure to glutaraldehyde is 0.5 part glutaraldehyde to 1 million parts air during any part of the work day. Monitoring of the work area and employee exposure is not required by OSHA; however, monitoring should be employed when high levels of exposure are suspected (OSHA, 2015).
311. Glutaraldehyde that is heated will achieve microbial killing faster than glutaraldehyde at room temperature. Some automated systems are programmed to heat glutaraldehyde. However, when glutaraldehyde is heated, the vapor pressure is raised, which in turn increases the amount of vapor released into the air.

Ortho-phthalaldehyde

312. *Ortho*-phthalaldehyde (OPA) is a non-glutaraldehyde disinfectant used in operating rooms and endoscopy suites. Because it achieves disinfection faster than glutaraldehyde and does not release any irritating odors, OPA has replaced glutaraldehyde in many facilities.
313. *Ortho*-phthalaldehyde has a very low vapor pressure; as a result, it is rarely irritating to staff. Although there are no OSHA requirements and no monitoring requirements for OPA, high-level disinfectant monitoring systems are available.
314. *Ortho*-phthalaldehyde will stain protein and items that are not thoroughly cleaned and rinsed prior to immersion. It will stain gray in spots where there are protein residuals.

Quality Control

315. Disinfectant solutions have an expiration date that represents the length of anticipated

- effectiveness, as indicated on the label. Date of mixing and expiration date should be indicated on the container in which the disinfectant is stored.
316. Some disinfectant solution instructions for use call for a specific quality control test prior to initial use to ensure that the required effective concentration is present. In addition to an initial quality control test, concentration testing should be conducted before each use. A disinfectant can lose its minimum effective concentration (MEC) before the expiration date. The number of times the solution is used, the amount of debris introduced into the solution, and any dilution that occurs when items are washed, rinsed, and not dried before immersion can all affect the MEC and cause a solution to fail.
 317. One should never rely entirely on the label for proof of the expiration of the solution. The MEC of disinfectant solutions should be monitored before each use with indicators designed for this purpose, usually supplied as paper or plastic strips that are dipped into the solution and then observed for appropriate color change as indicated on the label. Indicators are not interchangeable, and only those supplied with a particular product should be used to test that product.
 318. Chemical properties and appropriate hazard warnings should be posted.

Documentation

319. When liquid chemical germicides are used for high-level disinfection, the following should be documented:
 - Results of quality control testing—performed according to the manufacturer’s instructions
 - Results of testing for minimum effective concentration
 - Date solution is mixed/activated/opened/prepared
 - Expiration date—should be visible on the container
 - Person responsible for mixing
 - Item disinfected
 - Patient for whom the disinfected item was used

Section Questions

1. Describe disinfection. [Ref 292]
2. What is the difference between sterilization and disinfection in relation to spores? [Ref 293]
3. How are disinfectants selected? [Ref 295]
4. Identify some disinfectant chemicals. [Ref 296]
5. Explain the factors that influence the efficacy of disinfection. [Ref 298]
6. Differentiate among high-, intermediate-, and low-level disinfection. [Refs 299–302, Exhibit 3-1]
7. Which level of disinfection is used for surgical instruments? [Ref 303]
8. What are the most commonly used high-level disinfectants for instrument disinfection? [Ref 303]
9. How is a high-level disinfected instrument prepared for patient use? [Ref 304]
10. What is the effect of not thoroughly rinsing and drying instruments on the disinfectant? [Ref 305]
11. Which factors affect the length of time it takes to disinfect an item with glutaraldehyde? [Ref 309]
12. Describe the responsibilities associated with using glutaraldehyde. [Refs 308–310]
13. What is the impact of heat on glutaraldehyde? [Ref 311]
14. Describe the characteristics of OPA. [Refs 312–314]
15. How does the MEC correlate with the expiration date of a disinfectant solution? [Ref 316]

Reuse of Single-Use Devices

-
320. Under current FDA (2000) regulations, any hospital that chooses to reprocess single-use Class 3 devices (devices that carry a significant risk in the event of failure) that have been opened and used will be held to the same standard as the original manufacturer of that item. The requirements for the original manufacturer are extremely stringent and virtually impossible for a hospital to replicate.
 321. The perioperative nurse in the operating room should never attempt to reprocess a single-use device. When a question arises about whether a single-use device will be reprocessed, a group including infection preventionists and risk management should refer to the FDA's (2000) "Guidance Document: Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" to determine the facility policy.

Storage of Sterile Items

-
322. Sterilized items should be stored in a well-ventilated, limited-access area, with controlled temperature and humidity, at least four air exchanges per hour, and that is clean and dust free.
 323. To reduce dust accumulation, wire mesh shelving is preferable to closed shelving. The bottom shelf should be solid or items on the bottom shelf should be stored in bins.
 324. Cabinets and shelves should permit adequate cleaning and air circulation.
 325. Closed cabinets are best for items that are used infrequently.
 326. Storage cabinets and shelves should be far enough away from floors, ceiling fixtures, vents, sprinklers, and lights to prevent contamination. Shelves should be at least 18 inches below the ceiling or level of a sprinkler head, 2 inches from outside walls, and 8 to 10 inches above the floor (AAMI, 2013, §8.9).
 327. Sterile items should be stored separately from clean items. If sterile and clean items are stored on the same cart, sterile items should be on the uppermost shelves and clean items on lower shelves.
 328. Sterile items should not be stored under or next to sinks or other areas where they might become wet.
 329. Wrapped packages should not be bent, crushed, crammed, or stacked.

