

3

Prevention of Infection

Preparation of Instruments and Items Used in Surgery: Sterilization and Disinfection

LEARNER OBJECTIVES

1. Identify the critical factors that determine whether an item must be sterile or whether disinfection is sufficient.
2. Describe at least four methods of sterilization.
3. Discuss critical factors that determine selection of the appropriate sterilization method and cycle.
4. Discuss advantages and disadvantages of each method of sterilization.
5. Identify methods for monitoring sterilization and disinfection processes.



LESSON OUTLINE

- I. Desired Patient Outcomes
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Desired Patient Outcomes

1. Freedom from infection is a critical desired patient outcome.
2. 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 and cost of care, increased pain and suffering, and even death. SSIs have also been shown to increase mortality, readmission rates, and length of stay (Institute for Healthcare Improvement [IHI], 2012).

3. Surgical-site infections are the second leading cause of hospital-associated infections, following urinary tract infections; they account for 17% of all hospital-acquired infections (Centers for Disease Control and Prevention [CDC], 2012). SSIs can double the cost of a surgical experience (Alexander et al., 2011). It is estimated that 750,000 to 1 million SSIs occur in the United States each year, requiring 3.7 million extra hospital days and costing more than \$1.6 billion in excess hospital charges (Edmiston et al., 2011).
4. Skin is the body's first line of defense against infection. Surgical incisions interrupt skin integrity, providing a portal of entry for pathogenic microorganisms. Invasive drains, catheters, and monitors also alter skin integrity and contribute to the risk for infection.
5. Perioperative nursing activities are directed toward preventing infection, with the desired outcome that the patient will be free from infection following the operative procedure.
6. Pathogenic microorganisms are capable of causing disease when they invade human tissue. Invasive surgical procedures increase a patient's risk of getting an infection by giving bacteria a route into normally sterile areas of the body. Contaminated surgical instruments are a potential source of surgical-site infections (Linkin et al., 2005, pp. 1014–1015). Every effort must be made to remove microorganisms from articles and instruments that contact human tissue during surgical interventions.
7. Sterilization and disinfection—the cornerstones of infection control—are processes used to destroy microorganisms. Preventing infection requires the perioperative nurse to have an in-depth understanding of principles and practices of sterilization and disinfection.
8. Advances in surgical techniques have resulted in the proliferation and routine use of a wide variety of complex, sophisticated, and expensive surgical instrumentation. For example,

Definitions

Autoclave: A steam sterilizer.

Bioburden: A population of viable microorganisms on a product.

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 and that steam can penetrate a specified pack.

Chemical indicator: A device used to monitor one or more process parameters in the sterilization cycle. The device responds with a 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.

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.

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.”

Spore: An inactive or dormant, but viable, state of a microorganism, which is notably 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.

fiber-optic and robotic instruments costing many thousands of dollars are standard components of many procedures.

9. Cleaning, disinfection, and sterilization procedures are determined by the composition and configuration of the instrumentation, which dictate its compatibility with the disinfection and sterilization methods available within the healthcare facility. Manufacturers' instructions for processing of instruments and devices must be considered when purchasing and processing decisions are made.
10. Most instrument processing is performed by ancillary personnel; however, the perioperative nurse is a partner in this process and assumes varying degrees of responsibility for the care and preparation of instruments. Selecting the appropriate method of processing requires a broad knowledge of disinfection and sterilization principles and procedures.
11. When disinfection and sterilization are accomplished within the operating room department, it is often the perioperative nurse who is responsible for the process.

Sterilization and Disinfection

Critical, Semicritical, and Noncritical Items

12. How an instrument should be processed depends on its intended use. The Spaulding classification of devices, developed in 1968 by Earle Spaulding, was adopted by the Centers for Disease Control and Prevention (CDC). It categorizes devices as critical, semicritical, or noncritical (AORN, 2012, p. 473). This categorization is used today to determine whether an item must be sterilized or whether disinfection is sufficient.

Critical Items: Examples

13. Critical items come in contact with sterile tissue or the vascular system (i.e., devices introduced beneath a mucous membrane). These items must be sterile—that is, all living microorganisms, including spores, must be destroyed.
14. Critical items contaminated with microorganisms present a high risk of infection.
15. Examples of critical items include surgical instruments, orthopedic implants, sutures, and cardiac catheters.

Semicritical Items: Examples

16. Items that contact unbroken mucous membranes but do not penetrate them are considered semicritical items. Semicritical items may be sterile but must at least be high-level disinfected.
17. Examples of semicritical items include thermometers, cystoscopes, laryngoscope blades, and dental dams.

Noncritical Items: Examples

18. Noncritical items contact intact skin and require only low-level disinfection or cleaning.
19. Examples of noncritical items include crutches, blood pressure cuffs, and stethoscopes.

Sterility Assurance Level

20. The process of sterilization provides the greatest assurance that items are sterile (i.e., free of known and unsuspected microorganisms).
21. Devices sterilized for use 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 level of sterility assurance. For example, in some industries, a sterility assurance of 10^{-3} (one chance in 1000) might be acceptable.
22. In addition to the requirement for such a high level of sterility assurance, manufacturers of sterilizers must demonstrate that the sterilizer kills 1 million spores in half the programmed exposure time. For example, if the exposure phase in the sterilization cycle (the time within the cycle when the parameters required for sterilization are achieved) is programmed for 4 minutes, the sterilizer manufacturer must demonstrate that the kill is achieved in 2 minutes. In other words, 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).
23. Certain pathogenic bacteria such as *Clostridium tetani* (which produces tetanus), *Clostridium perfringens* (which results in gas gangrene), and *Clostridium difficile* are capable of developing spore forms. The environmental

conditions that facilitate spore formation are unknown; however, spores can remain alive for many years. When conditions are favorable for growth, such as when the spore is permitted entry into the body, the spore will germinate to produce a vegetative cell.

24. Spores are more resistant than other bacteria to heat, drying, and chemicals. In fact, they can survive even after long exposure to these processes.
25. Disinfection—a process that kills all living microorganisms, with the exception of high numbers of bacterial spores—does not provide the margin of safety associated with sterilization. Disinfectants vary in their ability to destroy microorganisms and are classified according to their cidal activity (i.e., their ability to kill microorganisms).
26. Only sterilization can render an item free of all microorganisms, including spores.

Section Questions



1. Which factors determine the appropriate processing method for an item? [Ref 12]
2. Define “critical items” according to the Spaulding classification. [Ref 13]
3. Give three examples of items that would be considered “critical” according to the Spaulding classification. [Ref 15]
4. Define “semicritical items” according to the Spaulding classification. [Ref 16]
5. Which level(s) of processing are appropriate for semicritical items? [Ref 16]
6. Give three examples of semicritical items. [Ref 17]
7. Define “noncritical items” according to the Spaulding classification. [Ref 18]
8. Which level of processing is appropriate for noncritical items? [Ref 18]
9. Give three examples of noncritical items. [Ref 19]
10. Explain the meaning of the sterility assurance level of 10^{-6} that is required for items sterilized for use in surgery. [Ref 21]
11. If a sterilization cycle in surgery is 4 minutes, at which point in the cycle must the manufacturer demonstrate that 1 million spores have been killed? [Ref 22]
12. Why can some pathogenic bacteria such as *Clostridium perfringens* and *Clostridium difficile* be particularly difficult to kill? [Ref 23]
13. Why are spores used to demonstrate the effectiveness of the sterilization process? [Ref 24]
14. What does “cidal activity” mean? [Ref 25]
15. What is the only level of processing for instruments that can render an item free of all microorganisms, including spores? [Ref 26]

Methods of Sterilization

Overview

27. The choice among methods of sterilization depends on the compatibility of the item to be sterilized with the sterilization process, the configuration of the item, the required equipment, cost, availability, safety factors, packaging of the item, and the length of time of the sterilization process.
28. Steam and ethylene oxide have been used in hospitals for sterilization for more than 50 years. Currently the most commonly used methods of in-house sterilization are steam and hydrogen peroxide gas plasma; the latter has replaced ethylene oxide (EtO) in many facilities. Hydrogen peroxide gas plasma was introduced in the 1990s; hydrogen peroxide vapor and ozone were introduced in the early 2000s. Each method has both advantages and disadvantages.

29. Steam is used for heat- and moisture-stable items. Hydrogen peroxide gas plasma, hydrogen peroxide vapor, O₂, and EtO are appropriate for items that cannot withstand moisture or high temperatures.
30. Two other accepted methods of sterilization are dry heat and ionizing radiation.
31. Because of equipment, safety, and cost considerations, ionizing radiation is confined to industrial settings and is used for bulk sterilization of commercially prepared items.
32. Dry heat is appropriate for powders, oils, and petroleum products that cannot be penetrated by steam or ethylene oxide or other sterilizing agents. Most of these products are supplied in sterile condition from the manufacturer; therefore, dry-heat sterilization is rarely used in hospitals in the United States.