330. No outside shipping containers or corrugated cartons should be brought into the sterile storage area.

Shelf Life

331. Shelf life is the amount of time following sterilization that an item may be considered sterile.
332. Event-related sterility: Theoretically, if an item is not contaminated during transport and storage, it will remain sterile indefinitely. Shelf life is related to the events that can occur that will cause an item to become contaminated. A package remains sterile until it is opened or an event occurs that renders the package unsterile.
333. Proper packaging, handling, and storage can prevent contamination. Poor quality wrappers, poor storage conditions, and improper handling of sterile items increase the potential for contamination.
334. A small percentage of institutions have policies requiring that an expiration date be placed on stored items. Most institutions have eliminated the use of expiration dates.
335. Before any package is opened for surgery, it must be visually inspected to determine whether the package may have been compromised. Stains, pinholes, and tears are obvious examples of potential contamination that would preclude using the item in surgery.
336. Shelf life is determined by many factors:
 - Type and configuration of packaging material: Items packaged in rigid container systems may have a longer shelf life than items packaged with woven and nonwoven materials, which are more readily contaminated.
 - Use of dust covers: Plastic pouches specifically designed to prolong the shelf life of sterilized items by protecting them from moisture and dust can extend shelf life.
 - Conditions of storage: Dust, temperature, humidity, and traffic can affect shelf life.
 - Number of times a package is handled before use: The more the package is handled, the greater the risk for contamination.
337. Expiration dates on commercially prepared items may indicate that the integrity of the device or material will be compromised (material degradation) after the indicated date, and the item should not be used once this date has been reached.

Section Questions

1. What is the FDA requirement for reprocessing Class 3 devices? [Ref 320]
2. Describe the type of shelving best suited for storing sterile items. [Ref 322]
3. What are the required distances from walls, floor, and ceiling for stored items? [Ref 326]
4. When sterile items are stored with clean items, how should they be arranged in relation to one another? [Ref 327]
5. What should be done with outside shipping containers and corrugated cartons? [Ref 330]
6. Explain event-related sterility. [Ref 332]
7. What factors lead to potential contamination of sterile packages? [Ref 333]
8. What is the responsibility of the perioperative nurse prior to opening a sterile package? [Ref 335]
9. What factors impact the shelf life of sterile packages? [Ref 336]
10. What is the significance of the expiration date on commercially sterilized packages? [Ref 337]

References

- Al-Ghoul, A., Charukamnoetkanok, P., Dhaliwal, D., Allinson, R., Law, S., Charles, A., & Brown, L. (2014). Toxic anterior segment syndrome. Retrieved from <http://emedicine.medscape.com/article/1190343-clinical#showall>
- American National Standards Institute (ANSI), & Association for the Advancement of Medical Instrumentation (AAMI). (2001). *Processing CJD: Contaminated patient care equipment and environmental surfaces* (ST79: 2013 & A1:2010 & A2:2011 Annex C). Washington, DC: Author.
- ANSI/AAMI (2001). *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. ST79: 2010 & A1:2010 & A2:2011. Washington, DC: ANSI/AAMI.
- Association for the Advancement of Medical Instrumentation (AAMI). (2013). *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* (ST79:2010/A4:2013). Arlington, VA: Author.
- Association of periOperative Registered Nurses (AORN). (2015). *Guidelines for perioperative practice*. Denver, CO: Author.
- Center for Biofilm Engineering at Montana University. (2011). *BIOFILMS: The hypertextbook*. V4.3. Retrieved from <http://www.hypertextbookshop.com/biofilmbook/v004/r003/>
- Centers for Disease Control and Prevention (CDC). (2008). *Guideline for disinfection and sterilization in healthcare facilities*. Retrieved from http://www.cdc.gov/hicpac/Disinfection_Sterilization/13_0Sterilization.html
- Centers for Disease Control and Prevention (CDC). (2015a). *CDC statement: Los Angeles County/UCLA investigation of CRE transmission and duodenoscopes*. Retrieved from <http://www.cdc.gov/hai/outbreaks/cdcstatement-LA-CRE.html>
- Centers for Disease Control and Prevention (CDC). (2015b). *Interim protocol for healthcare facilities regarding surveillance for bacterial contamination of duodenoscopes after reprocessing*. Retrieved from <http://www.cdc.gov/hai/organisms/cre/cre-duodenoscope-surveillance-protocol.html>
- Centers for Disease Control and Prevention (CDC). (2015c). *Procedure-associated events: Surgical site infection (SSI) event*. Retrieved from <http://www.cdc.gov/nhsn/PDFs/pscManual/9pscSSICurrent.pdf>
- Dancer, S. J., Stewart, M., Coulombe, C., Gregori, A., & Verdi, M. (2012). Surgical site infections linked to contaminated surgical instruments. *Journal of Hospital Infection*, 81(4), 231–238.
- Facility Guidelines Institute. (2014). *Guidelines for design and construction of hospitals and outpatient facilities*. Chicago, IL: American Hospital Association.
- Favero, M., & Bond, W. (2001). Chemical disinfection of medical and surgical materials. In S. S. Block (Ed.), *Disinfection, sterilization, and preservation* (5th ed., pp. 881–915). Philadelphia, PA: Lippincott Williams & Wilkins.
- Henning, C. (Ed.). (2011). *Care and handling of ophthalmic microsurgical instruments* (3rd ed.). San Francisco, CA: American Society of Ophthalmic Registered Nurses.
- Occupational Safety and Health Administration (OSHA). (2012a). *Toxic and hazardous substances: Bloodborne pathogens*. Retrieved from http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051