Thermal Sterilization—Steam Under Pressure: Moist Heat

33. 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. It is the most common sterilization method used within healthcare facilities. Sterilization by this method is accomplished in a steam sterilizer referred to as an autoclave.
34. For an item to be sterilized, steam must penetrate every fiber of the packaging and contact every surface of the item. In addition, the intended parameters of moisture, temperature, and time must be met.
35. Steam that is saturated (i.e., contains the greatest amount of water vapor possible) and is heated to a sufficient temperature is capable of destroying all living microorganisms, including spores, within a relatively short amount of time.
36. 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.
37. 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.
38. An increase in pressure of 15 to 17 pounds per square inch will increase steam temperature to 250°F–254°F (121°C–123°C). Twenty-seven pounds of pressure per square inch will increase steam temperature to 270°F (132°C).
39. 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°F–275°F (132°C–135°C), although 250°F (121°C) is also used (Association for the Advancement of Medical Instrumentation [AAMI], 2011, p. 63).
40. 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).

Advantages of Steam Sterilization

41. Steam sterilization has many advantages:
 - Steam is readily available (most often supplied from the healthcare facility boiler).
 - Steam is economical.
 - Steam sterilization is fast—destruction of most resistant spores occurs quickly.
 - Steam is compatible with most in-house packaging materials.
 - Steam leaves no toxic residue and is environmentally safe.
 - Steam sterilization is suitable for a wide range of surgical instrumentation. (The majority of items used for surgery can withstand repeated steam sterilization without sustaining damage.)

Disadvantages of Steam Sterilization

42. Steam sterilization is also associated with several disadvantages:
 - A variety of instruments and devices used in surgery cannot withstand moist heat at temperatures of 250°F (121°C) or higher.
 - Steam sterilization is prone to operator error with regard to preparation and packaging of items, cycle selection, setting of parameters, and loading of the autoclave.
 - Timing of the sterilization cycle must be adjusted based on the type of cycle, variances in materials, device configuration, and size of the load.
 - A temperature of 270°F cannot be used to sterilize all items. The temperature may need to be reduced from 270°F to 250°F to be

compatible with a specific item being sterilized, or the temperature may need to be increased to comply with the manufacturer's instructions.

43. Efficacy of steam sterilization depends on attention to detail. Improper preparation of

items or improper placement within the autoclave can result in trapping of air, which can prevent steam contact with all surfaces and thereby cause inadequate sterilization. Items must be disassembled and thoroughly cleaned for steam to contact all surfaces.

Section Questions



1. Identify at least six factors that influence the choice of sterilization method for a particular item. [Ref 27]
2. What are the most common methods of sterilization at this time? [Ref 28]
3. For which types of items is steam the most appropriate sterilization modality? [Ref 29]
4. Which characteristics of surgical instruments and supplies make them appropriate for sterilization using hydrogen peroxide gas plasma, hydrogen peroxide vapor, ozone, and EtO? [Ref 31]
5. Why are dry-heat sterilization and ionizing radiation confined to industrial settings? [Refs 30–31]
6. Which items would be sterilized with dry heat? [Ref 32]
7. Why is dry-heat sterilization rarely found in hospitals in the United States? [Ref 32]
8. What is an autoclave? [Ref 33]
9. What is the importance of steam contact with every surface of an item to be sterilized? [Ref 34]
10. What are the three parameters involved in steam sterilization? [Ref 34]
11. What are the characteristics of steam required for it to be capable of killing all living microorganisms on an item, including spores? [Ref 35]
12. What is the process through which steam kills microorganisms? [Ref 36]
13. What must be done to increase the temperature of steam sufficiently to kill microorganisms? [Ref 37]
14. What is the minimum steam temperature required for sterilization to occur? [Ref 39]
15. What is the typical temperature used for steam sterilization? [Ref 39]
16. Besides temperature, which factor must be calculated to achieve sterilization? [Ref 40]
17. List the advantages of steam sterilization. [Ref 41]
18. List the disadvantages of steam sterilization. [Ref 42]
19. What are some aspects of steam sterilization prone to operator error? [Ref 42]
20. How does trapped air that can result from improper packaging or improper placement of items in an autoclave affect the sterilization process? [Ref 43]

Steam Sterilizers: Autoclaves

Overview

44. A steam sterilizer, referred to as 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 activated, steam and heat fill the jacket and are maintained at a constant pressure, keeping the autoclave in a heated, ready state (Figure 3-1).
45. 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 the chamber and from the contents of the load. As the pressure rises, steam penetrates the packaging and contacts all surfaces of the item(s) within. The steam forces the air out through a discharge port outlet at the bottom front of the autoclave.



Figure 3-1 Steam sterilizer

Source: Courtesy of Steris Corporation, Mentor, OH.

46. It is essential that all the air in the chamber be displaced by steam. Air that is trapped will act as an insulator that interferes with heating and prevents moisture contact with every surface of every item, thereby compromising the sterilization process. 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.
47. 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.
48. The actual exposure or sterilization time does not begin until the thermometer senses that the steam has reached the necessary preset temperature.
49. If air is not trapped and the parameters of time, moisture, and temperature have been met, microbial destruction will occur.
50. Items such as cups or basins must be placed within the sterilizer so that water will not collect in them and compromise the sterilization process.
51. When the exposure time is complete, the steam is exhausted through the outlet port and, if desired, a drying cycle follows. A drying cycle must always be used for wrapped items.
52. Wrapped packages and instrument containers should be allowed to cool on the sterilizer rack. They should not be touched during this time. A minimum of 30 minutes is recommended, although some instrument sets may require as much as 2 hours to adequately cool (AAMI, 2011, p. 85).
53. 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.
54. Two types of steam sterilizers or autoclaves are used: gravity displacement and dynamic air removal (high vacuum, prevacuum, and pulse pressure). These autoclaves differ in how air is removed from the chamber during the sterilization process.
55. Sterilizers vary in terms of their design and performance characteristics. Some sterilizers offer both a gravity-displacement and a dynamic-air-removal cycle, and some offer only one type of cycle.
56. The nature of the items and the container in which they are sterilized determine the necessary time and temperature for sterilization. There is no single setting that is appropriate for all items. The manufacturers' instructions for use for the items and for the autoclave must be consulted to determine the correct cycle settings.

Gravity Displacement

57. In a gravity-displacement cycle or autoclave, steam replaces the air in the chamber by gravity.
58. 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 3-2).

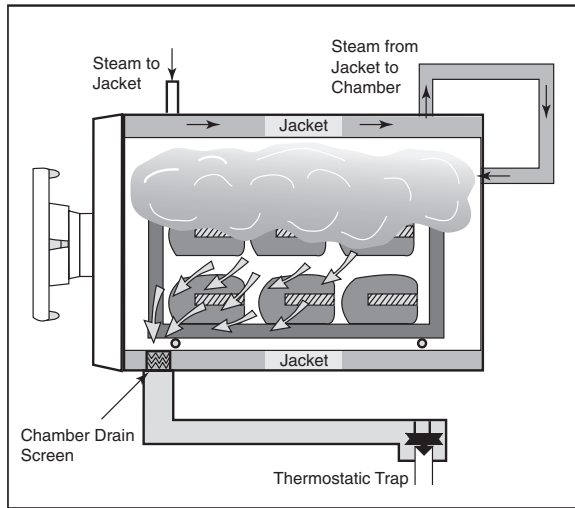


Figure 3-2 Steam sterilizer—steam entry and air removal

Source: Photo courtesy of AMSCO International Inc.

59. Most gravity-displacement autoclaves are operated at temperatures between 250°F and 274°F (121°C–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, 2011, p. 82). Certain powered equipment may require prolonged exposure times of as much as 55 minutes.
 60. 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} .
 61. 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.
 62. Gravity-displacement cycles should not be used when a prevacuum or steam–flush–pressure–pulse cycle is available.
 63. Gravity-displacement sterilizers are common in dentist and physician offices, clinics, and small surgicenters. Sterilizers that operate only with 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 offer gravity-displacement cycles as well).
 64. A gravity-displacement cycle is most appropriate for liquids, although liquids are rarely sterilized within healthcare facilities. Liquids that must be sterile are generally supplied in sterile forms by the manufacturer. Some medical devices, because of their design, may require a gravity-displacement cycle. The device manufacturer’s instructions should be consulted before selecting the cycle type, time, and temperature.
- Dynamic Air Removal (Prevacuum Sterilizer)**
65. 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 but may be longer, essentially creates a vacuum within the chamber. When the steam enters the chamber, the force of the vacuum causes instant steam contact with all surfaces of the contents. Steam will penetrate almost instantly to every surface without regard to the size of the package or load.
 66. Following the prevacuum phase, an exposure time of 3 to 4 minutes at 270°F to 275°F (132°C to 135°C) is the usual recommended time and temperature for accomplishing sterilization (AAMI, 2011, p. 83).
 67. It is imperative that the device manufacturer’s instructions for use be consulted before selecting the cycle time and temperature.
- Extended Cycles**
68. Although a 4-minute exposure time is typically used, required exposure times of 5, 8, and 15 minutes are not uncommon. These cycles are commonly referred to as extended cycles. As the number and types of devices have proliferated, the variety in cycle times has likewise proliferated. Temperature requirements vary from 270°F to 275°F (132°C to 135°C). In other words, one cycle does not fit all devices. The manufacturer’s instructions for sterilization of any instrument will determine the correct cycle. It should not be assumed that a 4-minute exposure at 270°F (132°C) is always appropriate.
 69. If a device calls for an extended exposure 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.