- Occupational Safety and Health Administration (OSHA). (2012b). *Toxic and hazardous substances: Ethylene oxide*. Retrieved from https://www.osha.gov/pls/oshaweb/owadispl.show_document?p_table=standards&p_id=10070
- Perkins, J. J. (1969). *Principles and methods of sterilization*. Springfield, IL: Charles C. Thomas.
- Petersen, B., Chennat, J., Cohen, J., Cotton, P. B., Greenwald, D. A., Kowalski, T. E., . . . Rutala, W. A. (2011). Multisociety guideline on reprocessing flexible GI endoscopes. *Infection Control and Hospital Epidemiology*, 32(6), 527–537.
- Rutala, W., & Weber, D. (2010). Guideline for disinfection and sterilization of prion-contaminated medical instruments. *Infection Control and Hospital Epidemiology*, 31(2), 107–117. Retrieved from http://www.shea-online.org/Assets/files/other_papers/Prion.pdf
- Saito, Y., Kobayashi, H., Uetera, Y., Yasuhara, H., Kajiura, T., & Okubo, T. (2013). Microbial contamination of surgical instruments used for laparotomy. *American Journal of Infection Control*, 42, 43–47. Retrieved from <http://www.ajicjournal.org/article/S0196-6553%2813%2901102-4/pdf>
- Society of Gastroenterology Nurses and Associates (SGNA). (2013). *Guideline for use of high level disinfectants & sterilants for reprocessing flexible gastrointestinal endoscopes*. Retrieved from http://www.sgna.org/Portals/0/Issues/PDF/Infection-Prevention/6_HLDGuideline_2013.pdf
- U.S. Department of Health and Human Services (HHS). (2013). *National action plan to prevent health care-associated infections: Roadmap to elimination*. Retrieved from http://www.health.gov/hcq/prevent_hai.asp#hai
- U.S. Food and Drug Administration (FDA). (2000). *Guidance document: Enforcement priorities for single-use devices reprocessed by third parties and hospitals*. Retrieved from <http://www.fda.gov/regulatoryinformation/guidances/ucm107164.htm>
- World Health Organization (WHO). (2003). *WHO manual for surveillance of human transmissible spongiform encephalopathies including variant Creutzfeldt-Jakob disease*. Retrieved from <http://www.who.int/bloodproducts/TSE-manual2003.pdf>

Post-Test

Read each question carefully. A question may have more than one correct answer.

1. Disinfection differs from sterilization in what way?
 - a. High-level disinfection and sterilization are the same.
 - b. Sterilization kills all spores; disinfection does not.
 - c. High-level disinfection kills vegetative bacteria; sterilization does not.
 - d. Disinfection and sterilization both kill microorganisms, but only disinfection kills high numbers of spores.
2. Which of the following definitions is correct?
 - a. Bioburden represents the population of viable organisms on an item.
 - b. A Bowie-Dick test demonstrates that air and noncondensable gases are adequately removed from the chamber of any steam sterilizer.
 - c. An autoclave is another term for any sterilizer.
 - d. A chemical indicator is a sterilization monitor with a known population of resistant spores.
3. Which of the following statements is/are true?
 - a. Surgical-site infections are responsible for increased length of stay and increased healthcare costs.
 - b. Contaminated surgical instruments are a known source of infection.
 - c. Perioperative diagnoses include increased risk for infection.
 - d. Sterilization and disinfection are cornerstones of infection prevention.
4. Which of the following is the most valid reason for the perioperative nurse to have a comprehensive knowledge of instrument processing?
 - a. Perioperative nurses rotate through the SPD and need to be prepared.
 - b. Perioperative nurses must have a frame of reference when they are complaining to the SPD about instruments.
 - c. The perioperative nurse is a partner in instrument processing and assumes varying degrees of responsibility for the care and preparation of instruments.
 - d. There is an instrument-processing department in most operating rooms.
5. Critical items
 - a. contact sterile tissue and the vascular system.
 - b. must undergo high-level disinfection.
 - c. do not penetrate mucous membranes.
 - d. include thermometers, crutches, and blood pressure cuffs.
6. Semicritical items include
 - a. surgical instruments.
 - b. cystoscopes and laryngoscopes.
 - c. blood pressure cuffs and crutches.
 - d. warming blankets and sequential compression devices.
7. The sterility assurance level is
 - a. the number of organisms killed during sterilization.
 - b. the amount of time it takes to kill 1 million organisms.
 - c. a mathematical expression of the time, temperature, and pressure needed to kill microorganisms.
 - d. a mathematical expression of the probability of a viable microorganism being present on an item after sterilization.

8. Spores are used to test for sterility because they are
 - a. more resistant than any other bacteria to heat, drying, and chemicals.
 - b. easier to process, incubate, and analyze.
 - c. larger than bacteria and easier to see.
 - d. a form of bacteria that is also representative of viruses and fungi.
9. The choice of sterilization technology for an item depends first on
 - a. what is most convenient for the facility.
 - b. what is least expensive and readily available.
 - c. the compatibility of the item with the sterilization process.
 - d. the type of wrapping that must be used for sterilization.
10. For an item to be successfully steam sterilized
 - a. it must be sequentially wrapped and placed upright in the sterilizer.
 - b. steam must penetrate the packaging completely and the intended parameters of moisture, temperature, and time must be met.
 - c. it must be subjected to unsaturated steam for the appropriate amount of time and under the correct amount of pressure.
 - d. the temperature must remain at 250°F at atmospheric pressure for the proper amount of time.
11. Which statement(s) is/are true about steam sterilization?
 - a. Moist heat under pressure is economical.
 - b. Steam sterilization denatures and coagulates protein.
 - c. Steam sterilization occurs at atmospheric pressure.
 - d. Parameters of steam sterilization include time and temperature.
12. What are some advantages of steam sterilization?
 - a. One cycle time is appropriate for all items.
 - b. Cycles are preprogrammed to prevent operator error.
 - c. It is economical and sterilization is achieved quickly.
 - d. It is suitable for all surgical instruments.
13. Which statement(s) is/are true about autoclaves?
 - a. Air trapped in the chamber will interfere with sterilization.
 - b. Sterilization begins only when the correct temperature has been reached.
 - c. Cups and basins must be placed so that water will collect in them and form steam.
 - d. Wrapped packages should be removed from the sterilizer immediately and allowed to cool for at least 2 hours.
14. How might trapping of air in a steam autoclave interfere with sterilization?
 - a. The presence of air forces the temperature above the target range.
 - b. Air in the chamber prevents the sterilizer from reaching the target pressure.
 - c. Air interferes with the humidity level in the chamber.
 - d. Trapped air acts as an insulator that interferes with heating and prevents contact of steam with every surface of every item.

15. Which statement(s) is/are true about steam sterilizers?
 - a. A Bowie-Dick test is done once each day in all gravity-displacement sterilizers.
 - b. Exposure time in a prevacuum sterilizer is longer because it takes a while to create the vacuum.
 - c. Prevacuum sterilizers are used for liquids.
 - d. Prevacuum sterilizers are less affected by incorrect arrangement of objects in the chamber.
16. Which statement(s) is/are true about immediate-use steam sterilization?
 - a. IUSS is not intended for sterilizing sets of instruments.
 - b. IUSS is intended for urgent situations in which there is no sterile replacement for an item that has been contaminated.
 - c. Drying time is the same in IUSS as with regular sterilization.
 - d. In an emergency, items can be rinsed in the scrub sink and sterilized with IUSS.
17. Which statement(s) is/are true about immediate-use steam sterilization?
 - a. IUSS is perfect for implants that arrive immediately before a procedure.
 - b. IUSS is not an alternative to purchasing an adequate supply of instruments.
 - c. IUSS is appropriate when there is only one specialty set of instruments.
 - d. IUSS can be done only in a prevacuum sterilizer.
18. Which statement(s) is/are true about immediate-use steam sterilization?
 - a. Only devices with manufacturer's IFU for IUSS should be sterilized in this manner.
 - b. Proper cleaning is critical to effective sterilization with IUSS.
 - c. OSHA validates specific rigid containers for IUSS.
 - d. Any rigid container can be used for IUSS.
19. The two most challenging factors involved with processing items using IUSS are that
 - a. most device manufacturers don't validate their items for IUSS.
 - b. aseptic transfer of the sterilized item to the sterile field may require traversing an unsterile area.
 - c. many operating rooms don't have a cleaning process equivalent to the sterile processing department.
 - d. the IUSS sterilizer is small and it takes too long to process trays of instruments between procedures.
20. What are some advantages of H₂O₂ sterilization?
 - a. Items to be sterilized can be wrapped in any material.
 - b. There is a single cycle for all items.
 - c. There are no toxic residues remaining following the cycle.
 - d. Cycle times are preset and the sterilizer is easy to operate.
21. The spore used to monitor H₂O₂ sterilization is
 - a. *Bacillus atrophaeus*.
 - b. *Geobacillus atrophaeus*.
 - c. *Geobacillus stearothermophilus*.
 - d. *Bacillus subtilis*.
22. Which packaging materials can be used for H₂O₂ sterilization?
 - a. Muslin wrappers
 - b. Tyvek pouches
 - c. Polypropylene wraps
 - d. Paper pouches