70. An extended cycle of 18 minutes at 270°F (134°C) minutes is also required for instruments exposed to prions (AAMI, 2011, p. 166).
71. 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.
 - The autoclave may be used to a maximum capacity, allowing more supplies to be sterilized within a given time.
72. 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 and inhibit sterilization.

Bowie-Dick Test

73. To test whether air is effectively being eliminated from the chamber, dynamic-air-removal autoclaves are subjected to a Bowie-Dick test on a daily basis. A Bowie-Dick test verifies that air removal is sufficient to achieve steam penetration of a standard load.
74. The Association for the Advancement of Medical Instrumentation recommends this test be performed daily before the first processed load (AAMI, 2011, p. 119).
75. A commercially prepared sheet of paper with various patterns of heat-sensitive ink is used to perform a Bowie-Dick test. The sheet is placed in a specially constructed pack of towels or contained in a commercially prepared package, and is sterilized in an otherwise empty autoclave. A uniform color change indicates successful creation of a vacuum (Figure 3-3).
76. A daily air removal test is another commercially prepared test that may be used to test for air removal.

Steam-Flush-Pressure-Pulse Sterilizer

77. 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.

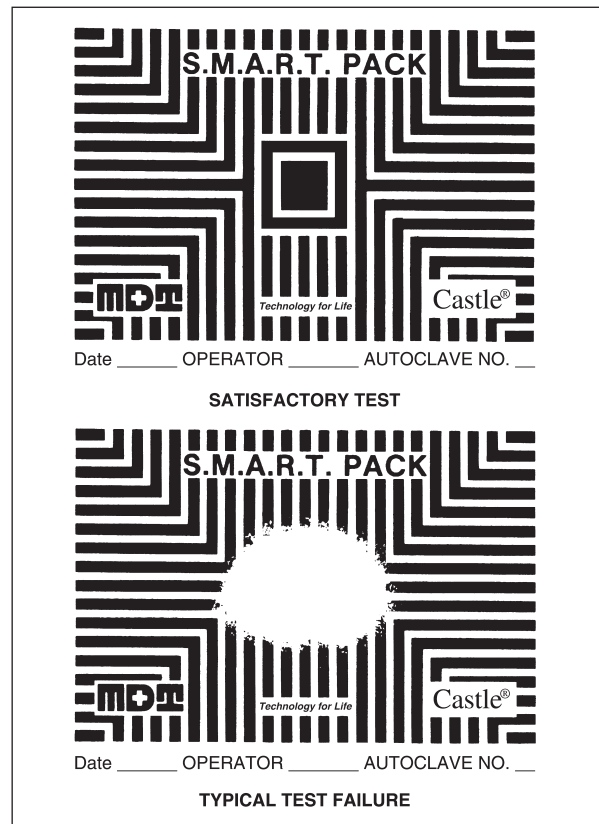


Figure 3-3 Air removal test

Source: Courtesy of MDT Biologic Company, Rochester, NY.

78. A variety of cycle times can be selected, based on the nature of the items to be sterilized.
79. 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

80. “Immediate use” means the shortest possible time between the removal of a sterilized item from the sterilizer and its aseptic transfer to the sterile field. Immediacy implies that a sterilized item is used during the procedure for which it was sterilized, in a manner that minimizes its exposure to air and other environmental contaminants. A sterilized item intended for immediate use is not stored for future use, nor held from one case to another (AAMI, 2011, p. 241).
81. Immediate-use steam sterilization (IUSS) has replaced the term “flash sterilization,” which came from “sterilization in a flash,” meaning it was a quick way to sterilize an unwrapped

- item. “Just in time” sterilization is appropriate only for processing an item needed urgently, and for which there are no replacements immediately available, such as when an item is dropped during surgery and that item is necessary to complete the surgery.
82. IUSS should not be used for routine sterilization of instruments and was never intended for sterilizing whole sets of instruments.
 83. IUSS should be used only in carefully selected, urgent clinical situations and should not be used to sterilize implantable devices (AORN, 2012, p. 550; Mangram et al., 1999). Use of IUSS is discouraged by a number of standards-setting organizations.
 84. 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 (AORN, 2012, p. 500).
 85. Items subject to IUSS have historically been sterilized unwrapped in an open tray. They should, however, be sterilized in containers specifically intended for IUSS. These containers facilitate aseptic delivery of the item to personnel at the sterile field; they are not intended, nor cleared by the US Food and Drug Administration (FDA), for storage of sterilized items for later use. Because there is little or no dry time with an IUSS cycle, items may be wet or moist at the end of the process.
 86. Rigid containers not intended specifically for IUSS should not be used for this process. IUSS cannot be used for items to be terminally sterilized in packaging or containers intended for storage. The sterilization cycle includes dry time, and items may be stored and used at a later date.
 87. IUSS may be done in a gravity-displacement or a dynamic-air-removal (prevacuum or steam-flush–pressure–pulse) sterilizer. The cycle for IUSS is preset by the sterilizer manufacturer according to the type of sterilizer and the load contents.
 88. 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 nonlumened 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 (AORN, 2012, p. 552). If a dedicated 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.
 89. 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 instructions for use when selecting the cycle type, time, and temperature. Inconsistencies between the device manufacturer’s and the sterilizer manufacturer’s instructions should be resolved before sterilization. If instructions are not available within the operating room, the perioperative nurse should consult with personnel from the sterile processing department. In the absence of instructions, the device should not be sterilized. It is important to refer to the most recent manufacturer’s instructions for use, as instructions for sterilization continue to evolve.
 90. Cleaning is absolutely critical to proper instrument processing, as inadequate cleaning will compromise the sterilization process. Instruments prepared for IUSS are often cleaned and prepared under less-than-ideal conditions. The processes and resources available in the sterile processing department (SPD) to clean instruments may not be available in the operating room. In addition, a separate decontamination area for cleaning instruments may not exist in the operating room. Regardless of where instruments are cleaned, the cleaning process should be consistent and in compliance with accepted standards. Appropriate personal protective equipment (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.
 91. Although items that are sterilized via IUSS are usually sterilized in a “flash” container, a single wrapper may be used for certain types of instruments if sterilizer instructions indicate this approach is appropriate.
 92. Another disadvantage of IUSS is that, following sterilization, transfer of the item from the autoclave to the sterile field may be difficult. Because the sterilizer may be located outside the actual operating room, there is a risk of contamination during transport.

Section Questions



1. What is the purpose of the jacket in an autoclave? [Ref 44]
 2. How does every surface of an item to be sterilized come into contact with steam? [Refs 45–46]
 3. When does the actual sterilization cycle begin? [Ref 48]
 4. Which parameters must be met for sterilization to occur? [Ref 49]
 5. Where should sterilized wrapped packages and instrument containers be left to cool? [Ref 52]
 6. What is the danger of placing a warm package on a cool surface? [Ref 53]
 7. Which process differentiates a gravity-displacement sterilizer from a dynamic-air-removal sterilizer? [Ref 54]
 8. What determines the appropriate time and temperature for sterilizing items in an autoclave? [Ref 56]
 9. What are the disadvantages of a gravity-displacement autoclave? [Ref 61]
 10. For which items is a gravity-displacement cycle most appropriate? [Ref 64]
 11. How does the prevacuum autoclave remove air from the chamber? [Ref 65]
 12. How do you manage the sterilization of items with different time requirements for sterilization? [Refs 68–69]
 13. What is the cycle time for sterilizing instruments that have been exposed to prions? [Ref 70]
 14. Discuss the advantages and disadvantages of dynamic-air-removal sterilization. [Refs 71–72]
 15. For what purpose is a Bowie-Dick test run? [Ref 73]
 16. When does AAMI recommend that the Bowie-Dick test be run? [Ref 74]
 17. When examining the Bowie-Dick results after the test has been run, what determines if the cycle was successful? [Ref 75]
 18. How does a steam-flush-pressure-pulse sterilizer differ from a dynamic-air-removal sterilizer? [Ref 77]
 19. What is the advantage of a steam-flush-pressure-pulse-sterilizer? [Ref 79]
 20. What would you do with an item sterilized with IUSS if it is not used for the current procedure? [Ref 80]
 21. When is it appropriate to use IUSS? [Refs 81–84]
 22. How are items prepared for IUSS? [Ref 85]
 23. Why should a container specifically intended for IUSS be used? [Ref 86]
 24. How must instruments for IUSS be processed for sterilization? [Ref 90]
 25. Discuss disadvantages of IUSS. [Ref 92]
93. Using the special containers designed for use with IUSS reduces the risk of contamination during transfer from the autoclave to the sterile field. Ideally, a sterilizer used for IUSS would open into the actual operating room. This configuration facilitates transport without contamination.
94. 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 radio-frequency or electrical energy on hydrogen peroxide vapor within a vacuum (Figure 3-4).
95. Items to be sterilized are placed in a sterilizing chamber, a vacuum is established, and liquid 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 a 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.