23. Which statement(s) is/are true about ethylene oxidesterilization?
- EtO is a toxic gas that must be closely monitored and vented.
 - EtO is appropriate for items that cannot tolerate the temperature and moisture of steam sterilization.
 - EtO provides a rapid cycle and is the sterilization option of choice when heat- and moisture-sensitive items are required quickly.
 - Aeration must be done for all loads sterilized using EtO.
24. Which statement(s) is/are true about liquid chemical processing?
- It is a low-temperature, nonterminal process.
 - Items must be used immediately following processing; they cannot be packaged or stored for later use.
 - Only one flexible endoscope can be processed at a time.
 - Peracetic acid disrupts protein bonds and inactivates cell systems, causing immediate cell death.
25. Which statement(s) is/are true about liquid chemical processing?
- The unit has connectors to insure circulation of sterilant through lumens.
 - The units must be vented and therefore are not very portable.
 - The process is lengthy, taking nearly an hour to complete a cycle.
 - There is no biological monitor appropriate for monitoring peracetic acid.
26. Which statement(s) is/are true about sterilization monitoring?
- Physical monitors record activities within the sterilizer chamber.
 - Chemical indicators exhibit a visual change when sterilization has been achieved.
 - A chemical indicator should be placed both on the inside and on the outside of each package.
 - The nurse relies on the outside indicator to determine whether the contents of a sterilized package are sterile.
27. A Class 5 indicator is a(n)
- process indicator that demonstrates an item has been exposed to the sterilization process.
 - single-parameter indicator designed to react to one of the critical parameters of the sterilization process.
 - integrator that reacts to all of the critical parameters of the sterilization process.
 - emulator that reacts to all parameters of the sterilization process and is cycle specific.
28. Which statement(s) is/are true about biological indicators?
- A biological indicator is the most accurate method of establishing that items within the load have been sterilized.
 - A biological indicator contains a known quantity of a highly resistant virus.
 - A biological indicator must be incubated before it can be read.
 - A biological indicator should be contained within a process challenge device (PCD) for cycles used for terminal sterilization.
29. Which statement(s) is/are true about a “failed load”?
- It should be reported immediately, the load quarantined, and the cause of failure researched.
 - Failure can be caused by incorrect packaging, incorrect cycle, items incompatible with the process, or incorrect placement within the sterilizer.
 - When the cause of failure is unknown, all items from the failed load must be located and recalled for reprocessing.
 - Items from a failed load that have already been used in or for a patient must be reported to The Joint Commission.

30. Documentation of sterilization should include
 - a. a supervisor's signature for every sterilizer load.
 - b. a list of each item included in the sterilizer load.
 - c. indication that biological tests were run in every sterilizer twice a day.
 - d. Bowie-Dick test results for gravity-displacement sterilizers.
31. A biofilm
 - a. consists of microorganisms living within a polysaccharide matrix that adheres to a surface.
 - b. prevents sterilant from reaching the microorganisms incorporated within the glycocalyx.
 - c. prevents antibiotics from reaching cells.
 - d. is readily dissolved by disinfectants.
32. Which statement(s) is/are true?
 - a. In the operating room, any item that is not sterile is considered contaminated.
 - b. Following surgery, items on the sterile field that have not come in contact with the patient are processed separately from the ones that were used.
 - c. Decontamination is a process that renders a contaminated item safe for handling.
 - d. Decontamination is an automated process.
33. Which statement(s) is/are true about nursing responsibilities?
 - a. Cleaning, packaging, and storing of sterile supplies requires judgment and an understanding of scientific principles.
 - b. The SPD processes instruments and supplies and makes the final determination of what is sterile and what is not.
 - c. The perioperative nurse may assume primary responsibility for high-level disinfection and IUSS.
 - d. Assuming responsibility for ensuring that all instruments and supplies delivered to the sterile field are, in fact, sterile is part of the perioperative nurse's commitment to advocating for patient safety.
34. Sterilization is required for
 - a. all semicritical items.
 - b. all instruments that contact mucous membranes.
 - c. all instruments that penetrate mucous membranes.
 - d. anything used in the operating room.
35. The first and most important step in instrument decontamination is
 - a. disinfecting with an enzyme soak.
 - b. cleaning
 - c. decontamination.
 - d. sterilization.
36. How should instruments be managed after a surgical procedure?
 - a. Separate the used from the unused instruments.
 - b. Close all clamps and scissors to protect the tips and blades.
 - c. Use enzymatic spray or gel to prevent debris from drying.
 - d. Store contaminated instruments in a safe place before returning them to the SPD at the end of the day.

37. What should be used to keep instruments clean on the sterile field?
- Soak them in a basin of normal saline.
 - Wipe them with a moist sponge.
 - Spray them with an enzymatic detergent.
 - Wipe or flush them with sterile water.
38. Which statement(s) is/are true about instrument cleaning?
- An instrument can be clean, but not sterile.
 - An instrument can be sterile, but not clean.
 - Instruments opened for a procedure should be cleaned immediately following the procedure, whether they were used or not.
 - Instruments should be kept as clean as possible on the sterile field.
39. Which statement(s) is/are true about postoperative cleaning?
- Used instruments from a set should be returned to the set before returning them to the SPD.
 - Blood and debris allowed to dry on instruments can cause rusting and pitting.
 - Instruments for IUSS can be washed in the scrub sink.
 - Instruments can remain in water safely for an unlimited period of time.
40. Before instruments are sent to the SPD
- remove disposable sharps and discard them in a sharps container.
 - reusable drill bits should be wiped clean.
 - heavy instruments should be placed on the bottom of the tray, with lighter instruments on the top.
 - scissors and clamps should be closed to protect blades and tips.
41. Which statement(s) is/are true about manual cleaning?
- It should be done where required supplies and equipment are available.
 - A higher concentration of detergent is necessary to remove heavy debris.
 - Brushes, syringes, and compressed air should be available.
 - Instruments should first be washed in hot water.
42. Immersible items should be cleaned below the surface of the water
- to be sure that all surfaces are wet.
 - to drown microorganisms.
 - to prevent aerosolization of debris.
 - to avoid wasting water.
43. Which statement(s) is/are true about TASS?
- TASS is caused by foreign matter that is not removed from instruments during cleaning and sterilization.
 - TASS is a noninfectious inflammation of the anterior segment of the eye.
 - TASS can result in permanent visual impairment.
 - Endotoxins from bacteria in ultrasonic cleaners have been associated with TASS.
44. Which statement(s) is/are true about prions?
- A prion is an infectious protein particle.
 - Creutzfeldt-Jakob disease, a prion disease of the central nervous system, is always fatal.
 - Prions can be managed by routine sterilization and disinfection routines.
 - Brain, spinal cord, and dura mater are considered high-risk tissues for transmission of prion disease.

45. Instruments that are exposed to tissue at high risk for prions should be
 - a. kept dry until cleaned or contaminated.
 - b. kept separate from instruments not exposed to high-risk tissue.
 - c. cleaned with all other instruments as soon as possible following the procedure.
 - d. soaked overnight in a phenolic solution.
46. Which statement(s) is/are true about ultrasonic cleaning?
 - a. Ultrasonic cleaning is used to flush all ports and articulations of robotic instruments.
 - b. Ultrasonic cleaning removes tenacious debris through cavitation.
 - c. Cavitation is the implosion of bubbles generated by sound waves.
 - d. Ultrasonic cleaning is especially well suited to removing debris from lensed and powered instruments.
47. Which statement(s) is/are true about ultrasonic cleaning?
 - a. Only instruments of the same type of metal should be processed at one time.
 - b. It is especially useful for difficult-to-clean instruments.
 - c. Instruments do not need to be free of gross soil before immersion in the ultrasonic cleaner.
 - d. Instruments that rest on the bottom of the ultrasonic cleaner are subject to the strongest cavitation.
48. Which statement(s) is/are true about lubrication and inspection?
 - a. Oil-based lubricants are most protective and extend instrument life.
 - b. Water-soluble lubricants permit penetration of sterilant.
 - c. Items that are defective should be tagged before being placed in sets.
 - d. Defective instruments can result in injury to the patient.
49. Which statement(s) is/are true about packaging materials?
 - a. Packaging materials must be compatible with the method of sterilization.
 - b. The purpose of packaging material is to maintain sterility of the package contents until their intended use.
 - c. Packaging materials must be able to maintain an adequate seal.
 - d. Packaging materials must allow for aseptic delivery to the field.
50. Which statement(s) is/are true about nonwoven wrappers?
 - a. They are virtually lint free, are tear resistant, and provide excellent barrier protection.
 - b. They are disposable and synthetic.
 - c. They can display memory, creating a potential for contamination when packages are opened.
 - d. The same synthetic wrapper can be used for all sterilization technologies.
51. Which statement(s) is/are true about pouches?
 - a. The same pouch cannot be used for both steam and hydrogen peroxide sterilization.
 - b. Pouches are inexpensive and permit visualization of the contents.
 - c. One side of a pouch is clear and the other side is opaque.
 - d. Plastic/paper and plastic/Tyvek pouches display memory and provide little resistance to puncture.
52. Which statement(s) is/are true about pouches?
 - a. They can hold multiple small items in a sealed inner pouch contained within an outer pouch.
 - b. The inner pouch should be positioned within the outer pouch so that the contents of the inner pouch are visible.
 - c. Pouches should be stacked loosely on top of one another in the autoclave to provide maximum penetration of the sterilant.
 - d. Pouches can be used to contain small items within instrument trays.