Chemical Sterilization: Low-Temperature Hydrogen Peroxide Gas Plasma

Description



Figure 3-4 Sterrad NX hydrogen peroxide sterilizer

Source: Courtesy of Advanced Sterilization Products, Irvine, CA.

Packages are dry at the end of the cycle and may be used immediately or stored for future use.

Advantages

96. Advantages of low-temperature hydrogen peroxide gas plasma sterilization are as follows:
- 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, personal protective equipment 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.
 - 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.

Disadvantages

97. Disadvantages of low-temperature hydrogen peroxide gas plasma are as follows:

- Hydrogen peroxide gas plasma is not compatible with powders, liquids, textiles, and other cellulose-containing items such as linen, gauze, and paper.
- Packaging materials are limited to nonwoven polypropylene wraps, Tyvek and Mylar pouches, or specific container systems.
- In some hydrogen peroxide gas plasma sterilizer models, lumen restrictions may prevent long, narrow-lumened devices, such as ureteroscopes, from being processed by this method.

Chemical Sterilization: Low-Temperature Vapor-Phase Hydrogen Peroxide

Description

98. 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 hydrogen peroxide diffuses and contacts surfaces, an oxidative process inactivates microorganisms. Devices that are sterilized using this process do not require additional aeration beyond what is provided with the cycle, because the byproducts of the process are oxygen and water vapor in the form of humidity.
99. Three 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.
100. All items to be sterilized must be thoroughly cleaned, rinsed, and dried before being packaged and loaded into the chamber.
101. Items should be arranged in a single layer with minimal overlap to ensure proper diffusion of sterilant vapor throughout the load.
102. Each of the three cycles has three phases:
- 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.
 - Sterilization: A series of four pulses create a vacuum and introduce 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.
103. Monitoring includes a special chemical indicator designed to change color in the presence of H₂O₂ and a biological indicator containing the spore *Geobacillus stearothermophilus*.

Advantages

104. Advantages of low-temperature hydrogen peroxide vapor sterilization are as follows:
- 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.

Disadvantages

105. Disadvantages of vaporized hydrogen peroxide are as follows:
- 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.

Chemical Sterilization: Ethylene Oxide Gas

Description

106. Ethylene oxide (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.
107. A wide variety of surgical items that cannot withstand moist heat without incurring damage may be sterilized with ethylene oxide

gas. Commonly gas-sterilized items are flexible and rigid endoscopes, plastic goods, instruments with electrical components, and delicate instruments with sharp edges that will dull with exposure to repeated steam sterilization.

108. Because EtO is toxic, the sterilizers must be housed in a location that is closely monitored and vented. Even though EtO sterilizers are not found in the operating room, it is important to understand the technology and its associated responsibilities.
109. The essential parameters of gas sterilization are gas concentration, temperature, humidity, and exposure time.
110. Gas concentration varies with the size of the chamber, the temperature and humidity within the chamber, and the type of gas sterilizer used. Gas sterilizers operate at temperatures between 85°F (29°C) and 145°F (63°C). Optimal humidity levels are between 30% and 60%. Exposure times generally range from 3 to 7 hours. The sterilizer manufacturer's and the device manufacturer's recommendations must be followed carefully to determine exposure time. Items exposed to EtO must be thoroughly aerated to remove vestiges of the chemical from the packaging and the sterile items.
111. Ethylene oxide, which is supplied in a 100% concentration, is packaged in small unit-dose cartridges. Because this gas is flammable and explosive when supplied in large tanks, it is mixed with inert gases such as hydrochlorofluorocarbons (HCFCs) or carbon dioxide. The selection of 100% EtO or a mixture is determined by the sterilizer design.
112. In the EtO sterilization cycle, the air is evacuated from the chamber and its contents, the load is preheated, and humidity is introduced. This phase is termed the preconditioning phase. EtO is then released into the chamber, where it permeates and penetrates the load. EtO sterilization operates under negative pressure. The advantage to this approach is that if a leak occurs, the EtO will be drawn into the chamber rather than being vented to the outside work environment.

Advantages

113. Advantages of EtO sterilization:
- EtO is effective against all types of microorganisms.

- EtO does not require high heat.
- EtO is noncorrosive.
- EtO effectively penetrates large bundles and permeates all porous items.

Disadvantages

114. Ethylene oxide is a toxic gas, and the sterilization process can be complex and potentially hazardous. Because of the toxic and hazardous nature of ethylene oxide sterilization, items that can tolerate steam sterilization should not be sterilized with EtO.

115. Other disadvantages:

- The sterilization cycle time is lengthy.
- EtO is highly flammable, and EtO cylinders and cartridges must be handled and stored carefully.
- The diluent HCFCs used in EtO sterilization are subject to strict local, state, and federal regulations and are being phased out because they deplete the ozone layer in the atmosphere.
- EtO sterilization is more expensive than steam sterilization.
- Toxic byproducts can form under certain conditions. For example, ethylene oxide combined with water yields the toxic byproduct ethylene glycol.
- Because a variety of materials can absorb EtO during the sterilization process, residual EtO must be removed from the load contents through an aeration or detoxification process following sterilization. Aeration times in a mechanical aerator may be as short as 8 hours or less or longer than 24 hours. The length of aeration time needed depends on the item, packaging, density of the load, type of sterilization and aeration system, and temperature in the aeration chamber. Items made from materials such as polyvinyl chloride require the most lengthy period of aeration. Sterilizer and device manufacturer guidelines for exposure and aeration must be followed. Items should never be removed from the aerator until the aeration cycle is complete.
- EtO is regarded as a human carcinogen by the Occupational Safety and Health Administration (OSHA). Personnel working with EtO must be provided with PPE and

instruction in the hazards associated with EtO.

- EtO is also recognized as having the potential to cause adverse reproductive effects in humans. In areas where EtO is utilized, a sign must be posted that reads as follows: “Danger: ethylene oxide, cancer hazard and reproductive hazard. Authorized personnel only. Respirators and protective clothing may be required to be worn in this area” (OSHA, 2011).
 - 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.
 - Concentrations of EtO must be identified in the areas where EtO sterilization occurs. Monitoring devices that produce an alarm in the event of EtO exposure must be in place.
 - The OSHA standard for exposure to EtO is an 8-hour time-weighted average (TWA) that limits personnel to one part EtO per million parts of air in 8 hours. OSHA requires a monitoring program to ensure compliance with this standard. Employees who work with EtO must periodically wear monitors that detect the amount of EtO in the work area.
 - EtO gas must be vented to the outside to avoid personnel exposure. In addition, some states have abatement requirements that add to the cost of EtO processing. Abaters convert waste ethylene oxide into nontoxic gases that are then vented to the outside.
116. Because of safety issues and because prolonged aeration time means that instruments may be unavailable when needed, many healthcare facilities have significantly reduced or eliminated the use of EtO by switching to newer low-temperature sterilization methods that do not have the same safety issues, lengthy process, and aeration time as EtO.

Liquid Chemical Sterilant Processing System

Description

117. Peracetic acid solution contains acetic acid and hydrogen peroxide. Peracetic acid is acetic acid

plus an extra oxygen atom. It disrupts protein bonds and cell systems; the extra oxygen atom inactivates cell systems and causes immediate cell death.

118. Liquid peracetic acid is a low-temperature, nonterminal process that can be used to process reusable heat-sensitive devices such as endoscopes and their accessories that cannot be processed using steam.
119. The items to be processed are placed in a dedicated tray, then placed into the tabletop unit. The sterilant circulates through the tray, contacting all surfaces of the items. Items are then rinsed with filtered and UV-treated water.
120. 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. The manufacturer of each device should be consulted to determine if the device is validated for use in a liquid peracetic acid processing system. Both the device manufacturer and the liquid chemical sterilant processor manufacturer should be consulted to determine the appropriate irrigator adaptor(s).
121. Contact time is standardized at 12 minutes at a temperature of 50°C to 55°C (122°F to 131°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.
122. 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.
123. 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.
124. No biological indicator for this system is currently available. The system uses microprocessors to ensure that the required parameters are met.

Advantages

125. Advantages of liquid chemical peracetic acid processing include the following features:
 - 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 sterilization using existing sterilization technologies.

Disadvantages

126. Disadvantages of liquid chemical peracetic acid processing include the following features:
 - 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.

Chemical Sterilization: Low-Temperature Ozone/Hydrogen Peroxide

127. Ozone is an emerging low-temperature technology. Current technology combines ozone and hydrogen peroxide to form a powerful oxidizing agent. Highly reactive particles such as hydroxyl radicals (—OH) oxidize a variety of organic compounds. Ozone has an effect similar to plasma; however, ozone can penetrate lumens and hard-to-reach areas. At the end of the cycle, ozone and hydrogen peroxide are converted to nontoxic byproducts of oxygen and water. Cycle times for the currently available sterilizer are 46, 56, and 100 minutes.