53. Which statement(s) is/are true about rigid containers?
- There may be a valve system to permit entry and exit of sterilant.
 - Rigid containers are durable and protect instruments from damage.
 - They are lightweight; an empty container weighs no more than 5 pounds.
 - Cleaning before placing instruments inside a rigid container involves checking gaskets, valves, or filters.
54. Which statement(s) is/are true about packaging for steam sterilization?
- Placing a towel in the instrument set creates condensate and delays drying.
 - The surfaces of all instruments must be exposed to the sterilant.
 - Scissors and clamps must be open to allow contact of sterilant with inner surfaces.
 - Instruments with multiple parts may be assembled to prevent loss or misplacement of the individual pieces.
55. Which statement(s) is/are true about packaging for steam sterilization?
- The combined weight of the tray and instrument cannot exceed 15 pounds.
 - Peel packs are used to contain small items within instrument sets.
 - Pouches used within instrument sets should not be sealed.
 - Basins and bowls should be positioned vertically to prevent pooling of water.
56. Which statement(s) is/are true about low-temperature H₂O₂ sterilization?
- Items must be thoroughly dried before being placed in the sterilizer.
 - Cellulose wrappers cannot be used with H₂O₂ sterilizers.
 - The end products of the sterilization process are oxygen and water vapor.
 - The system is flexible; it has no plumbing or drain and can be plugged in anywhere.
57. Which statement(s) is/are true about low-temperature EtO sterilization?
- EtO sterilizers are not usually located in the operating room because EtO is a human carcinogen and must be closely monitored and vented.
 - Aeration is required so materials can absorb EtO during the sterilization process.
 - Exposure times are relatively short, ranging from 30 to 90 minutes.
 - Proximity to EtO requires monitoring PPE because exposure is irritating.
58. Which statement(s) is/are true about process indicators?
- A process indicator shows that a package has been exposed to the sterilization process.
 - A process indicator is placed at the very center of the package or instrument set.
 - Pouches sometimes have a built-in process indicator.
 - Pouches with a built-in process indicator do not need a second chemical indicator.
59. What are the parameters of steam sterilization?
- Steam concentration, time, pressure
 - Relative humidity, time, temperature
 - Steam concentration, relative humidity, time
 - Time, temperature, steam quality
60. What are the parameters for H₂O₂ sterilization?
- Relative humidity, H₂O₂ concentration, time
 - H₂O₂ concentration, time, pressure
 - Time, pressure, temperature
 - H₂O₂ concentration, pressure, time, temperature

61. Which statement(s) is/are true about indicators?
- One or more chemical indicators should be placed inside of each sterile package.
 - There should be an indicator on each layer of a sterile multilevel set.
 - An indicator that functions properly will ensure that the set is sterile.
 - If the indicator is questionable or the internal indicator is missing, the set can be used if the process indicator on the outside of the pack demonstrates that the set has been exposed to the parameters of sterilization.
62. Which statement(s) is/are true?
- A pouch that has been opened but not used can be resealed if the type of seal permits it.
 - The assembler must label the package clearly with the contents and initials of the assembler.
 - Lot control numbers can be used to track packaged items from a “failed load.”
 - Packages should be marked on the paper side of the pouch.
63. Which statement(s) is/are true about shelf life?
- Solid steel shelving is preferable to mesh shelving because it is durable and supports heavy sets.
 - Shelves should be 8 to 10 inches above the floor and at least 18 inches from the ceiling or sprinkler head.
 - Shipping cartons should be placed on lower shelves to avoid contaminating sterile items.
 - Expiration dates on commercial packages indicate that the contents’ integrity may degrade and should not be used after the expiration date has been reached.
64. Which statement(s) is/are true about shelf life?
- When clean and sterile items are stored in the same unit, clean items should be on the uppermost shelves.
 - Shelf life is the amount of time following sterilization that an item can be considered sterile.
 - Poor-quality wrappers, poor storage conditions, and inappropriate handling of sterile items can increase the likelihood of contamination.
 - Event-related sterility is based on the theory that an item remains sterile until something contaminates it.
65. Which statement(s) is/are true about reuse of single-use devices?
- The FDA holds facilities that choose to reprocess single-use devices to the same standards as the original manufacturer of the item.
 - Perioperative nurses should choose single-use items carefully for resterilization, inspecting them carefully for contamination.
 - Items opened but not delivered to the field are not considered contaminated and can be resterilized.
 - The facility’s infection preventionist can determine which single-use items can be resterilized.

Competency Checklist: Instrument Processing

Under “Observer’s Initials,” enter initials upon successful achievement of competency. Enter N/A if competency is not appropriate for institution.