Section Questions



1. How are items sterilized by hydrogen peroxide plasma? [Refs 94–95]
2. What makes H₂O₂ a safe alternative to ethylene oxide (EtO)? [Ref 96]
3. Which materials are compatible with H₂O₂ plasma? [Ref 96]
4. Which materials are incompatible with H₂O₂ plasma? [Ref 97]
5. Which packaging materials are used for wrapping items to be sterilized with H₂O₂? [Ref 97]
6. Which lumen characteristics may be restricted from H₂O₂ sterilization? [Ref 97]
7. Describe the process of sterilization with H₂O₂ vapor. [Refs 98–99]
8. How must instruments be prepared before being packaged for H₂O₂ vapor sterilization? [Ref 100]
9. How are instruments arranged in an H₂O₂ sterilizer to ensure proper contact with sterilant? [Ref 101]
10. Describe the three cycles involved in H₂O₂ vapor sterilization. [Ref 102]
11. Which spore is used for biological testing of the H₂O₂ vapor sterilizer? [Ref 103]
12. Describe advantages and disadvantages of H₂O₂ vapor sterilization. [Refs 104–105]
13. How does ethylene oxide achieve sterilization? [Ref 106]
14. For which types of instruments and supplies is EtO sterilization used? [Refs 106–107]
15. Identify the three essential parameters of gas sterilization. [Ref 109]
16. What length of time does it take to sterilize items with EtO? [Ref 110]
17. Describe advantages of EtO sterilization. [Ref 113]
18. Identify the primary disadvantage of EtO sterilization. [Ref 114]
19. Describe the effects of exposure to EtO. [Ref 115]
20. For what primary reasons has EtO use been reduced significantly in healthcare facilities? [Ref 116]
21. What are the components of peracetic acid? [Ref 117]
22. By which mechanism does peracetic acid kills microorganisms? [Ref 117]
23. What are the applications of a peracetic acid processing system? [Ref 118]
24. Describe the components of the peracetic acid sterilization process. [Refs 119–121]
25. How are the processed items handled in peracetic acid sterilization? [Ref 122]
26. Why is peracetic acid sterilization considered a “just in time” process? [Ref 123]
27. Which type of indicator is used to determine effective processing in peracetic acid sterilization? [Ref 124]
28. Describe the advantages and disadvantages of liquid chemical peracetic acid processing. [Refs 125–126]
29. Describe the emerging ozone sterilization technology. [Ref 127]
30. How does ozone sterilization compare to H₂O₂ plasma sterilization? [Ref 127]

Sterilization: Quality Control

Overview

128. Before it can be assumed that a sterilizer is working properly and that an article can be considered sterile, certain parameters of time, humidity, pressure, and temperature must have

been met. Chemical and mechanical process indicators and biological testing are used to monitor these parameters. Indicators provide an opportunity for a variety of personnel to check the process. The person removing the item from the sterilizer, the circulating nurse, and the scrub person all share responsibility for checking these monitors.

Physical Monitors

129. Physical monitors are graphs, temperature and pressure recorders, digital printouts, and gauges that record activities within the chamber during the sterilization cycle.
130. Historically, temperature graphs, using stylus and ink, indicated the temperature reached within the chamber and the length of time that this temperature was sustained, and provided information about the time of day during which the autoclave was used and the number of cycles run during a 24-hour period. Modern sterilizers employ a printout rather than a temperature graph.
131. A digital printout record correlates the exact times, temperatures, and pressures achieved during the conditioning, exposure, and exhaust phases of the sterilization cycle. The printout includes space for documentation items such as load identification and identity of the operator (Figure 3-5).
132. 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.
133. With liquid peracetic acid, a diagnostic cycle in which electricity supply, filters, temperature, pressure, and system integrity are checked is run at the beginning of each day, and a printout of the results is provided. A microprocessor system will abort the cycle if parameters are not met.

Chemical Indicators

134. Chemical indicators are impregnated with a dye or chemical that develops a visual or physical change when certain conditions have been achieved. Indicators are manufactured in the form of tapes, strips, or labels.
135. Chemical indicators referred to as integrators provide results that are based on the integration of some or all of the parameters that need to be met.
136. Chemical indicators should be placed both inside and outside of all packages. The chemical indicator on the outside of the package is inspected before the product is opened, and the ones inside are inspected after opening. It is possible that an outside indicator might

indicate the proper conditions have been achieved, yet an inside indicator in the same product might fail. Improper packaging is one reason an inside indicator may fail while the outside one does not. Typically the circulating nurse, or whoever obtains the instruments for a procedure, will be the person in a position

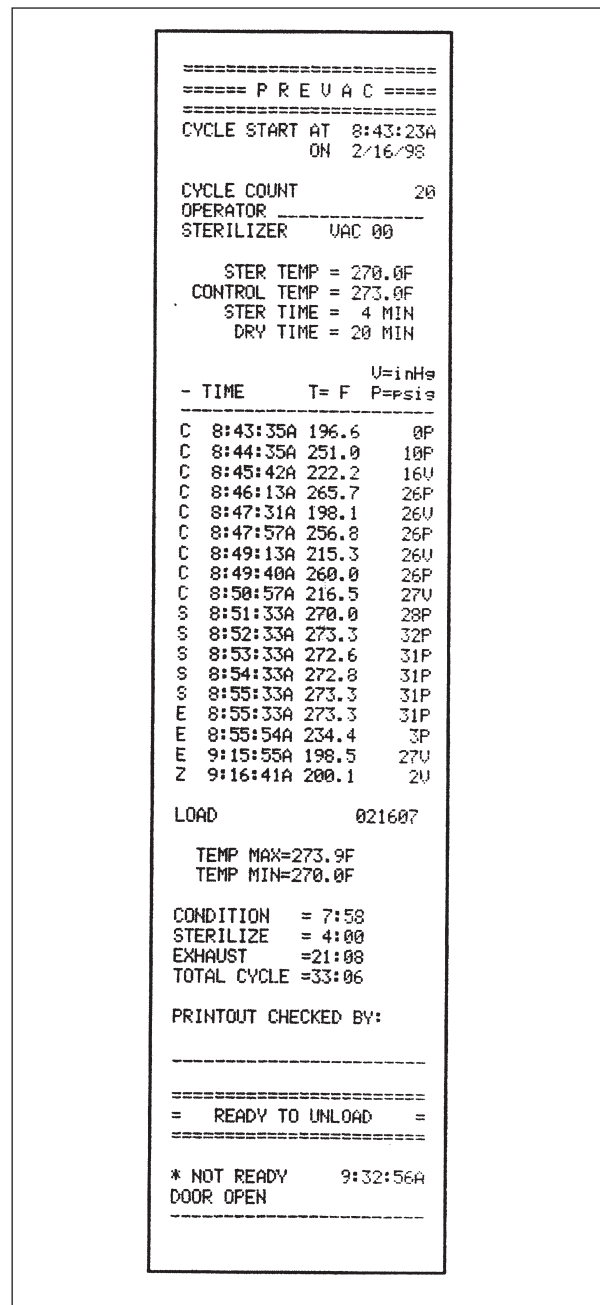


Figure 3-5 Typical printout

Source: Copyright © Steris Corporation, Mentor, OH.

to inspect the outside indicator, and the scrub person will inspect the inside indicator.

137. Six classes of indicators are available:

- Class 1—Process indicator: Chemical indicator intended to demonstrate that the item has been exposed to the sterilization process. It typically consists of a tape or a paper strip that changes color and distinguishes between processed and unprocessed items. A Class 1 chemical indicator is an external indicator (Figure 3-6).
- Class 2—Bowie-Dick test indicator: Indicator designed to test the efficacy of air removal and steam penetration in dynamic-air-removal sterilizers.
- Class 3—Single-parameter indicator: Chemical indicator designed to react to one of the critical parameters of sterilization to indicate exposure to a sterilization cycle at a stated value of the chosen parameter.
- Class 4—Multiparameter indicator: Chemical indicator designed to react to two or more of the critical parameters of a sterilization cycle at stated values of the chosen parameters (Figure 3-7).
- Class 5—Integrating indicator: Chemical indicator designed to react to all critical parameters over a specified range of sterilization cycles and whose performance has been correlated to the performance of the stated test organism under the labeled conditions of use (AAMI, 2011, p. 103) (Figure 3-8).
- Class 6—Emulating indicator. A cycle-specific indicator that can be used only for the cycle specified in its instructions for use (Figure 3-9).