Name _____

	Observer’s Initials	Date
Point of Use		
1. Items are rinsed/wiped/irrigated during the procedure.	_____	_____
2. Disposable sharps and trash are discarded appropriately.	_____	_____
3. All instruments are returned to proper sets for return to SPD.	_____	_____
4. Enzymatic soak solution, spray, or gel is applied before transport to the decontamination area.	_____	_____
5. Contaminated instruments are contained during transportation to the decontamination area.	_____	_____
Cleaning		
6. Personal protective equipment is worn during cleaning.	_____	_____
7. Items requiring cleaning by hand are separated from those going to the washer/disinfector.	_____	_____
8. Manual cleaning:		
a. Detergent is prepared according to IFU.	_____	_____
b. Spray nozzle is held close to instruments in sink to avoid splashing.	_____	_____
c. Manual cleaning is performed under the surface of the water to avoid aerosolization.	_____	_____
d. Proper approach is selected for decontamination of equipment according to IFU.	_____	_____
9. Washer/disinfector is properly used.	_____	_____
a. Appropriate items are selected for washer/disinfector.	_____	_____
b. Machine is loaded properly.	_____	_____
10. Ultrasonic cleaner is loaded properly (single layer; same type of metal).	_____	_____
11. Appropriate instruments are lubricated.	_____	_____
12. Instruments are inspected for cleanliness and good condition; all components are present.	_____	_____
Packaging		
13. Rigid containers are inspected and assembled appropriately:		
a. Caskets and inner baskets are thoroughly cleaned between uses.	_____	_____
b. Gaskets, valves, and filters are checked prior to placement of instruments.	_____	_____
c. Following assembly, the lock is placed and contents are identified.	_____	_____
14. Instrument sets are assembled properly.	_____	_____
a. Items are placed in a tray/container compatible with the sterilization method.	_____	_____
b. Multi-part instruments are disassembled.	_____	_____
c. Hinged instruments are opened.	_____	_____
d. Small, multi-part, and delicate instruments are organized in appropriate containers (no peel packs).	_____	_____
e. Heavy items are on bottom; more delicate on top.	_____	_____
f. Items with broad surfaces are placed on edge.	_____	_____
g. Nested items are separated with porous material and placed facing the same direction.	_____	_____
15. Appropriate chemical indicator(s) are in place.	_____	_____
16. Set is wrapped properly in packaging material appropriate to the method of sterilization.	_____	_____
17. Package is sealed with the appropriate process indicator.	_____	_____
18. Package is labeled with contents and initials.	_____	_____

Sterilization

- 19. Appropriate method of sterilization is identified for each item. _____
- 20. Appropriate process indicator is confirmed on outside of package. _____
- 21. Load lot sticker is placed on each item in the load. _____
- 22. Chamber is loaded properly so that sterilant can contact surfaces of all items. _____
 - a. Heavy trays lie flat in a single layer. _____
 - b. Small wrapped packages are loosely stacked. _____
 - c. Peel packs are placed on edge and all facing in the same direction. _____
 - d. Basins (anything that can trap moisture) are placed on edge to promote draining. _____
- 23. Appropriate sterilization cycle is chosen. _____
- 24. Sterilizer is operated according to the manufacturer’s instructions. _____
- 25. When sterilization is complete: _____
 - a. Printout/to is reviewed to insure all parameters achieved. _____
 - b. Package is allowed to cool before it is removed from autoclave and distributed. _____

Immediate-Use Steam Sterilization (IUSS)

- 26. Items are cleaned properly (IFU) before sterilization. _____
- 27. Appropriate container is selected for sterilization. _____
- 28. Correct sterilization cycle is chosen for item. _____
- 29. Inspection of printout: _____
 - a. Patient information is included. _____
 - b. Printout is signed or initialed. _____
- 30. Sterile item is transported aseptically to sterile field. _____

Sterilization Monitoring

- 31. Demonstrates or verbalizes the process for running a Bowie-Dick/DART sterilization monitor: _____
 - a. Correct autoclave (dynamic air removal) _____
 - b. Correct monitor _____
 - c. Correct placement of monitor (IFU) _____
 - d. No other items in autoclave during test run _____
 - e. Documentation correct _____
- 32. Demonstrates or verbalizes the process for running a biological monitor: _____
 - a. Appropriate monitor _____
 - b. Correct placement of monitor (IFU) _____
 - c. Prepares ampoule and incubates monitor correctly _____
 - d. Documents results correctly _____
 - e. Verbalizes the process following a failed monitor _____
- 33. Demonstrate or verbalizes the documentation process for each sterilizer load: _____
 - a. Envelope for each sterilizer to contain sterilization documentation for a 24-hour period _____
 - b. Results of Bowie-Dick testing _____
 - c. Results of biological monitoring _____
 - d. Documentation of each load _____
 - i. Sterilizer printout for each load _____
 - ii. Load lot sticker _____
 - iii. Load list _____
 - iv. Chemical indicator (if run in load) _____
 - v. Biological indicator (if run in load) _____

High-Level Disinfection

- 34. Demonstrates or verbalizes the process for high-level disinfection. _____
- 35. Appropriate items are identified for high-level disinfection. _____
- 36. Appropriate personal protective equipment (PPE) is donned during preparation and use of disinfectant. _____
- 37. Disinfectant is properly prepared (IFU). _____

- 38. The minimum effective concentration (MEC) test is performed and results are documented. _____
- 39. Items are disinfected properly: _____
 - a. Appropriately washed and dried before being disinfected _____
 - b. Rinsed after being disinfected and before use _____
 - c. Handled so as to prevent contamination _____
- 40. Documentation is appropriate. _____

Storage

- 41. The fire safety/AAMI criteria for locating shelving in sterile storage is verbalized. _____
- 42. Sterile items are protected from being compressed, dropped, ripped, or getting wet. _____
- 43. Sterile items are shelved so that those sterilized first are first in line for use. _____
- 44. Heavy sets are placed on center shelves; stacking heavy packages is avoided. _____
- 45. Peel packs are stored in a container to protect and organize them. _____

Observer's Signature _____ Initials _____ Date _____

Orientee's Signature _____