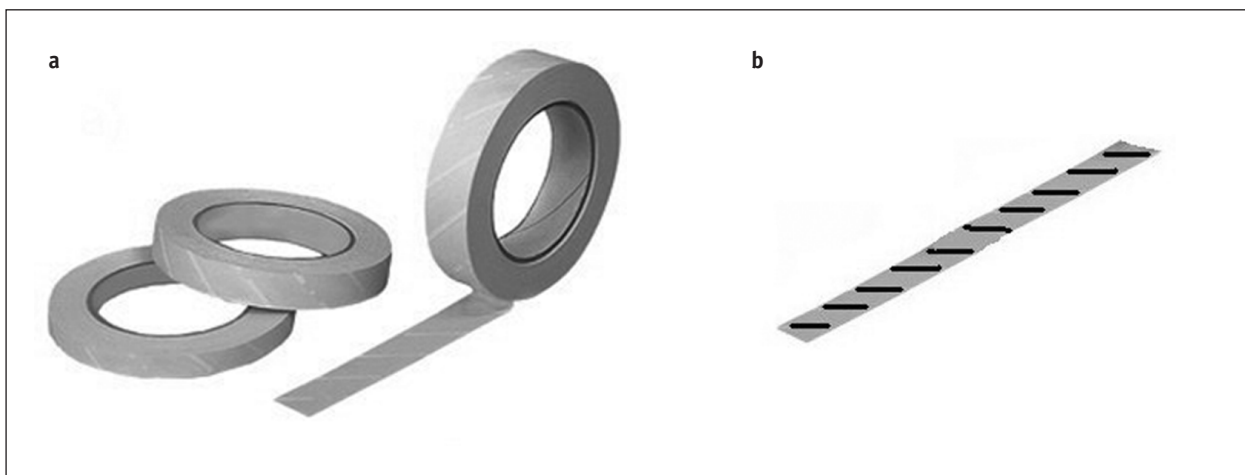


Figure 3-6 Class I process indicator (external) for steam sterilizer: a) before exposure b) after exposure

Source: Copyright © Steris Corporation, Mentor, OH.

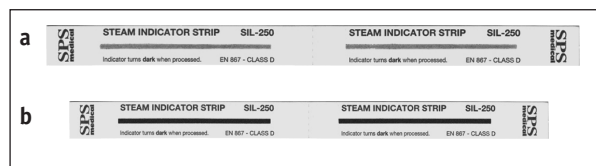


Figure 3-7 Class 4 multiparameter indicator for steam sterilizer a) before exposure b) after exposure

Source: Courtesy of SPSmedical, Rush, NY.

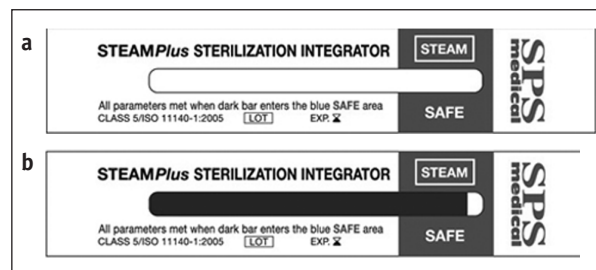


Figure 3-8 Class 5 integrating indicator: a) before exposure b) after exposure

Source: Courtesy of SPSmedical, Rush, NY.

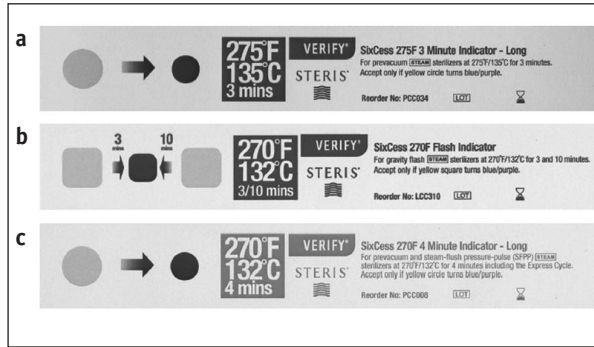


Figure 3-9 Class 6 emulating indicators for different steam sterilization cycles: a) 270°F/132°C 4 minute cycle, b) 275°F/135°C 3 minute cycle, c) IUSS 3 and 10 minute cycles

Source: Copyright © Steris Corporation, Mentor, OH.

138. Chemical indicators do not establish sterility. They are simply tools to determine whether conditions of sterilization have been met.

Biological Monitors

139. Biological monitoring is a process used to determine the efficacy of a sterilizer. It is the most accurate method of ensuring that the conditions necessary for sterilization have been achieved.
140. 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 3-10, 3-11, and 3-12).
141. *Geobacillus stearothermophilus* spores are used to test steam autoclaves and hydrogen peroxide sterilizers. Ethylene oxide sterilizers are tested with *Bacillus atrophaeus* spores. Both are highly resistant nonpathogenic microorganisms.
142. 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, and the sterilizer is activated. For cycles used for terminal sterilization, the biological monitor should be contained within a process challenge device (PCD). A PCD is a device that constitutes a defined challenge to the sterilization process. It may be assembled by the user, but a commercially prepared PCD is commonly used. Commercially prepared PCDs are equivalent in performance to an AAMI BI test pack (Figure 3-13). For IUSS



Figure 3-10 Self-contained biological indicators containing a known population of spores

Source: Courtesy of SPSmedical, Rush, NY.

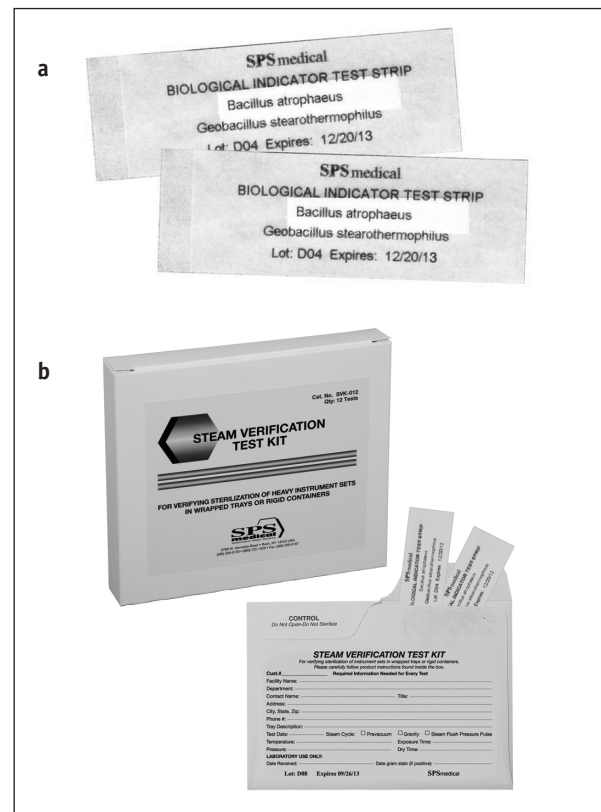


Figure 3-11 Biological indicator spore strips—dual (steam, EtO, dry heat, and chemical vapor): a) Hospitals sometimes send spore strips to an outside validation lab for third party verification; b) Clinics and office-based surgery often use a biological indicator mailing system.

Source: Courtesy of SPSmedical, Rush, NY.



Figure 3-12 Spore ampoules—used primarily for monitoring liquid cycles in steam sterilizers

Source: Courtesy of SPSmedical, Rush, NY.



Figure 3-14 Self-contained biological incubator (note ampoule crusher to the right of the indicator wells...)

Source: Courtesy of SPSmedical, Rush, NY.

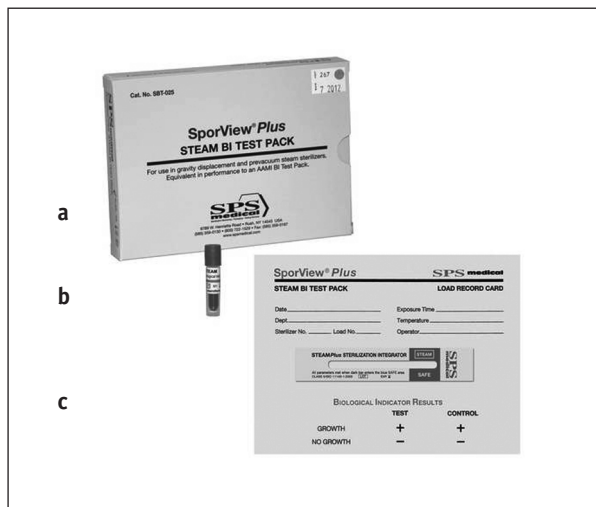


Figure 3-13 Process challenge device: a) test pack containing the self-contained biological indicator, an integrator, and a recording card for permanent documentation; b) ampoule with known quantity of *Geobacillus stearothermophilus*; c) recording card with integrator affixed to complete and file for documentation

Source: Courtesy of SPSmedical, Rush, NY.

cycles, the biological monitor is placed directly in the tray/container to be used, as the tray/container is considered to be the PCD.

143. Following the sterilization cycle, the spores are incubated. Capsules are crushed to expose spores to the culture medium. Spores in ampoules are already suspended in the culture medium. The length of their incubation varies according to the manufacturer's instructions. Growth is almost

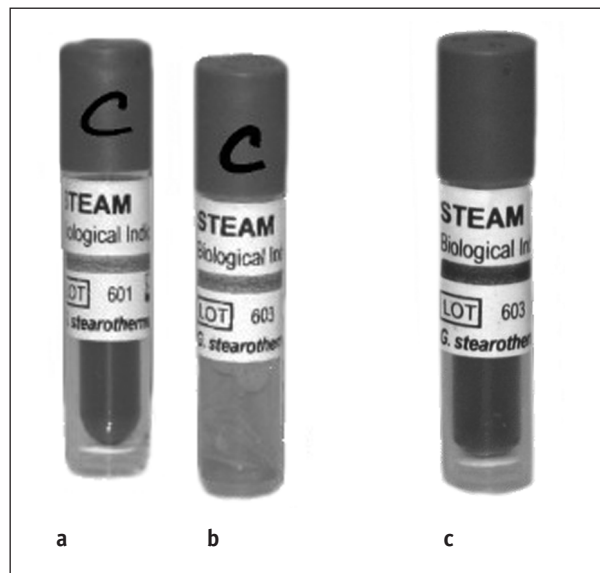


Figure 3-15 Biological capsule indicator control: a) before processing, marked clearly with a “C” for “control;” b) after incubation there is a change in color of ampoule contents indicating bacterial growth; c) biological capsule indicator that has been processed—there is a change in the color of the indicator strip compared to the control

Source: Courtesy of SPSmedical, Rush, NY.

always visible within 24 hours; however, manufacturers are working to reduce biological incubation time (Figure 3-14).

144. A positive BI reading (demonstrating bacterial growth) indicates that sterilizing conditions have not been met; this indicates a “failed load” (Figure 3-15).

145. 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.
146. In addition to sterilizer malfunction, a positive reading can indicate incorrect packaging, an incorrect cycle, items incompatible with the process, or incorrect placement within the sterilizer.
147. 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.
148. 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.
149. The sterilizer is returned to service after repair and subsequent BI testing is negative
150. Identification of items to recall is made from the load/lot numbers, and SPD advises the operating room staff of those instruments and supplies to be recalled.
151. Because incubation of some biological indicators may be lengthy, because biological indicators may not be used with every load, and because sterilized items might be sent to the operating room prior to the receipt of biological testing results, a portion of the contents of the sterilizer may have been used.
152. It is essential that all of the items from the sterilizer be accounted for. Unused items are returned to the SPD for reprocessing; where items have been opened for procedures and patient exposure is known, facility policy determines the notification process, which usually involves the infection prevention staff and the operating surgeon.
153. Steam autoclaves should be tested at least weekly and preferably daily, and a BI should be run with every load containing an implant. EtO sterilizers should be tested with every load (AORN, 2012, p. 563). Hydrogen peroxide gas plasma and H₂O₂ vapor sterilizers should be tested daily.
154. Implants should not be implanted until the results of biological monitoring are known and are negative for growth.

Rapid-Readout Biological Monitors

155. A rapid-readout enzyme-based biological indicator is another type of monitor available for



Figure 3-16 Rapid-readout biological monitor

Source: Courtesy of 3M Health Care, St. Paul, MN.

- testing steam and ethylene oxide sterilizers (Figure 3-16).
156. Rapid-readout biological monitors for steam contain a standardized population of *Geobacillus stearothermophilus* spores. Ethylene oxide rapid-readout biological monitors contain a standardized population of *Bacillus atrophaeus* spores.
157. Fluorescence that occurs when an enzyme present within the *Geobacillus stearothermophilus* spores or *Bacillus atrophaeus* spores breaks down is noted by a color change that indicates that the conditions for sterilization have been achieved. The enzyme activity correlates to inactivation of the spores. Depending on the product used, a result is available within 1 to 3 hours after incubating. Because these monitors contain spores, it is possible, if desired, to incubate for a longer time to obtain spore testing results.
158. The benefit of a rapid-readout biological indicator is that monitoring results are available soon after testing. In the event that an emergency requires IUSS of an implant, a rapid-readout biological monitor should be used, as results can be obtained in 1 to 3 hours depending on which cycle is used.
159. Biological monitors are not interchangeable and must be selected according to the sterilizer type and the cycle being tested.

Sterilization: Documentation

160. The following records should be filed and kept as a permanent record:

- Results of Bowie-Dick/air evacuation test.
- Sterilizer graphs and printouts, which should be initialed by the operator for verification of cycle parameters. Everyone participating should initial the record (if one person puts in a load and another removes it, both persons should initial the document).
- Results of chemical and biological monitoring.
- Records indicating specific load contents and load control numbers used to designate which sterilizer was used for which items.
- Implantable biologic test results.
- Sterilizer failure results.

Section Questions



1. What are the parameters that must be assessed to ensure that a sterilizer is working properly? [Ref 128]
2. Who is responsible for checking to be sure that these parameters are met before introducing an item onto the sterile field? [Ref 128]
3. Which items are considered physical monitors? [Ref 129]
4. What is recorded on a digital printout? [Ref 131]
5. How is liquid peracetic processing monitored? [Ref 133]
6. How does a chemical indicator function? [Ref 134]
7. What is an integrator? [Ref 135]
8. Explain the purpose of using a chemical indicator both inside and outside of a package. [Ref 136]
9. Describe each of the six classes of indicators. [Ref 137]
10. In which type of sterilizer is the Class 2 (Bowie-Dick) indicator used? [Ref 137]
11. What is an emulating indicator (Class 6)? [Ref 137]
12. What is the purpose of a chemical indicator? [Ref 138]
13. What is the purpose of a biological monitor? [Ref 139]
14. Describe a biological monitor. [Ref 140]
15. Which spores are used to test steam, H₂O₂, and EtO sterilizers? [Ref 141]
16. What is a process challenge device? [Ref 142]
17. What is the implication of a positive BI? [Refs 144–145]
18. What might cause a BI to be positive? [Ref 146]
19. How is a positive BI managed? [Refs 147–152]
20. What is the minimum frequency for testing steam and EtO sterilizers with a BI? [Ref 153]
21. How is a BI used for implantable devices? [Ref 154]
22. How does a rapid-readout BI work? [Ref 157]
23. In what period of time can results be obtained from a rapid readout BI? [Ref 158]
24. How are BIs selected? [Ref 159]
25. What are the components of permanent documentation of sterilizer monitoring? [Ref 160]

161. IUSS records should be fully traceable to the patient on whom the instruments were used.

Disinfection

Overview

162. Disinfection is a process that destroys pathogenic microorganisms through the use of a

liquid chemical germicide. 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.

163. Chemicals used to destroy microorganisms on inanimate objects are identified as disinfectants. Chemicals used to destroy microorganisms on body surfaces are identified as antiseptics.

Levels of Disinfectants: Application

164. Disinfection is used to destroy pathogens on inanimate objects such as walls, tables, small equipment, and surgical instruments. Liquid chemicals are used for disinfection. 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.
165. Examples of disinfectants include alcohol, chlorine and chlorine compounds, formaldehyde, glutaraldehyde, hydrogen peroxide, iodophors, ortho-phthalaldehyde, phenolics, and quaternary ammonium compounds. Disinfectants vary in their ability to destroy microorganisms, and they are not interchangeable. Disinfectants are categorized as high level, intermediate level, and low level.
166. 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.
167. 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 and because a product that is intended for immediate use is needed, high-level disinfectants are not used for sterilizing instruments. Such disinfectants are used only for disinfecting instruments and medical devices; they are not used on environmental surfaces.
168. Intermediate-level disinfectants inactivate most vegetative bacteria, the tubercle bacillus, fungi, and viruses, but not necessarily bacterial spores. Low-level disinfectants kill most vegetative bacteria, some fungi, and some viruses; they do not kill the tubercle bacillus. Intermediate- and low-level disinfectants are formulated to be used on environmental surfaces and are never to be used on instruments and medical devices.
169. 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.

170. Following exposure to the solution, the device must be thoroughly rinsed, preferably in sterile water. It is important to refer to the manufacturer's instructions, as some disinfectant products require as many as three separate rinses.

Glutaraldehyde

171. 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 instructions and institutional policy should be consulted for the exact required immersion time.
172. 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. 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.
173. Like all disinfectants, glutaraldehyde must be mixed and used strictly according to the manufacturer's instructions for use and the standards of practice. Information regarding mixing instructions, temperature, use, immersion time, toxicity, and length of effectiveness can be found on the product's label.
174. The current OSHA limit for exposure to glutaraldehyde is 0.2 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, 2011).
175. 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

176. Ortho-phthalaldehyde (OPA) is a nonglutaraldehyde disinfectant widely 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.
177. Ortho-phthalaldehyde has a very low vapor pressure; as a result, it is rarely irritating to staff. There are no OSHA requirements and no monitoring requirements for OPA high-level disinfectants.
178. 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.

Hydrogen Peroxide Vapor

179. Use of hydrogen peroxide vapor (HPV) to decontaminate healthcare spaces such as patient rooms or an operating room is an evolving technology that has recently been introduced in some facilities. Ozone hydrogen peroxide vapor is an advanced oxidative process providing a rapid and effective means of disinfecting healthcare spaces with numerous surface types and poorly accessible areas such as rooms vacated by patients with highly infectious pathogens (Zoutman et al., 2011, p. 873).
180. The advantages of vaporized biodecontamination compared to liquid cleaning agents include effective antimicrobial activity, wide dispersal, lack of residue, material compatibility, safety, and rapid turnaround time with limited disruption to the area under treatment (Galvin et al., 2012, p. 67). Application of this technology to operating rooms is fairly recent.

Disinfection: Quality Control

181. To avoid dilution of the disinfectant and compromise of the disinfection process, all items to

be disinfected should be thoroughly cleaned, rinsed, and dried prior to immersion.

182. 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.
183. A disinfectant can lose its minimum effective concentration 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 minimum concentration and cause a solution to fail. One should never rely entirely on the label for proof of the expiration of the solution.
184. The minimum effective concentration (MEC) of disinfectant solutions should be monitored before each use with indicators designed for this purpose. These indicators are usually supplied in the form of 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.
185. Chemical properties and appropriate hazard warnings should be posted.

Disinfection: Documentation

186. 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 disinfected item was used

Section Questions



1. Describe disinfection. [Refs 162, 164]
2. Differentiate between a disinfectant and an antiseptic. [Ref 163]
3. Identify some disinfectant chemicals. [Ref 165]
4. Explain the factors that influence the efficacy of disinfection. [Ref 166]
5. Differentiate among high-, intermediate-, and low-level disinfection. [Refs 167–168]
6. Why are high-level disinfectants not often used to sterilize instruments? [Ref 167]
7. Which level of disinfection is used for surgical instruments? [Ref 169]
8. How is a high-level disinfected instrument prepared for patient use? [Ref 170]
9. Which factors affect the length of time it takes to disinfect an item with glutaraldehyde? [Ref 171]
10. Describe the responsibilities associated with using glutaraldehyde. [Refs 172–173]
11. What is the impact of heat on glutaraldehyde? [Ref 175]
12. Compare ortho-phthalaldehyde with glutaraldehyde. [Ref 176]
13. Describe the characteristics of OPA. [Refs 177–178]
14. How is hydrogen peroxide vapor used as a disinfectant? [Ref 179]
15. What are the advantages of HPV? [Ref 180]
16. Describe the importance of cleaning, rinsing, and drying items before beginning the process of disinfection. [Ref 181]
17. Discuss the implications of the expiration date on prepared disinfectant solutions. [Refs 182–183]
18. How is the minimum effective concentration of disinfectants determined? [Ref 184]
19. How should the environment in which chemical disinfectants are used be managed? [Ref 185]
20. Discuss documentation related to liquid chemical disinfection. [Ref 186]

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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 sterilization may be used for all medical devices
2. Which of the following definitions are correct? (More than one definition may be 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 a steam sterilizer.
 - c. An autoclave is another term for gravity-displacement steam sterilizer.
 - d. A chemical indicator is a sterilization monitor with a known population of resistant spores.
3. Which statement(s) is (are) true?
 - a. Surgical-site infections are the second leading cause of hospital-acquired infection.
 - b. Contaminated surgical instruments are a potential source of infection.
 - c. Perioperative nursing activities are directed at preventing infection.
 - d. Sterilization and disinfection are cornerstones of infection prevention.
4. If instruments are processed outside of the operating room, why does the perioperative nurse need to know about sterilization and disinfection?
 - 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 the process and assumes varying degrees of responsibility for the care and preparation of instruments.
 - d. Instrument processing is a core competency 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. thermometers 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.

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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 method depends 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 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. Steam sterilization is a function of 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 inexpensive 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 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. Air pockets prevent steam from contacting all surfaces of an item, compromising the sterilization process.
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. A prevacuum sterilizer is more efficient and preferred over a gravity-displacement sterilizer.
 - 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. Items sterilized with IUSS cannot be stored or held for use on a future case.
 - 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 appropriate only in urgent clinical situations.
 - 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 instructions for IUSS should be sterilized in this manner.
 - b. There is risk of contamination during transport following IUSS.
 - c. Items for IUSS cannot be wrapped.
 - d. A rigid container should be used for IUSS.
19. 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. The process is an efficient alternative to EtO sterilization.
 - d. Cycle times are preset and the sterilizer is easy to operate.
20. The spore used to monitor H₂O₂ sterilization is
 - a. *Bacillus atrophaeus*.
 - b. *Geobacillus atrophaeus*.
 - c. *Geobacillus stearothermophilus*.
 - d. *Bacillus subtilis*.
21. Which packaging materials can be used for H₂O₂ sterilization?
 - a. muslin wrappers
 - b. Tyvek pouches
 - c. polypropylene wraps
 - d. Mylar pouches
22. Which statement(s) is (are) true about EtO sterilization?
 - a. EtO is a toxic gas that must be managed according to strict regulations.
 - b. EtO is appropriate for items that cannot tolerate the temperature and moisture of steam sterilization.
 - c. The essential parameters of EtO sterilization are gas concentration, temperature, humidity, and exposure time.
 - d. Aeration must be done for all loads sterilized using EtO.
23. What are some advantages of EtO sterilization?
 - a. The process is rapid.
 - b. The process is safe for items that cannot tolerate high heat and humidity.
 - c. EtO is noncorrosive.
 - d. EtO effectively penetrates large bundles and permeates all porous items.

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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 cell systems, causing immediate cell death.
25. Which statement(s) is (are) true about sterilization monitoring?
- Physical monitors record activities within the sterilizer chamber.
 - Chemical indicators exhibit a visual or physical 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.
26. A Class 5 indicator is
- A process indicator that demonstrates an item has been exposed to the sterilization process.
 - A single-parameter indicator designed to react to one of the critical parameters of the sterilization process.
 - An integrator that reacts to all of the critical parameters of the sterilization process.
 - A multiparameter indicator that reacts to two or more parameters of the sterilization process.
27. Which statement(s) is (are) true about biological indicators?
- A biological indicator is the most accurate method of establishing that the conditions of sterilization have been met.
 - 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.
28. 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.
 - In any instance, 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 TJC.
29. Which statement(s) is (are) true about biological monitors?
- Rapid-readout enzyme-based biological indicators are available for steam and EtO sterilizers.
 - Rapid-readout monitors rely on fluorescence, which occurs when an enzyme present within the bacterial spore breaks down, to determine that the conditions for sterilization have been met.
 - Rapid readouts show results within 30 minutes.
 - A rapid readout can be used if an implant must be sterilized using IUSS.
30. Documentation of sterilization should include
- a supervisor’s signature for every sterilizer load.
 - records indicating which sterilizer was used for which items.
 - an indication that biological tests were run in every sterilizer twice a day.
 - Bowie-Dick test results for gravity-displacement sterilizers.



Competency Checklist: Sterilization and Disinfection



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

Name _____

	Observer’s Initials	Date
1. Identifies appropriate method of sterilization for item to be sterilized.	_____	_____
2. Steam sterilization		
a. Sets appropriate cycle	_____	_____
b. Sets appropriate time	_____	_____
c. Sets appropriate temperature	_____	_____
d. Places appropriate chemical indicator inside and outside of package	_____	_____
e. Selects tray compatible with sterilization method	_____	_____
f. Packages correctly	_____	_____
g. Loads correctly—sterilant can exit and enter packages	_____	_____
h. Documents required information	_____	_____
i. Operates sterilizer according to the manufacturer’s instructions	_____	_____
j. Observes printout/indicator for parameters	_____	_____
k. (IUSS) Transports without contamination following sterilization	_____	_____
l. (Wrapped) Allows package to cool before removing from autoclave	_____	_____
3. Biological monitor—steam		
a. Selects appropriate monitor	_____	_____
b. Documents date, autoclave, and operator	_____	_____
c. Places biological indicator correctly within the chamber (follows the manufacturer’s instructions for placement)	_____	_____
d. Sets appropriate cycle, time, and temperature	_____	_____
e. Incubates processed biological monitor and control according to the manufacturer’s instructions	_____	_____
4. Hydrogen peroxide gas plasma sterilization		
a. Places appropriate indicator outside and inside of package	_____	_____
b. Selects tray or container appropriate for sterilization process	_____	_____
c. Packages correctly	_____	_____
d. Loads correctly	_____	_____
e. Operates sterilizer according to the manufacturer’s instructions	_____	_____
f. Documents required information	_____	_____
5. Biological monitor—hydrogen peroxide gas plasma		
a. Selects appropriate monitor	_____	_____
b. Documents date, sterilizer, and operator	_____	_____
c. Correctly places within chamber (follows the manufacturer’s instructions for placement)	_____	_____
d. Incubates processed biological monitor and control according to the manufacturer’s instructions	_____	_____

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	Observer's Initials	Date
6. Disinfection		
a. Identifies items appropriate for high-level disinfection	_____	_____
b. Prepares disinfectant according to the manufacturer's instructions	_____	_____
c. Wears appropriate personal protective equipment during preparation of disinfectant and use	_____	_____
d. Performs the MEC test and documents results	_____	_____
e. Documents required information	_____	_____
7. Items are:		
a. Appropriately washed and dried before being disinfected	_____	_____
b. Rinsed after being disinfected and before use		
c. Handled so as to prevent contamination		

Observer's Signature _____ Initials _____ Date _____

Orientee's Signature _____